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COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on maximum residue levels of pesticides in products of plant and animal origin

(presented by the Commission)

EXPLANATORY MEMORANDUM

SUMMARY

This 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 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

OBJECTIVES OF PROPOSAL:

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.

MAIN ISSUES ADDRESSED IN PROPOSAL:

The proposal:

1. Takes into account problems encountered in the practical implementation of the existing directives.

2. Acts on the issues raised in the Report of the Commission to the Council on the implementation of Articles 7 and 4 respectively of Council Directives 86/362/EEC and 90/642/EEC, concerning the monitoring of pesticides residues (COM/2000/98 final).

3. Is in line with the conclusions of the Agriculture Council of 20 November 2001 and the Environment Council of 12 December 2001 in response to the Report of the Commission on progress in evaluating active substances under Council Directive 91/414/EEC (COM/2001/444 final), both of which call on the Commission to propose amendments the residues directives. It also responds to the resolution of the European Parliament of 30 May 2002 and also adopted in response to the Report of the Commission.

4. Sets the groundwork to prepare the Commission and the Member States to deal more effectively with the extensive workload expected in and after 2003 in the framework of Council Directive 91/414/EEC when several hundreds of active substances of plant protection products will be withdrawn from the market and where MRLs will need to be set for food commodities in the absence of the all of information required to guarantee an adequate protection of the consumer (use of default MRL of 0.01 mg/kg).

5. Uses the new comitology procedures.

6. Takes note of developments outlined in the White Paper on Food Safety including but not limited to those regarding the European Food Safety Authority established by Regulation 178/2002 of the Parliament and the Council as well as its competence in matters of risk assessment and the provision of independent scientific advice.

7. Establishes a framework within which Member States can set fees for the evaluation of dossiers. The resources needed for this area of work are expected to increase dramatically in the future and the current legislation does not provide a basis to recover the costs incurred.

8. Establishes a framework within which the Commission and the Member States can work with the European Food Safety Authority in this area - separating risk assessment from risk management.

9. Takes account of the provisions of the Commission proposal for a Regulation of the Council and the European Parliament on official feed and food controls.

10. Takes into account the recommendations of the SLIM V exercise of 2001.

11. Allows for the possibility that in some cases MRLs can be set on the basis of monitoring data.

12. Allows for the possibility that in some cases, the normal shelf-life of products should be considered in fixing dates of entry-into-force of MRLs

13. Allows for the possibility to set import tolerances where different agricultural practices outside the European Union lead to different residue levels on imported products.

14. Repeals the original 4 Directives and replaces them with a single Regulation.

15. Establishes transitional measures for setting temporary MRLs of active substances that have not yet been evaluated in the framework of Council Directive 91/414/EEC on the placing of plant protection products on the market and in doing so, removes the competence of Member States to act unilaterally in this area of food safety.

OVERVIEW OF LEGISLATION ON PESTICIDES MRLS:

Legislation on pesticide residues in food and feed includes provisions for the setting of maximum residue levels, for sampling as well as for monitoring, control and reporting. Residues in babyfood are covered by separate legislation and using a different approach.

Setting of MRLs:

Pesticides MRLs are currently set in four Council Directives: 76/895/EEC (for some crops and categorised by customs codes - not a satisfactory directive by today's standards), 86/362/EEC (cereals), 86/363/EEC (products of animal origin) and 90/642/EEC (products of plant origin other than cereals).

With about 160 crops and up to 1,000 pesticides in or out of use, then up to 160,000 MRLs are possible for raw commodities (including animal feed). The Community is gradually harmonising all of these (see status below). The directives also permit Member States to act at national level pending Community decisions on individual MRLs. The directives also allow MRLs to be set for processed and for composite foods. In practice this is not done at Community level for logistics reasons although the Community does step in where there are problems. Processing factors for individual substances are normally agreed during the evaluation of a 91/414/EEC dossier and are used in the consumer intake assessments performed to check the acceptability of a MRL.

Matters are complicated by the fact that Council Directive 91/414/EEC on the placing of plant protection products on the market also permits Member States to set MRLs when granting national authorisations of plant protection products. It includes a procedure to ensure that the residues directives take account of such MRLs. Furthermore, under WTO rules introduced late in the 1990's, Codex MRLs should be respected. Many Codex MRLs are not acceptable to the Community, particularly those set prior to the late 1990's but where the Commission did not formally object to them at the time. Therefore the Authority will have to critically examine on a case-by-case basis whether Codex MRLs ensure the same high level of sanitary protection that would be expected from Community MRLs.

1.1.1. Objective of setting an MRL:

Extract from Foreward to 'FAO Guidelines on Pesticide Residue Trials to provide Data for the Registration of Pesticides and the Establishment of Maximum Residue Levels'

Adequate data from properly conducted trials involving agricultural plants or farm animals intended for the production of food are needed to establish the parameters of "good agricultural practices in the use of pesticides". The levels of residues of pesticides remaining unavoidably in food products entering trade following such practices, form the basis for setting maximum residue levels. It is important that the results of residue analysis in supervised trials relate to those chemical species in the residue which are relevant for the purpose of setting maximum residue levels. It is equally important that the food products examined, as well as portions thereof examined, be relevant to the commodity moving in trade. Other aspects should also be borne in mind during pesticide residue trials, which have a bearing on the usefulness of the residue data used in setting maximum residue levels.

MRLs for pesticides used in plant protection products have been set by the Community since 1976 to facilitate trade. Unusually by the standards of today, the 1976 Directive permits Member States to set MRLs at higher levels than the Community ones but not at lower levels. In this respect, these older pesticides MRLs differ from the more recent directives where MRLs are primarily set to protect the consumer. however, the MRL is normally set for the product moving in trade and not for the product as consumed by the consumer e.g. dried tea leaves vs. the liquid beverage.

1.1.2. How MRLs are set:

Generally, an authorisation for use of a pesticide will only be given on the basis of submitted scientific data showing that the use is safe for the user, the environment and the consumer. The consumer assessment part of the procedure relates to data on the residues in the crop from 'supervised trials' data. If, inter alia, the proposed conditions of use result in residue levels that are safe for the consumer, then (i) an authorisation for use specifying the use conditions ('good agricultural practice' - GAP) can be issued and (ii) a MRL can be set and the product can move in trade.

The mechanisms and methods used to fix MRLs are fairly well-standardised at Community level and well-developed data requirements exist. Various authorised uses in one or more countries or regions on a given crop may give rise to various levels of residues. The GAP giving rise to the highest levels (the so-called 'critical' GAP) is used to set the MRL as all other authorised uses should be covered by it. If the residues arising from the critical GAP are not safe for the consumer, then that use is not authorised and the next critical GAP is examined.

In a minority of cases where residues might be expected but where there are no authorised uses e.g. from environmentally persistent substances such as DDT, then MRLs can be set (provided they are safe for the consumer) using monitoring data that is regularly reviewed. There have also been calls for the Commission to set MRLs using monitoring data for substances still in use for minor commodities e.g. spices and where residues arise as adventitious contamination e.g. honey. This proposal opens up this possibility.

Since risk is a combination of hazard and exposure, then due to differences in national eating habits, an acceptable consumer assessment in one country may not be acceptable in another. In the Community, diets in all Member States are examined when setting MRLs and intakes by adults, children and toddlers are assessed. Total intake of a substance from all dietary sources is examined every time a MRL is set for a substance on a crop. Acceptable methodologies are not yet available to systematically look at aggregate exposure (from other sources such as home and workplace) or cumulative exposure (intake from all dietary sources of similarly-acting substances). These are being developed.

1.1.3. What the setting of a MRL at the Limit of Determination (LOD) signifies:

The LOD is the lower limit of analytical determination i.e. the limit below which residues cannot be detected using suitable analytical methods in accredited laboratories and following agreed quality assurance guidelines and criteria. The LOD is therefore dependent on the substance, the method and the matrix. For example, LODs for substances in oily crops such as nuts or oilseeds are often higher than those in 'watery crops' because of analytical difficulties. The LOD needs to be carefully defined to ensure that legal enforcement measures seen to be neither arbitrary nor capricious.

Setting a MRL at the LOD is not equivalent to banning a substance and conversely, banning a substance does not mean that the MRL is set at the LOD. For many of the cases where MRLs are set at LOD, the MRLs could be increased without compromising consumer safety. There are eight cases where MRLs would normally be set at the LOD.

(a) No residue expected because obsolete: The substance is obsolete and is no longer used anywhere. This would also normally preclude that residues would be present on products but illegal uses cannot be excluded nor that contamination may occur from old stocks. No judgement needs to be made in such cases on the consumer-protection aspects of the acceptability of residues.

(b) No residue expected and no residue wanted: Following an evaluation, the use of the substance is banned in the Community because e.g. its residues are genotoxic. Residues on imported products would also be unwelcome.

(c) No residues expected because of use pattern: Following an evaluation, it has been demonstrated that the authorised uses of the substance do not leave residues in the harvested crop e.g. it is used as a soil or seed dressing or if residues degrade quickly. This could also apply to animal-origin products if a substance is used on crops that are not fed to animals.

(d) No residues expected because not (yet) used on certain crops: Particularly for new substances, in early years only a few major crops e.g. cereals would be treated. For untreated crops, no residues would be expected. As new uses are developed, the LODs for those latter crops would have to be reviewed. This will also be true in future for existing substances because, with the loss of half of all existing substances in 2003, the others will find wider uses.

(e) No residue expected because no longer authorised for use in the Community: In 2003, about 400 substances will have been withdrawn from the market and most withdrawals will have been for economical reasons (and without any prior evaluations) rather than because of concerns. They might still be used in third countries and residues could be present on imported produce.

(f) Existing high residue levels are possibly unsafe (although lower levels would be acceptable): Often new data becomes available showing that a substance is not as safe as formerly thought and that existing MRLs for some crops are too high. In these cases, the MRLs need to be reduced to safe levels. If a good agricultural practice exists giving rise to the lower safe levels then the MRL can be reduced. If not, then the MRL is set at LOD as a precautionary measure. If afterwards, a new GAP is developed giving rise to low, but safe, residue levels then the MRL can be increased again.

(g) Where a substance is banned because of environmental or worker safety considerations then MRLs would also normally be set at the LOD. However, there may be safe consumer exposure levels and residues could be accepted on (i) imported produce and (ii) domestic or imported produce where soil is contaminated and persistent residues are taken up by crops e.g. DDT. In both cases a consumer safety assessment would be required. In addition, in the former case, one cannot under WTO rules use MRLs to block trade where an assessment shows that allowing the imports would protect the consumer. In the latter case the MRLs would be set using monitoring data that is regularly reviewed.

(h) Insufficient data: Where the minimum data requirements to set a MRL are not met for a substance/crop combination, then a policy decision can be taken to set the MRL at LOD (see

below). When additional data becomes available, the need to set a higher MRL can be reconsidered.

1.1.4. Use of default LOD:

Various approaches exist around the world on the use of a default MRL for non-authorised uses.

One approach e.g. U.S.A., Codex, sees MRLs being set (whether at LOD or at a higher level) only where adequate data is available. In its absence, there is no MRL and no possibility of trade. It supposes that in all cases where any residues are detected and where there is no MRL, the result will be confiscation of the consignment. In the absence of agreed certified analytical methods for each substance/matrix combination, this approach is open to capricious use and a strong risk of trade problems. A variation of this policy approach is to allow trade in the absence of a MRL with the intention of eventually setting a MRL.

