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from :	General Secretariat
to :	Working Party on Agricultural Questions (Pesticide Residues)
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No. Cion prop. :	7635/03
Subject :	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

In preparation for the Working Party on 2 and 3 March 2004, delegations will find attached a document reflecting the outcome of discussions to date, and also containing Presidency drafting suggestions.

Chapter I
Subject matter, scope and definitions

Article 1
Subject matter

This Regulation establishes, in accordance with the general principles laid down in Regulation (EC) n. 178/2002, harmonised Community provisions relating to maximum residue levels of pesticides in food and feed of plant and animal origin.

Article 2
Scope

1. This Regulation shall apply to fresh and processed **and/or composite** products of plant and animal origin or parts thereof **listed in Annex I** to be used as food or feed, on or in which pesticide residues may be present.

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

   (a) the manufacture of products other than food or 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 Annex I intended for export to third countries and treated before export, where it has been 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.

4. This Regulation shall apply without prejudice to [...] Directives 98/8/EC, 2002/32/EC [...] and Regulation 2377/90/EC.

Article 3
Definitions[1]

For the purpose of this Regulation, the definitions in Regulation (EC) No 178/2002, and the definitions in Article 2 points 1 and 4 of Directive 91/414/EEC shall apply.

The following definitions shall also apply:[2]

(4) 'good agricultural practice' (GAP): means the nationally recommended, authorised or registered safe use of plant protection products 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;

(11) ***'critical GAP' means the GAP, where there is more than one GAP for an active substance/product combination, which gives rise to the highest acceptable level of pesticide residue in a treated crop and is the basis for the MRL established.***

(1) 'pesticide residues': means residues, including where appropriate active substances, metabolites and/**or** breakdown or reaction products of active substances currently or formerly used in plant protection products as defined in Article 2 point 1 of Directive 91/414/EEC, which are present in or on the products referred to in Annex I of this Regulation, including **in particular** those 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 or on [...]** food or feed;

(12) 'CXL': means an MRL set by the Codex Alimentarius Commission;

(3) 'Limit of Determination' (LOD): means the validated lowest residue concentration which can be quantified and reported by routine monitoring with validated control methods;

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1 A new definition of "product" might be added if necessary.
2 The definitions have been reordered.

(5) ‘import tolerance’: means a MRL 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 Community 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 performed by each laboratory;

(7) ‘acute reference dose': means the estimate of the amount of substance in food, [...] 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 [...] 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) [...][3]

(10) [...][4]

[3] The definition of "composite foodstuffs" has been deleted. (See Articles 14-16.)
[4] The definition of "processing" has been deleted. (See Articles 14-16.)

Article 17
List [*of groups*] *of products* [...] *for which harmonised MRLs shall apply*

1. The [...] products, [product groups] and/or parts of products referred to in Article 2(1) [...] to which harmonised MRLs shall apply, shall be defined and listed in Annex I in accordance with the procedure referred to in Article 49(2). Annex I shall include all commodities for which MRLs are explicitly set, as well as the other products for which it is appropriate to apply harmonised MRLs in particular in view of their relevance in the diet of [...] **consumers** or in trade. Products shall be grouped in such a way that MRLs may as far as possible be set for a group of similar or related commodities.

2. Annex I shall be first established within **3 months** from the entry into force of this Regulation and shall be revised when appropriate, in particular, at the request of a Member State.

Chapter II[5]
Procedure for applications for MRLs

SECTION 1
SUBMISSION OF APPLICATIONS FOR MRLS

Article 22
Applications

1. Where a Member State, envisages to grant an authorisation or a provisional authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC, the Member State shall consider whether as a result of such use, an existing MRL set out in Annex II or III [6] to this Regulation needs to be modified or whether it is necessary to set a new MRL, and if necessary it shall require the **party** requesting the authorisation to submit an application in accordance with **Article 6**.

