



European Economic and Social Committee

NAT/347

**Placing plant protection
products on the market**

Brussels, 31 May 2007

OPINION

of the

European Economic and Social Committee
on the

**Proposal for a Regulation of the European Parliament and of the Council concerning the
placing of plant protection products on the market**

COM(2006) 388 final – 2006/0136 COD

On 15 September 2006, the Council decided to consult the European Economic and Social Committee, under Articles 37(2) and 152(4)(b) of the Treaty establishing the European Community, on the

Proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market
COM(2006) 388 final – 2006/0136 COD.

The Section for Agriculture, Rural Development and the Environment, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 8 May 2007. The rapporteur was Mr Van Oorschot.

At its 436th plenary session, held on 30-31 May 2007 (meeting of 31 May 2007), the European Economic and Social Committee adopted the following opinion by 65 votes to one, with one abstention.

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1. **Summary of the conclusions and the recommendations**

- 1.1 The EESC welcomes the European Commission's proposal to introduce a new Regulation on the placing of plant protection products on the market (fungicides, insecticides, herbicides and similar products for use in agriculture and horticulture).
- 1.2 In addition to the goal of ensuring that the plant protection products placed on the market are effective and safe, a further top priority objective is to ensure that these products are used in a sustainable and safe way. The EESC therefore welcomes the fact that the European Commission is presenting, together with the proposal for a Regulation under review, a proposal for a Directive regulating the sustainable use of plant protection products.
- 1.3 The EESC notes that in the preamble to the proposal for a Regulation, strong emphasis is placed on preventing and limiting harmful consequences for humans and the environment arising from the use of plant protection products. It is, in the EESC's view, vital to prevent harmful consequences for the environment and human beings arising from the use of plant protection products. The EESC does, however, draw attention to the fact that, one aspect of an approach geared to ensuring sustainability is that, economic considerations, too, must carry equal weight. In addition to the growing level of interest in organic farming products, the vast majority of present-day consumers is interested mainly in being provided with high-quality products which are, furthermore, available throughout the year and at an acceptable price. The

safety of products for consumers is an absolute prerequisite in this context. This requires considerable efforts to be made in the agricultural production value chain. The availability of adequate supplies of good, safe plant protection products is, in this connection, indispensable.

- 1.4 The EESC expresses its concern over the introduction of criteria for the approval of plant protection products based on the intrinsic properties of the active substances and the consequences which this measure may have with regard to innovation in respect of new and better plant protection products. Rigid application of these criteria may result in a substance which fails to meet one criterion, whilst representing an improvement vis-à-vis all the other criteria, being denied approval. The EESC calls for a risk assessment to be carried out which takes greater account of actual use and exposure.
- 1.5 The EESC takes the view that the proposed introduction of zonal authorisation and mutual recognition represents a first step along the road towards complete harmonisation of authorisations in Europe. The EESC proposes that mutual recognition of authorisations also be made possible on a cross-zonal basis, in the case of (neighbouring) states where similar climatic and agricultural conditions prevail.
- 1.6 The EESC supports the principle of carrying out comparative assessments of plant protection products containing substances that are candidates for substitution. The EESC does, however, call for evaluations to be carried out at less frequent intervals and for the normal period of data protection to be applied in the case of the abovementioned substances in order to maintain a degree of readiness to invest in these substances on the part of industry and thereby prevent bottlenecks in the agricultural sector.
- 1.7 The EESC considers that the proposal for a Regulation contains too few incentives for the authorisation of plant protection products for minor uses. The EESC proposes two measures for improving this situation. Firstly, a system could be introduced under which the initial applicant would be granted a longer period of data protection, the greater the number of minor uses that are included. Secondly, the EESC asks the European Commission to facilitate the drawing-up of an up-to-date list for the benefit of the Member States, setting out all the authorised (minor) uses.

2. **Introduction**

2.1 **General observations**

- 2.1.1 Plant protection products are used to afford protection and to promote plant health. They enable farmers to increase their yield and to make their production methods more flexible. This ensures reliable production of affordable, safe (food) products in local regions.
- 2.1.2 The vast majority of European consumers is becoming ever more demanding with regard to the quality of food and its availability throughout the year; food safety is regarded as an

absolute prerequisite and a self-evident requirement in this respect. As a result, the agricultural production chain is facing major challenges. If it is to be in a position to satisfy the exacting demands of this large group of consumers, it must be able to have available a sufficiently broad package of good, safe plant protection products.

- 2.1.3 On the other hand, a number of other factors need to be taken into consideration: the use of plant protection products may have an impact on agro-ecosystems; these products may pose risks to the health of users; and they may have an impact on food quality and harmful effects on the health of consumers, particularly in cases where harmful residues of plant protection products remain in food products, as a result of inappropriate use of plant protection products (uses which are not in accordance with good practice).

