Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2006/0136(COD)
Placing of plant protection products on the market Amended by 2013/0140(COD) Amended by 2013/0169(COD) Amended by 2016/0084(COD) See also 2016/2978(RSP) See also 2017/2128(INI) See also 2017/2801(RPS) Amended by 2018/0088(COD) Subject 3.10.03 Marketing and trade of agricultural products and livestock 3.10.09.02 Plant health legislation 3.70.13 Dangerous substances, toxic and radioactive wastes (storage, transport)	Procedure completed

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	Verts/ALE BREYER Hiltrud	29/11/2005
Former committee responsible		
ENVI Environment, Public Health and Food Safety (Associated committee)	Verts/ALE BREYER Hiltrud	03/10/2006
Former committee for opinion		
IMCO Internal Market and Consumer Protection (Associated committee)	PPE-DE WEISGERBER Anja	04/10/2006
AGRI Agriculture and Rural Development (Associated committee)	ALDE VIRRANKOSKI Kyösti	11/09/2006
ITRE Industry, Research and Energy	PSE CORBEY Dorette	12/09/2006
Former committee for opinion on the legal basis		
JURI Legal Affairs	PSE MEDINA ORTEGA Manuel	26/02/2007

Council of the European Union

Council configuration	Meeting	Date
Competitiveness (Internal Market, Industry, Research and Space)	2963	24/09/2009
Agriculture and Fisheries	2904	18/11/2008
General Affairs	2888	15/09/2008
Agriculture and Fisheries	2881	23/06/2008
Agriculture and Fisheries	2867	19/05/2008
Environment	2842	20/12/2007
Agriculture and Fisheries	2841	17/12/2007

	Environment	2812	28/06/2007
	Agriculture and Fisheries	2806	11/06/2007
	Agriculture and Fisheries	2774	19/12/2006
	Agriculture and Fisheries	2763	20/11/2006
	Agriculture and Fisheries	2750	18/09/2006
European Commission	Commission DG	Commissioner	
	Health and Food Safety	VASSILIOU Androulla	

Key events

05/09/2006	Committee referral announced in Parliament, 1st reading		
18/09/2006	Debate in Council	2750	Summary
20/11/2006	Debate in Council	2763	
19/12/2006	Debate in Council	2774	
26/04/2007	Referral to associated committees announced in Parliament		
11/06/2007	Debate in Council	2806	
28/06/2007	Debate in Council	2812	
12/09/2007	Vote in committee, 1st reading		Summary
05/10/2007	Committee report tabled for plenary, 1st reading	A6-0359/2007	
22/10/2007	Debate in Parliament		
23/10/2007	Results of vote in Parliament		
23/10/2007	Decision by Parliament, 1st reading	T6-0445/2007	Summary
17/12/2007	Debate in Council	2841	
20/12/2007	Debate in Council	2842	
19/05/2008	Debate in Council	2867	
25/09/2008	Committee referral announced in Parliament, 2nd reading		
05/11/2008	Vote in committee, 2nd reading		Summary
18/11/2008	Debate in Council	2904	
12/01/2009	Debate in Parliament		
13/01/2009	Decision by Parliament, 2nd reading	T6-0011/2009	Summary
24/09/2009	Act approved by Council, 2nd reading		
21/10/2009	Final act signed		
21/10/2009	End of procedure in Parliament		
24/11/2009	Final act published in Official Journal		

Technical information

Procedure reference	2006/0136(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amended by 2013/0140(COD) Amended by 2013/0169(COD) Amended by 2016/0084(COD) See also 2016/2978(RSP) See also 2017/2128(INI) See also 2017/2801(RPS) Amended by 2018/0088(COD)
Legal basis	EC Treaty (after Amsterdam) EC 037-p2; EC Treaty (after Amsterdam) EC 152-p4b
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/61876

Documentation gateway

Legislative proposal		COM(2006)0388	12/07/2006	EC	Summary
Document attached to the procedure		SEC(2006)0930	12/07/2006	EC	
Document attached to the procedure		SEC(2006)0931	12/07/2006	EC	
Committee of the Regions: opinion		CDR0316/2006	13/02/2007	CofR	
Committee draft report		PE388.326	13/04/2007	EP	
Committee opinion	IMCO	PE382.584	18/04/2007	EP	
Committee opinion	AGRI	PE382.298	24/04/2007	EP	
Committee opinion	ITRE	PE382.540	07/05/2007	EP	
Amendments tabled in committee		PE390.444	29/05/2007	EP	
Economic and Social Committee: opinion, report		CES0800/2007	31/05/2007	ESC	
Committee opinion	JURI	PE390.623	12/06/2007	EP	
Amendments tabled in committee		PE390.401	14/06/2007	EP	
Amendments tabled in committee		PE390.442	14/06/2007	EP	
Committee report tabled for plenary, 1st reading/single reading		A6-0359/2007	05/10/2007	EP	
Text adopted by Parliament, 1st reading/single reading		T6-0445/2007	23/10/2007	EP	Summary
Commission response to text adopted in plenary		SP(2007)6028	21/11/2007	EC	
Modified legislative proposal		COM(2008)0093	11/03/2008	EC	Summary
Council statement on its position		12553/2008	08/09/2008	CSL	

