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**COMMISSION STAFF WORKING DOCUMENT**

**SUMMARY OF THE IMPACT ASSESSMENT**

**Accompanying document to the**

**Proposal for a**
**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**
**concerning the placing on the market and use of biocidal products**

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Directive 98/8/EC (the Directive) seeks to harmonise the placing of biocidal products on the market whilst guaranteeing a high level of protection for humans, animals and the environment.

Although the Directive has been successful in removing a number of undesirable products from the EU market, and in bringing structure to an area that was regulated in a fragmented way in the Member States, during the first eight years of the implementation of the Directive, several problems have been identified. These include the slow progress in the active substance Review Programme, the high level of withdrawal of certain active substances[1] and products and the lack of incentives for the development of new active substances.

The main reasons for these consequences are:

– the loopholes and the lack of clarity relating to the scope of the Directive;

– the extensive data requirements for dossier preparation leading to high costs;

– the low attractiveness of simplified procedures for low-risk and basic substances;

– the uncertainty regarding the application of the Directive in particular in relation to data protection and data waiving possibilities; and

– the high and heterogeneous fees for approval of active substances and authorisation of products.

It appears, therefore, necessary to modify certain provisions of the Directive (policy issues 2 to 5) in order to make it more effective and efficient, reducing unnecessary burdens for Member States and industry whilst maintaining a high level of protection of human health and environment. In addition, the need to ensure coherence and to establish a level playing field between EU producers and third-country producers of treated materials necessitates a change of the scope of the Directive (policy issue 1).

The Impact Assessment addresses five policy issues that require action:

**POLICY ISSUE 1: SCOPE**

[1] Withdrawal refers here to the situation when some companies decided not to support existing active substances in the Review Programme or the information provided by them was not sufficient.

– Unchanged policy;

– Extend scope to cover processing aids and food contact materials;

– Extend scope to cover treated materials.

The policy options are cumulative. The assessment concluded that including treated materials in the scope of the Directive would significantly increase the costs to industry. However, although the equal treatment of industry, and environmental and human health benefits are difficult to quantify, they are likely to be significant. Including, in particular food processing aids in the scope of the Directive is likely to result in a complicated process of authorisation under two legal frameworks[2] which may lead to some duplication of efforts. The related costs are likely to outweigh the limited benefits resulting from better control of environmental impacts and greater regulatory certainty.

**POLICY ISSUE 2: PRODUCT AUTHORISATION**

– Unchanged policy;

– Strengthening of mutual recognition;

– Single Member State authorisation;

– Community authorisation.

The policy options are alternatives but within them certain elements could be combined. The assessment concluded that a Community authorisation or a single Member State authorisation would be the most efficient systems and would provide incentives for innovation of products based on new active substances/low risk products. However, as the Member States have expressed significant concerns about a full centralisation of the product authorisation or a single Member State authorisation due to reduced role for the Member States, a combination of the Community authorisation for certain products with the strengthening of the mutual recognition process for other products appears to be the most realistic solution.

**POLICY ISSUE 3: DATA SHARING**

– Unchanged policy;

– Mandatory sharing of vertebrate animal test data at product authorisation stage;

– Mandatory sharing of vertebrate animal test data at product authorisation stage and active substance approval stage.

The policy options are mutually exclusive; they address the same problem and offer different solutions to it. The assessment concluded that the last option of mandatory data sharing at product authorisation and active substance approval stage implies the highest total cost savings to applicants, possibly the highest number of safer products remaining on the market and the highest number of animals saved.

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[2] For processing aids used on food of animal origin, this would include the Regulation (EC) No 853/2004 and the Biocides Directive. For processing aids used on food of plant origin, this would include the national legislation, where available, and the Biocides Directive.

**POLICY ISSUE 4: DATA REQUIREMENTS**

– Unchanged policy;

– Rewording provisions concerning data waiving and the use of existing information;

– Reformulating the system for low-risk substances/products.

The policy options are cumulative and address two types of problems: high data requirements and low attractiveness of the simplified procedures, in particular for low risk and basic substances. The assessment concluded that all the options have significant potential to reduce costs for industry and that the last two options would also significantly reduce the numbers of vertebrate animal tests. In order to meet the objectives of the revision, the best option seems to be a combination of data waiving with the use of existing information and a new approach to low risk biocidal products.

**POLICY ISSUE 5: FEES CHARGED BY MEMBER STATES FOR CARRYING OUT THE PROCEDURES OF THE DIRECTIVE**

– Unchanged policy;

– Partially harmonised fee structure;

– Centralised fee system;

– Specific provisions for SMEs.

The policy options are alternatives but within them certain elements could be combined. The assessment concluded that a partially harmonised fee structure may encourage the development of more new active substances and the retention of more existing active substances. It should also reduce the costs for the inclusion of substances for several product types. The last option will make the procedure less costly for SMEs, which should help them to stay on the market. A fully centralised fee system would raise questions concerning the subsidiarity principle as it would transfer the competences over setting the levels of fees from the Member States to the Community.

**OVERALL COSTS AND BENEFITS**

If left unchanged, the current legal framework for biocides would result in very high costs for the industry in order to comply with the provisions on the evaluation of active substances and authorisation of biocidal products. The total costs and benefits of the policy options presented in the impact assessment should be seen in light of this fact.

The impact assessment shows that the **combined overall costs of all preferred options** to the industry would amount to a range from **€193.6 to 706 million[3] over a period of 10 years**. These costs are attributable to the extension of the scope of the Directive to treated materials

[3] Net present value € 162.2 million to 591.6 million

and cover the costs of including additional active substances in Annex I, the costs of the authorisation of additional products and the labelling costs of treated materials.

The **overall cost savings of all the preferred options for the industry** could range from **€2.7 to 5.7 billion[4] over a period of 10 years**. Due to reasons described in detail in Section 6 (Comparing the options), it is, however, unlikely that the cost savings would materialise in such scale. The actual savings are likely be closer to the lower end of the range but would certainly outweigh the total costs.

Concerning the environment and human health impacts, the impact assessment shows that the extension of the scope to treated materials will result in significant environmental and human benefits even though these are difficult to quantify. The other policy options will help maintain the current high level of environmental and human health protection.

Regarding the social impacts, no significant impacts on employment are expected. However, the individual policy options, in particular the changes in product authorisation, obligatory data sharing, improved waiving provisions and the revised concept for low risk biocidal products may have positive impacts on employment.

[4] Net present value € 2.3 billion to 4.8 billion