2.2 Regulatory framework

- 2.2.1 The proposal for a Regulation under review involves replacing the currently applicable Directive 91/414/EEC on the marketing of plant protection products. This Directive seeks to take action at source in order to preclude risks by making provision for the application of a very comprehensive risk-assessment procedure in respect of each active substance and the products which contain these substances, before these products may be marketed and used.
- 2.2.2 The proposal under review also involves repealing the current Directive 79/117/EEC prohibiting the placing on the market and the use of plant protection products containing certain active substances.
- 2.2.3 The EU's regulatory framework for plant protection products also includes Regulation (EC) 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC which sets maximum residue levels (MRLs) of active substances in agricultural products.
- 2.2.4 Together with the proposal for a Regulation under review, a proposal is also presented for a Directive of the European Parliament and of the Council establishing a framework for Community action to achieve a sustainable use of pesticides (COM(2006) 373 final). The aim of this Directive is to regulate the use and distribution of pesticides insofar as these phases are not addressed in the proposal for a Regulation.

2.3 Background to the proposal for a Regulation

- 2.3.1 In connection with the European Commission's evaluation of Directive 91/414/EEC, the European Parliament and the Council called, in 2001, for the Directive to be amended with a view to:
- establishing criteria for the approval of active substances;

- tightening up criteria for the approval of substances with a high risk profile;
 - introducing a simplified procedure for substances with a low risk profile;
 - introducing the principle of applying comparative assessment and substitution;
 - improving mutual recognition by introducing product authorisation zones for plant protection products.
- 2.3.2 Following an extensive period of consultation (lasting five years) with all stakeholders and the establishment of an impact assessment, the Commission presented its proposal for amending Directive 91/414/EEC in July 2006. The Commission decided to replace the Directive by a Regulation with a view to achieving simplification and further harmonising legislation in the EU Member States.
- 2.4 Short summary of the proposal for a Regulation**
- 2.4.1 A positive list of active substances is to be drawn up at EU level by the Standing Committee on the Food Chain and Animal Health. Approval of the active substances is to be based on a set of clear criteria which will seek to ensure a high level of protection for human beings, animals and the environment.
- 2.4.2 When active substances are being assessed, there must, as a minimum requirement, be at least one use which is safe for both the user of the product and the consumer and there must not be any unacceptable impact on the environment. Clear deadlines are laid down for the various stages of the assessment and in respect of decision-making on the approval of active substances.
- 2.4.3 Member States, themselves, will continue to be responsible for the authorisation of plant protection products at national level; these products must be based on active substances included in the list of approved active substances.
- 2.4.4 When assessing the dossiers submitted in connection with applications for authorisation, the Member States should apply harmonised criteria, if such criteria are available, and take account of national circumstances.
- 2.4.5 In the case of substances with a low or normal risk profile, the Commission is introducing a system involving mandatory mutual recognition of authorisations for plant protection products within "authorisation zones". Under this system, in any of the three proposed climate zones (the Commission divides the EU into three zones), a Member State takes a decision on a national authorisation for a given product and the product is to be authorised only in those Member States where the producer has also applied for mutual recognition of the authorisation in question.

3. General observations

3.1 The importance of plant protection products to the supply of high-quality food to the EU

3.1.1 In the preamble to the Directive the recitals are listed which led to the drawing-up of the proposal for a Regulation. Express mention should also be made, in this preamble, of the importance, in respect of the reliable supply of safe and high-quality food to demanding European consumers, of having available adequate quantities of plant protection products.

3.2 Making provision for provisional authorisations subject to certain conditions

3.2.1 The Directive makes no provision for Member States to issue provisional national authorisations. This can delay the marketing of substances which update and improve those currently available. The Commission is endeavouring to tackle this situation by applying shorter deadlines designed to lead to the more rapid inclusion of new substances on the positive list.

3.2.2 The EESC proposes that the Regulation still provides for provisional authorisations to be granted at national level in cases where the set deadlines have been exceeded because of administrative delays and where the obligation in respect of maximum residue levels (MRLs), set out under Regulation (EC) 396/2005, has been complied with.

4. Specific observations

4.1 Risk assessments in connection with the application of the criteria for approving active substances

4.1.1 Article 4 of the proposal for a Regulation deals with the approval criteria for active substances, with reference to Annex II. Strict application of these criteria would result in active substances being denied approval already on the basis of a single property since all the requirements must always be met.