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5 The Cion entered a scrutiny reserve on Chapter II.
6 Reference to Annex IV needs to be added.

2. Parties demonstrating, through adequate evidence, a legitimate interest, including manufacturers, **[...],** growers and producers of products referred to in Annex I may also present to a Member State an application in accordance with **Article 6**.

3. Where a Member State considers that the setting, modification or deletion of an MRL is necessary, that Member State may also compile and evaluate an application for setting, modifying or deleting the MRL in accordance with **Article 6**.

4. **[...].**

4bis Applications for import tolerances shall be submitted to rapporteur Member States designated in accordance with Directive 91/414/EEC or if no such rapporteur has been designated in accordance with Directive 91/414/EEC, applications shall be made to member States designated by the Commission in accordance with procedure referred to in Article 49(2) at the request of the applicant. Such applications shall be made in accordance with Article 6.

Article 6

Requirements relating to applications for MRLs

1. The applicant shall include in an application for an MRL the following particulars and documents:

   (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;

      (iv) a copy of the relevant GAP applying to the specific use of that active substance.

(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 and data on routine analytical methods for use in monitoring labs, as well as plant and animal metabolism data.

However, where relevant data are already publicly available, in particular, when an active substance has already been evaluated under Directive 91/414/EEC or where a Codex Alimentarius Commission CXL[7] exists **and are submitted by the applicant**, a Member State may **also** use such information in evaluating an application. In such cases, the evaluation report shall include a justification for using **or not using** such data.

2. The evaluating Member State 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 Member State.

Article 4

[...][8]

Article 4 bis

Evaluation of Applications

1. A Member State to which an application complying with Article 6 is submitted pursuant to Article 22 shall draw up an evaluation report without undue delay.[9]

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7 The following definition is to be added in *Article 3*: "CXL: means an MRL set by the Codex Alimentarius Commission".

8 Article 4 is deleted.

9 Scrutiny reserve by NL and the Cion who preferred a specific timeline.

2. Applications shall be evaluated in accordance with the relevant provisions of the Uniform Principles for the Evaluation of Plant Protection set out in Annex VI to Directive 91/414/EEC or specific **evaluation principles** to be fixed **by a Commission Regulation** in accordance with the procedure referred to in Article 49(2).

3. By way of derogation from paragraph 1 and further to an agreement between the Member States concerned, evaluation of the application might be carried out by the rapporteur Member State designated in accordance with Directive 91/414/EEC for that active substance.

4. Where a Member State encounters difficulties in evaluating an application or in order to avoid duplication of work, it may be decided in accordance with the procedure set out in Article 49(2) which Member State shall evaluate particular applications.

Article 5

Submission of Evaluated Applications to the Commission and the Authority

1. After completion of the evaluation report, the Member State shall forward the application together with the evaluation report and the supporting dossier to the Commission. The Commission shall without delay inform the Member States and forward the application, the evaluation report and the supporting dossier 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, the evaluating Member State and the Commission without delay. The acknowledgement shall state the date of receipt of the application and the accompanying documents.

Article 7

[...][10]

SECTION 2

CONSIDERATION OF APPLICATIONS CONCERNING MRLS BY THE AUTHORITY

Article 8

[...][11]

Article 9

The Authority's opinion on applications concerning MRLs

1. The Authority shall assess the applications and the evaluation reports and give a reasoned opinion on, in particular, the risks to the consumer **and where relevant to animals**[12] associated with 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 **[...]** intake due to the residues on the commodity for which the MRLs was requested;

   (d) any other element relevant for the risk assessment.

[...]

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10 Article 7 and Annex VI are deleted.

11 Article 8 is deleted.

12 ES and FIN entered a scrutiny reservation on the added wording.

2. The Authority shall forward its reasoned opinion to the applicant, the Commission, and the Member States. The reasoned opinion shall clearly define the basis for each conclusion reached.