A second approach e.g. Germany, sees a default MRL of 0.01 mg/kg being applied to everything unless a specific higher MRL has been established for a particular crop/substance combination. This has the advantage of protecting against the unforeseen but also gives rise to trade problems for imported produce - especially for produce treated with new pesticides that have not been used and not yet evaluated in the country of destination. Canada currently applies this approach with a default of 0.1 mg/kg but is currently considering moving to the U.S.A. approach.

The Community approach up to now has been to gradually set MRLs for every substance and once these MRLs have been set for a substance then these Community MRLs apply everywhere. This approach allows national policies and MRLs to apply for the substances not yet harmonised at Community level. A drawback of this is that it means different policies and different MRLs in each Member State for many substances and this results in continuing trade problems in the Internal Market. When setting MRLs for a substance, the current Commission approach is to explicitly set MRLs at the LOD for those crops for which there is no or insufficient data. This approach in itself requires data (on the definition of the residues, on analytical methods etc) but such data is normally available from the dossiers on the other crops for which MRLs are being set. Setting a default MRL at or near the LOD also gives Member States an additional legal instrument with which illegal uses of pesticides can be controlled.

The approach initially proposed for the future was based on the U.S.A. one. This was supported by SLIM but rejected by the Member States. The approach now proposed is similar to the Canada/Germany one. The new 'default' approach is necessary because of the hundreds of substances being withdrawn from the market in 2003 for which we do not have the necessary residue and analytical data to set explicit MRLs. However, the use of a Community default MRL is not compatible with the practice of letting Member States set national MRLs for those substances still in use but for which Community MRLs have not yet been set. The proposal includes provisions for temporary MRLs in these cases (see 'Single Market Issues' below).

Why choose 0.01 mg/kg as a default MRL?

Since many residues can be detected with modern sophisticated methods at levels lower than 0.01 mg/kg, the question is often asked as to why this level is conventionally set at 0.01 mg/kg.

Firstly, it is not possible to set MRLs at zero because there is no analytical method that is capable of detecting 'zero' levels of residues and background analytical noise and uncertainty increase as zero is approached. Actual detection limits are dependent on the matrix, the substance and the analytical method. It is not practical to determine and to certify these individually for the more than 160,000 possible combinations. Therefore a default needs to be selected and from practical experience this is 0.01 mg/kg. A lower value may not be attainable for certain substance/matrix combinations and a higher default value is not necessary.

Secondly, for almost all cases investigated of pesticides in use, a MRL at 0.01 mg/kg is protective of the consumer. In exceptional case where this may not be true, a lower level could be explicitly set.

Thirdly, monitoring laboratories do not have the resources to routinely examine every possible crop/substance combination and they have to prioritise their efforts. They normally use certified multi-residue methods for screening levels of more than a hundred substances at a time in any one commodity and can look at e.g. up to 50 samples in any one run. Multi-residue methods are not as sensitive as targeted methods that can only detect one substance at a time but at much lower levels than the multi-residue methods which are generally able to detect levels down to 0.01 mg/kg. It is considered that screening 50 samples for more than a hundred substances each is more protective of the consumer than spending the same time analysing 10 samples for one substance. An exception is where there is a suspected infringement or a rapid alert - in which cases a more targeted sampling and analysis can be made.

Sampling:

Sampling for pesticides residues in products of plant origin was covered by Commission Directive 79/700/EEC. This was recently repealed and replaced by Commission Directive 2002/63/EC which (i) extended sampling provisions to include pesticides in products of animal origin and (ii) incorporated into EC legislation the sampling provisions of Codex that the Community agreed to in 2000. Article 33 of the proposal addresses sampling.

Monitoring, reporting and control:

The objectives of monitoring are two-fold. Firstly, monitoring is done to permit an estimation to be made of the real exposure of consumers to pesticides residues. The second objective of monitoring to ensure compliance (i) with existing Community and national MRLs and (ii) to guard against illegal use of pesticides. MRLs are set on the basis of data arising from legal authorised uses and, as a corollary, in this sense the legally permitted residues should not be considered as contaminants.

In the Community, national monitoring programmes are complemented by a co-ordinated Community monitoring programme which has as its first objective to estimate the exposure of consumers to pesticides residues. Monitoring is done at all points in the food production and distribution chain. To cover all major pesticides and crop groupings, monitoring programmes have been organised over a five-year period. The first such period has just expired and a contract is being prepared to analyse the results.

MRLs for babyfood:

The above-mentioned existing Community legislation on MRLs applies without prejudice to the 'babyfood' directives (Directives 91/321/EEC and 96/5/EC) where MRLs are also set. It differs from them in several respects.

1. The basic intention of the legislation on Baby Food is to control the production chain in order that no pesticides are used in the manufacturing process. In absence of ways to directly control this MRLs are set at such levels that do not permit the use of pesticides.

2. Babyfood legislation applies a default MRL of 0.01 mg/kg unless other (higher or lower) MRLs are explicitly set (this is the approach proposed in the current proposal);

3. Babyfood MRLs apply to a specific sector rather than to all of the population;

4. Since babyfoods are often composite, processed foods, the MRLs are set and are applicable for the food to be eaten and calculated as the whole diet. The toxicological endpoint (acceptable daily intake) is the starting point. In the MRL directives, GAP is the starting point and the MRLs apply to the raw commodity (or part thereof). Processing/composition factors are applied for the consumer intake assessment.

This different approach is justification not to include babyfood MRLs in the current proposal.

OBJECTIVES TO BE ATTAINED BY PROPOSED MEASURES:

Consolidation:

Four Council Directives and most of their provisions are being replaced with a single Regulation of the European Parliament and the Council.

Simplification:

The SLIM recommendations are taken up in the proposal which is a Regulation rather than a Directive. Many of the procedures in the existing directives have been simplified in the proposal.

Legal basis for expenditure:

The current directives do not contain any legal basis for expenditure and, in 2002, it was considered appropriate to use the 'veterinary model' as a basis for drafting new text.

In the area of pesticides residues there are two types of Community expenditure. One relates to monitoring, enforcement and control and the second is related to the development of technical guidelines, data requirements and methods to set MRLs. Although the second type of work should be transferred to the EFSA as soon as it becomes operational, a legal basis is still required for the first category and expenditure in the second category will still be required during the transition period during which EFSA becomes operational. Therefore, the proposal covers both types, recognising that the second type could be removed in the medium-term.

Single Market issues:

The biggest Single Market problem is related to the non-harmonised substances and the different national policies and MRLs governing them. In addition, uses of 461 substances will be withdrawn in 2003 and a harmonised approach to setting their MRLs in the absence of specific data, as well as to dealing with imports from third countries will be necessary. It can be seen from the Table below (penultimate row in rightmost column) that at the end of 2003, there will be a withdrawal from the market of about 386 substances for which there are no Community MRLs. Since most will be withdrawn because of lack of data, it will be impossible to set explicit MRLs for them on a substance by substance basis. A default 'MRL at LOD' approach together with the setting of import tolerances where appropriate, is the only realistic way to control them. This approach would also apply to 75 substances to be withdrawn for which we currently have harmonised Community MRLs.

The problem with applying the default LOD approach will lie with the 388 substances that will remain on the market but for which MRLs are not yet harmonised (middle row, rightmost column). Their uses, currently covered by national MRLs, would be blocked by the application of a default LOD. Therefore, the proposal includes an annex of temporary MRLs that will be based on the existing national MRLs. Filling this annex is not a trivial task (screening of MRLs in 15 Member States times up to 388 substances times up to 160 crops) and it could be one of the first tasks given to the EFSA. Since there are not yet any agreed Community (or even Codex in almost all cases) toxicological endpoints for the substances, then national (or JMPR or OECD) data would have to apply in the first instance. The setting of temporary Community MRLs carries a risk that some of the national MRLs upon which they are based may be unsafe. However, it should be recalled that (i) 91/414/EC dossiers will be available or forthcoming for all of them, (ii) unsafe MRLs will be identified by EFSA, the Commission or the Member States and will be reduced accordingly and (iii) since the MRLs already apply then the situation for the consumer will not be any worse than at present during the temporary transition period and (iv) this proposal includes a safeguard clause. The proposal foresees that as soon as a substance is evaluated under 91/414/EEC and Community toxicological endpoints are agreed, then the temporary 'national-based' MRLs will be deleted from that annex and new Community MRLs will be fixed based on the agreed 91/414/EEC endpoints. Under this scheme, all Community MRLs will be harmonised in one way or the other and there should be no more trade problems in the Community due to this issue.

MRL status on 9/1/2003 of substances under evaluation under Directive 91/414/EEC

	Number of substances	**of which harmonised (or about to be)**	**and of which not yet harmonised**
Substances likely to stay on the EC market for the foreseeable future (best-case scenario)			
Existing Already in Annex I	25	22	3
List 1	42	25	17
List 2	52	20	32
List 3	163	23	140
List 4[1]	136	4	132[2]
New	89	23	66
Sub-total	507	117	**390**[3]

[1] Preliminary data from the ongoing notification procedure set up for this stage by Commission Regulation (EC) N° 1112/2002.

[2] MRLs may not applicable to most of the substances.

3 National MRLs apply under current legislation. The proposal foresees temporary Community MRLs for most of these pending 91/414/EEC evaluations and decisions.

Substances withdrawn or likely be withdrawn in the foreseeable future			
Existing List 1	23	23	0
List 2	97	29	68
List 3	225	11	214
List 4	96	0	96
New	7	1	6
Other banned substances (Dir. 79/117/EEC)	17	17	0
Sub-total	465	81	**384**[4]
TOTAL	972	198	774

Coherence with Directive 91/414/EEC:

Directive 91/414/EEC on the placing of plant protection products on the market is the primary piece of Community legislation for plant protection products and their active substances. It provides for a Community evaluation of the active substance and for Member States to evaluate and authorise the uses of products containing them - using agreed hazard endpoints and risk assessment criteria. The Commission cannot authorise uses (it can oblige Member States to withdraw uses however) and Member States consistently invoke the principle of subsidiarity on every occasion that they feel their competence to authorise uses is threatened. In the 1990's, the Community assessment of active substances almost ground to a halt while trying to evaluate all uses of each substance. The scope of the assessments went beyond what was foreseen in the directive but it was felt that as much as possible should be done at Community level. This view and approach has changed as a result of experience. More recently, the focus is on a limited range of representative uses when assessing active substances at Community level.

Directive 91/414/EEC allows Member States full control of all authorisations e.g. whether for use of an insecticide on an edible crop, a herbicide along railway tracks and motorways, or as a growth regulator in parks and sports arenas. In allowing any use, Member States have to ensure that users, bystanders, soil, non-target terrestrial and aquatic animals and plants, succeeding crops, water, air, and consumers are protected. In the latter case, MRLs are required and, for new active substances and for substances in its Annex I, the Directive permits Member States to set provisional MRLs pending a notification to EFSA and a later endorsement from the Commission after comitology.

The current proposal takes account of this possibility but modifies the current procedure - recognising that an amendment of Directive 91/414/EEC is also necessary. In addition, the proposal blocks the Member States from setting MRLs in future.