4.1.2 The application of such approval criteria for plant protection products, based solely on the intrinsic properties of their active substances without taking account of actual use and levels of exposure, would undermine the principle that decisions are to be taken on the basis of risk assessments. This situation will result in the gradual disappearance from the market of a number of existing products/applications, which may well be required in order to meet the need to have a broad range of products available.

4.1.3 In this way, Article 4 will prevent the marketing of innovative products which bring about improvements in respect of all criteria but fail to fulfil the requirements in respect of just one criterion. The EESC cannot endorse these provisions since they would unnecessarily curtail

innovation in respect of new and better products. It takes the view that the intrinsic approval criteria for active substances should only be used to identify candidates for substitution and not to reject products in advance without carrying out a thorough evaluation.

4.2 Extending zonal authorisation and mutual recognition

- 4.2.1 The EESC believes that the system of zonal authorisation and mutual recognition represents an important step on the road towards establishing a completely harmonised European system for the marketing of plant protection products.
- 4.2.2 Introduction of compulsory mutual recognition of authorisations in the Member States in respect of same authorisation zone, alongside the standard authorisation procedure at national level, will prevent the duplication of work in the Member States and make innovative, environmentally-friendly plant protection products available more quickly.
- 4.2.3 The EESC proposes that provision be made for mutual recognition of authorisations also on a cross-zonal basis, in the case of neighbouring countries having comparable conditions of production.
- 4.2.4 In the case of the use of plant protection products in greenhouses and in the case of post-harvest treatment, the Commission proposes that provision be made for compulsory mutual recognition by all the Member States in all zones (Article 39). The EESC takes the view that seed treatment, one of the cornerstones of integrated plant protection (IPS), should also be included under this regime.

4.3 Adjustments to the comparative assessment procedure

- 4.3.1 In the case of plant protection products based on more critical substances (candidates for substitution), Member States are to carry out a comparative assessment within a period of four years from the authorisation of the product (Article 48). This assessment is to be carried out with a view to finding an alternative substance, thereby making it possible to replace the more harmful substances, except in cases where the substance in question continues to be necessary in order to provide ongoing protection in the event of the development of resistance.
- 4.3.2 The EESC takes the view that (a) the stipulation that comparative assessments are to take place within four years of the granting of authorisation and (b) the seven-year period of data protection afforded to candidates for substitution do not provide the industry with adequate security and will lead to the early withdrawal of such products from the market, with possible damaging consequences as regards the availability of satisfactory products in the case of resistance and minor uses.
- 4.3.3 The EESC calls for comparative assessments to be carried out at less frequent intervals and for the application of the normal period of data protection in the case of candidates for

substitution in order to maintain a degree of readiness to invest in such substances on the part of industry, thereby preventing bottlenecks in agricultural production and bottlenecks further on in the value chain in the direction of the consumer.

4.4 Inadequate incentives for minor uses

- 4.4.1 Article 49 entitles, amongst others, professional users and professional agricultural organisations to request that the authorisation of a plant protection product be extended to cover minor uses. Under this article, Member States are also to establish and regularly update a list of minor uses.
- 4.4.2 The EESC welcomes this article but notes that it does not provide holders of authorisations, themselves, with sufficient incentives to seek to bring about extensions of authorisations for minor uses.
- 4.4.3 The EESC proposes that holders of authorisations be given a bonus in the form of an extension of the period of data protection in cases where, following the granting of an authorisation, they are the first applicants to request several extensions of authorisations to include minor uses.
- 4.4.4 The EESC proposes that the European Commission facilitates the drawing-up of a centralised European list of minor uses and makes such a list available for inspection by the Member States, in place of the proposed lists to be drawn up by individual Member States under Article 49(6).

4.5 Provision of information

- 4.5.1 Under the proposal for a Regulation, it is possible to make it obligatory to inform any neighbours who have requested to be informed and who could be exposed to the spray drift; such neighbours are to be informed before the product is used (Article 30).
- 4.5.2 Whilst the EESC believes that transparency with regard to the use of plant protection products makes very good sense, it does, however, take the view that the proposed obligation to provide information would undermine the confidence in the law, on which the marketing of plant protection products is based. We are, after all, dealing here with the use of products which are deemed to be safe and imposing an obligation to inform neighbours could convey the opposite assumption.

- 4.5.3 The EESC believes that implementation of this article is not conducive to mutual understanding between users of plant protection products and their neighbours; it may, on the contrary, upset social cohesion in rural communities since making it obligatory to inform neighbours may give rise to the impression that the products being used are unsafe. This provision would, in this sense, be counterproductive.

Brussels, 31 May 2007.

The President of the European Economic and Social Committee	The Secretary-General of the European Economic and Social Committee
Dimitris Dimitriadis	Patrick Venturini