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 as soon as possible and at the latest within three months from the date of receipt of the application;

2. Where the Authority requests supplementary information, the time limit laid down in paragraph 1 is suspended until that information has been provided. Such suspensions are subject to the provisions of Article 21(bis).

Article 21

Assessment of existing MRLs by the Authority

1. The Authority shall, within a period of 12 months[13] from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC after the entry into force of this Regulation, submit a reasoned opinion **based in particular on the relevant assessment report prepared under Directive 91/414/EEC** to the Commission and the Member States **[...]** on:

[13] See second paragraph of Article 23.

(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, **or its inclusion in Annex IV;**

(c) specific processing factors as referred to in Article 15(2) that may be needed for that active substance;

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

2. For substances included in Annex I to Directive 91/414/EEC before the entry into force of the present Regulation, the opinion referred to in paragraph 1 shall be delivered within 12 months[14] of the entry into force of the present Regulation.

Article 21 bis

Administrative review

Any decision taken under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly or individually concerned.

For that purpose, a request shall be submitted to the Commission within two months after the day on which the party concerned became aware of the act or omission in question.

The Commission shall take a decision within two months requiring, if appropriate, the Authority to withdraw its decision or to remedy its failure to act within a set time-limit.[15]

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[14] D expressed the view that this was not realistic.

[15] See GM food and feed additives regulations (1829/2003 and 1831/2003).

SECTION 3

SETTING, MODIFYING OR DELETION OF MRLS

Article 11[16]

Decisions on applications concerning MRLs

1. Upon receipt of the opinion of the Authority and taking into account that opinion a Regulation on the setting, modification or deletion of an MRL or a decision rejecting the application shall be prepared by the Commission without delay **and at the latest within 3 months**, and submitted for adoption in accordance with the procedure referred to in Article 49 (2).

2. In deciding account shall be taken of

   (a) the scientific and technical knowledge available;

   (b) the possible presence of pesticide residues arising from sources other than current plant protection uses of active substances;

   (c) the results of an assessment of any potential risks to the consumer and, where appropriate, to animal**s [...]**;

   (d) the results of any evaluations and decisions to modify the uses of plant protection products;

   (e) a Codex Alimentarius Commission CXL or a GAP implemented in a third country for the legal use of an active substance in that third country;

   (f) other legitimate factors relevant to the matter under consideration.

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[16] In response to concerns by several delegations, the Commission might be in the position to make the following declaration:
"The Cion will maintain its current practice of including more than one active substance in a proposal when this is unlikely to slow down the adoption of the proposal".

3. The Commission may request at any time that supplementary information be provided by the applicant or by the Authority. The Commission shall make available any supplementary information received to the Member States and the Authority.

Article 23

Inclusion of new or modified MRLs in Annexes II and III

1. The Regulation referred in Article 11(1) shall:

   (a) Set new or modified MRLs and list them in Annex II to this Regulation where the active substances have been included in Annex I to Directive 91/414/EEC;

   (b) Where the active substances have not been included in Annex I of Directive 91/414/EEC and where they are not included in Annex II to this Regulation, set **or modify** temporary MRLs, and list them in Annex III to this Regulation; or

   (c) In the cases mentioned in Article 27, set temporary MRLs, and list them in Annex III to this Regulation.

2.[17] Where a temporary MRL is set as provided in paragraph 1(b), it shall be deleted from Annex III by a Regulation adopted in accordance with the procedure referred to in Article 49(2) after one year from the date of the inclusion or non-inclusion in Annex I to Directive 91/414/EEC of the active substance concerned. However, where one or more Member States so request, it may be maintained for an additional year pending confirmation that any scientific studies necessary for supporting an application for setting a MRL have been undertaken. Only in cases where such confirmation is provided the temporary MRL shall be maintained for an additional two years, provided that no unacceptable safety concerns for the consumer have been identified.

[17] The Presidency undertook to reward this paragraph.

