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COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**establishing the Programme for single market, competitiveness of enterprises, including
small and medium-sized enterprises, and European statistics and repealing Regulations
(EU) No 99/2013, (EU) No 1287/2013, (EU) No 254/2014, (EU) No 258/2014, (EU) No
652/2014 and (EU) No 2017/826**

{COM(2018) 441 final} - {SEC(2018) 294 final}

Annex 15: Programme specific annex on *COSME*

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

1.1. Scope and context

This is the impact assessment for the successor to COSME - the EU programme for the competitiveness of enterprises, in particular SMEs - for the post-2020 Multi-Annual Financial Framework. It builds on the results of the evaluations performed on the individual parts of the COSME programme as well as on the interim evaluation of the programme. It satisfies the requirements of the Financial Regulation in respect of preparing an ex-ante evaluation. The COSME programme could be adopted as a stand-alone programme or as one of the pillars of the Single Market Programme.

The COSME programme (2014-2020) addresses the market failures affecting SMEs and promotes entrepreneurship and the creation and growth of companies. COSME is a small EU programme, with a budget of €2.3 billion for the period 2014-2020, with a high impact, due to its leverage effect, flexibility and visibility among beneficiaries, Member States and the European Parliament.

COSME contributes to addressing current trends and new challenges, and could bring important results to any of the 5 scenarios presented in the reflection paper on EU finances. Its EU added value lies in addressing jobs and growth through an extended network of intermediaries that allows COSME to be present across the EU and beyond. COSME contributes to reducing economic divergences between Member States by offering financial instruments and business support through the intermediaries to all kinds of SMEs. As pointed out in the White Paper on the Future of Europe, there is also scope to strengthen industrial and cluster cooperation towards the emergence of European "Silicon Valleys" (scenarios 3-5).

The Council called in its conclusions on the renewed EU Industrial policy strategy for the "further development of the European cluster policy, with the aim of linking-up and scaling-up regional clusters into cross-European world class clusters, based on smart specialisation principles, in order to support the emergence of new value chains across Europe".¹

In its draft report on the next MFF² the European Parliament states its support to a renewed and budgetary reinforced COSME programme in order to support SMEs.

¹ <http://www.consilium.europa.eu/en/press/press-releases/2018/03/12/eu-industrial-policy-strategy-council-adopts-conclusions/> These conclusions echoed that of stakeholders expressed for instance during the 2018 EU Industry day and the 2017 GROWyour REGION conference, see https://ec.europa.eu/growth/content/300-participants-co-create-inspiring-future-cluster-initiatives-grow-your-region-conference_en.

² <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2F%2FEP%2F%2FNONSGML%2BCOMPARL%2BPE-615.478%2B01%2BDOC%2BPDF%2BV0%2F%2FEN>

The Committee of the Regions, in its opinion on the future of the COSME programme³, calls for a renewed and strengthened successor programme. In particular, easing access to finance for the broadest possible range of SMEs, extending and upgrading EEN, promoting entrepreneurship and continue the mentoring scheme for new entrepreneurs (formerly Erasmus for Young Entrepreneurs) are identified as priority areas.

The EESC has in several occasions supported the continuation and the further development of the COSME programme, including in a recent opinion on "Think Small First"⁴.

[Table 1: Synergies with other MFF related proposals - to be developed with other services]

| Proposed programmes for the new MFF | Links to future COSME+ |
|--|--|
| European Regional Development Fund European Social Fund European Agricultural Fund for Rural Development European Maritime and Fisheries Fund | <p>The future European Regional Development Fund (ERDF) will dedicate an important part of its budget to support and develop the business environment ecosystems. The collaborative approach as applied under the thematic Smart Specialisation Platform for Industrial Modernisation, where both regional RIS3 partnerships of Managing Authorities of Structural Funds and cluster partnerships supported under COSME is foreseen to be strengthened, notably during the implementation of the Joint Cluster Initiatives.</p> <p>The EEN has a strong regional presence, often using ERDF funded infrastructures and complementing the ERDF supported SME advisory, incubation, scale-up, technology transfer etc. services and funding. It also supports the cooperation with initiatives financed by European Territorial Cooperation programmes under the ERDF (like for example the inter-regional cooperation and mutual learning projects involving SMEs and SME support bodies).</p> <p>The Green paper on Entrepreneurship in Europe called on to better foster entrepreneurial interest and talent amongst different groups (including the young, women and immigrants) by making people more aware of self-employment as an attractive career option, and by providing them with the necessary education and skills to turn their ambitions into successful ventures. In line with the needs the mentoring scheme for new entrepreneurs will enable people with skills technical as well as personal to create business as well as new jobs. This complements the European Social Fund support. Also the EAFRD and the EMFF provide support to SMEs in their respective sectors.</p> |
| InvestEU Fund | The SME loan guarantee facility is expected to be implemented under the SME Window of the InvestEU Fund. |
| Framework Programme (FP) 9 | SME participation in the Framework Programmes continues to be a priority both for their participation in collaboration projects and by specific actions like the SME Instrument and the future EIC. Enterprise Europe Network helps SMEs participate in the FP and provides key account management services to the beneficiaries of the SME Instrument. The EEN plans to continue playing an important role with tailored support to SME in FP9. The Scaling-up instrument can leverage the commercialisation of innovative |

³ <http://cor.europa.eu/en/activities/opinions/pages/opinion-factsheet.aspx?OpinionNumber=CDR%203215/2017>

⁴ <https://www.eesc.europa.eu/en/our-work/opinions-information-reports/opinions/sme-think-small-first>

| | |
|--|---|
| | solutions from FP9 and help to bring them to a larger group of SMEs, including through the Joint Cluster Initiatives. |
| Digital Europe Programme | Cooperation is ongoing in the framework of the Start-up initiative with the EEN. The Scaling-up instrument has the potential to make a contribution to the uptake of digitalisation amongst SMEs and a related Joint Cluster Initiative for digital industries, if chosen, could also link cluster partnerships to other initiatives and key actors of the Digital Europe Programme, which could also support the implementation of Scaling-up instrument. |
| Programme for the Environment and Climate Action, including Energy Efficiency | SMEs are key stakeholders and contributors to climate action activities. As one of its activities, the Enterprise Europe Network and Joint Cluster Initiatives encourages SME to become more resource efficient, e.g. through the implementation of the Scaling-up instrument. The Network operated sector group on renewable energy, environment and sustainable construction to help them build partnerships in the EU and abroad and make use of the European Resource Efficiency Knowledge centre (EREK). The Scaling-up Instrument will support the uptake of low-carbon and resource-efficient solutions and could be specifically be supported through the Programme for the Environment and Climate Action, including Energy Efficiency. The clusters participating in the partnerships of the Joint Cluster Initiatives can facilitate the recruitment of relevant SMEs for joint international business projects, as done for instance in the EU's Low-Carbon Business Actions in Brazil and Mexico supported through the EU Foreign Partnership Instrument. |
| External instrument, including a prominent Neighbourhood Window | The needs of the economy and European industry should be taken into account in EU external policies, instruments and actions, in particular regarding the financial arm of EU economic diplomacy. Supporting access to finance for European business internationalisation will help to make concrete steps towards important external policy objectives such as climate change, circular economy, sustainable development goals and migration. It will also create jobs and growth in Europe, improve business competitiveness and access to fast growing markets outside Europe. As the internationalisation of European businesses need both investment inside and outside Europe, the financial instrument under the external policy of MFF will be complementary to the Invest EU financial instruments. Facilitating cooperation with SMEs from Neighbouring Countries will be part of several COSME+ actions. As an example for EEN and the mentoring scheme for new entrepreneurs intermediary organisations are present in nearly all Neighbouring Countries. The clusters participating in the partnerships of the Joint Cluster Initiatives can facilitate the recruitment of relevant SMEs for joint international business projects, as done for instance in the EU's Low-Carbon Business Actions in Brazil and Mexico supported through the EU Foreign Partnership Instrument. |

1.2. Lessons learned from previous programmes

1.2.1. COSME Interim Evaluation

The interim evaluation of COSME gives an overview of the programme implementation and **positive results achieved** during the first three years of the programming period. The programme implementation is on track to reach the objectives set out in the legal

basis by the end of 2020. COSME actions have been judged as highly relevant in addressing the challenges related to fostering economic growth and creating employment opportunities and as strongly aligned to the evolving needs of SMEs.

The strength of the programme lies in particular in the use of intermediaries who have a direct and longstanding contact with SMEs for the implementation of the programme. COSME exploits the proximity of these intermediaries to SMEs and facilitates the integration of services provided by COSME with services provided by these intermediaries in their national and regional contexts. This allows for the provision of customised SME support tailored to the needs and challenges of specific sectors, such as tourism, textiles, creative industries etc. and to reach a high multiplier effect of actions. COSME has thus a **good level of European added-value**. The European dimension constitutes the very essence of the design of COSME actions. Moreover, COSME actions have helped to enhance national, regional and local level measures for SME support and the teaming up of actors across EU value chains to boost internationalisation and industrial modernisation.⁵ The feed-back from beneficiaries is generally positive with a substantial majority reporting a good cost-benefit ratio for their participation.

The interim evaluation also sets out a number of **proposals on how to further improve the performance of the programme**:

First, as stipulated by the COSME regulation, some 80% of the budget is used for promoting SMEs' access to finance and access to markets. The remaining 20% is allocated between a number of smaller actions with a limited budget and with a low cost-benefit ratio regarding the implementation. EASME (Executive Agency for SMEs) implements 35% of the overall programme budget, with two flagship COSME actions (Enterprise Europe Network and the mentoring scheme for new entrepreneurs) as well as a host of smaller projects. The fragmentation of actions and **limitations in terms of budget** (as flagged out for the the mentoring scheme and cluster measures) hampers the effective implementation⁶. Therefore, without losing the flexibility to react quickly to emerging policy needs, there is scope for simplification and **cutting down the number of small, one-off actions**⁷ and devote the resources towards the key areas of intervention whereby a sustained effort and economies of scale will yield the highest efficiency and the biggest impact at EU level.

⁵ This also confirms earlier evaluations such as the results of the 2014 evaluation of the European Cluster Initiatives managed by DG ENTR (2014) by Technopolis. European Commission (2014) Evaluation – Cluster initiatives managed by DG Enterprise and Industry, final report ENTR/172/PP/2012 – LOT 4: managed by Technopolis Group in a consortium with EY and VVA, <http://bookshop.europa.eu/en/cluster-initiatives-managed-by-dg-enterprise-and-industry-pbNB0114004/>

⁶ For example, 16 FTE in EASME implemented 91 contracts with a budget of 58 million for the EEN in 2017 compared to 36 FTEs who implement 47 actions divided into 80 contracts for a budget of 45 million.

⁷ To improve the business environment of SMEs and their competitiveness, COSME also supports the implementation of the Commission's policy priorities through an SME-angle. For example, some actions translate the Better Regulation agenda or the Blueprint for Skills initiative into concrete actions with a specific focus on industrial sectors and SMEs. The network of national SME Envoys supports the implementation of the Commission's flagship initiatives, such as digitalisation or the Single Market Strategy in the Member States by the exchange of good practices. These actions might consist in grants or procurement for raising awareness, disseminating knowledge and good practices and involving stakeholders in the field of SME policy or sectors, including public authorities. Moreover, COSME supports the emergence of competitive industries with market potential, by helping SMEs to go international, take up new business models, capacities and skills and integrate into new value chains through cluster partnering.

The Interim Evaluation support study concluded on the following options: " The Commission might want to consider the following possibilities to strengthen the relative cost-effectiveness of COSME: 1) deploying its existing resources in a more focused / strategic manner; 2) entering new strategic partnerships with other EU programmes or Directorate Generals which could increase or however sustain the range of activities despite the limited budget, for example by strategically sharing the responsibility for interventions in specific areas; and 3) increasing its overall budget"

Second, while COSME is successful in fostering economic growth and the creation of employment opportunities, there is scope for strengthening its responsiveness to EU objectives related to EU global competitiveness and sustainable and inclusive growth. COSME's main instruments are designed to address all SMEs, independently of their sector and industrial specialisations. They only indirectly address challenges such as climate change, gender mainstreaming or youth unemployment.

Third, while there are no major overlaps with other policy initiatives, there is scope for creating further synergies with other EU, national and regional actions. For instance, COSME's distinct use of intermediaries and its focus e.g. on improvement of skills, capacities, networking and entrepreneurship are complementary to Horizon2020 and the future FP's focus on break-through technological innovation that could further help to spread its results and reach a larger number of SMEs and not only the most innovative enterprises. Similarly, low-carbon and resource-efficient solutions developed under LIFE and solutions developed under other programmes could be better brought to SMEs. In addition, there are opportunities for more complementarities for SME internationalisation actions, notably supported through clusters, currently limited due to its relative low budget. Similarly, complementarities can be enhanced with the European Regional Development Fund in addressing SMEs and in strengthening the linkages between the industrial, innovation and regional orientation, e.g. by supporting the strategic partnering of clusters and other SME intermediaries in an aligned manner and complementing the ERDF funded SME support services and investments.. The current approach already tested for industrial modernisation and smart specialisation actions under COSME could be a model. This targets actors engaged in strategic inter-regional collaboration linked to the Thematic Smart Specialisation Platform for Industrial Modernisation.

Fourth, in relation to monitoring the evaluation points out to a lack of centralised data about implementation and indicators are mostly based on outputs rather than on long term effects.

1.2.2. Access to finance

The Loan Guarantee Facility (LGF) for SMEs has been thoroughly assessed by the European Court of Auditors in the context of a performance audit, which comprised also the InnovFin SME Guarantee Facility of Horizon 2020⁸ and in the context of the COSME interim-evaluation⁹.

⁸ European Court of Auditors (2017), *EU-funded loan guarantee instruments*, Special Report Number 20

⁹ <http://ec.europa.eu/DocsRoom/documents/28084>

- **Observations made by the European Court of Auditors¹⁰**

The LGF has achieved the positive results intended, but needs some better targeting of beneficiaries and more coordination with national schemes. The Court concluded that "the main aim of the Loan Guarantee Facility [...] has been to foster growth. Econometric evidence shows that the loan guarantees delivered what they were designed to do. They helped beneficiary companies grow more in terms of total assets, sales, employee numbers and productivity".

However, the Court also concluded that a future facility should better target viable businesses lacking access to finance and a better coordination should occur between central EU guarantee facilities and those established at national level.

- **Conclusions from COSME interim evaluation**

The interim-evaluation¹¹ concluded that the COSME LGF has been successfully set-up and is fully on track to delivering on the targets set in terms of SMEs to be financed and volume of financing to be made available. The evaluation confirms that the "COSME actions fully respond to the SMEs' current needs to access finance".

The interim-evaluation has concluded after fully eliminating the dead-weight effect that for each €1 million invested into the LGF (effects fully attributable to the Loan Guarantee Facility):

- additional employment of 491 will be created;
- additional €22 million in turnover will occur in treated SMEs;
- 470 SMEs will be supported.

While acknowledging – based on the available evidence – the strength of the COSME financial instruments to deliver a financial support to the SMEs that most needed it, the evaluators identified several areas for improvement:

- Better links between financial instruments and other parts of the future SME programme
- Better co-ordination between financial instruments and national EU schemes
- Discontinuation of the €150 000 threshold which has a negative impact on the efficient delivery of the guarantee facility and created significant administrative burden

The interim evaluation recommends that a future EU loan guarantee facility should help to ensure "a more level playing field for SMEs [...] in those countries where, according to current studies, the needs among SMEs are highest." As regards the existing Equity Facility for Growth, the interim-evaluation concluded that the facility is effective. Nevertheless, it has been recommended to reduce the number of financial products and to align the Equity Facility for Growth with the equity facilities established under EFSI.

In response to the assessments made, the following changes are proposed:

¹⁰ ECA Special report No 20/2017: https://www.eca.europa.eu/Lists/ECADocuments/SR17_20/SR_SMEG_EN.pdf

¹¹ Technopolis (2017): "Interim Evaluation of the COSME Programme – Final Report"

- To improve the internal coherence of different parts of the programme, better linkages will be established by further strengthening the existing cooperation with the Enterprise Europe Network¹² (use the Enterprise Europe Network as a stronger signposting element);
- A better upstream co-ordination between financial instruments for SMEs established by Member States and those established under the SME window of the InvestEU Fund will be sought by using the existing SME Envoys Network¹³ as an information exchange forum;
- To reduce administrative burden for SMEs and financial intermediaries and to improve the impact of the SME guarantee facility, the €150,000 threshold will be eliminated.

1.2.3. The Enterprise Europe Network

The COSME interim evaluation indicated that there is a clear market failure for SMEs regarding information, funding, accessing new markets and networking. The Network has been directly relevant to these failures via information and advisory services. The Impact Evaluation of the Network (2008-2014)¹⁴ concluded that the average net effect for SMEs participating in the Network was 3.1% increased annual growth. This result was confirmed in the COSME interim evaluation where SMEs present an overall growth rate that is nearly 6.5 percentage points higher than a comparison group.

The 625+ Network organisations help about 250.000 SMEs per year to increase their competitiveness and innovativeness in the Single Market and beyond by offering integrated services and helping them to internationalize their business outside the home country. Network organisations provide information on funding opportunities made available by the various EU programmes such as COSME financial instruments, Horizon2020 SME Instrument and Structural Funds.

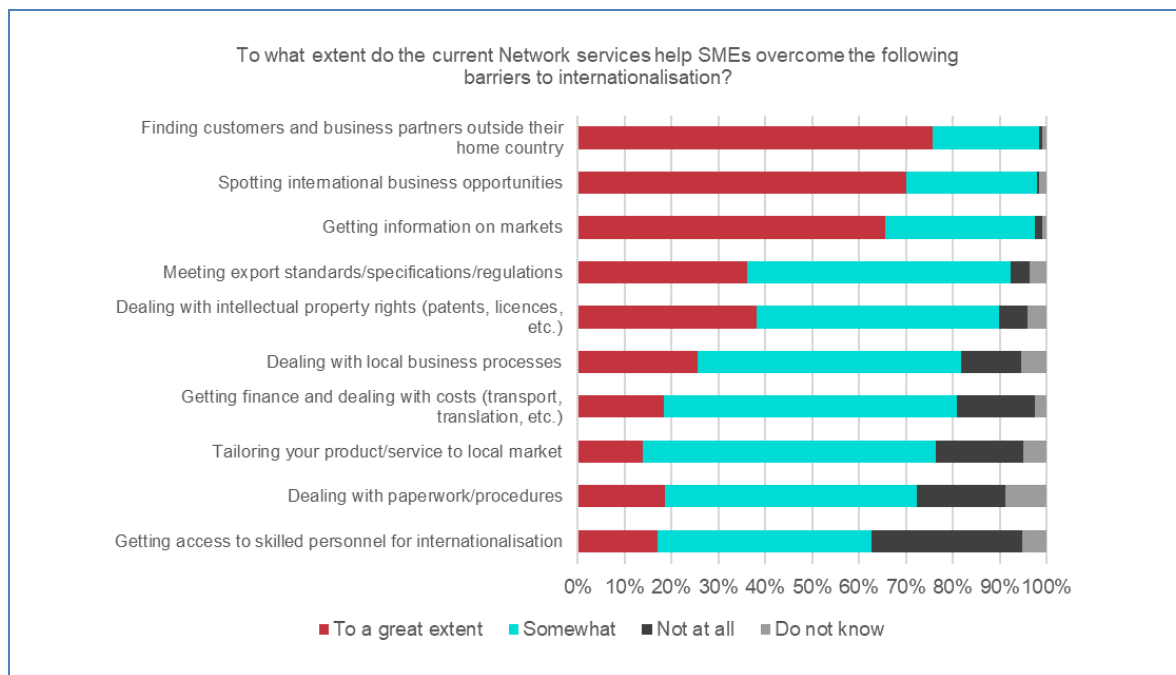
The SMEs themselves indicated that the more and longer they worked with the services of the Network, the more satisfied they became with the impact on their business. They indicated that the partnering services were the most important to them (leading to 2.500 signed agreements between SMEs every year), while the services related to providing feedback were the least important. Moreover, in the interviews the Network organisations indicated that their services matched the needs of companies and SMEs very well. They argued that the core role of the Network is to help companies grow and find new partners, and that the Network services are adequate in doing so, which is further reflected in the high rates of satisfaction where 86% of SME clients surveyed are satisfied with the Network's services and 93% would recommend its services to others.

The figure below gives Network members' views on the extent to which Network services help SMEs to overcome barriers.

¹² <https://een.ec.europa.eu/>

¹³ http://ec.europa.eu/growth/smes/business-friendly-environment/small-business-act/sme-envoys_en

¹⁴ <https://publications.europa.eu/en/publication-detail/-/publication/d4cf03ed-972c-11e5-983e-01aa75ed71a1/language-en>



Source: COSME Interim Evaluation (Technopolis, based on survey data)

European Business Organisations recognize the key role that the Network plays for SMEs to internationalise, grow and innovate. "Eurochambres" states that the added value of the Network is clear, as it allows a scale and quality of services that would not be possible at national level. They stress that the focus of the services offered by the Network should remain on access to markets, particularly within the Single Market. International expansion in third countries should be coherent with trade policy objectives. They also suggest simplifying the reporting and administrative requirements for Network organisations. "BusinessEurope" states that the Network should remain a key instrument for the internationalization of SMEs, based on an enhanced portfolio of services meeting companies evolving needs, and focus on areas where it can bring added value compared to national initiatives.

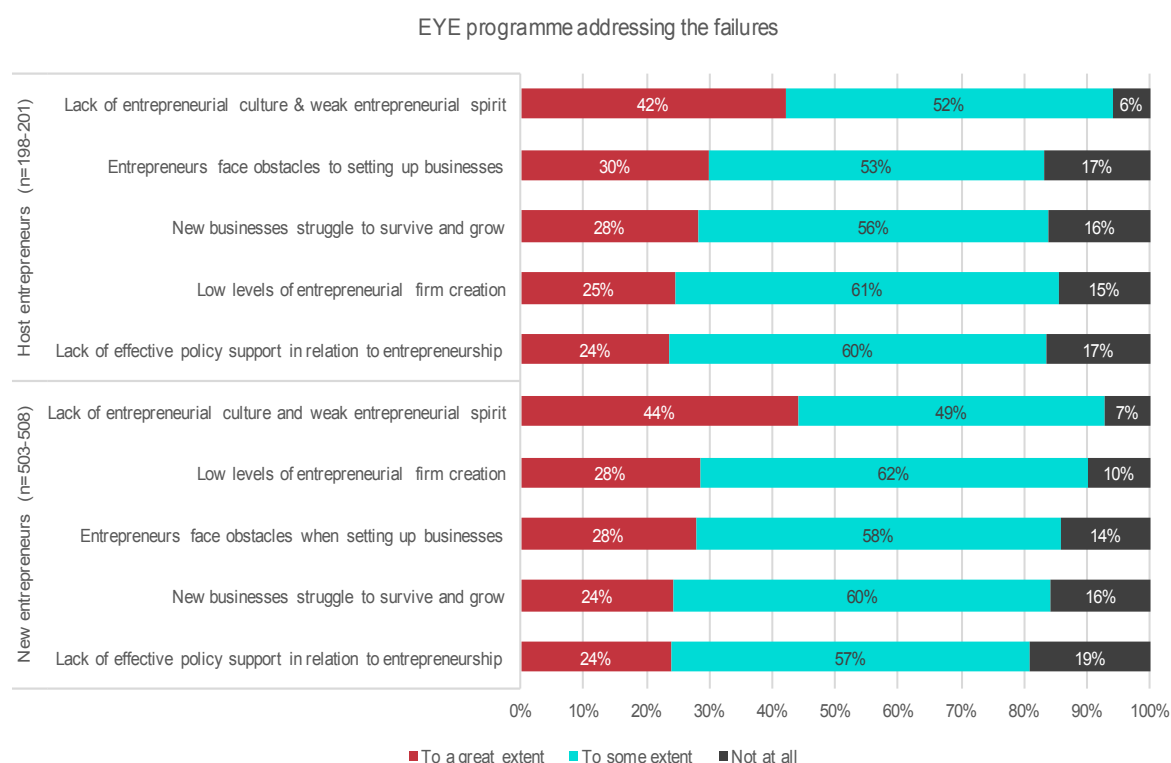
1.2.4. The mentoring scheme for new entrepreneurs (formerly Erasmus for Young Entrepreneurs, EYE)

The mentoring scheme has been established as pilot project in 2008, followed up by preparatory action and fully running under CIP and since 2014 incorporated under COSME.

The COSME interim evaluation identified that, the mentoring scheme has a high level of relevance to the needs of the respective target groups, with no major gaps identified. As part of the evaluation, a large numbers of Host and New Entrepreneurs who had participated in the mentoring scheme during the 2014-2016 period were surveyed. These (potential) entrepreneurs were asked to assess the extent to which a series of barriers to entrepreneurship were present in their country today. Their responses provide widespread confirmation of the existence of market and systemic failures in this area. The large majority (jointly, 92%+) agreed that entrepreneurs face obstacles to setting up businesses, that new businesses struggle to survive and grow, and that there is a lack of effective policy support related to entrepreneurship. There was also a widespread (though

less strongly held) belief that there is a lack of entrepreneurial culture, weak entrepreneurial spirit, and low levels of entrepreneurial firm creation in Member States.

Figure below shows that more than 90% of these survey respondents agreed that COSME – through its largest entrepreneurship action, the mentoring scheme - helped to address all these areas to some extent, and particularly the lack of entrepreneurial culture and spirit.



Source: Technopolis, based on survey data.

Further 99% of mid term evaluation respondents believe that it is important that the mentoring scheme for new entrepreneurs continues.

The COSME evaluation further argues that the mentoring scheme has been particularly effective in reaching its knowledge- and skills-related objectives and has laid the ground for important outcomes in terms of business relationships and internationalization, both for the New and Host Entrepreneurs. Also in this case, however, the scale of the activities (in total about 2,000 new entrepreneurs) poses limits to the importance of this action line within the overall programme portfolio.

1.2.5. IPR SME Helpdesks

The evaluation of the IPR SME helpdesks reveals that the action is very relevant and that results indicate it could reach its objective on the medium and long term. Evidence shows that it has been well designed to make EU SMEs aware about their Intellectual Property

Rights (IPR) in third countries' markets and contributes to the overall objective of the COSME programme.

In April 2017 the activity had registered 3154 helpline users. With 1347 registered helpline users against 1000 targeted, China performs well. The Latin-America also with 1217 registered against 800 targeted. Due to the belated implementation of its helpline, the South-East HD reached only 590 users against 1000 targeted.

After three years of experience under the COSME programme, the action has been showing effectiveness and should now focus the resources to gain in efficiency. To that effect it is needed to improve quality of the services, tackle the problems of insufficient promotion of activities and improve partnering services. There is no need for additional means in order to achieve more impacts, however the use of the current ones could be optimised. The fact that intermediaries act as multipliers, can be seen as an efficiency lever, provided the visibility increases concurrently thanks to more promotion efforts. The strategy to reach the critical mass of SMEs needs to be improved. The reporting mechanism for KPIs is burdensome and not sufficiently quality oriented and the measurement of indicators should be improved. The evaluation concludes on the need for continued funding for the three regions and considers extending this type of service to India.

On coherence, a better cooperation with the Cluster Internationalisation actions will be a priority for the future. The interaction between the three helpdesks should be maintained, as well as with other COSME initiatives (mainly the EEN) and other EU and national initiatives.

The action adds value at EU level by developing and broadening its expertise to all EU SMEs. In order that any SME in any EU MS have access to an equivalent quality of IPR service, it is of specific value to be able to offer them an IPR one-stop-shop to accompany them in their globalisation projects.

1.2.6. SME policy

The SME Performance Review aims at informing policy-makers. It is perceived as an important building block for evidence-based policy-making; most national representatives that were interviewed state that it provides reliable statistical data and analysis on EU SMEs and SME policies. It is effectively used to monitor the implementation of the SME policy as well as the related SME elements of the EU2020 strategy. The SME Performance Review also feeds into the European Semester, which provides a framework for the coordination of economic policies across the European Union.

The SME Envoys Network consists of 29 Envoys (one per country and an EU SME Envoy), and meets four times a year. Together with the SME Assembly, the SME Envoy Network forms the governance structure of the SME policy. For instance, since 2013 the

Envoys report annually on the state of the SMEs and the implementation of the Small Business Act to the Competitiveness Council.

Overall, stakeholders are satisfied with the results. The Envoys perceive the network as a highly valuable EU-level forum where ideas and practices are exchanged. The SME Performance Review as well as the factsheets are used by the national representatives and are considered to be of high quality. Many events are organised throughout Europe during the SME Week, and the SME Assembly gathers stakeholders from all MS. The main outreach tool, Business Planet, is broadcasted on Euronews. There is a general perception that the activities organised at the EU-level contribute to a convergence of SME policies across COSME countries.

1.2.7. Competitiveness of sectors

For the Tourism programme, the consulted stakeholders and beneficiaries indicated as direct results the creation of new strategic partnerships across borders and more visibility in international markets of touristic destinations in the EU. While few SMEs were directly involved (100), the involvement of professional associations and local, regional and national public tourism agencies created the basis for potentially strong multiplier effects.

The key objective of the Tourism programme is to strengthen the competitiveness of the EU Tourism sector and enhance the capacity of SMEs in the sector to expand their frontiers, both from a service/product offer and geographical point of view. The Tourism programme is geared towards the involvement of actors along the value chain. Based on the data available, the programme directly involved about 100 companies, active in the tourism sector, and an additional 50 private enterprises active in other sectors. The remaining 200 organisations were mainly business associations (mainly active in tourism), public agencies, user organisations, and professional service providers (eg marketing specialists).

1.2.8. Cluster initiatives

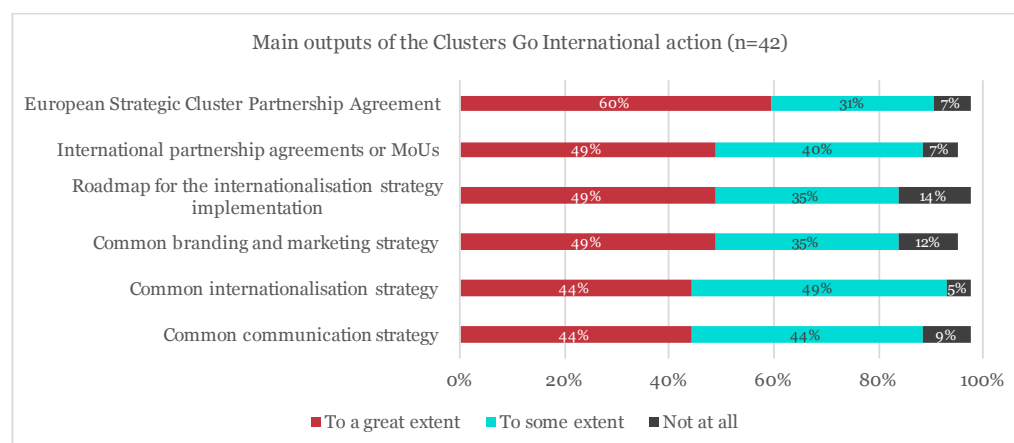
The "*Clusters Go International*" action shows a particularly strong alignment with the need of the clusters to internationalise their activities, both within Europe and beyond. It concluded that the actions show good potential to lead to an **improved strategic position in global value chains** and an **enhanced access to potential inward investors** as survey respondents and interviewees alike highlighted that the activities are based on a strategic analysis, while flagging out the **limited budget** as a hurdle for their internationalisation activities that was reported by 90% of the clusters as an important bottleneck. Moreover, it judged a **positive coherence** in relation to the complementarities and synergies created

with other COSME activities geared towards internationalisation and indicated that the emerging markets of the main EU trade partners are covered through the action.¹⁵

The interim evaluation revealed that the Cluster Go International action reached 3,800 SMEs per € 1 million invested and it flagged out that the clusters involved can also play a major role to facilitate the recruitment of the most relevant European SMEs across regional industrial ecosystems to enter into joint business projects with partners in third countries¹⁶ for other related actions, such as the **EU's Low-Carbon Business Actions** in Brazil and Mexico, supported through the EU Foreign Partnership Instrument¹⁷.

At the time of the COSME interim evaluation in October 2017, the Clusters Go International action involved 25 European Strategic Cluster Partnerships (ESCPs), launched under the "*Clusters Go International*" action representing 145 cluster organisations across 23 European countries and more than 17,000 European SMEs. Only 15 out of the 25 selected ESCPs were funded, though, due to budget constraints; the other 10 partnerships were awarded the ESCP label and encouraged to continue their partnerships on a voluntary basis, without COSME funding. The 15 co-funded partnerships account for approximately 95 clusters reaching out to over 10,300 European SMEs. Consequently, the interim evaluation concluded that the Clusters Go International action **succeeded in involving a high number of clusters, some even at a voluntary level**, testifying the **high interest in this action** in the EU cluster community. Moreover, it reported that projects show **overall good progress** in reaching the outputs expected, such as partnership agreements.¹⁸

Outputs of the Cluster Internationalisation programme



Source: Technopolis Group, based on survey data (2017), Interim Evaluation of the COSME Programme

¹⁵ The horizontal actions of the European Cluster Collaboration Platform and the European Observatory for Clusters and Industrial Change also provide support within the umbrella of cluster initiatives.

¹⁶ In Mexico, at least 50% of European participants were informed about the LCBA project through cluster organisations. 90% of those clusters were members of the European Cluster Collaboration Platform (ECCP)

¹⁷ <http://www.lowcarbonbrazil.com/index>, <http://www.lowcarbon.mx/>

¹⁸ Each ESCP-4i developed a series of joint actions for their members (i.e. business missions, cooperation agreements, gateway services, export consortia, etc.) strengthening European SMEs access to specific third markets and putting in motion a long-term cooperation agenda with strategic partners in third countries.

The overall achievements of the 1st generation of European Strategic Cluster Partnerships (ESCPs) for going international 2016-2017 prove their success in supporting SME internationalisation. Over a 24 months period, they involved 2000 SMEs in activities targeting international third-markets generating 85 concrete business cooperation cases with international partners. 370 Cluster-to-Cluster events and 3010 Business-to-Business events have been conducted, whilst 39 Memoranda of Understanding and 45 collaboration projects implemented between EU clusters and international peer organisations. The interest in the action remained high for 2018-2019 with 23 new partnerships having been established since.¹⁹

The interim evaluation highlighted the Cluster Go International program (with its fostering of European partnerships among clusters in order jointly to develop and implement internationalisation strategies) amongst those COSME action lines with a **very high EU added value**, where the scale and depth of support goes well beyond the support that can be offered to European SMEs through national or regional initiatives.²⁰

It also concludes the action is very relevant to the overall need of SMEs in building trust in finding suitable partners. It points out though that it does not address the barrier of high costs that come with building trust in finding suitable partners. As a result, it concludes that a **potential upgrade of the programme could therefore include other types of support**, such as demonstration projects, feasibility studies and knowledge-acquisition activities.

The results of the COSME interim evaluation also echoed those of a separate evaluation of cluster initiatives from 2014²¹, which concluded for instance that the European cluster initiatives **"generated added value through structuring cluster cooperation contributing to the emergence of European meta-clusters"** and have reached out to a wide range of clusters, while flagging out that they **lacked the financial means to involve SME sufficiently**.

Given the highlighted limitation in terms of budget, a possible merging with other small actions (such as the Cluster Excellence Programme) and the newly launched European Strategic Cluster Partnerships for smart specialisation investments (under the heading of industrial modernisation) as well with other larger actions under other programmes (such as INNOSUP-1 cluster projects under Horizon2020) needs to be carefully considered.

The intermediate results of the cluster projects for new industrial value chains (INNOSUP-1) shows how clusters can be used to effectively channel direct support to SMEs for cross-sectoral and cross-regional collaboration and innovation support, which

¹⁹ <https://www.clustercollaboration.eu/eu-cluster-partnerships/escp-4i/first-generation/achievements> and <https://www.clustercollaboration.eu/news/clusters-go-international-partnering-event-2018-sharing-experiences-boost>

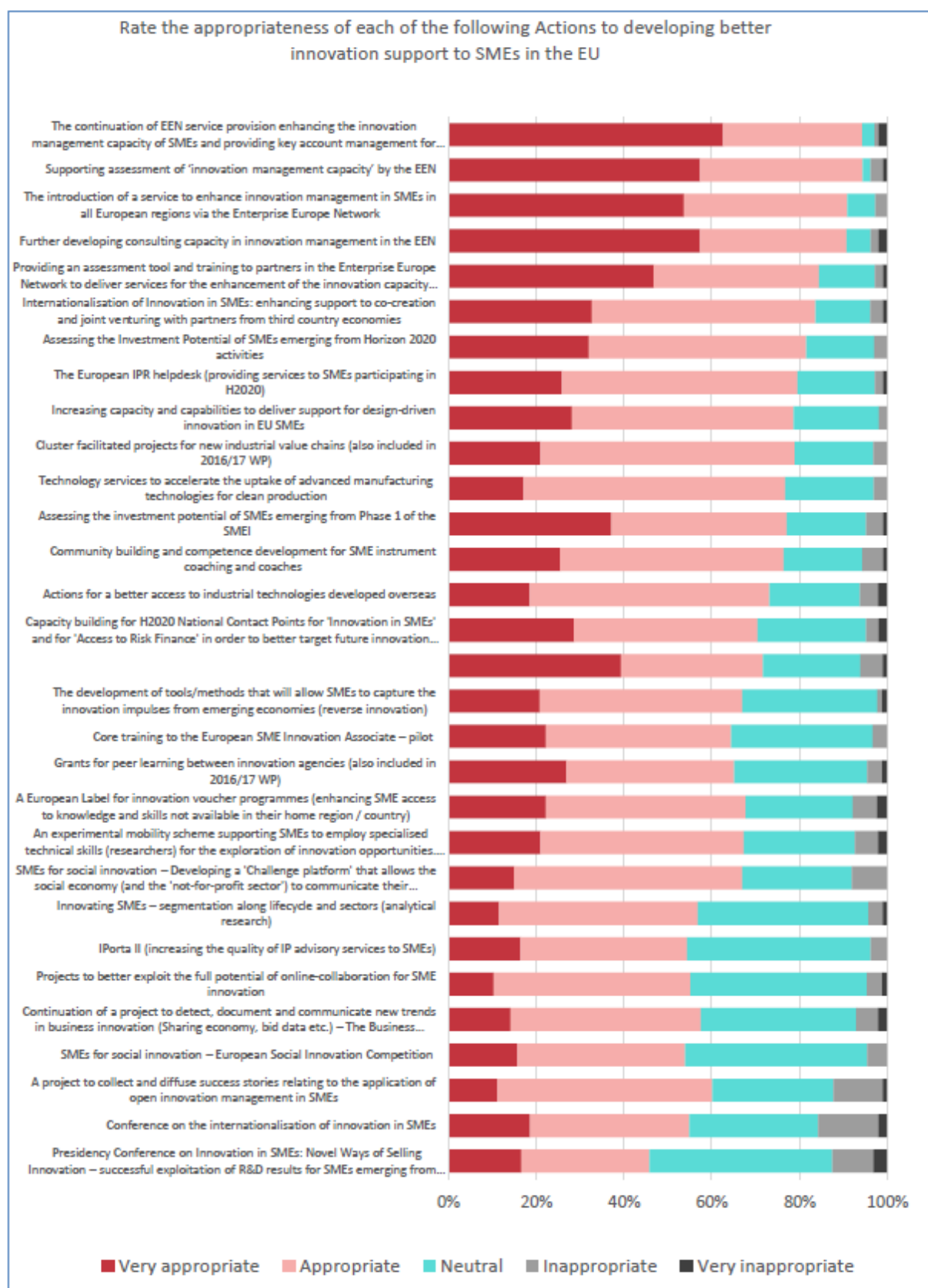
²⁰ The European cluster initiatives are designed to complement and support efforts taken at regional and national level, with a particular focus on supporting strategic interregional partnering.

²¹ Technopolis, EY & Danish Technologica Institute (2014) Evaluation - Cluster initiatives managed by DG Enterprise and Industry, ENTR/172/PP/2012 – LOT4, available at <https://publications.europa.eu/en/publication-detail/-/publication/c1ad8410-9bae-49df-b1f1-69b36071cf30/language-en>

appropriateness was rated by the survey results presented in the interim evaluation of Horizon2020.²² Nearly 80% of respondents rate this innovation action as very appropriate or appropriate, thus being amongst the **top ten rated actions for appropriateness to develop better innovation support to SMEs** in the EU out of the 30 actions.

²² SWD (2017)221 final, Interim Evaluation of Horizon2020, Annex 2. See [https://ec.europa.eu/research/evaluations/pdf/archive/h2020_evaluations/swd\(2017\)221-interim_evaluation-h2020.pdf](https://ec.europa.eu/research/evaluations/pdf/archive/h2020_evaluations/swd(2017)221-interim_evaluation-h2020.pdf)

Figure 161 - Appropriateness of the INNOSUP 2014/15 and 2015/16 Actions



Source: Technopolis, based on Agency survey data Sample size: 79 - 110 (excludes "don't know" answers).

The preliminary impact monitoring further revealed that the six ongoing INNOSUP-1-2015 projects that started in 2016/2017 **reached out to over 2800 SMEs** (e.g. through matchmaking events, call for ideas/collaboration projects etc.) and that already **449 SMEs are supported directly** (e.g. through innovation vouchers). Overall, the initiative is on track to support directly over 2000 SMEs by 2020 to take-up and adapt solutions across sectors and regions.

The lessons learned from the cluster initiatives and consultations with stakeholders such as during the 2017 GROWyourREGION conference²³ and at the EU Industry Day revealed the following main conclusions:

- Cluster initiatives shifted its focus from supporting clusters to using clusters for creating growth opportunities for SMEs and investments
- High need to support SMEs in their internationalisation activities and overcome sectoral and regional silos, e.g. by focussing on value chains & related industries
- High need for more strategic connections across eco-systems and stronger link to smart specialisation, for which the right mix of partners is needed
- Missing funding pipeline to make strategic partnerships sustainable across industrial specialisations

1.2.9. e-skills

The **e-Skills** action line entailed three actions:

- The ‘e-skills for jobs’ action, an awareness campaign (a budget of €2m)
- An action for the ‘Development and implementation of a European Framework for ICT professions’, ie an action mainly focused on framework development and coordination (€500k), and
- The action ‘Promotion of e-leadership skills in Europe’, an action geared to the development, validation and dissemination of a new, comprehensive policy agenda on leadership skills for digital and KETs (€500k).

All actions funded reached the outputs expected. Stakeholders interviewed were positive especially in their assessment of the effectiveness reached by the ‘e-skills for jobs’ awareness campaign. In 2016, it covered 21 different countries where events were organised and many stakeholders and high-level policy-makers were involved, including members of the European Parliament. Stakeholders and survey respondents unanimously indicated the effective engagement of various stakeholders such as education and training organisations, employees and entrepreneurs as the most important factor in driving

²³ https://ec.europa.eu/growth/content/300-participants-co-create-inspiring-future-cluster-initiatives-grow-your-region-conference_en

progress towards an enhanced awareness and especially an enhanced availability of digital skills.

1.2.1. EU-Japan Centre for Industrial Cooperation

The EU-Japan Centre for industrial cooperation (co-financed and co-managed by the EU and the Japanese sides) was effective in fostering industrial cooperation, including trade cooperation between the EU and Japan, providing policy analysis (Policy seminar, EU-Japan business round table, Minerva fellowship programme), providing services to business (e.g. get ready for Japan, Kaizen webinars, Vulcanus in Japan and in the EU), providing SME support (e.g. on tax and public procurement), organising information events and knowledge-sharing opportunities, as well as networking activities with the objective of facilitating and fostering the cooperation between European and Japanese companies and clusters. Actions for increasing its impact and potential synergies with other actions will be further considered.

1.2.2. Consultations

The consultations in the context of the interim evaluation of the COSME programme included:

- 121 bilateral interviews with stakeholders for the four programme specific objectives (access to finance, access to markets, favourable environment and entrepreneurship);
- eight qualitative consultations targeting two specific objectives (access to finance and favourable environment) and mostly including open ended questions;
- seven quantitative consultations targeting five specific COSME measures (loan guarantee facility, Enterprise Europe Network, Clusters for International, Tourism calls and the mentoring scheme for new entrepreneurs) mostly including closed ended questions;
- an open public consultation²⁴.

Intermediaries and beneficiary SMEs were approached for the qualitative and quantitative consultations. In total, 4,100 responses were received. The public consultation received 195 responses and 14 position papers.

Overall, the respondents to the open public consultation recognised that COSME is successful in implementing its objectives (access to finance, access to market, improve the business environment and promote entrepreneurship).

In order to increase the socio-economic impacts of COSME, it would be important to increase the budget of the financial instruments (75% of respondents), to provide more

²⁴ https://ec.europa.eu/info/consultations/interim-evaluation-programme-competitiveness-enterprises-and-small-and-medium-sized-enterprises-cosme-2014-2020_en

business advisory services (73% of respondents), to expand entrepreneurship mobility schemes (58% of respondents) and to substantially expand actions to support the uptake of new technologies, skills and new business models (73% of respondents).

73% of the contributors also considered the increase of synergies and coordination with other EU/national/regional programmes to be important.

All the position papers advocated for a continuation of the programme under the new MFF and most of them called for its strengthening. They insisted that an SME driven programme focusing on SMEs needs and characteristics is necessary due to the importance of SMEs in the EU economy. This programme could target all SMEs and would be based on an integrated business support approach that covers the entire life-cycle of an SME and delivers tangible benefits for entrepreneurs with a strong focus on simplification.

Results of open public consultation on next MFF – Cluster R&D, SMEs and single market

A public consultation on EU funds in the area of investment, research & innovation, SMEs and single market was conducted from 10 January to 9 March. While only 8.3% of respondents had experience with the COSME programme, around 25% declared that their replies refer to the EU support for SME and entrepreneurship (1.034 respondents).

Around 77% of them think that the SME and entrepreneurship support provided by the EU has a good or large added value compared to what Member States can achieve at national, regional and/or local level. Foster research and innovation (61%), support education, skills and training (47%) and support industrial development (43%) are among the better-addressed challenges by the current SME and entrepreneurship support. They consider that ensure a clean and healthy environment, facilitate digital transition of economy and facilitate SME access to finance are a slightly less well addressed (from 36% to 32%).

Concerning the obstacles preventing the current EU SME and entrepreneurship funds/programmes to achieve their objectives, the selected respondents believe that the complex procedures (75%), the lack of flexibility (58%), the insufficient synergies with other EU programmes (56%) and the difficulty to combine EU and other public support are the main difficulties. The lack of EU standards, the inadequate IT capabilities and the insufficient critical mass are considered less important.

SME stakeholders²⁵ generally supported COSME and its continuation in the next MFF. As SMEs have a central role in the European economy their competitiveness and development should be at the heart of the EU support strategy. The stakeholders

²⁵ Position papers received in the latest Commission consultations by stakeholders (Business Organisation such as BusinessEurope or Eurochambres, sectoral business organisations, national and regional administrations etc.). The consultations focused on: EU funds in the area of investment, research & innovation, SMEs and single market; COSME interim evaluation; Start-up and scale-up Initiative

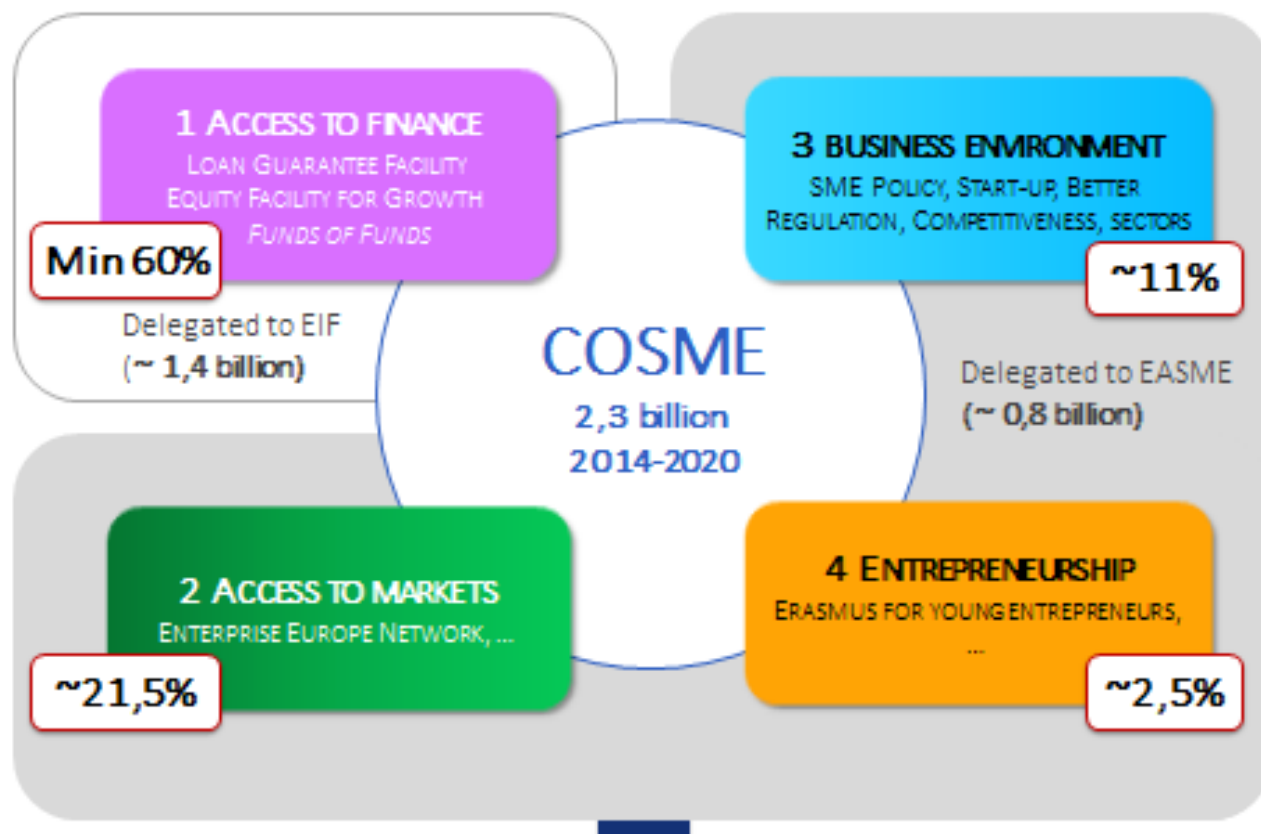
identified as key elements of the future SME support the financial instruments, EEN and the mentoring scheme for new entrepreneurs. They proved to be valuable in the current programme and should be therefore continued and strengthen in the next MFF. The new programme should also have simplified rules, building on the example of Horizon 2020, and ensure better synergies with other EU programmes.

2. THE OBJECTIVES

2.1. Challenges for the programmes of the next MFF

2.1.1. Key features of COSME 2014-2020

COSME Programme



COSME supports the creation and growth of small and medium sized enterprises. With a € 2.3 billion budget for the 2014-2020, COSME contributes to the Commission's top political priority to create more growth and jobs and filling the gap in investment in the EU. The COSME programme has a regulation that sets four objectives:

- At least 60% of the programme, that is 1.4 billion, is devoted to ease **access to finance** for SMEs, both through guarantees and equity. Due to the high leverage effect, COSME is expected to help up to 330.000 SMEs by mobilising around €20 billion in guaranteed loans and up to nearly 4 billion for equity finance.
- Second, COSME supports SMEs in **access to markets** and internationalisation. The Enterprise Europe Network with contact points in more than 60 countries²⁶ through

²⁶ In Japan our contact point is the EU-Japan Centre for industrial cooperation

its more than 600 local contact points. Since 2016, the EEN is implementing, in addition to its normal activities, also the start-up and scale-up initiative, a priority of the Single Market Strategy.

- Third, COSME contributes to the creation of a **favourable environment for enterprises** such as clusters and **support their competitiveness**. This includes several activities such as the platform for better regulation or several actions relating to SME policy.
- Fourth, COSME **promotes entrepreneurship, particularly** with the mentoring scheme for new entrepreneurs, where participants acquire a business experience in a successful SME in another country.

| COSME 2014-2020 | Nominal (in million €) | Baseline post 2020 (-15%) |
|--|-------------------------------|----------------------------------|
| Access to Finance (financial instruments) | 1440 | 1224 |
| Enterprise Europe Network | 375 | 319 |
| EU-Japan Centre | 20 | 17 |
| IPR SME helpdesks | 18 | 15.3 |
| Other actions and support measures | 91 | 77.35 |
| Access to Markets (subtotal) | 504 | 428.4 |
| Modernisation of Industry | 60 | 51 |
| Sector's competitiveness | 48 | 40.8 |
| Clusters | 40 | 34 |
| SME Policy | 38 | 32.3 |
| Better Regulation | 6 | 5.1 |
| Other actions and Support Measures | 46 | 39.1 |
| Business Environment and Competitiveness (subtotal) | 238 | 202.3 |
| The mentoring scheme for new entrepreneurs | 65 | 55.25 |
| Other actions and Support Measures | 25 | 21.25 |
| Entrepreneurship (subtotal) | 90 | 76.5 |
| Management and Administration | 25 | 21.25 |
| EASME | 60 | 51 |
| Programme Administration (subtotal) | 85 | 72.25 |
| Total | 2357 | 2003.45 |

2.1.2. Challenges for COSME

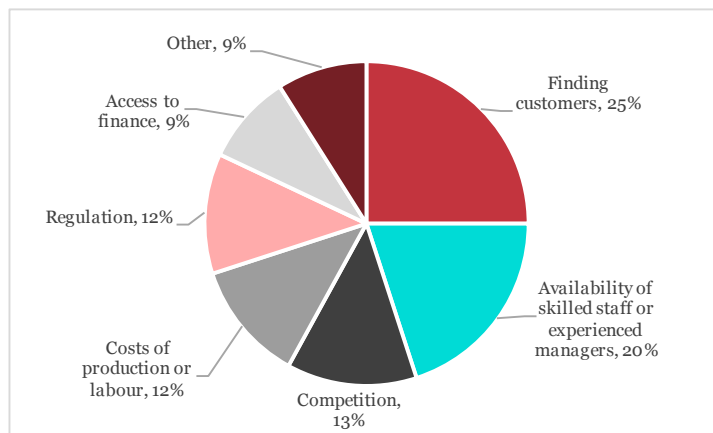
The conditions for starting-up a business in the EU (in terms of cost and time to create a company) has progressed in the last ten years. However, the situation is uneven across Member States. Furthermore the administrative burden to operate a business, such as obtaining permits and licenses, remains high. In addition, there is a lack of entrepreneurial spirit and a large heterogeneity of entrepreneurship support services. Newly created companies and smaller firms still face difficulties in accessing finance. They are not able to reap sufficiently the opportunities offered by the Single Market and by markets beyond the EU. This means that the full growth potential of SMEs remains unlocked as they are not sufficiently integrated in industrial value chains with the EU and globally. They face also difficulties in taking up the benefits of innovation, creativity, new business models and resource-efficient solutions; they do less business on-line than bigger firms and have difficulties in finding the right skills. While SMEs are essential to generate jobs and growth, their contributions are limited by these barriers. It is the objective of COSME to address these difficulties for scaling-up by providing adapted financial instruments, generating business opportunities in the single market and beyond, stimulating cooperation between Member States to reduce the administrative burden, promoting entrepreneurship, supporting the modernisation of industry and creation of favourable business eco-systems such as clusters²⁷ as well as linkages between them so that SMEs can flourish and scale-up.

In the specific case of the outermost regions' SMEs, the difficulties they encounter are particularly significant because their regional markets are small, depend heavily on exchanges with Europe and face high competition from neighbouring third countries. As outlined in the Commission's communication "A stronger and renewed strategic partnership with the EU's outermost regions"²⁸, it will be important to further enhance the capacity of the outermost regions' businesses to operate: their specific concerns should be considered in the future programme (the successor of COSME) to help enhance their competitiveness in international markets and reap the benefits of globalisation.

²⁷ See, for instance, the 2016 European Cluster Panorama of the European Cluster Observatory (available at https://ec.europa.eu/growth/content/european-cluster-panorama-2016-published-0_en) & Smart Guide to Cluster Policy (available at <http://ec.europa.eu/DocsRoom/documents/16903/attachments/1/translations/en/renditions/native>) that show that fast-growing enterprises (so-called gazelles) based in strong clusters employ 35 employees on average compared to 24 outside of strong clusters and that clusters overall account for 39% of European jobs and 55% of European wages. Moreover, various academic articles such as Delgado, M., Porter, M.E. & Stern, S. (2012) Clusters, Convergence and Economic Performance show that clusters offer a favourable regional eco-systems for innovation and entrepreneurship in which companies are more innovative, conduct more market research, cooperate more and register more international trademarks and patents than companies that do not operate in a cluster. It also shows that regions with strong clusters have positive spill-over effects on neighbouring regions and related clusters. SMEs active in clusters are thus more likely to master complexity and benefit from growth opportunities in clusters of related emerging industries.

²⁸ COM(2017)623

Figure 1: Most important problems faced by firms in EU28, April-September 2016



Source: European Commission, (2016): Survey on the access to finance of enterprises (SAFE), Analytical Report 2016

2.1.3. Challenges for Access to finance

The COSME Loan Guarantee Facility (LGF) is being successfully implemented in terms of geographic scope and in terms of reaching the right beneficiaries, i.e. SMEs which have problems in accessing finance. It is geared towards supporting any type of SME higher risk financing transaction. From a technical point of view, this is being achieved by offering portfolio guarantees free of charge to financial intermediaries across the participating countries. In return for such free of charge guarantees, financial intermediaries must commit to build portfolios of new financing transactions which constitute higher risk financing or to significantly increase the volumes of existing higher risk SME financing products.

The Loan Guarantee Facility has been effective in reaching those SMEs which experience particular difficulties in obtaining finance, namely start-ups (defined as businesses in their first five years of existence), which account for almost 50% of all financing transactions supported (as of 09/2017). Furthermore 91% of all supported enterprises are micro enterprises. The facility is also successful in supporting SMEs in a wide range of sectors. Over 12% of support has gone to knowledge-intensive services so far. But support has also gone to SMEs in the more traditional sectors such as wholesale, retail and construction and manufacturing as indicated below.

The average transaction size stands at €35,500. This is significantly lower than the average transaction size under the SME Guarantee Facility of the Competitiveness and Innovation Programme (the predecessor facility), where the average transaction size was approximately €65,000. The low average transaction size under COSME is most likely due to the €150,000 threshold introduced under the COSME LGF, above which financial intermediaries must by means of a checklist demonstrate that an SME is in principle not able to comply with any of the more than 10 different innovation criteria established

under the InnovFin SME guarantee facility of Horizon 2020.²⁹ This application of the checklist has been criticised during the mid-term evaluation as to onerous and cumbersome (significant administrative burden) for financial intermediaries and SMEs and has been mentioned as blocking an efficient implementation of the facility.

The key challenge to the implementation of an SME guarantee facility under the next Multiannual Financial Framework period will be to operate under the following market conditions:

1. **Significantly differing access to finance conditions across Member States require a flexible design of the guarantee facility:** Following the financial crisis a significant number of policy interventions coupled with positive economic developments have led to an improvement in the availability of bank finance, and the conditions for access to finance have on average recovered³⁰. However as regards volume of lending, pre-crisis levels have not been reached yet. Plus we observe significant differences in the access to finance situation for SMEs across Member States in terms of availability of finance, risk appetite of the commercial sector, conditions of finance (interest rates charged and collateral required) and product diversification. SMEs, however, rely on local providers of finance and are unable to overcome the national access to finance barriers.
2. **Differing degrees of public support activities in the Member States and significantly differing market gaps require a facility which is more responsive to those Member States which require most support, rather than relying on a roll-out purely based on demand; Member States alone will not be able to sufficiently address the market gaps:** The estimated market gap in EU 27 over the 7-year period (2011 – 2017) for new SME financing has come down from €42 billion in 2014 to less than €30 billion in 2017.³¹ However, this is the EU27-wide market gap after a significant amount of guarantee and loan support measures in the order of magnitude of €110 billion per annum are provided at a) national level (approximately €90 billion), b) under ESIF (mainly ERDF) (approximately €10 billion) and through EU central financial instruments (approximately €13 billion). Had the support at any of these three levels been lower, it can be assumed that the size of the market gap would have been higher. Going forward it is expected that Member States with strong budgetary positions may maintain or even increase the financial support for access to finance for SMEs. However, Member States with strained are in weaker financial positions and also have inadequate capacities to operate support schemes, will have to continue to rely on financial instruments established under EU programmes under shared management and those established at central EU level.
3. **Simplification of central EU guarantee support schemes for SMEs needed:** As set out in the Reflection Paper on the Future of EU Finances³², there is a *'need to ensure policy coherence among EU instruments to ensure that they all support EU objectives and facilitate reforms in Member States. For instance, in the area of SME*

²⁹ http://www.eif.org/what_we_do/guarantees/single_eu_debt_instrument/innovfin-guarantee-facility/

³⁰ Survey on the Access to Finance of Enterprises in the euro area April to September 2017, section 3.1: <https://www.ecb.europa.eu/pub/pdf/other/ecb.accessstofinancesmallmediumsizedenterprises201711.en.pdf?beb1832df4af9efa945a5a1f7b99eeb7>

³¹ Using the Upper bound method used in the ex-ante assessment for the SME initiative

³² https://ec.europa.eu/commission/sites/beta-political/files/reflection-paper-eu-finances_en.pdf

financing the same beneficiaries may be eligible to receive support through several instruments covered under different programmes (COSME, Horizon 2020 and EFSI) or implemented by Member States through cohesion policy. This overlapping product offer has caused some confusion for financial intermediaries as to which scheme to apply. Rules and conditions applying in the same policy area should be aligned.'

4. **Fintech companies as potential challengers to banks as the main providers of SME debt finance:** The financing of SMEs in Europe through the banking sector has a long tradition. However, the banking market is undergoing significant structural changes. The number of financial institutions is continuously reducing and new players (fintech) are emerging which are ready to challenge the traditional banking sector. *'There is no doubt that the landscape has changed for banks. [.....], the digital revolution is lowering cost, distance, time and barriers to entry, creating space for new fintech players to enter the market'*³³. Despite the fact that fintech is a nascent industry, it is likely to have an impact on the SME financing markets in the next 10 years. While many banks are investing heavily in technology, industry experts have gone as far as to state that *'Banks may face their “Kodak moment” unless they embrace disruptive technologies. However, since banks are profiting from business-as-usual, there is little incentive for them to innovate and cannibalize their own business'*³⁴.

