




Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed 2003/0052(COD)
Pesticides: maximum levels of residue in or on food and feed of plant and animal origin (repeal. Directives 76/895/EEC, 86/362/EEC, 86/363/EEC, 90/642/EEC, amend. Directive 91/414/EEC)	
Amended by 2006/0294(COD) Amended by 2013/0140(COD) Amended by 2013/0169(COD)	
Subject 3.10.08.01 Feedingstuffs, animal nutrition 3.10.09.02 Plant health legislation 3.10.10 Foodstuffs, foodstuffs legislation 4.60.04.04 Food safety	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety		20/09/2004
		PPE-DE STURDY Robert	
	Former committee responsible		
	ENVI Environment, Public Health, Consumer Policy		09/09/2003
		PPE-DE STURDY Robert	
	Former committee for opinion		
	AGRI Agriculture and Rural Development		29/04/2003
		PPE-DE REDONDO JIMÉNEZ Encarnación	
Council of the European Union	Council configuration	Meeting	Date
	Agriculture and Fisheries	2635	24/01/2005
	Agriculture and Fisheries	2599	19/07/2004
	Agriculture and Fisheries	2578	26/04/2004
	Agriculture and Fisheries	2555	18/12/2003
European Commission	Commission DG	Commissioner	
	Health and Food Safety		

Key events			
13/03/2003	Legislative proposal published	COM(2003)0117	Summary
27/03/2003	Committee referral announced in Parliament, 1st reading		
18/12/2003	Debate in Council	2555	
06/04/2004	Vote in committee, 1st reading		
05/04/2004	Committee report tabled for plenary, 1st reading	A5-0260/2004	

19/04/2004	Debate in Parliament		
20/04/2004	Decision by Parliament, 1st reading	T5-0299/2004	Summary
18/07/2004	Council position published	09262/1/2004	Summary
16/09/2004	Committee referral announced in Parliament, 2nd reading		
24/11/2004	Vote in committee, 2nd reading		Summary
28/11/2004	Committee recommendation tabled for plenary, 2nd reading	A6-0049/2004	
14/12/2004	Debate in Parliament		
15/12/2004	Results of vote in Parliament		
15/12/2004	Decision by Parliament, 2nd reading	T6-0098/2004	Summary
24/01/2005	Act approved by Council, 2nd reading		
23/02/2005	Final act signed		
23/02/2005	End of procedure in Parliament		
16/03/2005	Final act published in Official Journal		

Technical information

Procedure reference	2003/0052(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amended by 2006/0294(COD) Amended by 2013/0140(COD) Amended by 2013/0169(COD)
Legal basis	EC Treaty (after Amsterdam) EC 152; EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/23707

Documentation gateway

Legislative proposal		COM(2003)0117	14/03/2003	EC	Summary
Economic and Social Committee: opinion, report		CES0927/2003	16/07/2003	ESC	
Economic and Social Committee: opinion, report		CES0951/2003 OJ C 234 30.09.2003, p. 0033-0036	16/07/2003	ESC	
Committee opinion		PE329.795/DEF	25/11/2003	EP	
Committee draft report		PE340.782	05/02/2004	EP	
Amendments tabled in committee		PE340.782/AM	15/03/2004	EP	
Committee report tabled for plenary, 1st		A5-0260/2004	06/04/2004	EP	

reading/single reading					
Text adopted by Parliament, 1st reading/single reading		T5-0299/2004 OJ C 104 30.04.2004, p. 0035-0278 E	20/04/2004	EP	Summary
Document attached to the procedure		09994/2004	06/07/2004	CSL	
Council position		09262/1/2004 OJ C 025 01.02.2005, p. 0001-0018 E	19/07/2004	CSL	Summary
Commission communication on Council's position		COM(2004)0587	08/09/2004	EC	Summary
Committee draft report		PE347.230	11/10/2004	EP	
Amendments tabled in committee		PE349.878	28/10/2004	EP	
Committee recommendation tabled for plenary, 2nd reading		A6-0049/2004	29/11/2004	EP	
Text adopted by Parliament, 2nd reading		T6-0098/2004 OJ C 226 15.09.2005, p. 0072-0202 E	15/12/2004	EP	Summary
Commission response to text adopted in plenary		SP(2005)239	19/01/2005	EC	
Commission opinion on Parliament's position at 2nd reading		COM(2005)0022	25/01/2005	EC	Summary
Follow-up document		C(2012)3699	04/06/2012	EC	
Follow-up document		C(2012)4302	26/06/2012	EC	
Follow-up document		COM(2020)0208	20/05/2020	EC	
Follow-up document		SWD(2020)0087	20/05/2020	EC	