Council position		11119/8/2008	15/09/2008	CSL	Summary
Committee draft report		PE412.104	18/09/2008	EP	
Commission communication on Council's position		COM(2008)0578	22/09/2008	EC	Summary
Amendments tabled in committee		PE412.111	16/10/2008	EP	
Amendments tabled in committee		PE414.992	22/10/2008	EP	
Committee recommendation tabled for plenary, 2nd reading		A6-0444/2008	12/11/2008	EP	
Text adopted by Parliament, 2nd reading		T6-0011/2009	13/01/2009	EP	Summary
Commission opinion on Parliament's position at 2nd reading		COM(2009)0145	30/03/2009	EC	Summary
Draft final act		03608/2009/LEX	21/10/2009	CSL	
Follow-up document		COM(2014)0082	18/02/2014	EC	Summary
Follow-up document		COM(2020)0208	20/05/2020	EC	
Follow-up document		SWD(2020)0087	20/05/2020	EC	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Regulation 2009/1107
OJ L 309 24.11.2009, p. 0001 Summary

Final legislative act with provisions for delegated acts

Placing of plant protection products on the market

PURPOSE : to lay down new harmonised EU rules for plant protection products, which aim to reinforce the protection of public health and the environment, support sustainable development in agriculture, reduce animal testing, boost competitiveness for producers and increase availability of plant protection products for farmers.

PROPOSED ACT : Regulation of the European Parliament and of the Council.

CONTENT : the use of plant protection products (PPP) may involve risks and hazards for humans, animals and the environment, especially if placed on the market without having been officially tested and authorized and if incorrectly used. Therefore harmonized rules should be adopted on the placing on the market of PPP.

This proposal follows extensive consultations with Member States and stakeholders over the past 5 years, as well as a comprehensive impact assessment. The proposed Regulation is fully in line with the overall Commission strategy on pesticides, and will complement the Commission?s proposal for a Directive on the sustainable use of pesticides (refer to COD/2006/0132).

The proposed Regulation replaces Directive 91/414/EEC concerning the placing of plant protection products on the market and repeals Council Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances. In a nutshell, it consists of the following elements:

- establishment at EU level of a positive list of active substances, safeners, synergists and a negative list of co-formulants;

- the time-span for the approval of active substances is shortened, with strict deadlines laid out for Member States, the European Food Safety Authority and the Commission;

- authorisations of active substances will no longer have to be renewed every 10 years (just once, after the first 10 year period), in order to avoid a backlog of unnecessary applications which have already been found to be acceptable for use. However, a review of an authorisation can still be carried out at any time if new concerns arise about its safety;

- the EU will be divided into 3 zones with similar climatic and ecological features, and plant protection products authorised by any one Member

State will automatically be cleared for use in the other Member States in that particular zone;

- national authorities will still be allowed, however, to impose specific national risk mitigation measures if deemed necessary;

- data protection rules are also simplified, to allow more transparency, greater competition and a level playing field for small and medium sized producers, while ensuring that this does not hamper innovation;

- provisions on packaging, labelling and advertising;

- obligation to keep records and to carry out controls;

- establishment of criteria for approval of active substances, safeners or synergists.

The proposal also includes new provisions which aim to protect human health, animal welfare and the environment:

- the safety evaluations of active substances will be founded on strict criteria, also based on health considerations and the effects on the environment (e.g. persistence in the environment);

- the European Food Safety Authority (EFSA) has a central role in the evaluation procedure;

- control measures are reinforced in the Commission?s proposal, and farmers and other professional users will have to keep records of their use of plant protection products. These will have to be made available on request to the drinking water industry and neighbours;

- avoid repetition of testing on vertebrates

- protect non-professional users.

For further information concerning the financial implications of this measure, please refer to the financial statement.

Placing of plant protection products on the market

The Council took note of information provided by the Commission on a proposal for a Regulation concerning the placing of plant protection products on the market.

Giving their first reactions, certain Member States identified a number of issues that will require further examination, including the need for specific rules on parallel imports, the proposed principle of compulsory mutual recognition within a three-zone system, and ways of taking into account the varying needs of individual Member States and ensuring that plant protection products are available for minor crops.

Placing of plant protection products on the market

The Committee on the Environment, Public Health and Food Safety adopted a report drawn up by Hiltrud BREYER (Greens/ALE, DE), and amended, in the first reading of the co-decision procedure, the proposal for a regulation concerning the placing of plant protection products on the market.

The main amendments are as follows : :

Objective and legal bases: Members specified that Articles 152 (4)(b) and 175(1) should be used as dual legal bases since the purpose of the Regulation is to ensure a high level of protection of both human and animal health and the environment. The purpose of the Regulation is furthermore to harmonise the rules on the placing on the market of plant protection products in order to harmonise the availability of plant protection products between farmers in different Member States. Member States may not be prevented from applying the precautionary principle in restricting or prohibiting pesticides. They may establish any pesticide-free zones they deem necessary in order to safeguard drinking water resources. Such pesticide-free zones may cover the entire Member State. Member States may impose a ban on the use and marketing of EU-authorised pesticides where they are found in measurable quantities outside the root zone.

Definitions: the Committee inserted and amended several definitions. It specified, particularly, that ?plant protection products? should be replaced with ?pesticides? and in the relevant places ?pesticide products'.