2.1.4. Access to markets and global value chains

One of the main challenges to be addressed in the new MFF is the lack of SMEs' capacity to develop their activities outside their home country, especially in the Single Market but also in markets outside the EU. The main problems identified are (1) finding customers and business partners outside their home country, (2) spotting international business opportunities and (3) getting information on other markets. In this respect, the provision of information services will continue to be a challenge.

European industry faces increasing competition from abroad across the whole value chain, and it must internationalise further to face it. Hence, supporting the internationalisation of European business is a crucial element in the strategy to widen and deepen internationalisation of the EU economy as a whole.

Putting in place support for structures that help EU businesses penetrate foreign markets is an important dimension of this internationalisation strategy, in particular for SMEs but also for all types of business which need advice and services on key aspects such as IP, standardisation, regulatory environment, public procurement, etc.

To this end, EU business support structures in third countries have an important role to play in synergies with the EEN vision for the future that are developed, in particular the EEN members (BCC) in third countries. Already now the EU SME Centre in China, the

³³ <http://www.smefinanceforum.org/post/banks-and-fintech-companies-come-together-to-discuss-vision-2030-for-small-business-finance>

³⁴ <http://www.smefinanceforum.org/post/banks-and-fintech-companies-come-together-to-discuss-vision-2030-for-small-business-finance>

ELAN-biz project in Latin America and the EU-Japan Centre for Industrial Cooperation are also playing this role.

Hence the need for EU support in third country to help business to establish presence and access local markets. EU support should be complementary to that of MS and should focus on areas with the highest added value.

SMEs' expectations are changing towards a more tailored approach of information provisioning and specialised advice addressing specific needs. Synergies and efficiency gains will be realised by further integrating the mentoring scheme for new entrepreneurs in the Network's activities, creating a one-stop-shop service for SMEs. The Enterprise Europe Network intends to link-up and use existing and new information sources such as the Single Digital Gateway to address the information asymmetry challenge.

The Network intends to continue and further develop its synergies with other Community programmes such as Horizon 2020 with the services provided to SME beneficiaries of the EIC, encouraging and promoting the participation of SMEs in Horizon2020, and the support and cooperation with initiatives financed by EU regional funding (like for example the macro-regional cooperation projects involving SMEs). The identification of business partners abroad will continue to be a major challenge as SMEs that fail to innovate or internationalize run the risk of losing ground to competitors, losing key staff, or simply operating inefficiently; this also includes the need to co-operate along their value and supply chains. The Network also intends to continue its cooperation with EU financed Business Centres abroad, based on the good practices and lessons learnt with the business centre in Beijing who became a Network node in 2015.

The Network will have to continue building on existing strengths and evolve structures and services to help SMEs survive, innovate and grow in an increasingly competitive world and address the challenge of shortcoming managerial capacities of SMEs to increase their competitiveness in the Single Market and abroad. It requires the Network to further develop the client centric approach where tailor made advisory services will be provided with Network consortia working together to support the client to innovate, grow and internationalise.

The survey of entrepreneurs participating in the mentoring scheme (part of the mid-term review of COSME) confirmed the existence of market and systemic failures in the area of entrepreneurship. These include obstacles setting up businesses, difficult Framework conditions that result in new businesses struggling to survive and grow. Furthermore, there is a lack of effective policy support related to entrepreneurship.

There is also a widespread belief that there is a lack of entrepreneurial culture, weak entrepreneurial spirit, and low levels of entrepreneurial firm creation in Member States.

With regards to further implementation of the mentoring scheme the main challenges are: the demand for expansion of the programme (increased number of participants) confronted with reduced resources available as well as future geographical extension

together with further efficiency gains. Some efficiency gains were reached thanks to the introduction of a Framework Partnership grant procedure intended for experienced mentoring scheme intermediary organisations in 2016. In the post-2020 period, further synergies and efficiency gains will be realised by further integrating the mentoring scheme into the portfolio of EEN activities. This would create a one-stop-shop for entrepreneurs and enterprises supporting them from the start-up phase, to scaling-up and internationalisation.

2.1.5. Challenges for business environment and industrial modernisation

Doing business remains cumbersome in large parts of the EU and barriers to scaling-up persist. Furthermore, the administrative burden to operate a business, such as obtaining licenses or permits, remains high.

SMEs face difficulties in taking up the benefits of innovation, creativity, new business models and resource-efficient solutions. They also do less business on-line than bigger firms and have difficulties in finding the right skills. While SMEs are essential to generate jobs and growth, their contributions is limited by these barriers. Supporting the modernisation of industry and creation of favourable business eco-systems, such as clusters³⁵, as well as linkages between them is thus crucial for helping SMEs to flourish and scale-up.

Various reports and studies have shown that insufficient investments in industrial modernisation and the fragmentation of business eco-systems and clusters are hampering future EU competitiveness and create an innovation divide. It is therefore crucial to complement the excellence-based focus of R&D support to develop breakthrough innovation under the FP with support for bringing solutions to mainstream SMEs across the EU that facilitates their adoption and redeployment in different sectors and regions and takes industrial specialisations into account.³⁶

The heavy decrease in the number of SMEs introducing product and process innovation (by 18.2%) between 2010 and 2016 reported by the 2017 European Innovation Scoreboard illustrates this problem. SMEs account for only one-fifth of EU business R&D expenditures. On top, the Scoreboard also shows that innovative SMEs only marginally collaborate more with others (0.5%) and that employment in fast-growing firms based in innovative sectors has declined by 5.4%.³⁷

³⁵ See, for instance, the 2016 European Cluster Panorama of the European Cluster Observatory (available at https://ec.europa.eu/growth/content/european-cluster-panorama-2016-published-0_en) & Smart Guide to Cluster Policy (available at <http://ec.europa.eu/DocsRoom/documents/16903/attachments/1/translations/en/renditions/native>) that show that fast-growing enterprises (so-called gazelles) based in strong clusters employ 35 employees on average compared to 24 outside of strong clusters and that clusters overall account for 39% of European jobs and 55% of European wages. Moreover, various academic articles such as Delgado, M., Porter, M.E. & Stern, S. (2012) Clusters, Convergence and Economic Performance show that clusters offer a favourable regional eco-systems for innovation and entrepreneurship in which companies are more innovative, conduct more market research, cooperate more and register more international trademarks and patents than companies that do not operate in a cluster. It also shows that regions with strong clusters have positive spill-over effects on neighbouring regions and related clusters. SMEs active in clusters are thus more likely to master complexity and benefit from growth opportunities in clusters of related emerging industries.

³⁶ JRC Policy insights – Industrial R&I, February 2018, For a transformative industry & innovation strategy

³⁷ Moreover, the 2015 European cluster trends report of the European Cluster Observatory shows that the intensity of transregional cooperation patterns is diverse across Europe.

A recent study³⁸ on advanced manufacturing shows that there are barriers to the uptake of innovation, such as sufficient know-how, adequate human capital and organisational and managerial capacity. Small firms have much larger problems to overcome these barriers than large firms. While 75% of companies indicate the high costs of investment in advanced manufacturing technologies, an EIB study also shows that over 90% of smaller companies active in key enabling technologies struggle to raise the finance they need. More than 90% of SMEs in Europe also feel lagging behind in digital innovation. They also do less business on-line than bigger firms and have difficulties in finding the right skills. As the specialised competences are often concentrated in few countries³⁹ and SMEs struggle to find the right partners, too few SMEs in the EU embrace advanced and additive manufacturing, artificial intelligence and augmented reality and master new service offerings, especially in traditional manufacturing sectors.

Similarly, inter-regional collaboration and SME support efforts are currently not sufficiently strategically pooled across industrial policy priorities. Making a better use of SME intermediaries, including clusters, and supporting their teaming up offers scope to better link actors, notably SMEs, across specialised eco-systems in the EU and thus to deliver a stronger EU added value.⁴⁰

To facilitate the take-up of advanced technologies (e.g. advanced manufacturing, digital, Big Data), new business models and low-carbon and resource-efficient solutions as well as to promote internationalisation activities, partnering and skills development to embrace industrial transformations are the objective of the scaling-up instrument to be channelled via specialised SME intermediaries under Joint Cluster Initiatives.

For an effective implementation, it will be important to overcome the significant hurdle of the limited budget for existing cluster actions that was highlighted in the COSME interim evaluation as otherwise the indicated good potential of supporting SMEs positioning in global value chains cannot be achieved. The interim evaluation reveals that the Cluster Go International action, that aims at supporting clusters in designing and implementing an internationalisation strategy, reaches 3,800 SMEs per € 1 million invested. The European Cluster Collaboration Platform gathers more than 730 cluster organisations with an average of 100 SMEs per cluster, reaching out to about 73 000 SMEs across Europe. These actions together with capacity-building efforts under the European Cluster Excellence Programme and newly launched European Strategic Cluster Partnerships for smart specialisation investments produce impact but are limited by the available budget.

To overcome the limited budget and make more strategic use of clusters in supporting SME growth, a consolidation and reinforcement of cluster initiatives is foreseen, ideally together with cluster-related actions under Horizon2020. Therefore, the interim evaluation's suggestion of an "integrated approach" for SME growth support to cover all stages of firm's development and the "reinforcement of ecosystems" is followed. By merging the various activities under Joint Cluster Initiatives and reorganising them

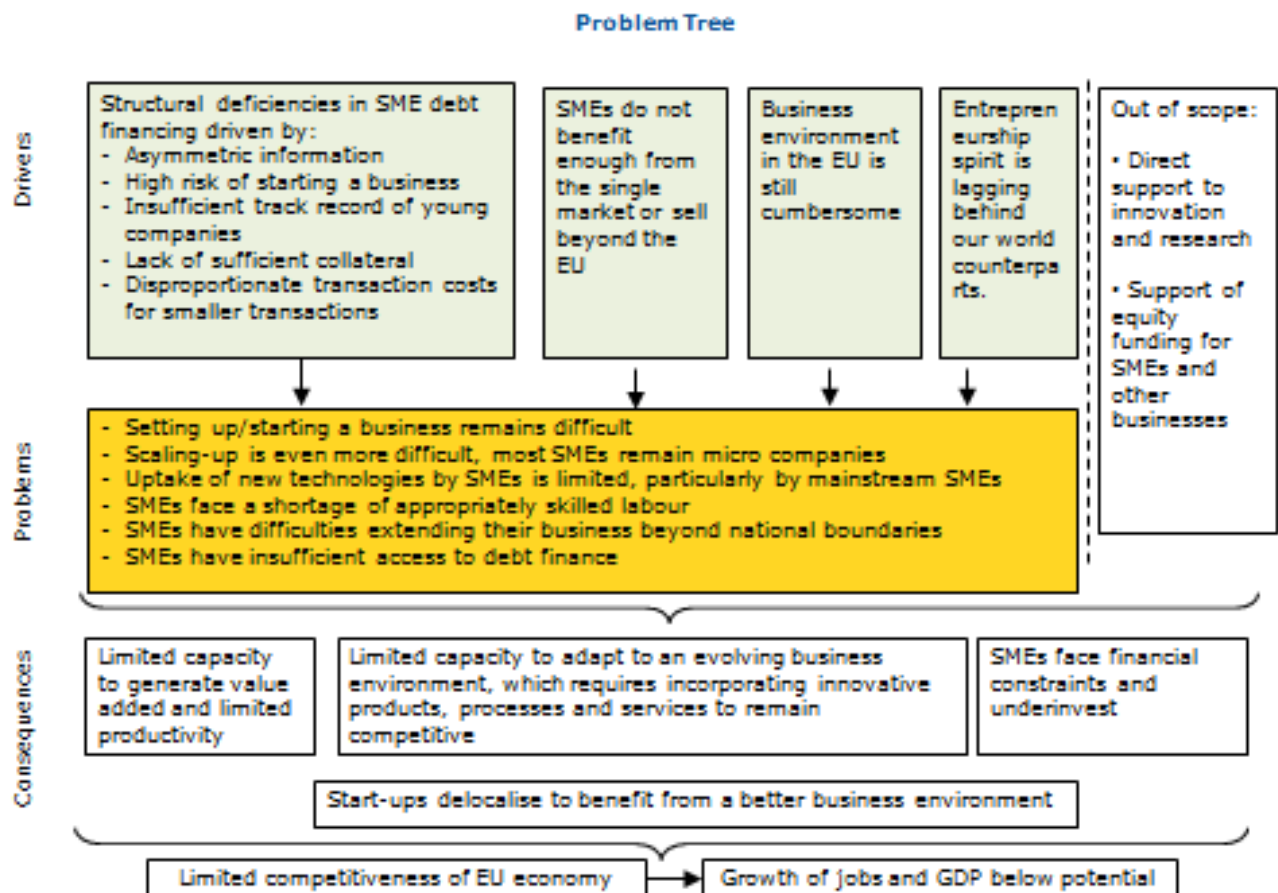
³⁸ Kroll et al. (2016) An analysis of drivers, barriers and readiness factors of EU companies for adopting advanced manufacturing products and technologies.

³⁹ Out of 1350 technology centres offering services to SMEs in Europe, 60% are concentrated in 6 EU Member States according to a mapping of technology centres for key enabling technologies.

⁴⁰ See also Communication on "A renewed EU Industrial Policy Strategy" (COM/2017/0479 final), the Start-up and Scale-up Initiative (COM/2016/0733) and the Smart Specialisation Communication on "Strengthening Innovation in Europe's Regions" (COM(2017) 376 final)

towards an effective tool to implement industrial policy and SME support⁴¹ that teams up actors across Europe under 10 to 20 related industrial specialisations and applying a simplified and streamlined implementation⁴², COSME will be able to contribute to the strengthening and linking of business eco-systems to help SMEs to start-up and grow.

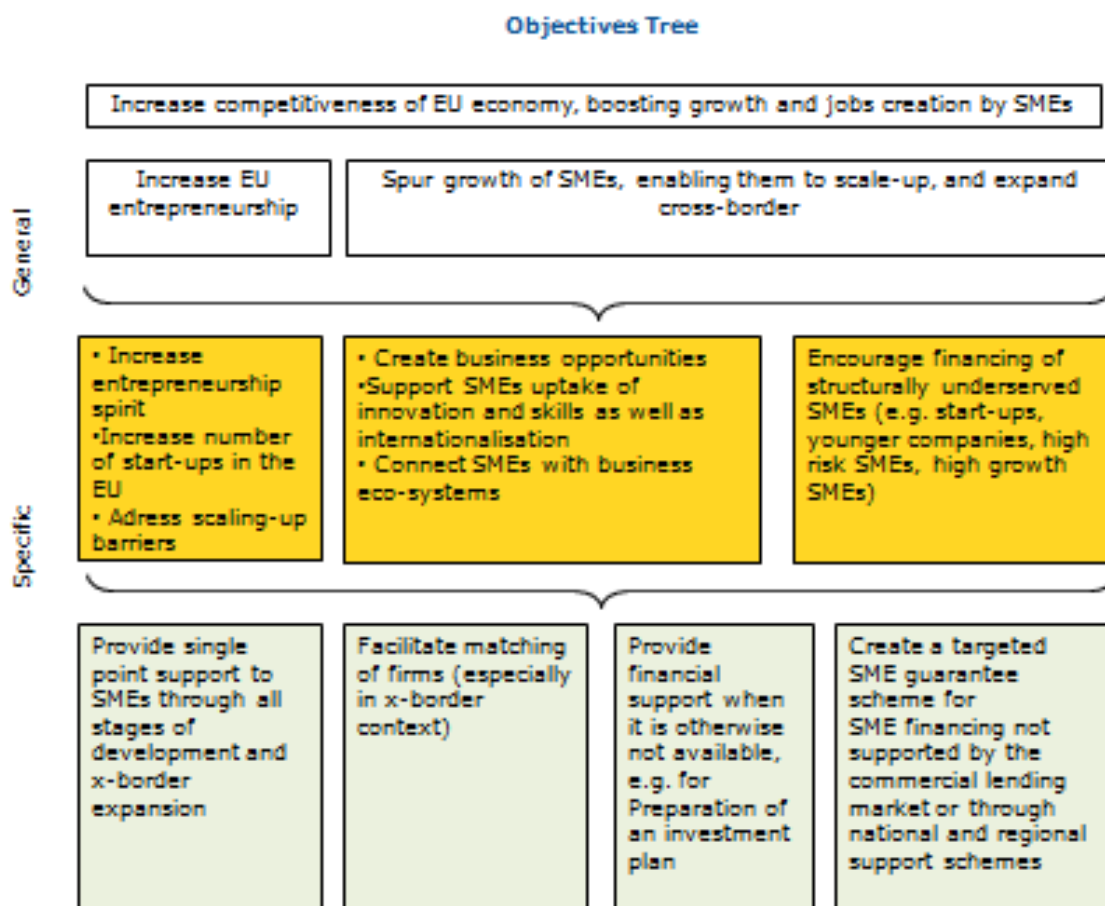
This means that the full growth potential of SMEs remains unlocked as they are not sufficiently integrated in industrial value chains with the EU and globally.



⁴¹ The evaluation of the previous ERDF and Cohesion Fund programming period shows, for instance, that the promotion of networking through clusters has been among the most successful instruments for supporting innovation in SMEs and nurturing their development, even if their number was marginal within the whole set of instruments. See Ex-post evaluation of Cohesion Policy Programmes 20017-2013 Financed by the ERDF and the CF, WP2 Support to SMEs, Increasing research and innovation in SMEs and SME development, Contract Nr. 2014CE16BAT002

⁴² This is facilitated by the possibility to use lump sums and financing linked to the fulfilment of achievements of results expected to be allowed by the revision of the Financial Regulation.

2.2. Objectives of the programmes of the next MFF



Deriving from the analysis of the problems and challenges, the general objectives of the COSME+ programme do not differ from the COSME regulation.

The **general objectives** of the COSME+ programme are:

- Promoting the creation and sustainable growth of enterprises, in particular SMEs.
- Strengthening the competitiveness of enterprises, boosting industrial modernisation and fostering entrepreneurship.

The analysis of the relevance of the Interim Evaluation of COSME shows its objectives are still pertinent with a different emphasis for some of them.

The specific objectives of the COSME+ programme are:

1) **Access to finance (including the SME loan guarantee)**

- Addressing the **access to finance** gap for SMEs and obstacles for investments;

2) **Access to Markets (including the EEN and the mentoring scheme)**

- Facilitating SMEs' access to markets (public and private) and supporting them in addressing **global and societal** challenges;
- Supporting **business internationalisation**, notably of SMEs, and strengthening **EU industrial leadership** in global value chains.

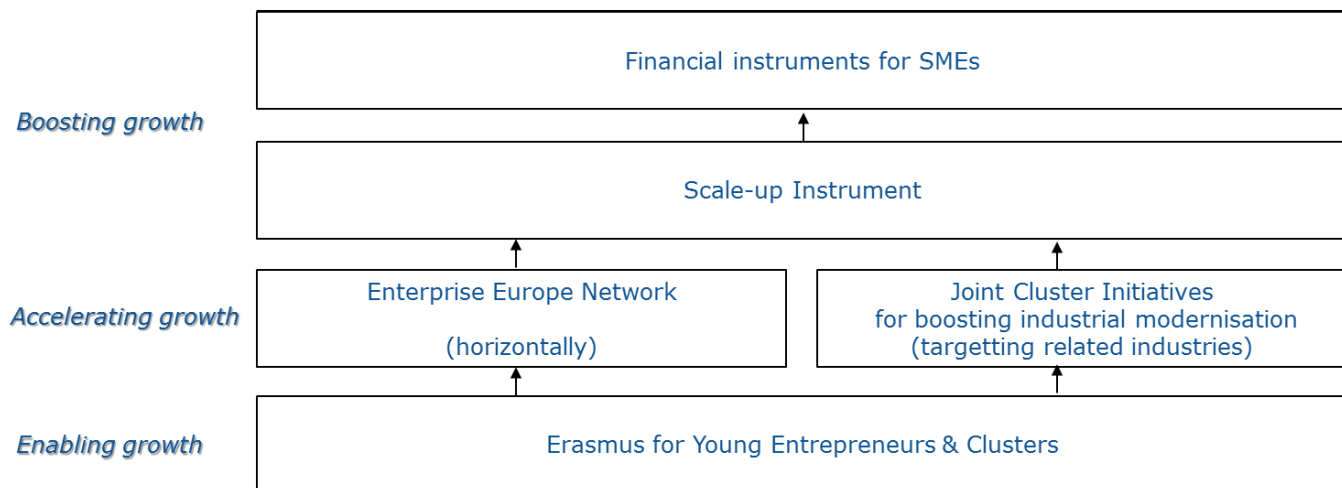
• 3) **Business Environment, Industrial Modernisation, Competitiveness and Entrepreneurship**

- Addressing **market barriers**, administrative burden and creating a favourable business environment towards helping SMEs to benefit from the **Single Market**;
- Facilitating the growth of **business, including skills development, and industrial transformation** across manufacturing and service sectors. Supporting SMEs' **uptake of innovation** and value chain collaboration through strategically **connecting ecosystems and clusters**;
- Promoting the exploitation of **entrepreneurial and market opportunities**, by fostering an entrepreneurial business environment and culture favourable to sustainable enterprises, and supporting start-ups, business sustainability and scale-ups.

3. PROGRAMME STRUCTURE AND PRIORITIES

3.1. Programme structure and priorities

The following diagram shows the logic of intervention in the life-cycle of an SME. This life-cycle logic will be integrated into COSME+ by favouring synergies between instruments. The goal is to be able to provide combined support to entrepreneurs and SMEs.



On the basis of the effectiveness demonstrated by the Interim Evaluation, COSME+ will focus on the actions that produced results in the current programming period:

- The Loan Guarantee Facility
- The Enterprise Europe Network
- The Cluster initiatives
- The mentoring scheme for new entrepreneurs.

This will result in the following overarching specific objectives at regulation level:

- **Access to finance (including the SME loan guarantee)**
- **Access to Markets (including the EEN and the mentoring scheme)**
- **Business Environment, Industrial Modernisation, Competitiveness and Entrepreneurship (including consolidated Joint Cluster Initiatives)**

The internal coherence of the programme will be strengthened by creating strong synergies between actions. Synergies can be found, for example, by increasing the links and cooperation between the Enterprise Europe Network, the mentoring scheme for new entrepreneurs and Cluster initiatives. The service proposed by each of these instruments could benefit the same groups of SMEs or entrepreneurs in a business development logic, notably those targeted by strategic interregional collaboration along and across clusters of industrial (smart) specialisations and EU value chains. For example, the would-be entrepreneurs benefitting from the mentoring and initial business matchmaking in the mentoring scheme for new entrepreneurs could be encouraged by collaborating clusters

to participate and be redirected to the EEN for more specialised business advisory services, broadened partnership opportunities or receive advice on financial instruments for funding needs. This forms part of the integrated approach based on the life-cycle of SMEs that the programme will follow. The Enterprise Europe Network and the mentoring scheme for new entrepreneurs will be upgraded, based on the existing synergies and similarities in their implementation modalities: for example by reinforcing the Enterprise Europe Network entrepreneurship support community, and the EEN scale-up advisors to help entrepreneurs with a proven business model to develop their activities bringing them in contact with potential business partners, hence providing a continuous support for SME throughout their lifecycle, which is a crucial element and a specific feature of COSME (missing in other programmes). The interlinks between the two actions is also demonstrated by the fact that already about 10% of the mentoring scheme for new entrepreneurs implementing organizations on the territory are also EEN Network members.

The number of smaller actions will be limited to a reduced number of supporting measures and management activities. We will define also a set of smaller scale actions to test new actions and then if successful scale up. It makes sense to have a mix of established larger-scale projects and smaller more experimental approaches. In order to reduce the existing complexities specific attention will be paid in providing integrated support (e.g. financing, advice, match-making) by using a 'one-stop-shop' approach.

The programme will also include horizontal measures for policy support, cross-sectoral cooperation, transnational cooperation of SMEs/joint business ventures, developing socio-economic knowledge and analysis for the competitive growth of SMEs in different sectors, support to entrepreneurship and micro enterprises in particular or enterprises with higher difficulty in accessing funding.

COSME's EU added value lies in contributing to jobs and growth creation through an extended network of intermediaries (such as the Enterprise Europe Network and clusters) by providing integrated support services for SMEs to innovate, to foster cross-border opportunities and cooperation and the internationalisation of SMEs. COSME contributes to reducing economic divergences by addressing market gaps through the SME guarantee facility which are not (sufficiently) addressed at Member State level

| COSME + Baseline post 2020 | Nominal (in million €) | Ambitious scenario |
|--|-------------------------------|---------------------------|
| Access to Finance (financial instruments) | 1200 | 2400 |
| Enterprise Europe Network + the mentoring scheme | 400 | 600 |
| EU-Japan Centre | 17 | 17 |
| IPR SMEs helpdesks | 18 | 18 |
| Other actions and support measures | 33 | 33 |
| Access to Markets (subtotal) | 468 | 668 |
| Joint Cluster initiative & Modernisation of Industry | 150 | 300 |

| | | |
|--|-------------|-------------|
| Scale-up instrument | | 1000 |
| Sector's competitiveness | 40 | 40 |
| SME Policy | 32 | 32 |
| Better Regulation | 5 | 5 |
| Other actions and Support Measures | 33 | 33 |
| Business Environment, Industrial Modernisation, Competitiveness and Entrepreneurship (subtotal) | 260 | 1410 |
| Management and Administration | 20 | 20 |
| EASME | 55 | 70 |
| Programme Administration (subtotal) | 75 | 90 |
| Total | 2003 | 4568 |

3.2. Access to finance

3.2.1. Priorities

The objective is to ensure that no instruments are created which have a sub-optimal size. Given the importance of access to debt finance for SMEs in EU27, it is proposed to use all available budgetary resources to only support guarantees and counter-guarantees for portfolios of debt finance operations under COSME+.

The existing option under the COSME Loan Guarantee Facility to support securitisation transactions, i.e. provide guarantees for a mezzanine tranche of securitisation transactions, has not been met with any market demand. It is therefore suggested that this implementation option is discontinued under the COSME+ programme.

Moreover, equity support instrument will be created under the SME window of the InvestEU Fund providing seamless support for SMEs and small mid-caps from the pre-seed stage all the way to the expansion and growth stage. Such a broad-based facility will enable flexibility, create economies of scale, operate more efficiently and be easier to market towards potential financial intermediaries. Therefore, it is suggested to discontinue equity support under COSME+ and focus only on the guaranty facility.

3.2.2. Expected minimum size for the intervention

The expected minimum size of the intervention, about €1.2 bn, comprises the total budget for financial instruments under the existing COSME programme reduced by 15% (baseline scenario).

As the SME guarantee facility will be implemented through the SME window of the InvestEU Fund, which is based on a budgetary guarantee rather than a fully funded financial instrument, a budget of €1.2 bn transferred to a budgetary guarantee translates into available resources of €1.5 bn (based on an expected provisioning rate of 85%).

The anticipated leverage for this facility ranges between 1:15 to 1:25. With available resources of €1.5 billion, new higher risk debt financing of €22.5 bn to €37,5 bn over the lifetime of the programme could be made available. On average, it is expected that between €3.2 and €5.4 billion would be made available annually.

The budget for the baseline scenario is based on the current COSME budget decreased by 15%, which assumes that EUR 1.2 billion will be made available for budgetary guarantee. Considering 85% provisioning rate, this would enable available investments of the guarantee facility of EUR 1.41 billion, which is broadly in line with the expected full budget of COSME Loan Guarantee facility supported by EFSI for the period 2014-2020. This budget would allow keeping the EU intervention at the same level and therefore the market gap would not increase further by EUR 4 billion annually, while contribution to more than 690,000 jobs being maintained or newly created over the programme implementation period.

3.2.3. EU-added value of the intervention

The EU-added value of SME guarantee facility to be set-up under the SME window of the InvestEU Fund will be to:

- create synergies by addressing market gaps not addressed at regional or national level: the market gap analysis has demonstrated that the size of the SME debt financing market gap is significant despite considerable interventions at Member State level and through central EU guarantees for SMEs. This will help to address the persistent market fragmentation and therefore strengthen the Single Market;
- create synergies by address market gaps in clearly defined underserved economic sectors and in those contributing to the achievement of EU policy priorities;
- improve the effectiveness by addressing market gaps through supporting cross-border financing solutions: despite the fact that SMEs rely largely on national or regional providers of finance, there is a small, nascent market for financial intermediaries which provide finance on a cross-border basis,
- improve effectiveness by fostering the transfer of best practices between financial intermediaries with a view to encourage the emergence of a broad product offering for higher risk SMEs suitable for their specific financing needs across the Member States. Transferring skills and capacity building across Member States could play a significant role in aligning national policies, in reducing the competitiveness gap between European economies and in accelerating economic growth in Europe;
- improve efficiency through economies of scale (i.e. Member States may be reluctant to create support schemes on their own because of cost efficiency considerations, lack of critical mass or expertise. Hence a EU response is essential to avoid even bigger market fragmentation and disparities).

3.3. Access to Markets

The EU added value of the Enterprise Europe Network is clearly shown in the networking function, the coverage, and the infrastructure as well as by the Network services. The connections set up between regional support intermediaries provide a lot of

value that would not be established by these organisations themselves. The coverage allows for service provision in every corner of Europe based on the availability, the specific needs of SMEs in the region taking into account the regional SME support and innovation strategies. These services, and especially the partnering services, show very high EU added value as they help SMEs to make effective use of the Single Market. Knowing that the funds at national and regional level are not able to substitute the EU funding shows that the continuation of the Network is dependent on EU level funds. The diversity of services provided addressing the specific needs of SMEs requires consortia of intermediary organisations with a strong local presence in every region of the EU. Experiences from the current implementation show that 500+ organisations with highly skilled staff are needed to provide these integrated services and to reach out to the very diverse target group of SMEs (with respect to the various sectors of activities).

The EU added value is clearly shown within the mentoring scheme due to its international matching function. Beyond the entrepreneurial mentoring and skills development aspects, the creation of links and fostering of cooperation in view of future growth and job creation is an outcome the programme aims at achieving.

Experiences from the current implementation show that at least about 180 organisations are needed to reach at least the current number of exchanges.

An increased combined budget of up to € 500 million for EEN would allow to Implement new initiatives for EEN and increase the number of SMEs served from 250.000 SMEs/Year to 400.000 SMEs/Year. The increased budget would allow to improve the internationalization service to help SMEs find partners in third countries; to provide an extended support to SMEs seeking access to finance; to upgrade EEN's assistance for tailored coaching services for SMEs including in developing their managerial skills; to provide more targeted services for start-ups/ scale-ups and outreach to incubators as well as to increase local communications actions.

For the mentoring scheme, an increased budget of up to € 100 million would allow for the expansion of the programme enabling 20.000 matches. Furthermore the geographic coverage of the programme could also be increased both within Europe (by covering more regions with more intermediary organisations) and beyond Europe (by opening up the programme to third countries). The expansion would be further in line with the recommendation of the COSME mid-term evaluation.

3.4. Business Environment, Industrial Modernisation, Competitiveness and Entrepreneurship (including consolidated Joint Cluster Initiatives)

The actions to create a favourable business environment to boost industrial modernisation and the competitiveness of SMEs and entrepreneurship will place a particular priority on cluster actions given the positive evaluation of cluster initiatives and the highlighted restriction in terms of limited budget and recommended upgrade.

The expected minimum size of the intervention of **consolidated Joint Cluster Initiatives for boosting industrial modernisation** is about € 150 million, which comprises the total budget for cluster initiatives under the existing COSME programme (of around 40 million) and under Horizon 2020 (of around 130 million) reduced by 15% (baseline scenario). This would allow to keep the impact at the same level as currently.

This would bring together the various cluster measures separated into different initiatives under both COSME and Horizon2020 in order to achieve a better coherence and critical mass to be used as a strategic tool to implement industrial policy and deliver scaling-up support to SMEs. The purpose of the Joint Cluster Initiatives is to accelerate the growth and development of strategic EU industrial value chains while positioning Europe's business, notably SMEs, for global leadership in strategic industrial specialisations.

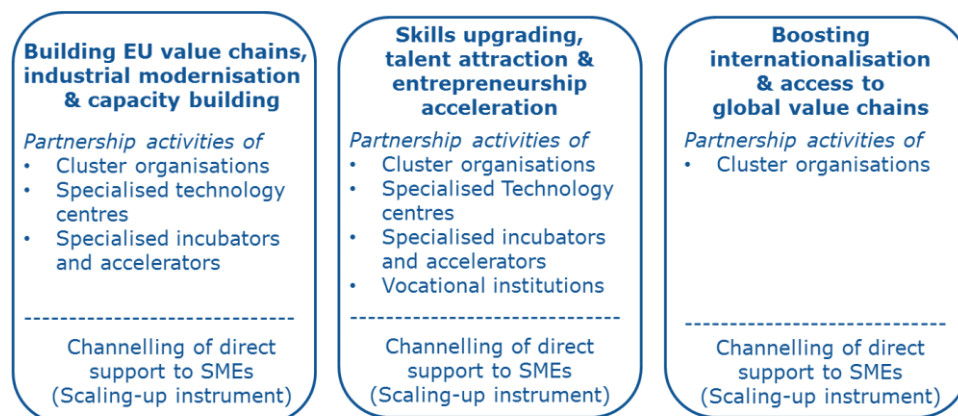
It will connect specialised eco-systems and foster strategic interregional collaboration to strengthen EU value chains that are globally competitive and create investment opportunities for SMEs. It will support the setting up of up to 10 Joint Cluster Initiatives to facilitate strategic and sustainable European partnerships with activities to boost industrial modernisation and the scaling-up of SMEs across multiple industrial specialisations (e.g. Circular Economy, Mobility industries, Creative industries, Experience Industries including tourism etc.).

The aim of the Joint Cluster Initiatives is to launch industry-led missions to foster collaboration and the up-take of advanced technologies, new business models and resource-efficient solutions by SMEs across EU value chains. This will be complemented with activities to facilitate skills upgrading, talent attraction and the acceleration of entrepreneurship as well as by activities to boost internationalisation and access to procurement markets and to global value chains.

The partnerships launched under the Joint Cluster Initiatives will consist of smart groupings of actors of regional ecosystems that will improve the business environment and overcome market fragmentation addressing the particular problems of SMEs in the related sectors. The partnerships will offer clear strategic guidance and support to engage in true cooperation at EU level. This should include a joint strategic vision and common goals to promote joint EU solutions in global markets. They would be supported with strategic analysis and partner search tools of the European Cluster Collaboration Platform. In this way, they would act as strong engines of future EU competitiveness creating highly favourable conditions to attract talents, start-ups and investments and thus nurturing excellence and global leadership.

Joint Cluster Initiatives

- *Industry-focused missions led by clusters across 10-20 industrial specialisations*
- *Actions guided by joint strategies of specialised SME intermediaries*
- *Thematically targeted, with cross-regional and cross-sectoral outreach to SMEs*



The Joint Cluster Initiatives build upon the current cluster initiatives (under COSME and under Horizon2020) that successfully reach out to SMEs but groups them in one single initiative. It further extends its scope beyond cluster organisations to link also specialised technology centres, co-working centres, incubators, accelerators and other specialised SME support actors to facilitate industrial modernisation and growth.

The action would be implemented through a staged funding approach with call for proposals (mainly for grants and lump-sum funding) every 2-3 years, with the possibility for continued funding to gather industry interest and achieve sustainability of the partnering. This means that partnerships, which achieve sufficient levels of ongoing performance indicators and participation rate can receive continuation funding - potentially scaled according to the performance indicators as has been practiced by national initiatives such as the French pôles de compétitivité – to create a strategic long-term funding pipeline for the whole duration of the next programming period. The grants would cover for joint partnering activities between the SME intermediaries, on the one side, and the provision of corresponding matchmaking and support services directly to SMEs of the partners engaged in the Joint Cluster Initiatives, including channelling the Scaling-up instrument to them.

The minimum size of intervention would, however, not allow to unlock the full potential to better use clusters to support industrial transformation and the scaling-up and growth of SMEs.

With an increase in resources and a budget of €300 million in next programming period, (ambitious scenario) it will be possible to strategically connect ecosystems and clusters and foster value chain collaboration at EU level through the specialised SME intermediaries in 10-20 industrial specialisation areas. It would allow to increase the expected reach-out to SME from 254,600 to 467,400 (based on the current reach of 3800 SMEs per 1 million invested indicated by the COSME interim evaluation) and channel the majority of the funding (€177 million) directly to over 2500 SMEs (based on the monitoring figures of the INNOSUP-1 cluster actions under Horizon2020). This increase would respond to the recommendations of the COSME interim evaluation to upgrade the action, but would still be modest in terms of engage only a small share of 23 million European SMEs in strategic inter-regional collaboration and support their industrial transformations and growth. In this way, the very high EU added value and appropriateness of the cluster actions as highlighted in the COSME and Horizon2020

interim evaluation could be leveraged to complement cluster policy efforts at regional and national level, of which some are of considerable higher investments.⁴³

With a significant increase and a budget of 1.3 billion, it would be possible to potentially reach out to over 1 million SMEs and raise the direct support to SMEs to € 1 billion that could directly support over 20,000 SMEs engaged in strategic interregional collaboration. This support is also scaleable. The Joint Cluster Initiatives and the Scaling-up instrument could be reinforced significantly with funding from other programmes, to, cover their respective challenges (as outlined below in last exemplary scenarios for the implemented in the table below).

This could make a real contribution to the uptake of growth of business, including SME internationalisation activities, skills development and uptake of advanced technologies, new business models and low-carbon and resource-efficient solutions.

| Scenario | Scenario 1: Baseline | Scenario 2: Ambitious scenario with Increase for clusters | Scenario 3: Ambitious scenario with increase for clusters + Scaling- up instrument | Scenario 4: Ambitious scenario with increase for clusters + Scaling- up instrument, incl.funding from other programmes |
|---|-------------------------|---|---|--|
| Impact | €150 million | €300 million | €1.3 billion | €4.3 billion |
| Indirect support to SMEs via activities of SME intermediaries | €67 million | €123 million | €300 million | €300 million |
| Number of SMEs reached | 254,600 | 467,400 | 1,140,000 | 1,140,000 |
| Direct (financial) support to SMEs | €83 million | €177 million | €1000 million | €4000 million |
| Number of SMEs to be supported directly | 1,700 | 2,522 | 20,512 | 82,051 |

⁴³ Some Member States such as France's competitiveness cluster programme (*poles de compétitivité*) and Germany's leading edge cluster competition (*Spitzencluster-Wettbewerb*) have channelled considerable higher amounts support through clusters. In France, 1,313 collaborative R&D projects received public financing of €2.37 billion between 2005 and 2013, including more than €1.45 billion granted by the French State through the dedicated fund (FUI). These projects, amounting to nearly €6 billion in R&D expenditure, involved close to 15,000 researchers. In Germany, € 860 million have been channelled through clusters between 2008 and 2017. See <http://competitivite.gouv.fr/policy-of-the-clusters-906.html> and https://www.bmbf.de/pub/Deutschlands_Spitzencluster.pdf

3.5. Newly proposed activities

Increased SME Guarantee Fund

This scenario proposes a significant increase in the budget for support of SME financing. This would give the European economy a strong investment and employment boost. A budgetary guarantee of EUR 3.5 billion would enable available investments of the guarantee facility of EUR 4.12 billion, enabling wide range of interventions and specific intervention areas requiring higher risk coverage. It is expected that such an intervention would contribute to more than 2,000,000 jobs maintained or created over the programme implementation period. Moreover, the market gap for SME finance would be positively impacted with approximately EUR 8 billion of additional financing compared to baseline, which is approximately 30% of the median market gap from our analysis. Therefore, the preferred option would be to significantly increase the budget and close major part of the SME financing gap.

| Scenario | Scenario 1: Baseline | Scenario 2: Discontinuation of the activity | Scenario 3: Significant increase in resources |
|--|--|---|--|
| Impact | €1.2 billion budgetary guarantee | No budgetary allocation | €3.5 billion budgetary guarantee |
| Employment maintained or created | 690,000 jobs | Decrease in employment | 2,000,000 jobs |
| Additional turnover expected in treated SMEs | €31 million | Decrease in turnover | €90 million |
| Number of SMEs to be supported | 663,000 | No support provided | 1,935,000 |
| Volume of financing supported | €28 billion | No support provided | €82 billion |

New Scaling-up instrument:

A new scaling-up instrument will encourage the uptake of results from other EU programmes (Horizon, LIFE, Galileo, Copernicus, ERDF, EAFRD, EMFF) and

strengthen the link between SME support under regional and industrial policies to unlock the growth opportunities of SMEs. It is designed as a tool to support scaling-up activities of SMEs across regional, sectoral and technological boundaries in order to help them to embrace industrial transformations, to access global industrial value chains and international markets, and engage in strategic interregional collaboration. The instrument will therefore offer growth acceleration support to help groups of SMEs to jointly foster internationalisation activities, access to procurement markets, business and new skills development and to test and take-up advanced technologies (e.g. advanced manufacturing, digital, Big data), new business models and low-carbon and resource-efficient solutions to reduce production costs or to integrate them into new or emerging industrial value chains.

The action would be implemented through yearly call for proposals that will provide mainly lump-sum grants and coaching services to cover feasibility plans for joint internationalisation activities, innovation take-up, resource-efficiency etc. for a maximum of 60,000 euros. It is therefore not a financial instrument but a SME growth support instrument. While the action would thus follow a simplified implementation process inspired by the current SME instrument under Horizon2020, it would follow a different and focussed implementation approach – given its wider growth support logic not limited to breakthrough innovation.

Rather than supporting SMEs individually and targeting solely the most innovative SMEs wherever they are, the scaling-up instrument will act as a multiplier by connecting and supporting groups of SMEs from a wide range of industrial specialisations and sectors and in combination with other actions. This type of implementation approach has already been tested successfully by the cluster projects for new industrial value chains under Horizon2020 (INNOSUP-1) as the interim evaluation results and monitoring of cluster initiatives presented in section 2.28 have shown. The difference would be that a standardised implementation tool (similar to the SME instrument phase 1) would be used by the SME intermediaries of cluster partnerships to channel lump sums to third party SMEs instead of each partnership designing their own innovation voucher scheme or similar.

A distinct feature is that the support would be channelled via SME intermediaries from the Enterprise Europe Network and especially those engaged in Joint Cluster Initiatives (see section 4.4) and thus prioritised on where joint activities are embedded in strategic partnering across the EU. In this way, the implementation would feature a similar very high EU added value and appropriateness as current cluster actions (evaluated by the COSME and Horizon2020 interim evaluation) and be truly complementary to actions taken at national and regional level and to strategic partnering of regional authorities under European Structural and Investment Funds.

As shown in section 4.4. and below, an ambitious scenario that would make use of a Scaling-up instrument to accelerate the growth of SMEs should allow to support 20,512 SMEs directly that are targeted as part of the reach-out of cluster initiatives to 1.14 million SMEs engaged in clusters, notably those that created joint collaboration projects. The Scaling-up instrument should therefore not be viewed as a stand-alone instrument but an integral part implemented with the Joint Cluster Initiatives and support from the Enterprise Europe Network. Its expected impact should therefore also not be seen as being limited to the expected 20,512 SMEs that should receive funding.

In terms of expected impact, the results of SME instrument can offer some guidance⁴⁴. The SME instrument will invest €3 billion in 7,500 companies until 2020 as part of Horizon2020 and has so far received 31,000 applications and funded around 2,500 companies in 3 years. While the reported average increase of 250% increase in turn-over and 122% increase in employment for phase 2 companies after one year cannot be the benchmark (given the Scaling-up instrument restriction to the testing of solutions and smaller support amounts – i.e. phase 1 only – and not targeting only innovative SMEs, this shows at least the potential scope of possible support. Moreover, each euro invested for the SME instrument generated one euro of private investment. Just as statistics for SMEs supported under phase 1 of the SME instrument shows, the chances of SMEs supported through a Scaling-up instrument to have access to finance should increase, with the testing of solutions and working on wider growth acceleration business concepts.

As this instrument makes strategic use of the SME intermediaries that deliver impact, it can deliver not only boost to the scaling-up of SMEs and industrial modernisation but can also be used to achieve other policy objectives, such as achieving technological cohesion and narrowing the innovation divide or carbon reductions. This instrument is scalable upwards in terms of budget and should be made available for use by other programmes, if there is an interest in using it.

The strategic use of the Scaling-up instrument could make a significant contribution to the number of SMEs introducing product and process innovation (which has declined by 18.2% between 2010 and 2016 according to the 2017 European Innovation Scoreboard) and the number of SMEs collaborating with each other as well help to bring solutions to a larger number of SMEs across the EU.

| Scenario | Scenario 1: Baseline | Scenario 2: Ambitious scenario with Scaling-up instrument | Scenario 4: Ambitious scenario with increase with Scaling-up instrument, incl. funding from other programmes |
|--|---------------------------------|--|---|
| Impact | No budget allocation | €1 billion | €4 billion |
| Direct (financial) support to SMEs | No support provided | €1000 million | €4000 million |
| Number of SMEs to be supported directly | No support provided | 20,512 | 82,051 |
| Increase of SME collaborating with others or | No change | Considerable increase of supported SMEs | Considerable increase of a larger number of |

⁴⁴ See https://ec.europa.eu/easme/sites/easme-site/files/2016_smei_report_updated.pdf - and full report at: https://ec.europa.eu/easme/sites/easme-site/files/accelerating_innovation_in_europe_horizon_2020_smei_impact_report.pdf

| | | | |
|--|-----------|---|--|
| introducing product or process innovation | | | supported SMEs |
| Additional turnover expected | No change | Considerable increase of supported SMEs | Considerable increase of a larger number of supported SMEs |
| Employment created | No change | Considerable job creation of supported SMEs | Considerable job creation by a larger number of supported SMEs |

4. DELIVERY MECHANISMS OF THE INTENDED FUNDING

4.1. Governance

COSME+ would follow the governance mechanisms put in place by the Single market Regulation.

We would propose as a novelty to create a network of national contact points, composed of representatives of the member states and of the participating third countries, for the monitoring of the take-up of activities in their country. They will have the possibility to provide a feedback on implementation to the Commission to adopt appropriate measures in case of insufficient take-up. This responds to a finding of the Interim evaluation reporting an unbalanced geographical distribution in the implementation.

In order to introduce a more strategic piloting of the programme and coherence with other EU programmes, it is foreseen to create a Commission inter-service group to guide the elaboration of the work programmes.

4.2. The Implementing Bodies

The management mode will be the direct centralised mode, with the exception of the financial instruments. In the continuity of the CIP and COSME programmes, the European Investment Fund will be tasked with the implementation of the SME guarantee scheme. Grants and tenders will be delegated to an executive agency.

COSME intends to maintain the use of intermediaries that ensure proximity to SMEs. These intermediaries are selected and managed by two important actors of the programme: EASME and EIF.

4.3. The Executive Agency

COSME delegates on average 110 million per year and about 35% of the total budget and more than 90% of the non-financial instruments. Half of this amount relates to the Enterprise Europe Network, the other half is constituted of a big number of smaller actions.

COSME actions under direct management of DG GROW will be delegated to the Agency except for corporate communication, IT related activities and tasks involving sensitive or political choices. In addition we do not delegate, for efficiency or legal reasons small financial operations (such as Reimbursement of experts; subscriptions fees;

Small workshops and meetings) and Administrative arrangements with JRC or specific grants with international organisations.

We intend to keep the same line for COSME+. We will not delegate more in terms of budget but we want to delegate better by reducing the number of actions delegated and increasing the size of actions delegated. 1 For example, 16 FTE in EASME implemented 91 contracts with a budget of 58 million for the EEN in 2017 compared to 36 FTEs who implement 47 actions divided into 80 contracts for a budget of 45 million.

Under reserve of the future CBA on the implementation of the agency, the experience of delegating the major parts of COSME to the agency has proved to be cost-efficient. The operational and financial management of a big activity such as the Enterprise Europe network involves a big volume of routine and repetitive operations. This is typically the kind of operations that are delegated to executive agencies.

The establishment plan foresaw the following evolution of staff for COSME in the agency:

| | Year 2014 | | Year 2015 | | Year 2016 | | Year 2017 | | Year 2018 | | Year 2019 | | Year 2020 | |
|---|--------------|----|--------------|----|----------------|----|--------------|----|--------------|----|--------------|----|--------------|----|
| | Phasing-in | | | | Cruising-speed | | | | | | | | | |
| Establishment Plan Posts ⁴⁵ | COM | EA | COM | EA | COM | EA | COM | EA | COM | EA | COM | EA | COM | EA |
| Seconded TA | | 4 | | 6 | | 6 | | 6 | | 6 | | 6 | | 6 |
| Other TA | | 18 | | 18 | | 19 | | 19 | | 21 | | 21 | | 22 |
| Sub-total | 2.7 | 22 | 2.7 | 24 | 2.7 | 25 | 2.7 | 25 | 2.7 | 27 | 2.7 | 27 | 2.7 | 28 |
| External personnel | COM | EA | COM | EA | COM | EA | COM | EA | COM | EA | COM | EA | COM | EA |
| Contract agents | 0.0 | 65 | 0.0 | 73 | 0.0 | 76 | 0.0 | 76 | 0.0 | 79 | 0.0 | 80 | 0.0 | 82 |
| Seconded National Experts | | | | | | | | | | | | | | |
| Sub-total | 0.0 | 65 | 2.7 | 73 | 0.0 | 76 | 0.0 | 76 | 0.0 | 79 | 0.0 | 80 | 0.0 | 82 |

The evolution of staff in EASME for COSME has been fairly stable and according to the establishment plan above. In 2017 the number of second TAs was 19.6 and the number of contractual agents was 76.7, in total 96 persons were delegated in 2017, which is below the establishment plan.

⁴⁵ In line with Commission Regulation 58/2003, §18.1.: Community officials seconded Temporary Agents and other Temporary Agents

4.4. Delivery mechanisms

Grants, tenders and financial instruments for SMEs will be the main implementing tools.

Grants will be used in two cases. First, we will fund the activities of the intermediaries (such as the EEN, the mentoring scheme or Joint Cluster initiatives) that ensure the proximity and support to SMEs and the necessary activities to improve the business environment. Second, and departing from the philosophy of indirect support used up to now for COSME, we will directly fund, in the case of the scaling-up instrument, SMEs' activities (feasibility plans).

Simplification is a major objective of the new programme. According to the COSME interim evaluation, reporting obligations represent a substantial administrative burden for both intermediaries and other beneficiaries of grants. Consequently, before the beginning of the programme we will study the most appropriate form of Simplified Cost Options for grants.

The Enterprise Europe Network which is constituted by more than hundred consortia, employs on average more than 4000 FTEs. In addition, there is a unit managing the action in DG GROW and one in EASME. Any reduction of administrative burden has the potential to reduce administration cost and free FTEs for operational tasks.

Tenders will be used for studies, communication and awareness raising activities.

4.5. Delivery of the SME loan guarantee facility through the SME window of the InvestEU Fund

The reflection paper on the future of EU finances⁴⁶ proposes to integrate the various EU financial instruments into a single fund which would provide loans, guarantees and risk sharing instruments. This will help to simplify access to EU financial instruments and a more efficient use.

In line with the Commission's overall objectives of streamlining, increasing efficiency and achieving a better visibility of the EU support, the SME guarantee facility will be implemented under the SME window of the InvestEU Fund and under the rules (e.g. in relation to implementing bodies, for financial intermediaries, State Aid, monitoring, reporting, auditing, budgetary management, etc.) established for the InvestEU Fund by the respective regulation.

To this end, the allocated budget under the COSME + programme shall be made available to the guarantee fund linked to the InvestEU Fund with the caveat that such resources shall underpin the implementation of an SME guarantee facility which is focused on supporting higher risk SME financing transactions under the SME window of the InvestEU Fund.

The delivery of the guarantee facility under the InvestEU Fund is more efficient, as the InvestEU Fund is based on a budgetary guarantee rather than a fully funded financial instrument. Example: A budget of €1.0 bn transferred to a budgetary guarantee translates

⁴⁶ https://ec.europa.eu/commission/sites/beta-political/files/reflection-paper-eu-finances_en.pdf

into available resources of €1.18 bn (based on an expected provisioning rate of 85%) and therefore immediately leads to a higher leverage.

The equity facility created under the SME window of EFSI targets the same type of investments as the COSME equity facility for growth, however the EFSI facility is broader in scope as it supports not only SMEs but also small mid-caps. As a result the demand (pipeline) for the COSME EFG has reduced significantly as transactions which in principle could have been signed under the COSME EFG are being signed under EFSI. As it is envisaged that an equity support mechanism will be created under the SME window of the InvestEU Fund, which will provide seamless support for businesses from the pre-seed stage all the way to the expansion and growth stage, including support for small mid-caps, it is considered more efficient to create such seamless equity support under the InvestEU Fund and to discontinue equity support under COSME+. A broad-based facility under the InvestEU Fund will create more flexibility and will be easier to market towards potential financial intermediaries.

4.6. Evolution of the EEN and the mentoring scheme for new entrepreneurs

Involving the Enterprise Europe Network intermediary organisations across the EU, which provide integrated services to SME, requires a delivery mechanism that ensures cooperation between the relevant stakeholders at regional or national level. The delivery mechanism should also encourage cooperation and seek for synergies with other local SME support stakeholders in the regions. Our proposed delivery mechanism will continue to make use of call for proposals directly involving the relevant stakeholders in the region, and by extension other stakeholders who contribute to the implementation on the action. We intend to continue using framework partnership agreements for the Network for a period corresponding the next MFF cycle, this ensures that host organisations plan and invest in resources on a longer term, which allows for expertise, technical capacity and visibility to be build up. We also propose the Network to be the EU's implementing tool for SME support and propose to further integrate the the mentoring scheme for new entrepreneurs in the Network's activities. A single call for proposals, grant management system, governance, communication strategy, reporting and monitoring system will allow for economies of scale and simplification for both the beneficiaries and the Commission and its implementing agencies. It will also allow for an increased visibility and more efficient internal signposting of SMEs (leading to the no wrong door approach).

In the COSME+ programme, the mentoring scheme should be integrated within the EEN portfolio of services with the priority of even better regional coverage for the programme and assuring better synergies and more effective follow-up of the entrepreneurial exchange stays, by providing a seamless flow of relevant support services to new entrepreneurs.

The integration will have positive aspects, but also will bring considerable change to the programme implementation.

Main changes: Currently the programme is based on international consortia of intermediary organisations. Incorporating it in the EEN would need a transformation and integration into national/regional consortia of business support organisations. This would allow further integration into the regional SME and entrepreneurship support ecosystem. This change needs to be carefully planned, taking into account and preserving the knowledge and experience of intermediary organisations of the current mentoring

scheme, especially the outreach and specific support to start-ups and nascent entrepreneurs.

We aim at enhancing the role of EEN being the EU's reference implementing tool for SME support also integrating other successful actions into the EEN activities such as the the mentoring scheme for new entrepreneurs, as it is the case with SMEs innovation management support envisaged in other programmes. A single call for proposals, grant management system, governance, communication strategy, reporting and monitoring system will allow for economies of scale and simplification for both the beneficiaries and the Commission and its implementing agencies. It will also allow for an increased visibility and more efficient internal signposting of SMEs (leading to the no wrong door approach). The name of Erasmus for Young Entrepreneurs is modified to the mentoring scheme for new entrepreneurs in order to avoid confusion with the Erasmus + actions and to link the mentoring scheme more clearly with SME-support networks.

5. HOW WILL PERFORMANCE BE MONITORED AND EVALUATED?

5.1. Recommendations from the interim evaluation

The Interim evaluation pointed out to the need to improve the data management of the programme.

The lack of a single database (where all data on the programme is collected for a centralised management of the COSME data) constitutes a major barrier to efficient management of the programme.

Besides a more centralised management, the development of a more standardised monitoring system would be beneficial. The analysis shows a need for more attention to the ongoing assessment of progress towards the achievement of the expected results. The KPIs defined for the different actions show considerable variations in the balance between assessing outputs and setting the basis for the investigation of longer-term outcomes and results.

5.2. Data Management

The data management of the programme will be improved by creating a centralised database for monitoring data. Five different types of data are needed for monitoring the programme:

1. Financial information on budget, commitments and payments;
2. Information on the implementation of calls and the rate of participation;
3. Information on the results produced by the different projects implemented and on the final beneficiaries of projects, i.e. SMEs or entrepreneurs;
4. Information relating to the degree of satisfaction of final beneficiaries;
5. Micro- and macro-economic data to assess the relevance the actions and to allow for factual and counterfactual analysis.

While the first two types of data are easily available by the Commission services, the Agency or the EIF, the data collection has to be performed in a systematic and timely manner and organised to produce coherent information for comprehensive monitoring and reporting.

The results produced by the projects are collected by the intermediaries, the agency and the EIF. This information can be collected at the end of projects or two or three years after the end of projects to measure longer term impacts. In order to reduce administrative burden, performing surveys to reach beneficiaries and intermediaries should be limited to the strict minimum, preferably at the occasion of interim or ex-post evaluations.

The programme finances several studies and annual reports. This information is useful for evaluating SME policy and the general relevance of the programme. The SAFE study on access to finance and the SME performance review are organised on a yearly basis.

5.3. Monitoring system

The COSME for 2014-2020 foresees a yearly monitoring report, an interim and a final evaluation. The financial regulation foresees an ex-post evaluation two years after the end of the programme.

For COSME+ the same monitoring system could be used. However, the timing of the reporting needs to be adapted to the availability of data. To have complete data on implementation can take two or three years. The interim evaluation report should ideally be prepared from the fourth year of implementation.

The content of monitoring should follow the life-cycle of a programme and take into account the availability of data in time.

The monitoring should be based on a set of indicators adapted to the different stages of the programme's lifecycle.

- Short-term indicators should measure whether the structure needed for implementation is in place (e.g. How many contracts were signed timely with intermediaries? Were the first calls published on time and what is their rate of success?). These indicators are of importance for the first two years of the programme.
- Medium-term indicators should measure whether the outputs delivered are reaching the milestones set for the programme (e.g. Did we reach the target at medium term in numbers of SMEs reached or in number of partnerships concluded). These indicators will be particularly useful for yearly monitoring and for the interim evaluation.
- Long-term indicators should measure whether the desired effects are produced (e.g. Did our action create jobs and growth? What is the evolution of reached SMEs in terms of turnover and employment? What is the cost-effectiveness of our action?). These indicators can start to be measured in the final evaluation and for the ex-post evaluation.

The number of indicators needs to be reduced by focussed on the general and specific objectives of the programme. For yearly monitoring and specific activities, more specific indicators can be developed.

General Indicator: "Number of SMEs/Entrepreneurs reached by the programme".

Corporate indicators:

- Implementing rate of the budget, globally and per objective;
- Number of beneficiaries awarded in calls in proportion to applications received;
- Geographical coverage of the measure per capita.

- Number of SMEs supported and volume of funding provided through financial instruments;
- Number of companies participating in matchmaking events;
- Number of companies supported having concluded business partnerships;
- Number of entrepreneurs or SMEs receiving business advisory services;
- Number of SMEs created after participation of entrepreneurs in actions of the programme;
- Satisfaction rate of beneficiaries of the programme or participants to the programme;
- Increase in turnover and employment of companies participating to the programme.

These indicators will be further developed after the final evaluation of COSME. DG GROW will consult JRC in order to assess the indicators that the most adapted for yearly monitoring and for evaluation. We need to assess the availability of data in order to organise data management and develop a simplified monitoring system that can feed monitoring and evaluation.