Article 27

Procedure for setting temporary MRLs in certain circumstances

1. The Regulation referred to in Article 11(1) may also set a temporary MRL to be listed in Annex III in the following circumstances:

   (a) in exceptional cases, in particular where pesticide residues may arise as a result of environmental or other contamination or from uses of plant protection products pursuant to article 8(4) of directive 91/414; or

   (b) where the products concerned constitute a minor component of the diet of consumers **and where relevant of animals [...]**; or

   (c) for honey; or

   (d) where essential uses of a plant protection products have been identified by a Decision not to include or to delete an active substance in Annex I to Directive 91/414/EEC.

2. The inclusion of temporary MRLs as referred to in paragraph 1 shall be based on 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 the temporary MRLs referred to in paragraph 1 (a), (b) and (c) shall be re-assessed at least once every 10 years and any such MRLs shall be modified or repealed as appropriate.

   The MRLs referred to in paragraph 1 (d) shall be reassessed at the expiry of the period for which the essential use was authorised.

Article 12

Modifications of MRL following revocation of authorisations of plant protection products

Amendments to Annexes II or III, needed to delete an MRL following the revocation of an existing authorisation for a plant protection product can be adopted without seeking the opinion of the Authority.

Chapter III

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

Article 20

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

1. Active substances of plant protection products evaluated under Directive 91/414/EEC for which no MRLs are required shall be defined in accordance with the procedure referred to in Article 49(2) and listed in Annex IV, taking into account the uses of those active substances and the matters referred to in Article 11(2) points (a), (c) and (d).

2. Annex IV shall be first established within **12 months** from the entry into force of this Regulation.

Article 13

Compliance with maximum residue levels

1. The products referred to in Annex I shall not contain, from the time they are placed on the market as food or feed, or fed to food producing animals, any pesticide residue exceeding:

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

(b) 0.01 mg/kg for those products for which no specific MRL is set out in Annexes II or III, or for active substances not listed in Annex IV **unless different default values are fixed for an active substance in accordance with the procedure referred to in Article 49(2) while taking into account the routine analytical methods available. Such default values shall be listed in Annex IV bis.**

2. Member States may not prohibit or impede the placing on the market or the feeding to food producing animals within their territories of the products referred to in [...] Annex I on the grounds that they contain pesticide residues provided that:

(a) such products comply with Articles 13(1) and 15 [...]; or

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

3. By way of derogation from paragraph 1 Member States may authorise, on its own territory, the residue levels of active substance which exceed the limits specified in Annexes II and III for a product referred to in Annex I where these active substance/product combinations are listed in Annex x provided that

a. These products are not intended for immediate consumption;

b. Appropriate controls are in place to ensure that the products cannot be made available to the end user or consumer, if they are supplied directly to the latter, until the residues no longer exceed the maximum levels specified in Annex II or III;

c. The other Member States and the Commission have been informed of the measures taken;

The active substance/product combinations listed in Annex x shall be defined in accordance with the procedure referred to in Article 49(2).[18]

[18] It should be noted that "defaut values" will be explained in the recitals to this Regulation.

Article 14
[*Prohibition Concerning Processed and/or Composite* [...] *Products*]

It shall be prohibited to process, mix or otherwise dilute the products referred to in Annex I not complying with Article 13(1) or 15 [...] with a view to placing them on the market as [...] food or feed **or fed to food-producing animals**.

Article 15
MRLs applicable to processed and/or composite [...] *products*

1. Where MRLs are not set out in Annexes II or III for processed and/or composite food or feed, the MRLs applicable shall be those provided in Article 13(1) for the relevant product referred to in Annex I, taking into account changes in the levels of pesticide residues caused by processing and/or mixing.

2. Specific concentration or dilution factors for certain processing and/or mixing operations or for certain processed and/or composite products may be included in the list in Annex V in accordance with the procedure referred to in Article 49(2).

