Placing of plant protection products on the market

2006/0136(COD) - 11/03/2008 - Modified legislative proposal

A number of Parliamentary amendments that, from a technical and editorial point of view, improved the initial proposal were adopted by the Commission, whilst others were partially accepted only.

Legal basis:

Although Parliament proposed Article 152(4)b and 174(1) of the EC Treaty as the legal basis for the Regulation, the Commission has decided to stick to its original proposal, namely that Articles 37(2) and 152(4)b should form the legal basis of this proposal.

Scope:

The Commission retains its view that there is no need to introduce a “future limitation” to the scope of the Regulation that excludes micro-organisms, viruses, pheromones and biological products once a separate Regulation to these products has been adopted. This is because there is no need for such a specific Regulation as such data requirements and criteria for authorisation are in place already. This amendment has, as a result, not been endorsed.

Definitions:

Parliamentary amendments that clarify the proposed definitions and which are linked to other amendments have been adopted by the Commission. Those that clarify definitions relating to: low risk; parallel trade; vulnerable groups; non chemical methods of plant protection; and minor uses were also acceptable to the Commission.

Approval criteria and range of uses:

The Commission’s initial proposal stated that for category 1 and 2 substances, a substance can not be approved – unless exposure is negligible. Parliamentary amendments concerning this proposal have mostly been accepted by the Commission. In cases where Parliament has sought to extend the proposed criteria in Annex II, the Commission has decided to keep the original proposal in line with related European legislation and has decided to clarify the text. It has decided to clarify that neurotoxin and immunotoxic substances should be approved as candidates for substitution.

An amendment on “negligible exposure” was deemed acceptable given that it keeps the risk-based approach, as foreseen in the original proposal, as well as clarifying the provision. On the matter of “evaluation of representative uses”, the Commission has opted to retain the format of the initial proposal and suggest that a limited number of uses must be evaluated at EU level and other uses left to the Member States, who are required to apply uniform criteria when granting authorisation.

Approval procedure, renewal and review:

The Commission has decided to reject a Parliamentary amendment concerning the role of the EFSA as coordinator of the approval procedure. The EFSA, in the Commission’s opinion, should coordinate scientific evaluation only. It should not be responsible for the approval procedure. Also rejected were variations from the proposed extension (or reduction) of the deadlines foreseen for various consultations

and decisional phases. Amendments on renewal and review were accepted by the Commission, where they clarified the original proposal.

Low risk and basic substances:

An amendment on defining low risk substances has been incorporated into the revised proposal, although an amendment concerning different criteria biological control agents has not. Amendments relating to basic substances have been rejected on the ground that they should be approved for an unlimited period and on the basis of evaluations performed in other areas. Similarly, the Commission has decided not to accept a Parliamentary proposal to introduce a new article on reduced risk plant protection products and setting out different periods of data protection for the two categories of low risk products.

Safeners, synergists and co-formulants:

An amendment deleting temporary derogation for safeners and synergists has been rejected by the Commission. Further, any changes to the approval of co-forumlants have been rejects as it would create an overlapping obligation with respect to existing legislation on chemicals (REACH).

Zonal authorisation system and provisional authorisation:

Parliament was seeking to reject the zonal authorisation system for plant protection products that are linked to compulsory mutual recognition of authorisation within a zone. This, however, would have removed one of the proposal's key elements. As the proposal stands, Member States can only impose stricter national measures for worker protection, given that EU legislation seeks minimum harmonisation only. A further amendment, on a system of provisional authorisation, has similarly been rejected by the Commission on the grounds that it is incompatible with the zonal authorisation system and EU legislation on maximum residue levels for pesticides.

Systematic information:

The Commission has decided not to include a new provision whereby farmer's records would have been made available to the public and residents - the so called "pesticide passport". Instead the Commission has decided to retain the original text of the proposal which provides that information should be made available to neighbours "upon request." It would, argues the Commission, be impossible to maintain a pesticide passport for every lot of fruit and vegetables given that batches of crops are mixed in trade. Moreover, one side effect may be that controls are done only on declared pesticides.

Comparative assessment and substitution principle:

The Commission has decided not to endorse amendments that sought to extend comparative assessment to all plant protection products and to reduce the approval period for substances which are candidates for substitution. This option has not been adopted because it is not based on risk.

Minor uses:

Most proposed amendments relating to facilitating the extension of authorisations for minor uses have been taken on board by the Commission subject to some legal rewording, albeit that the proposed "European Promotion Fund" for minor uses has been rejected given that it does not fall within the proposal's main objectives.

Parallel trade:

The Commission has decided to adopt new provisions concerning the trade of plant protection products that have already been authorised in other Member States. Some of the wording has been revised in order to make it compatible with the Treaty and Cases Law of the Court of Justice.

Data protection and data sharing:

Certain Parliamentary amendments on data protection and sharing have been rejected by the Commission on the grounds that they would weaken competition and reduce the availability of plant protection products to farmers. This issue has been carefully analysed in the impact assessment. The Commission is of the view that all studies on vertebrate animals should be protected in the same way as other studies. However, there is an obligation to share results and not to repeat studies.

Confidentiality and public access to information:

A Parliamentary suggestion to offer confidentiality to the Institutes or persons involved in vertebrate studies has not been taken up by the Commission. This is because under Article 60 of the proposal any person can request that disclosure of information, which may undermine their privacy and integrity.

Integrated Pest management and Good Environmental Practice:

Two amendments, the first on making integrated pest management (IPM) obligatory as from 2012 and the second, deleting an obligation for compulsory compliance with the principle of good environmental practice, have been rejected by the Commission.

Comitology and the link between the proposed Regulation and Regulation (EC) No 396/2005:

The Commission agrees to align procedures for the exercise of implementing powers conferred on Commission to the normal regulatory procedure. However, in cases where the Commission sees the need for curtailment of time limits for certain cases (such as respecting time limits for renewing procedures), the Commission has decided that the normal regulatory procedure should apply, rather than the regulatory procedure with scrutiny.

For cases that involve setting data requirement for safeners and synergists, the Commission can accept use of the regulatory procedure with scrutiny but not the co-decision procedure. Nor, argues the Commission, is it appropriate to use the co-decision procedure for technical provisions which need to be continuously updated.

On a final point, the Commission points out that the situation regarding the procedure affecting maximum residue levels (MRLs), will need to be clarified after the Plenary session of the European Parliament end November 2007.