These indicators can then be adapted to each specific objective of the programme:

| COSME | | | | | | | |
|---|---|------------------|-----------------|---------------------------------------|--------------------------|----------|---|
| Specific Objective | Indicator | Definition | Unit of measure | Source of data | Frequency of Measurement | Baseline | Target |
| 1. Addressing the access to finance gap for SMEs | Number of SMEs receiving support and total volume of financing made available to SMEs supported | Output indicator | Units, euros | EIF | annual | 2020 | To be set in function of the available budget |
| 2. Facilitating SMEs' access to markets and supporting them in addressing global and societal challenges; | Number of companies participating in matchmaking events | Output indicator | units | Executive Agency, activity monitoring | Annual, or bi-annual | 2020 | To be set in function of the available budget and results in 2020 |
| | Number of companies | Output indicator | units | Executive Agency, activity | Annual, or bi-annual | 2020 | To be set in function of the |

| | | | | | | | |
|--|--|------------------|------------|---------------------------------------|----------------------|------|---|
| | supported having concluded business partnerships; | | | monitoring | | | available budget and results in 2020 |
| | Number of entrepreneurs or SMEs receiving business advisory services | Output indicator | units | Executive Agency, activity monitoring | Annual, or bi-annual | 2020 | To be set in function of the available budget and results in 2020 |
| | Number of SMEs created after participation of entrepreneurs in actions of the programme | Output indicator | units | Executive Agency, activity monitoring | Annual, or bi-annual | 2020 | To be set in function of the available budget and results in 2020 |
| | Satisfaction rate of beneficiaries of the programme or participants to the programme; | Output indicator | percentage | activity monitoring or surveys | Annual, or bi-annual | 2020 | none |
| 3)Business Environment, Industrial modernisation, Competitiveness and Entrepreneurship | Number of partnerships, agreements or projects generated by collaborative or networking activities | Output indicator | units | EASME, activity monitoring | Annual, or bi-annual | 2020 | To be set in function of the available budget and results in 2020 |
| | Satisfaction rate of beneficiaries of the programme or participants to the | Output indicator | percentage | Activity monitoring, survey | Annual or Bi-annual | none | none |

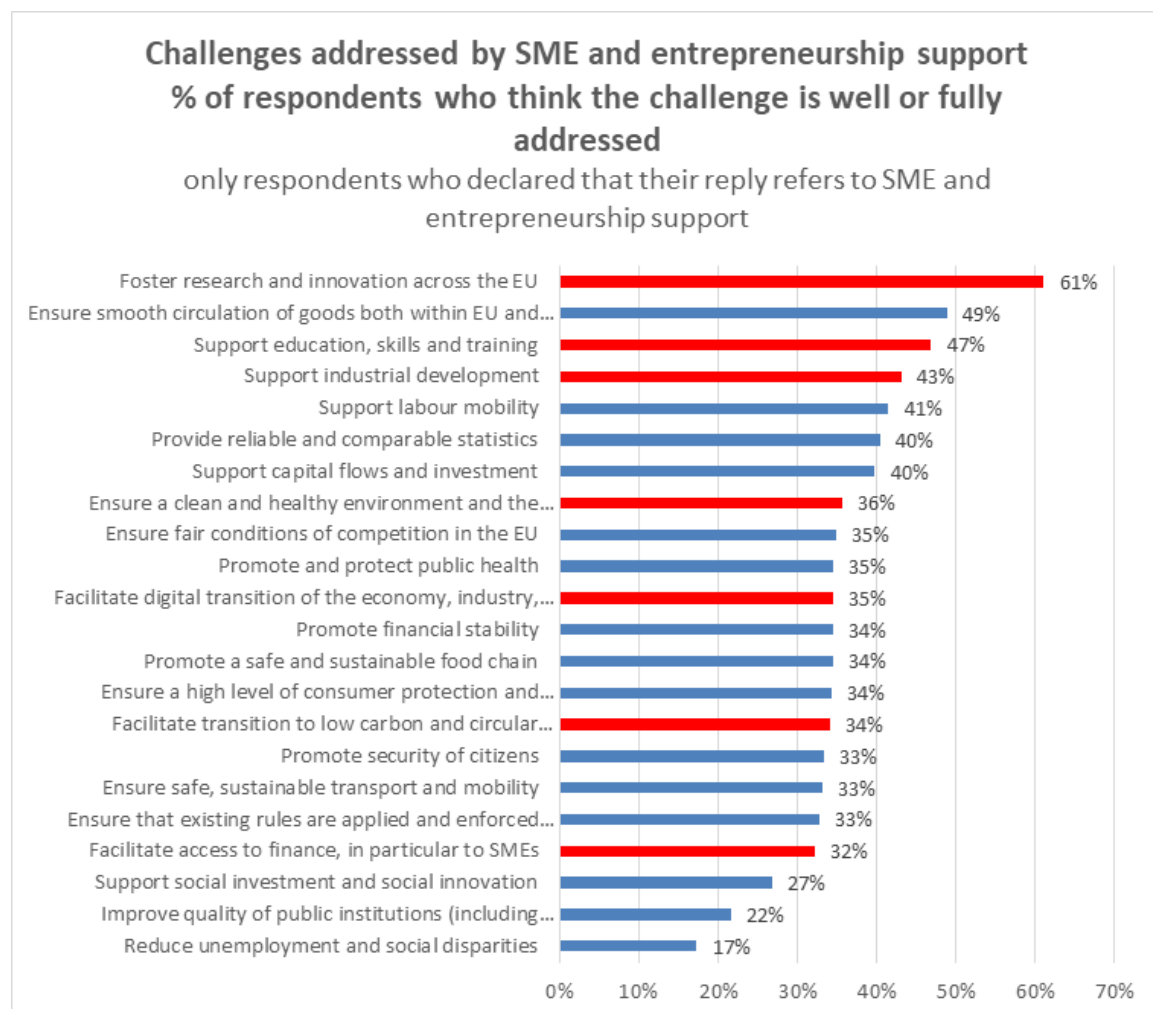
| | | | | | | | |
|--|---|---|-----------------|-----------------------------|--|------|---------------------|
| | program me; | | | | | | |
| | Number of SMEs/Entrepreneurs benefitting from outputs generated by the measures of this objective | Output indicator | units | Activity monitoring, survey | Annual or Bi-annual | None | None |
| All objectives | Budget Implementation rate | Measures the degree to which the implementation follows the budget allocation | percentage | ABAC | annual | none | Between 95 and 100% |
| All objectives | Number of beneficiaries awarded in calls in proportion to applications received | Measures the success of calls published | Percentage | Agency IT tool | annual | none | none |
| All objectives | Geographical coverage of the measure per capita | Measures the distribution of the funding across participating countries | euros | EIF, EASME, Eurostat | annual | none | none |
| All objectives except access to finances | Employment and turnover increase by companies having been supported | Impacts and results measurement | Units and euros | Surveys | Evaluations, principally final and ex-post | none | none |

Annex 2: Stakeholder consultation

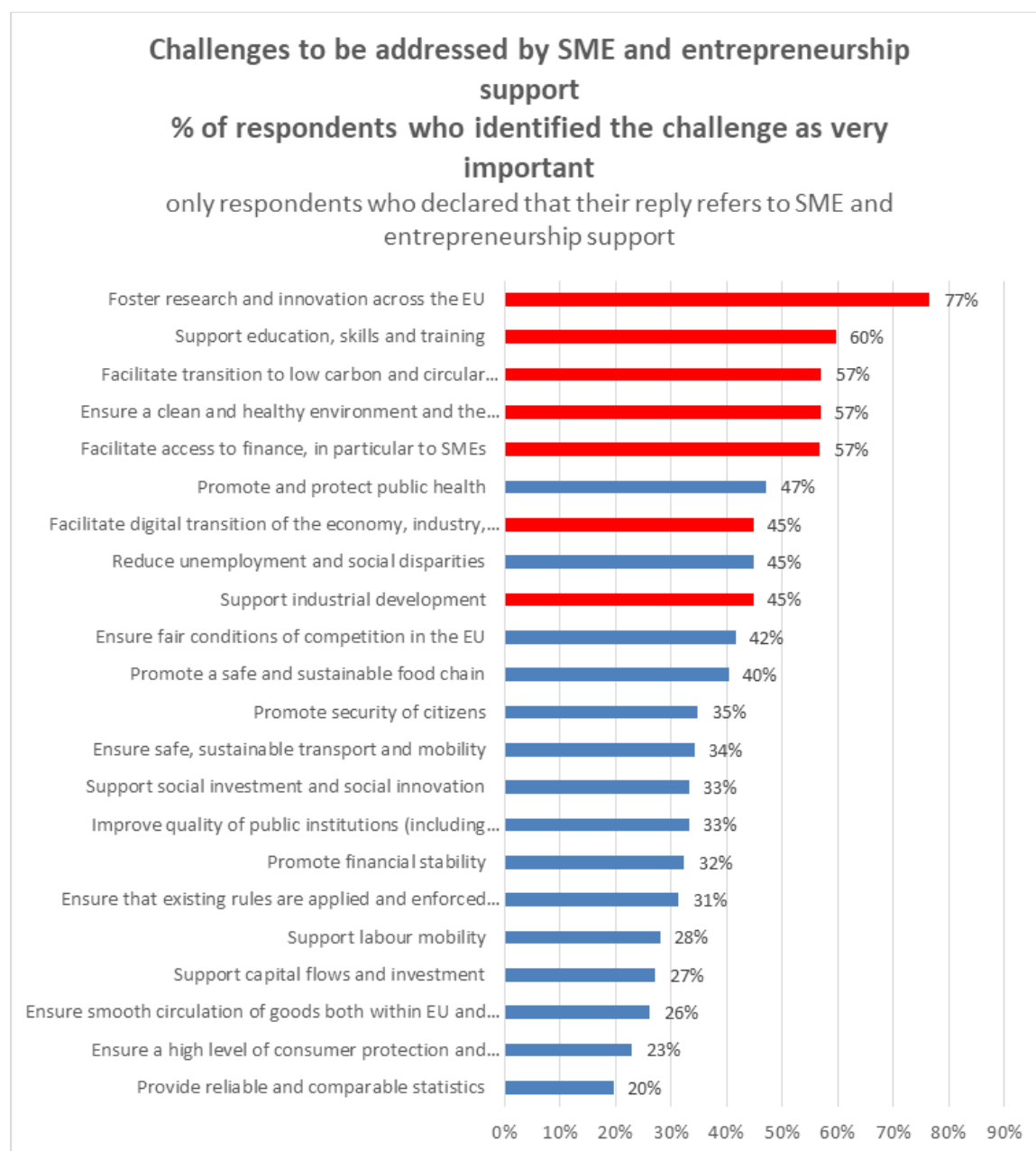
Results of open public consultation on next MFF – Cluster R&D, SMEs and single market

A public consultation on EU funds in the area of investment, research & innovation, SMEs and single market was conducted from 10 January to 9 March. While only 8.3 of respondents had experience with the COSME programme, around 25% declared that their replies refer to the EU support for SME and entrepreneurship (1.034 respondents).

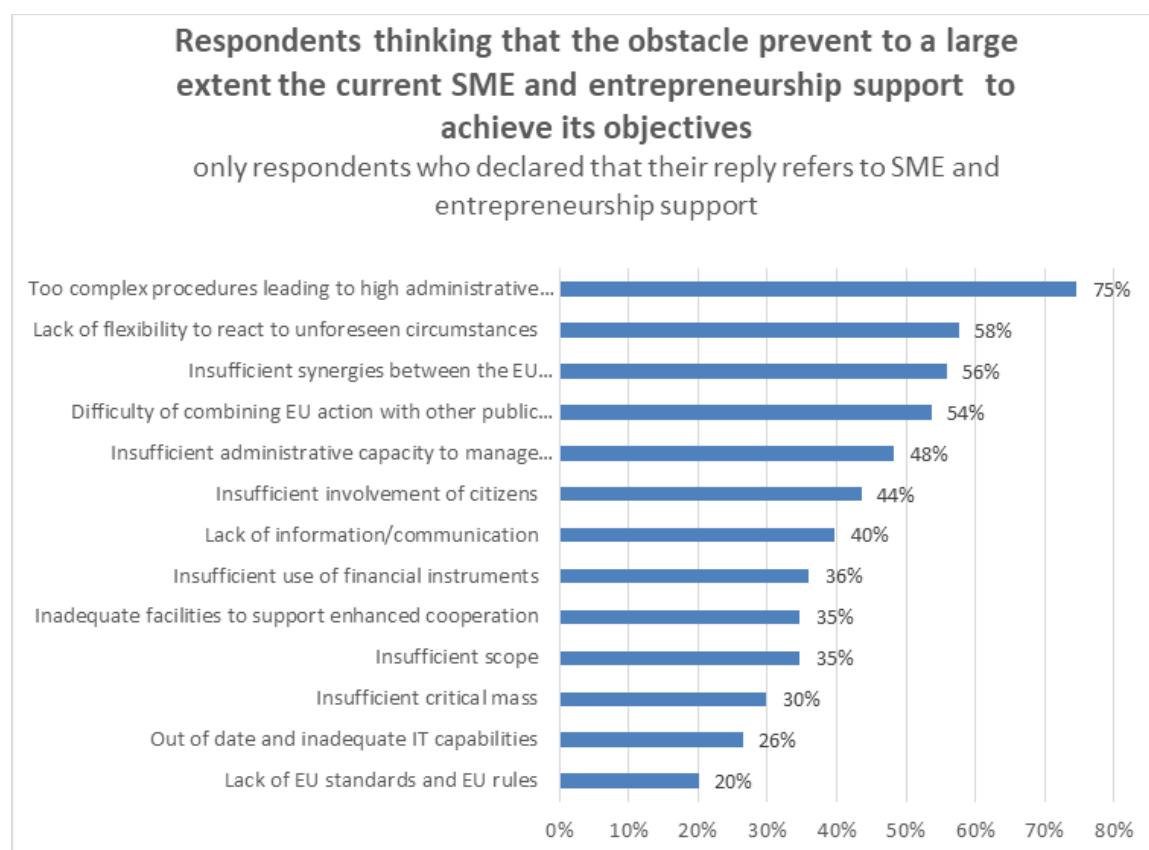
Around 77% of them think that the SME and entrepreneurship support provided by the EU has a good or large added value compared to what Member States can achieve at national, regional and/or local level. Foster research and innovation (61%), support education, skills and training (47%) and support industrial development (43%) are among the better-addressed challenges by the current SME and entrepreneurship support. They consider that ensure a clean and healthy environment, facilitate digital transition of economy and facilitate SME access to finance are a slightly less well addressed (from 36% to 32%).



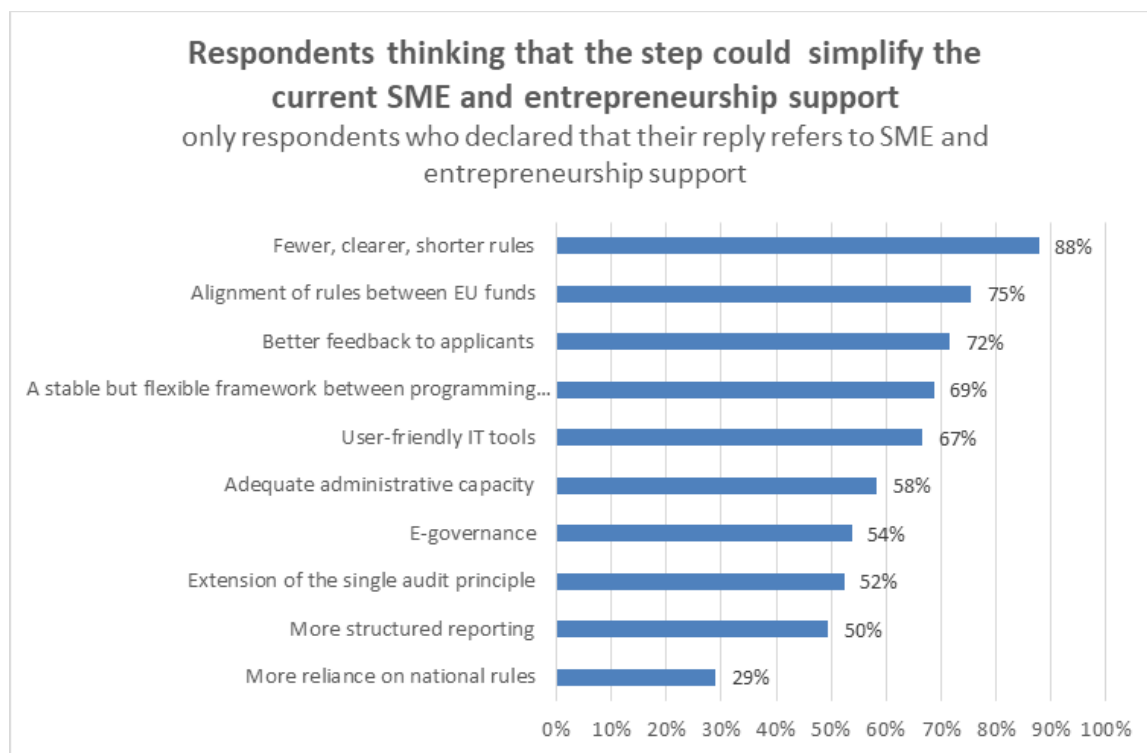
In their opinion, the future SME and entrepreneurship support should address among others the following challenges: foster research and innovation (77%), support education, skills and training (60%), facilitate transition to low carbon and circular economy (57%), ensure a clean and healthy environment (57%), facilitate SME access to finance (57%), facilitate digital transition of economy (45%) and support industrial development (45%).



Concerning the obstacles preventing the current EU SME and entrepreneurship funds/programmes to achieve their objectives, the selected respondents believe that the complex procedures (75%), the lack of flexibility (58%), the insufficient synergies with other EU programmes (56%) and the difficulty to combine EU and other public support are the main difficulties. The lack of EU standards, the inadequate IT capabilities and the insufficient critical mass are considered less important.



Finally the steps which could simplify the current SME and entrepreneurship support are mainly the rules which could be clearer, fewer and shorter (88%) and aligned between the different EU funds (75%), better feedback to the applicant (72%), a stable but flexible framework (69%) and user-friendly IT tools are also considered key elements.



POSITIONS PAPERS

General support to COSME which should continue in the next MFF. Key elements of the SME support are the financial instruments, EEN and Erasmus for Young Entrepreneurs. Simplified rules, taking as example Horizon 2020, and better synergies with other EU programmes are suggested.

Eurochambres

Given the importance of SMEs in relation to economic growth, job creation, competitiveness and innovation, the **SME dimension should be central in the next MFF**. This translates into the need to allocate adequate funding to areas of key importance to SMEs, i.e. Single Market, internationalisation, skills and training, entrepreneurship, digitalisation, access to finance, innovation, capacity building in the areas of energy and environment, the integration of refugees into the labour market and enlargement and neighbourhood. Among the existing actions, the **Enterprise Europe Network and Erasmus for Young Entrepreneurs** have proven to be particularly valuable in supporting SMEs and entrepreneurship and deserve to be strengthened and enhanced in the next MFF. Another successful action is Erasmus +, which should focus more on Vocational Education and Training in the future. Crucial to SMEs and start-ups is also the continued availability of **financial instruments** that facilitate their access to finance. **More synergies and further simplification should be achieved throughout the various programmes** and actions, so as to ensure the maximum effectiveness in the use of EU resources.

BusinessEurope

SMEs are a key asset that should be integrated in any strategy aimed at fostering a return to sustained growth in the EU. The post-2020 MFF should therefore include projects of real European added value that deliver concrete benefits in the areas of SME competitiveness and SME development, including through their interaction with larger companies. Some SME-geared actions should naturally be integrated in broader EU flagship initiatives. For example, SME-geared actions will need to be deployed in the areas of RD and innovation, as is the case with Horizon 2020. But deploying EU SME-geared actions only under flagship initiatives or thematic programmes is not enough to give the right visibility to the EU SME policy. BusinessEurope therefore insists that the **post2020 MFF should contain a specific EU programme dedicated to the promotion of the competitiveness of SMEs, like the current COSME programme** (the EU programme for the competitiveness of SMEs). Financial instruments and EEN as key elements.

EUROCITIES (consultation on start-up initiative)

COSME is a useful funding programme but its budget and co-funding rates should be increased. Financial instruments, EEN and clusters development are considered important initiatives to be continued and reinforced.

Tourist Guide Association

COSME should be continued with better synergies with other programmes (Horizon)

COSME Subannex – Access to Finance for SMEs

Glossary

| <i>Term or acronym</i> | <i>Meaning or definition</i> |
|------------------------|--|
| AECM | European Association of Guarantee Institutions |
| CCS | Cultural and creative sector |
| CGS | Credit Guarantee Schemes |
| COSME | Programme for the Competitiveness of Enterprises and small and medium-sized enterprises (2014 – 2020) |
| COSME+ | Successor programme to COSME |
| CRR/CRD | Capital Requirements Regulation (CRR) and Capital Requirements Directive (CRD) |
| ECB | European Central Bank |
| EFG | Equity Facility for Growth |
| EFSI | European Fund for Strategic Investments |
| EIB | European Investment Bank |
| EIF | European Investment Fund |
| ESIF | European Structural and Investment Funds |
| ERDF | European Regional Development Fund |
| ESF | European Social Fund |
| EAFRD | European Agricultural Fund for Rural Development |
| EMFF | European Maritime and Fisheries Fund |
| EU27 | EU28 without United Kingdom |
| GDP | Gross Domestic Product |
| LGF | Loan Guarantee Facility |
| NEFI | Network of European Financial Institutions for SMEs |
| NPB | National Promotional Banks |
| OPC | Commission's Open Public Consultation on EU funds in the area of investment, research & innovation, SMEs and single market |
| SAFE | The Survey on the Access to Finance of Enterprises |
| SMEI | SME Initiative |
| SMEs | Small and medium-sized enterprises |

Country codes

| | | | | | | | |
|----------------|------|---------|------|-------------|------|----------|------|
| Belgium | (BE) | Greece | (EL) | Lithuania | (LT) | Portugal | (PT) |
| Bulgaria | (BG) | Spain | (ES) | Luxembourg | (LU) | Romania | (RO) |
| Czech Republic | (CZ) | France | (FR) | Hungary | (HU) | Slovenia | (SI) |
| Denmark | (DK) | Croatia | (HR) | Malta | (MT) | Slovakia | (SK) |
| Germany | (DE) | Italy | (IT) | Netherlands | (NL) | Finland | (FI) |
| Estonia | (EE) | Cyprus | (CY) | Austria | (AT) | Sweden | (SE) |

| | | | | | | | |
|---------|------|--------|------|--------|------|----------------|------|
| Ireland | (IE) | Latvia | (LV) | Poland | (PL) | United Kingdom | (UK) |
|---------|------|--------|------|--------|------|----------------|------|

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

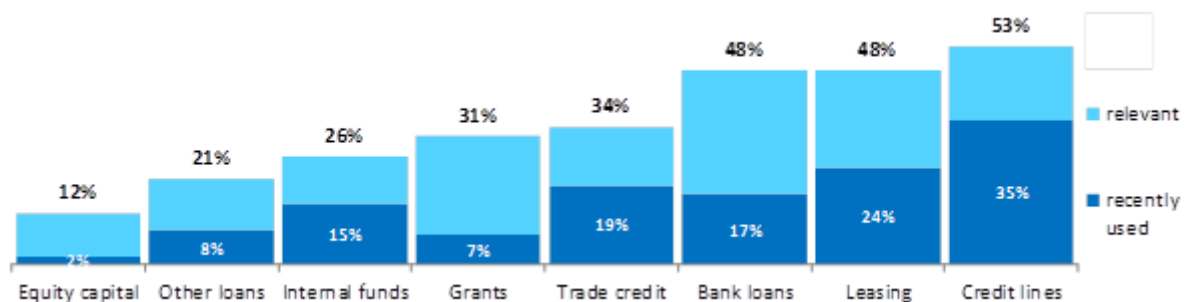
1.1. Scope and Context

This Staff Working Document constitutes the Impact Assessment of the financial instruments of the successor programme of COSME and also serves the purpose of an ex-ante evaluation.

Small and medium-sized enterprises (SMEs) are the engine of the European economy. There are over 23 million enterprises⁴⁷ in the EU. Without SMEs the EU economy would consist of only 45 000 firms. The EU's SMEs employed 93 million people in 2016, accounting for 67% of total private-sector employment and generated 57% of value added in the EU28 non-financial business sector. About 85% of newly created jobs in the EU are accounted for by SMEs.

However, obtaining financing in the form of debt or equity is a major hurdle for company creation and growth. As shown by the graph below, SMEs rely heavily on debt finance, in the form of credit lines, bank loans or leasing, to finance themselves. Internal sources appear to be insufficient to meet their funding needs.

Graph 1: Sources of financing for SMEs in Europe



Source: The Survey on the Access to Finance of Enterprises (SAFE), published in November 2017⁴⁸

⁴⁷ Relates to industrial companies in the NACE sectors B-N

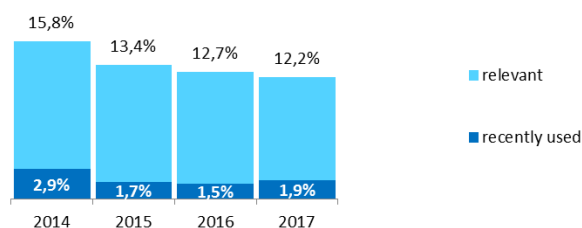
⁴⁸ Responses to the following question (multiple answers possible): Are the following sources of financing relevant to your enterprise, that is, have you used them in the past or considered using them in the future? Please provide a separate answer in each case. If Yes: Have you used such a type of financing in the past six months?

Graph 1 above shows that market-based instruments (e.g. equity) are only considered relevant by 12% of SMEs and that external equity is, in fact, used by only 2% of SMEs. The results differ widely across Member States. For instance, the use of equity financing ranges from 16% in Sweden to less than 1% in Bulgaria, Czech Republic, Hungary, Italy and Spain.

Moreover, as Graph 2 below indicates, equity finance is now considered less relevant than 4 years ago, confirming that any form of debt finance is the preferred financing mechanism of European SMEs, even though, in many cases, equity (risk capital) is more suitable, as small companies often lack collateral or have irregular cash-flows (equity does not impose a specific repayment schedule, hence it can be less of a burden during times of economic stress).

The bulk of SME financing is based on bank loans and the banking sector is therefore instrumental for the provision of more SME financing. Alternative financing sources are important as well, but they are not in a position to replace bank financing.

Graph 2: Relevance and usage of equity financing



Source: The Survey on the Access to Finance of Enterprises (SAFE) published annually by the European Commission & European Central Bank

Discontinuation of equity support for SMEs in COSME +

While support for equity finance is considered important from a policy point of view, the conclusion of this ex-ante assessment is that equity support should be discontinued under the

<http://ec.europa.eu/growth/safe> (infographic with the EU results :
<https://ec.europa.eu/docsroom/documents/26625/attachments/1/translations/en/renditions/native>)

future programme. As indicated in section **Error! Reference source not found.**, the Equity Facility for Growth (EFG) of COSME is considered effective. Nevertheless, it has been recommended to reduce the number of financial instruments and to align the EFG with equity facilities established under the European Fund for Strategic Investments (EFSI).

The equity facility created under the SME window of EFSI targets the same type of investments as the EFG, but the former is broader in scope as it supports not only SMEs but also small mid-caps. As it is envisaged to create an equity support mechanism under the SME window of the InvestEU Fund, which will provide seamless support for businesses from the pre-seed stage all the way to the expansion and growth stage, including support for small mid-caps, it is considered more efficient to create such seamless equity support under the InvestEU Fund and to discontinue equity support under COSME+.

This ex-ante assessment focuses on the European SME debt financing market only. A separate equity market assessment will be conducted for the InvestEU Fund (successor to EFSI).

1.2. The size and development of the European SME debt financing market

No official statistics exist for the size of the SME debt financing market in EU27. Studies estimate the stock of bank loans to SMEs to be approximately €1.5-1.7 trillion.⁴⁹ Furthermore, despite the fact that a SME definition exists at European level⁵⁰, this definition is not used to differentiate between debt financing of large corporations and SMEs.

The European Central Bank has initiated the AnaCredit⁵¹ project, which has set up requirements for a dataset containing detailed information on individual bank loans in the euro area, harmonised across all Member States. “AnaCredit” stands for *analytical credit datasets*. The project was initiated in 2011 and data collection is scheduled to start in September 2018. The availability of such data should allow a better assessment of the EU SME debt financing market in the future.

⁴⁹ SWD(2013) 517, European Parliament (2013), *Banking system soundness is the key to more SME financing*, European Banking Authority (2016), *Report on SMEs and SME supporting factor*

⁵⁰ Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises

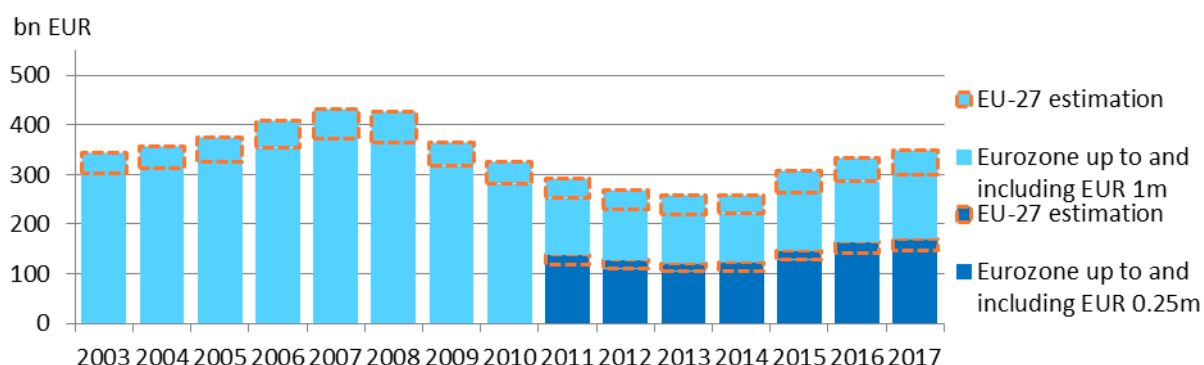
<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003H0361&from=EN>

⁵¹ https://www.ecb.europa.eu/stats/money_credit_banking/anacredit/html/index.en.html

In the absence of available data, we are using a proxy approach to gain a better understanding of the order of magnitude of the EU27 SME debt financing market. We are making use of the monthly statistics published by the European Central Bank (ECB), which reports on new lending to non-financial corporations with durations of more than 12 months. While this data does not distinguish between lending to big corporations and to SMEs, the reporting is split according to size of new lending transaction. One available size category is up to €1 million and another (only available since the reporting period June 2010) is available for new lending up to €250,000. New lending up to €1 million is considered to be a reasonable proxy for lending to SMEs, which encompass businesses with up to 249 employees and with an annual turnover not exceeding €50 million and/or an annual balance sheet total not exceeding €43 million.

It should be pointed out that the ECB statistics only cover new lending in the Eurozone (in early 2018 the Eurozone consisted of the following countries: Austria, Belgium, Cyprus, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Slovakia, Slovenia and Spain). Therefore, in order to arrive at the estimated market size of the full EU, we grossed-up the statistics based on the Eurozone's share in EU gross domestic product.

Graph 3: New bank lending to non-financial corporations (original maturity over 1 year)



Source: European Central Bank - Statistical Data Warehouse, MFI Interest Rate Statistics⁵²

Graph 3 does not include any forms of trade credit, short-term (up to one year) bank lending facilities. It does not allow an understanding of the overall size of the market (i.e. the stock of all

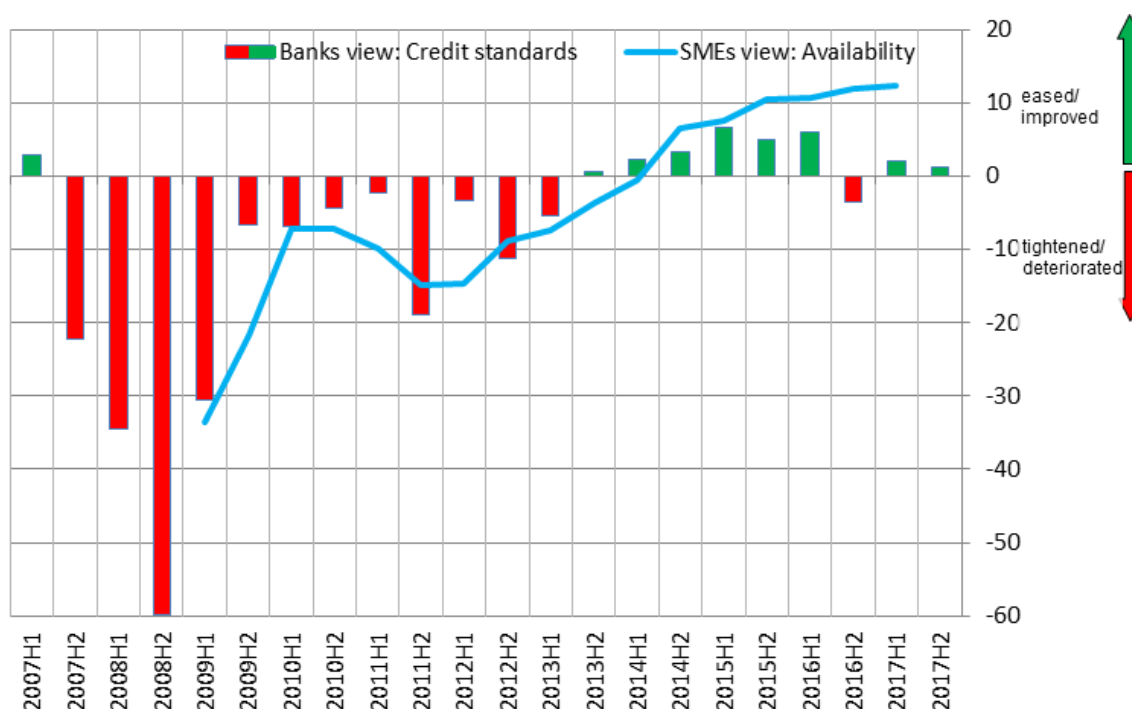
⁵² Loans other than revolving loans and overdrafts, convenience and extended credit card debt, new business volume to non-financial corporations, Euro area (changing composition), over EUR 0.25 million and up to EUR 1 million amount and up to and including EUR 0.25 million, floating and fixed initial rate, with original maturity over 1 year, monthly data summed for the years (available since June 2010); 2003-2010 estimation based on average share of over 1 year maturity loans in total loans in 2010-2017; EU-28 estimations based on share of Eurozone in EU gross domestic product, Eurostat yearly data at market prices

outstanding debt finance) but provides a proxy for an order of magnitude of annual new SME lending in the Eurozone of currently more than €350 billion per annum, of which about half is made available for financing transactions of up to €250,000.

As indicated by Graph 3, following the financial crisis triggered by the collapse of Lehman Brothers in the autumn of 2008, new bank lending contracted considerably and the SME securitisation market in Europe collapsed.⁵³ New regulatory requirements, leading to higher capital requirements (e.g. CRR/ CRD⁵⁴) and the need for banks' deleveraging, negatively impacted banks' willingness and ability to lend and to accept risk.

This had a major negative effect on available SME bank finance across the EU. Credit standards tightened considerably, particularly for SMEs, which, as a consequence, experienced a credit crunch. Credit standards only started to ease after 2013 when SMEs also started to have a more positive perception of the availability of bank loans.

Graph 4: Changes in credit standards and availability of loans



⁵³ European Investment Fund (2015), *SME Securitisation at a crossroads*

⁵⁴ Capital Requirements Regulation (CRR) and Capital Requirements Directive (CRD)

Source: Data on credit standards was extracted from the ECB Bank Lending Survey; data on the perception of the availability of bank loans was extracted from the Survey on the Access to Finance of Enterprises (SAFE)

To alleviate the negative impacts of stricter capital rules by the CRR and CRD IV on the SME lending market, and in the context of credit tightening after the financial crisis, a capital reduction factor for loans to SMEs was introduced by the CRR. The so-called SME supporting factor allowed credit institutions to counterbalance the rise in capital requirements and to provide an adequate flow of credit to this particular group of companies. The SME supporting factor was implemented in 2014, thus reducing the capital requirements for exposures to SMEs in comparison with the pre-CRR/CRD IV framework.

Since late 2014 we can see an increase in new lending to corporations in line with economic growth in the Eurozone and the positive impact of policy/regulatory instruments, such as the introduction of the SME supporting factor in 2014 or the start of quantitative easing by the ECB in March 2015.⁵⁵ All of these activities have led to an improvement in the availability of bank finance, and the conditions for access to finance have on average recovered.⁵⁶ However, as regards volume of lending, pre-crisis levels have not been reached yet.

While the aggregate situation of new SME lending in EU27 has markedly improved, Graph 3 also shows that the financing of transactions up to €250,000 has not recovered to the same extent as the financing of transactions of a larger size. The positive trend is much less pronounced for smaller loan amounts and hence for smaller SMEs. In 2017 the growth in new loans in the Eurozone was 5% lower for small loan amounts of up to €250,000 than for larger loans of up to €1 million.

1.3. The size and development of SME debt financing markets in selected Member States

Eurozone aggregate data analysed in the previous section masks considerable cross-country differences. As shown in Graph 5 below, between 2011 and 2013 credit growth was negative across the Eurozone, although the order of magnitude of market contraction differed considerably.

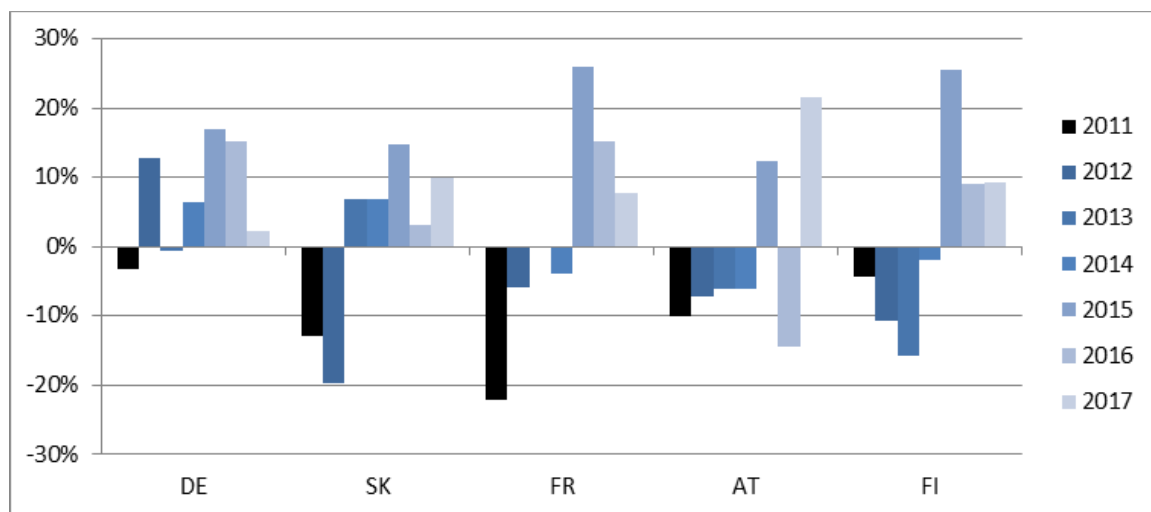
⁵⁵ <https://www.ecb.europa.eu/mopo/implement/omt/html/index.en.html>

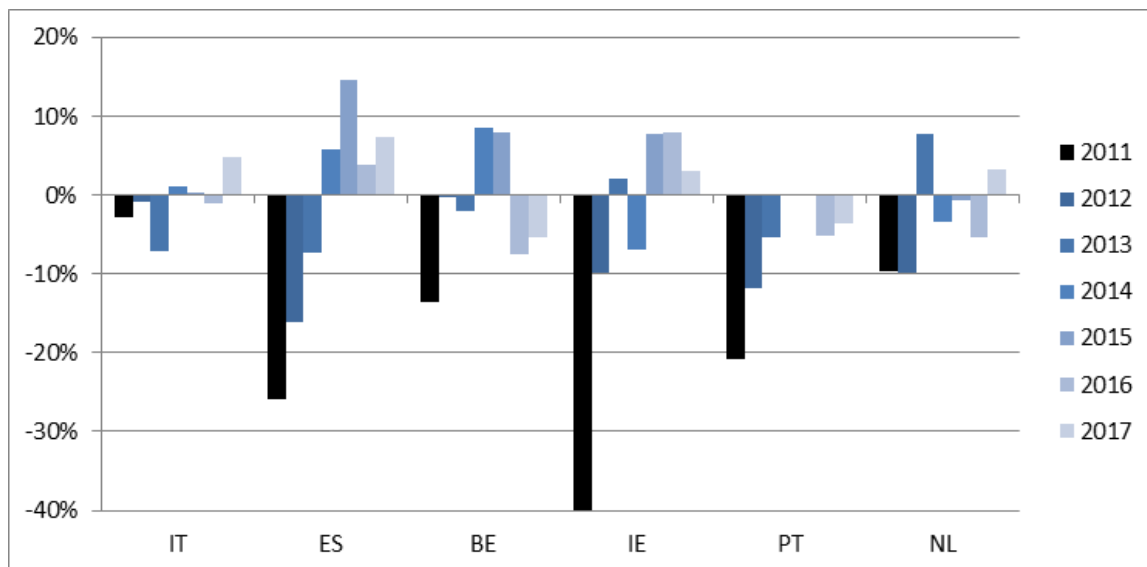
⁵⁶ Survey on the Access to Finance of Enterprises in the euro area April to September 2017, section 3.1: <https://www.ecb.europa.eu/pub/pdf/other/ecb.accesstofinancesmallmediumsizedenterprises201711.en.pdf?beb1832df4af9efa945a5a1f7b99eeb7>

2014 was a turning year where some Eurozone countries started to experience positive credit growth but this trend is uneven and in most countries the positive growth has not yet compensated for the loss following the crisis.

While Germany, Slovakia, France, Austria and Finland have recovered in terms of new loan volumes, countries like Italy, Spain, Belgium, Ireland, Portugal and the Netherlands have not yet recovered to pre-crisis levels in the area of SME lending of up to €250,000.

Graph 5: Credit growth of loans to corporations of up to €250,000 across selected Eurozone countries



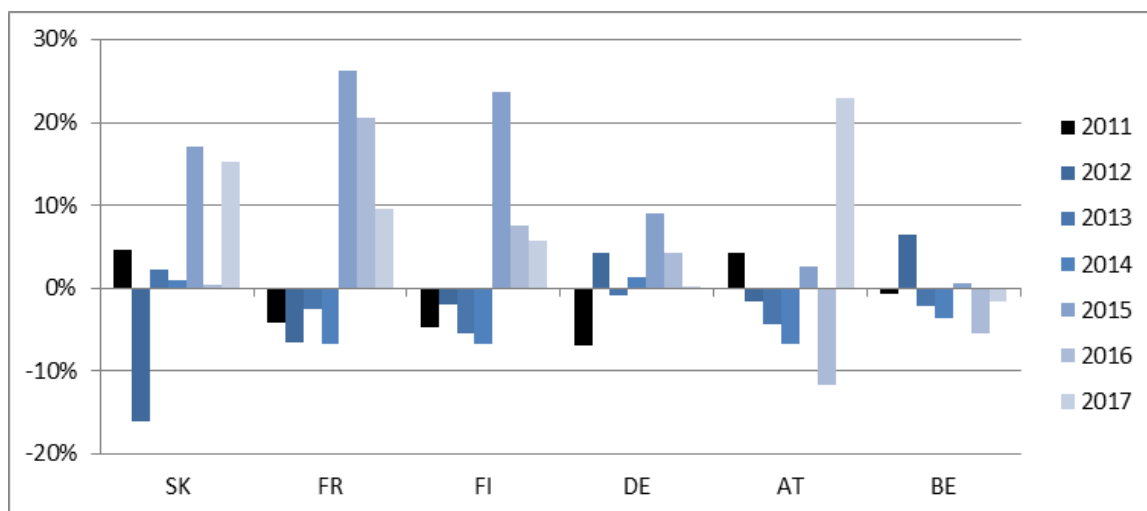


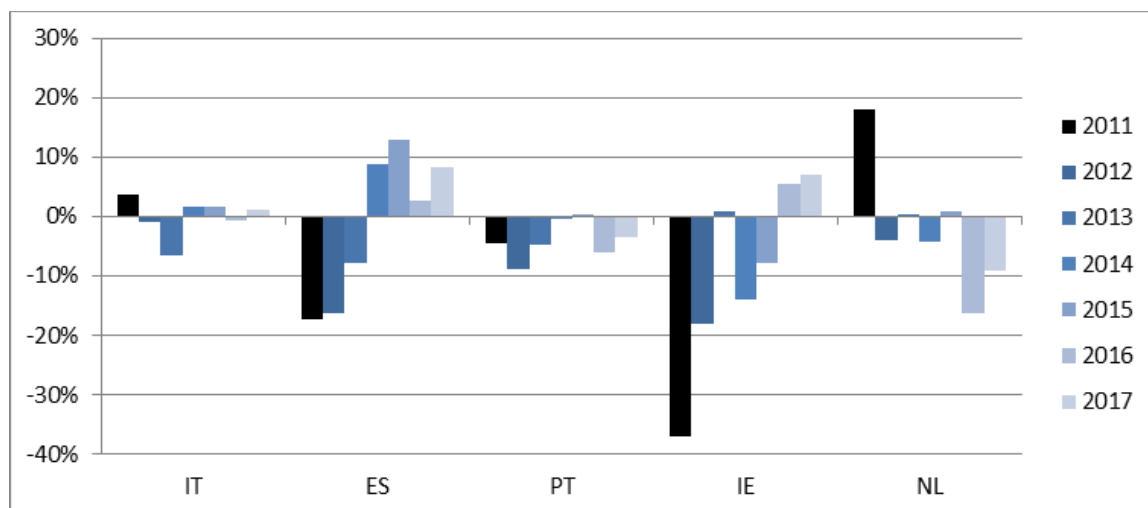
Source: ECB MFI Interest Rate Statistics 2018

A similar picture presents itself for lending of up to €1 million, as shown in Graph 6 below.

Graph 6: Credit growth of loans to corporations of up to €1 million across selected Eurozone countries

(includes loans of up to €250,000)





Source: ECB MFI Interest Rate Statistics 2018

The diverging trends across Eurozone countries can be explained by economic, business and structural differences. SMEs in some countries might have more demand for loans above €250,000 whilst SMEs operating in a Member State with more uncertain economic environment may be more prudent with respect to taking on new debt financing. Financial institutions in some countries may also be able to increase the supply of financing more than in others that might suffer from problems related to non-performing loans, liquidity or capital requirements.

Alongside financial fragmentation on the loan supply side, other factors such as cross-country differences in SMEs' profitability or indebtedness are acting on both supply of and demand for credit and contribute to divergences in interest rates and lending volumes. On the supply side, banks request a higher risk premium for loans to SMEs with lower profitability, which, in turn, further reduces their profitability, while loan demand can also be negatively affected by low profitability. A study shows that there are differences in funding conditions between comparable enterprises that are located in two different euro area countries.⁵⁷

The interest rate spreads between "North" and "South" countries have been narrowing over the last few years, while remaining substantial. Graph 7 below shows the interest rate differentials between selected countries of the Eurozone when compared to interest rates charged to German companies.⁵⁸

⁵⁷ European Commission (2013), *European Economic Forecast Autumn 2013*

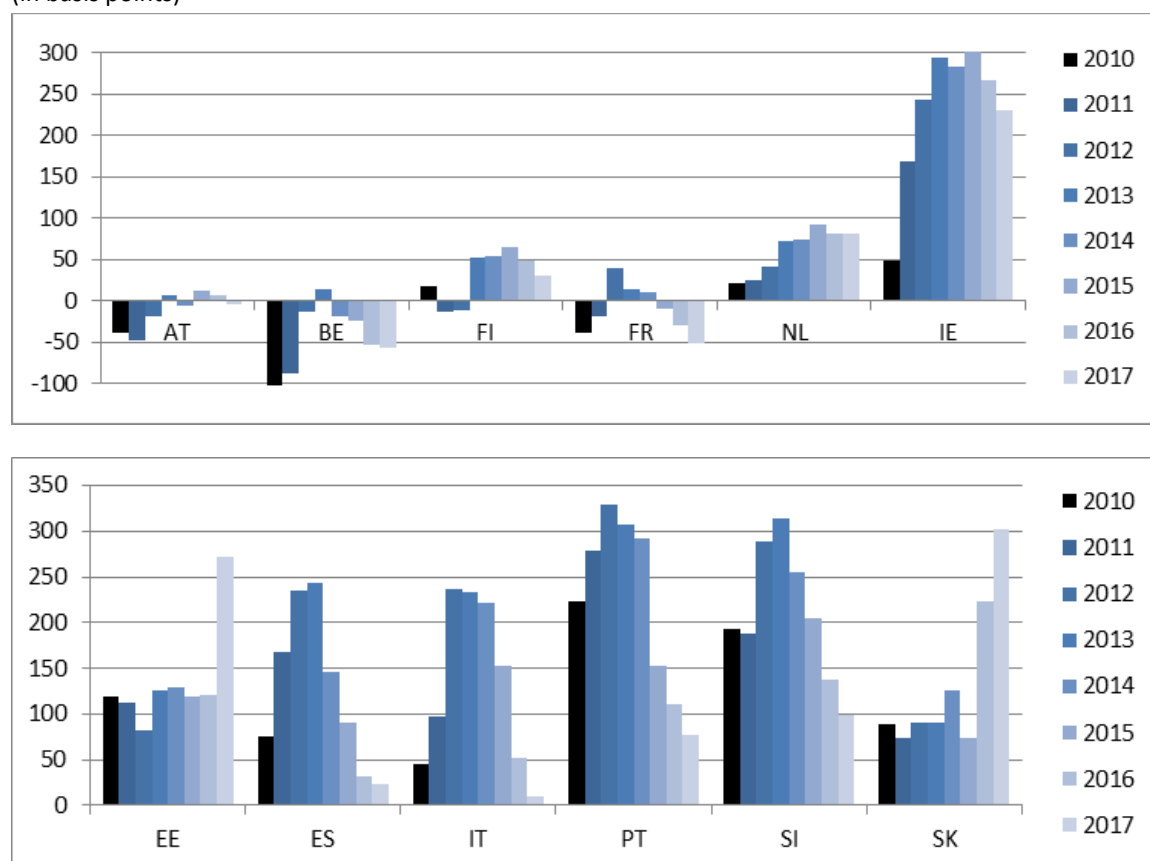
⁵⁸ Germany is taken as baseline because it is the largest economy in the Eurozone

Ireland shows by far the highest premium charged. In 2017, most countries are within a 100 basis points differential when compared to Germany. Entities in Austria, Belgium and France are reported to pay on average even lower interest rates than businesses in Germany.

Estonia, Ireland and Slovak Republic, on the other hand, are clear outliers where premiums of 200 – 300 basis points need to be paid when compared to Germany.

Graph 7: Interest rate spreads for new loans of up to €1 million compared to Germany

(in basis points)



Source: ECB MFI Interest Rate Statistics 2018

While part of this differential reflects differences in macroeconomic risk/country risk among euro area countries, this could also indicate that SMEs with similar risk profiles tend to suffer from higher lending costs depending on the country in which they are located. This fragmentation can most likely be explained by the still fragile situation of many banks in some Member States, which are plagued with high levels of non-performing loans.⁵⁹ Indeed, banks

⁵⁹ OECD (2016), *2016 Economic Survey of the Euro Area*

with high levels of non-performing loans tend to lend less, as they are less profitable, with weaker capital buffers and higher funding costs.⁶⁰

1.4. Conditions restricting SMEs' access to debt finance

As indicated in section **Error! Reference source not found.**, SMEs are heavily reliant on external sources of finance as internal funding is generally insufficient to meet their financing needs.

As set out in section **Error! Reference source not found.**, following the financial crisis, higher capital requirements and the need for banks' deleveraging negatively impacted banks' willingness and ability to lend and to accept risk. This had a major negative effect on available SME bank finance across the EU. Credit standards tightened considerably and, as a consequence, SMEs experienced a credit crunch. While the situation has recovered, there are still considerable differences among Member States.

The 2018 OECD scoreboard on Financing SMEs and Entrepreneurs notes that "new lending to SMEs depicts a more negative picture than in previous years". Growth in new SME loans in 2016 was negative in 15 out of 25 countries covered by the OECD scoreboard. The decline in new lending can be attributed to several factors, often depending on national circumstances. In some countries this can be attributed to lower demand linked to weak investment dynamics. In other countries, such as Greece, Slovenia and Portugal, financial institutions appeared to have become more risk-averse when lending to SMEs.

Moreover, financial markets in the Member States show different degrees of development, in terms of the number of players present in the market, the diversity of financial institutions present, product offerings and risk appetite. SMEs have no means of overcoming these national differences because they rely on local/national providers of finance. SME financing is predominantly provided within national boundaries due to regulatory constraints, investor home bias and the regional focus of many SMEs. Cross-border lending is only at a nascent stage, predominantly fuelled by the emergence of Fintech companies.

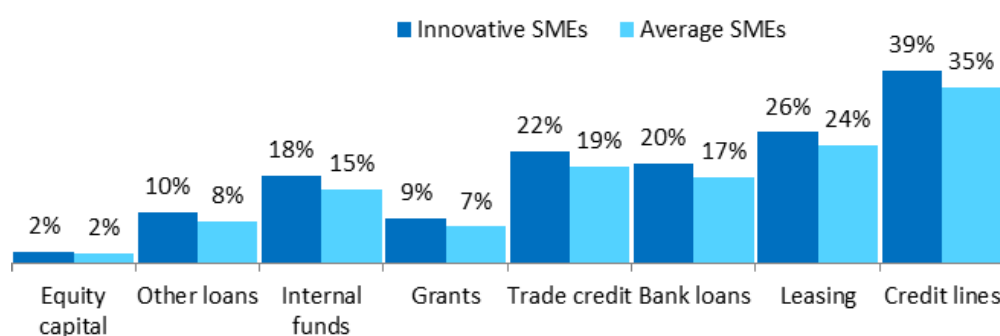
The financing problem is acute for firms that are undertaking activities with significant financial, technological, organisational or business-model risk and those wanting to finance growth projects that do not result in the acquisition of fixed assets that could be collateralised (e.g. in the area of culture and creativity, digitisation, internationalisation, etc.).

⁶⁰ Aiyar, S. et al. (2015), *A strategy for resolving Europe's problem loans*, IMF Staff Discussion Note, No. SDN/15/19, International Monetary Fund, Washington DC

Furthermore, undertaking innovative and other high-risk activities, which are poorly understood by finance providers, results in low credit scores and leads to high interest charges to compensate for the perceived risk, provided that a finance provider is willing to offer the finance at all, rather than reject the application outright.

While financing through equity is often regarded as the appropriate source of funding for innovative firms, the limited size of the European venture capital industry (see separate ex-ante assessment conducted for equity investments into SMEs annexed to the impact assessment for the InvestEU Fund Regulation) and the ‘bank culture’ predominant in the Member States lead to the fact that **many innovative firms rely on ‘classic’ debt financing**. As indicated in Graph 8 below, the use of equity financing by innovative⁶¹ SMEs is the same as for average SMEs and, in terms of usage of other types of finance, the differences are also not that significant.

Graph 8: Usage of different types of financing



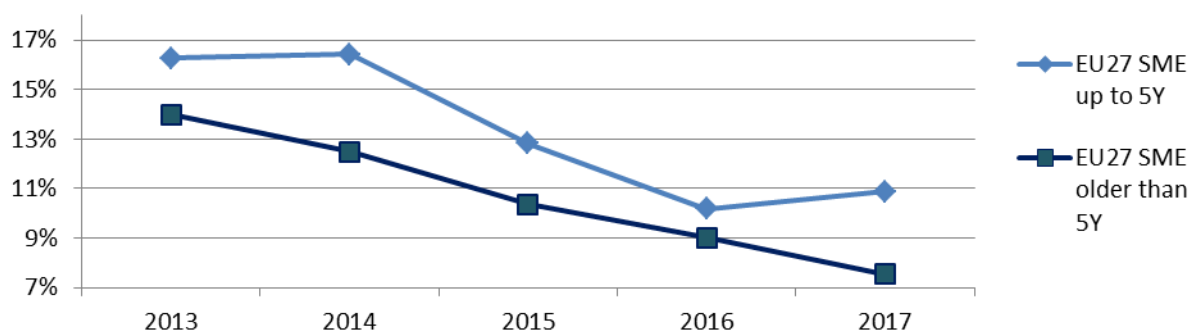
Source: The Survey on the Access to Finance of Enterprises (SAFE) published annually by the European Commission & European Central Bank

Younger and smaller companies or those requiring rather small financing amounts are faced with a structural financing gap due to information asymmetries, lack of financial track records and disproportionate file costs.

⁶¹ Innovative SMEs for the purpose of the SAFE survey are those SMEs that indicate they have introduced either a new or significantly improved product, service, production process, organisation of management or way of selling goods or services in the past twelve months.

Younger companies, i.e. companies in their first five years of existence, are perceived to be very risky by lenders because they have no financial track record and statistics indicate that less than 50% of businesses survive during the first five years of their establishment.⁶² The SAFE survey results confirm that younger companies consider access to finance to be more problematic than more established SMEs.

Graph 9: SMEs reporting access to finance as the most important problem: younger and older EU-27 SMEs



Source: SAFE 2009-2017

This structural financing gap is independent of the economic cycle or the home country of SMEs. If financing is offered at all, it is offered at unreasonable conditions in terms of interest rates applied, maturities, repayment terms and collateral required.

These market failures – prevalent across Member States – hinder the start-up and growth of companies. Companies rarely have the internal funds they need and consequently seek external financing.

This market environment results in an access to finance gap for SMEs that have a perceived higher risk profile or insufficient collateral, which is independent of their sector of operation. An SME financing gap can be defined as a “mismatch between the demand and the supply [...] in the different types of financial instruments for SMEs in a given area of the EU”.⁶³ It is a situation where firms that would merit financing cannot get it due to market imperfections.

⁶² see Eurostat business demography statistics or OECD (2015), *Cross-Country evidence on start-up dynamics*, OECD Science technology and industry working papers

⁶³ European Court of Auditors (2012). Special Report No 2/2012, *Financial instruments for SMEs co-financed by the European Regional Development Fund*

1.5. Assessment of the market gap for access to SME debt finance

Given the challenges faced by SMEs in obtaining debt finance, it is crucial for policy intervention to determine the extent of the financing gap. The objective of this ex-ante assessment is to analyse the market demand and the need for EU intervention in more detail.

As shown in section **Error! Reference source not found.**, SMEs rely heavily on bank financing, so the financing gap is typically expressed and measured with reference to the bank lending market.

As already indicated in the ex-ante evaluation for the COSME programme, a precise measurement of the phenomenon is an inherently complex exercise, as it involves unobservable variables, i.e. the lending transactions that could have occurred if certain frictions (e.g. informational asymmetries, transaction costs, sufficient collateral) had not existed. Under these conditions, it is inevitable to resort to proxies, such as loan rejection rates, rates of discouraged potential borrowers and the share of firms offered unfavourable lending conditions, in terms of maturity and/or interest rates.

1.5.1. Methodologies

Taking into account the relevant literature, this assessment is based on the methodologies of past ex-ante assessments carried out for the COSME Programme⁶⁴ and for the SME Initiative⁶⁵.

The assessment is done by exploring financial market failures in each EU Member State in providing credit to financially viable borrowers. The approach uses SME survey data from 2011-2017⁶⁶ to gauge the number of SMEs unsuccessful in obtaining a loan, while being financially viable and thus creditworthy. Multiplying this number by the average SME loan amount, an estimate can be provided of the unmet financing needs of financially viable SMEs during 2011-2017.

A detailed explanation of the methodology used for the ex-ante assessments referred to above is given below.

⁶⁴ Economisti Associati et al. (2011), *Combined ex-ante evaluation and impact assessment of the successor to the Entrepreneurship and Innovation Programme under the Competitiveness and Innovation Framework Programme 2007-2013*

⁶⁵ SWD(2013) 517

⁶⁶ Annual SAFE surveys 2011-2017 conducted by the European Commission and European Central Bank

Methodology used for the ex-ante assessment of the COSME Programme:

$$\text{Gap} = \text{number of SMEs} \times \% \text{ unsuccessful SMEs} \times \text{average SME loan size} \times 20\%$$

where

| | |
|------------------------|--|
| average SME loan size: | average size of loans granted to SMEs |
| % unsuccessful SMEs: | SMEs that applied x (SMEs rejected + SMEs partly successful + SMEs refused) + SMEs discouraged |

where

| | |
|-------------------------|---|
| SMEs that applied: | share of SMEs that applied for a bank loan |
| SMEs rejected: | share of SMEs that applied for a bank loan and whose demand was rejected by the bank |
| SMEs partly successful: | share of SMEs that applied for a bank loan and did not receive the whole amount requested |
| SMEs refused | share of SMEs that applied for a bank loan and refused the proposed bank loan (presumably because of unfavourable conditions) |
| SMEs discouraged: | share of SMEs that did not apply for a loan (presumably for fear of rejection) |

Rejection rates are not *per se* an indication of the existence of a 'market failure', as a loan application may well be turned down for fully justified reasons.

According to industry sources and some studies, a significant share of rejections, in the order of 15-30%, refer to potentially sound banking transactions that do not materialise for reasons linked to the existence of market imperfections. Therefore, the ex-ante assessment of the COSME programme conservatively assumed that 20% of unsuccessful SME loan applications merit financing.

Methodology used for the ex-ante assessment of the SME Initiative (SMEI):

The starting point is the percentage of financially viable SMEs that are unsuccessful in obtaining loan finance. This is computed using the following formula:

$$\text{Unsuccessful SMEs} = [\text{SMEs that applied} \times (\text{SMEs rejected} + \text{SMEs refused})] + \text{SMEs discouraged}$$

where

SMEs that applied: share of financially viable SMEs that applied for a bank loan

SMEs rejected: share of financially viable SMEs that applied for a bank loan and whose demand was rejected by the bank

SMEs refused: share of financially viable SMEs that applied for a bank loan and refused the proposed bank loan because of high interest rates

SMEs discouraged: share of financially viable SMEs that did not apply for a loan for fear of rejection

Using the estimated Unsuccessful SMEs, the SME loan debt financing gap is calculated as follows:

$$\text{debt financing gap} = \text{number of SMEs} \times \text{financially viable SMEs} \times \text{unsuccessful SMEs} \times \text{average SME loan size}$$

where

financially viable SMEs: share of SMEs exhibiting positive turnover growth*

unsuccessful SMEs: share of financially viable SMEs unsuccessful in
obtaining loan financing (see above)

average SME loan size: average size of loans granted to SMEs

* The proportion of “financially viable” SMEs is proxied with the proportion of SMEs that experienced a turnover growth higher than 20% in the previous 3 years = lower bound, or higher than 0% in the previous 6 months = upper bound.

1.5.2. Assumptions

Due to lack of complete data, an accurate quantification of this gap is difficult and was therefore based on a number of estimations and assumptions.

Data on SME loan amounts per country was based on figures from AECM⁶⁷, historical amounts of loans supported by EU financial instruments⁶⁸ and the ORBIS database from 2011-2017. None of these sources provided robust data on loan amounts for all EU Member States. Hence, we based our calculations on average amounts from all three sources, equally weighted. AECM statistics are the key data source, but suffer from several limitations.⁶⁹ For instance, as mentioned in a recent study by the European Investment Fund (EIF)⁷⁰ the coverage rate of credit guarantee rates in Europe varies significantly. The survey finds average minimum/maximum coverage ratios across Europe amounting to 34%/81% respectively. We used AECM data on guarantee amounts

⁶⁷ European Association of Guarantee Institutions

⁶⁸ Source: quarterly reports on implementation of CIP & COSME financial instruments.

⁶⁹ AECM membership varies from year to year, not only by the countries that have AECM “members” but also by AECM membership within a given country. EU Member States not covered by AECM data are Cyprus, Denmark, Finland, Croatia (2011-2012), Ireland, Malta, Sweden, Slovak Republic, United Kingdom (2011-2014)

⁷⁰ European Investment Fund (2017), Working Paper 2017/42, *Credit Guarantee Schemes for SME lending in Western Europe*

and an average guarantee rate of 70% to calculate loan amounts. No data was available to calculate the loan amounts based on individual guarantee rates for the different EU Member States.

Data from the implementation of EU financial instruments must also be treated with caution.⁷¹ Other loan data was extracted from the ORBIS database⁷². ORBIS is a commercial database with accounting, legal and financial information of public and private companies. ORBIS data is only available in terms of loan stock, which would create an upward bias, but it excludes long run debt, which would create a downward bias.