Zonal licensing: in view of the objectives of the regulation, the Committee did not consider the Commission?s proposed introduction of zones and corresponding zonal licensing of pesticidal products to be useful, since it felt that dividing the EU into arbitrary zones did not meet environmental or nature-conservancy criteria. Risk assessment and risk management should be set up in accordance with smaller, differentiated nature conservancy areas and soil-climate conditions. In addition, each Member State should retain the option of going beyond the Community standard in its fundamental standard of protection or of making decisions in product licensing in order to implement established objectives of national pesticide action plans, health programmes or environmental protection measures. Each Member State should also be allowed to decide to link licensing decisions to a test of usefulness based on specific national conditions. The Committee stipulated, instead of arbitrary zones, that the principle of mutual recognition of national licensings should be retained, but that the Member States should, in the spirit of the subsidiarity principle, be allowed to make national or regional specifications. Member States should be entitled to confirm, reject or restrict the authorisation granted by another Member State on the basis of their specific agricultural needs or to maintain a higher protection level in line with their National Pesticide Action Plan.

Active substances: Members clarified that active substances that have no adverse effect on humans, animals or the environment can be considered as low-risk. The Commission may review the approval of an active substance at any time and will give due consideration to requests for review from a Member State, the European Parliament and other stakeholders, based on current scientific and technical knowledge and monitoring data. The Committee made clear that a derogation will not apply to any active substance classified in accordance with Directive 67/548/EEC as: carcinogenic, mutagenic, toxic to reproduction, sensitising, or to substances that are qualified as: persistent with a half-life of more than 60 days; endocrine disrupters appearing on the EU list of suspected endocrine disrupters; toxic; bioaccumulative and non-readily degradable. On e year after entry into force of the legislation, the Commission must review and if necessary specify the criteria for treating an active substance as a low risk substance and, if appropriate, submit proposals.

Approval criteria for an active substance or a metabolite in the use-phase: the Committee stated that cut-off criteria will be used for the exclusion of active substances, in order to protect human health and the environment against intrinsic hazards of certain substances. They must not have any harmful effects on human health, in particular that of users who are in direct contact with the products, residents, bystanders and vulnerable groups, such as pregnant and nursing women, embryos and foetuses, infants and children. All testing and decision-making strategies must follow this principle, and current scientific knowledge must be borne in mind in the process. Furthermore, to prevent animal testing, tests on vertebrate animals should for the purposes of the Regulation be carried out only as a last resort. The use of non-animal tests and intelligent testing strategies shall be promoted, and duplicate vertebrate animal testing shall be prohibited. Dossiers for each test or study involving vertebrate animals must show a justification of the steps taken to avoid animal testing and duplicative testing on vertebrate animals.

Substitution principle and comparative assessment: the Committee considered it important to follow the principles of the REACH and biocide directives, and to introduce the substitution principle and comparative assessment in order to reduce the risks and dangers of pesticides. Products that contain a candidate for substitution will not be approved by Member States if there are safer alternatives or methods available for a given crop. While Member States must not authorise any plant protection product where a comparative assessment shows the existence of safer alternatives, priority in comparative assessment and substitution shall be given to candidates for substitution. In addition, the aims of the Thematic Strategy on the compulsory introduction of standards of integrated pest management and integrated plant protection into agriculture should be incorporated into the definitions and measures of ?good technical practice? and ?proper handling of pesticides? in the regulation. These conditions should become a compulsory component of the licensing process by 2012 instead of 2014.

Approval procedure: the Committee stated that the Authority must be responsible for coordinating the approval procedure, and in doing so, the Authority will rely on the competent authorities of Member States. An application for the approval of an active substance or for an amendment to the conditions of an approval shall be submitted by the producer of the active substance to the Authority (rather than the ?rapporteur Member State ?). The Authority shall inform the competent authorities of the Member States of the applications it has received. A Member State may choose an active substance for which an application for approval has been received by the Authority, with the aim of becoming the rapporteur Member State. Disagreement should be solved in comitology, on the basis of objective criteria, such as geographic, agricultural and climatic conditions, especially with regard to the target organisms, the performance and impartiality of the competent authority and the reference laboratory, and the absence of interests linked to the producing companies.

Renewal of approval: whilst the Commission had specified that the renewal shall be for an unlimited period of time, the Committee stated that the approval may be renewed once or repeatedly for a period not exceeding 10 years. The approval period should be proportional to the possible risks inherent in the use of such substances and should be limited to a maximum of 15 years for low risk substances, 5 years for candidates for substitution and 10 years for other substances.

Transparency and competition: Members consider the greatest possible transparency in licensing and use, all the way through to the consumer, to be essential. For this reason information on permitted substances should be published on the Internet, and consumer-relevant information (e.g. eco-toxicological data) from the licensing procedure, as well as the results of residue monitoring, should be published. In addition to the proposed rule on keeping records on pesticide use, the Committee suggests a ?pesticide pass?, with which greater transparency and traceability in the food chain could be achieved. Lastly, Members specified the need for a clear definition and a minimum set of community harmonized rules regulating the placing of products on the market through parallel trade.

Placing of plant protection products on the market

The European Parliament adopted a resolution drafted by Hiltrud BREYER (Greens/ALE, DE), and made some amendments to the proposal for a regulation concerning the placing of plant protection products on the market. With specific regard to the approval regime, the Commission's zone-based approach was rejected by Parliament, which preferred Member States to maintain national control over product approval.