Article 16

[...][19]

[19] Article 16 is deleted**.**

Chapter IV
Special provisions relating to the incorporation of existing MRLs into the present Regulation

Article 18
First establishment of MRLs

1. MRLs for products referred to in Annex I shall be first established and listed in Annex II in accordance with the procedure referred to in Article 49(2), incorporating the MRLs provided for under Directives 86/362/EEC, 86/363/EEC and 90/642/EEC, taking into account the criteria mentioned in Article 11(2).

[...]

2. Annex II shall be established within **12 months** from the entry into force of this Regulation.
[...]

Article 19
First establishment of temporary MRLs

~~1.~~ 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 first established and listed in Annex III, unless already listed in Annex II, in accordance with the procedure referred to in Article 49(2), taking into account the information provided by the Member States, where relevant the opinion [...] mentioned in Article 25, the factors referred to in Article 11(2) [...] and the following MRLs:

[...]

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

(b) hitherto unharmonised national MRLs. [...]

2. Annex III shall be established within **12 months** from the entry into force of this Regulation in accordance with the [...] provisions in Articles 24 to 26.

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

Where [...] an active substance is not yet included in Annex I to Directive 91/414/EEC and where a Member State has set, by the date of entry into force of Annex I at the latest, a national MRL for [...] that active substance [...] for a product referred to in Annex I, [...] or has decided that no MRL is required for that active substance, the Member State concerned shall notify the Commission, in a format and by a date to be established in accordance with the procedure referred to in Article 49(2), of the following:

the national MRL, or the fact that no MRL is required for an active substance, and where relevant and at the request of the Commission:

- the GAP;

- where the critical GAP is applied in the Member State, and where available, summary data on supervised trials and/or monitoring data;

- 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. At the request of the Commission, the Authority shall [...] provide a reasoned opinion to the Commission on potential risks to consumer health arising from:

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

   (b) 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 [...] the scientific and technical knowledge available, and in particular, data submitted by the Member States as required by Article 24. [...]

[...][20]

[20] Article 25bis is deleted.

Article 26
Setting of temporary MRLs

Taking into account the opinion of the Authority, temporary MRLs for active substances referred to in Article 24 [...] may be set and listed in Annex III, pursuant to Article 19(1) or, as appropriate the active substance may be included in Annex IV pursuant to Article 20(1).

[...][21]

Chapter V
Official controls, reports and penalties

SECTION 1
OFFICIAL CONTROLS OF MRLS AND ACTIVE SUBSTANCES

Article 32
Official controls

1. Without prejudice to Directive 96/23/EC Member States shall carry out official controls on pesticide residues in order to enforce compliance with this Regulation, in accordance with the relevant provisions of Community law relating to the official controls for food and feed.

2. Such controls on pesticide residues shall, in particular, consist of sampling [...] and subsequent [...] analysis of the samples and identification of the pesticides present and their respective residue levels. [...]

Article 33
Sampling

1. Each Member State shall take a sufficient number and range of samples [...] to assure that the results are representative of the [...] market, [...] taking into account the results of previous control programmes. Such sampling shall be carried out as close to the point of supply as is reasonable, to allow for any subsequent enforcement action to be taken.

[21] Articles 30 and 31 have been moved to Chapter VIII.

2. The sampling methods necessary for carrying out such [...] controls of pesticide residues in products, other than those provided for in Commission Directive 2002/63/EC[22], shall be determined in accordance with the procedure referred to in Article 49(2).

Article 34
Methods of Analysis

2. [23] The methods of analysis of pesticide residues shall comply with the criteria set out in the relevant provisions of Community law relating to the official controls for food and feed.

1. [...] Technical guidelines dealing with the specific validation criteria and quality control procedures [...] in relation to the methods of analysis for the determination of pesticide residues may be adopted [...] in accordance with the procedure referred to in Article 49(2).

3. All laboratories analysing samples for the official controls [...] on pesticide residues shall participate in the Community Proficiency Test for pesticide residues as referred to in Article 43 (b) and organised by the Commission.