When not enough robust data for a specific country was available, we took average loan amounts. We corrected figures for the impact of outliers. We defined outliers as excessive loan amounts (60% higher or lower than country average or 80% higher or lower than the EU average). In these cases we used an historical average of the specific country. If no historical average for a specific country could be calculated, we used the EU average loan amounts.

Information from the ORBIS database, the SAFE survey⁷³ and the SME performance review⁷⁴ only provides data from selected sectors, which distorts our estimates for the SME debt financing gap. As more exhaustive data was not available at the time of conducting this ex-ante assessment, our calculation excluded the potential financing gap of companies from certain sectors, such as the financial and insurance industries (NACE K).

The above methodologies and assumptions allowed us to calculate an SME debt financing gap range for each Member State for the years 2011-2017. The debt financing market gap can be expressed in absolute amounts (€ billion) and as a percentage of Gross Domestic Product (GDP) to allow better comparison across countries.

Market gaps are driven by the absolute size of the debt financing market of a Member State, as well as by the loan rejection rates, which vary considerably among Member States.

⁷¹ In some Member States or some years no data on loan amounts is available due to a lack of a financial intermediary. In some cases, data on loan amounts point to outliers. This could be linked to the fact that for some agreements intermediaries only serve a very particular financing need with specific loan characteristics (low loan amounts for start-ups or higher loan amounts for fast-growing companies). In addition, it is unclear whether the average size of EU-guaranteed loans is equal to the average size of all SME loans.

⁷² Average loan stock amounts across sectors (NACE B-J, L-N) weighted by their share in non-financial GDP. The sample at the top and bottom 10% was winsorised and sectors with fewer than 10 SMEs were dropped.

⁷³ Industry (NACE B, C, D, E). Construction (NACE F), Trade (NACE G), Services (NACE H, I, J, L, M, N, R, S).

⁷⁴ The data cover the non-financial business economy (sections B-J and L-N).

Based on the methodologies outlined before, it is therefore possible to carry out calculations of the debt financing gap in terms of the number of SMEs and indicative loan volumes, both for the EU as a whole and, with more caveats due to data unreliability and unavailability, for each Member State.

1.5.3. EU-level debt financing market gap

At EU27 level, the proportion of SMEs that have faced problems in accessing bank financing between 2011 and 2017 is 13.5%, calculated as the weighted average of all EU countries participating in the SAFE Survey in a given year. This figure is in line with the estimates provided in the Ex-Ante Assessment for the SME Initiative (12.6%). The estimated interval for the proportion of financially viable SMEs lies within the range 14.3% to 39.1%.

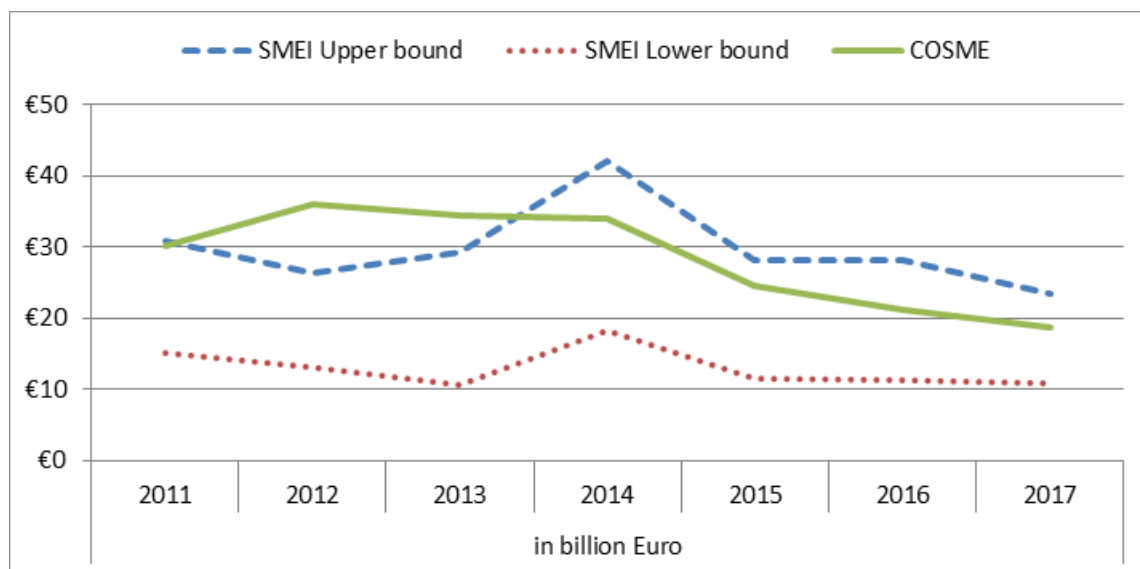
Overall, the loan financing gap affected annually between 444,000 and 1,211,000 viable European SMEs over the period 2011-2017. Therefore, up to 5.2% of European SMEs were not able to obtain a loan for reasons unrelated to financial viability.

By matching data obtained from the ORBIS Database with information on loan shares provided by AECM and implementation of EU financial instruments⁷⁵, this assessment produces an average SME loan size of €80,000.

Despite the strong support of the SME debt financing market through public support schemes by the EU and Member States, EU27 still suffered from a substantial debt financing gap, peaking at €42 billion in 2014, which has subsequently seen a reduction to less than €30 billion. The figures show an overall improvement of the conditions for accessing loan financing at EU27 level compared to earlier years.

Graph 10: Aggregated loan financing gap for SME debt finance in EU27 according to different calculation methodologies

⁷⁵ CIP/COSME financial instruments



SMEI Upper bound: Debt financing needs of SMEs with a positive turnover growth rate according to methodology used for the SME Initiative (SMEI)

SMEI Lower bound: Debt financing needs of high-growth SMEs (i.e. SMEs that have shown a turnover growth rate higher than 20%) according to methodology used for the SME Initiative

COSME: Debt financing needs of SMEs according to methodology used for the COSME ex-ante assessment.

We can conclude that over the 7-year period, the aggregated market gap for new SME financing was about €200 billion. Even if one were to consider a much narrower group of SMEs, i.e. those with a turnover growth rate of higher than 20%, the aggregated market gap was approximately €90 billion.

The analysis of the debt financing gap is expected to be underestimated for a number of reasons:

- The reported figures only represent the measured gap in terms of loan financing. Due to the fact that SMEs are also heavily reliant on alternative debt financing instruments (i.e. leasing, bank overdraft, trade credit, etc.), the overall debt financing gap in Europe is expected to be higher.
- This study produces an average SME loan size of €80,000 whilst other studies estimate the loan size between €100,000 and €130,850.⁷⁶ Estimates of the total debt financing gap would be higher if higher average loan sizes were assumed.

⁷⁶ Economisti Associati et al. (2011), *Combined ex-ante evaluation and impact assessment of the successor to the Entrepreneurship and Innovation Programme under the Competitiveness and Innovation Framework Programme 2007-2013*; SWD(2013) 517

- According to Eurostat statistics, the number of new market entrants and companies exiting the market approximately cancels out. The average number of SMEs used for the purposes of calculation does not fully reflect the fact that especially the new entrants have financing needs that are normally considered to be too risky by the commercial financial sector to bear.

1.5.4. Individual Member States' debt financing market gaps

The aggregated market gap for 2017 has been computed based on the individual market gaps per Member State, which are set out in Graph 11 below. The minimum/maximum financing gaps represent the lowest/highest estimate of the financing gap using the three different methods from the ex-ante assessment of the COSME programme and the SME Initiative (lower/upper bound).

Graph 11: SME debt financing gap for 2017 per Member State

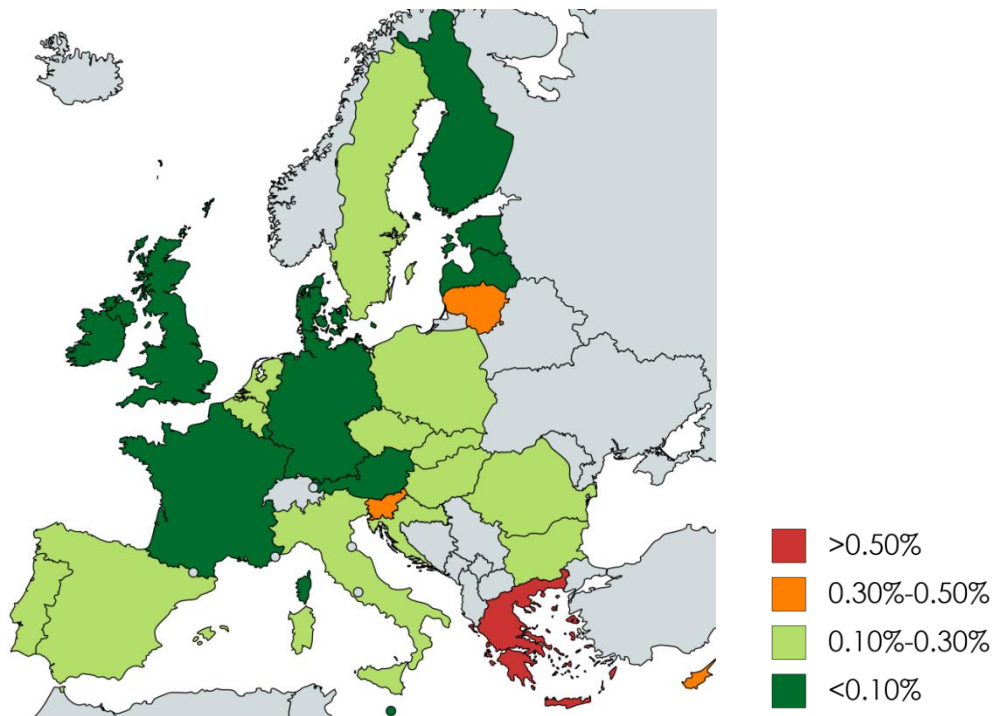
| Market gap range | | | | | | Average loan size |
|------------------|---|------|---|------|---------|-------------------|
| AT | € | 0.19 | - | 0.55 | billion | € 121,566 |
| BE | € | 0.56 | - | 1.01 | billion | € 97,906 |
| BG | € | 0.17 | - | 0.44 | billion | € 57,724 |
| CY | € | 0.15 | - | 0.42 | billion | € 96,079 |
| CZ | € | 0.00 | - | 0.96 | billion | € 98,744 |
| DE | € | 0.95 | - | 1.69 | billion | € 119,623 |
| DK | € | 0.00 | - | 0.38 | billion | € 91,410 |
| EE | € | 0.00 | - | 0.09 | billion | € 85,522 |
| EL | € | 2.68 | - | 3.93 | billion | € 88,137 |
| ES | € | 0.36 | - | 2.34 | billion | € 58,308 |
| FI | € | 0.09 | - | 0.27 | billion | € 77,406 |
| FR | € | 0.61 | - | 1.21 | billion | € 35,007 |
| HR | € | 0.07 | - | 0.28 | billion | € 95,785 |
| HU | € | 0.11 | - | 0.38 | billion | € 64,795 |
| IE | € | 0.29 | - | 0.78 | billion | € 84,428 |
| IT | € | 0.69 | - | 2.53 | billion | € 65,190 |

| | | | | | | |
|------|---|-------|---|-------|---------|-----------|
| LT | € | 0.21 | - | 0.42 | billion | € 99,340 |
| LU | € | 0.00 | - | 0.01 | billion | € 52,210 |
| LV | € | 0.04 | - | 0.09 | billion | € 68,611 |
| MT | € | 0.02 | - | 0.04 | billion | € 96,079 |
| NL | € | 0.96 | - | 2.15 | billion | € 94,834 |
| PL | € | 0.17 | - | 0.59 | billion | € 54,843 |
| PT | € | 0.76 | - | 1.42 | billion | € 72,482 |
| RO | € | 0.35 | - | 0.69 | billion | € 71,101 |
| SE | € | 0.21 | - | 0.71 | billion | € 98,125 |
| SI | € | 0.31 | - | 0.59 | billion | € 106,571 |
| SK | € | 0.15 | - | 0.76 | billion | € 60,541 |
| EU27 | € | 10.09 | - | 24.70 | billion | € 79,227 |
| UK | € | 0.65 | | 0.91 | billion | € 78,296 |
| EU28 | € | 10.74 | | 25.61 | billion | |

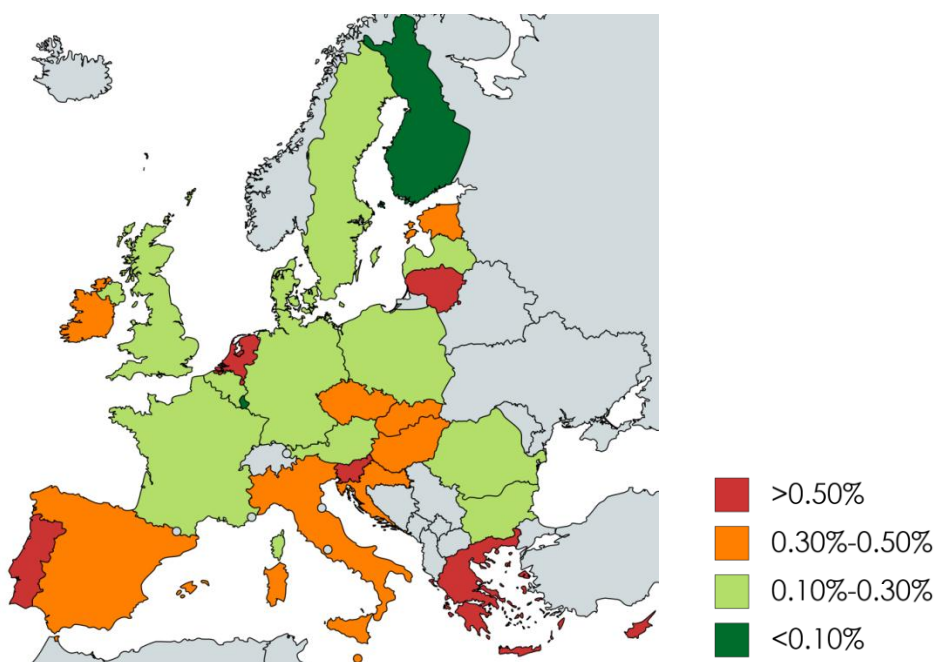
Graph 11 above provides an overview of the debt financing gap in each Member State in 2017 in absolute terms. Graph 12 displays the distribution of the loan financing gap across EU Member States. Note that values are expressed as percentages of national GDP and reflect the average values observed during the 2011-2016 period. Countries may have recovered significantly in terms of provision of loan financing to financially viable SMEs.

Graph 12: SME debt financing gap in 2011-2016: Country overview

a. Minimum financing gap (% of GDP)



b. Maximum SME debt financing gap (% of GDP)



Based on findings of other studies, the debt financing gap expressed in this assessment as a percentage of GDP appears to be underestimated.

Silanes Molina et al (2015) study the financing gap in five European countries and confirm the existence of a loan financing gap as well as the discrepancy across individual Member States. They use data on SME outstanding loans to estimate the supply of SME financing and information from the SAFE survey to assess loan demand. The study finds that the loan gap as a percentage of GDP in 2013 is more pronounced in the Netherlands (6-16%) and Poland (5-15%) than in Germany (3-6%), France (3-5%) or Romania (1-4%).

1.6. EU action geared towards addressing the SME debt financing gap

The EU, together with Member States, has adopted a wide range of different initiatives to strengthen banks' ability to lend and to accept risk, as well as to increase their liquidity.

1.6.1. Centrally-managed debt EU financial instruments for SMEs

EU financial instruments are "Union measures of financial support provided on a complementary basis from the budget in order to address one or more specific policy objectives of the Union. Such instruments may take the form of equity or quasi-equity investments, loans or guarantees, or other risk-sharing instruments, and may, where appropriate, be combined with grants."⁷⁷

To address the debt financing gap, several EU debt facilities have been set up to extend greater financing volumes at better conditions to a riskier set of enterprises. Those facilities aim to foster the development of a pan-European SME finance market and to address market failures that are more appropriately tackled at EU level given their widespread nature.

The Commission has entrusted the European Investment Fund (EIF) with the implementation of these facilities. The EIF, a subsidiary of the European Investment Bank (EIB), is an experienced implementation partner operating across the EU and beyond. The EU guarantees are either based on a mandate (all risk is borne by the EU budget) or based on risk-sharing (risk is partially borne by EU budget and partially by the EIF). All facilities are implemented based on calls for expression of interest and interested financial intermediaries from across the participating countries of the relevant programmes can apply.

The following central debt EU financial instruments (2014-2020) help to mobilise about **€13.0 billion of financing per year**:

- SME Loan Guarantee Facility (COSME Programme based on a mandate): Guarantees for supporting new portfolios of higher risk SME transactions. Anticipated resource

⁷⁷ Art. 2(p) of the Financial Regulation.

allocation for the full period 2014–2020: €1.52 billion (including the existing EFSI top-up of €550 million), which is expected to mobilise up to **€44 billion of financing**.

- InnovFin SME Guarantee Facility based on risk sharing between Horizon 2020 and the EIF: The facility provides direct and indirect guarantees helping to address the financing gap for innovative SMEs and Small Midcaps (with up to 499 employees) for their investments in innovative products and processes containing significant technology or application risks. Anticipated resource allocation for the full period 2014–2020: €1.94 billion (including the existing EFSI top-up of €880 million), which is expected to mobilise up to **€16 billion of financing**.
- Cultural and Creative Sectors Guarantee Facility (Creative Europe Programme based on a mandate): The facility provides guarantees to banks dealing with cultural and creative SMEs, thereby strengthening financial capacity in those sectors. The scheme began in 2016. Anticipated resource allocation for the period 2016–2020: €183 million (including an EFSI top-up of €60 million), which is expected to mobilise up to **€0.8 billion of financing**.
- Programme for Employment and Social Innovation (EaSI): The EaSI Micro-finance and Social Entrepreneurship axis mobilises microfinance for vulnerable groups and micro-enterprises and supports the development of social enterprises through, inter alia, a guarantee facility. Indicative resource allocation for the EaSI Guarantee over the period 2014–2020: €196 million (including the existing EFSI top-up of €100 million), which is expected to mobilise up to **€1.9 billion of financing**.
- The European Fund for Strategic Investments (EFSI) is a joint initiative by the European Commission and the European Investment Bank (EIB) Group to help overcome the investment gap in the EU by mobilising private financing for strategic investments. EFSI is one of the three pillars of the Investment Plan for Europe that aims to revive investment in strategic projects around Europe to ensure that money reaches the real economy. It comprises 1) an Infrastructure and Innovation Window and 2) an SME Window. Under the SME Window, equity and debt financing is supported. The support for debt financing for the benefit of SMEs and small mid-caps has been implemented mainly in the form of top-ups, as outlined above, so the impact of EFSI on SME debt finance is already captured under these top-ups. In addition, further top-ups are expected to be introduced for an amount of €1.6 billion, which is expected to mobilise an additional **€26.6 billion of financing**.
- The EU SME Initiative, designed as a crisis-response instrument, provides uncapped guarantees and/or securitisation to improve access to finance for SMEs, including innovative and high-risk SMEs. The initiative combines different EU funding resources in one financial instrument – namely resources from European Structural and Investment Funds (ESIF), COSME or Horizon 2020 and EIB Group resources. Below are the expected resources committed and financing amounts:

| Member State participating | Amounts committed by Member State | Amounts committed from Horizon or COSME | Expected new financing supported |
|----------------------------|-----------------------------------|---|----------------------------------|
| Bulgaria | €102 million | €1.8 million | €0.6 billion |
| Finland | €40 million (*) | €0.8 million | €0.4 billion |
| Malta | €15 million | €0.2 million | €0.06 billion |
| Italy | €133 million | €1.6 million | €1.3 billion |
| Romania | €100 million | €2.1 million | €0.54 billion |
| Spain | €800 million | €14.3 million | €5.7 billion |
| Total: | €1,190 million | €20.8 million | €8.6 billion |

(*) includes €20 million from national budget

1.6.2. EU financial instruments implemented in shared management (ESIF)

During the period 2007-13, EU27 committed around €17 billion in the Operational Programmes to financial instruments, of which €10.7 billion in Structural Fund resources. EU27 almost doubled the previous amounts to around €20 billion for 2014-20 Operational Programmes.⁷⁸

Comparisons between countries and time periods cannot be easily made, since total EU amounts vary widely - in some Member States these have increased, while in others they have declined or remained stable. Nevertheless, we can see a positive trend of the increasing importance of financial instruments in the 2014-20 funding period compared to 2007-13.

Data from December 2017 (for the period 2007–2013) provides an overview of the product mix of financial instruments supported by Structural Funds ranging from 37% loans, 38% equity, 11% guarantees and 14% other. Expected leverage, as reported in funding agreements, varies between 0.96 and 7.5 for loans and from 4 to 25 for guarantees.⁷⁹

Assuming a similar product mix and average leverage effect throughout the whole programming period, **we can expect that, during the 2014-2020 programming period, ESIF will mobilise up to EUR 70 billion of loans.**

In light of the increasing scarcity of public resources, financial instruments are thus expected to continue to be a key priority for the European Structural and Investment Funds in the 2021-2027 programming period. However, significant efforts will need to be undertaken in those Member States where past experience has shown that implementation has been delayed for lack of resources, capacity (including knowledge) and the lack of suitable institutions.

⁷⁸ EPRC (2017) on behalf of the European Commission, *Improving the take-up and effectiveness of financial instruments*

⁷⁹ European Commission (2018), *Financial instruments under the European Structural and Investment Funds Summaries of the data - Situation as at 31 December 2016*

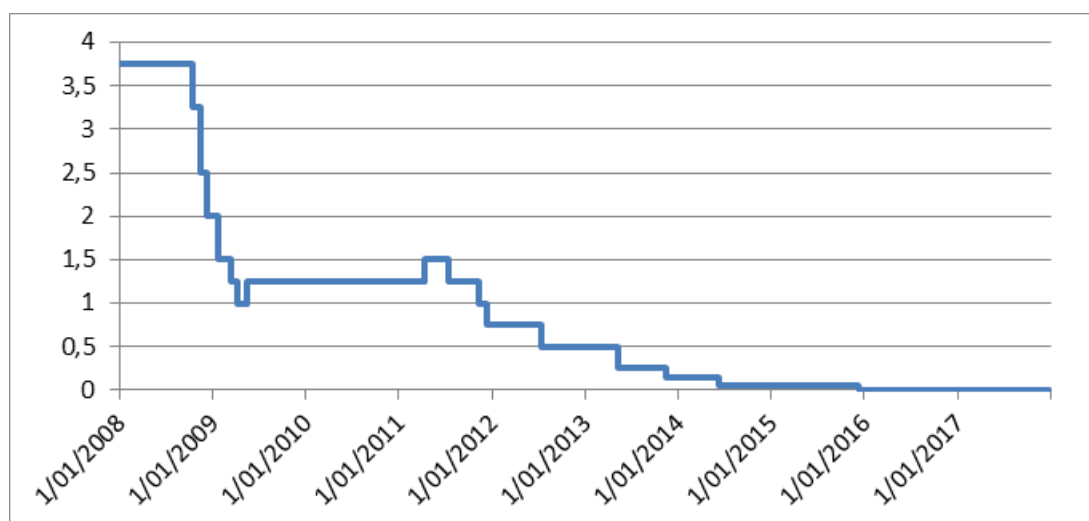
1.6.3. EU action geared towards strengthening the liquidity of banks

European Central Bank

In January 2015 the ECB announced an expanded asset purchase programme. ECB monthly purchases in the public and private sector securities amounted to €60-€80 billion. Following quantitative easing by the ECB, bank lending has increased, including lending to SMEs. However, significant regional disparities have been observed in lending. The direct effect of quantitative easing on their bank lending decisions has been estimated to be very limited. If anything, it is having an impact on the terms and conditions of loans, not the quantity of credit.⁸⁰

The ECB decided in January 2018 to reduce net purchases to a monthly pace of €30 billion until the end of September 2018. The intention is for securities purchases to be carried out until the Governing Council sees a sustained adjustment in the path of inflation that is consistent with its aim of achieving inflation rates below, but close to, 2% over the medium term. Key ECB interest rates have remained at a record low since 2016. For instance, the ECB interest rate on the main refinancing operations, which provide the bulk of liquidity to the banking system, stands at 0%. It remains to be seen when economic conditions will allow an increase of the key ECB interest rates and how this will impact credit growth to SMEs.

Graph 13: ECB interest rate for main refinancing operations



European Investment Bank Group

The EIB and the European Investment Fund (EIF) are mobilising financing to SMEs and midcaps by using own resources, in addition to EU budget funds.

⁸⁰ European Parliament (2016), *Effectiveness of the ECB programme of asset purchases*

The EIF is providing credit enhancements for SME loan portfolios by providing guarantees to banks and financial institutions allowing them to diversify their funding sources and to achieve economic and regulatory capital relief through credit risk transfer through providing guarantees for tranches of securitised portfolios.⁸¹

The EIB is providing intermediated lending for SMEs and midcaps⁸². In these operations, the EIB provides liquidity to financial intermediaries at favourable rates, which such financial intermediaries are required to pass on when lending to SMEs and mid-caps in the form of interest rate reductions. In these transactions, the EIB does not share the risk from financing the SMEs and mid-caps but accepts the risk that the financial intermediary may not repay the liquidity (counterparty risk). In 2016 total signatures by the European Investment Bank (own resources) towards SMEs and mid-caps in the EU28 amounted to €21.3 billion, compared to €19.8 billion in 2015. These signatures are expected to mobilise €42.6 billion of financing to SMEs and mid-caps in 2016 (2015: €39.6 billion).

The EIB plans to continue its financial support for SMEs in Europe in the form of loans to partner financial institutions for on-lending to SMEs. The EIB's signatures for its own resources in the area of SMEs and midcaps are expected to stay between €18.3-18.9 billion for 2017-2019. This is a significant increase compared to the period 2005-2011, where annual signatures were approximately €10 billion.⁸³ It remains to be seen whether the support by the EIB Group will at some point be scaled back to historical levels due to the impact of the UK's departure from the EU.

1.6.4. Use of Member State resources

In addition to the instruments implemented under ESIF, Member States also implement financial instruments under their own budgetary resources. We therefore try to extend the ex-ante assessment performed by looking at the potential impact of national financing support schemes.

1.6.4.1. SME debt financing support at Member State level in absolute amounts

Member States have set up numerous public financial institutions to improve SMEs' access to finance (see Appendix). Some Member States have put in place financial instruments that are

⁸¹ http://www.eif.org/what_we_do/guarantees/credit_enhancement/index.htm

⁸² <http://www.eib.org/products/sheets/intermediated-lending-smes-midcaps-features.htm>

⁸³ The EIB Group Operational Plan 2017-2019, EIB SME Report 2015-2016, EIB Ex post evaluation of EIB Intermediated Lending to SMEs in the EU 2005-2011

successful in addressing the local financing gap of SMEs proven by past evaluations.⁸⁴ Other Member States appear to be facing difficulties in properly addressing local financing gaps due to budget/time constraints, lack of capacity/knowledge and the lack of a well-functioning local commercial financing market or financial fragmentation. As a consequence, SMEs in those Member States face particular financing problems compared to their peers/competitors in other Member States.

There is no study or source available to provide a complete overview of national financing programmes in the EU as a basis to quantify the absolute amount of public credit support. The OECD published the 2018 scoreboard on financing SMEs and entrepreneurs⁸⁵, which summarises the types of measures in place across a selection of OECD countries:

Graph 14: Government policy instruments to foster SME access to loans in 2016

| | Government loan guarantees | Government export guarantees, trade credit | Direct lending to SMEs | Subsidised interest rates | Credit mediation/ review/ code of conduct |
|----------------|----------------------------|---|------------------------|---------------------------|---|
| Austria | X | X | X | X | |
| Belgium | X | X | X | | X |
| Czech Republic | X | X | X | X | |
| Denmark | X | X | | | |
| Estonia | X | X | X | | |

⁸⁴ See, for instance, Ernst and Young (2014), *Assessment of Member State policies to facilitate access to finance for SMEs*, study conducted on behalf of the European Commission

⁸⁵ Only some EU Member States are members of the OECD. The following EU countries provide information to the OECD scoreboard: Austria, Belgium, Czech Republic, Estonia, Finland, France, Greece, Ireland, Latvia, Luxembourg, Poland, Portugal, Spain, Sweden and United Kingdom

| | | | | |
|-----------------|---|---|---|---|
| Finland | X | X | X | |
| France | X | X | X | X |
| Greece | X | X | X | |
| Hungary | X | X | X | X |
| Ireland | X | | X | X |
| Italy | X | | | |
| Latvia | X | X | X | |
| Luxembourg | X | X | | |
| Netherlands | X | X | | |
| Poland | X | | | |
| Portugal | X | X | X | X |
| Slovak Republic | X | X | X | X |
| Slovenia | X | | X | |
| Spain | X | X | X | X |
| Sweden | X | X | X | |

These measures carry different costs for public budgets, ranging from significant costs (e.g. government direct lending and loan guarantees), to cost-neutral (e.g. bank targets for SME lending) and to even negative costs (e.g. negative interest rates for bank deposits at the central bank). These measures also imply varying degrees of engagement by public agencies.

The Network of European Financial Institutions for SMEs (NEFI), covering 19 European promotional institutions, estimates that its members supported 454,000 SMEs with more than €60.9 billion of financing in 2015. We complemented these figures by extracting information on SME financing support from annual reports of other national public banks or public guarantee societies in 17 EU countries representing over 88% of EU GDP. In 2015 these institutions mobilised over €77 billion of financing (see Graph 15 below). Assuming a similar proportion of SME support in terms of GDP in other countries, the total amount of financing by public financial institutions in the EU27 can be estimated at over €88 billion in 2015.

The OECD scoreboard on financing SMEs and entrepreneurs provides information on annual amounts of Government-backed guarantees/loans in 2016. 10 EU Member States representing 45% of EU27 GDP supported over €42 billion of guarantees/loans in 2016. Assuming a similar proportion of SME support in terms of GDP in other countries, the total amount of financing by national support schemes in Europe can be estimated at €92 billion in 2016.

Data available on national support is distorted, as existing data does not exclude the impact of support through EU programmes, such as European Structural and Investment Funds, central EU financial instruments or support from the EIB Group, as some of the instruments offered through these institutions are guaranteed under central EU financial instruments. Moreover, the amounts per Member State are not collected based on the same methodology, nor is the focus of all these instruments primarily on SME financing.

Graph 15: Overview of public support for SME debt financing in selected countries

| | 2015 | | 2016 | | 2015 | 2016 |
|---------|----------------|-------|------|-------|----------------|-------|
| Source: | Annual Reports | | OECD | | Annual Reports | OECD |
| | in billion | | | | as % of GDP | |
| AT | € | 0.83 | € | 0.87 | 0.25% | 0.27% |
| BE | € | 0.37 | € | 0.97 | 0.10% | 0.25% |
| BG | € | 0.21 | € | N.A. | 0.21% | N.A. |
| CZ | € | 0.60 | € | 0.19 | 0.23% | 0.07% |
| DE | € | 20.40 | € | N.A. | 0.69% | N.A. |
| EE | € | 0.16 | € | 0.08 | 0.55% | 0.27% |
| ES | € | 9.67 | € | 20.97 | 0.79% | 1.69% |
| FI | € | 1.12 | € | 0.55 | 0.64% | 0.31% |
| FR | € | 21.30 | € | 8.40 | 1.05% | 0.41% |
| HR | € | 0.26 | € | N.A. | 0.37% | N.A. |
| HU | € | 0.98 | € | N.A. | 0.50% | N.A. |
| IT | € | 15.57 | € | N.A. | 0.93% | N.A. |
| LT | € | 0.23 | € | N.A. | 0.37% | N.A. |
| LV | € | 0.19 | € | N.A. | 0.53% | N.A. |
| NL | € | 0.56 | € | N.A. | 0.09% | N.A. |
| PL | € | 3.65 | € | 3.72 | 0.48% | 0.49% |
| PT | € | N.A. | € | 5.71 | N.A. | 2.46% |
| RO | € | 1.15 | € | N.A. | 0.36% | N.A. |
| SE | € | N.A. | € | 0.35 | N.A. | 0.10% |
| | | | | | | |
| UK | € | 0.18 | € | 0.24 | N.A. | 0.01% |

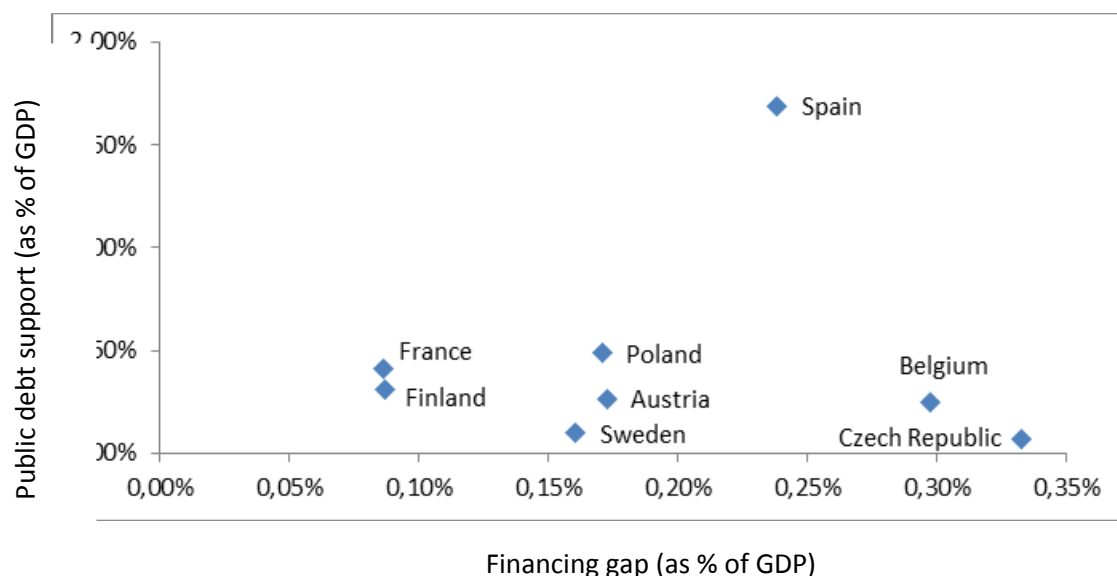
Source: Annual reports of National Public Banks or Public Guarantee Societies, OECD; (N.A. = Not Available)

1.6.4.2. SME debt financing support at Member State level in relative terms

In this section the assessment concentrates on identifying the relative debt financing support at Member State level. For this, an assessment is made of the level of support provided by national debt financial instruments by using data from available studies.⁸⁶ Comparing the results across the available data sources is expected to stabilise the findings. In order to compare the results across countries, GDP data is taken to quantify the degree of public support relative to the size of the economy. Graph 15 above provides an overview of the magnitude of national support schemes for SME debt financing as a percentage of GDP in 2015.

As a next step, we compare the results of both exercises: the credit financing gap across EU Member States and the size of public credit support (both relative to the size of the economy as a percentage of GDP). Graph 16 below shows the results of our estimates of the maximum financing gap in selected EU countries in 2016. The table also indicates the order of magnitude of estimated public debt support in the selected countries based on available data from OECD.

Graph 16: Credit financing gap and public support in a selection of EU countries in 2016⁸⁷



The result presents a diverse picture across Member States. Some Member States provide stronger SME debt financing support relative to the size of the financing gap and the size of their economy than others (such as Poland compared to Austria or Sweden compared to Czech

⁸⁶ OECD (2018), *Financing SMEs and Entrepreneurs 2018: An OECD Scoreboard*, annual reports of public financial institutions and guarantee societies from 2012-2017

⁸⁷ Maximum financing gap as % of GDP (AT=0.17%, BE=0.30%, CZ=0.33%, ES=0.24%, FI=0.09%, FR=0.09%, PL=0.17%, SE=0.16%), Government support (OECD data): AT=0.27%, BE=0.25%, CZ=0.07%, ES=1.69%, FI=0.31%, FR=0.41%, PL=0.49%, SE=0.10%

Republic). The above graph indicates that the relative financing gap is unequally addressed across Member States by current national financing programmes.

1.6.5. Outlook and Summary

Future SME financing conditions and financing gap are likely to be affected by several economic, regulatory and policy factors. While the evolution of some specific factors affecting the future development of SMEs' access to finance remains uncertain, the overall prospects appear to point towards a stable or better outlook for SMEs in the EU in terms of access to finance.

Outlook of regulatory framework conditions

According to Commission analysis, compliance with the new capital framework of CRDIV is expected to reduce the stock of loans on average by 1.8% and increase loan rates on average by some 29 basis points by 2020-2030.⁸⁸ However, the flow of loans to SMEs should be less severely impacted taking into account the following factors:

- SMEs transact more with smaller banks, whose capital shortfalls are estimated to be lower than other banks;
- in the course of the negotiations it has been agreed to introduce a 'supporting factor' on exposures to SMEs which will 'neutralise' the increase in own funds requirements for loans to SMEs and should ease lending conditions for SMEs over time (see article 501 of Regulation n. 575/2013).

EU economic outlook

The Commission's economic forecast⁸⁹ predicts that the EU economy will continue to grow above 2% in the next years. However, growth rates vary widely across EU Member States. Some countries such as Ireland, Malta, Poland, Romania and Slovenia are expected to grow by more than 4% in 2018; whilst growth rates are expected to stay below 2% for Belgium and Italy.

Government debt

SMEs across the EU will face different economic conditions in their home country. The divergence in financing conditions (see section **Error! Reference source not found.**) across the EU is also expected to continue in the future. Public authorities should be able to continue structural, regulatory and policy reforms to continue supporting SMEs. However, some Member

⁸⁸ See Commission Staff Working Paper Impact Assessment accompanying the document Regulation of the European Parliament and the Council on prudential requirements for the credit institutions and investment firms –SEC 949(2011)

⁸⁹ European Commission 2018 winter economic forecast

States might face more stringent budgetary constraints that will limit their possibility to introduce new support schemes, such as financial instruments. Budgetary difficulties experienced by several Member States may also translate in a further reduction of government support to SME credit.

According to the Commission's forecast⁹⁰, public debt will remain above 100% in terms of GDP until 2019 in Belgium, Greece, Italy and Portugal. Elevated debt figures above the EU27 average of 79% will also remain in Cyprus, France and Spain.

The result of the analysis in this section **Error! Reference source not found.** indicates that:

- a significant SME debt financing gap, albeit in a different order of magnitude, exists in every Member State; at EU level the financing gap has reduced to about €25 billion per annum;
- This financing gap is observed, despite the fact that significant efforts are undertaken at Member State level (through Member State resources), through ESIF, through central EU guarantee facilities and through EIB/EIF measures to support debt financing for SMEs;
- The aggregated support to SME debt financing is estimated to be around €113 billion per annum (€90 billion at Member State level, €10 billion through ESIF and €13 billion through central EU guarantees). Without such support the SME debt financing gap would have likely been significantly higher;
- In the next programming period, it is expected that Member States continue supporting SME debt financing at least at the same level through national budgets.
- EU funds under share management should continue to be used at least to the same extent as was the case in previous programming periods to address the difficulties of access to debt finance for SMEs.
- The severity of the financing gap justifies continued support through a central EU SME guarantee, which should complement the efforts of the Member States and focus particularly on those countries where access to debt finance is most pronounced (in absolute and relative terms).

1.7. Lessons learned from the implementation of COSME

The Loan Guarantee Facility for SMEs of the COSME programme has been thoroughly assessed twice. First of all, by the European Court of Auditors in the context of a performance audit, which comprised the COSME Loan Guarantee Facility and the InnovFin SME Guarantee Facility of

⁹⁰ European Commission 2017 autumn economic forecast

Horizon 2020 (published December 2017)⁹¹ and, secondly, in the context of the COSME interim evaluation (published January 2018)⁹².

These assessments have shown that the Loan Guarantee Facility is working very successfully. It is properly designed to help SMEs, which would otherwise struggle to obtain finance, to grow more in terms of total assets, sales and employees when compared to the general SME population. The impact of the facility could be further strengthened by better targeting the beneficiaries and coordinating better with Member State activities.

In response to the assessments made, the following changes are proposed for the successor programme of COSME:

- Improve the internal coherence of different parts of the programme, better linkages will be established by further strengthening the existing cooperation with the Enterprise Europe Network⁹³ (use the Enterprise Europe Network as a stronger signposting element);
- Seek better upstream co-ordination between financial instruments for SMEs established by Member States and those established under the SME window of the InvestEU Fund by using the existing SME Envoys Network⁹⁴ as an information exchange forum;
- Reduce administrative burden for SMEs and financial intermediaries and improve the impact of the SME guarantee facility by eliminating the €150,000 threshold.

1.7.1. Observations made by the European Court of Auditors⁹⁵

As highlighted already in the title of the dedicated European Court of Auditors' report, the Loan Guarantee Facility (LGF) has achieved the positive results intended but needs better targeting of beneficiaries and more coordination with national schemes.

The Court concluded that "the main aim of the Loan Guarantee Facility [...] has been to foster growth. Econometric evidence shows that the loan guarantees delivered what they were designed to do. They helped beneficiary companies grow more in terms of total assets, sales, employee numbers and productivity".

⁹¹ European Court of Auditors (2017), *EU-funded loan guarantee instruments*, Special Report Number 20

⁹² <http://ec.europa.eu/DocsRoom/documents/28084>

⁹³ <https://een.ec.europa.eu/>

⁹⁴ http://ec.europa.eu/growth/smes/business-friendly-environment/small-business-act/sme-envoys_en

⁹⁵ ECA Special report No 20/2017: https://www.eca.europa.eu/Lists/ECADocuments/SR17_20/SR_SMEG_EN.pdf

However, the Court also concluded that a future facility should better target viable businesses lacking access to finance and that there should be better co-ordination between central EU guarantee facilities and those established at national level.

1.7.2. Conclusions from COSME interim-evaluation

The interim evaluation⁹⁶ concluded that the COSME LGF has been successfully set up and is fully on track to deliver on the targets set in terms of SMEs to be financed and volume of financing to be made available. The evaluation confirms that the "COSME actions fully respond to the SMEs' current needs to access finance".

The interim evaluation has concluded that, after fully eliminating the dead-weight effect, for each €1 million invested into the LGF (effects fully attributable to the Loan Guarantee Facility):

- additional employment of 491 will be created;
- an additional €22 million in turnover will occur in beneficiary SMEs;
- 470 SMEs will be supported.

While acknowledging – based on the available evidence – the ability of the COSME financial instruments to deliver a financial support to the SMEs that most needed it, the evaluators identified several areas for improvement:

- Better links between financial instruments and other parts of the future SME programme
- Better co-ordination between financial instruments and national EU schemes
- Discontinuation of the €150,000 threshold, which has a negative impact on the efficient delivery of the guarantee facility and created a significant administrative burden.

The interim evaluation recommends that a future EU loan guarantee facility should help to ensure "a more level playing field for SMEs [...] in those countries where, according to current studies, the needs among SMEs are highest." As regards the existing Equity Facility for Growth, the interim evaluation concluded that the facility is effective. Nevertheless, it is recommended to reduce the number of financial products and to align the Equity Facility for Growth with the equity facilities established under EFSI.

1.7.3. Responses to the Open Public Consultation (OPC) with regard to the COSME programme

The OPC on 'EU funds in the area of investment, research & innovation, SMEs and single market' was conducted between 10 January 2018 and 9 March 2018. A total of 4,047 responses were received.

⁹⁶ Technopolis (2017): "Interim Evaluation of the COSME Programme – Final Report"

According to the responses received, facilitating access to finance, in particular for SMEs, remains one of the key challenges, with over 50% of respondents indicating that it is very/rather important.

| <i>Facilitating access to finance, in particular to SMEs, is:</i> | Responses provided | In % |
|---|--------------------|------|
| Very important | 1,067 | 26.4 |
| Rather important | 1,299 | 32.1 |
| Neither important nor unimportant | 814 | 20.1 |
| Rather unimportant | 249 | 6.2 |
| Not important at all | 104 | 2.6 |
| No opinion / no reply | 514 | 12.6 |
| TOTAL | 4,047 | 100 |

The respondents were also asked to what extent the current policies successfully address the identified challenges. The replies submitted indicate that the current policies address the challenge of access to finance, in particular to SMEs, to a certain extent.

Only 207 responded that this challenge is fully addressed, while 1,036 responded that it is addressed fairly well. 1,253 respondents indicated that this challenge is addressed to some extent only, while 216 said that it is not addressed at all. A total of 1,335 respondents either indicated that they had no opinion on this issue or did not provide any reply.

The Commission has preliminarily identified a number of possible obstacles that could prevent the current programmes/funds from achieving their objectives. Insufficient use of financial instruments was suggested as one of the possible obstacles. In replying to this question, 278 respondents indicated that insufficient use of financial instruments is an obstacle to a large extent and 758 to a fairly large extent. 1,149 replied that it is an obstacle to some extent only and 567 not at all.

These findings are confirmed in stakeholders' position papers. Replies indicate, in particular, that financing conditions remain challenging for businesses, especially for the smaller ones, in many parts of Europe.

Stakeholders' comments also support the continued availability of financial instruments that facilitate access to finance, in particular to SMEs and start-ups. Respondents also stressed that the amount of funding dedicated to COSME financial instruments should be higher in the future programming period.

A number of respondents highlighted the positive impact of centrally managed financial instruments, in particular the COSME Loan Guarantee Facility, when combined with funding from national and regional resources (including under ESIF).

However, there seems to be an agreement that the financial instruments at the EU, national and regional levels should be better aligned and optimised.

Regarding the practical implementation of the centrally-managed financial instruments relative to SMEs, stakeholders indicated, amongst others, the following elements:

- Financial instruments at the EU level should be merged and one SME window should be created under the InvestEU Fund;
- The instruments should be designed to allow the combination of different sources of funding (e.g. EU funding with resources at Member States' level, including from ESIF, financial instruments with grants) in a flexible way;
- The design of the SME financial instruments should be such as to ensure flexible and comprehensive coverage and to allow new, currently unforeseen market failures to be addressed;
- The current ceiling of € 150,000 applied under COSME LGF should be abandoned;
- Regarding COSME LGF, some respondents advocate an extension of the current maximum guarantee coverage period beyond 10 years and abandoning the (counter-) guarantee cap rate;
- The implementation of SME financial instruments should be as simple as possible;
- State aid rules applicable to financial instruments should be simplified.

2. THE OBJECTIVES OF THE SME DEBT GUARANTEE FACILITY

2.1. Key features of the Loan Guarantee Facility under COSME

The European Commission has entrusted the EIF with the implementation of this facility due to the EIF's proven ability to implement European schemes across the Member States and participating countries.

The COSME Loan Guarantee Facility is being successfully implemented, both in terms of geographic scope and in terms of reaching the right beneficiaries, i.e. viable SMEs that have problems in accessing finance.

A loan guarantee is a commitment by a 'guarantor' regarding the repayment of a loan received by an enterprise from a commercial bank. In practice, if the borrower fails to repay the loan, the guarantor steps in and pays the bank. In order to minimise the risk of moral hazard, loan guarantees typically provide only partial protection against the risk of default, with the 'guarantee rate' typically ranging between 50% and 80%. Loan guarantees are issued by specialised entities, the so-called Credit Guarantee Schemes (CGS), which may be public entities

(sometimes with a corporate form) or self-help organizations established by business associations, the so-called 'mutual' CGS.⁹⁷

Loan guarantees play a role in cases where commercial providers of finance will only provide finance against collateral requirements that an SME cannot meet, because the SME either has no collateral or only insufficient collateral to offer (SMEs considered to be too high a risk). In such cases, CGS step in and, in lieu of providing collateral, the SME will offer a guarantee from the CGS to the commercial lender, for which the SME generally has to pay a fee to the CGS.

Loan guarantees are also used by public entities (e.g. regional or national promotional banks - NPBs) that work through on-lending schemes. Under such on-lending schemes the NPBs create debt financing products that are not offered by the NPBs directly but through the commercial banking sector with whom the NPBs co-operate. In such cases the SME will conclude the financing contract with the commercial bank but each individual financing transaction is guaranteed through the NPB. As is the case for the CGS, guarantee rates typically range between 50% and 80% depending on the product offered and the risk inherent to such products.

This section describes some of the successful features of the COSME Loan Guarantee Facility, which are supposed to be maintained in the successor facility. A continuation of these characteristics will facilitate successful implementation and allow for a smooth transition from the current EU guarantee facilities to the SME guarantee facility in the next programming period. Subsequent sections will describe which features need to be adapted to address recommendations from evaluations and changing market conditions.

2.1.1. Coverage of higher-risk SME financing transactions

The COSME Loan Guarantee Facility is geared towards supporting any type of SME higher-risk financing transaction. From a technical point of view, this is being achieved by offering portfolio guarantees free of charge to financial intermediaries across the participating countries. In return for such free-of-charge guarantees, financial intermediaries must commit to build portfolios of new financing transactions that constitute higher-risk financing or to significantly increase the volumes of existing higher-risk SME financing products.

⁹⁷ Combined ex-ante evaluation and impact assessment of the successor to the Entrepreneurship and Innovation Programme under the Competitiveness and Innovation Framework Programme 2007-2013 of 24 May 2011

SME lending that financial intermediaries are conducting under their existing credit policies (i.e. risks that financial intermediaries are comfortable managing without public support), and for which sufficient resources are available, are excluded from the potential coverage of the guarantee.

In order to operationalise the concept of supporting only higher-risk SME financing transactions, two options are available for potential financial intermediaries:

1. A financial intermediary chooses to create a lending product that has significantly higher expected losses than existing lines of business, which can be achieved through the following means:
 - a. A dedicated start-up debt financing product is created (only possible for those cases where such dedicated start-up products do not yet exist or would not exist without EU support);
 - b. Features of existing debt financing products are changed, such that the expected losses will increase (e.g. existing products are now offered with much longer financing durations or significant reduced collateral requirements – hard collateral requirements may be reduced to nil);
 - c. Financing products are offered to previously excluded groups (e.g. certain sectors), provided it can be shown that by making financing available to such groups expected losses increase significantly;
 - d. A financing product with a significantly higher risk profile is set up (e.g. subordinated financing).
2. A financial intermediary commits to increase significantly the volume of existing higher-risk financing products (EU guarantee is only provided in those cases in which the higher volumes are met).

The above approach, which provides a framework for risk-taking requirements within which debt financing products can be established, has proven to be a key element for the successful implementation of the SME Guarantee Facility under COSME.

First of all, the approach has ensured that the support provided in the form of guarantees or counter-guarantees is additional to what has already been supported by financial intermediaries in the market.

Secondly, the approach has provided significant flexibility for financial intermediaries to set up those higher-risk products that are suitable for the particular geographies and contexts within which they operate. Such flexibility is key to addressing the significant differences in debt financing markets. As pointed out in section **Error! Reference source not found.**, the debt financing markets in the Member States differ significantly in terms of the risk appetite of financial intermediaries, the type of SME financing products offered, the collateral required and the public support schemes provided.

The result of this approach is that financial intermediaries have started creating financing products that, in such form, did not previously exist in their respective markets and have therefore offered financing to SMEs that would have had difficulties in obtaining finance or would have obtained finance under sub-optimal conditions (with shorter maturities or with higher collateral requirements). Some financial intermediaries have also chosen to create dedicated financing products for specific sectors (e.g. agriculture) for which such support schemes did not exist before.

2.1.2. Capped versus uncapped portfolio guarantees

The EU has a long tradition in providing capped portfolio guarantees to support SME financing. When the ex-ante assessment for the COSME Loan Guarantee Facility⁹⁸ was established, the creation of an uncapped guarantee facility was contemplated and was subsequently established under Horizon 2020 as the InnovFin SME Guarantee facility. A model for an uncapped SME guarantee facility was also established under the SME Initiative launched in 2012⁹⁹.

Under the capped model used for COSME, the cap rate is set individually, based on the expected losses of the future portfolio (maximum permissible cap rate is 20%¹⁰⁰) and the individual guarantee rate is set at a maximum of 50%. This means, in practice, that up to half of the expected losses of a future portfolio are covered through the COSME guarantee; the remaining risk has to be borne by the financial intermediary.

Simplified example¹⁰¹: Let's assume a financial intermediary is willing to commit to building a new portfolio of financing transactions with start-ups only for a total volume of €100 million, and the expected losses of such future portfolio are 15% (i.e. a total of €15 million). The COSME guarantee covers half of such expected losses, i.e. €7.5 million. This is the budget amount allocated to such transaction. The remaining risk remains with the financial intermediary.

If an uncapped approach were to be deployed, then half of all potential losses (expected and unexpected) would have to be borne under the EU guarantee. The Graph 17 below illustrates the two examples.

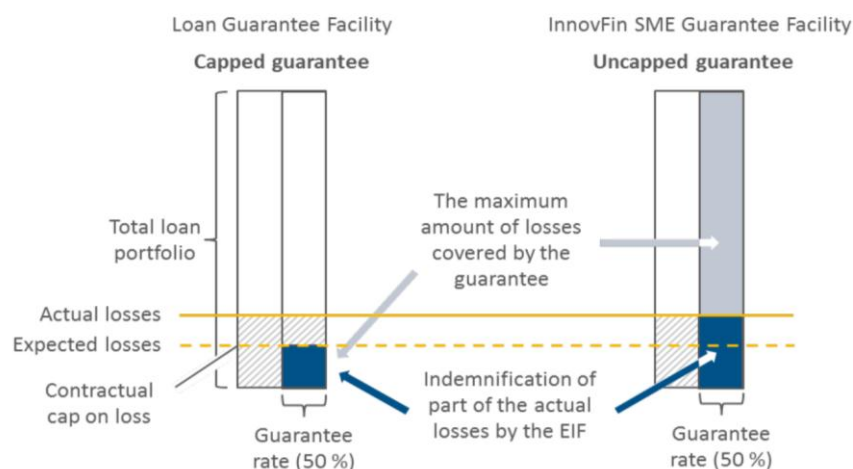
⁹⁸ Economisti Associati et al. (2011), *Combined ex-ante evaluation and impact assessment of the successor to the Entrepreneurship and Innovation Programme under the Competitiveness and Innovation Framework Programme 2007-2013*

⁹⁹ SWD(2013) 517

¹⁰⁰ Observed cap rates across guarantee agreements signed as of 30/09/2017; average at about 10%

¹⁰¹ The implementation can be much more complex, depending on whether guarantees or counter-guarantees are provided. Especially in the case of counter-guarantees, it is possible that multiple financial intermediaries are involved in the implementation chain.

Graph 17: Capped and uncapped guarantee



Source: Court of Auditor's Special Report N° 20/2017

While it has been pointed out in the COSME ex-ante assessment that an uncapped approach would potentially extend the reach of the facility, as more financial intermediaries may be interested in applying, practice has demonstrated that the capped approach, which provides for a significantly higher leverage, has been sufficient to entice financial intermediaries to apply and to encourage them to create higher-risk debt financing products. Implementing a capped model also means that no 'balance sheet' is required from the entrusted entity implementing the facility (the European Investment Fund).

The main financial intermediaries under the COSME LGF are national & regional promotional institutions and public & private guarantee schemes. These institutions have been willing to accept a central EU capped guarantee, which they have turned into uncapped guarantees vis-à-vis the commercial lenders in their respective markets, sometimes at guarantee rates of up to 80% (e.g. in the case of supporting the financing of start-ups). By using the 'balance sheets' of these financial intermediaries, the COSME LGF has been efficiently implemented and combined effectively with national/regional resources.

As of 09/2017, 43% of the LGF budget had been implemented through Credit Guarantee Schemes, 29% through national/regional promotional institutions, 24% through commercial banks and 4% through leasing companies. The implementation through commercial / private

financial intermediaries occurs largely in those countries where no national support schemes are available or where the commercial sector is not able to obtain support under national schemes.

2.1.3. Successful implementation of the COSME Loan Guarantee Facility

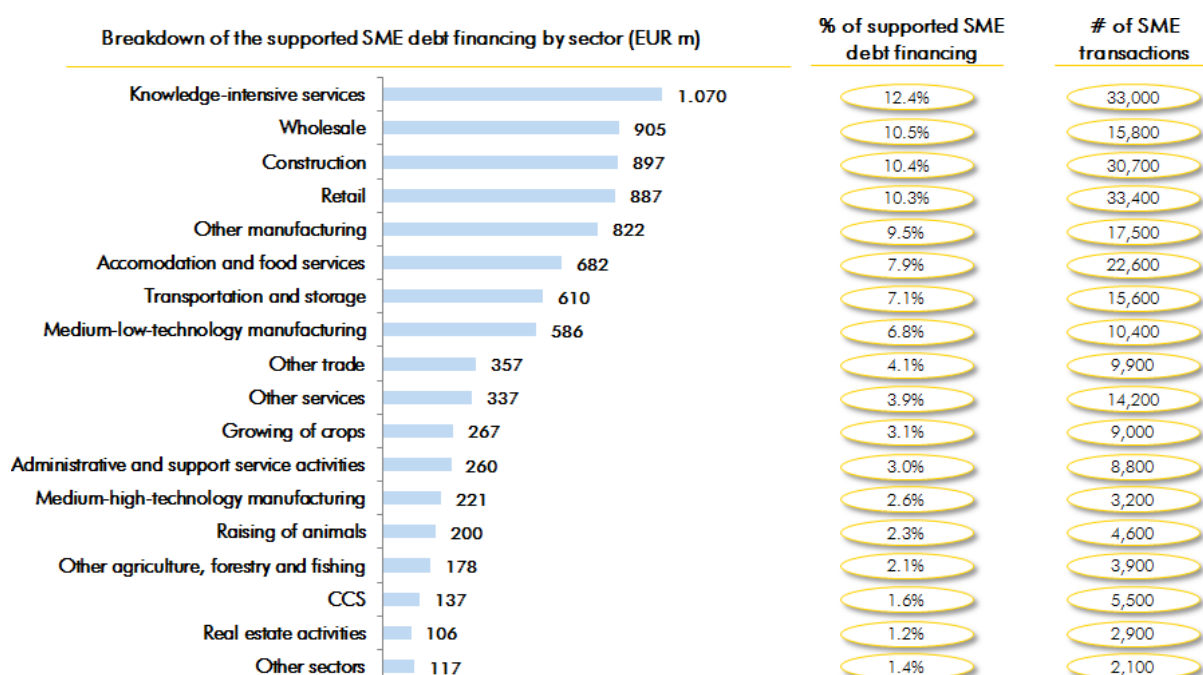
The budget allocated to the LGF (expected to be €950 million for the period 2014–2020) has been insufficient to meet market demand and therefore a top-up of €550 million has occurred under the SME Window of the European Fund for Strategic Investments.

As of 09/2017, the EIF had signed guarantee operations with financial intermediaries for a total of €790 million (i.e. budget allocated to guarantee operations signed). Under these signed guarantee operations, intermediaries are expected to provide a total of €25 billion to over 700,000 SMEs¹⁰². Actual financing already provided stands at €10.4 billion (to 237,000 SMEs) as of 09/2017.

The Loan Guarantee Facility is effective in reaching those SMEs which experience particular difficulties in obtaining finance, namely start-ups (defined as businesses in their first five years of existence), which account for almost 50% of all SMEs supported (as of 09/2017). Furthermore, 91% of all supported enterprises are micro-enterprises. The facility is also successful in supporting SMEs in a wide range of sectors. Over 12% of support has gone to knowledge-intensive services so far but support has also gone to SMEs in the more traditional sectors, such as wholesale, retail and construction and manufacturing as indicated below.

Graph 18: Breakdown of support by COSME LGF by sector

¹⁰² Once a guarantee agreement is signed, the financial intermediary is generally allowed a period of up to 3 years to generate the new SME higher financing transactions. These numbers will be achieved if the financial intermediaries generate the new SME financing as planned at the time of signature of the guarantee agreement.



Source: EIF reporting to Commission as per 30/09/2017 (CCS: creative and cultural sector)

The average transaction size stands at €35,500. This is significantly lower than the average transaction size under the SME Guarantee Facility of the Competitiveness and Innovation Framework Programme (the predecessor facility), where the average transaction size was approximately €65,000. The low average transaction size under COSME is most likely due to the €150,000 threshold introduced under the COSME LGF, above which financial intermediaries must (by means of a checklist) demonstrate that an SME is in principle not able to comply with any of the more than 10 different innovation criteria established under the InnovFin SME guarantee facility of Horizon 2020.¹⁰³ This application of the checklist has been criticised during the mid-term evaluation and the OPC as too onerous and cumbersome (significant administrative burden) for financial intermediaries and SMEs and has been mentioned as blocking an efficient implementation of the facility.

2.2. Key challenges for the SME Loan Guarantee Facility (COSME+)

The key challenge to the implementation of an SME guarantee facility under the next Multiannual Financial Framework period will be to operate under the following market conditions:

¹⁰³ http://www.eif.org/what_we_do/guarantees/single_eu_debt_instrument/innovfin-guarantee-facility/

5. **Continued central EU-level support is required but more focused on Member States with the most severe market gaps:** Following the financial crisis, a significant number of policy interventions, coupled with positive economic developments, have led to an improvement in the availability of bank finance and the conditions for access to finance have, on average, recovered¹⁰⁴. However, at aggregate EU level, pre-crisis levels in terms of volume of lending have not been reached yet. Furthermore, significantly differing market gaps in access to debt finance, coupled with differing degrees of public support activities in the Member States require a facility that is more responsive to those Member States requiring most support. Member States alone will not be able to sufficiently address the market gaps, even if they were to double the use of financial instruments under EU funds under shared management during the period 2021–2027 (please see section **Error! Reference source not found.** for a detailed analysis).
6. **Continued use of a fully flexible SME guarantee scheme needed:** Significantly differing access to finance conditions in terms of risk appetite, diversity of product offering, collateralisation requirements and interest rates charged across Member States require a continued flexible design of the guarantee facility (please see section **Error! Reference source not found.** for a more detailed analysis) so as to allow the tailoring of interventions suitable for the respective market.
7. **Simplification of central EU guarantee support schemes for SMEs needed while maintaining the integrated SME support under the COSME+ programme:** As set out in the Reflection Paper on the Future of EU Finances¹⁰⁵, there is a *'need to ensure policy coherence among EU instruments to ensure that they all support EU objectives and facilitate reforms in Member States. For instance, in the area of SME financing the same beneficiaries may be eligible to receive support through several instruments covered under different programmes (COSME, Horizon 2020 and EFSI) or implemented by Member States through cohesion policy. This overlapping product offer has caused some confusion for financial intermediaries as to which scheme to apply. Rules and conditions applying in the same policy area should be aligned.'* It is therefore necessary to couple the integrated SME support provided under a future COSME+ programme with the benefits of a streamlined implementation of instruments under the future InvestEU Fund.
8. **Fintech companies as potential challengers to banks as the main providers of SME debt finance:** The financing of SMEs in Europe through the banking sector has a long tradition. However, the banking market is undergoing significant structural changes. The number of financial institutions is continuously reducing and new players (fintech) are emerging who are ready to challenge the traditional banking sector. *'There is no doubt that the landscape has changed for banks. [...], the digital revolution is lowering cost, distance, time and barriers to entry, creating space for new fintech players to enter the*

¹⁰⁴ Survey on the Access to Finance of Enterprises in the euro area April to September 2017, section 3.1: <https://www.ecb.europa.eu/pub/pdf/other/ecb.accesstofinancesmallmediumsizedenterprises201711.en.pdf?beb1832df4af9efa945a5a1f7b99eeb7>

¹⁰⁵ https://ec.europa.eu/commission/sites/beta-political/files/reflection-paper-eu-finance_en.pdf

*market*¹⁰⁶. Despite the fact that fintech is a nascent industry, it is likely to have an impact on the SME financing markets in the next 10 years. While many banks are investing heavily in technology, industry experts have gone as far as to state that '*Banks may face their “Kodak moment” unless they embrace disruptive technologies. However, since banks are profiting from business-as-usual, there is little incentive for them to innovate and cannibalize their own business*'¹⁰⁷.

