



COMMISSION OF THE EUROPEAN COMMUNITIES

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**COMMUNICATION FROM THE COMMISSION
TO THE EUROPEAN PARLIAMENT**

pursuant to the second subparagraph of Article 251 (2) of the EC Treaty

concerning the

common position adopted by the Council with a view to the adoption of a Regulation of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC

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1- BACKGROUND

Date of forwarding of the proposal to the EP and Council (document COM(2003)117 final – 2003/0052 COD):	14 March 2003
Date of the opinion of the European Economic and Social Committee:	16 July 2003
Date of the opinion of the European Parliament (First Reading)	20 April 2004
Date of forwarding of the amended proposal	26 April 2004*
Date of adoption of the Common Position	19 July 2004.

* In view of the tight timelines, with political agreement being reached in Council six days after the 1st Reading, - the Commission did not have time to adopt an amended proposal based on the final version of the EP opinion. The Commission accepted the text on which political agreement was reached and expresses in this Communication its considered views on the EP amendments.

2- AIM OF THE COMMISSION'S PROPOSAL

1. The aim of the proposed draft Regulation is to replace, codify and simplify the four existing Council Directives on Maximum Residue Levels (MRLs) for plant protection products (Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC), to harmonise all MRLs at EU level and to define the roles of the Member States, the Commission, the European Food Safety Authority (EFSA) and other parties in the process of setting MRLs.
2. The Regulation provides for MRLs to be directly applicable and enforceable in the Member States, underpinned by publicly available consumer risk assessments for which EFSA has overall responsibility. Where plant protection products are not authorised for use in the Community, where uses outside the Community are

unacceptable in terms of consumer intake of residues, or where data are insufficient to complete a risk assessment, a default value of 0.01 mg/kg shall apply.

3. The Regulation defines the obligations of the Member States with regard to control and enforcement of MRLs and reporting data concerning control and enforcement to EFSA and the publication of these data in an annual report by EFSA.

3- COMMENTS ON THE COMMON POSITION

3.1. GENERAL REMARKS

The common position adopted by the Council by unanimity 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 (see Annex) to ensure that EFSA's role is respected and that in a later stage the co-ordination of the work will be reviewed.

Other provisions included at the request of the Council were: the possibility that the default MRL could be replaced by the lowest effective limit of analytical determination (LOD) for substances where the data are available, derogations concerning emergency MRLs and fumigation treatments, the introduction of the administrative review clause and the changing of reporting dates regarding the annual report. 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. Several other requests by the Council were identical to amendments proposed by the EP and are discussed in the next paragraphs.

3.2. SPECIFIC REMARK

In article 14(1) the wording “submitted for adoption” should be replaced by “to be adopted” to reflect the correct wording for a comitology procedure.

3.3. AMENDMENTS MADE BY THE EUROPEAN PARLIAMENT AT FIRST READING

Amendments incorporated in the Common Position:

The Council has included in the common position several amendments adopted at first reading by the European Parliament and also accepted by the Commission. These amendments concern aspects of fees to be paid by applicants to fund control, enforcement and evaluation activities, the timeframe for setting final MRLs after evaluation of a substance under Directive 91/414/EEC, additions of commodities to

the list, such as herbal infusions, and providing extra protection of vulnerable groups such as children.

Amendments not incorporated in the Common Position, which were nevertheless found acceptable by the Commission as such or in a slightly reworded form or not in the exact place where the EP had wanted them.

These amendments concern reporting information on the names of transgressors and requiring EFSA to inform the general public about the risks of pesticides. The Commission has also a positive attitude toward the idea of taking into account cumulative exposure and has the intention of requesting the EFSA to develop methodology to permit such assessments to be done. Some points are already addressed or should be addressed in other specific legislation concerning authorisation of the use of pesticides (Council Directive 91/414/EEC) e.g. integrated pest management, immunotoxicity, endocrine disruptors etc.

Amendments not acceptable

Some amendments imposing restrictions on import tolerances are not accepted by the Commission as they would be open to challenge in the WTO because they discriminate against farmers outside the EU for reasons not permitted under the WTO-SPS-agreement. Conditions for import tolerances should be no more severe than conditions imposed on EU farmers and should be in line with specific WTO rules.

4- CONCLUSIONS

For the above reasons, the Commission supports the Common Position adopted by the Council.

5- COMMISSION AND COUNCIL DECLARATIONS

The following declarations by Council and Commission:

- Commission statement concerning the expansion of the list of commodities for which MRLs are set.
- Commission statement on the intention not to complicate MRL setting by combining conflictual proposals in one package.
- Commission statement on the intention to consult the Member States with respect to financial resources
- Statement by Council concerning MRLs for emergency measures taken by Member States
- Declarations by Commission and Council concerning the role of EFSA and the Member States in MRL evaluations;

These declarations are attached to this Communication.

ANNEX

COMMISSION AND COUNCIL DECLARATIONS

Concerning Article 4: Statement by the Commission

"The Commission will endeavour to ensure that the introduction of new products to Annex I will be timed in such a way as to minimise disruption to trade or to animal husbandry."

Concerning Article 14: Statement by the Commission

"The Commission will maintain its current practice of including more than one active substance in a proposal only when this is unlikely to slow down the adoption of the proposal."

Concerning Article 18: Statement by the Council

"The Council recalls the obligations for Member States to control the use of plant protection products pursuant to Article 8(4) of Directive 91/414/EEC and to provide for effective official controls pursuant to Chapter V of this Regulation. Such controls should in particular apply to products put on the market pursuant to Article 18(4) and be aimed at assuring that they are only marketed in accordance with the provisions of that paragraph."

Concerning Article 37: Statement by the Commission

"The Commission will maintain its current practice of consulting with Member States in the framework of the Standing Committee with respect to the measures referred to in Article 36(1)."

Concerning the Evaluation Arrangements and the Role of EFSA: Statements by the Council and the Commission

"The Council considers that the evaluation arrangements provided by the Regulation reflect the need to ensure a smooth transition to the new fully harmonised procedure for the fixing of MRLs while respecting the current arrangements concerning national authorisations for plant protection products.

The Council invites the Commission to present a report together with any appropriate proposal concerning improvements which will appear necessary in the light of the experience in applying this Regulation."

"The Commission notes that the Council has reached a unanimous consensus on this issue. Nevertheless, the Commission wishes that in the future examination of this proposal further consideration be given to improving the coordination between EFSA and Member States' national authorities so that requests for authorisation can be processed in the most effective manner