The main points are as follows:

Objective and legal bases: Members specified that Articles 152 (4)(b) and 175(1) should be used as dual legal bases since the purpose of the Regulation is to ensure a high level of protection of both human and animal health and the environment. The purpose of the Regulation is furthermore to harmonise the rules on the placing on the market of plant protection products in order to harmonise the availability of plant protection products between farmers in different Member States. Member States may not be prevented from applying the precautionary principle in restricting or prohibiting pesticides. They may establish any pesticide-free zones they deem necessary in order to safeguard drinking water resources. Such pesticide-free zones may cover the entire Member State. Member States may impose a ban on the use and marketing of EU-authorised pesticides where they are found in measurable quantities outside the root zone.

Active substances: Members introduced a definition of 'active substances' as substances, including their metabolites present in the use phase, micro-organisms and viruses, having general or specific action against target organisms or on plants, parts of plants or plant products. They clarified that they must not have any harmful effects on human health, in particular that of users who are in direct contact with the products, residents, bystanders and vulnerable groups. Parliament accepted an amendment in plenary that such substances shall not have any unacceptable effect on the environment taking into account cumulative and synergistic effects and all relevant exposure routes to organisms in the environment. Methods to assess such effects will be presented by the European Food Safety Authority. A derogation will not apply to any active substance classified in accordance with Directive 67/548/EEC as: carcinogenic, mutagenic, toxic to reproduction, sensitising chemicals, or to substances that are qualified as: persistent with a half-life of more than 60 days; endocrine disrupters appearing on the EU list of suspected endocrine disrupters; toxic; bioaccumulative and non-readily degradable. On e year after entry into force of the legislation, the Commission must review and if necessary specify the criteria for treating an active substance as a low risk substance and, if appropriate, submit proposals. The Commission may review the approval of an active substance at any time and shall give due consideration to requests for review from a Member State, the European Parliament and other stakeholders, based on current scientific and technical knowledge and monitoring data.

Parliament added as part of the definition of ?substance of concern? that any substance that has or potentially has either carcinogenic, mutagenic, endocrine disrupting, neurotoxic, immunotoxic, reprotoxic or genotoxic capabilities should be regarded as a substance of concern.

Zonal licensing: Parliament rejected the Commission?s proposal regarding the introduction of zones and corresponding zonal licensing of pesticidal products. It specified instead that authorisations granted by one Member State should be notified to other Member States. Member

States should be entitled to confirm, reject or restrict the authorisation granted by another Member State on the basis of their specific agricultural needs or to maintain a higher protection level in line with their National Pesticide Action Plan. A new recital states that good administrative co-operation between Member States should be increased during all steps of the authorisation procedure and should be facilitated by a European Helpdesk.

Approval procedure: Parliament stated that the Authority must be responsible for coordinating the approval procedure, and in doing so, the Authority will rely on the competent authorities of Member States. An application for the approval of an active substance or for an amendment to the conditions of an approval shall be submitted by the producer of the active substance to the Authority (rather than the ?rapporteur Member State ?). The Authority shall inform the competent authorities of the Member States of the applications it has received. A Member State may choose an active substance for which an application for approval has been received by the Authority, with the aim of becoming the rapporteur Member State. Disagreement should be solved in comitology, on the basis of objective criteria, such as geographic, agricultural and climatic conditions, especially with regard to the target organisms, the performance and impartiality of the competent authority and the reference laboratory, and the absence of interests linked to the producing companies.

The authorisation setting out the requirements relating to the placing on the market and use of the plant protection product will include indications for proper use according to the principles of Integrated Pest Management as defined in the legislation, to apply from 2012 onwards.

Renewal of approval: whilst the Commission had specified that the renewal shall be for an unlimited period of time, Parliament endorsed the views of its competent committee and stated that the approval may be renewed once or repeatedly for a period not exceeding 10 years. The approval period should be proportional to the possible risks inherent in the use of such substances and should be limited to a maximum of 15 years for low risk substances, 5 years for candidates for substitution and 10 years for other substances. After the first renewal, a regular review of substances should take place.

Substitution principle and comparative assessment: Member States must not authorise for use in a given crop a plant protection product either containing a candidate for substitution or posing a higher risk where a comparative assessment weighing up the risks and benefits, as set out in Annex IV, shows that safer alternatives are available, as defined in the legislation. While Member States must not authorise any plant protection product where a comparative assessment shows the existence of safer alternatives, priority in comparative assessment and substitution shall be given to candidates for substitution.

Minor uses: Member States must establish a list of minor uses. This list shall be made available to the public through official websites of the Member State and of the Commission. Not later than one year after entry into force of the legislation, the Commission must present a proposal to the European Parliament and the Council for establishing a European promotion fund for minor uses. The Fund shall also be entitled to finance additional residue tests for minor uses. Comparative assessments shall take authorised minor uses into account.