Additional information

European Commission

[EUR-Lex](#)

Final act

[Regulation 2005/396](#)
[OJ L 070 16.03.2005, p. 0001-0016](#) Summary

Final legislative act with provisions for delegated acts

Pesticides: maximum levels of residue in or on food and feed of plant and animal origin (repeal. Directives 76/895/EEC, 86/362/EEC, 86/363/EEC, 90/642/EEC, amend. Directive 91/414/EEC)

PURPOSE : to harmonise at the European level the maximum residue levels (MRLs) of pesticides permitted in products of plant and animal origin. **CONTENT** : the proposed draft Regulation of the European Parliament and the Council replaces the four Council Directives on Maximum Residue Levels (MRLs) for plant protection products. The primary objectives of the proposal are to consolidate and to simplify the existing legislation in this area and to define the roles of the different actors, particularly that of the EFSA in the process. To this end, existing legislation was examined in the fifth Simpler Legislation for the Internal Market (SLIM V) exercise of the Commission during 2001, the recommendations of which are incorporated in the proposal. A secondary objective is to solve existing practical, Single Market and third-country trade problems. The consequence of this draft Regulation entering into force will be that all MRLs for plant protection products will become harmonised after a transitional 'phase-in' period, and will thenceforth only be set at the European level. It removes all trade barriers that were the result of the current situation whereby Member States can set their own national MRLs in the absence of Community MRLs. It provides for the role of the European Food Safety Authority (EFSA) and of the Commission in the process of setting MRLs. Risk assessment will become a responsibility of EFSA acting with its network of experts and institutes in the Member States and where EFSA will have the responsibility for giving an opinion on the safety of each MRL. The Commission will be responsible for the risk management, by deciding on

the setting of MRLs based on the opinion of EFSA. Member States authorities will provide EFSA with data on national diets, the authorisations and their agricultural practices. EFSA will base its opinions on assessments of these data, other data obtained in the process of evaluation of active substances under Directive 91/414/EEC and additional data to be supplied by applicants. MRLs not yet harmonised both for existing and new substances, previously set at the national level will be compiled by EFSA, screened for their safety based on the data available and set as temporary MRLs. These MRLs will be revisited on a substance-by-substance basis after the final conclusions on each of the 91/414/EEC evaluations. In all cases where there is no use of a pesticide on a commodity or when no data are available to demonstrate that residues do not endanger consumer health, no residues may be permitted at levels higher than 0.01 mg/kg which is an enforceable default for zero. Exceptions will be made for substances where a level of 0.01 is not safe for the consumer by setting MRLs at a lower level.?

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The European Parliament adopted a resolution drafted by Robert STURDY (EPP-ED, UK), broadly backing the proposal. Parliament stated that the aim of the Regulation is to set harmonised maximum residue levels (MRLs) for pesticides in products of plant and animal origin in order to protect all European consumers against possible health effects. MRLs should therefore be set at the lowest reasonably achievable level with the aim of ensuring the best possible consumer protection, and with a view to protecting vulnerable groups such as children and the unborn, and in order to minimise possible combined effects of multiple residues. Aggregate MRLs should be set after consultation of the European Food Safety Authority, who will submit proposals for the calculation of aggregate MRLs. In addition: - Maximum Residue Level (MRL) is now defined as the upper legal level of concentration for a pesticide residue, based on the best available agricultural methods of crop protection, i.e. integrated pest management in a given climate zone, and the lowest consumer exposure necessary to protect all vulnerable consumers; if an MRL is exceeded, measures are to be taken to withdraw a product from the market; - the role of the Commission, Member States and the Authority are more tightly defined by the amendments. The Commission must have the final say in setting, modifying or deleting an MRL. Parliament lists a series of factors that must be taken into account before a decision is made; - Member States must, on a quarterly basis, publish all results of national residue monitoring on the Internet, providing all individual data. Where MRLs are exceeded, Member States may name the retailers, traders or producers concerned; - The annexes on the maximum safe amounts of pesticide residues have not been prepared and Parliament has set deadlines for their entry into force.?

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The Council's common, adopted by unanimity, broadly accords with the positions taken by the Commission and the Parliament. It confirms the objectives and most of the arrangements proposed by the Commission and supported by the European Parliament as well as including a large number of the amendments adopted at first reading by the European Parliament. Notably, the Council agreed with a series of parliamentary amendments aiming to ensure the smooth functioning of the new procedures and to increase consistency between the new Regulation and other Community legislation. In addition, the Council felt that it was appropriate to introduce further amendments, for example, to allow Member States the flexibility to deal with MRL exceedences that arise in certain exceptional cases. The Council also reordered and reformatted parts of the text of the Regulation so as to clarify the roles of the Member States, EFSA and the Commission and to separate transitional provisions from the standard procedures under the new regime.