The proposal also recognises the need for coherent timing of decisions on substances in the two sets of legislation. Annex I inclusion decisions under Directive 91/414/EEC often include risk mitigation measures and in any case always oblige Member States to review all existing authorisations in the light of the new agreed 91/414/EEC endpoints and the uniform principles for risk assessment in Annex VI of that Directive. The proposal provides that MRLs would normally be set for active substances after their inclusion in Annex I to the Directive because full assessment reports would then be available (excluded substances would have MRLs set at the LOD after allowing for sell-out or phase-out periods).

[4] Almost no data will be available. A significant number of 'import tolerance' requests is expected.

On a related matter, the proposal also recognises that, under the current legislation, when MRLs are reduced for reasons other than health concerns, then produce on the market could become illegal from one day to the next. This is particularly problematic for produce which has a long shelf-life and the proposal provides for 'phase-in' dates to resolve the problem in cases where there are no health concerns.

Key dates:

The key date for Directive 91/414/EEC is 2003 (withdrawal of about 400 substances from the market). Another key date is 2008 (finalisation of review programme and start of re-evaluations).

The key date for residues legislation is 2004. At this time, decisions have to be made on MRLs for about 400 substances used on crops during 2003 but that in 2004 are no longer on the market. Decisions also have to be made on MRLs for up to 388 substances still on the market but with national MRLs. Since at least one Member State has stated that it would ban, in 2004, all trade in commodities containing residues of the 388 substances, a Community solution before that time would be desirable.

ROLES AND PROCEDURES:

Role of the European Food Safety Authority (EFSA):

EFSA should take on those tasks related to risk assessment of plant protection products under Directive 91/414/EEC and the risk assessment of pesticides residues under the pesticides residues legislation.

Given the fact that EFSA is not yet operational, the approach taken in drafting the current proposal was to ensure that the present work continues and that the transition to EFSA be as smooth as possible. Therefore, the text is as specific as possible about the role of EFSA without always explicitly detailing the exact procedures and timelines under which EFSA should work in this area. Although these details will eventually be necessary, the proposal provides that they can be adopted as implementing measures through comitology at a later stage. The proposal foresees two additional tasks for EFSA.

Firstly, it should be recalled that one of the objectives of pesticide residue monitoring is to assess actual consumer exposure to residues. Since this exposure, coupled to the hazard profile of a substance, is what determines risk, then it is considered proper that this task be handled by the EFSA which will be well-placed to modify the design and requirements of monitoring programmes so as to improve its risk estimates. The task of compiling, analysing and publishing the monitoring data and reports, currently managed by the Commission, is proposed to be transferred to EFSA and this is also considered to be consistent with the risk communication remit of EFSA.

Secondly, risk can only be properly assessed if all the data elements are available. On the exposure side of the risk equation, detailed data on dietary intakes from all sources (all food types - including portion sizes - as well as water and other sources) are required. Therefore, the Regulation proposes that EFSA maintain a database of all uses of plant protection products in the Community to complement a second database on dietary intakes of each type of food among various population subgroups. It will be well-placed to maintain this

information through its complementary activities on the assessment of plant protection products under Council Directive 91/414/EEC and on intakes of other substances in food.

Role of the Commission :

The Commission will be responsible for risk management, by deciding on the setting of MRLs taking into account the opinion of EFSA. This will not be an automatism relying fully on EFSA's judgement. The Commission has its own responsibility will have to verify the risk assessment and the opinion of EFSA. Apart from setting MRLs the Commission shall also make proposals for Monitoring Decisions and publish guidelines for submission of data, methods of sampling etc.

Under what circumstances can and should MRLs be deleted?

Normally MRLs would be deleted (i) where there are no authorised uses or (ii) where there is insufficient data on which to set a MRL, or (c) where there is evidence that a MRL is not safe for the consumer (see also the discussion on default MRLs above). Under all these circumstances, the default MRL of 0.01 mg/kg would apply. However, there may be circumstances where an assessment shows that a MRL of 0.01 mg/kg would not be protective of the consumer. In such cases, a specific, lower MRL could be set.

Under what circumstances can and should MRLs be set?

The proposal foresees two types of MRL - fixed and temporary. Fixed MRLs are foreseen for all existing MRLs in Directives 86/362/EEC, 86/363/EEC and 90/642/EEC - irrespective of their 91/414/EEC inclusion status and of whether the substances are considered as existing or new in the context of Directive 91/414/EEC. These MRLs can actually be modified at any time and all would be reviewed case-by-case after 91/414/EEC inclusion or exclusion decisions. To avoid continuing trade problems in the Single Market, temporary MRLs are foreseen to be created in a one-off exercise for all existing substances for which there is not yet a Community MRL as well as for substances with MRLs in Directive 76/895/EEC. These would be reviewed and either transferred to the 'fixed-MRL' annex after a 91/414/EEC Annex I inclusion decision, or deleted after an exclusion decision. Temporary MRLs would also be set for new active substances prior to a 91/414/EEC Annex I decision where Member States have issued provisional authorisations under that directive. These would also be reviewed, and either transferred to the 'fixed-MRL' annex after an Annex I inclusion decision, or deleted after an exclusion decision

The existing legislation provides for a number of circumstances under which the Commission or the Member States can set MRLs. That number is reduced in this proposal, as is the competence of Member States to set MRLs. Assuming that 'default LOD' approach of the proposal is adopted, then there are five (eventually to be reduced to four) sets of circumstances under which MRLs are required and which are foreseen in the proposal. The five sets of circumstances are, as well as the proposed approaches to deal with them, illustrated graphically on the following pages in the diagrams accompanying the text. They are:

1. New or changed use for a substance (Article 22).

2. Import tolerances (Article 29).

3. One-off creation of an annex of Temporary MRLs (Article 24).

4. Cases of concern (Article 42).

1. New or changed use for a substance:

This is foreseen as the normal or standard procedure for setting MRLs. Where a new or changed use for a substance is developed (Article 22 of proposal), MRLs often need to be modified. Annex I inclusion decisions under Directive 91/414/EEC often include risk mitigation measures and in any case always oblige Member States to review all existing authorisations in the light of the newly-agreed 91/414/EEC endpoints and the uniform principles for risk assessment in Annex VI of that Directive. Hence, many such cases are foreseen. In these cases, a 91/414/EEC dossier and assessment report would be available already and the extra workload for any one individual use would normally be marginal. In addition, due to the withdrawal of so many substances, new extensions of uses of the remaining existing substances should become a very common practice - even before annex I decisions are taken. Since a default LOD will be already in place for a new use, an upwards revision of the MRL would be necessary.

For a changed use of a new or existing substance after Annex I inclusion, the MRL could need changing in either direction. Article 4.1.f of Directive 91/414/EEC already allows Member States to do this nationally but on a provisional basis. This possibility will be removed by the proposed Regulation and the normal procedure will have to be followed. It is anticipated that Member States will object strongly to this but their concerns can be allayed if there are guarantees that such MRLs can be set quickly at Community level.

Where a new use for a new substance is developed in a Member State, this procedure also applies. Most new substances are developed and assessed initially for one or two major crop types and in the first instance are only introduced into one Member State. The 91/414/EEC assessment process takes several years and during this period the substance can be introduced into other Member States with different growing conditions or pest pressures. Articles 4.1.f and 8.1 of Directive 91/414/EEC provide that Member States may issue provisional authorisations and, where appropriate, provisional MRLs (this possibility has to be removed in the amendment of Directive 91/414/EEC). In addition, as experience is gained, extension to other crops is common and even expected. Since a default LOD will be in place, an upwards revision of the MRL would be necessary - in many cases even before Annex I inclusion. In such cases, temporary MRLs would be set pending Annex I decisions under 91/414/EEC.

Currently, where there is no harmonised MRL at Community level, Article 8.2 of Directive 91/414/EEC permits Member States to authorise new or extended uses of existing active substances and to set national MRLs pending the eventual harmonisation of MRLs for the substance at Community level. This proposal will not permit this in future as the national MRLs will be replaced by temporary Community MRLs (see case 3 below). The procedure outlined here would also apply to the modification of temporary Community MRLs.

2. Import tolerances:

There are three cases where 'import tolerances' would be required (Article 29 of proposal).

(a) Where an importer wants to import a commodity containing residues of a substance used in the Community but where the commodity is not produced in the Community e.g. papayas. In this case there would usually be expertise (Rapporteur Member State) and 91/414/EEC data in the Community and the additional workload would be slight-to-moderate.

(b) Where an importer wants to import a commodity treated with a substance no longer or not yet used in the Community. In this case, there would normally not be expertise in the Community and full toxicological and residues data would be required. A significant workload would be expected for each individual evaluation - for which there could be many due to our withdrawal of 461 substances from the market. An exception would be for substances that had been evaluated at Community level and which were withdrawn for reasons of consumer protection e.g. because they were genotoxic. For the small number of cases where this has happened, no import tolerance could be considered.

(c) Where an importer wants to import a commodity treated with a substance in use in the Community but where the foreign GAP gives higher residues than the Community critical GAP. In this case, marginal data specific to the GAP for the crop would be needed since a dossier and Rapporteur Member State would be available. The additional workload would be slight.

3. Temporary MRLs:

Temporary MRLs (Article 24 of proposal) are required for non-harmonised substances that are still in use in the Community as a pre-requisite to applying a default LOD policy for the up to 500 substances that will be withdrawn from the market. Their use is discussed more fully in the main body of the text in the context of the Single Market. It is envisaged that such MRLs be deleted after 91/414/EEC Annex I inclusion decisions are taken and that they be then replaced with fixed MRLs.

This temporary category would include MRLs that have already been set in Directive 76/895/EEC since Member States are allowed to set higher MRLs arnd therefore they are not fully harmonized MRLs. When they were set these MRLs were not always backed up by data meeting the quality standards required today.

4. Cases of concern:

In cases of concern (Article 42 of proposal), where a Member State or other party has new information indicating that an existing MRL may not be safe and needs to be revised downwards (with or without triggering a safeguard clause). For example, new toxicological data may require that the acceptable daily intake (ADI) or the acute reference dose (ARfD) be revised downwards or new dietary information may become available indicating that people are eating more of a certain commodity than was estimated during the intake assessment. As a temporary risk management measure, the MRL could be reduced downwards pending an assessment of the data and a final decision on a new MRL.

2003/0052 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on maximum residue levels of pesticides in products of plant and animal origin

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular the third subparagraph of Article 37(2), Article 95(1) and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the European Economic and Social Committee[2],

Having regard to the opinion of the Committee of the Regions[3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[4],

Whereas:

(1) Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables[5], Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals[6], Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin[7], and Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on products of plant origin, including fruit and vegetables[8], have been substantially amended several times. In the interests of clarity and simplicity, those Directives should be repealed and replaced by a single act.