2.3. Objectives of the SME Loan Guarantee Facility

As set out in sections **Error! Reference source not found.** to **Error! Reference source not found.**, SMEs are heavily reliant on debt finance during their start-up phase and when trying to grow their business but a significant number are facing obstacles in obtaining the financing they need.

The objective of the SME guarantee facility is to support such SMEs as they play a significant role in supporting the Commission's policy priorities of creating jobs and boosting growth. Indirectly, the SME guarantee facility is also expected to contribute to

- easing the transition to a circular economy
- promoting the internationalisation of European businesses
- fostering a stronger digital single market
- strengthening the financial capacity of the cultural and creative sectors
- supporting farm investments for restructuring and modernisation, as well as rural entrepreneurship
- improving energy efficiency
- decarbonising the economy

and to support any new policy priorities which may emerge in the future.

In order to address the SME debt financing market gap, guarantee instruments are considered to be the most appropriate implementation option, as they have proven their worth and provide relief for the risk-aversion of the financial sector identified in section **Error! Reference source not found.** SME lending is held back by the willingness of the banking sector to accept SME risk rather than by a lack of liquidity. In addition, guarantees tend to significantly leverage the available EU resources.

The objective for the SME guarantee facility is to build on the successful structure of the existing COSME Loan Guarantee Facility, which, despite its relatively low budget resources, has a

¹⁰⁶ <http://www.smefinanceforum.org/post/banks-and-fintech-companies-come-together-to-discuss-vision-2030-for-small-business-finance>

¹⁰⁷ <http://www.smefinanceforum.org/post/banks-and-fintech-companies-come-together-to-discuss-vision-2030-for-small-business-finance>

significant positive impact due to its high leverage (see section **Error! Reference source not found.** for the design features of the facility). In addition, the objective is to take into consideration the lessons learned from the implementation of the LGF (see section **Error! Reference source not found.**). Going forward, it is envisaged to adapt some roll-out features to increase the efficiency and the impact of the facility.

Features of the LGF which will be maintained

It is anticipated that the guarantee facility will continue to support higher-risk SME financing transactions, i.e. financing transactions with a perceived higher risk by the intermediary, as well as those transactions for which SMEs have no or insufficient collateral.

The capped guarantee model has also proved its efficiency in terms of achieving significant leverage, while being effective in enticing financial intermediaries to support higher risk financing transactions. The cap rate will continue to be set at the level of the expected losses of a future portfolio. It is anticipated that the individual guarantee rate for the financing transaction will remain at 50%. A higher guarantee rate may be contemplated for those types of higher-risk financing transactions that financial intermediaries would otherwise not be willing to support (an approach pursued for specific sectors of political priority).

An uncapped guarantee approach may be envisaged in duly justified circumstances, i.e. in those situations where no financial intermediary is willing to serve identified market gaps on the basis of a capped guarantee.

It is also anticipated to maintain the flexible approach, i.e. allowing financial intermediaries to determine which types of higher-risk financing products are most appropriate for their particular market. For example, a focus on start-ups or on subordinated financing, significantly reducing collateral requirements. However, financial intermediaries may also decide to focus on financing of projects that support broader policy objectives, e.g. in the area of digitisation or internationalisation, provided that it can be demonstrated that the respective transactions have a higher inherent risk than the transactions that the financial intermediary finances within its normal business practices.

Features of the LGF which are expected to be adapted

The COSME Loan Guarantee Facility was rolled out purely based on demand (first come, first serve) and it was broadly advertised throughout all Member States, regardless of the severity of the financing gap per Member State. Going forward, efforts will be made to

- track the debt financing gap per Member State on a continuous basis (update at least on an annual basis) based on the methodologies laid out in section **Error! Reference source not found.** of this assessment. To this end, the regular access to finance surveys of the ECB will continue to be supported through the COSME successor programme;
- map the available debt financial instruments for SMEs at Member State level and ensure better upstream coordination between financial instruments for SMEs established by Member States and those established under the SME Window of the InvestEU Fund, with strong involvement of the existing SME Envoys Network¹⁰⁸;
- concentrate the marketing of the facility predominantly on those countries with the highest identified market gap (absolute amounts and relative to GDP);
- ensure that the central SME guarantee facility acts as support of last resort. It could be envisaged that, as part of the application process, a financial intermediary has to declare that the higher-risk financing transactions for which the guarantee coverage is requested can in principle not be covered through an existing national or regional support scheme. In this regard, the mapping exercise referred to above would serve as useful input;

The €150,000 threshold established under the COSME Loan Guarantee Facility is seen as hampering an efficient roll-out of the facility and as creating an unjustified administrative burden for financial intermediaries and SMEs. The threshold should therefore be eliminated.

The SME guarantee facility will not be implemented on a stand-alone basis but under the SME window of the InvestEU Fund. While the budgetary resources will come from the COSME+ programme and will thereby allow the provision of integrated SME support out of one programme, efficiencies will be created through streamlined implementation under the InvestEU Fund (see section **Error! Reference source not found.**).

¹⁰⁸ http://ec.europa.eu/growth/smes/business-friendly-environment/small-business-act/sme-envoys_en

3. STRUCTURE AND PRIORITIES

2.4. Priorities

The objective is to ensure that support measures are sufficiently resourced and that no instruments are created that have a sub-optimal size. Given the importance of access to debt finance for SMEs in the EU27, it is proposed to use all available budgetary resources to support only guarantees and counter-guarantees for portfolios of debt finance operations under COSME+.

The existing option under the COSME Loan Guarantee Facility to support securitisation transactions, i.e. provide guarantees for a mezzanine tranche of securitisation transactions, has not met any market demand (the same had been observed for the Securitisation Window under the predecessor programme – the Competitiveness and Innovation Framework Programme (CIP)). It is therefore suggested that this implementation option is discontinued under the COSME+ programme.

Moreover, an equity support instrument will be created under the SME Window of the InvestEU Fund, providing seamless support for SMEs and small mid-caps from the pre-seed stage all the way to the expansion and growth stage. Such a broad-based facility will enable flexibility, create economies of scale, operate more efficiently and be easier to market to potential financial intermediaries. Therefore, it is suggested to discontinue equity support under COSME+ and focus only on the guarantee facility.

2.5. Expected minimum size for the intervention

The expected minimum size of the intervention, about €1.2 billion, comprises the total budget for financial instruments under the existing COSME programme reduced by 15% (baseline scenario).

As the SME guarantee facility will be implemented through the SME window of the InvestEU Fund, which is based on a budgetary guarantee rather than a fully funded financial instrument, a budget of €1.2 billion transferred to a budgetary guarantee translates into available resources of €1.5 billion (based on an expected provisioning rate of 85%).

The anticipated leverage for this facility ranges between 1:15 and 1:25. With available resources of €1.5 billion, new higher risk debt financing of €22.5 billion to €37.5 billion over the lifetime of the programme could be made available. On average, it is expected that between €3.2 and €5.4 billion would be made available annually.

2.6. EU-added value of the intervention

The Better Regulations Guidelines¹⁰⁹ identify 3 potential sources of EU added value:

- Effectiveness: where EU action is the only way to get results to create missing links, avoid fragmentation and realise the potential of a border-free Europe.
- Efficiency: where the EU offers better value for money because externalities can be addressed, resources or expertise can be pooled, an action can be better coordinated.
- Synergy: where EU action is necessary to complement, stimulate and leverage action to reduce disparities, raise standards and create synergies. This can notably include the promotion of EU goals and policy priorities.

The EU added value of the SME guarantee facility to be set up under the SME window of the InvestEU Fund will be to:

- improve effectiveness by addressing market gaps through supporting cross-border financing solutions: despite the fact that SMEs rely largely on national or regional providers of finance, there is a small, nascent market for financial intermediaries that provide finance on a cross-border basis,
- improve effectiveness by fostering the transfer of best practices between financial intermediaries with a view to encouraging the emergence of a broad product offering for higher-risk SMEs suitable for their specific financing needs across the Member States. Transferring skills and capacity building across Member States could play a significant role in aligning national policies, in reducing the competitiveness gap between European economies and in accelerating economic growth in Europe;
- improve efficiency through economies of scale (i.e. Member States may be reluctant to create support schemes on their own because of cost efficiency considerations, lack of critical mass or expertise, so a EU response is essential to avoid even bigger market fragmentation and disparities).
- create synergies by addressing market gaps not addressed at regional or national level: the market gap analysis has demonstrated that the size of the SME debt financing market gap is significant, despite considerable interventions at Member State level and through central EU guarantees for SMEs. This will help to address persistent market fragmentation and therefore strengthen the Single Market;
- create synergies by addressing market gaps in clearly defined underserved economic sectors and in those contributing to the achievement of EU policy priorities.

¹⁰⁹ Better Regulations Guidelines tool #42 "identifying the evaluation criteria and questions"

4. DELIVERY MECHANISMS OF THE SME LOAN GUARANTEE FACILITY

2.7. Delivery of the SME loan guarantee facility through the SME window of the InvestEU Fund

The reflection paper on the future of EU finances¹¹⁰ proposes to integrate the various EU financial instruments into a single fund that would provide loans, guarantees and risk-sharing instruments. This will help to simplify access to EU financial instruments, as well as being more efficient.

In line with the Commission's overall objectives of streamlining, increasing efficiency and achieving better visibility of the EU support, the SME guarantee facility will be implemented under the SME Window of the InvestEU Fund and under the rules (e.g. in relation to implementing bodies, for financial intermediaries, State Aid, monitoring, reporting, auditing, budgetary management, etc.) established for the InvestEU Fund by the respective regulation.

To this end, the allocated budget under the COSME+ programme will be made available to the guarantee fund linked to the InvestEU Fund, with the caveat that such resources shall underpin the implementation of an SME guarantee facility focused on supporting higher-risk SME financing transactions under the SME window of the InvestEU Fund.

The delivery of the guarantee facility under the InvestEU Fund is more efficient, as the InvestEU Fund is based on a budgetary guarantee rather than a fully-funded financial instrument. Example: A budget of €1.0 billion transferred to a budgetary guarantee translates into available resources of €1.18 billion (based on an expected provisioning rate of 85%) and therefore immediately leads to higher leverage.

2.8. Scenarios for intervention

In this section we compare three different options for intervention.

Starting from the baseline scenario, we already assume that all budgetary resources will only be made available for providing (counter-) guarantees for the creation of higher-risk SME financing portfolios.

Furthermore, using a budgetary guarantee (instead of a fully-funded instrument) has proved to be a more efficient use of limited budgetary resources. We therefore propose implementation of the guarantee facility under a budgetary guarantee, which is expected to be provisioned for

¹¹⁰ https://ec.europa.eu/commission/sites/beta-political/files/reflection-paper-eu-finances_en.pdf

at 85%. This provisioning level would enable increase of available budgetary resources for investments by 1.18 times.

The COSME interim evaluation has concluded that, after fully eliminating the dead-weight effect, for each €1 million invested into the LGF:

- additional employment of 491 will be created;
- an additional €22 million in turnover will occur in beneficiary SMEs;
- 470 SMEs will be supported.

Scenario 1

The budget for the baseline scenario is based on the current COSME budget reduced by 15%, which assumes that €1.2 billion will be made available for the budgetary guarantee. With an 85% provisioning rate, this would enable investments of €1.41 billion, which is broadly in line with the expected full budget of COSME Loan Guarantee Facility supported by EFSI for the period 2014-2020. This budget would allow the EU intervention to be kept at the same level and therefore the market gap would not increase by a further €4 billion annually, while contributing to the creation of more than 690,000 jobs over the programme implementation period.

Scenario 2

In the second scenario, we consider discontinuation of the EU intervention. This approach would create negative impacts on the market, as it would contribute to a further increase of the market financing gap and a decrease in the level of investment and turnover, while also contributing to a decrease in employment levels. This scenario is disregarded due to its highly negative impacts on the economy.

As set out in section **Error! Reference source not found.** of this report, the overall conservatively calculated market gap for new SME financing in the EU27 over the 7-year period (2011–2017) has come down from €42 billion in 2014 to less than €30 billion in 2017. The financing gap in Europe would be much higher without the effect of central EU financial instruments. If the LGF support were to be discontinued, an annual average support of €4 billion would be lacking and the SME debt financing gap would increase even further.

Assuming similar financing conditions in the future, Member States would need to substantially increase their national financial instruments if a central SME guarantee facility was not continued in the next programming period.

The budget committed to debt financial instruments under EU funds under shared management would need to almost double in the next programming period to make up for the loss of central debt financial instruments. Alternatively, Member States would need to increase their national financing programmes by more than 10%.

Scenario 3

This scenario proposes a significant increase in the budget for support of SME financing. This would give the European economy a strong investment and employment boost. A budgetary guarantee of €3.5 billion would enable investments of €4.12 billion, enabling a wide range of interventions and specific intervention in areas requiring higher risk coverage.

It is expected that such an intervention would contribute to the creation of more than 2,000,000 jobs over the programme implementation period. Moreover, the market gap for SME finance would be positively impacted, with approximately €8 billion of additional financing compared to the baseline, which is approximately 30% of the median market gap from our analysis. Therefore, the preferred option would be to significantly increase the budget and close a major part of the SME financing gap.

| Scenario | Scenario 1: Baseline | Scenario 2: Discontinuation of the activity | Scenario 3: Significant increase in resources |
|--|-------------------------------------|---|---|
| Impact | €1.2 billion budgetary guarantee | No budgetary allocation | €3.5 billion budgetary guarantee |
| Employment maintained or created | 690,000 jobs | Decrease in employment | 2,000,000 jobs |
| Additional turnover expected in beneficiary SMEs | €31 million | Decrease in turnover | €90 million |
| Number of SMEs to be supported | 663,000 | No support provided | 1,935,000 |
| Volume of financing supported | €28 billion | No support provided | €82 billion |

5. HOW WILL PERFORMANCE BE MONITORED AND EVALUATED?

Measuring the impact of a financial instrument on employment and growth is a complex exercise and is only possible several years after the intervention occurred, i.e. after the SME has received the financing. The tool used in order to determine economic impacts is econometric studies.

The Commission has started to conduct econometric studies for selected markets to evaluate the impact of past EU SME guarantee instruments (established under the Competitiveness and Innovation Framework Programme). Such work will be further extended for the proposed SME guarantee facility.

In order to ensure that the allocated budget is meaningfully spent and leads to triggering the financing of SMEs that would have otherwise had difficulties in obtaining finance, milestones can be established and their accomplishments can be monitored. Not reaching a milestone will already provide first indications of whether a facility is on track to achieving the intended results.

Once a number of milestones have been reached, outputs can be quantified and can be compared to proposed targets. The achievement of impacts will only be measurable ex-post, i.e. after the guarantee facility has been fully implemented, which is expected to be three years following the end of the programme period.

Proposed milestones/outputs/ monitoring of the SME guarantee facility

| | Initial two years of the programme | Medium-term | Long-term | How would this be monitored? |
|---|--|--------------------|------------------|---|
| 1. Signature of agreement with entrusted entity (As the SME guarantee facility will be implemented through the SME Window of the Single Fund , the | X Target: within first year of the programme | N/A | N/A | Annual operational report from entrusted entity |

| | | | | |
|---|---|---|---|---|
| agreement for the single fund will have been signed and the respective product annex covering the SME guarantee facility will have been included) | | | | |
| 2. Launch of call for expression of interest¹¹¹ | X Target: within first year of the programme | N/A | N/A | Annual operational report from entrusted entity |
| 3. Signature of agreements with financial intermediaries | X Target: first agreement signed within first year of the programme | X Target: within the first three years, guarantee agreements signed in at least half of the countries identified as having a significant financing gap that is not covered through national/regional interventions (measured in % of GDP) | X Target: by the end of the programme period, guarantee agreements signed in all of the countries identified as having a significant financing gap that is not covered through national/regional interventions (measured in % of GDP) | Annual operational report from entrusted entity; reports on transactions signed DG GROW to track financing gap for SMEs per Member State on a regular basis (at least once per year) through continuously integrating latest available data ¹¹² |
| 4. Additionality of transactions / no crowding-out of existing national/regional support schemes | X Target: no justified complaints in writing about clearly identifiable crowding-out effects from national/regional support schemes | X Target: no justified complaints in writing about clearly identifiable crowding-out effects from national/regional support schemes | X Target: no justified complaints in writing about clearly identifiable crowding-out effects from national/regional support schemes | Annual operational report from entrusted entity (entrusted entity to report how existing support schemes have been taken into consideration when deciding on the scope of the guarantee agreements signed) COM to monitor official complaints |

¹¹¹ In accordance with Article 208 (4) of Financial Regulation 2018 (forthcoming)

¹¹² In accordance with Article 209 (2) (h) of Financial Regulation 2018 (forthcoming)

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| | | | | received by any of the Commission services ¹¹³ |
| 5. Additionality of transactions / no support of activities that financial intermediaries would have undertaken anyway in the absence of the guarantee support according to their business practices¹¹⁴ | X Target: no guarantee agreements identified that would allow financial intermediaries to finance activities within their normal business practices | X Target: no guarantee agreements identified that would allow financial intermediaries to finance activities within their normal business practices | X Target: no guarantee agreements identified that would allow financial intermediaries to finance activities within their normal business practices | COM to establish mechanism that allows monitoring of portfolio criteria established in the agreements with the entrusted entity; compliance to be verified before signature takes place Regular monitoring visits to financial intermediaries (COM may accompany entrusted entity) |
| 6. Additionality of transaction at the level of the final recipients (would the final recipient have received the financing for the same amount and under the same conditions in the absence of the guarantee?) | | X Target: Identified deadweight not more than 35% | X Target: Identified deadweight not more than 35% | On a survey/sample basis as part of the mid-term and ex-post evaluation <i>Please note that an ex-post monitoring or a detailed ex-ante assessment for each individual transaction or for a very significant number of transactions is unrealistic and would create significant administrative burden for financial intermediaries, final recipients and the Commission services involved. Therefore, a survey approach based on a sample is considered to be the most cost-effective option.</i> |
| 7. Number of SMEs supported | X Target: to be set as a function of the available budget | X Target: to be set as a function of the available budget | X Target: to be set as a function of the available budget | Through regular operational reports from the entrusted entity |
| 8. Financing made available to SMEs supported | X Target: to be set as a function of the available budget | X Target: to be set as a function of the available budget | X Target: to be set as a function of the available budget | Through regular operational reports from the entrusted entity |

¹¹³ In accordance with Article 209 (2) (b) of Financial Regulation 2018 (forthcoming)

¹¹⁴ In accordance with Article 209 (2) (b) of Financial Regulation 2018 (forthcoming)

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| (Assumptions made: target range 1:15 – 1:25 Average size of financing transaction: €100,000 ¹¹⁵) | (Formula to be used: Available budget * target range * average size of financing transactions) | (Formula to be used: Available budget * target range * average size of financing transactions) | (Formula to be used: Available budget * target range * average size of financing transactions) | |
| 9. Jobs maintained / employment created in supported SMEs | N/A | X Target: Employment growth in supported SMEs to exceed employment growth of the overall SME population | X Target: Employment growth in supported SMEs to exceed employment growth of the overall SME population | Annual employment/growth reports from the entrusted entity. Report to be submitted for the first time in the fourth year of the programme with data as per end of the third year of the programme. COM to monitor the general employment growth in the overall SME population (currently Commission prepares the annual report on European SMEs) As part of the ex-post evaluation: an econometric study to determine how employment has grown in supported SMEs compared to non-supported SMEs. |
| 10. Turnover growth in supported SMEs | N/A | X Target: Turnover growth in supported SMEs | X Target: Turnover growth in supported SMEs | Annual employment/growth reports from the entrusted entity. Report to be submitted for the |

¹¹⁵ Despite the average transaction of €37,000 under the COSME LGF, the average transaction size is estimated to be €100,000, based on the fact that the €150,000 threshold will be eliminated and the higher-risk financing transactions that are currently supported through InnovFin SMEG have an average transaction size of €450,000.

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| | | to exceed overall GDP growth | to exceed overall GDP growth | <p>first time in the fourth year of the programme with data as per end of the third year of the programme.</p> <p>COM to compare turnover growth in supported SMEs to general GDP growth.</p> <p>As part of the ex-post evaluation: econometric study to determine how turnover has grown in supported SMEs compared to non-supported SMEs.</p> |
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Appendix: Public institutions providing debt financial instruments in the EU¹¹⁶

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| AT | Austria Wirtschaftsservice operates longstanding loan-based measures financed, amongst others, from the original endowment of the Marshall Fund, the ERP Fund. The ERP fund has been integrated into AWS. AWS runs many different instruments, including: the ERP Fund, AWS Mittelstandsfonds and AWS Gründerfonds. |
| BE | <p>Société Régionale d'Investissement de Wallonie (SRIW), Société Wallonne de Gestion et de Participation (SOGÉPA) and Société Wallonne de Financement et de Garanties des PME (SOWALFIN) are the main actors offering financial instruments in Wallonia. SOWALFIN also offers financial instruments through its subsidiaries Sofinex, Novallia and Socamut, as well as a network of nine 9 'Invests' across the five Walloon provinces.</p> <p>Innovation and Enterprise Agency (Agentschap Innoveren en Ondernemen - AIO) and Investment Company Flanders (Participatiemaatschappij Vlaanderen - PMV) are the main actors in terms of financial instruments in Flanders.</p> <p>Finance.brussels is the main relevant agency in the Brussels Capital region, offering microcredit, loans and equity through its subsidiaries Brusoc, Brucofin, Exportbru, Brupart and Srib-Gimb. There is also the Brussels Guarantee Fund, which targets SMEs and microenterprises.</p> |
| BG | The Bulgarian Development Bank provides direct and indirect finance to SMEs. The National Guarantee Fund is a subsidiary of the Bulgarian Development Bank and provides guarantees to financial intermediaries. |

¹¹⁶ Source: EPRC (2017), *Improving the take-up and effectiveness of Financial Instruments*

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| CY | The Cyprus Entrepreneurship Fund is the main public finance fund established to support and strengthen entrepreneurship in the country by enhancing access to finance for SMEs. |
| CZ | The Czech-Moravian Guarantee and Development Bank focuses on providing assistance to SMEs aiming at giving them easier access to capital, sharing risk and reducing project costs through different types of support tools such as bank guarantees, preferential loans and financial subsidies. |
| | The National Innovation Fund aims to stimulate the national market with high-risk capital, especially in the forms of seed, start-up and early stage funding. |
| DE | <p>KfW Bankengruppe (KfW) offers numerous domestic support programmes for SMEs, municipalities and other target groups. Landwirtschaftliche Rentenbank also provides investment to SMEs and public finance.</p> <p>In addition to the domestic financial instruments offered at the national level, there are various instruments for SMEs offered by public promotional banks at the Länder level. In each Land there is at least one promotional bank.</p> |
| DK | The Danish Growth Fund (Vækstfonden) is a public investment fund backed by the Danish Government. The statutory purpose of the Danish Growth Fund is to promote innovation and development of the business sector in order to achieve a higher socio-economic return. |
| EE | KredEx is a fund that acts as a national promotional bank and provides guarantees for debt instruments offered by credit institutions and financial institutions, supporting export transactions and developing enterprises' export capacity, developing other financial services and providing these services within the business and housing sector. |
| EL | The Hellenic Fund for Entrepreneurship and Development (ETEAN SA) is fully owned by the Greek State. ETEAN SA's scope includes extension of guarantees and co-guarantees, the origination and management of innovative special purpose funds and co-financing loans and/or guarantees on attractive terms. |
| ES | <p>ICO – Instituto de Crédito Oficial (Official Credit Institute), Spain's public bank, provides finance for SMEs through intermediated lending.</p> <p>ENISA – Empresa Nacional de Innovación (National Innovation Company). The institutional mission of ENISA consists in providing financing to SMEs for business projects that add value to the Spanish economy, economically and in terms of job creation, as well as promoting Spanish design.</p> <p>CERSA – Compañía Española de Reafianzamiento (Spanish Counterguarantee Company) provides counter-guarantees.</p> |
| FI | Finnvera is Finland's main State-owned specialised financing company. It aims to supplement the financial markets by providing businesses with loans, guarantees, venture capital investments and export guarantees. Finnvera is also the official Export Credit Agency of Finland. |
| FR | <p>Bpifrance is France's main public investment bank. It operates as a bank and a fund manager. Created in 2012, Bpifrance regroups different institutional actors involved in investment activities and financial instruments under one name. It is the main public actor involved in SME support and business financing.</p> <p>Caisse des Depots et Consignations (created 1816) is a long-term State investor with 20 subsidiaries (including Bpifrance) that can provide loans, equity and guarantees through a regional network. It is a main investor in business equity (via Bpifrance) and in infrastructure and housing.</p> |

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| | In addition, Initiative France, a network of local associations, provide loans on trust, while France Active offers financial instruments via three financial structures: France Active Garantie (manages Guarantee Fund), France Active Investment Company (SIFA) (manages regional funds) and France Active Financement. |
| HR | The two main institutions providing public finance in Croatia are The Croatian Bank of Reconstruction and Development (HBOR) and The Croatian Agency for SMEs, Innovations and Investments (HAMAG-BICRO). |
| HU | <p>The National Bank of Hungary is Hungary's Central bank. It offers loans via the Széchenyi Growth Programme through commercial banks.</p> <p>The Hungarian Development Bank is a State-owned bank that finances local government infrastructure development, a business finance programme and a public transport financing programme.</p> |
| IE | The Strategic Banking Corporation of Ireland (SBCI) is a new, strategic SME funding company. Its goal is to ensure access to flexible funding for Irish SMEs. |
| IT | <p>Cassa Depositi e Prestiti, by far the largest institutional operator, is a national promotional institution involved in the supply of finance to international development cooperation bodies, to directly financing public interest projects, infrastructure projects and research investments, export finance, social housing and support for SMEs, with a general remit to support economic growth in Italy.</p> <p>Invitalia operates as an administrative body and is in charge of public aid measures (either grants or financial instruments).</p> <p>MedioCredito Centrale is a public bank operating at national level and with a focus on Convergence regions.</p> <p>At regional level, the function of supplying public finance is performed by regional development agencies (agenzie regionali di sviluppo) and regional financial institutions (finanziarie regionali).</p> |
| LT | INVEGA is a public body tasked with developing SMEs in Lithuania and facilitating their access to finance. It provides different types of financial instruments within the area of debt finance, covering loans, co-financing of loans, support to finance interest payments and loan guarantees. |
| LU | Société Nationale de Crédit et d'Investissement (SNCI) is Luxembourg's main State-owned bank, providing medium and long term financing contributions to economic development. |
| LV | AFI, a national specialised development finance institution, was created in December 2013 to implement financial instrument investment strategies. The process merged three government agencies – Latvian Guarantee Agency, ALTUM (former Lavijas Hipotēku un Zemes Banka) and Rural Development Fund into AFI with the objectives to increase efficiency in programme implementation, to strengthen coordination among programmes and to provide entrepreneurs with a “one-stop-shop” for State support mechanisms. Under this arrangement, ALTUM will continue programme implementation, keeping the same regional coverage and representation. |
| MT | Malta Enterprise is an economic development agency that offers a range of incentives – grants, soft loans, interest rate subsidies and loan guarantees. |
| NL | Netherlands Enterprise Agency (Rijks Dienst voor ondernemend Nederland – RVO) is the main financial State-owned institution in the Netherlands. It is part of the Dutch Ministry of Economic Affairs. Innovation Fund SME+ is a fund managed by the Netherlands Enterprise Agency that provides various forms of |

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| | repayable support to innovative SMEs. |
| PL | Bank Gospodarstwa Krajowego – BGK / The State Development Bank of Poland. BGK supports the social and economic growth of Poland and provides services to the public finance sector. BGK actively participates in the implementation of the State's economic objectives. |
| PT | SPGM - Sociedade de Investimento, S.A. has been a major tool for promoting the expansion of the Mutual Guarantee System in PT, targeting a large number of SMEs. |
| | <p>IAPMEI (Instituto de Apoio às Pequenas e Médias Empresas e ao Investimento – Institute for the Support to Small and Medium-sized Enterprises and Investment) manages financial assistance programmes and promotes SME access to the stock market and to alternative sources of financing.</p> <p>Instituição Financeira de Desenvolvimento (Financial Development Institution, IFD) was set up in 2014 to manage the ESIF financial instrument programmes. Its wider objectives included promoting greater efficiency and effectiveness in the management of financial instruments for supporting SMEs in Portugal.</p> <p>PME Investimentos – Sociedade de Investimento, S.A. aims to promote the development and increase of the financing offer to companies in the non-financial sector, notably SMEs, through management of special investment funds.</p> |
| RO | <p>Casa de Economii și Consemnațiuni (CEC) is Romania's national State-owned bank. The bank aims to support local businesses and SMEs. It provides: loans for SMEs, loans for rural financing, loans for recently-incorporated companies, State-aided loans, European Funds and loans to finance the Public Authorities.</p> <p>EximBank is another national State-owned bank. EximBank has been involved in supporting and promoting the Romanian business environment, by making available a wide range of financial instruments for local companies.</p> |
| SE | In Sweden, the key State-funded operators that provide equity capital to businesses are Almi, Fouriertransform (for manufacturing industry), Inlandsinnovation (only in north of Sweden) and Industrifonden. In addition, there are a number of State-owned regional companies that are jointly owned with the county councils or regional actors. |
| SI | <p>SID Bank (SID – Slovenska izvozna in razvojna banka) became a fully State-owned bank in 2008. SID Bank provides export credits and investment insurance services on behalf of the State. The main activity provided for its own account is financing of business transactions in the area of market gaps (SMEs, research, environment, internationalisation, etc.).</p> <p>The Slovene Enterprise Fund (SEF) is a State-owned fund. SEF was established for the purpose of granting financial support and incentives to the entrepreneurial sector in Slovenia. The Fund publishes annual public tenders for financial support for development-expansion investments of micro-, small and medium-sized enterprises in Slovenia.</p> |
| SK | <p>Slovak Guarantee and Development Bank (SZRB) is the key provider of finance to SMEs and local authorities.</p> <p>Slovak Investment Holding (SICAV SIF S.C.A.) has been established to support national investment priorities</p> |

providing financial instruments in various mainstream programmes financed through ESIF.

UK

The British Business Bank was set up in 2012 to integrate existing programmes supporting SMEs, as well as developing and managing new SME access to finance programmes.

Finance Wales is a publicly-owned company set up to provide finance to SMEs in Wales. Finance Wales makes commercial investments in SMEs based in Wales or willing to relocate.

The Scottish Investment Bank (Scottish Enterprise/Highlands and Islands Enterprise): Scottish Investment Bank is a department of Scottish Enterprise, a sponsored non-departmental public body of the Scottish Government that encourages economic development, enterprise, innovation and investment in business. Highlands and Islands Enterprise is the Scottish Government's economic and community development agency for the north and west of Scotland.

Invest NI provides government support for businesses in Northern Ireland by delivering the Government's economic strategies. Support offered includes advice, mentoring and funding. Funding includes both grants and financial instruments.

Annex 16: Programme specific annex on *Health programme*

Glossary

| <i>Term or acronym</i> | <i>Meaning or definition</i> |
|------------------------|---|
| AMR | Antimicrobial Resistance |
| AWP | Annual Work Programmes |
| CHAFEA | Consumers, Health, Agriculture and Food Executive Agency |
| CNCT | Directorate-General for Communications Networks, Content and Technology |
| COMP | Directorate-General for Competition |
| DG Home | Directorate-General for Migration and Home Affairs |
| DG RTD | Directorate-General for Research and Innovation |
| DIGIT | Directorate-General for Informatics |
| ECDC | European Centre for Disease Prevention and Control |
| EFSA | European Food Safety Authority |
| EMA | European Medicines Agency |
| ESTAT | Eurostat |
| EU | European Union |
| FISMA | Directorate-General for Financial Stability, Financial Services and Capital Markets Union |
| GNI | Gross national income |
| GROW | Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs |
| JUST | Directorate-General for Justice and Consumers |
| MAP | Multi-Annual Planning |
| MS | Member States |
| OECD | Organisation for Economic Co-operation and Development |
| R&D | Research and development |
| SANTE | Directorate General for Health and Food Safety |
| SoHO | Substances of Human Origin |
| SRSS | Structural Reform Support Service |
| TFEU | Treaty on the Functioning of the European Union |
| UN | United Nations |
| WHO | World Health Organization |

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| Budget line | A Budget line is a graphical representation of all possible combinations of two goods which can be purchased with given income and prices, such that the cost of each of these combinations is equal to the money income of the consumer. |
| eHealth | Digital health and care is the collective term used to refer to tools and services that use information and communication technologies (ICTs) that can improve prevention, diagnosis, treatment, monitoring and management of health and lifestyle. Digital health and care has the potential to improve access to care, quality of care, and increase the efficiency of the health sector. |
| eHealth Network | The eHealth Network is a voluntary network, set up under article 14 of Directive 2011/24/EU. It provides a platform of Member States' competent authorities dealing with eHealth. The Joint Action supporting the eHealth Network (JAseHN) provides scientific and technical support to the Network. |
| European Cancer Information System (ECIS) | ECIS provides the latest information on indicators that quantify cancer-burden across Europe. It permits the exploration of geographical patterns and temporal trends of incidence, mortality and survival data across Europe for the major cancer entities. The purpose of the web-application is to support research as well as public-health decision-making in the field of cancer and to serve as a point of reference and information for European citizens. |
| European Innovation Partnership on Active and Healthy Ageing | The European Innovation Partnership in Active and Healthy Ageing (EIP on AHA) is an initiative launched by the European Commission to foster innovation and digital transformation in the field of active and healthy ageing. |
| European Pharmacopoeia | The European Pharmacopoeia (Ph. Eur.) is Europe's legal and scientific benchmark for pharmacopoeial standards which contribute to delivering high quality medicines in Europe and beyond. The Ph. Eur. is applicable in 38 European countries and used in over 100 countries worldwide. |
| European Reference Network for rare disease | The European Reference Networks (ERNs) are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. |
| Health Technology Assessments | Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. (EUnetHTA) |
| National Focal Points | The National Focal Points (NFP) are the national experts for the Health Programme in member states and participating countries. NFP representatives are appointed by their national health ministries. (CHAFEA) |
| One Health Approach | One Health: is a term used to describe a principle which recognises that human and animal health are interconnected, that diseases are transmitted from humans to animals and vice versa and must therefore be tackled in both. The One Health approach also encompasses the environment, another link between humans and animals and likewise a potential source of new resistant |

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| | microorganisms. This term is globally recognised, having been widely used in the EU and in the 2016 United Nations Political Declaration on AMR. |
| Scientific Committees set up in accordance with Commission Decision 2008/721/EC | 2008/721/EC: Commission Decision of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC |
| (Seven) EU added value criteria | The EU's supporting competence in public health means that action can only be justified if it adds value above and beyond what the Member States and other actors could achieve on their own. The seven EU added value criteria are enshrined in the Regulation (EU) 282/2014 establishing the 3rd Health programme (2014-2020) |
| State of Health in Europe cycle | The State of Health in the EU is a two-year initiative undertaken by the European Commission that provides policy makers, interest groups, and health practitioners with factual, comparative data and insights into health and health systems in EU countries. The cycle is developed in cooperation with the Organisation for Economic Co-operation and Development (OECD) and the European Observatory on Health Systems and Policies. |
| The 3rd Health programme (2014-2020) | The Third EU Health Programme (2014-2020) is the main instrument that the Commission uses to implement the EU Health Strategy. Annual work plans of the Programme set out priority areas and the criteria for its funding actions. |

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

1.1. Scope and context

Summary

Health is a strategic component of growth in the Internal Market, and an invaluable resource for the society. It is also an inescapable dimension of a productive workforce, of sustainable public services and efficient social market economies, and of well-functioning democracies serving the citizens. The Lisbon Treaty has enhanced the importance of health policy in Article 168 of TFEU. The Treaty's health objectives are to be achieved by supporting Member States' policies, since the primary responsibility for health protection and, in particular, for the operation of healthcare systems lies with the Member States. National authorities acknowledge more and more the existence of cross-border problems, and the need to cooperate, use expertise and mutualise resources to respond to the cross-border nature and global dimension of health issues. The EU has successfully implemented a comprehensive policy, through the 3rd Health programme (2014-2020) by bringing together relevant stakeholders and Member States authorities to work on prioritised health issues.

Health is a strategic component of growth for the Internal Market and an invaluable resource for the society. The Treaty of Lisbon has enhanced the importance of health

policy, stipulating that “a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities” (Article 168 of TFEU). The EU has an important role to play in improving public health, preventing and managing diseases, mitigating sources of danger to human health, including by harmonising legislation on tobacco, medicinal products, medical devices, substances of human origin and patients' rights in cross-border healthcare, areas where health policies are directly linked with the Internal Market (Article 114 of TFEU).

More generally, the Treaty's health objectives are to be achieved through action intended to support Member States' policies and to foster cooperation and integrated work, since the primary responsibility for health protection and, in particular, for the operation of the healthcare systems continues to lie with the Member States.

National authorities acknowledge more and more the need to cooperate, use expertise and mutualise resources to respond to the cross-border and global dimension of health issues and also to fully develop and benefit from opportunities offered by the digital market, the rapid development of health technologies, the sharing and implementation of evidence-based best practices for achieving a "high level of human health protection", and aim to ensure healthy lives and promote well-being for all at all ages.

The EU has successfully implemented a comprehensive health policy, through the 3rd Health programme (2014-2020) by bringing together relevant stakeholders and Member States authorities to work on prioritised health issues. Through the Health Programme, the EU helps Member States to develop their initiatives at EU level for more cost-effective solutions to common health concerns, *e.g.* the establishment of European Reference Networks for rare diseases, the effective response to cross-border health threats as in the case of Ebola and Zika viruses outbreaks, the cancer screening guidelines, the joint Health Technology Assessments, etc.

1.2. Lessons learned from previous programmes

Summary

The mid-term evaluation¹¹⁷ of the third Health Programme's confirmed the importance of the outcomes of funded actions and stressed their high EU added value, notably in the form of increased capacity in the Member States to address health threats, of clear roadmaps for the improved access to healthcare for vulnerable migrants and refugees, of technical guidelines and recommendations for cancer, HIV/AIDS and TB prevention, of additional support for EU health legislation on medicinal products and medical devices, as well as the eHealth Network activities and Health Technology Assessment. It also recognised the added value of tools to control healthcare-associated infections and to step up coordinated efforts to fight against antimicrobial resistance, and of the extensive groundwork pursued through a number of Joint Actions to develop a common EU approach to Health Technology Assessment (HTA). The mid-term evaluation recognised as well the positive contribution of actions fostering interoperable and standardised cross-border exchange of health data, and of those setting up EU digital infrastructures for that purpose. It also was recognised that the establishment of 24 European Reference Networks for rare diseases, a new form of integrated work, has a huge potential to

¹¹⁷ [Mid-term evaluation of the 3rd Health Programme 2014-2020](#); COM(2017) 586 final; SWD(2017) 331.

improve the care provided to citizens across EU. However, a number of challenges need to be addressed such as the relatively high number of program priorities, some shortcomings in monitoring the implementation and prioritisation and dissemination of actions. Notably, Member States and EU stakeholders have declared an overwhelming support for continuing EU action in the area of health.

The mid-term evaluation of the 3rd Health Programme¹¹⁸ concluded that the Programme has overall valid and appropriate objectives in place leading to actions which are relatively focused and generate EU added value while accommodating existing needs and challenges. The 3rd Health Programme, currently running will end in 2020.

Compared with previous health programmes, the 23 thematic priorities of the 3rd Health Programme are a positive development and facilitate synergies and coherent action. However, these could still be streamlined and focused even more. The structure in place has supported relevant actions, especially in fields where there is legislative clarity and/or a clear cross-border dimension. In non-legislative areas where action can be more open-ended or broadly defined, there is a danger of those actions being less focused.

The Annual Work Programmes (AWP) and Multi-Annual Planning (MAP) processes implementing the 3rd Health Programme work well. The MAP in particular has enabled a more strategic approach to medium-term planning. The AWP process is already clear, well-defined and impartial but to avoid confusion and ensure greater buy-in, the process needs to be better explained to stakeholders.

The mid-term evaluation shows that the exceptional utility criteria¹¹⁹ for attracting participation from low gross national income (GNI) countries have not been sufficiently effective so far. However, despite the difficult economic context and the significant barrier of assuring the remaining co-financing, the Programme is still attracting a similar level of participation from low GNI countries as in the previous programme. Additional improvements are needed, since securing co-funding is only one part of the explanation for lower participation.

The 3rd Health Programme has already delivered significant progress by, for instance, establishing European Reference Networks, adopting new legislation on Health Technology Assessment, and by supporting capacity building of Member States to respond to outbreaks and continuous updating of skills to take into account emergent issues such as the migrant crisis.

The allocation of resources in the 3rd Health Programme has been found to be efficient overall and the programme management has been mostly effective and has improved since the previous 2nd Health Programme 2008-2013. For instance, new indicators are in place for monitoring the health programme and its specific actions.

Nevertheless, there are inefficiencies and inadequacies with the monitoring of implementation data, which holds back the ability of programme managers to keep an up-to-date overview of the programme's achievements. This will be appropriately

¹¹⁸ See at https://ec.europa.eu/health/funding/programme/2014-2020/midterm_evaluation_en

¹¹⁹ This allows for exceptional co-funding up to 80% to all participants in the action under specific criteria mentioned in the legal basis (Regulation (EC) N° 282/2014 , Article 7 (3) and in the Annual Work Programmes.

addressed. While significant strides have been made to ramp up dissemination, going forward and delivering progress in this area must be prioritised.

Furthermore the ongoing health programme has already been increasing its ability to target important health needs where it can add value (e.g. antimicrobial resistance, e-health, accreditation schemes for breast cancer screening, etc.). The fact that the seven EU added value criteria are written into the regulation and are built into the proposal evaluation process are positive achievements allowing potential beneficiaries to appropriately consider EU added value when preparing their proposals and in turn, for assessment panels to take it into account as part of the decision to award funding. However, there is scope to streamline the added-value criteria to focus on three key areas: addressing cross-border health threats; improving economies of scale; and fostering the exchange and implementation of best practices. This will make it easier to provide clear guidance of what the criteria mean and make it easier for them to be addressed more effectively.

The 3rd Health Programme has been found by the mid-term evaluation to be internally coherent, in part due to the revised structure of the programme. However, where the definition of action remains broad and ambitious, results are, harder to achieve. The 3rd Health Programme is also coherent with the Commission's policy priorities and has been shown to be an effective tool to respond to evolving needs.

Stakeholders participated in the mid-term evaluation through various consultations¹²⁰, including an open public consultation which covered aspects relating to the relevance, added value, efficiency, effectiveness, and coherence of the programme. This consultation engaged institutional stakeholders, notably the Programme Committee members and National Focal Points and grant beneficiaries. The stakeholders involved in the funded activities, especially non-governmental organisations, public health authorities, academic and research organisations, international organisations, professional associations, private companies and individual persons were also consulted through the open public consultation. In addition, targeted on-line consultations with public health experts and e-surveys with National Focal Points and Programme Committee members were conducted as part of the external evaluation study. These were complemented by targeted interviews of Commission and International Health Organisation officers, and grant recipients (beneficiaries), mainly project leaders and coordinators of actions funded under the Programme.

In the open public consultation Member States and EU stakeholders have declared an overwhelming support for EU health policies confirming that the cooperation in the area of health is essential and should be maintained (70%). The EU should continue supporting important health-related challenges facing EU citizens, governments and health systems reflected in the formulation of the Programme's objectives.¹²¹

¹²⁰ The results of the consultation activities are presented in the Annex V of the SWD (2017) 331 final of 11.10.2017) on

¹²¹ The results of the Open Public Consultation are publicly available on https://ec.europa.eu/health/funding/consultations/midterm_evaluation_en

Real life example of success story of synergies with other IMP programmes:

The spreading of antimicrobial resistance (AMR) is a natural biological phenomenon but lately a variety of factors have contributed to accelerate its dispersion. AMR is responsible for an estimated 25,000 deaths yearly and over EUR 1.5 billion of healthcare costs and productivity losses in the EU. Combating antimicrobial resistance has become a global public health challenge. AMR has also become a political priority within the EU, the G7, the G20, the UN and other international organisations.

In 2008, the European Council called upon the Member States to strengthen surveillance systems and improve data quality on antimicrobial resistance and on consumption of antimicrobial agents within both the human and veterinary sectors. The new 5 years EU Action Plan to combat antimicrobial resistance was adopted in 2017 to prevent and reduce the spreading of AMR, and preserve the capacity to fight microbial infections. The key objectives of this new strategy are built on three main pillars: (i) making the EU a best practice region on AMR; (ii) boosting research, development and innovation on AMR; and (iii) shaping the global agenda on AMR.

As part of this AMR Action Plan several other programmes (e.g. EU Programmes for Health and Food-and-Feed¹²², Horizon 2020) as well as the EU Agencies (EFSA, EMA and ECDC) collaborate and coordinate with different national authorities in order to reach the outlined objectives from a one Health perspective and in support of Member States' national action plans. This inclusive strategy with representation of all relevant actors at EU level and the aim to address gaps on the Health and Animal side holistically represent a successful example of the One Health approach.

2. THE OBJECTIVES

2.1. Challenges for the programmes of the next MFF

Summary

The current 3rd Health Programme (2014-2020) supports a broad range of activities to deliver on the objectives of Article 168 TFEU, with a total budget of EUR 449.4 million. The 23 thematic priorities stem out of four main objectives which are: promote health and healthy living and prevent diseases; protect Europeans from serious cross-border health threats; contribute to innovative, efficient and sustainable health systems; and facilitate access to better and safer healthcare for Europeans. The mid-term evaluation of the 2014-2020 programme concluded that while the programme objectives remain valid, several improvements should be made regarding its focus, content and structure in order to ensure that EU funding delivers visible outcomes with EU added value on the programme priorities and increase synergies and ensure the upscale of significant results through cooperation with other EU financial instruments. In particular, the need of streamlining and focusing the future programme's priorities and actions was identified. In light of mid-term evaluation findings and with the aim of designing a future Health

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programme as integral part of the *Single Market* Programme for the post-2020 period, the thematic areas of action have been streamlined to allow for a more results and added value oriented approach for EU funded actions, focused on cross-border health issues, on the potential to create economies of scale and on the exchange, dissemination and upscaling of best practices.

The current Health Programme (2014-2020) is the third programme of EU action in the field of health, established by Regulation (EU) N° 282/2014¹²³. With a budget of EUR 449.4 million over seven years, it is the Commission's main financial instrument to underpin and support EU health policy development. Designed to help inter alia Member States in investing in health, the programme contributes to the Europe 2020 objective of smart, sustainable and inclusive growth. The ongoing program aims to complement, support and add value to the Member States policies, in terms of improving the health of EU citizens and reducing health inequalities. The specific objectives and their financial envelopes for the period 2014-2016 are the following:

1. promote health and healthy living and prevent diseases (€54.1 million; from which (€16.8 million in 2014, €12.7 million in 2015 and €24.6 million 2016);
2. protect Europeans from serious cross-border health threats (€11.1 million; from which €5.3 million 2014, €1.4 million in 2015 and €4.4 million 2016);
3. contribute to innovative, efficient and sustainable health systems (€52.1 million; from which €17.6 million in 2014, €25.2 million in 2015 and €9.3 million 2016); and
4. facilitate access to better and safer healthcare for Europeans (€31.3 million; from which €10.5 million in 2014, €6.2 million in 2015 and €14.6 million 2016); horizontal activities (€17.3 million; from which €3.7 million in 2014, €10 million in 2015 and €3.6 million 2016).

A total budget of €100 million remains to be spent until the end of the current financial EU framework.

These four objectives are currently served by 23 thematic priorities, listed in Annex I to Regulation (EC) N° 282/2014:

Objective 1: Promote health, prevent disease and foster supportive environments for healthy lifestyles

- 1.1.Risk factors such as use of tobacco and passive smoking, harmful use of alcohol, unhealthy dietary habits and physical inactivity
- 1.2.Drugs-related health damage, including information and prevention
- 1.3.HIV / AIDS, tuberculosis and hepatitis

¹²³ OJ L86 of 21.3.2014, p. 1-13.

- 1.4.Chronic diseases including cancer, age-related diseases and neurodegenerative diseases
- 1.5.Tobacco legislation
- 1.6.Health information and knowledge system to contribute to evidence-based decision making

Objective 2: Protect Union citizens from serious cross border health threats

- 2.1.Risk assessment additional capacities for scientific expertise
- 2.2.Capacity building against health threats in MS, including, where appropriate, cooperation with neighbouring countries
- 2.3.Implementation of Union legislation on communicable diseases and other health threats, including those caused by biological, and chemical incidents, environment and climate change
- 2.4.Health information and knowledge system to contribute to evidence-based decision-making

Objective 3: Contribute to innovative, efficient and sustainable health systems

- 3.1.Support voluntary cooperation among MS on HTA
- 3.2.Innovation and e-health
- 3.3.Health workforce forecasting and planning
- 3.4.Setting up a mechanism for pooling expertise at Union level
- 3.5.European Innovation Partnership on Active and Healthy Ageing
- 3.6.Implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare
- 3.7.Health information and knowledge system including support to the Scientific Committees set up in accordance with Commission Decision 2008/721/EC

Objective 4: Facilitate access to better and safer healthcare for Union citizens

- 4.1.Establishment of a system of European reference networks
- 4.2.Effectively help patients affected by rare diseases
- 4.3.Strengthen collaboration on patient safety and quality of healthcare
- 4.4.Measures to prevent Antimicrobial resistance and control healthcare-associated infections
- 4.5.Implementation of Union legislation in field of tissues and cells, blood, organs,
- 4.6.Health information and knowledge system to contribute to evidence-based decision making

The main challenges to be addressed by the future 4th Health Programme [2021-2027] stem from the mid-term evaluation and from the need identified therein to better direct funding towards actions that show the greatest potential to generate visible impacts and produce concrete results in **addressing cross-border health threats, improving economies of scale, and fostering the exchange and implementation of best practices.**

The actions that have proven to deliver highest added value and on which the next health programme should concentrate its resources are supporting activities such as:

- the establishment and operation of European Reference Networks (ERNs),
- the "State of Health in Europe" cycle,
- work on EU cancer information system including the cancer registries (which provide information on treatments and outcomes), and more generally data and information collection, use of big data and real world data, to inform EU and Member States' health related policy action,
- technical assistance to Member States aimed at enabling health systems reforms in key areas such as Health Technology Assessment (HTA) and eHealth,
- the development of common methodologies and tools for integrated work (e.g. for the new HTA framework)) and the deployment of capacity building actions (e.g. the development of HTA capacity in Member States lacking this at the moment).
- AMR Action Plan promotes collaboration with different national authorities in order to reach the outlined objectives from a one health perspective and in support of Member States' national action plans.

The upcoming regulation on health technology assessment will imply additional funding requirements¹²⁴.

On the basis of the above considerations a review of the existing needs in the health area, conducted with the support of an external contractor and based on the mid-term evaluation results, has identified the necessity to focus EU action on the following problems:

- cross border health threats that are not stopped at the EU external frontiers and could be easily spread across borders and require coherent collective response without blocking the free movement of persons and goods in the EU;
- decision-makers need robust, comparable and timely health data, information, and expertise, to effectively tackle health policy challenges, to conduct structural reforms and improve accessibility, effectiveness and resilience of health systems while making strategic, long-term investments into them;
- effective rule making and enforcement action are needed to secure high standards of quality safety and efficacy for specific products improving or impacting health;

¹²⁴ Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on health technology assessment and amending Directive 2011/24/EU
https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51_en.pdf

this includes the need to support integrated work on Health Technology Assessment;

- the specificity of rare diseases requires cooperation across Member States to pool knowledge and expertise, increase access of patients to specialised centres and provide increased opportunities to R&D; the model of ERNs could be expanded to cover also other non-communicable diseases.

The above needs were translated in a refined intervention logic for the new Health Programme with a better definition of problems and objectives, conducive to a reduced and streamlined number of thematic areas of action (to replace the current 23 thematic priorities of the on-going 3rd Health Programme)¹²⁵.

The revised intervention logic addresses a number of further challenges identified by the mid-term programme evaluation, including the need to improve the monitoring arrangements through the establishment of relevant indicators and to clearly communicate on its expected EU added value.

The cross-cutting objectives of the post-2020 multi-annual financial framework – flexibility, performance, coherence and synergies, and simplification – will also be addressed, as appropriate.

Flexibility is particularly important in relation to the management of cross-border health threats, as past experience with the Zika and Ebola crises has demonstrated. In practical terms, more flexibility is necessary in particular to define the category of costs eligible for EU funding (e.g. the purchase of goods such as vaccines or protective equipment); the geographical scope shall be expanded to allow countering severe crises that occur outside the EU and threaten the lives of EU citizens. Such flexibility would allow to undertake interventions (contingency measures) in all countries where such intervention is considered in the interest of the EU (e.g. South American and African countries in the case of the Zika and Ebola outbreaks mentioned above).

Past experience has demonstrated that the budget for crisis preparedness and management may be insufficient in case of severe threats (e.g. in 2009, responding to the influenza crisis required the provision of an additional €4 million, made available by the European Parliament through a Preparatory Action on an EU Rapid Response Capability, and in 2015-2016 funds had to be redeployed from other actions of the 3rd Health Programme to contribute to the EU response to health related risks of the migrants' crisis). For this reason and in addition to what will be already covered by the Health Programme, access to the Emergency Reserve Fund is necessary to allow the programme to effectively respond to potential serious health crisis in future.

¹²⁵ See above in pp. 9-10. Or See in Annex I of the Regulation (EC) N° 282/2014.

Direct access to the Emergency Reserve Fund is required e.g. to purchase medical counter measures and allow the deployment of emergency support in case of unpredictable major epidemics or other crisis with a potential cross border impact on public health.

| Challenges Programme/line | Empowerment of citizens, consumers and businesses | Administrative cooperation and integration among Member States | Rule-making, standard setting and enforcement at EU institutions level | Health as a resources for the society and the internal market |
|------------------------------|--|--|---|---|
| Health Programme | the specificity of rare diseases requires cooperation across Member States to pool knowledge and expertise, increase access of patients to specialised centres and provide increased opportunities to R&D; the model of ERNs could be expanded to cover also other non-communicable diseases | decision-makers need robust, comparable and timely health data, information, and expertise, to effectively tackle health policy challenges to conduct structural reforms to improve accessibility, effectiveness and resilience and to make strategic, long-term investments in the health systems | ensure effective rule making, enforcement and high standards of quality safety and efficacy for specific products improving or impacting health | new health threats that easily spread across borders & require collective and coherent response |

2.2. Objectives of the programmes of the next MFF

Summary

In response to the mid-term evaluation and ongoing study findings the challenges and needs identified will be addressed the by the following updated specific objectives:

- 1. Prepare for and counter health crises¹²⁶** – strengthen crisis-preparedness, management and response to protect EU citizens against cross-border health threats.
- 2. Empower health systems with emphasis on their digital transformation** – empower Member States with data, information and knowledge for better decision-making providing tailored support, including technical assistance, to design and implement reforms for improving accessibility, effectiveness and resilience of the health systems, and to support health through the digital single market.
- 3. Support EU health legislation** – support the free circulation of products by developing, implementing and monitoring health legislation, while upholding citizens' rights to access cross-border healthcare.
- 4. Support integrated work** – support Member States' efforts to collaborate with the aim of producing economies of scale, pooling resources and fostering joint cooperation and implementation of validated best practices, e.g. through the ERNs.

A reduced number of 15 thematic areas of action with higher EU-added value will be proposed to reach the above-listed objectives while reinforcing some areas of action by increasing their outputs and further consolidating the critical mass of projects, as necessary. Monitoring arrangements including a monitoring plan and indicators will be established for the overall Programme and for each area, respectively.

¹²⁶ This has to be understood as every potential crisis with a health dimension.

The general objective of the future Health Programme is to complement support and add value to Member States policies to improve EU citizens' health; to implement and enforce legislation governing the placing on the market and use of health products in the EU, and patients' rights to cross-border healthcare.

In response to the mid-term evaluation¹²⁷ of the 3rd Health programme and to an ongoing study¹²⁸ findings, the challenges and needs identified will be addressed by the following updated specific objectives:

- 1. Prepare for and counter health¹²⁹ crises** – strengthen crisis-preparedness, management and response to protect citizens in the EU against cross-border health threats.
- 2. Empower health systems with emphasis on their digital transformation** – empower Member States with data, information and knowledge for better decision-making providing tailored support, including technical assistance, to design and implement reforms for improving accessibility effectiveness and resilience of the health systems, and to support the digital single market.
- 3. Support EU health legislation** – support the free circulation of products by developing, implementing and monitoring health legislation, while upholding citizens' rights to access cross-border healthcare.
- 4. Support integrated work** – support Member States' efforts, pooling resources and fostering joint cooperation and implementation of best practices, e.g. through the ERNs.

A reduced number of 15 thematic areas of action with higher EU-added value will be proposed to reach the above-listed objectives while reinforcing some areas of action e.g. by increasing their outputs and further consolidating the critical mass of projects, as necessary. Monitoring arrangements including a monitoring plan and indicators will be established for overall objectives and for each area, respectively. Delivery of the programme's objectives will be assessed using the following evaluation criteria: (i) the continued relevance of all specific objectives and thematic areas of action, namely the direct relationship between the actions and the necessity to solve the problems and meet the needs while reaching the general objective; (ii) the effectiveness of the implemented health measures in achieving the general and specific objectives, also in light of the progress measured through the improved monitoring system to be put in place; (iii) the

¹²⁷ Commission Report COM(2017) 586 final and Staff Working Document SWD(2017) 331 final of 11. 10. 2017. All evaluations reports including the external study are available on https://ec.europa.eu/health/funding/programme/2014-2020/midterm_evaluation_en

¹²⁸ Data-gathering study on the common financial framework for the management of expenditure under Regulation 282/2014

¹²⁹ This has to be understood as every potential crisis with a health dimension.

efficiency in the use of the financial resources spent under the health budget and their consistency with the results achieved; (iv) the coherence of the measures implemented within the Health Programme, both internally and with other EU interventions; (v) the EU added value created through measures receiving technical and financial support under this programme.

The specific objectives of the future Health Programme cross the main challenges of the *Single Market Programme* as depicted below:

| Challenges Health Programme 17 01 03 | Empowerment of citizens, consumers and businesses | Administrative cooperation and integration among Member States | Rule-making, standard setting and enforcement at EU institutions level | Health as a resources for the society and the internal market |
|--|---|---|---|--|
| 1. Prepare for and counter health crises | | | | Member States need to be prepared for health emergencies, and to be able to implement coherent measures protecting the lives of citizens in the EU and avoiding disruption of the Internal Market. |
| 2. Empower health systems with emphasis on their digital transformation | | Complete and comparable health data and information including increase use of eHealth tools are needed to support decision making both at EU and MS level and promote reforms of health systems quality and sustainability. | | Information on health services is essential for good decision making on health matters and in ensuring competitiveness of European health care providers, both public and private. The ehealth is part of the overall single digital market targets. |
| 3. Support EU health legislation | | | The regulatory framework for medical products and technologies (medical devices and substances of human origin), as well as on tobacco legislation and patients' rights on cross-border health is essential to health protection in the EU. Regulation, as well its implementation and enforcement, must keep pace with innovation and research advances and with societal changes in this area, while delivering on health objectives. | The EU health legislation has an immediate impact on the lives of citizens and on the Internal Market. |
| 4. Support integrated work on: Health Technology Assessment (HTA) | | The need to support joint cooperation on HTA promoting convergence in procedures and methodologies, reducing duplications/parallel work for national HTA authorities. | | |

| | | | | |
|------------------------------------|---|---|--|---|
| European Reference Networks (ERNs) | Citizens suffering from rare disease need access to quality healthcare. | The need to support ERN's development of the ERNs and integration into the national healthcare systems. | | 30 million patients from rare diseases need diagnosis and treatment. ERNs provide also increased opportunities for R&D in the Internal Market. |
| implementation of best practices | Best practices exist that are proven to be conducive to healthier lives, for the benefit of citizens and of health systems in the Member States. They should be shared and scaled up. | Member States competent authorities need to learn in an organised [and coordinated] manner one from each other. | | The implementation of best practices contributes to the achievement of sustainable development goals for healthy lives of all at all ages. |

The following table provides information concerning flexibility, simplification and synergies of the Health programme with other IMP Programmes. It is worth noting that a number of synergies that the Health Programme can have with other programmes outside the "IMP Framework" (such as Horizon 2020 of DG RTD, Structural funds, Security Programme of DG HOME, Emergency Fund, SRSS etc.) which are not part of the Single Market Programme may enhance synergies between different "Framework programmes".

| Candidate for Health Programme objectives | Flexibility (moving funds from one IMP programme to other) <i>*in case of severe crisis, the contribution of the emergency fund is currently discussed</i> | Simplification (*) | With which other IMP programmes there are potential synergies | |
|--|--|---------------------------|--|--|
| 1. Prepare for and counter health crises | N/A | Yes | CNCT JUST | |
| 2. Empower health systems with emphasis on their digital transformation | N/A | Yes | CNCT ESTAT | |
| 3. Support EU health legislation | N/A | Yes | JUST GROW | |
| 4. Support integrated work | N/A | Yes | CNCT | |
| √ -relevant to the objective, N/A not relevant | | | | |

| Potential for Programme/line | Simplification of your programme, and/or synergies and/or flexibility |
|--|--|
| 1. [Prepare for and counter] health crises | Flexibility: N/A Simplification: yes Synergies: CNCT, JUST, |
| 2. Empower health systems with emphasis on their digital transformation | Flexibility: N/A Simplification: yes Synergies: CNCT, , ESTAT, |
| 3. Support EU health legislation | Flexibility: N/A Simplification: yes Synergies: JUST, GROW |

| | |
|----------------------------|---|
| 4. Support integrated work | Flexibility: N/A Simplification: yes Synergies: CNCT, , , JRC |
|----------------------------|---|

(*)Simplification could also be seen in relation to the delivery mechanisms (section 4 below).