Transparency and competition: Producers, suppliers, distributors and professional users of plant protection products must keep records of the plant protection products they produce, store or use for at least 10 years after the end of production or use. They shall make the information contained in these records available to the competent authority. They shall also keep this information available for neighbours and residents, retailers or the drinking water industry who request direct access to it. The information on all applications of plant protection products on a given agricultural product shall be provided to retailers and wholesalers in the form of a pesticide passport. In addition, the Commission must maintain an updated list of approved active substances in Annex IIa and publish this list on the Internet. Lastly, Members specified the need for a clear definition and a minimum set of community harmonized rules regulating the placing of products on the market through parallel trade, and inserted a new Article on the granting of parallel trade permits.

Animal testing: in order to avoid animal testing, testing on vertebrate animals for the purposes of the Regulation must be undertaken only as a last resort. The use of non-animal tests and intelligent testing strategies must be promoted, and duplicate vertebrate animal testing shall be prohibited. Dossiers for each test or study involving vertebrate animals must show a justification of the steps taken to avoid animal testing and duplicative testing on vertebrate animals.

Placing of plant protection products on the market

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.

Placing of plant protection products on the market

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.

Placing of plant protection products on the market

The Commission takes the view that the common position fully reflects the key elements of its initial proposal and the spirit of many of the amendments of the European Parliament made in the first reading. The Commission therefore agrees with the common position as adopted by the Council by qualified majority.

The Commission made two written statements:

1) The Commission recognises that the procedure which allows possible approval of an active substance for a maximum period of 5 years, even if it does not satisfy the listed criteria, is a derogation from the standard procedure to approve active substances. The Commission stresses that the derogation would only apply in cases where documented evidence is submitted showing that there are no other available means to control a serious danger to plant health. The approval will be decided by comitology, thus involving all Member States in the evaluation not only of the dossier on the active substance, but equally on the documentation showing that there are no alternatives. Approval which may be proposed will be subject to strict conditions, including risk mitigation measures, which would be part of the approval decision and aim at minimising exposure to humans and the environment.

2) The Commission regrets the removal of Article 152.4(b) of the Treaty from the legal basis of the proposal. One of the main aims of the proposal is to achieve a high level of human and animal health and to protect the environment. In order to allow the legislative process to move forward with a view to the timely adoption of the proposed Regulation, the Commission accepts the common position of the Council given that the substance of the compromise reached, taken as a whole, meets the objectives of the proposal. Should the European Parliament re-introduce during the second reading Article 152 as one of the legal bases of the proposal, the Commission reserves the right to accept the relevant amendment.

Placing of plant protection products on the market

The Committee on the Environment, Public Health and Food Safety adopted a report drafted by Hiltrud BREYER (Greens/ALE, DE), and recommended amendments to the Council common position for adopting a regulation of the European Parliament and of the Council on the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. Most of the amendments were reinstatements of amendments from 1st reading. The main ones were as follows :

Legal bases: Members specified that Articles 152 (4)(b) and 175(1) should be used as dual legal bases since the purpose of the Regulation is to ensure a high level of protection of both human and animal health and the environment. The common position provides for Article 95 (internal market) and Article 37(2) (agriculture) to be used as legal bases.

Objective: the committee expanded considerably the purposes of the Regulation, stating that, in addition to autorisation and approval of active substances, purposes include: ensuring a high level of protection of both human and animal health and the environment; and harmonising the rules on the placing on the market of plant protection products in order to harmonise the availability of plant protection products between farmers in different Member States.

Precautionary principle: the Regulation is based on the precautionary principle in order to ensure that substances or products placed on the market do not adversely affect human or animal health or the environment. Member States may not be prevented from applying the precautionary principle in restricting or prohibiting pesticides. Member States may establish any pesticide-free zones they deem necessary in order to safeguard drinking water resources. Such pesticide-free zones may cover the entire Member State.

Active substances: Members re-introduced the definition of active substances that Parliament had proposed at 1st reading. With regard to the derogation from the criteria for the approval of a substance in case of a serious danger to plant health, the committee specified that there must be a public interest in controlling that danger. Such an active substance may be approved for a time-limited period necessary to control that serious danger but not exceeding 4 years (rather than 5 years) and a substitution plan on how to control the serious danger in two years' time by other means, including non-chemical methods, must be presented by the applicant. Regarding substances with endocrine-disrupting properties, the committee provides some examples of substances which may be considered as such. Further specific scientific criteria for the determination of endocrine disrupting properties shall be adopted in accordance with the regulatory procedure with scrutiny.

A new clause states that an active substance, safener or synergist shall only be approved if it is not considered to cause a significant risk (affecting at least one in a million citizens) of developmental neurotoxic or immunotoxic properties in humans, taking into account exposure during embryonic/foetal life and/or during childhood as well as likely combination effects, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, i.e. the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Regulation (EC) No 396/2005.

The committee also introduces in the criteria the consideration of risk to honeybees, honeybee larvae, honeybee behaviour, or colony survival and development.

Zoning: the committee deleted the proposed zoning system, since it felt that the latter undermines national authorisation and it is not in line with the EC principle of proportionality and subsidiarity because it is going beyond what is necessary to speeding up the decision making process. These objectives can be reached by amending the mutual recognition system without the concept of zoning. The committee proposes to keep the principle of compulsory mutual recognition of authorisations for plant protection products in the context of a one-zone system and introduces more flexibility for Member States to refuse mutual recognition. An amended recital states that authorisations granted by one Member State should be notified to other Member States in which the applicant wishes to put the product on the market. Those Member States should be entitled to recognise an authorisation issued by another Member State, amend it or refrain from authorising the plant protection product in their territory, if justified because of specific agricultural or environmental circumstances that may be, but do not need to be, limited to that Member State, or if the high level of protection of human or animal health or the environment set out in the Regulation cannot be achieved, or to maintain a higher protection level in their territory in line with their national action plan to reduce the risks associated with pesticides, adopted in accordance with Directive 2008/.../EC establishing a framework for Community action to achieve a sustainable use of pesticides.