(2) This Regulation directly concerns public health and is relevant to the functioning of the internal market. It covers products which are included in Annex I to the Treaty as

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1 OJ C , , p. .
2 OJ C , , p. .
3 OJ C , , p. .
4 OJ C , , p. .
5 OJ L 340, 9.12.1976, p. 26. Directive as last amended by Commission Directive 2002/79/EC, OJ L 291, 28.10.2002, p. 1
6 OJ L 221, 7.8.1986, p. 37. Directive as last amended by Commission Directive 2002/97/EC, OJ L 343, 18.12.2002, p. 23
7 OJ L 221, 7.8.1986, p. 43. Directive as last amended by Commission Directive 2002/97/EC, OJ L 343, 18.12.2002, p. 23
8 OJ L 350, 14.12.1990, p. 71. Directive as last amended by Commission Directive 2002/100/EC, OJ L 2, 7.1.2003, p. 33

well as products which are not. Consequently, it is appropriate to choose the third subparagraph of Article 37(2), Article 95(1) and Article 152(4)(b) as the legal basis.

(3) Differences in national maximum residue levels for pesticides can pose barriers to trade between Member States and trade between third countries and the Community. Accordingly, in the interest of free movement of goods, equal competition conditions among the Member States, as well as consumer protection, it is appropriate that maximum residue levels (MRLs) for products of plant and animal origin be set at Community level.

(4) A regulation establishing MRLs does not require transposition into national law in the Member States. It is therefore the most appropriate legal instrument to set MRLs for pesticides in products of plant and animal origin, as its precise requirements should be applied at the same time and in the same manner throughout the Community and accordingly permit a more efficient use of national resources.

(5) The production and consumption of plant and animal products play a very important role in the Community. The yield from plant production is continually being affected by harmful organisms. It is essential to protect plants and plant products against such organisms, not only to prevent a reduction in yield or damage to them but also in order to ensure the quality of the products harvested, to increase agricultural productivity, and to protect the natural environment by limiting the surface area needed for agricultural production.

(6) One of the most important methods of protecting plants and plant products from the effects of harmful organisms is the use of active substances in plant protection products. However, a possible consequence of their use may be the presence of residues in the treated commodities, in animals feeding on those commodities and in honey produced by bees exposed to them. It is necessary to ensure that such residues should not be present at levels presenting an unacceptable risk to human or animal health.

(7) A number of active substances are banned under Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances[9]. At the same time, many other active substances are not currently authorised under Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[10]. The residues of active substances in products of plant and animal origin arising from unauthorised use or from environmental contamination or from use in third countries should be carefully controlled and monitored.

(8) The basic rules with regard to feed and food law are laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety[11].

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9 OJ L 33, 8.2.1979, p. 36. Directive as last amended by the Act of Accession of Austria, Finland and Sweden.

10 OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2003/5/EC (OJ L 8, 14.1.2003, p. 7).

11 OJ L 31, 1.2.2002, p. 1.

(9) In addition to those basic rules, more specific rules are needed to ensure the effective functioning of the internal market and trade with third countries in relation to fresh, processed and composite plant and animal products intended for human consumption or animal feed on which pesticide residues may be present, whilst providing the basis for securing a high level of protection for human and animal health and the interests of consumers. Such rules should include the specification of MRLs for each pesticide on all food and feed products and the quality of the data underlying these MRLs.

(10) Specific rules for animal feed including marketing, storage of feed and feeding of animals are provided for in Directive 2002/32 of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed[12]. For certain products it is not possible to determine whether they will be transformed into food or animal feed. Therefore the Pesticide Residues on such products should be safe both for human and animal consumption. Accordingly it is appropriate that the rules set out in this Regulation also apply to those products in addition to the specific rules for animal nutrition.

(11) The basic rules with regard to official control of food and feed controls are laid down in Regulation (EC) No XXX/2003 of the European Parliament and of the Council of xx. 2003[13]. It is appropriate that specific rules concerning monitoring and control of pesticide residues be introduced.

(12) Council Directive 91/414/EEC provides basic rules with respect to the use and placing on the market of plant protection products. In particular the use of those products should have no harmful effects on human or animal health. Pesticide residues resulting from uses of plant protection products may have harmful effects on the health of consumers. It is therefore appropriate that rules for the M R Ls on the products intended for human consumption are defined that are linked to the authorisation for use of the pesticides as defined in the framework of Council Directive 91/414/EEC.

(13) Directive 91/414/EEC provides that Member States, when issuing authorisations, are to prescribe that plant protection products be used properly. Proper use includes the application of the principles of good plant protection practice as well as the principles of integrated control so that whenever possible and practicable, the use and the choice of pesticides does not interfere with the use of biological control methods. The MRLs should be set as low as is consistent with such biological control methods. Where the MRLs arising from an authorised use of a pesticide under Directive 91/414/EEC present a risk to the consumer such use should be revised to decrease the levels of pesticide residues. The Community should encourage the use of methods or products favouring a reduction in risk, and a reduction in the amounts of pesticides used to levels consistent with efficient pest control.

(14) It is necessary to define at Community level certain terms used for the setting, monitoring and control of MRLs in and on products of plant and animal origin.

(15) Directive 76/895/EEC provides for the possibility for the Member States to authorise higher levels of MRLs than are currently authorised at Community level. That possibility should cease to exist as, in view of the internal market, it could create obstacles to intra-Community trade.

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12 OJ L140, 30.5.2002, p.10

13 OJ LXXX, XX.YY.2002, p. Z – proposal submitted to Council (COM (2003) 52 final)

(16) The determination of MRLs for pesticides requires lengthy technical consideration and includes an assessment of potential risks to consumers. Therefore, MRLs cannot be set immediately for the residues of pesticides currently regulated by Directive 76/895/EEC or for pesticides for which Community levels have not yet been set.

(17) It is appropriate that the minimum data requirements to be used when considering the setting of MRLs for pesticides be laid down at Community level.

(18) In exceptional circumstances, for unauthorised pesticides that may be present in the environment as contaminants, it is appropriate to permit the use of monitoring data in setting MRLs for pesticides.

(19) MRLs for pesticides should be continually monitored and should be changed to take account of new information and data. MRLs should be set at the lower level of analytical determination where authorised uses of plant protection products do not result in detectable levels of pesticide residues. Where uses of pesticides are not authorised at Community level, MRLs should be set at an appropriate low level to protect the consumer from the intake of unauthorised or excess levels of pesticides residues. That level is conventionally set at 0.01 mg/kg although in the exceptional cases where such a level does not guarantee consumer protection, lower levels should be set.

(20) For feed and food produced outside the Community, different agricultural practices as regards the use of plant protection products may be legally applied, resulting in pesticide residues differing from those resulting from uses legally applied in the Community. It is therefore appropriate that MRLs are fixed for imported products that take these uses and the resulting residues into account provided that the safety of the products can be demonstrated using the same criteria as for domestic produce.

(21) Regulation (EC) No 178/2002 of the European Parliament and of the Council establishes procedures for taking emergency measures in relation to food of Community origin or imported from a third country. Those procedures allow the Commission to adopt such measures in situations where food is likely to constitute a serious risk to human health, animal health or the environment and where such risk cannot be contained satisfactorily by measures taken by the Member State(s) concerned. It is appropriate that these measures and their effect on human and animal health are evaluated by the European Food Safety Authority without delay.

(22) The lifetime exposure, and where appropriate the acute exposure of consumers to pesticide residues via food products should be assessed and evaluated in accordance with Community procedures and practices, taking account of guidelines published by the World Health Organisation.

(23) Through the World Trade Organisation, the Community's trading partners should be consulted about the MRLs proposed, and their observations should be taken into account, before the MRLs are adopted. MRLs set at the international level by the Codex Alimentarius Commission should also be considered when Community MRLs are being set.

(24) The European Food Safety Authority established by Regulation (EC) No 178/2002, has a key role to play in the assessment of risks to the consumer and should be involved in the scientific evaluation of applications to set MRLs and in the assessment of risks to consumers from pesticide residues.

(25) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.

(26) The development of a Community harmonised system for MRLs entails the development of guidelines, databases and other activities with costs associated. It is appropriate for the Community in certain cases to make a contribution to those costs.

(27) It is good administrative practice and is technically desirable to co-ordinate the timing of decisions on MRLs for active substances with decisions taken for those substances under Directive 91/414/EEC. For many substances for which Community MRLs have not yet been set, decisions are not due to be taken under that Directive before the date of entry into force of this Regulation.

(28) It is therefore necessary to adopt separate rules providing for temporary but mandatory MRLs, with a view to setting MRLs progressively as decisions are taken on individual active substances in the framework of the evaluations under Directive 91/414/EEC.

(29) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[14],

(30) In accordance with the principal of proportionality, it is necessary and appropriate for the achievement of the basic objectives of facilitating trade whilst protecting the consumer to lay down rules on MRLs in products of plant and animal origin. This Regulation does not go beyond what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 5 of the Treaty,

HAVE ADOPTED THIS REGULATION:

Chapter I
Subject matter, scope and definitions

Article 1
Subject matter

This Regulation shall apply to fresh, processed and composite plant and animal products or parts thereof listed in Annex I, intended for human consumption or animal feed on which pesticide residues may be present due to:

(a) the use of plant protection products falling within the scope of Directive 91/414/EEC;

(b) plant protection products applied outside the Community; or

(c) environmental contamination by substances formerly used as plant protection products.

[14] OJ L 184, 17.7.1999, p. 23.

This Regulation shall be subject to the rules on food and feed provided for by Regulation (EC) No 178/2002.

Article 2
Scope

1. This Regulation shall apply without prejudice to Council Directive 2002/32/EC

2. This Regulation shall not apply to the products referred to in Article 1 where it may be established by appropriate evidence that they are intended for:

   (a) the manufacture of products other than food intended for human consumption or animal feed; or

   (b) sowing or planting.

3. Maximum residue levels for pesticides set in accordance with this Regulation shall not apply in the case of products referred to in Article 1 intended for export to third countries and treated before export, where it may be established by appropriate evidence that the third country of destination requires or agrees with that particular treatment in order to prevent the introduction of harmful organisms into its territory.

Article 3
Definitions

For the purpose of this Regulation, the definitions in Regulation (EC) No 178/2002 shall apply.

The following definitions shall also apply:

(1) 'pesticide residues': means residues of plant protection products as defined in Article 2(2) of Directive 91/414/EEC which are present in or on the products referred to in Article 1 of this Regulation and which may arise as a result of use in plant protection, in veterinary medicine and as a biocide;

(2) 'Maximum Residue Level' (MRL): means the upper legal level of concentration for a pesticide residue, in excess of which measures are to be taken to withdraw a product from the market;

(3) 'Limit of Determination' (LOD): means the lowest level achieved and reported by routine monitoring with validated methods in accredited laboratories as defined in Regulation (EC) No XXX/2003[13];

(4) 'good agricultural practice' (GAP): means the nationally recommended, authorised or registered safe use of pesticides under actual conditions at any stage of production, storage, transport, distribution and processing of food commodities and animal feed necessary for effective and reliable pest control;

(5) 'import tolerance': means a MRL based on a Codex Alimentarius Commission MRL or on a GAP implemented in a third country for the legal use of an active substance in that third country where:

(a) the use of the active substance in a plant protection product on a commodity is not authorised in the Community; or

(b) an existing MRL is not sufficient to meet the needs of international trade;

(6) 'proficiency test': means a comparative test in which several laboratories perform analyses on identical samples, allowing an evaluation of the quality of the analysis by each laboratory;

(7) 'acute reference dose: means the estimate of the amount of substance in food or drinking-water expressed on a body weight basis, that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer on the basis of all known facts at the time of evaluation;

(8) 'acceptable daily intake': means the estimate of the amount of substance in food or drinking-water expressed on a body weight basis, that can be ingested daily over a life time, without appreciable health risk to the consumer on the basis of all known facts at the time of evaluation;

(9) 'composite food stuffs': means food containing a mixture of ingredients.