SECTION 2[24]
COMMUNITY CONTROL PROGRAMME

Article 36
Community Control Programme

1. The Commission shall prepare a co-ordinated multiannual Community control programme, identifying specific samples to be included in the national control programmes, and taking into account problems that have been identified regarding compliance with the MRLs set out in this Regulation, with a view to assessing consumer exposure and the application of current legislation.

[...][25]

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22 OJ L 187, 16.7.2002, p. 30.
23 Paragraphs 1 and 2 have been reordered.
24 The order of Sections 2 and 3 has been reversed.
25 Paragraph 2 is deleted.

3. The Community control programme shall be adopted and updated yearly in accordance with the procedure referred to in Article 49(2). [...] The Draft Community control programme shall be presented to the Committee referred to in Article 49(1), at least [...] six months before the end of each calendar year.

SECTION 3 ~~2~~
NATIONAL CONTROL PROGRAMMES

Article 35
National control programmes for pesticide residues

1. Member States shall establish multiannual national control programmes for pesticide residues. They shall yearly update their multiannual programme.

   Those programmes shall be risk-based and aimed in particular at assessing consumer exposure. They 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 pesticides [...] 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 taken for domestic and non-domestic products respectively;

      (iii) consumption of the products as a share of the national diet;

      (iv) the Community Control Programme, and

      (v) the results of previous control programmes.

2. Member States shall submit their updated national control programmes for pesticide residues, as mentioned in paragraph 1, to the Commission and to the Authority at least [...] three months before the end of each calendar year.

3. Member States shall participate in the Community [...] Control Programme as provided for in Article 36.

SECTION 4
INFORMATION BY THE MEMBER STATES AND [...] ANNUAL REPORT

Article 37
Information by the Member States

1) Member States shall submit the following information concerning the previous calendar year to the Commission, the Authority and the other Member States by [...] 31 August each year:

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

[...]

(c) the LODs applied in the national control programme as referred to in Article 35 and under the Community [...] Control 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 programme;

(e) details of the accreditation status of the analytical laboratories involved in the controls referred to in point (a); [...]

(f) where permitted by national legislation, details of enforcement measures taken.[26]

[26] Editorial change.

2. [...] Implementing measures relating to the submission of information by the Member States may be established in accordance with Article 49(2) after consultation with the Authority.

Article 39
The **[...]** *Annual Report on Pesticide Residues*

1. On the basis of the information provided by the Member States under Article 37(1) the Authority shall draw up a **[...]** Annual Report on pesticide residues. [...]

2. The Authority shall include information on at least the following in the Report:

(a) an analysis of the results of the [...] controls provided for in Article 32 (2);

(b) an analysis of the reasons why the MRLs were exceeded, together with any appropriate observations regarding risk management options;

(c) [...] an analysis of chronic and acute risks to the health of consumers from pesticide residues;

(d) an assessment of consumer exposure to pesticide residues based on the information provided under point (a) and any other relevant available information, including reports submitted under Directive 96/23/EEC.

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

3(bis) The format of the [...] Annual Report may be decided in accordance with the procedure referred to in Article 49(2).

4. The Authority shall submit the [...] Annual Report on Pesticide Residues to the Commission by 31 December each year.

4(bis) The report may include an opinion on the pesticides to be covered in future programmes.

5. The Authority shall make the Report, as well as any comments by the Commission or Member State concerned, public.

Article 40
Submission of the [...] *Annual Report on Pesticide Residues to the Committee*

The Commission shall submit the [...] Annual Report on Pesticide Residues to the Committee referred to in Article 49(1) without delay, for review and recommendations on any necessary measures to be taken regarding reported infringements of the MRLs set out in Annexes II and III.

SECTION 5
[...] SANCTIONS

Article 41
[...] *Sanctions*

The Member States shall lay down the rules on [...] sanctions applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The [...] sanctions 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 [...]