Approval procedure: the committee insisted that the Authority (EFSA) shall be responsible for coordinating the approval procedure. In doing so, the Authority shall rely on the competent authorities of Member States. Upon being informed which Member State will examine the application, the applicant shall immediately forward to the Authority the complete and the summary dossiers. Within 180 days, the Member States concerned shall grant or refuse authorisations.

Substitution of dangerous substances with safer alternatives: the approval time of candidates for substitution should not be the same as the general approval period. To ensure regular comparative assessment of products containing such substances, the approval period should be limited to 5 years (renewable) rather than 10. Furthermore, any authorisation of plant protection products containing a candidate for substitution without comparative assessment should be limited to a maximum of 3 years. The adoption of the list of substances that are candidates for substitution should be done after 3 years at the latest, rather than 6.

Animal testing: Members specified that, in order to avoid animal testing, testing on vertebrate animals for the purposes of the Regulation shall be undertaken only as a last resort. The use of non-animal tests and intelligent testing strategies shall be promoted, and duplicate vertebrate animal testing shall be prohibited.

Standardised format for information: Members want records of plant protection products produced, imported, exported, stored, used or placed on the market to be kept for at least 10 years after the end of production or use, rather than for 3 years. This information must be available for neighbours and residents, retailers or the drinking water industry who request direct access to it. The information on all applications of plant protection products on a given agricultural product shall be provided to retailers and wholesalers using a standardised format, which will be established in accordance with the advisory procedure.

Promotion fund for minor uses: not later than one year after entry into force of the legislation, the Commission shall present a proposal to the European Parliament and the Council for the establishment of a European promotion fund for minor uses. The Fund shall also be entitled to finance additional residue tests for minor uses.

Comitology: the Commission must be empowered to approve active substances, to renew or review their approval, to adopt harmonised methods to determine the nature and quantity of active substances, safeners and synergists, and where appropriate of relevant impurities and co-formulants, to adopt detailed rules for allowing derogations from authorisation of plant protection products for research and development and the list of approved substances. Rules on these matters must be adopted in accordance with the regulatory procedure with scrutiny.

Placing of plant protection products on the market

The European Parliament adopted a legislative resolution amending the Council's common position for adopting a regulation of the European Parliament and of the Council on the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

The recommendation for second reading (under the codecision procedure) had been tabled for consideration in plenary by Hiltrud BREYER (Greens/ALE, DE), on behalf of the Committee on the Environment, Public Health and Food Safety.

The amendments were the result of a compromise between Parliament and Council. The main amendments were as follows:

Legal bases: the compromise text stated that the legal bases were Articles 37(2) (agriculture), 95 (internal market) and 152(4)(b) (health).

Precautionary principle: the provisions are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human health or the environment. Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human, animal health or the environment posed by the plant protection products to be authorised in their territory.

Active substances: Members dropped the definition of active substances that Parliament had proposed at 1st reading. The compromise text states that where an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, such active substance may be approved for a time limited period necessary to control that serious danger but not exceeding five years even if it does not satisfy the approval criteria. Members States may authorise plant protection products containing active substances approved in accordance with this derogation only when it is necessary to control that serious danger to plant health in their territory. At the same time, they shall elaborate a phasing out plan on how to control the serious danger by other means, including non-chemical methods, and shall forthwith transmit it to the Commission.

CMR and endocrine disruptors: with regard to the derogation from the approval criteria for active substances, the text provides that the derogation shall not apply to active substances which are or have to be classified in accordance with Directive 67/548/EEC, as carcinogenic category 1, carcinogenic category 2 without a threshold, or toxic for reproduction category An active substance must not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects. Those products that are affected will only be banned once their current approvals come up for renewal.

Zoning system: Parliament accepted that the three-zones division should be maintained.

Residents: residents should be taken into account for the authorisation of plant protection products

Honeybees: An active substance, safener or synergist shall be approved only if it is established that it will result in a negligible exposure of honeybees, or that there are no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.

Application: assessment of an application may be performed by a number of Member States together under a co-rapporteur system. Scientific peer-reviewed open literature, as determined by the Authority, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last ten years before the date of dossier submission shall be added by the applicant to the dossier.

Animal testing: the summary dossier must include for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplicative testing on vertebrate animals. Furthermore, the Commission's work programme must include measures to minimise animal testing, in particular the use of non-animal test methods and intelligent testing strategies.

Testing on vertebrate animals: this may be undertaken only where no other methods are available. Repetition of tests and studies involving vertebrates shall be avoided. Seven years after entry into force of the regulation, the Commission shall report on the effects of the provisions concerning data protection of tests and studies involving vertebrate animals.