Chapter II
Community procedure for applications for MRLs

SECTION 1
SUBMISSION OF APPLICATIONS FOR MRLS

Article 4
Applicants for MRLs

An application to set, modify or delete an MRL may be made by:

(a) a Member State authorising the use of a plant protection product on its territory;

(b) interested parties, including manufacturers, growers, importers and producers of products referred to in Article 1;

(c) any party identifying an appropriate and scientifically substantiated possible concern for human or animal health due to the intake of pesticide residues.

Article 5
Applications to be submitted to the European Food Safety Authority

1. The application to set, modify or delete an MRL shall be submitted for an opinion to the European Food Safety Authority established by Regulation (EC) No 178/2002 (hereinafter referred to as "the Authority").

2. The Authority shall acknowledge in writing receipt of the application to the applicant without delay. The acknowledgement shall state the date of receipt of the application.

3. The Authority shall notify the Commission of the application.

Article 6
Requirements relating to applications for MRLs

1. The application to set, modify or delete an MRL shall be accompanied by the following information:

(a) the name and address of the applicant;

(b) a presentation of the application dossier including:

(i) a summary of the application;

(ii) the main substantive arguments;

(iii) an index of the documentation;

(c) where appropriate, scientifically substantiated reasons for concern.

(d) the data listed in Annexes II and III to Directive 91/414/EEC relating to data requirements for the setting of MRLs for pesticide residues, including, where appropriate, toxicological data as well as plant and animal metabolism data.

However, where an active substance has already been authorised for use in the Community under Directive 91/414/EEC or where a Codex Alimentarius Commission MRL exists, the Authority may consider that the applicant may be exempted from the submission of certain requirements for data, particularly as regards the toxicology. In such cases, the reasoned opinion of the Authority as referred to Article 9 shall include a justification for any such waivers granted.

2. The Authority may, where appropriate, request the applicant to provide supplementary information in addition to information required under paragraph 1 within a time limit specified by the Authority which in no event shall exceed six months.

Article 7
Guidelines relating to submission of data

The data as referred to in Article 6(1)(d) shall comply with the guidelines set out in Annex VI.

The Authority shall regularly make proposals for updating those guidelines to take account of scientific and technical progress.

SECTION 2
CONSIDERATION OF APPLICATIONS CONCERNING MRLS BY THE AUTHORITY

Article 8
Receipt of application concerning MRLs by the Authority

Upon receipt of an application to set, modify or delete an MRL, the Authority shall:

(a) verify that the application complies with Article 6;

(b) inform the applicant, the Commission and the Member States where an application does not comply with Article 6;

(c) make available to the Member States and the Commission a summary of each application, and, at the request of a Member State or the Commission, transmit the application dossier and any supplementary information supplied by the applicant.

Article 9
The Authority's opinion on applications concerning MRLs

1. The Authority shall give a reasoned opinion on applications complying with Article 6, on the setting, modification or deletion of an MRL. That opinion shall include:

   (a) an assessment on whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;

   (b) the anticipated LOD for the pesticide commodity combination;

   (c) an assessment of the risks of the acceptable daily intake or acute reference dose being exceeded as a result of the modification of the MRL; the contribution to the total intake due to the residues on the commodity for which the MRLs was requested.

2. The Authority shall forward its reasoned opinion to the applicant, the Commission, and the Member States.

3. Without prejudice to Article 39 of Regulation (EC) No 178/2002, the Authority shall make its reasoned opinion public.

Article 10
Time limits for the Authority's opinion on applications concerning MRLs

1. The Authority shall give its reasoned opinion as provided for in Article 9(1) within the following time limits from the date of receipt of the application :

   (a) three months where the toxicology of the active substance has already been evaluated at Community level;

   (b) twelve months where the toxicology of the active substance has not been evaluated at Community level.

2. Where the Authority requests supplementary information as provided for in Article 6(2), the time limits laid down in paragraph 1 are suspended until that information has been provided.

SECTION 3
SETTING, MODIFYING OR DELETION RELATED TO APPLICATIONS FOR MRLS

Article 11
Decisions on applications concerning MRLs

Upon receipt of a reasoned opinion of the Authority as provided for in Article 9(1), a reasoned decision shall be adopted on the setting, modification or deletion of an MRL, in accordance with the procedure referred to in Article 49 (2).

The decision shall take into account the opinion of the Authority.

The Commission may request at any time that supplementary information be provided by the applicant.

Article 12
Opinion of the Authority not required

Where amending Annexes II or III, in order to delete or to reduce to 0.01 mg/kg an MRL following the revocation of an existing authorisation for a plant protection product under Directive 91/414/EC.an opinion of the Authority shall not be required.

Chapter III
MRLs applicable to products of plant and animal origin and active substances

Article 13
Compliance with maximum residue levels

1. The products referred to in Article 1 shall not contain, from the time they are placed on the market any pesticide residue exceeding:

   (a) the MRLs for those products set out in Annexes II and III;

   (b) 0.01 mg/kg for active substances not listed in Annex IV for those products for which no specific MRL is set out in Annexes II or III;

2. Member States may not prohibit or impede the placing on the market within their territories of the products referred to in Article 1 on the grounds that they contain pesticide residues provided that:

   (a) the concentration of the pesticide residues does not exceed the appropriate MRLs set out in Annexes II or III; or

(b) the active substance is listed in Annex IV.

Article 14
Prohibited uses of processed and composite products

In the case of processed and composite products as referred to in Article 1, the following shall be prohibited:

(a) to dilute products not complying with the MRLs set out in Annexes II or III so as to reduce the pesticide residue levels below those MRLs ;

(b) to mix products which are to be subjected to a sorting technique or physical treatment with products intended for direct human consumption or as an ingredient in food or feed;

(c) to use products not complying with the MRLs set out in Annexes II or III as ingredients in the manufacture of other food or feed;

(d) to detoxify those products by chemical treatments.

Article 15
MRLs applicable to dried and other processed products

1. Where MRLs are not set out in Annexes II or III for dried and other processed products referred to in Article 1, the MRLs applicable shall be those set out in Annexes II or III for the appropriate commodity referred to in Annex I, taking into account:

(a) changes in the levels of pesticide residues caused by the drying process; or

(b) changes in the levels of pesticide residues caused by processing.

2. Specific concentration or dilution factors for certain drying or other processing operations or for certain dried or otherwise processed products may be included in the list in Annex V in accordance with the procedure referred to in Article 49(2).

Article 16
MRLs applicable to composite food and feed

The MRL to be applied to composite food and feed shall correspond to the MRLs of their ingredients as set out in Annexes II or III taking into account the relative concentrations of the ingredients in their composition and the provisions of Articles 13, 14 and 15.

Chapter IV
Establishing lists of commodities, MRLs and active substances

SECTION 1
PROCEDURE FOR THE ESTABLISHMENT OF LISTS OF GROUPS OF COMMODITIES, MRLS, ACTIVE SUBSTANCES AND ASSESSMENT OF MRLS

Article 17
Establishment of lists of groups of commodities of plant and animal origin

Lists of groups of commodities of plant and animal origin with examples of products in those groups and the parts of those products to which MRLs apply, to be set out in Annex I shall be established in accordance with the procedure referred to in Article 49(2). Those lists shall include animal feed as referred to in Article 1. Annex I shall include all commodities for which MRLs are explicitly set, grouped in such a way that MRLs may be set for a group of similar or related commodities.

Article 18
Establishment of lists of MRLs

The lists of MRLs for products of plant and animal origin to be set out in Annex II shall be established in accordance with the procedure referred to in Article 49(2), taking into account:

(a) the scientific and technical knowledge available;

(b) the possible presence of pesticide residues arising from other uses of active substances;

(c) the results of an assessment of any potential risks to the consumer and, where appropriate, to animal health;

(d) the results of any evaluations undertaken in accordance with Directive 91/414/EEC;

(e) modifications to the uses of products containing active substances that have arisen as a result of decisions under Directive 91/414/EEC;

(f) the following MRLs:

(i) MRLs provided for under Directives 86/362/EEC, 86/363/EEC and 90/642/EEC;

(ii) MRLs set by the Codex Alimentarius Commission;

(iii) Maximum residues limits (MRLs) listed in annexes I, II and III of Council Regulation (EEC) No 2377/90[15]

Article 19
Establishment of a list of temporary MRLs

The lists of temporary MRLs for active substances for which a decision on inclusion or non-inclusion in Annex I to Directive 91/414/EC has not yet been taken, shall be established in accordance with the procedure referred to in Article 49(2), taking into account the information provided by the Member States and the matters referred to in points (a)(b) and (c) of Article 18.

Such temporary MRLs shall include:

(a) remaining MRLs in the Annex to Directive 76/895/EEC;

(b) hitherto unharmonised national MRLs, as referred to in Article 24; and

(c) MRLs set according to the simplified procedure referred to in Article 27, to be set out in Annex III.

Article 20
Establishment of a list of active substances for which no MRLs are required

The list of active substances of plant protection products, evaluated under Directive 91/414/EEC and for which it is agreed by the Committee referred to in Article 49(1) that MRLs are not required , to be set out in Annex IV shall be established in accordance with the procedure referred to in Article 49(2), taking into account the uses of those active substances and the matters referred to in points (a) and (c) of Article 18.

Article 21
Assessment of existing MRLs by the Authority

The Authority shall, within a period of 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC, submit a reasoned opinion to the Commission and the Member States on that active substance and on:

(a) existing MRLs for that active substance set out in Annex II or III to this Regulation;

(b) the necessity of setting new MRLs for that active substance;

(c) specific drying and processing factors for that active substance that may be included in Annex V;

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[15] OJ L 224, 18.8.1990, p.1 - Council Regulation (EEC) N° 2377/90 of the 26 June 1990 laying down a Community procedure for establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin as last amended by Commission Regulation (EEC) N °61/2003, OJ L 11, 16.1.2003, p.12

(d) MRLs which the Commission may consider including in Annex II and on those MRLs which may be deleted or reduced to 0.01 mg/kg, related to that active substance.

SECTION 2
MRLS AND APPLICATIONS FOR AUTHORISATION OF PLANT PRODUCTION PRODUCTS UNDER DIRECTIVE 91/414/EEC

Article 22
MRLs corresponding to applications for authorisation and provisional authorisation of plant protection products under Directive 91/414/EEC

Where a Member State, in accordance with Directive 91/414/EEC, receives an application to grant an authorisation or a provisional authorisation for the use of a plant protection product, the Member State shall consider whether as a result of such use, an existing MRL set out in Annex II or III to this Regulation needs to be modified or whether it is necessary to set a new MRL.

Where a Member State considers that the setting, modification or deletion of an MRL is necessary, that Member State shall submit an application for setting, modifying or deleting the MRL under Chapter II of this Regulation.

Article 23
Inclusion of new or modified MRLs in Annexes II and III

1. Where a new or modified MRL is set following an application by a Member State as provided for in Article 22, the new or modified MRL shall be listed:

(a) in Annex II to this Regulation where the substance has been included in Annex I to Directive 91/414/EEC; or

(b) in other cases, as a temporary MRL, in Annex III to this Regulation.