More specifically, the main amendments introduced by the Council concern the following issues :

- Application Procedure: the Respective Roles of the EFSA and the Member States : although the Commission had foreseen an exclusive role for EFSA in scientific evaluation work and the setting of MRLs, the Council agreed with the Parliament that Member States should perform a preliminary analysis of MRL applications in line with established procedures under Directive 91/414/EEC. In addition, the Council agreed that a copy of MRL applications received by Member States should immediately be sent to the Commission and to EFSA.

- Procedure for Routine Work Performed by EFSA : the Council introduced a new article designed to avoid unnecessary consultation of scientific bodies on matters of routine, i.e. in cases where EFSA issues opinions purely based on well established scientific principles.

- Administrative Review : a new article was added with a view to providing a form of legal redress

regarding decisions taken by EFSA and also in the event of non-action by EFSA.

- Time Scale and Transition to the New Procedures : in order to ensure a smooth transition to the new provisions, the Council followed the Parliament in setting down specific deadlines for the completion of the principal technical annexes, which will set out a list of harmonised MRLs (Annex II), a list of harmonised temporary MRLs (Annex III), and a list of active substances for which no MRLs are required (Annex IV). In the same spirit, the Council also introduced a deadline for drawing up the annex listing the products to which harmonised MRLs will apply (Annex I). Like Parliament, the Council considered that the Regulation should not apply in full until after the crucial annexes have been drawn up.

- Possibility to Extend the Validity of Temporary MRLs : in order to facilitate a smooth transition to a fully harmonised regime (e.g. where Member States indicate that extra time is required to complete scientific studies on substances that have been authorised nationally), the Council decided that it

should be possible for temporary MRLs, which will normally be valid for one year, to be maintained in Annex III for up to three additional years in certain cases.

- The Use of Pesticides for Post-Harvest Treatment : a derogation was introduced in order to provide for the practice of post-harvest fumigation of products.

- The Use of Pesticides in Exceptional Circumstances : in order to provide for exceptional circumstances, emergency provisions were introduced allowing a Member State to authorise the placing on the market and/or the feeding to animals within its territory of food or feed that is not in compliance with the MRLs laid down in the Regulation. Such authorisations are to be notified to the other Member States, the

Commission and EFSA, with a view to setting temporary MRLs and taking any other necessary actions. Such authorisations can only be granted provided that the treated food or feed does not constitute an unacceptable risk to consumers.

- Definitions : the Council added two new definitions, namely, "critical GAP" (i.e. the Good Agricultural Practice that forms the basis for a harmonised MRL under the Regulation) and "CXL" (i.e. an MRL set by the Codex Alimentarius Commission), and deleted the definition of "composite foodstuffs." In addition, the Council followed the European Parliament in clarifying the definition of "pesticide residues".

Lastly, it should be noted that further discussion is needed, in particular, on issues associated with risk assessment, and on provisions concerning the use of plant protection products, where Council was unable to agree to a number of Parliament's amendments at this stage. Such items concern, in particular, approaches to exposure assessment in the context of MRL-setting, considerations surrounding the most appropriate way of providing information to the public, and the drafting of provisions concerning good agricultural practice and pest management.

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The Commission is of the opinion that the common position represents a balanced further elaboration of the Commission proposal, where various provisions requested by the Council were included, and in which several of the 1st Reading amendments of the European Parliament have been taken into account. The roles and tasks of the Member States and the EFSA in the evaluation processes before MRL-setting by the Commission have been modified in the revised proposal. As the possibility is left open that, in a later stage - based on a report by the Commission and appropriate further proposals - this division of roles and tasks could revert to the original Commission proposal, the Commission can accept the changes. At the time of reaching the political agreement on the text, the Commission and the Council made declarations to ensure that EFSA's role is respected and that in a later stage the co-ordination of the work will be reviewed. Moreover, the Commission questions the appropriateness for the administrative review clause and stresses that it should not interfere with the independence of the EFSA in providing scientific advice and technical assistance. The remaining changes are acceptable to the Commission. Lastly, the Commission supports the Common Position adopted by the Council.

