Placing of plant protection products on the market

2006/0136(COD) - 15/09/2008 - Council position

The Council adopted, by qualified majority, the common position in view of the adoption of a Regulation concerning the placing of plant protection products on the market. The Hungarian, Irish, Romanian and the UK delegations abstained.

The Council incorporated 19 amendments in full adopted by the European Parliament in its 1st reading. 59 other amendments were accepted in part or in principle. Certain amendments, such as those concerning provisional authorisations, renewal period for the approval of active substances, data protection for the studies necessary for renewal or review of the authorisation, confidentiality of names and addresses of persons involved in testing on vertebrate animals and cost recovery by Member States were totally or partially incorporated in the common position although they were not accepted initially by the Commission

The main issues of the common position:

Legal basis: the Council considered that, as the main purpose of the Regulation was to ensure the effective functioning of the internal market in plant protection products, Article 95 was the correct legal basis. The Council, however, decided to adopt a dual legal basis including Article 37(2) as a gesture towards the Commission.

Definitions: the Council took up those amendments which provide appropriate clarifications of the text of the definitions or which were essential because new provisions were introduced in the text. However, in some cases, the Council preferred to place the new definitions within the Articles containing the provisions on those areas (e.g. definitions of parallel trade, identical, rapporteur Member State or low-risk). The Council has deleted the definition of Integrated Pest Management from the Commission's proposal and has instead inserted a link to the Directive on sustainable use of pesticides. The Council could not incorporate an amendment as it considered that priority to non-chemical methods was not an essential element of good plant protection practice.

The Council has also inserted a number of additional definitions such as "authorisation holder", "professional user", "minor use", "greenhouse", "post-harvest treatment", "biodiversity", "competent authority", "advertisement", "relevant metabolite" and "impurity". It deleted the definitions of "animals" and "integrated pest management".

Approval of active substances: the Council introduced a sequential approach in the evaluation of the criteria set out in Annex II (procedure and criteria for the approval of active substances, safeners and synergists) whereby certain points of that Annex should be verified first before examining the rest of the criteria.

The Council has introduced in Annex II a clear definition of negligible exposure to carcinogenic, endocrine disrupting or toxic for reproduction substances and has established that mutagenic category 1 or 2 active substances should be banned even if human contact with those substances was negligible. It nevertheless thought it necessary to introduce, for exceptional cases, a derogation clause limited in time for those substances which are essential for the protection of a crop even if they do not meet the criteria.

The Council could not agree with the European Parliament's view that active substances with neurotoxic or immunotoxic properties should be excluded but it agreed to consider them as candidates for

substitution. Like the Parliament, the Council opposed the unlimited renewal of approval of active substances as proposed by the Commission but established a maximum period of 15 years instead of 10 as requested by the Parliament.

Procedures: the Council has endeavoured to further streamline the procedures for approval of active substances and authorisation of plant protection products. It has paid particular attention to tightening the deadlines and defining more precisely the roles of the various players involved (Member States, the Commission, the European Food Safety Authority (EFSA)). The Council has thus accepted in full or in part a number of European Parliament amendments that tend in this direction and rejected others which might either cause unnecessary delays, or not allow enough time for the adequate completion of some stages of the procedures.

Low-risk active substances: the Council, like the Parliament, thought it useful to further explain the concept of "low risk" but instead of adding a definition or extra clarifications as proposed by the European Parliament, it has inserted more detailed criteria in Annex II.

Regarding data protection for low-risk plant protection products, the Council has extended the period of protection to a maximum of 13 years instead of 15 as proposed by the European Parliament. In case the authorisation of a low-risk plant protection product is extended to minor uses the data protection period could then be extended to up to 15 years.

Candidates for substitution: the Council has also clarified the criteria for active substances to be identified as candidates for substitution. The Council felt it was necessary to extend the period of approval from 7 to 10 years and therefore did not accept the Parliament’s amendment.

The Council was unable to agree with a number of amendments extending, in particular, comparative assessment to all plant protection products. The text has nevertheless been redrafted in order to give Member States the option, in exceptional cases, of not authorising or of restricting the use of a plant protection product which does not contain a candidate for substitution or a low-risk substance if a non-chemical method exists.

Mutual recognition of authorisations: the Council was not able to accept those amendments relating to the zonal authorisation and mutual recognition. On the contrary, the Council has confirmed the division into authorisation zones as proposed by the Commission and the system of compulsory mutual recognition of authorisations as it believes it is a good way to ensure the reduction of administrative burdens and the quick and wider availability for European farmers of plant protection products. The Council has extended this system to plant protection products for minor uses and has provided additional flexibility (e.g. the recognition of authorisations between Member States belonging to different zones or the possibility for a professional organisation to apply for an authorisation). The Council introduced provisions establishing that Member States impose additional risk mitigation measures relevant to their territory and, exceptionally, can refuse authorisations granted in another Member State in order to protect human or animal health or the environment. The Council has also inserted a review clause whereby a report is to be drawn up by the Commission within five years of the Regulation's entry into force.

National Provisional Authorisations: Member States decided to bring back the provisional authorisations as a transitional measure as they feared delays in the authorisation of plant protection products. They thought the new system needed to be tested first to check if deadlines could be met. National provisional authorisations will only be granted for a limited period of time (3 years) and under certain circumstances. The Council and the Parliament's views substantially converge on this issue.

Animal testing: the Council has taken note of the European Parliament particular interest in avoiding or minimising animal testing.

Comitology: the Council has modified the Commission's proposal to bring it into line with the new Comitology Decision 2006/512/EC amending Decision 1999/468/EC and introducing the new regulatory procedure with scrutiny. In some cases the Council could not accept the regulatory procedure with scrutiny if the measures to be taken were of a purely implementational nature. In cases concerning the simple transfer of the requirements already contained in the Annexes to Directive 91/414/EC to the new Regulation or the adoption of non-binding guidelines, the Council was of the opinion that the advisory committee procedure was more appropriate. The Council thought instead that the most appropriate comitology procedure would be that of "regulatory with scrutiny" as the Regulations to be adopted following the provisions laid down in those articles would supplement the basic act by adding new non-essential elements.

The common position also includes other changes, not envisaged by the European Parliament, which address a number of concerns expressed by the Member States in the course of the negotiations:

Treated seeds: delegations considered that it was necessary to insert provisions on this area so as to protect the free movement of seeds treated with plant protection products in the EU unless they might pose a serious threat for human or animal health or the environment.

Parallel trade: the provisions concerning parallel trade were added by the Council following an almost unanimous request by Member States. The Council has thus incorporated the amendment and has adapted the provisions on parallel trade to the most recent jurisprudence. It has also introduced the requirement of official controls in this area.

Adjuvants: the Council has inserted provisions establishing that detailed rules for the authorisation of adjuvants should be set out following a comitology procedure.