2. Where a temporary MRL is included in Annex III to this Regulation as provided for in paragraph 1(b), it shall not be maintained in that Annex for a period exceeding one year from the date of the inclusion or non-inclusion in Annex I to Directive 91/414/EEC of the active substance concerned.

SECTION 3
SETTING TEMPORARY MRLS

Article 24
Information to be provided by the Member States on national MRLs

Where for an active substance of a plant protection product, not yet included in Annex I to Directive 91/414/EEC:

(a) an MRL is not set out in Annex II to this Regulation for a certain commodity set out in Annex I to this Regulation and

(b) a Member State has set, by 30 June 2004 at the latest, a national MRL for an active substance on the commodity referred to in (a), based on the use of a plant protection product on its territory

the Member State concerned as referred to under (b) shall notify the Commission and the Authority, in a format and by a date to be established in accordance with the procedure referred to in Article 49(2) of the following:

(c) the national MRL referred to under (b);

(d) the GAP;

(e) data on supervised trials;

(f) the acceptable daily intake and, if relevant, the acute reference dose used for the national risk assessment, as well as the outcome of the assessment.

Article 25
Opinion of the Authority on data underlying national MRLs

1. The Authority shall compile lists of the national MRLs notified in accordance with Article 24and use them as a basis to provide a reasoned opinion to the Commission on:

(a) a list of temporary MRLs that may be included in Annex III;

(b) a list of active substances that may be included in Annex IV.

2. In preparing the opinion referred to in paragraph 1, the Authority shall take into account:

(a) the following MRLs:

(i) MRLs set out in Annex II to Directive 76/895/EEC;

(ii) national MRLs set by Member States by 30 June 2004 at the latest, as referred to in Article 24;

(iii) MRLs adopted by the Codex Alimentarius Commission;

(b) MRLs listed in Annexes I, II and III of Regulation (EEC) N° 2377/90[15];

(c) the scientific and technical knowledge available, and in particular data submitted by the Member States on:

(i) the toxicological assessment, including potential excess of the acceptable daily intake and, if applicable, of the acute reference dose;

(ii) the GAP;

(iii) the data on supervised trials used by Member States to establish the national MRL.

Article 26
Setting of temporary MRLs

Taking into account the opinion of the Authority, and in accordance with the procedure referred to in Article 49(2), temporary MRLs for the active substances referred to in Article 24 may be included in Annex III, or, as appropriate the active substance may be included in Annex IV.

Article 27
Simplified procedure for setting temporary MRLs in certain circumstances

1. Temporary MRLs may be included in Annex III in accordance with the procedure referred to in Article 49(2) in the following circumstances:

(a) in exceptional cases, in particular where pesticide residues may arise as a result of environmental or other contamination;

(b) where the products concerned constitute a very minor component of the diet of European consumers or

(c) where the products concerned constitute a minor component of international trade.

2. The inclusion of temporary MRLs as referred to in paragraph 1, shall take into account the opinion of the Authority, monitoring data and an assessment demonstrating that there are no unacceptable risks to consumers or animals.

The continued validity of those temporary MRLs shall be re-assessed at least once every 10 years and any such MRLs shall be modified or deleted from Annex III as appropriate.

SECTION 4
HONEY

Article 28
Setting MRLs for pesticide residues in honey

MRLs may be set for pesticide residues in honey, as defined in Annex I of Council Directive 2001/110/EC[16], and included in Annex III of this Regulation on the basis of monitoring data and taking into account a reasoned opinion of the Authority, in accordance with the procedure referred to in Article 49(2).

The continued validity of those MRLs shall be re-assessed at least once every 10 years and any such MRLs shall be modified or deleted from Annex III, as appropriate.

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16 OJ L 10, 12.1.2002, p. 47.

SECTION 5
IMPORT TOLERANCES

Article 29
Setting import tolerances

Applications for import tolerances may be made by the Member States or the parties referred to in points (b) and (c) of Article 4 and shall be made in accordance with the provisions of Chapter II.

SECTION 6
INFORMATION TO BE SUBMITTED BY MEMBER STATES AND DATABASE

Article 30
Information to be submitted by the Member States

Member States shall submit to the Authority details of the GAPs and any dietary intake information necessary for the assessment of the safety of an MRL.

Article 31
Database of the Authority on MRLs

Without prejudice to the applicable provisions of Community and national law on access to documents, the Authority shall develop and maintain a database, accessible to the Commission and to the competent authorities of the Member States, containing the relevant scientific information and GAPs relating to the MRLs, the active substances and the processing factors set out in Annexes II, III, IV and V. In particular it shall contain dietary intake assessments, processing factors and toxicological endpoints.

Chapter V
Official controls, monitoring, fees, reports and penalties

SECTION 1
OFFICIAL CONTROLS AND MONITORING OF MRLS AND ACTIVE SUBSTANCES

Article 32
Official controls, monitoring and fees

1. Member States shall carry out official controls on pesticide residues in order to enforce compliance with this Regulation, in accordance with the provisions of Regulation (EC) No XXX/2003 of the European Parliament and of the Council [13].

The official controls on pesticide residues shall consist of sampling at the point of supply and subsequent chemical analysis of the samples and identification of the pesticides in the samples. The point chosen should allow for potential enforcement action.

2. Member States shall carry out monitoring on pesticide residues in particular, at the point of supply to the consumer. Such monitoring shall be in addition to any similar monitoring required under Council Directive 96/23/EC[17].

3. Member States shall establish fees to cover the costs of the official controls referred to in paragraph 1 in accordance with the principles established under Regulation (EC) No XXX/2003[13].

Article 33
Sampling

1. Each Member State shall take samples in a sufficient number and across a range of products and geographical areas to assure that the results are representative of their market, reflecting as appropriate, the respective contributions of national, Community and third country produce to its market.

2. The sampling methods necessary for carrying out such monitoring of products, other than those provided for in Commission Directive 2002/63/EC[18], shall be determined in accordance with the procedure referred to in Article 49(2).

Article 34
Methods of Analysis

1. Detailed rules on methods of analysis for pesticide residues including specific validation criteria and quality control procedures may be adopted and set out in Annex VII in accordance with the procedure referred to in Article 49(2).

2. The methods of analysis of pesticide residues shall comply with the criteria set out in Annex II to Regulation (EC) No 2003[13]/XXX.

3. All laboratories analysing samples for the official controls and monitoring on pesticide residues shall participate in the Community Proficiency Test.

SECTION 2
NATIONAL CONTROL AND MONITORING PROGRAMMES

Article 35
The obligations of Member States relating to national control and monitoring programmes for pesticide residues

1. Member States shall establish annually national control and monitoring programmes for pesticide residues for the following calendar year.

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17 OJ L 125, 23.5.1996, p. 10.
18 OJ L 187, 16.7.2002, p. 30.

Those annual national control and monitoring programmes shall comply with Article 43 of Regulation (EC) No XXX/2003[13] on multi-annual control plans for pesticide residues.

Those programmes shall specify at least the following:

(a) the products to be sampled;

(b) the number of samples to be taken and analyses to be carried out;

(c) the pesticide residues to be analysed;

(d) the criteria applied in drawing up such programmes, including:

(i) the pesticide-product combinations to be selected;

(ii) the number of samples to be taken in relation to the domestic production; and

(iii) consumption of the products.

2. Member States shall submit their annual national control and monitoring programmes for pesticide residues, to the Commission and to the Authority by 31 December each year.

3. Member States shall participate in the Community Monitoring Programme as provided for in Article 36.

SECTION 3
COMMUNITY MONITORING PROGRAMME

Article 36
Community Monitoring Programme

1. The Commission and the Authority shall prepare a co-ordinated Community monitoring programme, identifying specific samples to be included in the national control and monitoring programmes, and taking into account problems that have been identified regarding compliance with the MRLs set out in this Regulation.

2. The Authority shall submit to the Commission by 1 May each year, an opinion concerning the co-ordinated Community monitoring programme for the following calendar year, including its opinion on the specific samples which shall be included in the national control and monitoring programmes.

3. The Community monitoring programme shall be adopted in accordance with the procedure referred to in Article 49(2), and shall be presented to the Committee referred to in Article 49(1), by 1 July each year for the following calendar year .

SECTION 4
INFORMATION BY THE MEMBER STATES AND COMMUNITY ANNUAL REPORT

Article 37
Information by the Member States

In addition to the information to be submitted by the Member States to the Authority and the Commission in the annual reports provided for in Article 44 of Regulation (EC) No XXX/2003[13], Member States shall submit the following information to the Commission, the Authority and the other Member States by 31 December each year:

(a) the results of the official controls and monitoring as provided for in Article 32(1) and (2);

(b) the results of the analyses of the samples taken during the current year for pesticide residues in products of plant origin under their national control and monitoring programmes as referred to in Article 35 and under the Community monitoring programme as referred to in Article 36;

(c) the LODs applied in the national control and monitoring programme as referred to in Article 35 and under the Community monitoring programme as referred to in Article 36;

(d) details of the participation of the analytical laboratories in the Community proficiency tests and other proficiency tests relevant to the pesticide-product combinations sampled in the national control and monitoring programme;

(e) details of the accreditation of the analytical laboratories as provided for in Regulation (EC) No XXX/2003[13].

Article 38
Format for the submission of information to the Authority

1. The Authority may designate a format for the submission of information to be submitted by the Member States as provided for in Article 37.

2. The Authority shall collate and combine the information referred to in Article 37.

Article 39
The Community Annual Report

1. The Authority shall complete a Community Annual Report.

2. The Authority shall include information on the following in the Community Annual Report:

(a) an analysis of any possible significance of discrepancies in the results of the monitoring provided for in Article 32 (2);

(b) a report to the Commission on the the MRLs that were exceeded, together with any appropriate observations regarding the need to modify such MRLs, in relation to the underlying GAPs;

(c) a report on any acute or chronic risks to the health of consumers.

3. Where a Member State has not provided complete information by 31 December in accordance with Article 37, the Authority may disregard the information from that Member State when compiling the Community Annual Report.

4. The Authority shall submit the Community Annual Report to the Commission by 30 April of the following year.

5. The Commission may designate a format for the submission of the Community Annual Report by the Authority.

6. The Authority shall publish the Community Annual Report.

Article 40
Submission of the Community Annual Report to the Committee

The Commission shall submit the Community Annual Report to the Committee referred to in Article 49(1) before 31 January each year, for review and recommendations on any necessary measures to be taken regarding reported possible infringements of the MRLs set out in Annexes II and III.

SECTION 5
PENALTIES

Article 41
Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions and any subsequent amendment to the Commission without delay.

Chapter VI
Emergency measures

Article 42
Emergency measures and opinion by the Authority

1. Articles 53 and 54 of Regulation (EC) 178/2002 shall apply where as a result of new information or of a reassessment of existing information, pesticide residues or MRLs covered by this Regulation may endanger human or animal health requiring immediate action.

2. The Commission shall notify without delay the Authority of any emergency measures taken.

3. The Authority shall complete a full assessment of the risks and shall provide its opinion to the Commission on those risks within 15 days of the date of notification by the Commission.