3. PROGRAMME STRUCTURE AND PRIORITIES

Summary

The four objectives of the future Health Programme are equally important and complementary to each other, representing a comprehensive strategy for the future financing period. Action will be focused on 15 high EU-added value areas with high and medium priority replacing the current 23 "operational priorities". This will allow to further enhance the overall EU-added value of EU funding in this area and to consolidate (and build on) the critical mass of projects, which have proven to provide the highest returns ("budget for results"). The new intervention logic will allow a refocusing of funding in the streamlined areas of action through the creation of economies of scale, the improvement of crisis preparedness, and the rolling out of identified, high added value best practices. It will enable those available resources to be used to continue to sustain and enhance the critical mass of high added value projects under the future Health Programme and to bring to fruition and augment the EU-added value of ongoing ones. All areas of work are those for which a clear mandate is given to EU for action (Articles 114 and 168 of the TFEU) and a critical mass of actions from past programmes already exist on which the future one can rely for effective delivery of results.

In respect of achieving the programme objectives, 15 areas of action with higher EU-added value were identified, streamlined and ranked from high to medium priority as follows:

1. Strengthen crisis-preparedness, management and response in the EU to protect citizens against cross-border health threats.

- 1.1. Capacity-building measures for crisis preparedness, management and response **(high)**
- 1.2. Respond to cross-border health threats during crisis **(high)**
- 1.3. Support laboratory capacity **(high)**

2. Empower health systems with emphasis on their digital transformation

- 2.1. Support the digital transformation of health and care **(high)**
- 2.2. Support the development of a sustainable EU health information system **(medium)**

2.3 Support the national reform processes for more effective, accessible and resilient health systems **(medium)**

3. Support EU health legislation

3.1. Manage, maintain and implement the legislation on medical devices **(high)**

3.2. Support the implementation of Union legislation on medicinal products and on Health Technology Assessment (HTA) **(high)**

3.3. Monitor and support Member States in their implementation of legislation in the area of substances of human origin (SoHO) **(high)**

3.4. Support the implementation of tobacco legislation **(high)**

3.5. Support the implementation of Union legislation in the area of cross-border healthcare **(high)**

3.6. Support to the Commission's scientific committees on "Consumer Safety" and on "Health, Environmental and Emerging Risks" **(high)**

4. Support integrated work (e.g. ERNs, HTA and implementation of best practices)

4.1. Continue support for the European Reference Networks (ERNs) **(high)**

4.2. Support the development of cooperation on Health Technology Assessment (HTA) in preparation of new harmonised rules **(medium)**

4.3. Support the implementation of best practices to support structural innovation **(medium)**

Among the above mentioned areas of action some result from legal obligations and from the necessity to ensure that health legislation is properly implemented and enforced and remains fit for purpose (see objective 3). Actions under objective 1 cover crisis preparedness and management; their necessity is undisputed and their implementation critical for ensuring the good functioning of the Internal Market; in case of severe outbreaks and crises the necessary measures must be taken and resources made immediately available by the programme or through access to the [Emergency Reserve Fund].

The areas of action under objectives 2 and 4, have been assessed as delivering promising outcomes in the ongoing Health Programme (e.g. the European Cancer Information System; the European Reference Networks) and should be pursued and will be expanded in the future Programme absorbing all available budget, allowing long term benefits to be fully deployed, and rolled out to other areas. Some such areas of action are also linked to important Commission initiatives such as the digitalisation of health and care, or the support for structural reforms and innovation discussed at the level of the EU semester. Integrated work on Health Technology Assessment (HTA) – as "piloted" through a series of Joint Actions in past and current programming periods, and provided in the recent

HTA proposal adopted by the Commission¹³⁰ – and on implementation of best practices (selected from the vast repository built through previous programmes¹³¹) are also expected to deliver significant benefits in terms of EU added value.

Instrumental to the pursuit of the objectives above is the work of a number of expert groups such as the Expert Panel on Health and other fora, which brings health stakeholders together ensure close links to support the EU health policy making the Member States, fast access to country-specific knowledge, two-way sharing of relevant information and, most importantly, faster pathways for implementation as well as the independent opinions of the Scientific Committees on consumer safety, on health and environmental risks and on emerging and newly identified health risks.

There is a critical mass of funded projects for each area of action to ensure that the programme will work effectively [and efficiently] for crisis preparedness and management, health systems' improvement and digitalisation, respect of health legal obligations, and further integrated work with the Member States. The 15 thematic areas of action are prioritised based on their EU-added value building on and consolidating the outcomes of the previous health programmes, mainly the 3rd Health Programme.

Concerning subsidiarity and proportionality, the mid-term review of the current programme concluded that most actions deliver useful outcomes with high EU-added value. This conclusion will be a fortiori applicable to the new programme, whose more focused and EU added value oriented intervention logic will allow to concentrate action in areas where Member States acting in isolation cannot achieve the results of action funded at EU level.

In particular, the cooperation at EU level and coordination of preparedness plans and responses to health threats is one of the strongest and best-known aspects of the programme's EU-added value. Activities to support capacity building against health threats have helped to improve Member States preparedness plans and provided for sharing knowledge and expertise and develop coherent approaches to tackle appropriately cross-border health threats, enabling the EU to speak with one voice to the wider international community. The 3rd Health Programme also helped Member States to increase their capacities in various areas, pooling knowledge, expertise and resources across the EU to increase citizens' access to high quality healthcare and to contribute to the reduction of health inequalities both within and between EU Member States.

The 24 European Reference Networks on rare diseases, the collaboration between EU Health Technology Assessment bodies, the support given to the eHealth Network are all illustrations of how targeted EU funding can efficiently mobilise important resources at

¹³⁰ COM(2018) 51 final of 31.01.2018, see at

https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51final_en.pdf

¹³¹ DG SANTE is in the process of establishing a best practices portal that will allow to make available these and other best practices to interested users and in particular for purposes of implementation with the help of the Steering Group on Promotion and Prevention. The portal will be available in April 2018.

Member States level in those areas, and lead to lasting added value, beyond the specific activity. Cooperating, using and sharing knowledge is another thematic area where action has high EU-added value because the collection and analysis of comparable data depicting the situation of health in each of the EU-28 Member States (country-profiles) contribute to an enhanced political dialogue and informed decision making for health policies.

Last but not least, the exchange and implementation of best practice for promoting health and preventing diseases have also a high EU-added value, as they can help Member States in making their health systems more resilient to challenges resulting from demographic changes and the new burdens they create.

The Treaty of Lisbon has enhanced the importance of health policy, stipulating that "a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities" (Article 168 of TFEU). The EU has an important role to play in improving public health, preventing and managing diseases, mitigating sources of danger to human health, including by harmonising legislation on tobacco, medicinal products, medical devices, patients' rights in cross-border healthcare, areas where health regulations are directly linked with the Internal Market (Article 114 of TFEU).

4. DELIVERY MECHANISMS OF THE INTENDED FUNDING

Summary

The Health Programme will continue to use a direct management mode with delegation to CHAFEA, and both grants and public procurement will continue to be used. This ensures full flexibility and implementation of the program allowing funding in a proportionate manner, while offering important potential for economies of scope and of scale. In the case of grants, with a view to simplifying administrative procedures, under certain levels of EU co-funding and for certain categories of beneficiaries, the use of lump sums, unit costs or flat rates grants will be introduced. The participation of beneficiaries from low per-inhabitant GNI Member States will continue to be encouraged through the "exceptional utility" criterion (an increased EU co-funding rate to 80%). Public procurement will be used to acquire services, tools, and studies to support the implementation of legislation and, where appropriate, to purchase goods to achieve specific programme objectives, e.g. strengthening of crisis-preparedness management and response, support integrated work (e.g. for the European Reference Networks-ERNs). Finally, effective and EU swift reaction of the EU e.g. in case of severe outbreaks and health crises, will be funded through a direct access to the Emergency Reserve Fund of the Multiannual Financial Framework.

As for the current health programme, the future one will be implemented in direct management mode with an important part of its implementation entrusted to the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA); the remaining part will be carried out by Commission services. The programme will provide funding (e.g. grants, public procurement, prizes), and be complemented, where appropriate, by new mechanisms (e.g. lump sums, unit costs, flat rates) aiming to achieve programme specific objectives, in particular simplification and reduced cost of controls.

The programme will be open to the [participation][involvement] of third countries when this is necessary to counter cross-border health threats and prevent their spread within the EU.

The implementation of previous Health Programmes has shown that in some circumstances (e.g. below certain levels of EU co-funding or co-funding per beneficiary) the management of grants may entail inadequately high administrative costs for the Commission services and for the beneficiary entities. Moreover, depending on the type (and accounting practices) of the beneficiaries, the complex grant management rules and procedures may increase the risk of irregularities from the side of these beneficiaries and consequently the errors for the programme. To streamline the administrative procedures and reduce the risk of errors and irregularities, simplified forms of grants, such as lump sums, unit costs and flat rates will be used (e.g. for operating grants to non-governmental organisations and ERNs).

Public procurement procedures are used for the acquisition of services, tools, studies to support the implementation of legislation. Where appropriate, they may also be launched to purchase goods such as medical counter measures and equipment in case of health crisis in order to complement Member States capacities in crisis management and response, as well as joint financing of rare diseases therapies in support of the ERNs.

As in previous programmes, other instruments easy to manage in terms of administrative costs, will also be used: prizes (e.g. EU Health Award), membership fees, reimbursement of expert or auditor mission costs, administrative agreements (e.g. with the Joint Research Centre) and cross sub-delegation (e.g. to EUROSTAT for data collection on health-related topics).

The toolkit of delivery mechanisms is flexible enough to allow funding in a proportionate manner and adjusted to the objectives being pursued. It also offers important potential for economies of scope and economies of scale, which enhance the overall effectiveness and efficiency of EU funding. For example, the grants for joint actions can be used in case of pan-European collaboration at a technical and political level when the political momentum is sufficient for results to be applied in practice. They help address health issues when critical mass is needed with the potential for identifying best practices. As such, they do not go beyond what is needed and they complement the Member States policies through, for example, the up-take of identified best practices. Likewise, the *grants for projects* involve different organisations in several Member States, joining forces to perform tasks on a common set of challenges with a trans-national dimension which cannot be effectively addressed in other organisational/institutional settings.

Grants agreements show from past experience that the risks of errors and irregularities can be further reduced through information sessions for applicants where these mitigation measures will contain management rules, audits and on-the-spot checks.

The evaluation of past programmes also showed insufficient participation of beneficiaries from low per-inhabitant GNI countries (below 90% of the EU average per-inhabitant GNI). To facilitate participation of these beneficiaries, "*an exceptional utility*" criterion has been implemented and will continue to be used enabling the increase of maximum EU co-funding rates from 60% to 80% of eligible costs for beneficiaries established in low per-inhabitant GNI countries¹³².

Finally, concerning the *direct grants*, this funding mechanism enables to tap into the unique knowhow of other intergovernmental organisations, such as the OECD, the WHO or the Council of Europe work on European Pharmacopeia, for the purposes of serving the health programmes objectives. One example is the case of the development of a common health information system (including the EU, OECD and the WHO) with data and indicators validated and collected routinely across Member States while seeking to ensure systematically the visibility of EU participation and co-funding.

For effective and EU swift reaction to unforeseen developments, notably in case of severe outbreaks and health crises, the necessary measures for crisis management and emergency response will be funded through an access to the Emergency Reserve Fund of the Multiannual Financial Framework.

5. HOW WILL PERFORMANCE BE MONITORED AND EVALUATED?

Summary

The Commission will put in place arrangements for the monitoring and evaluation of the Programme's performance, notably through proportionate reporting requirements on the beneficiaries of EU funds and by ensuring efficient and timely data collection from complementary sources.

At Programme level, a list of indicators (quantitative whenever feasible and qualitative otherwise) and their associated targets were set out to measure the degree to which the Programmes specific objectives are being achieved.

The monitoring approach is defined. CHAFEA will monitor the implementation and progress of the different Programme actions and their corresponding amounts of EU co-funding per objective, priority, delivery mechanism and year, gathering and analysing available information on outputs and outcomes and where possible the impacts. An optimised, up and running electronic reporting system and standard templates, will serve as main tool for data gathering based on performance indicators and will be supplemented by additional data collected at less frequent rates from other sources (e.g. Eurostat, other Commission services, Member States authorities and their representatives in Committees, National Contact Points).

A mid-term independent evaluation will be carried out, four years after the beginning of implementation of the Programme to assess progress and to recommend possible adjustments and improvements. The final, ex-post evaluation will review and analyse Programme's performance and its outcomes and longer-term impact.

Building on existing processes and tools developed in the 3rd Health Programme, the Commission is developing a monitoring approach and will put in place all arrangements to follow Programme implementation and performance in delivering the results of actions

¹³² The conditions are defined in Article 7.3 of the Regulation (EU) No 282/2014 of the EP and the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020)

in respect to their corresponding objectives. To that end, proportionate reporting requirements will be requested from recipients of EU funds and from the Programme's National Focal Points, supplemented by additional data collected in an efficient and timely manner from other sources (e.g. Eurostat, other relevant Commission services, Member States authorities, targeted surveys). This will enable to collect the required data and information at different points in time using a set of indicators as input to the evaluation of the Programme performance.

Performance monitoring

The Programme supports and complements Member States action in health and healthcare and its success depends on complementarity to and compatibility with Member States' health national plans and strategies. Impacts on the health of population cannot be directly attributable to the only Health Programme for the reason mentioned above, moreover long years are necessary in the scale of a human life and this is not suitable for a seven years Programme. However the Programme creates leverage effects and is decisive for changes and improvements in the national health policies.

The *State of Health in the EU*¹³³, a bi-annual cycle of collection and analysis of data describing the health country profiles and identifying the specific needs of Member States, will be used as basis for evaluating how they are participating in the Health Programme and how they are making use of the financial support for their concrete needs to improve their public health capacity and reform their health systems.

A first step into measuring performance is to clearly communicate the targets of each Programme objective ideally already in the legal basis and inform Member States and potential applicants. Only actions contributing to those targets should be retained in the adoption of the Annual Work Programmes, and the applicants should be able to justify how their proposals add value to these targets and on which basis they can consider that their actions have succeeded or failed. This is important for avoiding past experiences where Programme evaluations have demonstrated that the Programme has had financed a series of individual successful actions but it was not possible to conclude if the Programme has achieved its own objectives.

Objective 1 : Prepare for and counter health crises

The target here is:

- effective deployment resources (more than 90% of resources deployed),
in the event of severe health crises

Objective 2: Empower health systems with emphasis on their digital transformation

The target is :

¹³³ https://ec.europa.eu/health/state/summary_en

- successful synergies with other EU funds and programmes enabling to reach sustainable transformations and reforms, while health systems continue to deliver high quality of health services and health outcomes.

Objective 3: Support EU health legislation

The target is :

- a high degree of transposition and implementation of EU health legislation into the national legal systems measured by regular evaluations

Objective 4: Support integrated work

The target is:

- an increased engagement of Member States in integrated work measured with an indicator resulting from the aggregation of indicators at thematic area of action level.

In the case of HTA, this will be translated by the fact that all Member States can make their citizens benefit from medicines and therapies by accessing/ using qualitative Technology Assessments jointly prepared at EU level with minimum cost (economies of scale);

In the case of ERNs, this will be translated by the fact that rare diseases patients independently of where they are living in the EU can have access to rapid diagnosis and treatment;

In the case of implementation of best practices, citizens can benefit from improved national health programmes that have integrated the best available scientific evidence. This will result in the long term to economies for the health systems and in longevity and healthier life years for the individuals.

Currently, the Commission is working with the help of external contractors to find the most appropriate (quantifiable if possible) indicators at the level of operational thematic areas for an improved monitoring system (see table below). This system, managed by the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA), will ensure the follow up of the implementation of the co-funded actions and support the monitoring of the Programme as a whole. A measure of success of the entire programme could be represented by the capability to create synergies with other EU programmes; appropriate indicators will be developed.

An overall indicator "Integrated work engagement strength" based on the aggregation of the indicators measuring the thematic areas of action under the specific objective "

Support integrated work" is suggested for measuring the health dimension of the Single Market Programme.

Monitoring arrangements

The Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) will ensure continuous monitoring of the Programme.

The *CORDA system* implemented by the Common Support Centre will centralise the results collected for all actions monitored through the use of the Horizon 2020 IT tools. It will be the key source of information for the evaluations of the future Programme and for the provision of policy feedback on the attainment of the Programme objectives and priorities, the types of actions and types of organisations co-funded. Additional data, for actions still remaining outside the Horizon 2020, including through forthcoming eProcurement IT tools will be incorporated in a single dashboard, enabling close to real-time monitoring and reporting.

This comprehensive Programme monitoring will ensure early detection of risks and possible deviations from target and timely adjustments, mitigation and corrective actions.

Further information will be gathered through data collected (e.g. statistics, surveys, specific studies/reports) at less frequent rate from other sources among which, Eurostat, the Joint Research Centre (JRC), other Commission Services, Member States authorities, Committees of Member States' Representatives, the National Contact Points (NCPs).

Concerning the preparation and countering of health crises and the support to EU legislation objectives, the main outcomes and impacts (preparedness plans, deployment of resources in case of health crises including availability of countermeasures, degree of national transposition of EU legislation) will be compiled by the responsible Commission services, on the basis of information received from Member States' authorities or from Members States' Representatives in relevant Committees.

The WHO monitoring process involves the assessment of implementation of International Health Regulations (IHR) core capacities (e.g., legislation and policy, coordination, surveillance, response, preparedness, risk and crisis communication, human resources, laboratory, events at points of entry), through a checklist of indicators using a composite measure based on capability indicators.

Programme evaluation and other reporting obligations

Every year, an analysis of progress on key dimensions of the Programme management and implementation will be published by the Commission services in the form of an annual implementation report which will be communicated to the European Parliament and the Council.

The Programme performance will be assessed through a mid-term review evaluation (4 years after the start of the Programme implementation) carried out by external and independent contractors with a focus on the implementation that far and actions' outputs or immediate results, progress towards the objectives of the Programme and recommendations for possible adjustments and improvements.

The period of four years is the minimum duration necessary before communicating on the mid-term review, as the majority of the funded actions have a three years period life

and at least 10 months are necessary for an external evaluation study to assess the first actions funded by the Programme.

A final, ex-post evaluation will be conducted by independent external contractors, at the end of the Programme to review its performance and final results as well as to assess its outcomes and longer-term impact.

| Health Programme | | | | | | | |
|---|---|--|---|--|---|--|---|
| Specific Objective & Actions | Indicator | Definition | Type of the indicator (quantitative or qualitative) | Source of data | Frequency of measurement | Baseline | Target (by end of the Programme) |
| 1. Prepare for and counter health crises¹³⁴ | Quality of EU response to future health crises -improvement | Assessment of the quality of EU response to future health crises, and in particular, in terms of observed improvement in comparison with previous crises | Qualitative | Evaluation/assessment reports prepared by the Commission and by EU other institutions or by relevant International Organisations, drawing lessons from previous crises | Depends on occurrence of severe health crises | Situation during the Ebola crisis: EU response mechanisms demonstrated added value, but lessons learnt from experience and capacity gaps were also highlighted | Improvement in the management of future cross-border health crises in comparison with previous occurrences |
| 1.1 Capacity-building measures for crisis preparedness, management and response | a. Quality & completeness of national preparedness plans | Availability, quality and completeness of preparedness plans and extent to which Member States have put them in place to counter future health threats, as shown by the transmission of these plans to the Health Security Committee and their subsequent analysis by the Commission | Quantitative/qualitative | Commission/DG SANTE/Health Security Committee (HSC) | Annual | Situation in year 2020, as regard quality and completeness of national preparedness plans | 90% of Member States reporting full compliance with the International Health Regulations, through annual reporting to WHO |
| | b. Level of uptake of tools by professionals/practitioners | Adoption and implementation by professionals and practitioners in Member States of tools developed during capacity building and other | Quantitative/qualitative / | Assessment by Commission/DG | Annual/permanent | Situation in year 2020 | Good to very good level by all MS Specific target will depend upon the |

¹³⁴ This has to be understood as every potential crisis with a health dimension.

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| | | knowledge sharing exercises (e.g. percentage of messages of those supposed to be transmitted through the Early Warning and Response System – EWRS) | level | SANTE/HS C | | | severity of case/issue/outbreak addressed (e.g. Ebola, Influenza) |
| 1.2 Response to cross-border health threats during crisis | a. Availability of vaccines and countermeasures during crises | Level of availability in terms of quantity and quality of vaccines and other medical countermeasures to be used during disease outbreaks and crises with health dimension obtained through joint procurement or any other mechanism supported by the Health Programme | number | Commission/DG SANTE | Annual/permanent | Situation in 2020: number of available medical countermeasures | Availability across EU of 3 additional vaccines/countermeasures at end of the Programme |
| 1.3. Support laboratory capacity | a. EULabCap index | EULabCap index is an aggregated index resulting from the annual survey carried out by the European Centre for Disease Prevention and Control – ECDC. The aggregated index provides a robust EU-wide assessment of collective laboratory capacity | Number – on a scale of 0-10 | The EULabCap survey methodology developed by the European Centre for Disease Prevention and Control – ECDC – Annual EULabCap Report released by ECDC | Annual | In 2015, the EULabCap aggregate index for EU/EEA was 7.5 on a scale of 0-10 | Regular increase of the aggregated EULabCap index |
| | b. Number of laboratories participating in Joint Actions | Number of laboratories participating in Joint Actions launched by the Programme with the aim to support laboratory capacity | Quantitative (number) | Beneficiaries of the grant agreements concluded in the context of the Joint Actions to support laboratory | Annual | 37 associated / collaborating partners from 25 European countries are participating in EMERGE Joint Action | expanding the involvement of relevant laboratories across the EU – 10 new members by 2028 covering most Member States + relevant partner countries |

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|--|---|---|-------------|--|-----------------------------|--|---|
| | | | | capacity | | | |
| 2. Empower health systems with emphasis on their digital transformation | Decrease in the costs related to management of information, resulting from increased digital transformation of health systems | EU-wide assessment of the decrease of the costs of management of information, linked with increased digital transformation of health systems | number | Comprehensive study to be carried out by Joint Research Centre – JRC, with a view to assessing, among others, the reduction of costs of management of the information, resulting from increased digitisation of health systems | multiannual | Situation in 2020: estimate of costs of information management by health systems, derived from the planned Study | Reduction, at the end of the Programme, by 20% of information management costs as compared to baseline |
| 2.1 Support the digital transformation of health and care | Number of eHealth solutions or tools up-taken and implemented in Member States' health systems | Number of eHealth solutions or tools up-taken and implemented in Member States' health systems per million euros invested from the Health Programme's budget | number | Member States, National contact points – NCPs, surveys | Annual/permanent | Situation in 2020 | At least 1 case of eHealth solution or tool up-taken and implemented per million euros invested from the Health Programme, over the duration of the Programme 2021-2028 |
| 2.2 Support the development of a sustainable EU health information system | Health networks sustainability | Depending on their needs and priorities, the sustainability of current and future networks on health information is defined in this context by their ability to continue their operations after the end of co-funding from the Health programme budget; | qualitative | Ad hoc report or survey carried out by Commission Services or by an external organisation acting on | At the end of the Programme | situation in 2020 | Sustainability of health information networks at end of the Programme, by 2028 |

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| | | | | behalf of Commission services | | | |
| 2.3 Support the national reform processes for more effective, accessible and resilient health systems | Number of health-related recommendations coming from the EU Semester process that are successfully addressed, with the support of the Health Programme (or of the ESF+ Programme) | Number of health-related recommendations coming from the EU Semester process that are successfully addressed, with the support of the Health Programme (or of the ESF+ Programme) | number | EU Semester Process, Commission services | Annual | In 2017, EU Semester country-specific recommendations related to health systems were issued to nine Member States | At least one country-specific recommendation relating to health systems successfully addressed, with support of the Health Programme (or of the ESF+ Programme) ¹³⁵ |
| 3. Support EU health legislation | Degree of transposition of EU health legislation into the national legal systems measured by regular evaluations | Degree of transposition of legislation into national laws/regulations and legal systems. The degree of transposition is measured among others by regular reports, some of which are foreseen in the concerned legal acts. | qualitative | Commission/MS authorities/ Evaluation reports | Frequency in accordance with the provisions in the relevant legal acts | Situation in 2020, as will have been assessed by the Commission and Member States | High degree of transposition by all Member States |
| 3.1. Manage, maintain and implement the legislation on medical devices | Percentage of Member States which have implemented the EU legislation in the field of medical devices in their national legal system | Percentage of Member States which have implemented the EU legislation in the field of medical devices in their national legal system, as reported by successive evaluation reports | percentage | Commission/MS authorities/ Evaluation reports | Same as the frequency provided for in the legal act | Situation in 2020, as will have been assessed by the Commission and Member States | 90% of Member States having implemented the EU legislation in the field of medical devices at the end of the Programme |
| 3.2. Support the implementation of Union legislation on medicinal products and on Health Technology | a. Number of projects by the Biological Standardisation Programme (BSP) for the quality control of biologicals | Number of projects by the Biological Standardisation Programme (BSP) for the quality control of biologicals. The activities by biological standardisation program ensure the independence of tests on biologicals, allows comparison | number | Commission/MS authorities/ Evaluation reports | Annual | 118 projects finalized since its inception, 4 | Around 4 BSP projects concluded annually |

¹³⁵ To be confirmed by the responsible operational unit

| | | | | | | | |
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| Assessment | | of tests, ensures high quality biologicals and aims to reduce animal testing in the EU. | | | | in 2016 | |
| | b. Number of Regulatory Members from Member States joining the ICH | Number of Regulatory Members from the Member States joining the ICH and implementing its guidelines | number | Commission/MS authorities | Annual | Situation in 2020, as provided by Commission services' evaluation | Regulatory Members from 14 additional Member States joining the ICH and implementing its guidelines at the end of the Programme |
| 3.3. Monitor and support Member States in their implementation of legislation in the area of substances of human origin (SoHO) | Percentage of Member States which have implemented the EU legislation in the field of substances of human origin (SoHO) in their national legal system | Percentage of Member States which have implemented the EU legislation in the field of substances of human origin (SoHO) in their national legal system, as reported by successive evaluation reports | percentage | Commission/MS authorities/ Evaluation reports | Same as the frequency provided for in the legal act | Year 2020 | 90% of Member States having implemented the EU legislation in the field of substances of human origin (SoHO) at the end of the Programme |
| 3.4. Support the implementation of tobacco legislation | Percentage of Member States which have implemented the EU legislation in the field of tobacco in their national legal system | Percentage of Member States which have implemented the EU legislation in the field of tobacco in their national legal system, as reported by successive evaluation reports | percentage | Commission/Member States Authorities | Same as the frequency provided for in the legal act | Situation in 2020, as provided by Commission services' evaluation | 90% of Member States having implemented the EU legislation in the field of tobacco at the end of the Programme |
| 3.5. Support the implementation of Union legislation in the area of cross-border healthcare | Percentage of Member States which have implemented the EU legislation in the field of cross-border healthcare in their national legal system | Percentage of Member States which have implemented the EU legislation in the field of cross-border healthcare in their national legal system, as reported by successive evaluation reports | percentage | Commission/MS authorities/ Evaluation reports | Annual or at least at frequency provided for in relevant legal act | Situation in 2020, as provided by Commission services' evaluation | 90% of Member States having implemented the EU legislation in the field of cross-border healthcare at the end of the Programme |
| 3.6. Support to the Commission' scientific committees on "Consumer Safety" and on "Health, | Number of scientific opinions issued and approved | Number of scientific opinions issued and approved by the Commission's scientific committees | number | Commission | Annual | 30 opinions finalized since 2016 | Continuous number of opinions in line with recent values: 10/year, (if the average number of issues arising in a given year is higher than 10) or all arising issues receiving a scientific opinion, in case their average annual |

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| Environmental and Emerging Risks" | | | | | | | number is less than 10. |
| 4. Support integrated work | Strength of integrated work engagement | The Strength of integrated work engagement indicator will be based on an equal weighting aggregation of the indicators of the 3 operational priorities below ¹³⁶ : ERNs, HTA, and Implementation of Best Practices | number | Commission/DG SANTE/C HAFE A | Annual | Situation in 2020 | Increase of the composite indicator by 20% at the end of the Programme |
| 4.1.ERNs | Number of patients supported by ERNs | Number of patients which were diagnosed and treated by ERN networks | number | Commission/DG SANTE/C HAFE A | Annual | Number of patients that made consultations in ERNs by 2020 | Early in its development, target to be established in 2020 |
| 4.2.HTA. | a. Transitional period. coordination level | Number of Member States which have joined the Coordination Group as members in the transitional period. | percentage | Commission/DG SANTE/N CPs | Annual | Situation in 2020, as provided by Commission services' evaluation | Increase by 20% ¹³⁷ |
| | b. Number of joint clinical assessments on medicinal products and on medical devices | Number of clinical assessments jointly carried out | number | Commission/DG SANTE/N CPs | Annual | Situation in 2020, as provided by Commission services' evaluation | 50 HTA |
| 4.3.Implementation of best practices | a. Number of best practices transferred per million of € invested | Number of best practices transferred to Member States (receiving MS) per million of € invested from the Health Programme | number | Commission/DG SANTE/N CPs/ad hoc survey | Annual | Situation in year 2020, as provided by estimations relating to the 4 th Health | na ¹³⁸ |

¹³⁶ The detailed aggregation methodology for defining the composite indicator from the indicators requires further information and data analysis in order to be finalised

¹³⁷ To be confirmed by responsible operational unit: applicable only before the adoption of HTA legislation. Once HTA legislation is adopted, the relevant indicator will be addressed under the *Support to EU health legislation* specific objective

¹³⁸ Due to lack of experience, the target will be set up in 2020, when more information and data become available

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| | | | | | | programme | |
| | b. Percentage of EU population of the geographical territory in which each best practice is transferred | Percentage of EU population of the geographical territory in which each best practice is transferred | percentage | Commission/DG Sante/NCPs/ad hoc survey | Annual | No baseline available | Maximizing the percentage of EU population of the geographical territory in which each best practice is transferred, with a target of at least 5% |
| Overall Programme Indicator | Reduction of the difference between the 5 best performing Member States (MS) in terms of Mortality rate and the 5 worst performing MS | Reduction of the difference between the 5 best performing Member States (MS) in terms of Mortality rate and the 5 worst performing MS | Quantitative | Commission/Member States/Health Security Committee | Frequency of available data in Eurostat's Database | Situation in 2020 | Reduction of observed inequality by 20% |

Sub-Annex 1: Evidence, sources and quality

6. EVIDENCE, SOURCES AND QUALITY

Summary for the main IA text:

The present impact assessment has been prepared on the basis, on the one hand, of information collected from the continuous implementation monitoring of the Health Programme, and on the other, of evidence and results from the independent evaluations of previous health programmes (e.g. final evaluation of the 2nd Health programme 2008-2013 and the mid-term evaluation of the ongoing 3rd Health Programme 2014-2020). For improved quality and robustness, the above primary sources have been supplemented and cross checked with additional evidence gathered from relevant audit and evaluation reports of certain components of the Programme (e.g. Decision EC 1082 on Cross-border threats to health), by opinions of experts groups established by the Commission (Scientific and Programme Committees, Expert Group on Effective Ways of Investing in Health) or from international organisations (WHO, OECD), and by synergies/complementarities with recent policy developments and finally by a specific study launched in order to gather additional evidence and close existing information gaps.

The systems put into place for the monitoring and management of previous health programmes enabled to efficiently collect data on various aspects of the implementation, including the type of actions, the types of beneficiary organisations, amount of EU co-funding.

Information and evidence from programme monitoring and management include deliverables and assessment of results at action level, enabling to measure the success of each funded action and its contribution to the overall objectives of the programmes.

The deliverables and results at action level feed into the dissemination plan at programme level and provide the opportunity to extract and present showcases of success showcases from which broader lessons can be drawn, as feedback and input to future actions/programmes.

The mid-term and final (ex-post) evaluations of the previous programme conducted by external independent contractors/organisations provided reliable evidence and necessary input to the preparation of the impact assessment of the subsequent Programme.

In this respect, the present impact assessment builds on evidence gathered from the mid-term evaluation of the 3rd Health Programme (2014-2020), carried out in 2017 (link to be added) and from of final (ex-post) evaluation of 2nd Health Programme (2008-2013) issued in 2016.

The robustness and quality of information derived from Programme monitoring and from mid-term and final evaluations has been assured by cross-checking with complementary evidence from independent other evaluations or audits of specific components of the Programme, such as the special report issued in 2016 by the European Court of Auditors on cross-border threats to health in the EU and the Commission report to the European Parliament and to Council on the implementation of Decision No 1082/2013/EU.

Robustness and quality can also be increased by taking into account reports and opinions delivered by other EU institutions (e.g. Council Recommendations on Vaccination, on AMR, and on lessons learned from the Ebola and Zika crises; European Parliament Resolutions on health-related issues and on specific aspects of the Health Programme).

In addition to opinion of the Members of the 3rd Health Programme Committee, the impact assessment took into account the opinion of Scientific Committees and advice from experts groups at EU-level (Expert Panel on Effective Ways of Investing in Health; Expert Groups represented in the EU Health Policy Platform) or in international organisations (cooperation with WHO, on the implementation of IHR and with OECD on health information and State of Health in the EU cycle).

At Commission level, the impact assessment included by up-to-date evidence from new policy developments and opportunities of synergies offered such developments (e.g. Action Plan on AMR, Digital Single Market Communication, and Communication on Vaccination, under-preparation).

Finally, in order to close remaining information gaps, the Commission launched a study on gathering with a view to analysing the impacts of possible actions in the future Health Programme and to proposing a programme monitoring and evaluation framework.

Sub-Annex 2: Stakeholder consultation

Summary for the main IA text:

In addition to the IMP public consultation launched during the 1st quarter of 2018, open consultations were carried out from November 2016 to February 2017 in the context of the mid-term evaluation of the 3rd Health Programme. Stakeholders participated in the mid-term evaluation of the 3rd Health Programme through these consultations, including an open public consultation which covered aspects relating to the relevance, added value, efficiency, effectiveness, and coherence of the programme. This served, notably, as input to the preparation of the impact assessment of the Health Programme post 2020.

In the open public consultation Member States and EU stakeholders provided an overwhelming support for EU health policies confirming that the cooperation in the area of health is essential and should be maintained (70%).

The EU should continue supporting important health-related challenges facing EU citizens, governments and health systems reflected in the formulation of the Programme's objectives.

In addition to the IMP public consultation launched during the 1st quarter of 2018, open consultations were carried in the context of the mid-term evaluation of the 3rd Health Programme. Stakeholders participated in the mid-term evaluation of the 3rd Health Programme through these consultations¹³⁹, including an open public consultation which covered aspects relating to the relevance, added value, efficiency, effectiveness, and coherence of the programme. This served, notably, as input to the preparation of the impact assessment of the Health Programme post 2020.

The consultations, carried out from November 2016 to February 2017, engaged institutional stakeholders, notably the Programme Committee members and National Focal Points and grant beneficiaries. The stakeholders involved in the funded activities, especially non-governmental organisations, public health authorities, academic and research organisations, international organisations, professional associations, private companies and individual persons were also consulted through the open public consultation.

In addition, targeted on-line consultations with public health experts and e-surveys with National Focal Points and Programme Committee members were conducted as part of the external evaluation study. These were complemented by targeted interviews of Commission and International Health Organisation officers, and grant recipients (beneficiaries), mainly project leaders and coordinators of actions funded under the Programme.

In the open public consultation Member States and EU stakeholders provided an overwhelming support for EU health policies confirming that the cooperation in the area of health is essential and should be maintained (70%).

The EU should continue supporting important health-related challenges facing EU citizens, governments and health systems reflected in the formulation of the Programme's objectives.¹⁴⁰

¹³⁹ The results of the consultation activities are presented in the Annex V of the SWD (2017) 331 final of 11.10.2017) on

¹⁴⁰ The results of the Open Public Consultation are publicly available on https://ec.europa.eu/health/funding/consultations/midterm_evaluation_en

Sub-Annex 3: Evaluation results

Summary for the main IA text:

The programme evaluations carried out are as follows:

Mid-term Evaluation of the third Health Programme (2014 – 2020),
Report on the implementation of Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health, released in 2015,
Ex-post Evaluation of the second Health Programme (2008 – 2013) released in 2016,
Mid-term Evaluation of the second Health Programme (2008 – 2013) released in 2011,
Ex-post evaluation of the (first) Public Health Programme (PHP) 2003-2008 released in 2011
Mid-term evaluation of the (first) Public Health Programme (PHP) 2003-2008, released in 2007

The programme evaluations carried out are as follows:

Mid-term Evaluation of the third Health Programme (2014 – 2020)¹⁴¹ released in 2017

Report on the implementation of Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health¹⁴²

Ex-post Evaluation of the second Health Programme (2008 – 2013)¹⁴³ released in 2016

Mid-term Evaluation of the second Health Programme (2008 – 2013)¹⁴⁴ released in 2011

Ex-post evaluation of the (first) Public Health Programme (PHP) 2003-2008¹⁴⁵ released in 2011

Mid-term evaluation of the (first) Public Health Programme (PHP) 2003-2008¹⁴⁶, released in 2007

¹⁴¹ https://ec.europa.eu/health/sites/health/files/programme/docs/2014-2020_evaluation_study_en.pdf

¹⁴² https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/report_decision_serious_crossborder_threats_22102013_en.pdf

¹⁴³ https://ec.europa.eu/health/sites/health/files/programme/docs/ex-post_ev-hp-2008-13_final-report.pdf

¹⁴⁴ https://ec.europa.eu/health/sites/health/files/programme/docs/mthp_final_report_oct2011_en.pdf

¹⁴⁵ https://ec.europa.eu/health/sites/health/files/programme/docs/ex_post_evaluation_en.pdf

¹⁴⁶ http://ec.europa.eu/health/archive/ph_programme/documents/evaluation/php_evaluation_en.pdf

Annex 17: Programme specific annex on *Food Chain Programme*

Glossary

| <i>Term or acronym</i> | <i>Meaning or definition</i> |
|---|---|
| Prerogative spending / Prerogative budget line | |
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| Legal Basis | |
| Legal Act | |
| Basic Act | |
| Programme | |
| AGRI | Directorate-General for Agriculture and Rural Development |
| AMR | Antimicrobial Resistance |
| BSE | Bovine spongiform encephalopathy |
| BTSF | Better Training for Safer Food |
| CAP | Common Agriculture Policy |
| CCP | Coordinated Control Plans |
| CHAFEA | Consumers, Health, Agriculture and Food Executive Agency |
| COMP | Directorate-General for Competition |
| DIGIT | Directorate-General for Informatics |
| ECDC | European Centre for Disease Prevention and Control |
| EFSA | European Food Safety Authority |
| EMA | European Medicines Agency |
| EU | European Union |
| EURCs | European Reference Centres |
| EURLs | EU Reference Laboratories |
| FISMA | Directorate-General for Financial Stability, Financial Services and Capital Markets Union |
| JRC | Joint Research Centre |
| MFF | Multiannual Financial Framework |

| | |
|---------------------------------------|---|
| NRL | National Reference Laboratories |
| SANTE | Directorate General for Health and Food Safety |
| SARS | Severe acute respiratory syndrome |
| SDGs | Sustainable Development Goals |
| TFEU | Treaty on the Functioning of the European Union |
| UN | United Nations |
| Better Training for Safer Food (BTSF) | Better Training for Safer Food (BTSF) is a Commission training initiative covering food and feed law, animal health and welfare and plant health rules. |
| Bovine spongiform encephalopathy | Bovine spongiform encephalopathy (BSE), commonly known as mad cow disease is a transmissible spongiform encephalopathy and fatal neurodegenerative disease in cattle that may be passed to humans who have eaten infected flesh. |
| Budget line | A Budget line is a graphical representation of all possible combinations of two goods which can be purchased with given income and prices, such that the cost of each of these combinations is equal to the money income of the consumer. |
| Comitology | Comitology refers to a set of procedures through which EU countries control how the European Commission implements EU law. Broadly speaking, before it can implement an EU legal act, the Commission must consult, for the detailed implementing measures it proposes, a committee where every EU country is represented. |
| EU Reference Laboratories | EU Reference Laboratories (EURLs) aim to ensure high-quality, uniform testing in the EU and support Commission activities on risk management and risk assessment in the area of laboratory analysis. |
| One Health Approach | One Health: is a term used to describe a principle which recognises that human and animal health are interconnected, that diseases are transmitted from humans to animals and vice versa and must therefore be tackled in both. The One Health approach also encompasses the environment, another link between humans and animals and likewise a potential source of new resistant microorganisms. This term is globally recognised, having been widely used in the EU and in the 2016 United Nations Political Declaration on AMR. |
| Sustainable Development Goals (SDGs) | <p>The 17 Sustainable Development Goals (SDGs) and their related 169 targets, which are at the heart of the UN's 2030 Agenda for Sustainable Development, provide a new policy framework worldwide towards ending all forms of poverty, fighting inequalities and tackling climate change.</p> <p>The adoption of the 2030 Agenda and its SDGs represent a change of paradigm of the international policies on development cooperation. The EU has committed to implement the SDGs both in its internal and external policies. For more details see <i>The Sustainable Development Goals</i> available at https://ec.europa.eu/europeaid/policies/sustainable-development-goals_en</p> |

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

1.1. Scope and context

Summary

Regulation (EU) No 652/2014¹⁴⁷ establishes a common financial framework (hereafter “the CFF Regulation”, or the “Food Chain Programme”)) for the management of the food chain spending over the 7-year programming period 2014-2020. The ceiling for expenditure for the whole period is established at EUR 1 891 936 000.

The Food Chain Programme covers both veterinary (animal) and phytosanitary (plant) measures, through either annual or multiannual programmes pre-approved by the Commission, and through emergency measures implemented to ensure a decisive response in the event of crises situation and unforeseeable events affecting animal or plant health. A number of official control related activities aimed to enhance the safety of EU food products and the correct application of food chain requirements are also financed at EU level, such as training for enforcement officials, a coordinated approach to testing and analyses through the activities of the EU Reference Laboratories, relevant studies and IT systems. This package of measures ensures that the EU has a credible framework of legislation and controls to promote high levels of safety along the entire food supply chain, creating in turn the conditions for a stable internal market where food, animals and plants can circulate freely.

Provisions for the management of the EU food chain expenditure for the 2014-2020 period are laid down in Regulation (EU) No 652/2014. The EU spending in this area, which mostly takes the form of direct (co-)financing to the Member States, covers veterinary measures, phytosanitary measures and official control related activities.

Animal health and plant health measures impact at several different levels, with specific actions depending on the prevalence of the (animal) disease or (plant) pest concerned in the EU territory. This cycle develops around four main pillars: (i) prevention; (ii) surveillance and early detection; (iii) rapid reaction; and (iv) eradication. If a disease or a pest is not present in the EU, but there is a risk that it could enter its territory, prevention measures are put in place to avoid its introduction. For some strategic diseases a vaccine stock ("vaccine bank") is also established at EU level to be immediately used in case of emergency situations. If a specific disease or pest is more likely to enter or has already entered the EU, surveillance activities are put in place to, respectively, timely detect its introduction or assess its epidemiological evolution since the initial outbreak(s). Early detection is of fundamental importance especially in the case of certain animal diseases

¹⁴⁷ REGULATION (EU) No 652/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC
<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0652>

which, once entered, may have a potential devastating effect on animal production and/or on public health, leading also to extensive trade disruption and economic losses. In case an outbreak occurs, early reaction measures are immediately implemented to contain the spread of the disease or the pest and to eradicate the outbreak. This is done in order to minimize the impact on, for instance, plant and animal production and trade. When a disease or a pest is endemic in the Union territory, a number of eradication activities are put in place to progressively eliminate it in the concerned area.

The funding of official control related activities covers a wide range of measures, including training programmes for enforcement staff in the Member States and in non-EU countries exporting to the EU (the “Better Training for Safer Food” initiative, which trains every year 7000 enforcement staff), the activities of 45 EU Reference Laboratories', which ensure high-quality and uniform testing in the EU, and provide training to hundreds of National Reference Laboratories (NRL) in a number of priority areas; Coordinated Control Plans (EU-wide coordinated controls to ascertain compliance across the EU with certain specific requirements, e.g. a specific plan directed at verifying the adulteration of honey, or the presence of undeclared ingredients in certain foodstuffs); studies and evaluations, and a number of important IT systems that enable enforcement authorities to trace foods subject to specific health requirements, to exchange in real time notifications concerning the emergence of a risk along the chain (for the health of humans, animals, plants), to inform and support one another in taking measures necessary to counter such risk, and to cooperate across borders on a daily basis in case of cross border violations (including those resulting from fraudulent and deceptive practices).

In line with the Commission's vision for the post-2020 financial framework¹⁴⁸, the technical and financial support provided at EU level for the implementation of the food chain activities contribute to help primary producers and the food industry to provide a safe and high-quality food supply, produced in a sustainable way at affordable prices for more than 500 million Europeans, while respecting the requirements for plant health, for animal health and welfare, and for the protection of the environment. The continuous improvement of the animal and plant health status in the EU also helps promote market access for EU food producers, contributing to the increase of exports and confirming the agri-food industry as a leading sector of the EU economy.

1.2. Lessons learned from previous programmes

Summary:

The measures receiving technical and financial support under the Food Chain Programme contribute to a safe and secure EU food supply chain, which is prosperous and sustainable, and strong on the global scene. Ensuring a high status of human, animal and

¹⁴⁸ https://ec.europa.eu/commission/publications/reflection-paper-future-eu-finances_en

plant health, these activities help to protect more than 500 million European citizens, and provide a solid foundation based on high levels of safety for the trade in agri-food products both within the internal market and with third countries.

Overall, the recently conducted mid-term evaluation revealed that the Regulation is functioning well within its policy context. All activities receiving EU financial support in this area have proven to serve the Food Chain Programme objectives as well as the Commission's overall priorities, including the functioning of an effective internal market and the support to trade with non-EU countries.

Nevertheless, some areas of concern are identified. Particularly, a specific mechanism to access a reserve for crises in case of large-scale emergencies needs to be identified; the monitoring system is to be improved and integrated with a cost-effectiveness analysis; the current grants system needs to be simplified, and the plant health funding strengthened.

The first three years of implementation of the common financial framework for the food chain (established by Regulation (EU) No 652/2014), namely the period 2014-2016, were assessed in the context of a mid-term evaluation exercise¹⁴⁹, whose scope included all spending areas expected to be covered by the next food chain programme.

Overall, the mid-term evaluation revealed that the programme is functioning well. All activities receiving EU financial support in this area have proven to serve the programme's objectives, namely the improvement of human, animal and plant health, as well as the overall Commission's priorities, including the functioning of an effective internal market and the support to trade with non-EU countries.

Based on the analysis performed, it was concluded that the majority of the activities covered by the programme proved to be effective in achieving their objectives, and showed progress in the indicators used to monitor the food chain measures implemented. Overall, the use of EU resources is efficient and consistent with the results achieved. Particularly, in the veterinary area, the improvement of the animal health status is accompanied by a progressive and significant reduction of the financial resources needed, allowing for resources to be re-deployed to address new priorities. The measures co-financed by the Food Chain Programme strongly contribute to creating EU added value: Member States benefit from the prioritised and targeted implementation of EU co-funded activities, especially for emergency, eradication, control and monitoring measures for animal diseases and plant pests throughout the Union. The EU financial provisions on

¹⁴⁹ REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Mid-term evaluation of Regulation (EU) No 652/2014 of the European Parliament and of the Council laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material [...] (COM(2017) 546 final) and accompanying staff working documents (SWD(2017) 314 final, SWD(2017) 315 final, and SWD(2017) 316 final).
https://ec.europa.eu/food/sites/food/files/cff_mid-term-evaluation_comm_report_en.pdf
https://ec.europa.eu/food/sites/food/files/cff_mid-term-evaluation_staff_work_doc_en.pdf
https://ec.europa.eu/food/sites/food/files/cff_mid-term-evaluation_exec_sum_en.pdf
https://ec.europa.eu/food/sites/food/files/cff_mid-term-evaluation_synopsys_report_en.pdf

animal health have been recognised, notably by the European Court of Auditors, as uniform and consistent in their application and enforcement in all EU Member States.

The Food Chain Programme has proven to be flexible to address emerging needs for co-financing especially in the occurrence of outbreaks. It also has proven to be coherent with other EU and national policies in the area of food safety. In this context, it has to be recalled that the CFF Regulation serves the financing needs of a comprehensive and broad part of the EU legislative framework (the food chain *acquis*), composed of important sectorial acts (on animal health, welfare, on plant health, on food and feed safety, food and feed additives, on hygiene requirements, just to name the most important ones). This opens the possibility to provide financial support to a quite substantial range of operational measures (listed in the CFF Regulation). Mostly the Food Chain Programme provides incentives which act as a catalyst for more substantial efforts by the Member States in the overall EU interest. This support also serves as a real example of EU solidarity (EU and the Member States) which in turn promotes an EU model for risk protection along the food chain.

In addition, the Food Chain Programme offers the possibility for providing financial support to measures which are not listed under the eligible costs in the Regulation itself; the formulation of this provision is very broad, as it generally refers to the possibility to fund additional measures in the animal and plant health areas "in exceptional and duly justified cases" such as awareness campaigns to inform all the concerned parties in case of outbreaks to further boost the measures implemented to fight against animal or plant diseases. To date, such requests have come from several Member States, confirming the flexibility and coherence of the CFF Regulation with other related EU programmes. The mid-term evaluation, in fact, concluded that requests in this sense could be considered as evidence of the fact that EU intervention in these areas already addresses all relevant needs and might be extended to other areas covered by the Regulation. A clear example of synergy between programmes covering complementary areas concerns primary agriculture and, more specifically, the interaction between the provisions of the CFF Regulation and the Common Agriculture Policy (CAP) Regulation in the event of an outbreak. While the CFF addresses eligible direct costs incurred to tackle animal diseases and plant pests, such as the compensation to owners, the costs of vaccination, and the slaughtering of animals or the culling of trees, the CAP has provisions to contribute to covering some indirect costs, such as market losses suffered by farmers.

In addition, the possibility should be noted to include under Horizon 2020 research projects to further improve knowledge of specific animal and/or plant diseases as well as new tools such as vaccination. This is another example of synergy between programmes covering complementary areas.

Also the outcome of the consultation process in the context of the mid-term evaluation¹⁵⁰ revealed a large appreciation of the EU financial contribution in those areas. This exercise mostly included an open public consultation and a targeted on-line stakeholder consultation, further complemented by targeted interviews of different stakeholders' representatives. There was general agreement among stakeholders that funding opportunities provided by the CFF regulation in the area of animal health are an essential tool to ensure disease prevention and the timely and efficient control of animal diseases. An overall call for specific attention to preventive measures was expressed.

Among the main achievements resulting from the long-term impact of the measures implemented even before 2014, a good example is the eradication of Bovine Spongiform Encephalopathy in cattle¹⁵¹, a disease which is transmissible to humans through the consumption of contaminated beef products. The long-term EU co-financing against this disease resulted in a drop in the number of positive cases from more than 2000 in 2001 to 5 cases only in 2016, getting close to its complete eradication. Another good case concerns rabies, an important zoonosis¹⁵² which has been almost eradicated in the EU in wildlife (complete eradication is expected by 2020), with the number of cases falling from 726 in 2010 to only 18 in 2016. A fall of the infections in poultry population (such as laying hens) by salmonella spp. has also been achieved following the implementation of EU co-funded salmonella control programmes. This has led also to benefits in terms of human health, as salmonellosis is an important zoonosis, (one of the main causes of human contamination is the consumption of eggs). The incidence of confirmed human cases decreased from 105.450 in 2010 to 94.600 in 2015.

From the administrative point of view, the CFF Regulation was envisaged to modernise and simplify the pre-existing financial provisions. The scope for simplification and rationalisation was addressed by: replacing the previous legal framework, over-complex and often out-of-date, with a single piece of legislation covering the whole food chain area; rationalising the funding rates, with the definition of three standard rates only, namely: 50%, 75% and 100%; aligning the procedures in the phytosanitary and veterinary fields under a harmonised framework to ensure clarity, transparency and a sound regulatory environment; reducing the use of Comitology and Commission Decisions in order to shorten the time for contract and payment.

An additional step towards the overall simplification of the system was the introduction of a unit cost system used for reimbursing the activities carried out to implement veterinary programmes. The new system was perceived by both the Commission and the Member States as facilitating the request for funding and for reimbursements. To date, it

¹⁵⁰ COMMISSION STAFF WORKING DOCUMENT Synopsis report accompanying the document Report from the Commission to the European Parliament and to the Council Mid-term evaluation of Regulation (EU) No 652/2014 of the European Parliament and of the Council laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material [...] (SWD(2017) https://ec.europa.eu/food/sites/food/files/cff_mid-term-evaluation_synopsys_report_en.pdf)

¹⁵² A disease which can be transmitted to humans from animals.

covers about 50% of the eligible costs and is currently under revision in view of further extending it to other spending areas, especially in the phytosanitary field.

Some adjustments were introduced to adapt the financial tools used in these spending areas to the provisions of the current Financial Regulation, notably the grants. However, experience shows that, taking into account the characteristics of the food safety expenditure (non-competitive funding consisting of reimbursement to the Member States), the allocation of grants can be further simplified.

From the monitoring point of view, a comprehensive set of performance indicators currently allows evaluating the achievements in the main areas covered by the Food Chain Programme. Nevertheless, those indicators are purely technical and are not accompanied by cost-effectiveness indicators. This shortcoming limits the possibility to investigate the causal effects behind the results and impacts achieved thanks to the food chain spending under the CFF Regulation. In the context of the "budget for results" approach, the development and implementation of a cost-effectiveness analysis in the food chain area is therefore needed in view of the next MFF. A specific study to identify a tailor-made model for cost-effectiveness analysis is currently ongoing.

The success of the current financing programme in avoiding a major crisis on the scale of past crises should not mask the vulnerability of the system, as outbreaks from animal diseases and plant pests tend to cyclically occur and reoccur in the EU territory. The need to establish a direct mechanism to react to large scale emergencies affecting food, animals and plants should be further considered. Under the EU 2014-2020 budget, the reserve for crises in the agricultural sector is not available for the food chain area. In the event of serious outbreaks of animal¹⁵³ and plant epidemics, whose budgetary impact might not be accommodated within the ceiling of the current programme, the financial support to implement eradication activities and to timely contain the spread of these epidemics would be difficult.

Further consideration will also have to be given to the funding of plant health activities, which is still at an initial phase, in order to properly respond to the needs in this area, e.g. in terms of integration between survey programmes and emergency measures. It is important to consider that the achievement of the eradication of certain pests is often more complicated than in the animal health area due the high number of host species, latency of symptoms and the nature of disease vectors, notably insects. This greatly complicates control and eradication measures in the event that a pest becomes established. In cases where eradication is no longer possible, a containment approach is still an effective way to prevent further spread of the pest into the rest of the EU territory.

¹⁵³ One example is the recent case of avian influenza, whose budgetary impact largely exceeds the annual CFF ceiling established at EUR 20 million for both animal and plant health emergencies. Notably, the 19 Member States affected by the epidemics since 2016 have claimed to date more than EUR 100 million, of which 35% only could be paid within the Food Chain budget. Extra resources still need to be found to cover the remaining amount.

Real life example of success story of synergies, with other IMP programmes:

The spreading of antimicrobial resistance (AMR) is a natural biological phenomenon but lately a variety of factors have contributed to accelerate its dispersion. AMR is responsible for an estimated 25,000 deaths yearly and over EUR 1.5 billion of healthcare costs and productivity losses in the EU. Combating antimicrobial resistance has become a global public health challenge. AMR has also become a political priority within the EU, the G7, the G20, the UN and other international organisations.

In 2008, the European Council called upon the Member States to strengthen surveillance systems and improve data quality on antimicrobial resistance and on consumption of antimicrobial agents within both the human and veterinary sectors. A new EU Action Plan to combat antimicrobial resistance was adopted in 2017 to prevent and reduce the spreading of AMR, and preserve the capacity to fight microbial infections. The key objectives of this new strategy are built on three main pillars: (i) making the EU a best practice region on AMR; (ii) boosting research, development and innovation on AMR; and (iii) shaping the global agenda on AMR

As part of this AMR Action Plan several other programmes (e.g. EU Programmes for Health and Food-and-Feed¹⁵⁴, Horizon 2020) as well as the EU Agencies (EFSA, EMA and ECDC) collaborate and coordinate with different national authorities in order to reach the outlined objectives from a one Health perspective and in support of Member States' national action plans. This inclusive strategy with representation of all relevant actors at EU level and the aim to address gaps on the Health and Animal side holistically represent a successful example of the One Health approach.

Real life example of problems due to lack of flexibility, coherence, separation from other programmes dealing with similar or complementary issues? The reserve for crises in the agricultural sector is set under Heading II of the EU Budget to provide additional support in case of major crises affecting agricultural production or distribution. The initial Commission proposal for a CFF Regulation provided that also DG SANTE could access this reserve, in order to cope with severe veterinary and phytosanitary crises whose budgetary impact might not be accommodated within the ceiling of Heading III. Following a difficult negotiation with the legislative authority, the possibility to use this reserve was eventually dropped from the CFF proposal.

In the event of a crisis, the costs associated would then have to be covered first within the CFF built-in reserve for financing emergency measures of EUR 20 million per year. Any additional amount would have to be financed from the margin of Heading 3 and/or by reprogramming. If (full) financing under Heading 3 were not possible, the Commission would have to examine any other possibility for financing the necessary measures in accordance with all relevant legislations, including in the field of the Common

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Agricultural Policy. Finally, should the severity of the crisis require further financial resources, the Commission would recur to alternative mechanisms, such as the flexibility instrument or the contingency margin. Still, those mechanisms are not immediately accessible and do not represent a guarantee of availability of financial resources to face the emergency. This constitutes an important risk also from the perspective of control and eradication as certainly on the availability of EU funding is a powerful instrument in taking quick and decisive measures to combat the spread of diseases and pests. The recent avian influenza example presented in this section (see footnote 5) confirms the risks related to similar situations.

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2. THE OBJECTIVES

2.1. Challenges for the programmes of the next MFF

Summary

Under the present MFF, the Food Chain Programme has an average annual budget of EUR 250 million, covering the three main spending areas of animal health, plant health and official controls related activities. For the post-2020 financial framework, animal health measures are expected to continue representing the largest share of the Food Chain Programme budget, followed by plant health measures and, third, official controls related activities.

In the light of the findings of the recent mid-term evaluation and consultations, the present food chain spending strategy remains valid for the next MFF. Nevertheless, a number of recent and emerging challenges, such as globalisation, an increasingly complex food supply chain and climate change, will pose significant threats and are therefore expected to influence the future EU approach in this area.

The optimisation of the administrative system is also expected to contribute to a more effective and efficient EU Food Chain Programme, improving its overall functioning as well as its capacity to respond to the present challenges, for example by exploring possible synergies or seeking further simplifications.

The 2014-2020 Food Chain Programme has an average annual budget of EUR 250 million, which covers the three main spending areas of animal health, plant health and official controls related activities. During the current MFF, the average annual envelope allocated to veterinary measures has amounted to EUR 180 million with the figure rising to almost 210 million in 2017 due to the Avian Influenza crisis, of which EUR 160 million on average for veterinary programmes and EUR 16 million, 23 million, and 51 million, respectively, for 2015, 2016, and 2016 for emergency measures, representing 75% of the total spending in this area. The second main envelope has concerned phytosanitary measures, with an annual average budget of EUR 12 million, of which almost the entire amount has been allocated so far to cover survey programmes. As regards the annual spending on official control related measures, EUR 16 million has been allocated to the EU Reference Laboratories, while the budget for the Better Training for Safer Food initiative has amounted to EUR 15 million. The remaining EUR 30

million have covered the spending for IT systems which support tracing of commodities, alert notifications and administrative cooperation for enforcement purposes, and other measures and supporting/administrative activities.

In view of the next MFF, animal health measures are expected to continue representing the largest share of the food chain budget, as animal diseases remain a major priority for Member States for health, trade and political reasons. Given their biological origin and character of vectors transmitting the diseases, the need to monitor and tackle them will continue. In addition, any deterioration in the current very satisfactory animal health status could quickly undermine the progress accomplished in recent years. For the post-2020 programme, veterinary measures should mostly focus on: disease prevention through veterinary programmes, in line with the increasing demand for safety and security, especially at the EU borders; emergency measures and crisis management, due to the increased risk of veterinary crisis as a result of globalisation of markets, intensification of production and climate change; availability of EU vaccine banks to complement the national capacity, which should be reinforced by both including provision for dealing with new diseases and increasing the capacity for existing ones.

Plant health measures are becoming growingly important due to increased globalisation and trade, being accompanied by new plant health threats. For the next MFF, phytosanitary measures should mostly target the following activities: phytosanitary programmes, with the systematic implementation of surveillance activities to early detect the presence of certain priority pests in the whole EU territory, and to increase the capacity of reaction of national phytosanitary services; emergency measures to be implemented at the very initial stage of the outbreak, with an early and decisive response system at EU level. Surveillance activities were only introduced by the present Food Chain Programme in order to complement the emergency intervention making the overall system to tackle plant pests more coherent and structured, with an increased attention paid to prevention.