Comitology: the regulatory procedure with scrutiny will apply to harmonised methods to determine the nature and quantity of active substances, safeners and synergists as well as relevant impurities and coformulants. It will also apply to detailed rules for the maximum quantities of plant protection products which may be released during experiments.

Minor uses: 2 years after entry into force of the legislation, the Commission shall present a report to the European Parliament and the Council on the establishment of a European fund for minor uses, accompanied, if appropriate, by a legislative proposal.

Advertising: Member States may prohibit or restrict the advertising of plant protection products in certain media subject to Community law.

Record-keeping: records must be kept for at least five years. Professional users of plant protection products shall keep records of the plant protection products they use, containing the name of the plant protection product, the time and the dose of application, the area and the crop where the plant protection product was used, for at least three years. 3 years after entry into force of the legislation, the Commission shall present a report on costs and benefits of the traceability of the information from users to retailers concerning the plant protection products' applications on agricultural products accompanied, if necessary, with appropriate legislative proposals. Producers of plant protection products shall undertake post-authorisation monitoring on request of the competent authorities and notify the competent authorities of the relevant results.

Placing of plant protection products on the market

The Commission accepts all the amendments voted by the EP. The outcome of the second reading in the EP was very satisfactory.

The Commission recalls that the European Parliament voted in second reading a consolidated text which contains a number of amendments to the text of the Common Position. The text is the result of negotiations between the Council, the European Parliament and the Commission. All amendments are mainly of technical nature and are in line with and strengthen the key principles of the initial proposal.

Placing of plant protection products on the market

PURPOSE: to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production.

LEGISLATIVE ACT: Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

CONTENT: following an agreement reached at second reading of the codecision procedure, the Council adopted a regulation concerning the placing of plant protection products on the market.

The proposed Regulation would replace the existing legislation on the placing on the market of plant protection products (Council Directive 91/414/EEC), thoroughly revising the procedures for the safety evaluation of active substances and plant protection products. However, it keeps the two steps procedure of the Directive:

1. Approval of active substances at EU level;
2. Authorisation of plant protection products, containing approved substances, by Member States.

For simplification, it would also repeal Council Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances. The main aim of the proposal is to maintain a high level of protection for humans, animals and the environment; to reduce the administrative burdens of the present approval and authorisation procedures and to achieve a higher level of harmonization.

This proposal should be seen as part of a package together with the Thematic Strategy on the Sustainable Use of Pesticides and the proposal for a Framework Directive, which fills a legal gap in the use phase of pesticides, as well as a proposal for a Regulation on the collection of statistics regarding the placing on the market and the use of plant protection products.

The main elements of this new Regulation are as follows:

Subject matter and purpose: this Regulation lays down rules for the authorisation of plant protection products in commercial form and for their placing on the market, use and control within the Community. It lays down both rules for the approval of active substances, safeners and synergists, which plant protection products contain or consist of, and rules for adjuvants and co-formulants.

The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production. The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory.

Criteria: strict cut-off criteria for the approval at EU level of active substances are laid down in the new Regulation which will ban from the market the most toxic substances currently available. However, in exceptional cases, temporary derogations from these criteria could be granted in case of a serious threat to plant health. Under the new Regulation, a substance shall only be approved if, inter alia:

- it has no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health. These include pregnant and nursing women, the unborn, infants and children, the elderly and workers and residents subject to high pesticide exposure over the long term;
- it has no unacceptable effects on the environment, having particular regard to the following considerations: (i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation; (ii) its impact on non-target species, including on the ongoing behaviour of those species; (iii) its impact on biodiversity and the ecosystem.

Derogations: where on the basis of documented evidence included in the application an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, such active substance may be approved for a limited period necessary to control that serious danger but not exceeding five years, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. This derogation shall not apply to active substances which are or have to be classified as carcinogenic category 1A, carcinogenic category 1B without a threshold, or toxic for reproduction category 1A.

Member States may authorise plant protection products containing active substances approved in accordance with this derogation only when it is necessary to control that serious danger to plant health in their territory. At the same time, they shall draw up a phasing out plan concerning the control of the serious danger by other means, including non-chemical methods, and shall without delay transmit that plan to the Commission.

Procedures: the procedures for the approval of active substances and authorisation of plant protection products have been harmonised and simplified, deadlines have been tightened, and the roles of the Member States, the Commission, and European Food Safety Authority (EFSA) have been clarified. First approval shall be for a period not exceeding 10 years. An application for the approval of an active substance or for an amendment to the conditions of an approval shall be submitted by the producer of the active substance to a Member State, (the rapporteur Member State), together with a summary and a complete dossier or a scientifically reasoned justification for not providing certain parts of those dossiers, demonstrating that the active substance fulfils the approval criteria provided for in this Regulation. A joint application may be submitted by an association of producers designated by the producers for the purpose of compliance with this Regulation. Scientific peer-reviewed open literature, as determined by the Authority, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier shall be added by the applicant to the dossier. Member States should, within a delay of 120 days, decided on the mutual recognition. The renewal of the approval should be for a period not exceeding 15 years.

Regular examinations of products: under this Regulation Member States should regularly examine plant protection products containing substances which pose a high risk for human health or the environment with the aim of replacing them by plant protection products containing active substances which require less risk mitigation or by non-chemical control or prevention methods. In addition, incentives should be given for the placing on the market of low-risk plant protection products.