Chapter VII
Community harmonised system on MRLs

Article 43
Harmonised system on MRLs for pesticide residues

A harmonised system for MRLs in the field of pesticide residues shall be established at Community level, including:

(a) a database for Community legislation on MRLs of pesticide residues and for making such information publicly available;

(b) Community proficiency tests as referred to in Article 34 (3) and 37(d);

(c) studies necessary for the preparation of legislation on pesticide residues;

(d) studies necessary for the estimation of the exposure of consumers and animals to pesticides residues.

Article 44
Community contribution to the harmonised system on MRLs for pesticide residues

The Community may make a financial contribution up to 100% of the cost of the harmonised system as provided for in Article 43.

The appropriations for that system shall be decided each year as part of the budgetary procedure.

Chapter VIII
Co-ordination of applications for MRLs

Article 45
Designation of national authorities

Each Member State shall designate an authority to co-ordinate co-operation with the Commission, the Authority, other Member States, manufacturers, producers, and growers for the purposes of this Regulation.

Each Member State shall inform the Commission and the Authority of the name and address of the designated authority.

Article 46
Co-ordination by the Authority of applications for MRLs

The Authority shall:

(a) co-ordinate with the rapporteur Member State designated in accordance with Directive 91/414/EEC for an active substance;

(b) co-ordinate with applicants referred to in Article 4 and the Member States and the Commission regarding applications on MRLs and import tolerances covered by this Regulation;

(c) ensure all necessary contacts with interested parties as referred to in Article 4(b);

(d) complete the scientific evaluations of dossiers and applications for the inclusion of MRLs in the lists in Annexes II and III.

Article 47
Rapporteur Member State and fees for applications for MRLs

1. Rapporteur Member States may establish a regime containing an obligation for applicants to pay a fee for the administrative costs for the evaluation of their applications.

2. The Rapporteur Member States shall ensure that the fee referred to in paragraph 1:

(a) is established in a transparent manner;

(b) corresponds to the real cost of the examination and administrative treatment of the applications;

(c) is received by the designated authority in the Rapporteur Member State as provided for in Article 45;

(d) is used to finance exclusively the costs actually incurred for the evaluation and administrative treatment of the application.

However, a scale of fixed charges based on average costs for the treatment of applications referred to in paragraph 1, may be established by Rapporteur Member States.

Chapter IX
Implementation

Article 48
Scientific opinion of the Authority

The Commission may consult the Authority for a scientific opinion on any measure related to the assessment of risks in the framework of the implementation of this Regulation. The Commission may specify the time limit within which such an opinion shall be provided.

Article 49
Committee Procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, instituted by Article 58 of Regulation No 178/2002 (hereinafter referred to as "the Committee".)

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof .

The period laid down in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 50
Implementing measures

In accordance with the procedure referred to in Article 49 (2) the following shall be established or may be amended:

(a) implementing measures to ensure the uniform application of this Regulation;

(b) the dates in Article 24(1)(b), Article 25(2)(a)(ii), Article 35(2), Article 36(2) and (3), Article 37, Article 39(3) and Article 40

(c) Annexes I to VII, as a result of developments in scientific or technical knowledge;

(d) technical guidance documents to assist in the application of this Regulation ;

(e) methods for analysis and assessment;

(f) quality control procedures;

(g) detailed rules concerning the scientific data required for the setting of MRLs; the opinion of the Authority shall be taken into account when adopting such rules.

Article 51
Report on implementation of this Regulation

Not later than 10 years after the entry into force of this Regulation, the Commission shall forward to the European Parliament and to the Council a report on its implementation and any appropriate proposals.

Chapter X
Final Provisions

Article 52
Repeal

Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC are repealed with effect from 1 January 2005.

References to the repealed Directives shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex VIII.

Article 53
Transitional Measures

Where it is necessary in order to allow for the normal marketing, processing and consumption of the harvested products, taking their normal shelf life into account, in order to safeguard legitimate expectations, transitional measures may be laid down for the implementation of certain MRLs provided for in Articles 18, 19, 23, 26, 27, 28 and 29.

Those measures which shall be without prejudice to the obligation to ensure a high level of consumer protection shall be adopted in accordance with the procedure referred to in Article 49(2).

Article 54
Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*

It shall apply from 1 January 2005 for fresh products and from 1 July 2005 for stored products.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEXES (I-VII to be established by comitology procedure)

ANNEX I: Groups of commodities of plant and animal origin with examples of products in those groups and the parts of those products to which MRLs apply - including animal feedstuffs as referred to in Article 1. This annex comprises the existing commodities listed in the annexes to the original four directives but also includes a new commodity - honey.

ANNEX II: MRLs for products of plant and animal origin, (in the first instance transferred) from the Annexes of 86/362/EEC, 86/363/EEC and 90/642/EEC as referred to in Article 18.

ANNEX III: Temporary MRLs for active substances for which a decision on inclusion in or exclusion from Annex I to Directive 91/414/EC has not yet been taken, including remaining MRLs in the Annex to Directive 76/895/EEC as well as hitherto unharmonised national MRLs, as referred to in Article 24 and MRLs set according to the simplified procedure referred to in Article 27.

ANNEX IV: List of active substances of plant protection products, evaluated under Directive 91/414/EEC and for which it is agreed by the Standing Committee that MRLs are not required (as referred to in Article 20).

ANNEX V: Specific concentration and dilution factors fixed after an evaluation as part of the 91/414/EEC dossier or developed after a 91/414/EEC decision has been adopted by the Commission (as referred to in Article 14).

ANNEX VI: Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market

ANNEX VII: Analytical methods, quality control procedures (as referred to in Article 35).

ANNEX VIII: Correlation Table

This Regulation	**Directive76/895**	**Directive 86/362**	**Directive 86/363**	**Directive 90/642**
Article 1	Article1(2)	Article 1(1)	Article 1(1)	Article 1(1)
Article 2(2)	Article 9(2)	Article 1(4)	Article 1(4)	Article 1(4)
Article 2(3)	Article 9(1)	Article 1(3)	Article 1(3)	Article 1(3)
Article 3	Article 2	Article 2	Article 2	Article 2
Article 4				
Article 5				
Article 6				
Article 7				
Article 8				
Article 9				
Article 10				
Article 11				
Article 12				
Article 13(1)		Article 4(1)	Article 4(1)	Article 3(1)
Article 13(2 a)	Article 3(1)	Article 3(2)	Article 3(2)	Article 5
Article 13(2 b)		Article 3(1)	Article 3(1)	Article 3(1)
Article 14				
Article 15		Article 4 (2)	Article 4 (2)	Article 3(2)
Article 16		Article 4(3)	Article 4(3)	Article 3(3)
Article 17				
Article 18				
Article 19				
Article 20				
Article 21				

Article 22				
Article 23				
Article 24(2)	Article 5	Article 10	Article 10	Article 7
Article 25				
Article 26				
Article 27				
Article 28				
Article 29				
Article 30				
Article 31				
Article 32(1)	Article 6(1)	Article 4(4)	Article 4(4)	Article 3(4)
Article 33(2)	Article 6(2)	Article 8(1)	Article 8(1)	Article 6(1)
Article 34(1)				Article 6(1)
Article 34(2)	Article 6(2)	Article 8(1)	Article 8(1)	Article 6(2)
Article 35(1)		Article 7(1)		Article 4(1)
Article 35(2)		Article 7(2a)		Article 4(2a)
Article 36(1)		Article 7(2b)		Article 4(2b)
Article 37		Article 7(3)	Article 7(1)	Article 4(3)
Article 38		Article 7(3)	Article 7(2)	Article 4(3)
Article 39(2b)		Article 7(3)		Article 4(3)
Article 39(6)		Article 7(3)		Article 4(3)
Article 40		Article 7(5)		Article 4(5)
Article 41		Article 7(3)		Article 4(3)
Article 42(1)	Article 3(2) Article 4(1)	Article 9(1)	Article 9(1)	Article 8
Article 43				
Article 44				

Article 45				
Article 46				Article 7
Article 47				
Article 48				
Article 49	Article 7 Article 8	Article 9(2)(3) Article 11 Article 12 Article 13	Article 9(2) Article 11 Article 12 Article 13	Article 8(2)(3) Article 9 Article 10
Article 50				
Article 51				
Article 52				
Article 53				

LEGISLATIVE FINANCIAL STATEMENT

Policy area(s): Health an consumer protection

Activities: Setting and controlling maximum levels of pesticides residues in products of plant and animal origin, monitoring the residue levels in food and feed.

Title of action: Regulation of the European Parliament and of the Council on maximum levels of pesticides residues in products of plant and animal origin

1. BUDGET LINE(S) + HEADING(S)

B-1-333 and B-1333A Phytosanitary measures. This budget line deals with plant health and phytosanitary issues. Pesticides residues measures form a part of the overall expenditure of this budget line.

2. OVERALL FIGURES

2.1. Total allocation for action (Part B): € million for commitment

To be fixed annually - generally about 0.3M€, reducing to 0.2M€ by 2008.

2.2. Period of application:

The activity will start in January 2003

2.3. Overall multiannual estimate of expenditure:

(a) Schedule of commitment appropriations/payment appropriations (financial intervention) *(see point 6.1.1)*

Not applicable.

(b) Technical and administrative assistance and support expenditure *(see point 6.1.2);* € million (*to three decimal places)*

Commitments	0.300	0.300	0.250	0.200	0.200	0.200	1.450
Payments	0.300	0.300	0.250	0.200	0.200	0.200	1.450

Subtotal a+b							
Commitments	0.300	0.300	0.250	0.200	0.200	0.200	1.450
Payments	0.300	0.300	0.250	0.200	0.200	0.200	1.450

(c) Overall financial impact of human resources and other administrative expenditure *(see points 7.2 and 7.3)*

Commitments/ payments	0.738	0.738	0.738	0.738	0.738	0.738	0.738

TOTAL a+b+c	0.768	0.768	0.768	0.768	0.768	0.768	0.768
Commitments	0.768	0.768	0.768	0.768	0.768	0.768	0.768
Payments	0.768	0.768	0.768	0.768	0.768	0.768	0.768

2.4. Compatibility with financial programming and financial perspective

[X] Proposal is compatible with existing financial programming.

2.5. Financial impact on revenue:[i]

[X] Proposal has no financial implications (involves technical aspects regarding implementation of a measure)

3. BUDGET CHARACTERISTICS

Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
Comp	Non-diff	NO	NO	NO	**Part A, B-1333**

4. LEGAL BASIS

Treaty articles 37, 95 and 152.4(b) of the Treaty

5. DESCRIPTION AND GROUNDS

5.1. Need for Community intervention[19]

5.1.1. Objectives pursued

The main objective of the proposal is to ensure that the presence of residues of pesticides in or on food or feed in the Community, whether domestically produced, or imported:

– does not present an unacceptable risk for human or animal health;

– is not used a non-tariff trade barrier;

This will be ensured by setting, at Community level, acceptable maximum levels of residues for each active substance and each product of plant or animal origin where residues might be likely to occur and to set a default level at the limit of analytical

[19] For further information, see separate explanatory note.

determination for all other combinations. The levels shall be set following an assessment of risks to the consumer. It also

– brings coherence to community legislation in a "farm to table" approach" by clarifying certain procedural aspects, inter alia with the provisions of Council Directive 91/414/EEC on the placing of plant protection products on the market;

– takes into account the entry into force of the European Food Safety Authority (hereunder called "*the Authority*" which will be responsible for the risk evaluation of residues.