Official controls related activities will continue providing support to Member States to implement sectorial measures, thus enabling the sophisticated EU enforcement system to work efficiently. Given the contribution of those measures to the overall protection needs, and their strategic support to the internal market and trade, the current approach remains valid for the next MFF, where these measures should cover: action to improve testing and analyses by laboratories serving the EU food chain enforcement needs (through activities carried out by the EURLs); training activities carried out under the BTSF initiative; Coordinated Control Plans (CCP) allow coordinated controls by Member States on specific priorities, including the fight against frauds in the food chain; EU IT systems, databases, alert and notification tools developed at Commission level, which are largely and daily used by the Member States and whose contribution can be strengthened thanks to increased digitisation of data. This comprehensive system is an essential tool for verifying and monitoring that relevant Union requirements are being implemented, complied with and enforced.

In light of the findings of the overall evaluation and consultation exercises recently conducted, the present food chain spending strategy is expected to be largely confirmed during the next MFF. Still, a number of recent and emerging challenges, most of which are mentioned in the paragraphs above, pose significant threats to the EU in the food chain area, and are therefore expected to influence the future EU approach in this area. The increasing complexity of food supply chains is a key aspect, with the globalisation of trade meaning more opportunities, but also increased risk due to global vectors and global diseases. In this context, increased emphasis needs to be put on prevention, particularly as concerns trans-boundary exotic diseases from neighbouring third countries. Other exogenous factors such as increased risk of vector borne diseases and climate change may alter disease emergence and spread patterns. Exceptional circumstances such as emergency situations related to animal and plant health may pose serious risks from both the sanitary and economic perspectives. The sustainability of the food system will be improved by increasing the general consumers' awareness as well as through public–private partnerships for reducing food waste all along the food chain. It will also be important to have performant risk analysis tools for preventing fraudulent practices. In addition, the sustainability issue is therefore of growing importance, especially with a view to the Sustainable Development Goals (SDGs). On top of that, opportunities for synergies between next Food Chain Programme and R&I FP ('FP9') should be explored. In particular the following areas to anchor to FP9 are: support EU health and food safety – and related animal health, welfare, plant health – legislation; connections to EITs Health and Food; support integrated work with MS on health and food safety research (i.e. Networking); legislative processes including innovation in health and food sectors.

In this changing and challenging context, there is a strong demand from citizens and consumers as well as from the national authorities for a continued EU engagement in this area, with citizens expecting the EU to protect them and their interests by guaranteeing strong interventions and controls all along the food chain, and to properly address these security and safety threats.

The optimisation of the administrative system might make the next EU food chain programme more effective and efficient in its overall functioning as well as in its capacity to respond to these challenges. While the present approach has proven to be flexible in adapting to new priorities and needs, new synergies with other EU spending programmes could be envisaged on horizontal activities such as studies and evaluations, information campaigns and communication, knowledge building and trainings, cross-border administrative cooperation and networking, as well as on IT tools, with a view of supporting the implementation of the legislation in the whole food chain area. Also the scope for simplification could be further addressed as described in section 1.2 above, contributing to improving and modernising the food chain system for the next MFF.

| Challenges | Empowerment of citizens, consumers and businesses | Administrative cooperation and integration among | Rule-making, standard setting and enforcement at EU | Health as a resources for the society and the internal market |
|------------|---|--|---|---|
|------------|---|--|---|---|

| Programme/line | | Member States | institutions level | |
|-----------------------------|---|---|---|--|
| Food Chain Programme | <ul style="list-style-type: none"> - Increased consumers' expectations regarding the integrity and safety of the food chain; - Insufficient incentive for sustainable consumption | <ul style="list-style-type: none"> - Cross-border public policy challenges in the food chain related areas, including with third countries - Limited cooperation/exchange of best practices between authorities | <ul style="list-style-type: none"> - Soft regulation and application of best practices | <ul style="list-style-type: none"> - Globalisation of trade - Climate change - Loss of biodiversity - Risk of pandemics, cross-border health and health security threats - Cyclical outbreaks of animal and plant pests - Food waste - High costs of cross-border health crises, food borne diseases, food fraud, animal diseases and plant pests |

| Candidate for Programme/line | Flexibility (moving funds from one IMP programme to other) | Simplification | With which other IMP programmes there are potential synergies | |
|---|---|--|---|--|
| Food Chain Programme: all spending areas | N/A | <ul style="list-style-type: none"> - Development of cost-effectiveness analysis / monitoring system - Exploring flat funding rates | See below | |
| Food Chain Programme: veterinary programmes | N/A | | N/A | |
| Food Chain Programme: phytosanitary survey programmes | N/A | <ul style="list-style-type: none"> - Introduction of lump sums for reimbursements | N/A | |
| Food Chain Programme: Studies / data gathering / evaluations | N/A | | Potentially all programmes - More visibility for those activities and improved knowledge and competence sharing | |
| Food Chain Programme: Information campaigns / external communication | N/A | | Potentially all programmes - Resource sharing and unified messages to the general public | |
| Food Chain Programme: Knowledge building / Trainings to Member State | N/A | | N/A | |
| Food Chain Programme: IT tools | N/A | | Potentially all programmes - Administrative cooperation/ network of MS; resource and data sharing | |

2.2. Objectives of the programmes of the next MFF

Summary

The post-2020 Food Chain Programme is expected to attain a key general objective, namely the contribution to a high level of health and welfare for humans, animals and plants along the food chain.

Under this overall umbrella, three sectorial objectives are then identified, for each of the three main spending areas expected to be covered by the Food Chain Programme itself. More specifically, veterinary measures will aim at improving the prevention, control and

eradication of animal diseases in the EU territory; phytosanitary measures at improving the prevention, containment and eradication of plant pests in the EU territory; and official controls related activities at improving the effectiveness, efficiency and reliability of the food supply chain.

The post-2020 Food Chain Programme is expected to attain the general objective of contributing to a high level of health and welfare for humans, animals and plants along the food chain while:

- improving the sustainability of European food and feed productions and increasing quality standards across the EU;
- ensuring a high level of protection for consumers and the environment, including the preservation of biodiversity;
- enhancing the competitiveness of the EU food and feed industry and favouring the creation of jobs.

This overarching objective is crystallised into three specific objectives, related to the three spending areas covered by the programme itself, namely:

- improving the prevention, control and eradication of animal diseases in the EU territory (animal health);
- improving the prevention, containment and eradication of plant pests in the EU territory (plant health);
- improving the effectiveness, efficiency and reliability of official controls related activities along the food supply chain, carried out with a view to implement and enforce EU rules in this area (official control related activities).

The sectorial measures implemented to achieve the specific objectives above will mostly consist of:

- for animal health:
 - programmes for the eradication, control and surveillance of animal diseases and zoonoses;
 - veterinary emergency measures;
- for plant health:
 - survey programmes concerning the presence of pests;
 - phytosanitary emergency measures;
- for official controls related activities:
 - EU Reference Laboratories and Centres' activities;
 - training of control staff;
 - Coordinated Control Programmes ;
 - Food waste prevention activities;
 - IT systems.

In order to assess whether the above-listed measures will contribute to the attainment of the Food Chain Programme objectives, monitoring arrangements will be established for each area and the following evaluation criteria will be used:

- the continued relevance of all objectives, namely the relationship between the needs and problems in the food chain area and the general and specific objectives and related measures identified for each of the spending areas covered by the programme itself;
- the effectiveness of the implemented food chain measures in achieving the general and specific objectives, also in light of the progress measured through the monitoring system in place;
- the efficiency in the use of the financial resources spent under the food chain budget and their consistency with the results achieved;
- the coherence of the measures implemented within the Food Chain Programme, both internally and with other EU interventions;
- the EU added value created thanks to the implementation of the food chain measures receiving technical and financial support under this programme.

| Challenges Programme/line | Empowerment of citizens, consumers and businesses | Administrative cooperation and integration among Member States | Rule-making, standard setting and enforcement at EU institutions level | Health as a resources for the society and the internal market |
|---|--|--|--|--|
| Programme 1 | | xxx | | |
| Food Chain Programme: veterinary measures | Improving the prevention, control and eradication of animal diseases in the Union territory | Improving the prevention, control and eradication of animal diseases in the Union territory | Improving the prevention, control and eradication of animal diseases in the Union territory | Improving the prevention, control and eradication of animal diseases in the Union territory |
| Food Chain Programme: phytosanitary measures | Improving the prevention, containment and eradication of plant pests in the Union territory | Improving the prevention, containment and eradication of plant pests in the Union territory | Improving the prevention, containment and eradication of plant pests in the Union territory | Improving the prevention, containment and eradication of plant pests in the Union territory |
| Food Chain Programme: official controls and related activities | Improving the effectiveness, efficiency and reliability of official controls related activities along the food supply chain, carried out with a view to implement and enforce Union rules in this area | Improving the effectiveness, efficiency and reliability of official controls related activities along the food supply chain, carried out with a view to implement and enforce Union rules in this area | Improving the effectiveness, efficiency and reliability of official controls related activities along the food supply chain, carried out with a view to implement and enforce Union rules in this area | Improving the effectiveness, efficiency and reliability of official controls related activities along the food supply chain, carried out with a view to implement and enforce Union rules in this area |

| Potential for Programme/line | Simplification of your programme, and/or synergies and/or flexibility |
|---|--|
| Food Chain Programme: veterinary measures | Flexibility: N/A Simplification: no simplification actions involving other IMP programmes are envisaged Synergies: between next Food Chain Programme and R&I FP ('FP9') |
| Food Chain Programme: phytosanitary measures | Flexibility: N/A Simplification: no simplification actions involving other IMP programmes are envisaged Synergies: between next Food Chain Programme and R&I FP ('FP9') |

| | |
|---|--|
| Food Chain Programme: official controls and related activities | Flexibility: N/A Simplification: no simplification actions involving other IMP programmes are envisaged Synergies: synergies on horizontal actions covered by the official controls related activities could be explored with all other IMP programmes on e.g.: studies, evaluations, data gathering activities, information campaign and external communication activities, IT tools. |
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3. PROGRAMME STRUCTURE AND PRIORITIES

Summary

The actions already receiving EU financial support in the food chain area will remain a high priority for the post-2020 programme targeting very diverse diseases and pests that impact on different animals and plants across the entire eco-system; new diseases also emerge such as BSE, SARS, Corona virus and mutations of avian flu, which present new risks. In these circumstances, the best approach is to aim for a high level of preparedness, which equips the EU and its Member States to deal with diseases in general, focusing on those which are already present. The findings of the mid-term review of the CFF Regulation confirm also that what is presently managed represents the critical mass of funding in order to make the programme work effectively. In addition, experience shows that EU added value in the food chain area goes beyond what individual Member States could achieve by implementing national measures without EU support. In continuity with Regulation (EU) No 652/2014, the next Food Chain Programme is also expected to take the form of a Regulation to be adopted through ordinary legislative procedure. The legal basis for establishing the upcoming proposal will be Articles 43, 114 and 168 of the Treaty on the Functioning of the European Union.

Based on the experience of their past and ongoing implementation, the actions already receiving EU financial support in the food chain area will remain a high priority for the post-2020 programme. The targeted diseases and pests are very diverse and impact on different animals and plants across the entire eco-system. However, while they differ hugely in their nature and structure, they all have the potential of a catastrophic impact on the health of the target species, be it animal or plant. This in turn can lead to huge trade disruption and losses for the agri-food sectors in question and in cases of zoonotic diseases in animals with an impact on human health. Experience, moreover, teaches that disease outbreaks and their impact are highly variable and subject to change due to climatic, trade and biological factors. New diseases also emerge such as BSE, SARS, Corona virus and mutations of avian flu, which present new risks. In these circumstances, the best approach is to aim for a high level of preparedness which equips the EU and its Member States to deal with diseases in general, focusing of course on those which are already present.

On this basis, the next Food Chain Programme is expected to achieve the specific objectives through the following measures:

- emergency measures, namely actions to contain and eradicate outbreaks of animal and pest diseases;

- crisis management activities, implemented in case of cross-border threats to reduce animal and plant health risks and mitigate their consequences;
- eradication programmes, through actions aimed at eradicating animal diseases and plant pests in the EU territory;
- control programmes, through actions aimed at containing the spread of a specific animal disease or plant pest and to minimise its impact;
- surveillance/survey programmes, aimed to collect and record data on specific animal diseases and plant pests to assess their epidemiological evolution and allow targeted control and eradication or containment measures;
- implementation and enforcement of EU Food chain rules through official controls related actions, such as:
 - BTSF, through training enforcement and control staff in the Member States and in third countries exporting to the EU;
 - Support and consolidate the network of EURLs and EURCs activities;
 - IT systems, with a view of maintaining and improving the integrated working of IT and networks which enable the Member States and the Commission to work jointly to counter health risks along the food chain, implement and enforce food chain rules across the EU and facilitate trade;
 - actions directed at raising awareness and promote innovation in preventing food waste along the food chain.

The findings of the mid-term review of the CFF Regulation also confirm that what is presently managed represents the critical mass of funding in order to make the programme work effectively. This base line is supported by data collected using existing performance indicators.

Experience shows that EU added value in the food chain area goes beyond what individual Member States could achieve by implementing national measures without EU support. The health status of the EU is only as strong as the weakest link. All Member States must therefore play their part in ensuring that there is a high level of health protection and of preparedness to deal with outbreaks. The achievement of a higher animal and plant health status in the EU was possible thanks to both the technical and financial support provided by the EU to the Member States: on the one hand, budgets of Member States alone, especially of those struggling with economic crisis or other constraints, have difficulties to secure appropriate financial resources to respond to the combination of present and potential challenges; on the other hand, the variety of measures to put in place to tackle pests and diseases requires a centralised management system in order to properly coordinate and organise the implementation of specific actions in the Member States. Member States which might not have a direct interest in combatting a particular disease or pest also have to be reminded of their obligation to look to the overall EU interest. This requires a centralised approach to ensure the necessary oversight and a high level of overall ambition in combatting diseases.

The EU added value provided by the EURLs activities and the BTSF programmes is linked to the nature of their activities: the network of laboratories ensures that all EU

Member States work within a consistent and uniform regulatory framework, while the EU training programme promotes a common approach towards the implementation and enforcement of EU legislation. This contribution towards the harmonisation of rules at Union level and the sharing of knowledge and expertise in the food chain and related areas is a concrete example of positive interaction within the EU, which could not be achieved through isolated efforts at national level and without the EU financial support.

Should the current approach to food chain funding be confirmed, the post-2020 programme is expected to continue contributing to achieving and supporting EU added value. Member States will still benefit from the prioritised and targeted implementation of EU co-funded activities, especially for emergency, eradication, control and surveillance measures for animal diseases and plant pest throughout the Union. The financial solidarity provided by the EU support will enable Member States to take the required actions to protect both own, and wider EU interests. Otherwise these may go beyond the financial and operational capacity of an individual Member State. The food chain programme funding will enable harmonised and robust controls, which satisfy an important need with respect to an effective food chain policy.

In continuity with the present legislation, namely Regulation (EU) No 652/2014 on the management of the expenditure in the food chain area, the next Food Chain Programme is also expected to take the form of a Regulation to be adopted through ordinary legislative procedure. The legal basis for establishing the upcoming proposal will be Articles 43, 114 and 168 of the TFEU. As the post-2020 Food Chain Programme will continue acting as a financial umbrella covering the management of expenditure in the areas of animal health, plant health, and official controls related activities, its scope will have to be aligned to the sectorial legislation in those fields, as recently revised/amended.

4. DELIVERY MECHANISMS OF THE INTENDED FUNDING

Summary:

The food chain expenditure implemented under Regulation (EU) No 652/2014 mostly consists of direct co-financing to the Member States. The principal delivery mechanism used is the grant with only three standard maximum rates to reimburse eligible costs, namely 50%, 75% and 100%. As this approach proved to be clear, effective and efficient, ensuring both flexibility to the financial and policy framework and consistency with the subsidiarity principle, its key elements will continue to be used in the next MFF. Procurement will continue to be the delivery mechanism for Better Training for Safer Food (BTSF). Further steps towards increased simplification will be considered for the upcoming Food Chain Programme, in order to e.g. reduce the administrative burden for both the Commission and the national competent authorities or facilitating the requests for reimbursements. In this view, the increased use of unit costs and ceilings, or the application of lump sums and flat rates will be explored, as well as a definition of a

minimum threshold for receiving financial support under the Programme.

The food chain expenditure implemented under Regulation (EU) No 652/2014 primarily consists of direct co-financing to the Member States, which are almost exclusive beneficiaries of the EU spending in this area. The Member States receive a reimbursement for the eligible costs incurred to carry out the eligible measures. The Union financial contribution mainly takes the form of a grant (the only exception being the voluntary payments to international organizations), implemented through grant decisions.

Within the present financial framework, all food chain activities are currently under direct management, and financing is mostly managed by Commission services (with the sole exception of the BTSF initiative which is implemented by the executive agency CHAFEA).

Regulation (EU) No 652/2014 establishes a standard reimbursement rate of no more than 50% of the eligible costs incurred to implement veterinary and phytosanitary measures (both annual/multiannual programmes and emergency measures); under certain conditions specified in the regulation itself, the applicable rate can be increased to 75% or 100%¹⁵⁵. The eligible costs for BTSF and EURL activities funded through procurement and grants, respectively, are covered in full.

Based on the findings of the recent mid-term evaluation of Regulation (EU) No 652/2014, the current financial arrangements – whose key elements are described above – ensure the good programme implementation as concerns both the efficiency and the effectiveness, as well as in terms of flexibility. Particularly, direct management has proven to be effective in this area, which is characterised by a comprehensive and complex legislation, requiring a high level of specialisation and a deep understanding of scientific developments. In this context, direct management has ensured a cost-effective and rational use of human resources, with a limited number of staff employed to manage these funds, liaising with the highly qualified scientific and technical experts at policy-making level.

As regards subsidiarity, budgets of some Member States alone, especially of those harder hit by economic crisis or other constraints, on one hand have difficulties to secure appropriate financial resources to respond to the combination of present and potential challenges. On the other hand, the variety of measures to put in place to tackle animal

¹⁵⁵ Article 5 (Maximum rates of grants) to Regulation (EU) No 652/2014

1. Where the Union financial contribution takes the form of a grant, it shall not exceed 50 % of the eligible costs.
2. The maximum rate referred to in paragraph 1 may be increased to 75 % of the eligible costs in respect of: (a) cross border activities implemented together by two or more Member States in order to control, prevent or eradicate pests or animal diseases; (b) Member States whose gross national income per inhabitant based on the latest Eurostat data is less than 90 % of the Union average.
3. The maximum rate referred to in paragraph 1 may be increased to 100 % of the eligible costs where the activities benefitting from the Union contribution concern the prevention and control of serious human, plant and animal health risks for the Union, and: (a) are designed to avoid human casualties or major economic disruptions for the Union as a whole; (b) are specific tasks which are indispensable for the Union as a whole as laid down by the Commission in the work programme adopted in accordance with Article 36(1); or (c) are implemented in third countries.

diseases and plant pests requires a centralised management system in order to properly coordinate and organise the implementation of specific actions in the individual Member States, within an EU framework where the overall system is only as strong as the weakest link.

In light of these considerations, the overall approach of the current system is expected to be confirmed for the period post-2020. By the same token, the present application of only three standard funding rates for animal and plant health measures, which has been largely welcomed by the beneficiaries since its introduction, is expected to be maintained. Experience shows that it is easy to manage and provide the system with great transparency since eligibility conditions are limited and clear, and in line with proportionality and solidarity criteria. The implementation of unit costs and ceilings in the area of veterinary programmes and emergency measures has already contributed to the simplification of the program implementation, leading to lower administrative burden for the Commission as well as for the Member States, and facilitating the requests for funding and for reimbursements. It currently covers about 50% of the eligible costs and a further revision of the program implementation is ongoing, in view of extending it to other food chain spending measures, such as the financing of EURLs. In the plant health area, the use of unit costs seems more difficult to apply because of the limited availability of historical data as well as due to the nature of costs themselves, which cannot be defined in detail as is the case of animal health. The use of lump sums covering all or certain categories of eligible costs is therefore being considered as an alternative method with a view of replacing real costs. Both unit costs and lump sums or, where applicable, flat rates would then be pre-established in such a way as to allow the payment of grants only upon achievement of concrete outputs and/or results.

With a view to reducing the administrative burden attached to EU funding – both for the Member States and for the Commission – the definition of a minimum threshold for receiving financial support under veterinary and phytosanitary measures is a further element which will be considered. In view of the next Food Chain Programme, the EU funding for small financial value programmes might therefore be discontinued for cost-effectiveness reasons, and also because the administrative costs attached to their implementation might equal or even exceed the eligible costs themselves, so as there will be no interest at national level to apply for EU financial support.

As regards synergies with other programmes of the Single Market Programme, opportunities are expected to arise for a coordinated approach in certain areas (training and capacity building, cross-border enforcement, data gathering and processing, support to networks of Member States authorities, awareness raising activities and IT related actions) as appropriate. Additional synergies with the ESF+, notably through actions on AntiMicrobial Resistance will be maintained and further exploited.

5. HOW WILL PERFORMANCE BE MONITORED AND EVALUATED?

Summary

The performance of the post-2020 Food Chain Programme will be evaluated through a comprehensive set of indicators, focused on both activities (output indicators) and results (outcome indicators), complemented by a number of economic indicators to assess the effectiveness of the relevant spending measures (cost-effectiveness indicators) implemented under the different policy areas covered. Both

intermediate and final targets will be defined for each selected indicator, subject to periodic (annual) adjustments based on the epidemiological evolution and other specific factors. Additional indicators covering the wider economic, social and environmental impacts (impact indicators) will also be monitored.

The assessment of the next Programme is expected to consist of an intermediate and a final evaluation, focused on the attainment of the specific objectives. The progress made should be evaluated taking into account the previously agreed indicators and defined targets.

The core objective of the Food Chain Programme is to protect human, animal and plant health from the risks of pests and diseases which are, largely but not exclusively, foodborne. Previous programmes and measures have been very successful in ensuring a high level of protection in this respect throughout the EU. This has delivered very important benefits for health but also the ability for trade to take place on a safe basis both within the EU and with third countries. The very substantial regulatory framework on food safety, animal and plant health at the heart of the Internal Market can only function effectively if there is a sufficient and continued investment in its implementation and enforcement.

Experience has taught us that it is imperative to have strong regulatory and administrative structures in place in the EU to protect against diseases and to react when, not if, there are incursions of these diseases. The absence of diseases or their low incidence is not, therefore, an excuse for complacency. On the contrary, it is necessary to remain very vigilant and to have in place the necessary support measures, including contingency plans, crisis preparedness measures and well trained officials to provide EU citizens, animals and plants with effective disease surveillance, control and eradication measures. The best measure of future success will remain the capacity to maintain the existing high health status in the EU, the smooth trade flows and the absence of major disease outbreaks with their devastating impact on health and the economy.

While the three areas currently receiving EU financial support, namely animal health, plant health and official controls related activities, are expected to be confirmed for the next Food Chain Programme, some adjustments to the present objectives (as presented under section 2 of the present Annex) are envisaged, to improve on the existing set of indicators used, especially in the areas of plant health and official controls related activities. The current technical indicators will then be revised in view of a transparent, effective and credible monitoring system, which for the first time is expected to be complemented by a cost-effectiveness analysis tailor-made for the food chain interventions.

The performance of the post-2020 Food Chain Programme will then be monitored through a comprehensive set of indicators, focused on both activities (output indicators) and results (outcome indicators), complemented by a number of economic indicators to evaluate the effectiveness of the relevant spending measures (cost-effectiveness indicators) implemented under the different policy areas covered. This core set will be accompanied by a number of additional indicators covering the wider economic, social and environmental impacts (impact indicators) which may be expected from the Food Chain Programme. For the first three categories of indicators, both intermediate and final targets for the next MFF will be established, as they are all directly related to the programme implementation. As regards impact indicators, even if the Food Chain Programme contributes significantly to their positive evolution, no direct and exclusive link can be established, due to time lags and the complexity of the factors which impact on disease outbreaks and their evolution. They are therefore expected to be monitored as a key qualitative indication of the relevance of the food chain policy, but no specific targets are likely to be established. In terms of data collection, technical and financial information needed to measure and monitor output, outcome and cost-effectiveness indicators will be handled at DG SANTE level: the main sources will be the intermediate and final reports submitted every year by the Member States, as well as the several notification (IT) tools in place in the areas concerned. Data on impacts, such as the value of agri-food production, trade flows and the evolution of exports, are expected to be mostly collected through other

tools/databases available at Commission level, such as the indicators monitored by EUROSTAT and the Number of (national) veterinary programmes and of (survey) phytosanitary programmes successfully implemented

periodic reporting from EFSA.

A preliminary analysis of the data needed to compile these indicators has been conducted in the context of ongoing studies: a JRC study on cost-effectiveness (currently in its final stages) and an external study on data gathering and analysis (still at inception phase). Both exercises have revealed that the present situation for monitoring and data collection is positive, particularly in the animal health area, and that needed information is largely already available at either DG SANTE or Commission level for both financial and technical aspects. In most cases, this data would therefore simply need to be continuously followed up in a structured and systematic way to allow proper ex-ante, ongoing and ex-post monitoring. They will represent a key tool to assist policy-makers throughout the whole policy cycle, in order to ensure a budget-for-results-oriented approach, which is transparent in the benefits it delivers for stakeholders and citizens. In this scenario, the present IT tools for notification, alert, digitization of data might need to be strengthened and further integrated.

In continuity with the present monitoring system¹⁵⁶, both intermediate and final targets will be defined for each selected indicator, subject to periodic adjustments based on endogenous aspects related to the nature of the measures implemented, notably the epidemiological situation actually prevailing. Targets design will also be based on the evolution of exogenous factors influencing the attainment of the objectives (as described in the previous sections when presenting emerging challenges and threats). The Commission experts will be discussing those aspects with the representatives of the Member States in the relevant institutional fora, notably in the context of the regulatory committee meetings, as well as on *ad hoc* basis, when there is a need to address veterinary or phytosanitary problems. Following this approach, a reasonable definition of targets for the three policy areas will be possible at the end of the present MFF, with 2020 as a baseline scenario, with annual updates agreed between the Commission and the national competent authorities¹⁵⁷.

The list of indicators for the post-2020 period is under development based on the ongoing studies addressing the future monitoring system. Taking into account this evolving scenario, a non-exhaustive proposal for key indicators is presented in the table at the end of the present section.

A composite indicator is suggested for the monitoring of the Single Market [and Health] Programme that is an aggregation of two programme indicators that is "Successfully implemented national veterinary and phytosanitary programmes".

In line with the provisions of Regulation (EU) No 652/2014, the assessment of the next Programme is also expected to consist of an intermediate and a final evaluation, focused on the attainment of the specific objectives. The progress made should be evaluated taking into account the previously agreed indicators and defined targets. In the light of the present experience, where the mid-term evaluation found a shortcoming in the limited availability of data, the interim evaluation exercise for the next Food Chain Programme is recommended to be conducted once satisfactory financial and technical data for the first three years of implementation (namely the period 2021-2023) is available. The findings of both the mid-term and the ex-post evaluations are expected to feed into Commission evaluation reports to be presented to the European Parliament and to the Council.

¹⁵⁶ https://ec.europa.eu/food/sites/food/files/safety/docs/cff_animal_vet-progs_guidance_progs_erad_2018-2020.pdf

¹⁵⁷ https://ec.europa.eu/food/sites/food/files/animals/docs/diseases_sanco-12915-2012_en.pdf
https://ec.europa.eu/food/sites/food/files/safety/docs/cff_animal_vet-progs_guidance_progs_erad_2018-2020.pdf

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---|--|--|---------------------|--|---|----------|--------|
| Animal health: improving the prevention, control and eradication of animal diseases in the Union territory | Number of national programmes successfully implemented | Following the submission of technical and financial final reports by the Member States, the Commission carries out the evaluation and decides on the final payment of the eligible costs incurred for each previously approved programme. Programmes whose implementation is in line with EU legislation and the terms agreed with the Commission are considered successful. | Percentage | Grant decisions (one per MS) and Final payment checklist | Annual | 2020 | 100% |
| | Number of emergency situations successfully addressed (by disease) | Following the submission of technical and financial final reports by the Member States, the Commission carries out the evaluation and decides on the final payment of the eligible costs incurred for each previously approved emergency measure. Measures whose implementation is in line with EU legislation and the terms agreed with the Commission are considered successful. | Percentage | Grant decisions (one per emergency , i.e. one per MS and per diseases) and Final payment checklist | Depending on needs (emergency measures are not predictable by definition) | 2020 | 100% |

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|--|-------------------------|--|---|--|--------|---|--|
| | Reduction of incidence | Incidence is a technical parameter used to monitor the epidemiological evolution of a given disease in a given population. It is the proportion of new cases within a specified time period divided by the size of the population initially at risk. | Percentage (of animal population) | Final technical reports (submitted by the MSs) | Annual | 2020 (e.g. expected result for 2020 in Portugal for bovine brucellosis is 30% (namely the minimum % of reduction compared to 2015 baseline (0,20)) | Specific targets for those indicators will be defined individually for each disease in each Member State based on their epidemiological evolution by 2020, and then updated every year as described in the main text |
| | Reduction of prevalence | Prevalence is a technical parameter used to monitor the epidemiological evolution of a given disease in a given population. It is the proportion of a particular population found to be affected by a disease. | Percentage (of animal population) | Final technical reports (submitted by the MSs) | Annual | 2020 (e.g. expected result for 2020 in Portugal for bovine brucellosis is 30% (namely the minimum % of reduction compared to 2015 baseline (0,24)) | Specific targets for those indicators will be defined individually for each disease in each Member State based on their epidemiological evolution by 2020, and then updated every year as described in the main text |
| | Number of outbreaks | Technical parameter used to monitor the epidemiological evolution of a given disease. | Number or percentage (depending on the disease) | Final technical reports (submitted by the MSs) | Annual | 2020 (e.g. expected result for 2020 in the Union for Avian influenza in domestic poultry is less than 85% compared to 2015 baseline) | Specific targets for those indicators will be defined individually for each disease in each Member State based on their epidemiological evolution by 2020, and then updated every year as described in the main text |

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|--|---|--|------------|--|--------|--|--|
| | Number of cases | Technical parameters used to monitor the epidemiological evolution of a given disease. | Number | Final technical reports (submitted by the MSs) | Annual | 2020 (e.g. expected result for 2020 in the Union for rabies in wildlife is 0 (2015 baseline was 128 cases)) | Specific targets for those indicators will be defined individually for each disease in each Member State based on their epidemiological evolution by 2020, and then updated every year as described in the main text |
| Plant health: improving the prevention, containment and eradication of plant pests in the Union territory | Number of surveys programmes (by pest / pest category) successfully implemented | Following the submission of technical and financial final reports by the Member States, the Commission carries out the evaluation and decides on the final payment of the eligible costs incurred for each previously approved programme. Programmes whose implementation is in line with the EU legislation and the terms agreed with the Commission are considered successful. | Percentage | Grant decisions (one per MS) and Final payment checklist | Annual | 2020 | 100% |
| | Number of emergency situations successfully addressed (by pest) | Following the submission of technical and financial final reports by the Member States, the Commission carries out the evaluation and decides on the final payment of the eligible costs incurred for each previously approved emergency measure. Programmes whose implementation | Percentage | Grant decisions (one per emergency , i.e. one per MS and per pest) and Final payment checklist | Annual | 2020 | 100% |

| | | | | | | | |
|---|--|---|--------------|--|---|------|---|
| | | is in line with the EU legislation and the terms agreed with the Commission are considered successful. | | | | | |
| | Reduction of number of outbreaks | Technical parameter used to monitor the epidemiological evolution of a given pest. | Number | Final technical reports (submitted by the MSs) | Depending on needs (emergency measures are not predictable by definition) | 2020 | Specific targets for this indicator will be defined individually for each pest in each Member State based on the epidemiological evolution by 2020, and then updated every year as described in the main text |
| Official controls related activities: improving the effectiveness, efficiency and reliability of the food supply chain harnessing official controls related activities, carried out with a view to implement and comply with the Union rules in this area | Number of activities successfully carried out by the EURCs | Quantitative and qualitative assessments on the laboratories activities performed following the EU request. Activities whose implementation is in line with the terms agreed with the Commission are considered successful. | Percentage | Annual Work programme and Final reports (submitted by each EURC) | Annual | 2020 | 100% |
| | Number of launched training actions as included in the annual work programme | Ability to respond to EU and national needs in a flexible and effective way through the organisation of thematic BTSF trainings (both standard and e-learning) | Percentage | Annual Work Programme and Final reports on the outcome of the training | Annual | 2020 | 100% |
| Animal health + Plant health + Official Controls related activities | Food and live animals: trade value | Evolution of extra EU-trade (export) | Million euro | Eurostat database (economic accounts for agriculture) | Monthly | N/A | N/A |

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|--|--|--|--------------|---|--------|------|------|
| | | | |) | | | |
| Animal health + Plant health + Official Controls related activities | Animal products: production value | Production value at basic prices | Million euro | Eurostat database (economic accounts for agriculture) | Annual | N/A | N/A |
| Animal health + Plant health + Official Controls related activities | Number of human cases due to a zoonoses | Evolution of human cases due to animal diseases transmissible to humans | Number | EFSA annual report | Annual | N/A | N/A |
| Composite IMP indicator | Successfully implemented national veterinary and phytosanitary programmes" | Following the submission of technical and financial final reports by the Member States, the Commission carries out the evaluation and decides on the final payment of the eligible costs incurred for each previously approved programme. Programmes whose implementation is in line with EU legislation and the terms agreed with the Commission are considered successful. That means the programmes submitted by the Member States are in line with the requirements listed in the specific EU legislation and additional guidelines (COM guidelines, COM working document on strategy against specific disease, recommendation by former FVO audits, specific task force, ...) and when all elements contained in the programmes | Percentage | Grant decisions (one per MS) + Final technical and financial report + Payment checklist | Annual | 2020 | 100% |

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| | | submitted by the Member States, previously approved by the Commission, are implemented by the national authorities. | | | | | |
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Sub-Annex 1: Evidence, sources and quality

6. EVIDENCE, SOURCES AND QUALITY

Summary for the main IA text:

The main evidence base used in the context of the present impact assessment is the outcome of the mid-term evaluation of Regulation (EU) No 652/2014, which included an external study and an internal assessment performed by the Commission. The mid-term evaluation report was presented by the Commission to the European Parliament and to the Council in September 2017. The evaluation was conducted in line with the Better Regulation requirements and provided good evidence of the positive implementation of the Common Financial Framework over the first three years of the present MFF. Nevertheless, two specific shortcomings affected this exercise, namely the limited time available to undertake the evaluation and the absence of a cost-effectiveness analysis implemented in this area.

The mid-term evaluation is currently being complemented by a soon-to-be finalised JRC study addressing the cost-effectiveness issue, and a data gathering study aimed at filling in some information gaps and analytical needs in view of the next Food Chain Programme. The intermediate results of both studies have progressively fed into the present impact assessment exercise.

The main evidence base used in the context of the present impact assessment has been the outcome of the mid-term evaluation of Regulation (EU) No 652/2014 on the management of expenditure in the food chain area. This evaluation exercise included a study carried out by an external contractor, whose final version was delivered in July 2017, and an internal assessment performed by the Commission, with a final evaluation report presented to the European Parliament and to the Council in September 2017. In this context, both targeted and open public consultations were conducted. The mid-term evaluation fully covered the implementation of the main food chain measures for 2014, 2015 and partially 2016, dependant on preliminary data available. Where relevant, it also took into account results on the long-term impact of the predecessor measures. It provided a qualitative and quantitative overview of the measures implemented under the

Regulation, and assessed them against the five evaluation criteria set by the Better Regulation policies in the European Commission: relevance, European added value, effectiveness, efficiency and coherence. There are however a number of issues to consider when assessing the strengths of the evidence base used for this study, specifically linked to the limited time available to undertake the evaluation:

- the mid-term evaluation exercise started in the second half of 2016, where complete technical and financial data were only available for the first two years of implementation of the CFF Regulation;
- a number of transitory measures applied during both 2014 and 2015, while the provisions laid down in the Regulation were fully applicable only from 2016.

Moreover, no cost-effectiveness analysis has been developed so far in the food chain area. Whilst a methodological approach to conduct this kind of economic analysis was expected to be delivered in the context of the external study, the task was not investigated as requested. Therefore, a significant instrument to perform the evaluation was missing.

These shortcomings have objectively limited the external analysis, which is mostly descriptive and largely based on the opinions of the stakeholders and on the perceptions of the beneficiaries of the EU financial support in this area. The overall evaluation exercise was nevertheless complemented by the internal assessment conducted at EU level, which largely relies on the continuous analysis performed at policy, technical and financial level by the Commission services, including the constant dialogue with all stakeholders/beneficiaries for both scientific and budgetary aspects. The monitoring of an existing set of robust operational technical indicators was particularly useful in the context of this evaluation: even if they do not provide cost-effectiveness results, those indicators allowed evaluating the achievements and/or the performance of the major activities implemented thanks to the EU funding in the areas covered by the Regulation.

To complement the economic evaluation of Regulation (EU) No 652/2014 in the specific area of cost-effectiveness, a targeted study is currently being carried out by the JRC. The objective is to develop and implement a comprehensive set of cost-effectiveness indicators for the main spending areas covered by the Food Chain programme, as well as to investigate the potential calculation of the cost of non-intervention at EU level. The study is in its last stages and the final report is expected to be validated by April 2018. Relevant intermediate findings were integrated into the present impact assessments, notably as concerns the monitoring system and the proposed indicators to be used for the post-2020 Food Chain Programme.

Concurrently, an external study focused on data gathering and analysis in the food chain area was launched in October 2017. It covers all policy areas under the food chain funding, and consists of two assignments: the first one focuses on gathering and analysing data on the cost-efficiency, benefits and EU added-value of the actions performed under the Food Chain Programme; the second one, based on relevant budgetary and policy indications made available, on designing detailed programme indicators for future monitoring and evaluation purposes, in relation to the actions that will be retained for the next Food Chain Programme. The final report is expected to be

delivered in May 2018. Still, its intermediate findings have fed into the preparation of the present impact assessment.

Sub-Annex 2: Stakeholder consultation

Summary for the main IA text:

The mid-term evaluation of the CFF Regulation included a comprehensive consultation exercise which addressed both the general public and targeted stakeholders from both public and private sectors. Overall, the findings of the consultation revealed the appreciation of the implementation of the EU spending in this area in terms of relevance with the EU needs, added value achieved at EU level, effectiveness of the measures implemented, efficiency of the resources invested and coherence with the EU policies and legislations. Emphasis was put on the need to increase attention to preventive measures and on the possible reduction of the administrative burden for both the EU and the Member States.

In the context of the mid-term evaluation of Regulation (EU) No 652/2014, a comprehensive consultation exercise was conducted. Its outcome is summarised in the Commission Staff Working Document Synopsis report¹⁵⁸ accompanying the mid-term evaluation report itself. The consultation covered aspects relating to the evaluation criteria used in this framework, namely relevance, added value, efficiency, effectiveness, and coherence. It addressed both the direct beneficiaries of the grants awarded under the Regulation, notably the central veterinary and phytosanitary Competent Authorities (CAs) of EU Member States, as well as the European and the National Reference Laboratories representatives, and stakeholders which are indirectly involved in the funded activities, especially farmers, consumers, food-industry and retailers representatives.

Stakeholders had the opportunity to provide their feedback on a Commission evaluation roadmap on the mid-term evaluation on Regulation (EU) No 652/2014¹, during a 4-week period starting on 9 June 2016. In addition, an open public consultation (OPC) of all interested parties has been conducted using the European Commission ‘Public consultations’ website and the DG SANTE ‘Consultations and feedback’ web page. The open public consultation was carried out between 16 December 2016 and 17 March 2017. Moreover, a round of targeted consultations was conducted by the external contractor, and included: stakeholders interviews addressing representatives of the European Commission (DG SANTE and DG AGRI), and selected stakeholders (CAs, industry representatives, targeted NGOs) in a number of MSs; targeted stakeholders interviews, to further investigate relevant aspects raised in the context of the previously conducted questionnaires; case study interviews, identified based on the assessment of the results from the desk study and questionnaires. While the participation in the OPC

¹⁵⁸ SWD(2017) 316 final

https://ec.europa.eu/food/sites/food/files/cff_mid-term-evaluation_synopsys_report_en.pdf

was low (only 5 contributions received), the response rate in the context of the targeted stakeholders' consultations was generally high.

The respondents in both the OPC and the targeted questionnaires generally evaluated the Regulation to be relevant and in line with the current food chain needs. Overall, they considered the Regulation to have a satisfactory EU added value. The respondents also considered the Regulation to be very efficient, and satisfactory in terms of effectiveness. While none of the participants in the OPC addressed the coherence issue, the large majority of respondents to the questionnaires agreed on the coherence of the Food Chain Programme with other EU policies, or evaluated it as at least complementary and/or synergistic with the EU legislation in the food chain area and with other EU policies. No particular conflict was identified and no specific need for additional synergy with any of the other IMP programmes was expressed in this context. Overall, an increasing call for specific attention for preventive measures in this area was highlighted, as well as the need to reduce administrative burden, e.g. in terms of reporting requirements, which in some cases is considered to be disproportionate.

The results of the different parts of the consultation exercise were largely coherent among each other, and a general appreciation for the food chain programmes was expressed in terms of both technical and financial support provided at EU level.

Sub-Annex 3: Evaluation results

Summary for the main IA text:

Being the first common financial framework established in the area of food chain, Regulation (EU) No 652/2014 was firstly evaluated at mid-term in the context of the recently conducted interim evaluation (final report adopted in September 2017).

Overall, the mid-term evaluation revealed that the CFF Regulation is functioning well within its policy context. All activities receiving EU financial support in this area have proven to serve the CFF objectives, namely the improvement of human, animal and plant health, as well as the overall Commission's priorities, including the functioning of an effective internal market and the support to trade with non-EU countries. The evaluation concluded that activities funded under the Regulation contribute to a EU which is safe and secure, prosperous and sustainable, social, and stronger on the global scene.

The mid-term evaluation of Regulation (EU) No 652/2014 consisted of an external study¹⁵⁹, whose final report was delivered by the selected contractor in July 2017, and a Commission mid-term evaluation report to the European Parliament and to the Council¹⁶⁰ which was established and presented in September 2017.

The evaluation focused on the measures implemented in the areas of animal health (veterinary programmes and emergency measures), plant health (survey programmes and emergency measures), laboratories (EURLs), and training (BTSF); particularly, it assessed whether, in terms of their results and impacts, these measures achieve the objectives set out the Regulation, as regards the efficiency of the use of resources and the added value at Union level. At case level, the evaluation covered all 28 Member States.

Overall, the mid-term evaluation concluded that the CFF Regulation is functioning well within its policy context. All activities receiving EU financial support in this area have proven to serve the CFF objectives, namely the improvement of human, animal and plant health, as well as the overall Commission's priorities, including the functioning of an effective internal market and the support to trade with non-EU countries. The EU financial provisions on food safety, animal and plant health have been recognised as uniform and consistent in their application and enforcement in all EU Member States. This ensures in turn that both citizens and businesses are confident that this financial

¹⁵⁹ Mid-term evaluation of Regulation (EU) No 652/2014 prepared by IBF International consulting (see attached staff working document)

¹⁶⁰ COM(2017) 546 final - Report from the Commission to the European Parliament and to the Council - Mid-term evaluation of Regulation (EU) No 652/2014 of the European Parliament and the Council laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material [...]
https://ec.europa.eu/food/sites/food/files/cff_mid-term-evaluation_comm_report_en.pdf

framework is fair and effective in promoting high safety standards in a key sector of the EU economy. The activities funded under the Regulation contribute to a EU which is safe and secure, prosperous and sustainable, social, and stronger on the global scene.

Before the entry into force of Regulation (EU) No 652/2014, the provisions for the management of the expenditure in the food chain area were scattered across many pieces of legislation. In line with the Communication 'A Budget for Europe 2020', the establishment of a common financial framework covering all spending areas concerned was envisaged to modernise and simplify the pre-existing financial system. The mid-term evaluation exercise finalised in September 2017 was therefore the first evaluation addressing a food chain spending programme. This evaluation was not submitted to the RSB for its scrutiny.

Annex 18: Programme specific annex on *Customs and tax policy development support budget line*

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

1.1. Scope and context

Both, the customs union and EU tax policy, are – at a different level - fundamental conditions for the smooth functioning of the Internal Market.

For 50 years, the customs union has been a significant example of successful integration in the EU. It is one of the few areas of exclusive competence of the EU and it remains a foundation of the Union and a fundamental enabler of the Internal Market and the other EU political priorities: without the customs union the elimination of internal frontiers would not have been possible. In addition, the harmonised legislative framework provides the basis for the collection of customs duties, which constitute 16% of the EU budget

Similarly, EU tax policy is a key element in efforts to strengthen the EU Internal Market. In the domain of indirect taxes (mainly VAT and excise) – the largest source of revenue for national budgets and a substantial contribution (12%) to the EU's budget - the Union developed a comprehensive set of legislation that is a fundament of the establishment and functioning of the Internal Market and the avoidance of distortion of competition. In the field of direct taxation (income tax and company tax) with the juxtaposition of 28 different tax systems, the EU can rely on the general provisions as regards the Internal Market (Art. 114-115) to provide overall tax governance and adopt relevant EU legislation supporting the functioning and completion of the internal market and fighting tax fraud and tax evasion.

Over the recent years, new challenges arose through a.o. rapidly changing technologies (digitalisation, connectivity, Internet of things, block-chain) and business models (e-commerce, supply chain optimisation), increasing volumes of world trade, international tax competition between countries and tax shopping by companies, reduced public financial means, a persistent transnational crime and security threat. These trends, if not addressed appropriately, risk creating distortions of competition and jeopardising the functioning of the Internal Market and the 4 freedoms, wrecking social fairness and undermining EU competitiveness.

In its role as guardian of the Treaties and in view of its prerogative for legislative initiatives, the Commission has a particular duty to remain alert, monitor and anticipate changes in the tax and customs environment and propose appropriate (legislative) action. Against this backdrop, it is of utmost importance that it has appropriate resources at its disposal to prepare and carry out the actions – beyond the overall framework for cooperation provided by the Fiscalis and Customs programmes – that support policy strategy and coordination.

1.2. Lessons learned from previous programmes

The budget line “Policy strategy and coordination” for taxation and customs has not been subject to evaluation in view of the limited budget allocated – 3,2 €m/yr in the on-going Multi-Annual Financial Framework – and the obvious added value of actions carried out.

The activities funded under this prerogative line include:

- Studies, analyses, data collection:
 - o In the area of indirect taxation policy: e.g. impact assessments, evaluation of existing VAT/excise legislation, specific VAT and excise duties issues, penalty system on tax compliance, the future of taxation etc.
 - o In the area of direct taxation policy: e.g. EUROMOD tool, issues linked to double taxation cases, transfer pricing, taxation of pension funds and life insurance companies, aggressive tax planning, tax analyser, tax compliance costs, taxation and financial stability, etc.
 - o In the area of customs: e.g. issues linked to impact assessment, comparative analyses, studies linked to legislative proposals e.g. on cash control, the implementation of the Union Customs Code, consultancy and expertise in waste and dangerous products, or the development of a framework to measure the performance of the Customs Union, etc.
- Information campaigns / external communication: production and development of awareness-raising materials;
- expenditure on Information Technology (IT) covering both equipment and services needed for internal market activities and as a complement to IT systems developed under Fiscalis and Customs programmes;
- Access to or acquisition of databases: e.g. acquisition of economic data for impact assessments and studies, activities in customs classification;
- Provision of publications, tools, library services and other supporting services related to the supply of tax and customs information;
- Similar actions supporting policy strategy and coordination in taxation and customs: e.g. visiting Fellows programmes, translation services, etc.

As this prerogative line addresses only the Commission’s own needs, no external consultation has been carried out and this proposal relies exclusively on experience drawn by Commission services.

This experience demonstrates that all existing characteristics of the prerogative line – areas covered, authorised actions, amounts at stake, etc.) are fit-for-purpose: the existing budget line does not only bring significant added value for policy definition but a fundamental element of the Commission’s capacity to deliver a vision and design tax and customs policies in view of new challenges and trends.

However, there would be room for optimising the administrative processes behind these actions, e.g. by establishing framework contracts for the provision of studies in cooperation with other domains covered by the Internal Market [Framework] Programme.

Against this background, it is proposed to place this prerogative line under the consolidated Internal Market [Framework] Programme in order to allow for more and enhanced synergies across complementary domains.

2. THE OBJECTIVES

2.1. Challenges for the programmes of the next MFF

| Challenges Programme/line | Empowerment of citizens, consumers and businesses | Administrative cooperation and integration among Member States | Rule-making, standard setting and enforcement at EU institutions level | Health as a resources for the society and the internal market |
|---|---|--|--|---|
| Policy strategy and coordination for taxation and customs | N/A | N/A | √ | N/A |
| LEGEND: √ -relevant to the objective, N/A not relevant | | | | |

The activities under the prerogative line relates exclusively to rule-making, standard setting and enforcement at EU institutions level. All other activities – e.g. administrative cooperation – are dealt with separately under the Fiscalis and Customs programmes¹⁶¹.

2.2. Objectives of the programmes of the next MFF

The specific objective of this prerogative line is to support the definition and coordination of policy strategy – i.e. rule-making, standard setting and enforcement at EU institutions level – in the tax and customs domains.

| Challenges Programme/line | Empowerment of citizens, consumers and businesses | Administrative cooperation and integration among Member States | Rule-making, standard setting and enforcement at EU institutions level | Health as a resources for the society and the internal market |
|---|---|--|---|---|
| Policy strategy and coordination for taxation and customs | N/A | N/A | Support the definition and coordination of policy strategy in the tax and customs domains | N/A |

3. PROGRAMME STRUCTURE AND PRIORITIES

This budget line being a prerogative line – i.e. a line to be used by the Commission at its own prerogative in view of new challenges and needs as part of policy strategy and coordination –, there is no relevance to define in advance a particular structure and it would be impossible to establish priorities at the start of the Multi-Annual Financial Framework. The key consideration here is to define the critical mass of funding needed to allow effective policy strategy and coordination by the Commission.

Over the 2014-2020 period, funding amounted to 3,2 €/yr. Whereas no significant increase seems necessary as most needs could be funded over the recent years, a minor increase to cope with inflation – estimated to about 15% - would be welcome as it would allow pursuing activities at the same level as in the past. On the contrary, a reduction by more than 25% – i.e.

¹⁶¹ Given their specific characteristics – a.o. their exclusive focus on tax and customs administrations and not on citizens, consumers and businesses, the importance of resources allocated –, the Fiscalis and Customs programmes are not concerned at all by possible synergies as contemplated in this integrated Internal Market Programme.

below a budget of 2,4 €/yr – would have non-negligible consequences as it would prevent carrying out several much needed studies or other activities.

4. DELIVERY MECHANISMS OF THE INTENDED FUNDING

As a prerogative line, this budget line is – and can only be – subject to direct management by the Commission.

5. HOW WILL PERFORMANCE BE MONITORED AND EVALUATED?

As a prerogative line, it is impossible to determine in advance the use of the allocated funds and thereby to define specific indicators as to the outputs, results or impacts. It is therefore proposed to monitor and evaluate performance on a financial basis, as is currently the case with the existing budget line. In other words, Commission services will focus on timely budget execution.

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---|-------------------------|--|-------------------------|------------------------------------|--------------------------|----------|--------|
| Support the definition and coordination of policy strategy in the tax and customs domains | Timely budget execution | Execution of more than 95% of budget by year-end | Use of budget available | ABAC (Commission financial system) | Annual | >95% | >95% |

Sub-Annex 1: Evidence, sources and quality

EVIDENCE, SOURCES AND QUALITY

Not applicable

Sub-Annex 2: Stakeholder consultation

Not applicable

Sub-Annex 3: Evaluation results

Not applicable

Annex 19: Programme specific objectives

This annex presents the detailed operational objectives for each of the programmes/budget lines included under the scope and how they each contribute to the identified content specific objectives of the Single Market Programme.

| Challenges Programme/line | Empowerment of citizens, consumers and businesses | Administrative cooperation and integration among Member States | Rule-making, standard setting and enforcement at EU institutions level | Health as a resources for the society and the internal market |
|---|--|--|---|--|
| An Ambitious Competition policy for a stronger Union in the digital age | | | | |
| Competition programme | To raise awareness of EU competition policy among a wider group of stakeholders concerned by the enforcement of EU competition rules, thereby strengthening the effectiveness and legitimacy of those rules. | To strengthen, deepen and extend cooperation and partnerships with European public administrations (including national competition authorities and courts) in the form of direct contacts as well as interoperable IT infrastructures ensuring the exchange of confidential documents and information. | To ensure that the enforcement of EU competition policy as well as policy guidance is supported by state-of-the-art tools and infrastructure (including software and hardware) as well as external technical expertise and information. To raise awareness of EU competition policy among a wider group of stakeholders concerned by the enforcement of EU competition rules, thereby strengthening the effectiveness and legitimacy of those rules. | N/A |
| IT and business solutions for the Single Market | | | | |
| 1. To support the efforts of the Member States and European Institutions in modernising and digitising the public sector organisations at all levels | The publication of open government data will allow easier access to information. | The provision of IT tools to public authorities (building on the results of ISA2 and other programmes) will strengthen administrative and judicial cooperation. | N/A | The digitisation, adoption of common standards and interoperability will affect all sectors, including healthcare. Health sector in particular, can benefit from more efficient internal processes, better information sharing, and communication with patients. |
| 2. To provide inclusive and | eParticipation tools will support | N/A | N/A | N/A |

| Challenges Programme/line | Empowerment of citizens, consumers and businesses | Administrative cooperation and integration among Member States | Rule-making, standard setting and enforcement at EU institutions level | Health as a resources for the society and the internal market |
|--|---|--|---|---|
| user-friendly end-to-end digital public services to all citizens and businesses in the Union | the representation of citizens' interests. | | | |
| 3. To contribute to the reduction of administrative burden by promoting administrative cooperation, interoperability through digital means and user engagement to allow citizens and businesses to enjoy user-centred services that address their needs. | Will lead to increased sharing and reuse of standardised open data, benefiting other public administrations, businesses and citizens. | The provision of IT tools to public authorities (building on the results of ISA2) will strengthen administrative and judicial cooperation. | N/A | N/A |
| 4. To ensure that policy makers in the EU have the necessary capabilities for making more evidence-informed policies, deciding rapidly between alternative options and better monitoring implementation. | The abundance of open data and the use of data analytics will contribute to better policy making. | N/A | The assessment of ICT implications will ensure that policy making takes into account ICT and the latest technological developments. | N/A |
| [European Statistical Programme (ESP)] | | | | |
| European Statistical Programme' (ESP) | To produce and communicate high quality statistics on Europe in a timely, impartial and cost-efficient manner, through enhanced partnerships within the European Statistical System and with all relevant external parties, using multiple data sources, advanced data analytics methods, smart systems and digital | To produce and communicate high quality statistics on Europe in a timely, impartial and cost-efficient manner, through enhanced partnerships within the European Statistical System and with all relevant external parties, using multiple data sources, advanced data analytics methods, smart systems and digital technologies.[| To produce and communicate high quality statistics on Europe in a timely, impartial and cost-efficient manner, through enhanced partnerships within the European Statistical System and with all relevant external parties, using multiple data sources, advanced data analytics methods, smart | To produce and communicate high quality statistics on Europe in a timely, impartial and cost-efficient manner, through enhanced partnerships within the European Statistical System and with all relevant external parties, using multiple data sources, advanced data analytics methods, smart |

| Challenges Programme/line | Empowerment of citizens, consumers and businesses | Administrative cooperation and integration among Member States | Rule-making, standard setting and enforcement at EU institutions level | Health as a resources for the society and the internal market |
|--|---|--|--|---|
| | technologies.[| | systems and digital technologies.[| systems and digital technologies.[|
| Implementation and Development of Single Market for Financial Services | | | | |
| Implementation and Development of Single Market for Financial Services | To provide evidence based policy making for a deeper and more integrated Capital Markets Union so as to ensure long-term effects on jobs and growth and contribute to a stronger Union. | To monitor the implementation of the Banking Union, in the Member States | To deliver an EU strategy on sustainable finance which is a priority action of the CMU Action Plan, as well as one of the key steps towards implementing the historic Paris agreement and the EU's agenda for sustainable development. | N/A |
| FISMA - Standards in the field of reporting and auditing | | | | |
| Standards in the field of reporting and auditing | N/A | N/A | To support standardisation organisations working towards standards settings in financial reporting and auditing | N/A |
| Enhancing the involvement of consumers and other end-users in Union policy-making in financial services (ICFS) | | | | |
| Capacity-building programme enhancing the involvement of consumers and other financial services end-users in Union policy making in the area of financial services. | To provide citizens with better information about financial services in order to take the right personal financial decisions. | N/A | To preserve a balanced and structured interaction with stakeholders to improve the calibration of the financial services rules | N/A |
| Company law and anti-money laundering | | | | |
| Company law and anti-money laundering | N/A | To develop and maintain tools and platforms required by EU law (e.g. maintain interconnection of the business interconnection as required by Directive 2017/1132 and develop interconnection of MS beneficial ownership registers under Directive 2015/849 – 4 th | To facilitate dialogue with civil society and other stakeholders (feedback gathering) Facilitate introduction of new technologies, in particular use of digital tools and processes To ensure the development, implementation, | N/A |

| Challenges Programme/line | Empowerment of citizens, consumers and businesses | Administrative cooperation and integration among Member States | Rule-making, standard setting and enforcement at EU institutions level | Health as a resources for the society and the internal market |
|--|---|---|--|---|
| | | AMLD including the most recent amendments – 5 th AMLD) | enforcement and monitoring of high-quality and effective Single Market rule making and standard setting (in the company law and anti-money laundering and counter terrorism financing field) | |
| Consumer programme and New Deal for consumers | | | | |
| Consumer programme and New Deal for consumers | <p>To Ensure consumers are aware of their rights and of consumer safety issues</p> <p>To Strengthen consumer organisations' roles in consumer policy-making and advocacy at EU and national levels</p> <p>To reduce vulnerability of consumers also linked to negative consequences of market digitalisation</p> <p>To enable assistance and redress systems for individual consumers including support to the ADR bodies, the ODR Platform, and the ECC-Net</p> <p>To ensure qualified entities in the meaning of the Injunctions directive can deliver on their injunctive role</p> | <p>Ensuring enforcement authorities competent in consumer and product safety laws can deliver a high level of compliance to the acquis</p> <p>To ensure the availability of market intelligence tools and joint actions in the field of product safety including in relation to testing of dangerous products</p> <p>To enable effective and coordinated EU-level enforcement actions in the field of consumer law and product safety</p> <p>To enable effective enforcement cooperation with third countries</p> | <p>To provide a high quality general information on consumer markets and conditions and behaviours and on safety issues</p> <p>To integrate and develop information on consumer markets with a view to develop evidence for enforcement actions at the EU level</p> <p>To generate evidence on market issues stemming from new technologies (IOT, IA, mobile e-commerce)</p> | N/A |

| Challenges Programme/line | Empowerment of citizens, consumers and businesses | Administrative cooperation and integration among Member States | Rule-making, standard setting and enforcement at EU institutions level | Health as a resources for the society and the internal market |
|---|---|---|---|--|
| | To promote sustainable consumption behaviours | | | |
| Internal Market governance tools | | | | |
| Internal Market governance tools | To enhance access to information, advice, improved problem-solving services and procedures on a cross-border basis | To Improve management of cross-border Single Market challenges, while promoting IT rationalisation | Giving SOLVIT a more prominent role in the overall EU Law enforcement. Ensure the coherent application of the single digital gateway quality standards | N/A |
| Internal Market – Support to standardisation | | | | |
| Support to Standardisation activities | To promote the participation and interests of the stakeholders in the European standardisation system, improving their information and use of standards and showing them the benefits of these. | N/A | To develop and promote use of standards in areas which are new or dominated by few players and Union financing is necessary to assure the participation of start-ups and newcomers in that market | Development and use of standards in support of Union legislation and policies for safety reasons and in areas which are new or dominated by few players and Union financing is necessary to assure the participation of start-ups and newcomers in that market |
| Internal Market for goods and services | | | | |
| Single market for goods and services | To improve the safety of citizens and the level playing field for businesses | To support the completion of the single market of goods and services. To enhance Member States' capacity to enforce EU harmonised product rules. To facilitate administrative cooperation of MS in several areas: market surveillance, mutual recognition, prevention of technical barriers, services and public procurement. | To provide a regulatory environment that promotes innovation and responds to new technological and societal challenge, | N/A |

| Challenges Programme/line | Empowerment of citizens, consumers and businesses | Administrative cooperation and integration among Member States | Rule-making, standard setting and enforcement at EU institutions level | Health as a resources for the society and the internal market |
|------------------------------|---|---|---|--|
| COSME | | | | |
| COSME | <p>1. Promoting the creation and sustainable growth of enterprises, in particular SMEs.</p> <p>2. Strengthening the competitiveness of enterprises and fostering entrepreneurship.</p> <p>Specific objectives</p> <p>1) Addressing the access to finance gap for SMEs</p> <p>2) Facilitating SMEs' access to markets and supporting them in addressing global and societal challenges;</p> <p>3) Business Environment, Industrial modernisation, Competitiveness and Entrepreneurship</p> | To address SME policy issues by sharing good practices and economic with Member States and participating countries. | | |
| Health programme | | | | |
| Health programme | | | Support EU health legislation | Prepare for and counter health crises |
| | | Empower health systems with emphasis on their digital transformation | | Empower health systems with emphasis on their digital transformation |
| | Support integrated work: Health technology assessment, ERNs and best practices | Support integrated work: Health technology assessment, ERNs and best practices | Support integrated work: Health technology assessment, ERNs and best practices | Support integrated work: Health technology assessment, ERNs and best practices |
| Food Chain Programme | | | | |
| Food Chain programme | Improve the prevention, control | Improve the prevention, control | Improve the prevention, control | Improve the prevention, |

| Challenges Programme/line | Empowerment of citizens, consumers and businesses | Administrative cooperation and integration among Member States | Rule-making, standard setting and enforcement at EU institutions level | Health as a resources for the society and the internal market |
|---|--|---|--|--|
| | and eradication of animal diseases in the Union territory | and eradication of animal diseases in the Union territory | and eradication of animal diseases in the Union territory | control and eradication of animal diseases in the Union territory |
| | Improving the prevention, containment and eradication of plant pests in the Union territory | Improving the prevention, containment and eradication of plant pests in the Union territory | Improving the prevention, containment and eradication of plant pests in the Union territory | Improving the prevention, containment and eradication of plant pests in the Union territory |
| | Improve the effectiveness, efficiency and reliability of official controls related activities along the food supply chain | Improve the effectiveness, efficiency and reliability of official controls related activities along the food supply chain | Improve the effectiveness, efficiency and reliability of official controls related activities along the food supply chain | Improve the effectiveness, efficiency and reliability of official controls related activities along the food supply chain |
| Customs and tax policy development support budget line | | | | |
| Customs and tax policy development support budget line | N/A | N/A | To support the definition and coordination of policy strategy in the tax and customs domains | N/A |

Annex 20: Programme specific Indicators

This annex presents the detailed monitoring indicators used for the programmes/budget lines included under the scope of the Single Market Programme.