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.

Chapter VII
Support measures for the application of harmonised pesticide MRLs [...]

Article 43
Support measures for the application of harmonised pesticide MRLs [...]

1. Support measures for the application of harmonised pesticide MRLs [...] shall be established at Community level, including:

(a) a consolidated 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.

(e) studies necessary to support control laboratories where analytical methods are not capable of controlling the MRLs established.[27]

[27] New text agreed.

2. Any necessary implementing provisions concerning the measures referred to in paragraph 1 may be adopted in accordance with the procedure referred to in Article 49(2).

Article 44[28]
Community contribution to the support measures for harmonised pesticide MRLs

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

The appropriations shall be authorised each financial year in the framework of the budgetary procedure.

Chapter VIII
Co-ordination of applications for MRLs

Article 45
Designation of national authorities

Each Member State shall designate [...] one or more national authorities to co-ordinate co-operation with the Commission, the Authority, other Member States, manufacturers, producers, and growers for the purposes of this Regulation. Where more than one authority is designated by a Member State, it shall indicate which of the designated authorities shall act as a contact point.

The national authorities may delegate tasks to other bodies. [...].

Each Member State shall inform the Commission and the Authority of the names and addresses of the designated national authorities.

[28] The Commission might be in the position to make the following declaration: "The Commission will maintain its current practice of consulting with Member States in the framework of the Standing Committee with respect to the implementing measures referred to in Article 43."

Article 46
*Co-ordination by the Authority of **information on** 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 the Member States and the Commission **regarding MRLs, in particular, for the purpose of fulfilling the requirements of Article 31.**

[...]

Article 30
Information to be submitted by the Member States

Member States shall submit to the Authority, at its request [...] any available [...] information necessary for the assessment of the safety of MRLs.

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.

Article 47
Member States and Fees

1. Member States may recover the costs of work associated with setting, modifying or deleting MRLs or import tolerances, or with any other work arising from obligations in this Regulation, by means of a fee or charge.

2. Member States shall ensure that the fee or charge referred to in paragraph 1:

   (a) is established in a transparent manner; and
   (b) corresponds to the real cost of the work involved.

It may include a scale of fixed charges based on average costs for the work referred to in paragraph 1.

Chapter IX
Implementation

Article 48
Scientific opinion of the Authority

The Commission or the Member States 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.

3. The Committee shall adopt its rules of Procedure.

Article 50
Implementing measures

In accordance with the procedure referred to in Article 49 (2), and, where appropriate, taking into account the opinion of the Authority, 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, Article 35(2), Article 36(3), Article 37(1), and Article 39(4).

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

(g) detailed rules concerning the scientific data required for the setting of MRLs.

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 and adaptation of legislation

1. Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC are repealed with effect from the date referred to in the [...] **first** indent of Article 54.

   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.

2. Article 4(1)f of Directive 91/414 is replaced by the following: **"Where appropriate, the MRLs in the agricultural products referred to in the authorisation have been set or modified in accordance with Regulation XXX/04."**[29]

Article 53
Transitional Measures

1. The requirements of Chapter III of the present Regulation shall not apply to products lawfully produced or imported into the Community before the date referred to in Article 54 [...] **first indent**.

   However, in order to ensure a high level of consumer protection appropriate measures concerning those products may be taken in accordance with the procedure referred to in Article 49(2).

2. Where it is necessary in order to allow for the normal marketing, processing and consumption of products, further transitional measures may be laid down for the implementation of certain MRLs provided for in Articles 18, 19, 23, 26, **and** 27. [...]

[29] For the sake of legal clarity, it is necessary to adapt the provisions in Article 4(1) of Directive 91/414/EEC in the light of the outcome of the present discussions.

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*

- Chapters II, III and V shall apply as from **6 months** from the publication of the regulation establishing annexes I, II, III and IV.

- 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*