The proposal lays down a procedure by which the Commission will set the maximum levels and requires that the Authority will have a key role in forwarding scientific assessments and opinions to the Commission.

On the basis of opinions forwarded by the Authority, the Commission will take decisions through a comitology procedure.

A secondary objective of the proposal is to consolidate four existing Council Directives on the setting of maximum levels for pesticides residues in products of plant and animal origin. In so doing, it includes the existing MRLs fixed in those directives and, for the currently-non-harmonised MRLs, it sets temporary MRLs based on those currently existing at national level, and pending the outcomes of evaluations undertaken in the framework of Directive 91/414/EEC.

The proposal also provides for:

- procedures for the monitoring and control of the levels of pesticides residues in products of plant and animal origin in the Member States as well as the collation, analysis and publication of the results of the monitoring;

5.1.2. Measures taken in connection with ex ante *evaluation*

Not applicable.

5.1.3. Measures taken following ex post *evaluation*

The existing pesticides residues legislation formed part of the SLIM exercise in 2001 and the current proposal takes the SLIM recommendations into account.

5.2. Action envisaged and budget intervention arrangements

General objectives: The general objective is to harmonise all MRLs at Community level whilst ensuring a high level of protection of the health of consumers and minimising trade problems.

Performance indicators selected:

Output indicators: number of MRLs set, numbers of meetings held and applications for MRLs/renewal/ modification/ suspension/ revocation, numbers of samples analysed in the annual monitoring programmes.

Impact indicators: number of authorisations for individual crops (under 91/414/EEC) granted, renewed, modified, suspended or revoked; number of interventions by trading partners in SPS; numbers of trade problems signalled by Member States or other stakeholders; rates of excedences of MRLs in annual monitoring programmes.

Details and frequency of planned assessments: Annual assessments of compliance and consumer exposure will be made. For MRLs based on monitoring data, assessments will be made at least once every ten years, All MRLs will be reassessed based on the outcomes of evaluations under Directive 91/414/EEC and the changing uses of substances resulting from those evaluations. The Regulation itself will be assessed after 10 years.

Assessment of the results obtained: the measures procedure provided for by the Regulation guarantee a high level of protection for human and animal health and the environment while preventing distortion of trade in the single market.

Target population: consumers are the ultimate beneficiaries. Other beneficiaries are producers and traders.

5.3. Methods of implementation

The work under the Regulation will be shared, as under Directive 91/414/EEC between the Commission, the Authority and the Member States. For each individual substance used in the Community, a Rapporteur Member has or will be nominated under Directive 91/414/EEC. Having the 'Community expertise' for that substance, it is envisaged that they will also act in this capacity in the area of residues and will be permitted to recover costs by levying fees upon interested parties for their work. The recommendations of the Rapporteur Member States will be assessed by the Authority which will then deliver an opinion to the Commission. For substances not used in the Community but where residues might be present in or on imported products, the Authority should act as Rapporteur.

It is envisaged that the work of the Authority in this area will require 12 full-time staff. Because of the significant increase in workload in this area in the coming years, it is not expected that the resource needs within the Commission will change as a result of the additional support to be provided by the authority.

6. FINANCIAL IMPACT

6.1. Total financial impact on Part B - (over the entire programming period)

6.1.1. Financial intervention

None

6.1.2. Technical and administrative assistance, support expenditure and IT expenditure (commitment appropriations)

	2003	2004	2005	2006	2007	2008	Total
1) Technical and administrative assistance							

a) Technical assistance offices							
b) Other technical and administrative assistance: - intra muros: - extra muros: *of which for construction and maintenance of computerised management systems*	0.075 0.075	0.075 0.075	0.050 0.050				0.200 0.200
Subtotal 1	0.075	0.075	0.050				0.200
2) Support expenditure							
a) Studies	0.165	0.165	0.140	0.140	0.140	0.140	0.890
b) Meetings of experts	0.060	0.060	0.060	0.060	0.060	0.060	0.360
c) Information and publications							
Subtotal 2	0.225	0.225	0.200	0.200	0.200	0.200	1.250
TOTAL	0.300	0.300	0.250	0.200	0.200	0.200	1.450

6.2. Calculation of costs by measure envisaged in Part B (over the entire programming period)[20]

(Where there is more than one action, give sufficient detail of the specific measures to be taken for each one to allow the volume and costs of the outputs to be estimated.)

Commitments (in € million to three decimal places)

Breakdown	Type of outputs (projects, files)	Number of outputs (total for years 1…n)	Average unit cost	Total cost (total for years 1…n)
	1	2	3	4=(2X3)
Action 1				
- Measure 1				
Action 2				
- Measure 1				
etc.				
TOTAL COST				

If necessary explain the method of calculation

[20] For further information, see separate explanatory note.

7. IMPACT ON STAFF AND ADMINISTRATIVE EXPENDITURE

7.1. Impact on human resources

Types of post		Staff to be assigned to management of the action using existing and/or additional resources		Total	Description of tasks deriving from the action
		Number of permanent posts	Number of temporary posts		
Officials or temporary staff	A	3		3	*Preparation of legislation, development of policy, organisation of meetings etc*
	B	1		1	
	C	1		1	
Other human resources					
Total		5		5	

7.2. Overall financial impact of human resources

Type of human resources	Amount (€)	Method of calculation *
Officials Temporary staff	540,000€	5* 108,000€
Other human resources - (specify budget line)		
Total	540,000€	

The amounts are total expenditure for twelve months.

7.3. Other administrative expenditure deriving from the action

Budget line - (number and heading)	Amount M€	Method of calculation
Overall allocation (Title A7)		
A0701 – Missions	0.024	12 missions/year x 2 A-staff x 1000€ =
A07030 – Meetings	0.039	10 per year; 650€x6 experts = 3900€x10
A07031 – Compulsory committees (Standing Committee on the Food Chain and Animal Health)[1]	0.059	Six meetings/yr x 15 delegates x 650€
A07032 – Non-compulsory committees (Consultative committee) [1]	0.026	Two 1-day meetings per year; 20 delegates x 650€ = 13000€x2
A07040 – Conferences	0.02	One every three years - cost spread over three years. Typically 0.06M€/3
A0705 – Studies and consultations	-	
Other expenditure (specify)	-	
Information systems (A-5001/A-4300)	-	
Other expenditure - Part A (specify)	-	
Total (M€)	0.198	

The amounts are total expenditure for twelve months.

[1] Specify the type of committee and the group to which it belongs.

I.	Annual total (7.2 + 7.3)	€ 738,000
II.	Duration of action	Open, first six years 2003-2008 are costed
III.	Total cost of action (I x II)	€ 4,428,000

The needs for human and administrative resources shall be covered within the allocation granted to managing DG in the current allocation procedure

8. FOLLOW-UP AND EVALUATION

8.1. Follow-up arrangements

See also point 5.2.

Member States are also obliged to take appropriate legal or administrative measures in case of non-compliance with MRLs and communicate those measures to the Authority and the Commission.

8.2. Arrangements and schedule for the planned evaluation

Regular, annual and multiannual evaluations of consumer exposure are planned. See also point 5.

9. ANTI-FRAUD MEASURES

Not applicable for the financial risks encountered.

IMPACT ASSESSMENT FORM

THE IMPACT OF THE PROPOSAL ON BUSINESS WITH SPECIAL REFERENCE TO SMALL AND MEDIUM-SIZED ENTERPRISES (SMEs)

TITLE OF PROPOSAL

Regulation of the European Parliament and of the Council on maximum residue levels of pesticides in products of plant and animal origin

DOCUMENT REFERENCE NUMBER

SANCO/2003/2555 rev. 9

THE PROPOSAL

1. Taking account of the principle of subsidiarity, why is Community legislation necessary in this area and what are its main aims?

   Pesticides residues in food and feed pose a risk to human and animal health. Maximum levels of residues need to set to ensure that any such risks remain within acceptable limits. These maximum levels need to be set at Community level to avoid trade problems that can and do arise due to differences in national levels. The main objective is to protect consumers while facilitating trade.

THE IMPACT ON BUSINESS

2. Who will be affected by the proposal?

   – which sectors of business

   Agricultural producers of food and feed, importers of food and feed into the Community.

   – which sizes of business (what is the concentration of small and medium-sized firms)

   No information is available on this point.

   – are there particular geographical areas of the Community where these businesses are found

   No.

3. What will business have to do to comply with the proposal?

   Ensure that food and feed placed on the market has been produced using authorised 'Good agricultural practices' with respect to pesticides.

4. What economic effects is the proposal likely to have?

– on employment

None.

– on investment and the creation of new businesses

None.

– on the competitiveness of businesses

None

5. Does the proposal contain measures to take account of the specific situation of small and medium-sized firms (reduced or different requirements etc)?

No but it allows the possibility that data requirements could be reduced for food and feed commodities that are minor in the diet and in trade.

IMPACT ON TRADING PARTNERS

Any MRLs being adopted under the Regulation will have to be notified under the SPS procedures of the World Trade Organisation. The Commission proposes to notify, in general terms during the fiest semester of 2003, the measures provided for in this regulation. In 2002 the Commission notified under the TBT procedures of the WTO, a list of 325 substances that will be withdrawn from the market in 2003 and where MRLs would be set at 0.01 mg/kg in 2005. It shall continue to notify any other substances to be withdrawn. This is considered sufficient time to permit trading partners to either change their agricultural use f pesticides or to generate the data necessary to set a higher MRL.

No impact is expected on trading partners from developed countries because the provisions of the annexes will in the first instance, reflect current provisions and they generally have the capacity to produce the data required for MRLs. There may be an impact on trading partners in developing countries and strenuous efforts have been made since 1999 to reduce or even eliminate these impacts. A major project 'The Pesticides Initiative Programme' has been established by the Commission to help ACP trading partners develop infrastructure, review and if necessary adapt their GAPs and to work together to generate the data necessary to set MRLs.

CONSULTATION

6. List the organisations which have been consulted about the proposal and outline their main views.

The revised proposal is based on the consensus recommendations of the SLIM exercise of 2001 which involved extensive discussions of an original proposal with stakeholders including industry, workers, consumers, Member States, environmental organisations and COLEACP which manages the Pesticide Initiative Programme with ACP countries on behalf of the Commission. One environmental organisation (PAN) does not support the proposal since it considers that if a product can be produced in one country or region without leaving pesticide residues, then no

pesticides residues should be permitted on that product regardless of its origin. In practice, this would prevent most countries from producing any food or feed at all. Industry (ECPA) considered that those elements of the babyfood directives dealing with pesticides should be brought within the scope of the proposal but has not insisted on this point. Member States were also consulted on several occasions in the residues working group of the Standing Committee on the Food Chain and Animal Health and stakeholders were again consulted in the Consultative Committee on Fruit and Vegetables.

The (almost-) consensus view is that the existing legislation needs to be consolidated and amended without delay and that a temporary solution needs to be found for the as-yet unharmonised pesticides. In addition, flexibility has to be introduced to allow for the marketing of products with long shelf lives.

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[i] For further information, see separate explanatory note.