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|--|------------------|---------------------|----------------|--------------------------|-----------------------|--------------------------------|
| An Ambitious Competition policy for a stronger Union in the digital age | | | | | | | |
| State-of-the-art enforcement and policy guidance | Estimate of customer benefits resulting from cartel prohibition decisions. | Impact Indicator | EUR | Inhouse | Annual | To be defined in 2020 | No target for 2021-2027 |
| State-of-the-art enforcement and policy guidance | Estimate of customer benefits resulting from merger interventions. | Impact Indicator | EUR | Inhouse | Annual | To be defined in 2020 | No target for 2021-2027 |
| State-of-the-art enforcement and policy guidance | Macroeconomic benefits modelling using customer benefits as an input. | Impact Indicator | EUR | Inhouse | Regular | To be defined in 2020 | No target for 2021-2027 |
| State-of-the-art enforcement and policy guidance | Stakeholder surveys on the perception of enforcement and policy guidance. | Result Indicator | Percentage | Survey | Regular | To be defined in 2020 | Increasing trend for 2021-2027 |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|---|------------------|---------------------|----------------|--------------------------|-----------------------|-------------------------|
| State-of-the-art enforcement and policy guidance | Number of published policy guidance texts with the purpose of interpreting antitrust, merger and State aid rules in light of market realities, contemporary economic and legal thinking as well as developments in the EU Courts' case-law. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | No target for 2021-2027 |
| State-of-the-art enforcement and policy guidance | Amount of fines imposed in antitrust, cartel and, merger decisions. | Output Indicator | EUR | Inhouse | Annual | To be defined in 2020 | No target for 2021-2027 |
| State-of-the-art | Amount of unlawful | Output Indicator | EUR | Inhouse | Annual | To be defined | No target |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|--|------------------|---------------------|--|--------------------------|-----------------------|--------------------------------|
| enforcement and policy guidance | State aid to be recovered pursuant to a Commission decision. | r | | | | d in 2020 | for 2021-2027 |
| State-of-the-art enforcement and policy guidance | 'Additionality': Amount of private investment leveraged by individual State aid measures, according to the counterfactual assessment made in a Commission decision (this may either be 'input' additionality (i.e. the beneficiary invests more own resources as a | Result Indicator | EUR | Inhouse; Member State reports ; Member State evaluations | Regular | To be defined in 2020 | Increasing trend for 2021-2027 |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|--|------------------|---------------------|----------------|--------------------------|-----------------------|---|
| | result of the aid) or 'output' additionality (i.e. the beneficiary generates higher output of eligible activities as a result of the aid). | | | | | | |
| State-of-the-art enforcement and policy guidance | Number of Commission decisions in the field of antitrust and cartels. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 ¹⁶² |
| State-of-the-art enforcement and policy guidance | Number of Commission statements of objections in the field of antitrust | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | No target for 2021-2027 |

¹⁶² It is not meaningful to set numerical targets for competition policy enforcement. Most of the indicators used to measure the Commission's performance include trends as targets (stable, increase, decrease, no target). On-going investigation by the Commission is always without prejudice to the final decision to be taken by the Commission in the case. However, DG Competition, like most competition authorities, provides the number of decisions (or intervention rate) to indicate the level of activity and output for the preceding year, also for deterrence purposes. As regards antitrust and cartel enforcement, a target would also depend on factors beyond the Commission's control (decisions of the parties or other market players to disclose infringements through the leniency programme, whistleblowing, complaints or the availability of information to the Commission to detect infringements ex officio). In each and every case, the Commission must fully respect the rights of defence of the parties. These considerations are also relevant for the following indicators: Amount of fines imposed in antitrust, cartel and, merger decisions; Number of Commission statements of objections in the field of antitrust and cartels; Number of Initiation of Proceedings in antitrust cases; Number of antitrust cases with ongoing monitoring of remedies or commitments.

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|---|------------------|---------------------|----------------|--------------------------|-----------------------|--|
| | and cartels. | | | | | | |
| State-of-the-art enforcement and policy guidance | Number of Initiation of Proceedings in antitrust cases. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | No target for 2021-2027 |
| State-of-the-art enforcement and policy guidance | Number of formal antitrust complaints. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | No target for 2021-2027 ¹⁶³ |
| State-of-the-art enforcement and policy guidance | Number of leniency applications in cartel procedures. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | No target for 2021-2027 ¹⁶⁴ |
| State-of-the-art enforcement and policy guidance | Number of antitrust cases with ongoing monitoring of remedies or commitments. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | No target for 2021-2027 |

¹⁶³ As the formal submissions of complaints by market participants are driven by factors beyond the control of the Commission, no output target can be set. In recent years, we have been facing a period of intense restructuring and M&A activity with no signs of abatement for the coming years. This has led to a steady increase in the number of merger notifications that we receive every year. 2017 was the second busiest year ever, with 380 notifications (5% more than in 2016; 37% more than in 2013). This number was exceeded only in 2007, just before the start of the financial crisis, when 402 cases were notified to the Commission. It can safely be anticipated that the period 2018/2019 will continue to be characterised by a very intense merger activity, in terms both of number of notifications and complexity of cases.

¹⁶⁴ DG Competition's leniency applications in cartel procedures are driven by the willingness of the cartels' participants to cooperate and the time they chose to do so. As this is a factor beyond the control of the Commission, no output target can be set.

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|---|------------------|---------------------|----------------|--------------------------|-----------------------|--|
| State-of-the-art enforcement and policy guidance | Number of Commission simplified and non-simplified decisions in the field of merger control. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | No target for 2021-2027 ¹⁶⁵ |
| State-of-the-art enforcement and policy guidance | Number of Commission merger decisions subject to commitments, withdrawals in phase two, or prohibitions (i.e. intervention decisions) | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | No target for 2021-2027 |
| State-of-the-art enforcement and policy guidance | Number of merger referral requests and decisions. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | No target for 2021-2027 |
| State-of-the-art enforcement | The share of GBER expenditure over | Result Indicator | Percentage | Inhouse | Annual | To be defined in | Increasing trend for |

¹⁶⁵ DG Competition's enforcement activities in the merger area are driven by merger activity on the markets and notifications by companies. As this is a factor beyond the control of the Commission, no output target can be set.

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|---|------------------|---------------------|----------------|--------------------------|-----------------------|--|
| and policy guidance | total expenditure on State aid. | | | | | 2020 | 2021-2027 ¹⁶⁶ |
| State-of-the-art enforcement and policy guidance | The percentage of horizontal State aid of all aid in the EU. | Result Indicator | Percentage | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 |
| State-of-the-art enforcement and policy guidance | Number of Commission decisions in the field of State aid. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | No target for 2021-2027 ¹⁶⁷ |
| State-of-the-art enforcement and policy guidance | Number of Commission decisions opening the formal investigation procedure in the field of State | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | No target for 2021-2027 |

¹⁶⁶ The trend may reach a plateau before 2027, as the share of GBER expenditure over total State aid expenditure was already high at the time of writing (97% of all new aid measures being implemented under the GBER, representing ; about 46 % of total spending (based on average country specific shares to reflect equally differences in Member States practice).

¹⁶⁷ Excluding aid in the field of agriculture. DG Competition's enforcement activities in the State aid area are also driven by notifications by Member States. As this is a factor beyond the control of the Commission, no output target can be set.

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|--|------------------|---------------------|------------------------|--------------------------|-----------------------|---|
| | aid. | | | | | | |
| State-of-the-art enforcement and policy guidance | Number of Commission recovery decisions in the field of State aid. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | No target for 2021-2027 |
| State-of-the-art enforcement and policy guidance | Amounts of State aid recovered under Commission decisions in the field of State aid. | Output Indicator | EUR | Inhouse | Annual | To be defined in 2020 | No target for 2021-2027 |
| State-of-the-art enforcement and policy guidance | Number of aids awards above EUR 500,000 published in accordance with the State Aid Modernisation | Output Indicator | Number | Member State reporting | Annual | To be defined in 2020 | Increasing trend for 2021-2027 ¹⁶⁸ |

¹⁶⁸ As a cornerstone of its State Aid Modernisation (SAM) initiative, the European Commission has introduced new transparency requirements concerning state aid granted by Member States to undertakings. For each state aid award above €500,000, Member States will be required to publish the identity of the beneficiary, the amount and objective of the aid and the legal basis. State aid transparency builds on the practice already existing under European Structural and Investment Funds or the Common Agricultural Policy.

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|---|------------------|---------------------|--------------------------|--------------------------|-----------------------|---|
| | transparency requirements. | | | | | | |
| State-of-the-art enforcement and policy guidance | Positive results of State aid 'transparency compliance checks' carried out by the Commission. | Result Indicator | Percentage | Checks by the Commission | Annual | To be defined in 2020 | Increasing trend for 2021-2027 ¹⁶⁹ |
| State-of-the-art enforcement and policy guidance | Number of State aid measures subject to ex-post monitoring. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 ¹⁷⁰ |
| State-of-the-art enforcement and policy guidance | Number of State aid schemes and their annual budget subject | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 |

¹⁶⁹ Positive results in the sense that Member States publish complete and accurate information in line with the State aid transparency requirement, as compared to negative 'non-compliance' findings; this trend is based on the premise that the number of samples analysed increases, so as to provide more total results as a meaningful basis.

¹⁷⁰ The Commission continuously monitors the implementation of state aid measures by Member States. This ex-post monitoring exercise involves a check of the legal basis and the list of beneficiaries and an evaluation of each beneficiary, the region in which the beneficiary is located and the principal economic sector in which the beneficiary has its activities. These requirements also apply mutatis mutandis to ad hoc aid. Such information must be kept for at least 10 years and must be available to the general public without restrictions.

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--------------------------------|---|------------------|---------------------|----------------|--------------------------|-----------------------|--------------------------------|
| | to the evaluation obligation. | | | | | | |
| Boosting internal partnerships | Number of national judges trained in EU competition law for national judges. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 |
| Boosting internal partnerships | Regular meetings of Directors General, the ECN Plenary, ECN working groups and sectorial subgroups. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 |
| Boosting internal partnerships | Opinions and amicus curiae briefs provided to national courts concerning the application of the EU antitrust and cartel rules and | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--------------------------------|---|------------------|---------------------|--------------------------|--------------------------|-----------------------|---------------------------------------|
| | replies to requests for information from courts. | | | | | | |
| Boosting internal partnerships | Number of national court judgments reported to the Commission by the Member States. | Output Indicator | Number | Reports by Member States | Annual | To be defined in 2020 | Increasing trend for 2021-2027 171 |
| Boosting internal partnerships | Regular meetings with the national competition authorities in the Merger working group. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 |
| Boosting internal partnerships | Number of envisaged decisions | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 172 |

171 Under Article 15(2) of Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty the "Member States shall forward to the Commission a copy of any written judgment of national courts deciding on the application of Article 81 or Article 82 of the Treaty. Such copy shall be forwarded without delay after the full written judgment is notified to the parties."

172 Article 11(4) states that "No later than 30 days before the adoption of a decision requiring that an infringement be brought to an end, accepting commitments or withdrawing the benefit of a block exemption Regulation, the

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--------------------------------|---|------------------|---------------------|----------------|--------------------------|-----------------------|--------------------------------|
| | signalled to the Commission under Article 11(4) of Regulation 1/2003. | | | | | | |
| Boosting internal partnerships | Number of documents exchanged between the National Competition Authorities and the Commission using the IT application available to them with this purpose. | Result Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 |
| Boosting internal partnerships | Number of State aid High-level fora and SAM-working | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 |

competition authorities of the Member States shall inform the Commission". To that effect, the national competition authorities shall provide the Commission with inter alia a summary of the case.

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--------------------------------|--|------------------|---------------------|----------------|--------------------------|-----------------------|---------------------------------------|
| | group meetings under the multilateral partnership. | | | | | | |
| Boosting internal partnerships | Number of sectoral and thematic working group meetings under the State aid multilateral partnership. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 |
| Boosting internal partnerships | Number of country visits under the bilateral State aid cooperation. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 |
| Boosting internal partnerships | Number of replies to 'eState aid WIKI' queries and trends in response time. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 173 |

173 'eState aid WIKI' is a platform for informal exchanges on general State aid matters (thus not case-specific) between the Commission's services and the Member States and EFTA countries (including the EFTA Surveillance Authority).

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--------------------------------|---|------------------|---------------------|------------------------------|--------------------------|-----------------------|---------------------------------------|
| Boosting internal partnerships | Trends in response time to 'eState aid WIKI' queries. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Decreasing trend for 2021-2027 |
| Boosting internal partnerships | Number of queries regarding mandatory State aid transparency requirements submitted by Member States. | Output Indicator | Number | Submissions by Member States | Annual | To be defined in 2020 | Decreasing trend for 2021-2027 174 |
| Boosting internal partnerships | Use of the IT-tool 'Transparency Award Module 'TAM' by Member States. | Result Indicator | Number | Use of Tool by Member States | Annual | To be defined in 2020 | Increasing trend for 2021-2027 |
| Boosting internal partnerships | Percentage of State Aid notifications that use the IT application available open to | Result Indicator | Percentage | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 |

174 Overall trend, which presupposes an increase in the quality and frequency of updates of the IT tool 'Transparency Award Module (TAM) and related user-guidance provided by the Commission. Temporary increases are not excluded, in particular after a Member State starts using TAM and is therefore likely to submit a large number of queries during the initial phase.

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--------------------------------|---|------------------|---------------------|----------------|--------------------------|-----------------------|--------------------------------|
| | Member State for this purpose. | | | | | | |
| Boosting external partnerships | Number of contributions by the Commission to increased international convergence of competition policy to multilateral fora (International Competition Network (ICN), OECD and UNCTAD). | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 |
| Boosting external partnerships | Number of technical assistance workshops organised by the Commission with third countries with a view to increased international | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--------------------------------|---|------------------|---------------------|----------------|--------------------------|-----------------------|--------------------------------|
| | convergence of competition policy. | | | | | | |
| Boosting external partnerships | Number of cooperation cases where the Commission cooperates with other third country competition authorities in merger and antitrust cases. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 |
| Boosting external partnerships | Number of third country competition authorities the Commission cooperates with on average per case. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 |
| Boosting external partnerships | Number of working visits to | Output Indicator | Number | Inhouse | Annual | To be defined in | Increasing trend for 2021- |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--------------------------------|--|------------------|---------------------|----------------|--------------------------|-----------------------|--------------------------------|
| | third country authorities with a view to increased international convergence of competition policy. | | | | | 2020 | 2027 |
| Boosting external partnerships | Number of competition cooperation agreements and free trade agreements containing provisions on competition and subsidies-related rules. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 |
| Wider stakeholder outreach | Number of outreach actions to raise awareness of EU competition policy. | Output Indicator | Number | Inhouse | Annual | To be defined in 2020 | Increasing trend for 2021-2027 |
| Wider stakeholder | Number of people/or organisation | Output Indicator | Number | Inhouse | Annual | To be defined in | Increasing trend for |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---|---|------------------|---------------------|----------------|--------------------------|-----------------------|--------------------------------|
| outreach | s reached with outreach actions aimed at raising awareness of EU competition policy. | r | | | | 2020 | 2021-2027 |
| Wider stakeholder outreach | Percentage of positive replies in opinion surveys agreeing that effective competition has a positive impact on consumers. | Result Indicator | Percentage | Survey | Regular | To be defined in 2020 | Increasing trend for 2021-2027 |
| Wider stakeholder outreach | Number of subscribers/ readers of DG Competition's publications | Output Indicator | Number | Inhouse | Regular | To be defined in 2020 | Increasing trend for 2021-2027 |
| IT and business solutions for the Single Market | | | | | | | |
| To facilitate the engagement and participation of public, private and | The number of users of IT Solutions under the | Output | number | Internal - | | | |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|---|------------|---------------------|---------------------------------------|--------------------------|----------|--------|
| civil society stakeholders in policy-making and collaborative public service design, co-creation and delivery. | Internal Market Programme that have a direct Public facing dimensions | | | | | | |
| To facilitate the engagement and participation of public, private and civil society stakeholders in policy-making and collaborative public service design, co-creation and delivery. | User centricity score of some public facing Digital Solutions | Output | Number/benchmarking | Externally conducted evaluation | | | |
| To facilitate the engagement and participation of public, private and civil society stakeholders in policy-making and collaborative public service design, co-creation and delivery. | Number of data sets that have been produced/published in open standards | Output | Number | tbd | | | |
| To identify, develop, pilot, deploy, maintain and promote the | Number of digital assets/components that | | number | Ideally Join-up unless impossible for | | | |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|--|------------|---------------------|---|--------------------------|----------|--------|
| digital enablers that would support the Internal Market programme objectives and facilitate information exchanges at all levels; | have been developed/reused/uptake | | | security purposes. | | | |
| To identify, develop, pilot, deploy, maintain and promote the digital enablers that would support the Internal Market programme objectives and facilitate information exchanges at all levels; | Number of successful cross-border pilots launched | results | number | Participants Survey + internal | | | |
| To ensure the promotion and uptake of the digital elements and their associated communities that contribute to an efficient Internal Market programme; | Number of conferences/engagement initiatives around Single Market digital elements | Output | Number | Internal - | | | |
| To ensure the promotion and uptake of the digital elements and their | Reuse of Single Market digital assets (core | Result | Number | NIFO survey combined with joined-up and | | | |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|--|------------|------------------------|---|--------------------------|----------|--------|
| associated communities that contribute to an efficient Internal Market programme; | vocabulary; building block, framework...) | | | possible results of technical assistance | | | |
| To facilitate sharing and re-use of solutions and best practices between Internal Market players; | Extent to which Member States include the principles of the European Sharing and Reuse Framework in their policies at national level | Result | Number – scale 0 to 12 | NIFO Questionnaire, National Interoperability Framework Observatory | | | |
| To undertake the necessary activities to ensure digital aspects are harnessed by design into Internal Market activities and optimally benefit citizens, businesses and administrations | Extent to which ICT is taken into account when preparing new Internal Market related legislation | output | Number | NIFO Questionnaire, National Interoperability Framework Observatory | | | |
| European Statistical Programme' (ESP) | | | | | | | |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|---|--|--|--|------------------------------|--|-------------------|
| To produce and communicate high quality statistics on Europe in a timely, impartial and cost-efficient manner, through enhanced partnerships within the European Statistical System and with all relevant external parties, using multiple data sources, advanced data analytics methods, smart systems and digital technologies | Impact of statistics published on the internet | Eurostat impact on Internet: number of mentions and percentage of positive/negative opinions | Web mentions and share of positive/negative opinions | Dashboards on Eurostat's impact on the web. Web "mentions" are any text mentioning Eurostat on websites or social networks | Annual (measured monthly) | 2020 | Increase |
| Implementation and Development of Single Market for Financial Services | | | | | | | |
| A new boost for jobs, growth and investment | Employment rate population aged 20-64 | | | EUROSTAT | Yearly | 69.2% (2014) | At least 75% |
| A deeper and fairer internal market with a strengthened industrial base | FINTEC – composite indicator of financial integration in Europe | | | ECB | Yearly | 0.5/0.3 | Increase |
| A deeper and fairer economic and monetary union | CISS – Composite indicator of systemic stress | | | ECB | Yearly | 0.25 in normal times 0.8 in a crisis mode | stable |
| Standards in the field of reporting and auditing | | | | | | | |
| To improve the conditions for | Number of | | | IFRS | Yearly | 135 | Maintain positive |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|---|---|---|--|--------------------------|-------------|---|
| the efficient functioning of the internal market by supporting the transparent and independent development of international financial reporting and auditing standards | countries using the IFRS | | | | | (2017 | trend |
| To improve the conditions for the efficient functioning of the internal market by supporting the transparent and independent development of international financial reporting and auditing standards | Percentage of standards endorsed in the EU compared to the number of standards issued by the IASB | | | FISMA | yearly | 97% | 100% |
| Enhancing the involvement of consumers and other end-users in Union policy-making in financial services (ICFS) | | | | | | | |
| To further enhance the participation and involvement of consumers and other financial services end-users in Union and relevant multi-lateral policy-making in the area of financial services. | Number of position papers and responses to public consultations for both beneficiaries. | Proxy value to measure pro-activity of beneficiaries to influence EU policy-making in the area of financial services. | Position paper or response to EU public consultation. | Beneficiaries' annual reports. | Annual. | 56 (2017) | Maintain positive trend. (minimum threshold for 2020 = 30) |
| To contribute to the information of consumers and other financial services end-users about issues at stake in the financial | Number of Twitter followers. | Proxy value to capture the reach of the beneficiaries' information | Twitter followers. | Beneficiary Twitter accounts for most up-to-date | Annual. | 1740 (2017) | >2500 |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|-------------------------|--|-------------------------|---------------------------------------|--------------------------|----------|--------|
| sector. | | dissemination activities. | | data. | | | |
| Company law and anti-money laundering | | | | | | | |
| <p>Company Law: support the development of the EU regulatory framework in the area of company law and corporate governance with a view to making business more efficient and competitive while providing protection for stakeholders affected by company operations; ensure appropriate evaluation and enforcement of the relevant acquis; inform and assist stakeholders and promote information exchange in the area.</p> <p>Anti-money Laundering and counter terrorism financing (AML/CTF): to enhance the correct and full implementation and application of EU legal framework for anti-money laundering and countering terrorism financing (AML/CFT) by</p> | Timely budget execution | Execution of more than 95% of budget by year-end | Use of budget available | ABAC (Commission on financial system) | Annual | >95% | >95% |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|--|--|--------------------------------------|--|--------------------------|--|--|
| the EU Member States, to develop future AML/CFT policies to address new challenges in the AML/CTF field. | | | | | | | |
| Consumer programme and New Deal for consumers | | | | | | | |
| General performance indicator | Improvement in the Consumer Conditions Index | Composite indicator reflecting consumers and traders perception on the functioning of retail markets | Index 100= maximum theoretical score | Consumer Scoreboard (Commission) | Every two years | 65 (2016) (current target for 2020: 66) | Improvement of 3 points over the period |
| Strengthening consumer organisations' roles in consumer policy-making and advocacy at EU and national levels | % of consumers who trust consumer organisations to protect their rights as consumers | % of consumers who agree (strongly agree or agree) that they trust consumer organisations to protect their rights as consumers | % | Regular survey on consumer attitudes towards cross-border trade and consumer protection (Consumer Conditions Scoreboard) | Every two year | 72% (2016) | 75% at the end of the reference period |
| Enabling assistance and redress systems for individual consumers including in a cross border context | Number of visits to the websites of the ECCs. | Total number of unique visitors on ECCs websites | Nb | ECCs | yearly | 4.3mio (2016) | +1% per year |
| Ensuring qualified entities in the meaning of the future Directive on representative actions (replacing the current Injunctions Directive) can deliver on their role to bring representative actions [subject to adoption of the Directive on representative actions] | Increased capacity of qualified entities | Number of qualified entities participating in cooperation and exchange of best practices mechanism | Nb | Commission | Every two years | | At least one qualified entity per country at the end of the period |
| Ensuring enforcement authorities competent in consumer and product safety laws can deliver a high level of compliance to the acquis | % of compliance rate in first level SWEEPS of the CPC network | % of websites checked by CPC authorities in a CPC sweep and found compliant to consumer law | % | Commission | yearly | N/A | Above 40% on average over the period |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|--|--|---------------------|---|--------------------------|--------------|--|
| | % of RAPEX notifications entailing at least one follow-up action (by other Member States) | % of RAPEX notifications entailing at least one follow-up action (by other Member States) | % | Commission | yearly | 46% in 2017 | Increase of 30 % over the MFF period to 60 % |
| Ensuring the availability of market intelligence tools and joint actions in the field of product safety including in relation to testing of dangerous products | Number of joint actions performed | Number of joint actions performed | Nb | Commission | Every two year | | At least 3 at the end of the period |
| Enabling effective and coordinated EU-level enforcement actions in the field of consumer law and product safety | Number of coordinated EU-level actions performed | Number of coordinated EU-level actions performed | Nb | Commission | Every two year | | At least 3 at the end of the period |
| Providing a high quality general information on consumer markets and conditions and behaviours and on safety issues | Publication of a relevant set of indicators on retail markets | Number of EU level report on consumer markets or conditions published by the Commission | Nb | Commission | yearly | 1 per year | 1 per year |
| Ensuring consumers are aware of their rights and of consumer safety issues | % correct answers to 3 questions on consumer knowledge of relevant legislation | Average percentage of correct answers given by consumers on 3 questions related to the following topics: rights in case of the reception of unsolicited products, faulty product guarantee and distance purchase cooling-off period. | % | Regular survey on consumer attitudes towards cross-border trade and consumer protection (Consumer Conditions Scoreboard) | Every two years | 49% (2016) | 53% at the end of the reference period |
| Reducing vulnerability of consumers also linked to negative consequences of market digitalisation | % of consumers who feel vulnerable because of the complexity of offers, terms and conditions | % of consumers who have declared to feel vulnerable or disadvantaged (either "to a great extent" or "to some extent") when choosing and buying goods or services, because of the complexity of offers, terms and | % | Regular survey on consumer attitudes towards cross-border trade and consumer protection (Consumer Conditions Scoreboard) | Every two years | 21.3% (2016) | 19% at the end of the reference period |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|--|---|--|--|--------------------------|---|--|
| | | conditions | | | | | |
| Promoting sustainable consumption behaviours | % of consumers who are influenced by the environmental impact when choosing goods/services | % of consumers who declared that considering everything they have bought during the last two weeks, the environmental impact of any goods or services also influence their choice (one of the following answers: "yes, for all or most of the goods/services bought", "yes, but only for some", "Yes, but only for one or two") | % | Regular survey on consumer attitudes towards cross-border trade and consumer protection (Consumer Conditions Scoreboard) | Every two year | 49.8% (2016) | 53% by the end of the reference period |
| Internal Market governance tools | | | | | | | |
| Enhancing access to information through the Your Europe public information website | Visits and user satisfaction | Number of visits to the Your Europe portal and user satisfaction | One individual person visiting a single webpage in a single on-line session. | YE users statistics | Yearly measurement | 20,1 million / 90% of user satisfaction / 2017 | Stable number of users (over 100 million visitors over the whole period) and user satisfaction |
| Enhancing access to information through the Your Europe public information website, ensuring full coverage of national information citizens and businesses need, in line with Annex I of the SDG proposed Regulation | Successful search | Percentage of businesses and citizens who indicate they have found the information they were looking for. | One individual person visiting a single webpage in a single on line session. | YE/SDG user statistics | Yearly measurement | Benchmark to be decided in year 1, upon launch of the SDG | Yearly increase from benchmark in Year 1, towards target of 90% |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---|-----------------------------|---|---|---------------------------|--------------------------|--|---|
| Enhancing access to advice and assistance through YEA | YEA performance | Performance of the YEA service in terms of number of enquiries received, ensuring continued high quality and speed of replies | Individual enquiries | YEA user statistics | Yearly measurement | 22662 enquiries received (of which 19042 eligible) in 2017 | +/- 20.000 eligible cases per year. |
| Giving SOLVIT a more prominent role in the overall EU Law enforcement. | SOLVIT performance | Maintain the performance standard of SOLVIT while ensuring good availability, particularly with regard to businesses | Number of days between receipt and closure of a case. | SOLVIT network statistics | Yearly measurement | 2.414 cases in 2017: 64 days average | +/- 60 days average. |
| Improve management of cross-border Single Market challenges, while promoting IT rationalisation | Policy areas covered by IMI | IMI performance in terms of policy areas covered | Policy area | IMI statistics | Yearly measurement | 12 policy areas covered in 2017 | Integrating at least 1 to 1.5 new policy area every year |
| Improve management of cross-border Single Market challenges, while promoting IT rationalisation | EPC applications | IMI performance in terms of submitted EPC applications | Each individual EPC application | IMI and EPC statistics | Yearly measurement | 2.309 EPC applications submitted in 2017 | Duplicating the issuance of EPC, depending on the expansion of the covered professions. |
| Improve management of cross-border Single Market | IMI bilateral requests | IMI performance in terms of | Bilateral requests | IMI statistics | Yearly measurement | 14.764 requests sent | Increase use of the system of 10% per |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---|--|--|---|-----------------|--------------------------|---|---|
| challenges, while promoting IT rationalisation | | number of bilateral requests | | | | | year. |
| Improve awareness of services available through the gateway | Monthly users | Trends in average number of monthly users. | One individual person visiting a single webpage in a single online session. | User statistics | Monthly measurement | Benchmark to be decided in year 1, upon launch of the SDG | Monthly increase from benchmark in month 1 |
| Eliminate or overcome duplication complexity, improve findability of information, advice, problem-solving services and procedures on a cross-border basis | Monthly users | Trends in average number of monthly users. | One individual person visiting a single webpage in a single online session. | User statistics | Monthly measurement | Benchmark to be decided in year 1, upon launch of the SDG | Monthly increase from benchmark in month 1, towards target of 90% |
| Improve quality across the board for all information, assistance and problem-solving services, as well as e-procedures | Satisfaction with quality | Percentage of business and citizens who indicate satisfaction with quality (based on criteria). | Quality criteria to be defined in the SDG Regulation. | User statistics | Yearly measurement | Benchmark to be decided in year 1, upon launch of the SDG | Yearly increase from benchmark in Year 1, towards target of 90% |
| Ensure that EU citizens and businesses can complete the most important part of their interactions with the administration online | Ability to complete procedures on-line | Percentage of businesses and citizens who indicate that they have been able to complete the available procedures fully | Individual users | User statistics | Yearly measurement | Benchmark to be decided in year 1, upon launch of the SDG | Yearly increase from benchmark in Year 1, towards target of 95% |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|--|---|--|----------------------|--------------------------|---|---|
| | | online. | | | | | |
| Make all procedures indicated in the SDG fully accessible for non-national citizens and businesses | Ability to complete procedures on-line | Percentage of cross-border businesses and citizens who indicate that they have been able to complete the available procedures fully online. | Individual users | User statistics | Yearly measurement | Benchmark to be decided in year 1, upon launch of the SDG | Yearly increase from benchmark in Year 1, towards target of 95% |
| Get a more systematic overview of obstacles encountered by cross-border users | Feedback | Usability of data from user feedback tool and from assistance services regarding obstacles in the Single Market and quality of resulting report | Data received through the user feedback tool | User feedback | Yearly measurement | Benchmark to be decided in year 1, upon launch of the SDG | Positive feedback from stakeholders on usefulness of reporting on Single Market obstacles |
| Support to Standardisation activities | | | | | | | |
| Impact of standardisation in the internal market | > 90% average of all EU members | Percentage of agreed EU standards that have been published/enforced at National level | Active published European standards at National level /Active European standards | CEN, CENEL EC | TRIMESTRIAL | 90% average of all EU members | 95% average of all EU members |
| Implementation of EU Regulation No | Acceptance of the report after | Report based on Art 24 EU | No infringements of the EU | CEN, CENEL EC, ETSI, | ANNUAL | Compliance with the provision | Positive report |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|--|---|--|--|--------------------------|--|--|
| 1025/2012 | positive assessment | Regulation No 1025/2012 | Regulation No 1025/2012 | organisations mentioned in the annex III of the EU Regulation No 1025/2012 | | n of the EU Regulation No 1025/2012 | |
| Publication of harmonised standards fulfilling essential requirements (KPI #1) | This KPI will have a weight of 30% in the overall performance index of each European standards organisation (CEN, CENELEC, ETSI) | This KPI is based on the Art. 10(6) of Regulation (EU) No. 1025/2012, and relates to the fulfilment of essential requirements by the CEN, CENELEC, ETSI harmonised standards sent by CEN, CENELEC, ETSI to the Commission for reference publication in the Official Journal of the European Union (OJEU). | <p>KPI #1 = $\left[\frac{\text{nbr of hs} - \text{nbr of EC fc}}{\text{nbr of hs}} \right] \times 100\%$</p> <p>Where hs is the number of harmonised standards sent by CEN, CENELEC, ETSI to the Commission for reference publication in the Official Journal of the European Union (OJEU).</p> <p>EC fc is the number of formal communication of non-publication received by CEN, CENELEC, ETSI from the EC within 2 months from the day the harmonised standard has been</p> | The KPI will use the formal communication of non-publication in the OJEU received by CEN, CENELEC, ETSI from the Commission (within 2 months from the day the reference of the harmonised standard has been sent to the Commission) to calculate the level of acceptance of the harmonised standards for | Annual | KPIs (1, 2, 3) will be combined into an Overall Performance Index (OPI) for the Partner, obtained as a weighted sum. | KPIs (1, 2, 3) will be combined into an Overall Performance Index (OPI) for the Partner, obtained as a weighted sum. |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---------------------------------------|--|---|---|--|--------------------------|--|--|
| | | | sent to the Commission by CEN, CENELEC, ETSI | reference publication. | | | |
| Timely delivery of standards (KPI #2) | This KPI will have a weight of 35% in the overall performance index. | This KPI aims at monitoring the capacity of the CEN, CENELEC, ETSI to manage the projects they undertake, for identified actions covered by the Operating Grant work programme and for standardization related work covered by Action Grants. | <p>a. Actions defined in the Operating Grant (Partial KPI #2a)</p> <p>Five (5) actions and their corresponding indicators will be jointly identified and agreed between the Commission and CEN, CENELEC, ETSI within the Operating Grant proposal.</p> <p>This partial KPI (KPI #2a) measures the percentage of achievement from the 5 actions identified.</p> <p>$KPI\ #2a = \left[\frac{\text{nbr of actions timely achieved}}{5 \text{ identified actions}} \right] \times 100\%$</p> <p>b. Deliverables defined in Action</p> | Information received by the CEN, CENELEC, ETSI | Annual | KPIs (1, 2, 3) will be combined into an Overall Performance Index (OPI) for the Partner, obtained as a weighted sum. | KPIs (1, 2, 3) will be combined into an Overall Performance Index (OPI) for the Partner, obtained as a weighted sum. |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--------------------|-----------|------------|--|----------------|--------------------------|----------|--------|
| | | | <p>Grants (Partial KPI #2b)</p> <p>CEN-CENELEC will follow up the implementation of the action grants and the contractual deliverables, in terms of:</p> <ul style="list-style-type: none"> • Overall quality of the cost justification files sent by CEN, CENELEC, ETSI to the Commission based on the Cost Control Strategy (KPI #2bsub1); • Providing information (KPI #2bsub2) to the Commission in the form of: payments forecast for the signed contracts; <p>and a status update for the new contract proposals.</p> <p>The format,</p> | | | | |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--------------------|-----------|------------|---|----------------|--------------------------|----------|--------|
| | | | <p>content and periodicity of the above reports will be jointly identified and agreed between the Commission and CEN, CENELEC, ETSI for the given year.</p> <p>KPI #2bsub1 = [(nbr of correct justification files) / (nbr of justification files sent)] x 100%</p> <p>KPI #2bsub2 = [(nbr of reports provided) / (nbr of reports agreed)] x 100%</p> <p>This partial KPI (KPI #2b) measures the percentage of deliverables achieved from these two sub-KPIs, as follows:</p> <p>KPI #2b = [(KPI #2bsub1 + KPI #2bsub2)] / 2</p> | | | | |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--------------------------------------|--|--|--|---|--------------------------|--|--|
| | | | <p>c.KPI calculation</p> <p>The final value for the KPI for timely delivery is the combination of the two partial KPIs, weighted at 80% for the Operating Grant deliverables and 20% for the Action Grants deliverables.</p> <p>KPI #2 = (KPI #2a x 80%) + (KPI #2b x 20%)</p> | | | | |
| 3. Reduced development time (KPI #3) | This KPI will have a weight of 35% in the overall performance index. | Action 3 of the strategy communication COM(2011) 311 pays a lot of importance to speeding up the standard development process and sets a target to reduce the development time with 50% by 2020. This KPI will only apply to | <p>KPI #3 = [Avg target (N) / Avg achieved (N)] x 100%</p> <p>Where: Avg target (N): Agreed target for the average development time for the year in question</p> <p>Avg achieved (N): The average development time achieved for the year in question</p> | Information received by the CEN, CENEL EC, ETSI | Annual | KPIs (1, 2, 3) will be combined into an Overall Performance Index (OPI) for the Partner, obtained as a weighted sum. | KPIs (1, 2, 3) will be combined into an Overall Performance Index (OPI) for the Partner, obtained as a weighted sum. |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---------------------------------|-----------|---|---|----------------|--------------------------|----------|--------|
| | | <p>home grown mandated standards.</p> <p>A home grown mandated standard is a standard developed by CEN-CENELEC-ETSI, not linked to ISO-IEC, following a standardization request (mandate) received from the Commission and accepted by CEN-CENELEC-ETSI, and which is intended to be referenced in the Official Journal of the European Union (OJEU).</p> | | | | | |
| Overall Performance Index (OPI) | OPI >85% | KPIs (1, 2, 3) will be combined into an Overall Performance Index (OPI) for the Partner, obtained as a | $\text{OPI} = (\text{KPI \#1} \times 30\%) + (\text{KPI \#2} \times 35\%) + (\text{KPI \#3} \times 35\%)$ | KPI (1, 2,3) | Annual | 85% | 95% |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|---|---|--------------------------------|-------------------------------|--------------------------|---|--|
| | | weighted sum. | | | | | |
| Single market for goods and services | | | | | | | |
| Increased cross-border and coordinated market surveillance for harmonised non-food products ^[1] | Joint market surveillance campaigns | Joint market surveillance campaigns in the area of harmonised product legislation with 80% or more participating MS | Number of campaigns | ICSMS | yearly | 5-7 campaigns/year with over half MS participating (2017) | 2021-2023 : 15 2023-2027: 30-40 |
| Increased cross-border and coordinated market surveillance for harmonised non-food products ^[1] | National enforcement strategies building enforcement capacities | | Number of strategies supported | ICSMS | yearly | - limited, ad-hoc best-practice exchange measures (2017) - 3 pilot strategies (2020) | 2021-2023: 7 2023-2027: 10 |
| Increased cross-border and coordinated market surveillance for harmonised non-food products ^[1] | Peer reviews of Member States' enforcement strategies and performance | In-depth peer reviews of member states' market surveillance conducted by the EU | Number of peer reviews | EU Product Compliance Network | yearly | None (2017) | 2021-2023: 3 2023-2027: 5 |

^[1] Regulation n° (EC) 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, Proposal for a Regulation on Compliance and Enforcement of Union harmonisation legislation on products (COM(2017)795, 19.12.2017)

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| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---|---|----------------------------|---------------------|---------------------------------------|--------------------------|----------|---|
| | nce | Product Compliance Network | | | | | |
| COSME | | | | | | | |
| 1. Addressing the access to finance gap for SMEs | Number of SMEs receiving support and total volume of financing made available to SMEs supported | Output indicator | Units, euros | EIF | annual | 2020 | To be set in function of the available budget |
| 2. Facilitating SMEs' access to markets and supporting them in addressing global and societal challenges; | Number of companies participating in matchmaking events | Output indicator | units | Executive Agency, activity monitoring | Annual, or bi-annual | 2020 | To be set in function of the available budget and results in 2020 |
| | Number of companies supported having concluded business partnerships; | Output indicator | units | Executive Agency, activity monitoring | Annual, or bi-annual | 2020 | To be set in function of the available budget and results in 2020 |
| | Number of entrepreneurs or SMEs receiving business advisory services | Output indicator | units | Executive Agency, activity monitoring | Annual, or bi-annual | 2020 | To be set in function of the available budget and results in 2020 |
| | Number of SMEs created after participation of entrepreneurs in actions of | Output indicator | units | Executive Agency, activity monitoring | Annual, or bi-annual | 2020 | To be set in function of the available budget and results in |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|--|---|---------------------|--------------------------------|--------------------------|----------|---|
| | the program me | | | | | | 2020 |
| | Satisfaction rate of beneficiaries of the program me or participants to the program me; | Output indicator | percentage | activity monitoring or surveys | Annual, or bi-annual | 2020 | none |
| 3)Business Environment, Industrial modernisation, Competitiveness and Entrepreneurship | Number of partnerships, agreements or projects generated by collaborative or networking activities | Output indicator | units | EASME , activity monitoring | Annual, or bi-annual | 2020 | To be set in function of the available budget and results in 2020 |
| | Satisfaction rate of beneficiaries of the program me or participants to the program me; | Output indicator | percentage | Activity monitoring, survey | Annual or Bi-annual | none | none |
| | Number of SMEs/Entrepreneurs benefitting from outputs generated by the measures of this objective | Output indicator | units | Activity monitoring, survey | Annual or Bi-annual | None | |
| All objectives | Budget Implementation rate | Measures the degree to which the implementation follows the | percentage | ABAC | annual | none | Between 95 and 100% |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---|---|---|---------------------|---|---|---|--|
| | | budget allocation | | | | | |
| All objectives | Number of beneficiaries awarded in calls in proportion to applications received | Measures the success of calls published | Percentage | Agency IT tool | annual | none | none |
| All objectives | Geographical coverage of the measure per capita | Measures the distribution of the funding across participating countries | euros | EIF, EASME, Eurostat | annual | none | none |
| All objectives except access to finances | Employment and turnover increase by companies having been supported | Impacts and results measurement | Units and euros | Surveys | Evaluations, principally final and ex-post | none | none |
| Health Programme | | | | | | | |
| 1. Prepare for and counter health crises¹⁷⁵ | Quality of EU response to future health crises - improvement | Assessment of the quality of EU response to future health crises, and in particular, in terms of observed improvement in comparison with previous | Qualitative | Evaluation/assessment reports prepared by the Commission and by EU other institutions or by relevant International Organisations, | Depends on occurrence of severe health crises | Situation during the Ebola crisis: EU response mechanisms demonstrated added value, but lessons learnt from | Improvement in the management of future cross-border health crises in comparison with previous occurrences |

¹⁷⁵ This has to be understood as every potential crisis with a health dimension.

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---|--|--|----------------------------------|--|--------------------------|---|---|
| | | crises | | drawing lessons from previous crises | | experience and capacity gaps were also highlighted | |
| 1.1 Capacity-building measures for crisis preparedness, management and response | a. Quality & completeness of national preparedness plans | Availability, quality and completeness of preparedness plans and extent to which Member States have put them in place to counter future health threats, as shown by the transmission of these plans to the Health Security Committee and their subsequent analysis by the Commission | Quantitative/qualitative | Commission/DG SANTE /Health Security Committee (HSC) | Annual | Situation in year 2020, as regard quality and completeness of national preparedness plans | 90% of Member States reporting full compliance with the International Health Regulations, through annual reporting to WHO |
| | b. Level of uptake of tools by professionals/practitioners | Adoption and implementation by professionals and practitioners in Member States of tools developed during | Quantitative/qualitative / level | Assessment by Commission/DG SANTE /HSC | Annual/permanent | Situation in year 2020 | Good to very good level by all MS Specific target will depend upon the severity of case/issue /outbreak |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---|---|---|---------------------|---------------------|--------------------------|--|---|
| | | capacity building and other knowledge sharing exercises (e.g. percentage of messages of those supposed to be transmitted through the Early Warning and Response System – EWRS) | | | | | addressed (e.g. Ebola, Influenza) |
| 1.2 Response to cross-border health threats during crisis | a. Availability of vaccines and countermeasures during crises | Level of availability in terms of quantity and quality of vaccines and other medical countermeasures to be used during disease outbreaks and crises with health dimension obtained through joint procurement or any other mechanism supported by the Health Programme | number | Commission/DG SANTE | Annual/permanent | Situation in 2020: number of available medical countermeasures | Availability across EU of 3 additional vaccines/countermeasures at end of the Programme |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---|---|--|-----------------------------|--|--------------------------|--|--|
| 1.3. Support laboratory capacity | a. EULabCap index | EULabCap index is an aggregated index resulting from the annual survey carried out by the European Centre for Disease Prevention and Control – ECDC. The aggregated index provides a robust EU-wide assessment of collective laboratory capacity | Number – on a scale of 0-10 | The EULabCap survey methodology developed by the European Centre for Disease Prevention and Control – ECDC – Annual EULabCap Report released by ECDC | Annual | In 2015, the EULabCap aggregate index for EU/EEA was 7.5 on a scale of 0-10 | Regular increase of the aggregated EULabCap index |
| 1.3. Support laboratory capacity | b. Number of laboratories participating in Joint Actions | Number of laboratories participating in Joint Actions launched by the Programme with the aim to support laboratory capacity | Quantitative (number) | Beneficiaries of the grant agreements concluded in the context of the Joint Actions to support laboratory capacity | Annual | 37 associated / collaborating partners from 25 European countries are participating in EMERGE Joint Action | expanding the involvement of relevant laboratories across the EU – 10 new members by 2028 covering most Member States + relevant partner countries |
| 2. Empower health systems with emphasis on their digital transformation | Decrease in the costs related to management of information, resulting | EU-wide assessment of the decrease of the costs of management of information | number | Comprehensive study to be carried out by Joint Research Centre | multiannual | Situation in 2020: estimate of costs of information management | Reduction, at the end of the Programme, by 20% of information management |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---|--|--|---------------------|---|-----------------------------|--|---|
| | from increased digital transformation of health systems | on, linked with increased digital transformation of health systems | | – JRC, with a view to assessing, among others, the reduction of costs of management of the information, resulting from increased digitisation of health systems | | ment by health systems, derived from the planned Study | ent costs as compared to baseline |
| 2.1 Support the digital transformation of health and care | Number of eHealth solutions or tools up-taken and implemented in Member States' health systems | Number of eHealth solutions or tools up-taken and implemented in Member States' health systems per million euros invested from the Health Programme's budget | number | Member States, National contact points – NCPs, surveys | Annual/permanent | Situation in 2020 | At least 1 case of eHealth solution or tool up-taken and implemented per million euros invested from the Health Programme, over the duration of the Programme 2021-2028 |
| 2.2 Support the development of a sustainable EU health information system | Health networks sustainability | Depending on their needs and priorities, the sustainability of current and future networks | qualitative | Ad hoc report or survey carried out by Commission Services or by an | At the end of the Programme | situation in 2020 | Sustainability of health information networks at end of the Programme, by |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---|---|---|---------------------|---|--|---|--|
| | | on health information is defined in this context by their ability to continue their operations after the end of co-funding from the Health programme budget; | | external organisation acting on behalf of Commission services | | | 2028 |
| 2.3 Support the national reform processes for more effective, accessible and resilient health systems | Number of health-related recommendations coming from the EU Semester process that are successfully addressed, with the support of the Health Programme (or of the ESF+ Programme) | Number of health-related recommendations coming from the EU Semester process that are successfully addressed, with the support of the Health Programme (or of the ESF+ Programme) | number | EU Semester Process, Commission services | Annual | In 2017, EU Semester country-specific recommendations related to health systems were issued to nine Member States | At least one country-specific recommendation relating to health systems successfully addressed, with support of the Health Programme (or of the ESF+ Programme) ¹⁷⁶ |
| 3. Support EU health legislation | Degree of transposition of EU health legislation into the national legal systems measured by regular evaluation | Degree of transposition of legislation into national laws/regulations and legal systems. The degree of | qualitative | Commission/MS authorities/Evaluation reports | Frequency in accordance with the provisions in the relevant legal acts | Situation in 2020, as will have been assessed by the Commission and Member | High degree of transposition by all Member States |

¹⁷⁶ To be confirmed by the responsible operational unit

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|--|--|---------------------|--|---|---|--|
| | ns | transposition is measured among others by regular reports, some of which are foreseen in the concerned legal acts. | | | | r States | |
| 3.1. Manage, maintain and implement the legislation on medical devices | Percentage of Member States which have implemented the EU legislation in the field of medical devices in their national legal system | Percentage of Member States which have implemented the EU legislation in the field of medical devices in their national legal system, as reported by successive evaluation reports | percentage | Commission/MS authorities/Evaluation reports | Same as the frequency provided for in the legal act | Situation in 2020, as will have been assessed by the Commission and Member States | 90% of Member States having implemented the EU legislation in the field of medical devices at the end of the Programme |
| 3.2. Support the implementation of Union legislation on medicinal products and on Health Technology Assessment | a. Number of projects by the Biological Standardisation Programme (BSP) for the quality control of | Number of projects by the Biological Standardisation Programme (BSP) for the quality control of biologicals. The activities by biological standardis | number | Commission/MS authorities/Evaluation reports | Annual | 118 projects finalized since its inception, 4 in 2016 | Around 4 BSP projects concluded annually |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---|---|--|---------------------|--|---|---|---|
| | biologicals | ation program ensure the independence of tests on biologicals, allows comparison of tests, ensures high quality biologicals and aims to reduce animal testing in the EU. | | | | | |
| 3.2. Support the implementation of Union legislation on medicinal products and on Health Technology Assessment | b. Number of Regulatory Members from Member States joining the ICH | Number of Regulatory Members from the Member States joining the ICH and implementing its guidelines | number | Commission/MS authorities | Annual | Situation in 2020, as provided by Commission services' evaluation | Regulatory Members from 14 additional Member States joining the ICH and implementing its guidelines at the end of the Programme |
| 3.3. Monitor and support Member States in their implementation of legislation in the area of substances of human origin | Percentage of Member States which have implemented the EU legislation | Percentage of Member States which have implemented | percentage | Commission/MS authorities/Evaluation reports | Same as the frequency provided for in the legal act | Year 2020 | 90% of Member States having implemented the EU legislation in the field of |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|--|--|---------------------|--------------------------------------|--|---|--|
| (SoHO) | n in the field of substances of human origin (SoHO) in their national legal system | the EU legislation in the field of substances of human origin (SoHO) in their national legal system, as reported by successive evaluation reports | | | | | substances of human origin (SoHO) at the end of the Programme |
| 3.4. Support the implementation of tobacco legislation | Percentage of Member States which have implemented the EU legislation in the field of tobacco in their national legal system | Percentage of Member States which have implemented the EU legislation in the field of tobacco in their national legal system, as reported by successive evaluation reports | percentage | Commission/Member States Authorities | Same as the frequency provided for in the legal act | Situation in 2020, as provided by Commission services' evaluation | 90% of Member States having implemented the EU legislation in the field of tobacco at the end of the Programme |
| 3.5. Support the implementation of Union legislation in the area of cross-border | Percentage of Member States which have | Percentage of Member States which have | percentage | Commission/MS authorities/Evaluation | Annual or at least at frequency provided for in relevant | Situation in 2020, as provided by | 90% of Member States having implemented the |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|---|---|---------------------|---------------------------|--------------------------|----------------------------------|---|
| healthcare | implemented the EU legislation in the field of cross-border healthcare in their national legal system | implemented the EU legislation in the field of cross-border healthcare in their national legal system, as reported by successive evaluation reports | | reports | legal act | Commission services' evaluation | EU legislation in the field of cross-border healthcare at the end of the Programme |
| 3.6. Support to the Commission' scientific committees on "Consumer Safety" and on "Health, Environmental and Emerging Risks" | Number of scientific opinions issued and approved | Number of scientific opinions issued and approved by the Commission's scientific committees | number | Commission | Annual | 30 opinions finalized since 2016 | Continuous number of opinions in line with recent values: 10/year, (if the average number of issues arising in a given year is higher than 10) or all arising issues receiving a scientific opinion, in case their average annual number is less than 10. |
| 4. Support integrated work | Strength of integrated work engagement | The Strength of integrated work | number | Commission/DG SANTE /CHAF | Annual | Situation in 2020 | Increase of the composite indicator by 20% at |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--------------------|--|---|---------------------|------------------------------|--------------------------|--|--|
| | nt | engagement indicator will be based on an equal weighting aggregation of the indicators of the 3 operational priorities below ¹⁷⁷ : ERNs, HTA, and Implementation of Best Practices | | EA | | | the end of the Programme |
| 4.1.ERNs | Number of patients supported by ERNs | Number of patients which were diagnosed and treated by ERN networks | number | Commission/DG SANTE /CHAF EA | Annual | Number of patients that made consultations in ERNs by 2020 | Early in its development, target to be established in 2020 |
| 4.2.HTA. | a. Transitional period. coordination level | Number of Member States which have joined the Coordination Group as members in the transitional period. | percentage | Commission/DG SANTE /NCPs | Annual | Situation in 2020, as provided by Commission services , evaluation | Increase by 20% ¹⁷⁸ |
| 4.2.HTA. | b. Number of joint clinical | Number of clinical | number | Commission/DG SANTE | Annual | Situation in 2020, as | 50 HTA |

¹⁷⁷ The detailed aggregation methodology for defining the composite indicator from the indicators requires further information and data analysis in order to be finalised

¹⁷⁸ To be confirmed by responsible operational unit: applicable only before the adoption of HTA legislation. Once HTA legislation is adopted, the relevant indicator will be addressed under the *Support to EU health legislation* specific objective

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---|---|--|---------------------|---|--------------------------|---|---|
| | assessments on medicinal products and on medical devices | assessments jointly carried out | | /NCPs | | provided by Commission services', evaluations | |
| 4.3.Implementation of best practices | a. Number of best practices transferred per million of € invested | Number of best practices transferred to Member States (receiving MS) per million of € invested from the Health Programme | number | Commission/DG SANTE /NCPs/ad hoc survey | Annual | Situation in year 2020, as provided by estimations relating to the 4th Health programme | na ¹⁷⁹ |
| 4.3.Implementation of best practices ⁴ | b. Percentage of EU population of the geographical territory in which each best practice is transferred | Percentage of EU population of the geographical territory in which each best practice is transferred | percentage | Commission/DG SANTE /NCPs/ad hoc survey | Annual | No baseline available | Maximizing the percentage of EU population of the geographical territory in which each best practice is transferred, with |

¹⁷⁹ Due to lack of experience, the target will be set up in 2020, when more information and data become available

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---|---|--|---------------------|---|---|-------------------|---|
| | | | | | | | a target of at least 5% |
| Overall Programme Indicator | Reduction of the difference between the 5 best performing Member States (MS) in terms of Mortality rate and the 5 worst performing MS | Reduction of the difference between the 5 best performing Member States (MS) in terms of Mortality rate and the 5 worst performing MS | Quantitative | Commission/Member States/Health Security Committee | Frequency of available data in Eurostat's Database | Situation in 2020 | Reduction of observed inequality by 20% |
| CFF for Food Chain | | | | | | | |
| Animal health: improving the prevention, control and eradication of animal diseases in the Union territory | a. Number of national programmes successfully implemented | Following the submission of technical and financial final reports by the Member States, the Commission carries out the evaluation and decides on the final payment of the eligible costs incurred for each previously approved programme. Programmes whose implementation is in line with EU legislation and the terms agreed with the Commission are considered successful. | Percentage | Grant decisions (one per MS) and Final payment checklist | Annual | 2020 | 100% |
| | b. Number of emergency situations successfully addressed | Following the submission of technical and financial final reports by the Member | Percentage | Grant decisions (one per emergency, i.e. one per MS and per | Depending on needs (emergency measures are not predictable by definition) | 2020 | 100% |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--------------------|----------------------------|--|-----------------------------------|---|--------------------------|--|--|
| | (by disease) | States, the Commission carries out the evaluation and decides on the final payment of the eligible costs incurred for each previously approved emergency measure. Measures whose implementation is in line with EU legislation and the terms agreed with the Commission are considered successful. | | diseases) and Final payment checklist | | | |
| | c. Reduction of incidence | Incidence is a technical parameter used to monitor the epidemiological evolution of a given disease in a given population. It is the proportion of new cases within a specified time period divided by the size of the population initially at risk. | Percentage (of animal population) | Final technical reports (submitted by the MSs) | Annual | 2020 (e.g. expected result for 2020 in Portugal for bovine brucellosis 30% (namely the minimum % of reduction compared to 2015 baseline (0,20)) | Specific targets for those indicators will be defined individually for each disease in each Member State based on their epidemiological evolution by 2020, and then updated every year as described in the main text |
| | d. Reduction of prevalence | Prevalence is a technical parameter used to monitor the epidemiological evolution of a given disease in a given | Percentage (of animal population) | Final technical reports (submitted by the MSs) | Annual | 2020 (e.g. expected result for 2020 in Portugal for bovine brucellosis 30% (namely | Specific targets for those indicators will be defined individually for each disease in each Member State based |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---|--|--|---|--|--------------------------|---|--|
| | | population. It is the proportion of a particular population found to be affected by a disease. | | | | the minimum % of reduction compared to 2015 baseline (0,24)) | on their epidemiological evolution by 2020, and then updated every year as described in the main text |
| | e. Number of outbreaks | Technical parameter used to monitor the epidemiological evolution of a given disease. | Number or percentage (depending on the disease) | Final technical reports (submitted by the MSs) | Annual | 2020 (e.g. expected result for 2020 in the Union for Avian influenza in domestic poultry is less than 85% compared to 2015 baseline) | Specific targets for those indicators will be defined individually for each disease in each Member State based on their epidemiological evolution by 2020, and then updated every year as described in the main text |
| | f. Number of cases | Technical parameters used to monitor the epidemiological evolution of a given disease. | Number | Final technical reports (submitted by the MSs) | Annual | 2020 (e.g. expected result for 2020 in the Union for rabies in wildlife is 0 (2015 baseline was 128 cases)) | Specific targets for those indicators will be defined individually for each disease in each Member State based on their epidemiological evolution by 2020, and then updated every year as described in the main text |
| Plant health: improving the prevention, containment and eradication of plant pests in the Union | a. Number of surveys programmes (by pest / pest category) successfully | Following the submission of technical and financial final reports by the | Percentage | Grant decisions (one per MS) and | Annual | 2020 | 100% |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--------------------|--|--|---------------------|---|--------------------------|----------|--------|
| territory | implemente d | Member States, the Commission carries out the evaluation and decides on the final payment of the eligible costs incurred for each previously approved programme. Programmes whose implementation is in line with the EU legislation and the terms agreed with the Commission are considered successful. | | Final payment checklist | | | |
| | b. Number of emergency situations successfully addressed (by pest) | Following the submission of technical and financial final reports by the Member States, the Commission carries out the evaluation and decides on the final payment of the eligible costs incurred for each previously approved emergency measure. Programmes whose implementation is in line with the EU legislation and the terms agreed with the Commission are considered | Percentage | Grant decisions (one per emergency, i.e. one per MS and per pest) and Final payment checklist | Annual | 2020 | 100% |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|---|---|---------------------|---|---|----------|---|
| | | successful. | | | | | |
| | c. Reduction of number of outbreaks | Technical parameter used to monitor the epidemiological evolution of a given pest. | Number | Final technical reports (submitted by the MSs) | Depending on needs (emergency measures are not predictable by definition) | 2020 | Specific targets for this indicator will be defined individually for each pest in each Member State based on the epidemiological evolution by 2020, and then updated every year as described in the main text |
| Official controls related activities: improving the effectiveness, efficiency and reliability of the food supply chain harnessing official controls related activities, carried out with a view to implement and comply with the Union rules in this area | a. Number of activities successfully carried out by the EURCs | Quantitative and qualitative assessments on the laboratories activities performed following the EU request. Activities whose implementation is in line with the terms agreed with the Commission are considered successful. | Percentage | Annual Work programme and Final reports (submitted by each EURC) | Annual | 2020 | 100% |
| | b. Number of launched training actions as included in the annual work programme | Ability to respond to EU and national needs in a flexible and effective way through the organisation of thematic BTSF trainings (both standard and e- | Percentage | Annual Work Programme and Final reports on the outcome of the training | Annual | 2020 | 100% |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|--|---|--|---------------------|---|--------------------------|----------|--------|
| | | learning) | | | | | |
| Animal health + Plant health + Official Controls related activities | a. Food and live animals: trade value | Evolution of extra EU-trade (export) | Million euro | Eurostat database (economic accounts for agriculture) | Monthly | N/A | N/A |
| | b. Animal products: production value | Production value at basic prices | Million euro | Eurostat database (economic accounts for agriculture) | Annual | N/A | N/A |
| | c. Number of human cases due to a zoonoses | Evolution of human cases due to animal diseases transmissible to humans | Number | EFSA annual report | Annual | N/A | N/A |
| Composite IMP indicator | Successfully implemented national veterinary and phytosanitary programmes | Following the submission of technical and financial final reports by the Member States, the Commission carries out the evaluation and decides on the final payment of the eligible costs incurred for each previously approved programme. Programmes whose implementation is in line with EU legislation and the terms agreed with the Commission are considered successful. That means the programmes submitted | Percentage | Grant decisions (one per MS) + Final technical and financial report + Payment checklist | Annual | 2020 | 100% |

| Specific Objective | Indicator | Definition | Unit of measurement | Source of data | Frequency of measurement | Baseline | Target |
|---|-------------------------|---|-------------------------|------------------------------------|--------------------------|----------|--------|
| | | by the Member States are in line with the requirements listed in the specific EU legislation and additional guidelines (COM guidelines, COM working document on strategy against specific disease, recommendation by former FVO audits, specific task force, ...) and when all elements contained in the programmes submitted by the Member States, previously approved by the Commission, are implemented by the national authorities. | | | | | |
| Customs and tax policy development support budget line | | | | | | | |
| Support the definition and coordination of policy strategy in the tax and customs domains | Timely budget execution | Execution of more than 95% of budget by year-end | Use of budget available | ABAC (Commission financial system) | Annual | >95% | >95% |