Definition of zones for the authorisation of plant protection products: the Regulation also sets out a system of three geographical zones (north, centre and south) for the mutual recognition of plant protection products which will increase the availability of plant protection products throughout the EU and reduce the workload for Member States. Nevertheless Member States will have the possibility to limit or reject the authorisations granted in another Member State in certain environmental or agricultural circumstances.

Animal testing: the Regulation stipulates that animal testing for the purposes of this Regulation should be minimised and tests on vertebrates should be undertaken as a last resort. Duplicative testing and duplication of tests and studies on vertebrates should be prohibited.

It should also be noted that an active substance, safener or synergist shall be approved only if it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist: (i) will result in a negligible exposure of honeybees, or (ii) has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.

Candidates for substitution: an active substance complying with the criteria shall be approved, for a period not exceeding seven years, as a candidate for substitution if it meets one or more of the additional criteria laid down in the regulation. By way of derogation, the approval may be renewed once or more for periods not exceeding seven years.

Other provisions: the new regulation also includes, in particular, rules on data protection, classification, packaging and labelling, advertising, record-keeping, parallel trade and on seeds treated with plant protection products.

Review clause: by 14 December 2014, the Commission shall present a report to the European Parliament and the Council on the functioning of mutual recognition of authorisations and in particular on the the division of the Community into three zones and on the application of the criteria for the approval of active substances, safeners and synergists as set out in Annex II and the impact thereof on the diversification and competitiveness of agriculture as well as on human health and on the environment. The report may be accompanied, if necessary, by the appropriate legislative proposals to amend those provisions.

By 14 June 2011, the Commission shall adopt the following: (a) a Regulation containing the list of the active substances already approved at the moment of adoption of that Regulation; (b) a Regulation on data requirements for active substances; (c) a Regulation on data requirements for plant protection products; (d) a Regulation on uniform principles for risk assessment for plant protection products; (e) a Regulation containing the requirements of the labelling of plant protection products.

ENTRY INTO FORCE: 14.12.2009.

APPLICATION: from 14.06.2011.

Placing of plant protection products on the market

The Commission presents a report on the establishment of a European fund for minor uses in the field of plant protection products.

Regulation (EC) No 1107/2009 regulates the placing of plant protection products (PPP) on the market and contains special provisions for the application and authorisation of so called minor uses. These are uses of PPP that are economically not sustainable for the plant protection industry, but important for growers.

Minor uses mainly concern minor or very minor crops (including most vegetables, fruit, nurseries and flowers) and it is estimated that they overall represent up to EUR 70 billion per year, representing 22% of the entire EU plant production value. It was estimated that direct impacts on the agricultural sector (i.e. crop production loss and additional growing costs for farmers) account for more than EUR 1 billion per year. Furthermore, most Member States consider minor uses to be so important that already today structural money and manpower amounting to approximately EUR 8 million are spent to address the issue.

The Regulation requires the Commission to present a report to the European Parliament and Council on the establishment of a European fund for minor uses, accompanied, if appropriate, by a legislative proposal. The aims of that report are:

- providing information regarding the situation on minor uses as reported by Member States and stakeholder organisations;
- presenting the strategy offered in Regulation (EC) No 1107/2009 as regards minor uses;
- presenting the options for action considered in the preliminary study funded by the Commission;
- informing the European Parliament and the Council about the Commission's conclusions on a possible legislative proposal for the establishment of a European minor uses fund.

Four options for action by the Commission have been considered :

- Option 1: no funding by the Commission;
- Option 2: re-installation of the EU Minor Uses Expert Group: the direct costs are estimated in the range of EU 44 000/year at the expense of the Commission, not including the resources needed in the Commission to attend and follow-up the meetings;
- Option 3: Commission partly funding a coordination facility (Technical Secretariat) comprising of an independent central secretariat which coordinates the work between Member States and stakeholders: the required budget for the implementation of option 3 has been estimated in the range of EUR 0.5 to EUR 0.7 millions/year to be shared between the Commission and Member State. The co-funding by the Commission could be implemented in the form of a grant;
- Option 4: Commission partly funding a coordination facility (Technical Secretariat) and specific projects. In the framework of this option, a budget estimated at EUR 1.2- EUR 6 million/year would be necessary depending on the number of projects funded. In this option the costs should be shared between the three stakeholder groups (industry, growers and the Commission/Member State).

The collection of views of Member States and stakeholders showed a clear demand for the establishment of a coordinated action at European level. While policy makers supported in majority option 3, a clear preference for option 4 was indicated by growers and the plant protection industry.

Noting that coordination at the European level is essential to solve the minor use problem, noting that Member States have already national efforts in place, and noting that there are currently a number of grassroots stakeholder activities ongoing, the Commission proposes the establishment of a coordination group.

The Commission is of the opinion that, in the short and medium term, the creation of a coordination platform would be sufficient, to which the Commission is prepared to financially contribute.

Once the facility has been established and becomes operational, the Commission will assess its functioning as well as the results achieved and may propose further appropriate measures.

The Commission also calls for the full involvement of relevant stakeholders to successfully implement Regulation (EC) No 1107/2009 and to find EU-wide viable solutions for minor crop pest problems. Special attention should be given to the implementation of integrated pest management practices and to low-risk active substances, bio-pesticides and basic substances.