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The committee adopted the report by Robert STURDY (EPP-ED, UK) amending the Council's common position under the 2nd reading of the codecision procedure. It retabled a number of amendments adopted by Parliament at 1st reading, as follows:

- the aim of the regulation should be to set harmonised MRLs for pesticides in products of plant and animal origin "in order to protect all European consumers against possible health effects". For this purpose MRLs should be set at the "lowest reasonably achievable level" with the aim of ensuring the best possible consumer protection;
- Member States should publish on a quarterly basis all the results of national residue monitoring on the Internet. Where MRLs are exceeded Member States should be able to name the retailers, traders or producers concerned;
- herbal infusions should be subject to a separate assessment due to their many component parts;
- subgroups which may consume more of particular products must be fully protected;
- the definitions of certain terms used in the regulation should be clarified: "good agricultural practice" should entail integrated pest control in certain climate zones, as well as using the minimum quantity of pesticides and setting MRLs at the lowest level. In addition, the concepts of an "acute reference dose" (the amount of a substance in food that can be ingested over a short time without appreciable risk to the consumer) and of "acceptable daily intake" (the amount of a substance that can be ingested daily over a lifetime) should take account of "known cumulative and synergistic effects of the different plant protection products, as well as the higher vulnerability of children and the unborn";
- in the case of temporary MRLs, the precautionary principle should apply and they should be set at the lowest level that can be achieved in all the Member States on the basis of good agricultural practice.

MEPs also adopted an amendment intended as a compromise text on "import tolerance". At 1st reading Parliament had deleted a clause allowing for a higher MRL limit for imported products where "an existing Community MRL is not sufficient to meet the needs of international trade", arguing that the requirements of international trade should not override public health concerns. As the Council had reinstated the original text, the committee adapted the provisions to allow for a different MRL for imported products where "the existing Community MRL was set for reasons other than public health reasons for the specific product and specific use".

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The European Parliament adopted, by a large majority, a compromise package reached by the rapporteur, Robert STURDY (EPP-ED, UK), other political groups and the Council presidency on pesticide residues. The agreed text now places greater emphasis on consumer protection. The text states that the MRLs should be set at the lowest achievable level consistent with good agricultural practice for each pesticide with a view to protecting vulnerable groups such as children and the unborn. In addition:

- the definition of "good agricultural practice" implies the application, in conformity with Directive 91/414/EEC, of the principles of integrated pest control in a given climate zone, as well as using the

minimum quantity of pesticides and setting MRLs/temporary MRLs at the lowest level which allows the desired effect to be obtained;

- the concepts of an "acute reference dose" (the amount of a substance in food that can be ingested over a short time without appreciable risk to the consumer) and of "acceptable daily intake" (the amount of a substance that can be ingested daily over a lifetime) should take account of "the sensitive groups within the population (e.g. children and the unborn)".
- To ensure that consumers are kept adequately informed, Member States should, in accordance with Regulation 882/2004/EC, publish the results of national monitoring residues annually on the internet, providing all individual data, including the place of collection and the names of retailers, traders and/or producers;
- Parliament laid down new time limits on supplementary information;
- Where MRLs are exceeded, Member States may name the retailers, traders or producers concerned.

Finally, the compromise states that MRLs for imported commodities should not normally exceed the MRL limits set for domestic commodities. The deal reiterates a demand for a separate assessment for herbal infusions due to their many component parts.

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The amendments adopted are the result of a compromise between European Parliament, Council and Commission reached in negotiations during the second reading of the Codecision procedure. The resulting text is a satisfactory compromise for the Commission. Some amendments on setting maximum levels for pesticide residues (MRLs) reflect already existing working practice, and make these explicit in the legislation. Other amendments provide for the development and application of new methodology. The Commission is in favour of all amendments and made this clear during the negotiations. The amendments are in line with the original proposal and an improvement relative to the existing legislation.

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PURPOSE: to set maximum residue levels of pesticides in food and feed in order to raise the level of consumer health protection

LEGISLATIVE ACT: Regulation 396/2005/EC of the European Parliament and of the Council.

CONTENT: The Council adopted a Regulation on maximum residue levels of pesticides in food and feed, designed to raise the level of consumer health protection

The aim of the new, harmonised provisions is twofold: to facilitate trade in food and feed products within the Single Market and with third countries, and to ensure a consistent level of consumer protection across the EU.

Under the Regulation, maximum residue levels will always be set at Community level. The role of the European Food Safety Authority (EFSA) is also defined; it will be responsible for risk assessment, based on reports from the Member States.

The proposal overhauls and streamlines pesticides legislation by replacing four Directives with a single Regulation, at the same time as amending Regulation 91/414/EEC.

ENTRY INTO FORCE: 05/04/2005.