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QUESTIONS AND ANSWERS ON THE PROCEDURE TO OBTAIN IMPORT TOLERANCES AND THE INCLUSION OF ACTIVE SUBSTANCES FOR PLANT PROTECTION USES IN THE EUROPEAN COMMUNITIES LIST

Communication from the European Communities

The following communication, dated 21 March 2005, is being circulated at the request of the Delegation of the European Communities.

Purpose of this paper

The European Communities (EC) SPS Enquiry Point has received recently numerous questions related to the withdrawal of active substances from Council Directive 91/414/EEC[1] on plant protection products (PPP). The questions have come as comments to EC proposals being notified to the Agreement and during the WTO Trade Policy Review Mechanism (TPRM) of the European Communities. This is also a recurrent issue in the regular meetings of the Committee on Sanitary and Phytosanitary Measures (SPS).

A majority of questions show concern on whether Maximum Residue Levels (MRL) set by Codex would be systematically dropped when a marketing authorization for an active substance is withdrawn. Others deal with the establishment of an MRL for a combination of PPP and imported agricultural product (i.e. "import tolerances") or the registration of active substances.

This paper aims to summarize the questions and responses provided by the EC SPS Enquiry Point and provides greater details than in the original responses.

[1] On the placing of plant protection products on the market (Official Journal L 230, 19/08/1991 pp.:1-32).

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I. THE PRESENT EC SYSTEM TO REGISTER PLANT PROTECTION PRODUCTS

1. The main policy instrument to ensure safety of a crop protection product is the Plant Protection Products (PPP) Directive 91/414/EEC. This Directive concerns the authorization, placing on the market; use and control within the European Communities of PPP in commercial form and of active substances used to protect plants or plant products against harmful organisms. EC member States will not allow a PPP to be placed on the market and used in its territory unless it has been authorized in accordance with the principles and procedures set out in this Directive. EC member States also ensure that a PPP is not authorized unless its active substances are listed in Annex I to the Directive and any conditions laid down therein are fulfilled. Under Article 15 of this Directive the conditions for packaging and labelling of PPP are listed. Modifications to this Directive are notified to the WTO Agreement on Technical Barriers to Trade (TBT).

2. Pesticide residues in food are regulated by four Council Directives: 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EC. A Commission proposal notified in G/SPS/N/EEC/196 (11 April 2003) to consolidate and amend these is currently being discussed in the Parliament and the Council.[2] The legislation covers the setting, monitoring and control of pesticide residues in products of plant and animal origin that may arise from their use in plant protection.

3. The maximum levels set are those consistent with good agricultural practice in EC member States and third countries. The levels are set after an evaluation of any risks to consumers of different age groups and they are only set if they are considered safe. The levels are intended to facilitate trade and are not toxicological limits. Any level that exceeds a maximum level is more an indication of an incorrect use of a pesticide than a risk to the consumer. Nonetheless, excedence is closely monitored, evaluated and communicated to the authorities in the EC member States through the Rapid Alert system for food whenever there is a potential risk to consumers.

4. More information can be found in the SANCO web in:

http://europa.eu.int/comm/dgs/health_consumer/index_en.htm

An overview of the existing system is available in:

http://europa.eu.int/comm/food/plant/protection/index_en.htm

A. WHAT IS CONTROLLED?

5. In a pesticide there is an active ingredient that is effective against a target pest (insect, weed or fungus) and that usually is the only component of the formulation listed on the pesticide label. Nevertheless, active or inactive isomers of the main active substance, contaminants and impurities are often a part of the pesticide product and can also cause adverse effects and are also responsible for product hazards. As a way of example, Dioxin and DDT are contaminants, which have not been purposefully added to pesticide formulae, but are a by-product of the "production process". In the European Communities, the control falls on the "Marker residue".

6. Marker residues are important for determining compliance with MRLs and related enforcement purposes; in virtually all instances it is a single compound although an exception would be stereo-isomers with the same general chemical structure but different geometrical configurations.

[2] An interactive Policy Making (IPM) online consultation on the Proposal concerning Amendments made to the Council Directive 91/414/EEC of 15 July 1991 concerning the Placing of Plant Protection Products on the Market has just been launched by DG SANCO of the European Commission. This consultation is open to all stakeholders both within the EU and outside and can be found at:
http://europa.eu.int/yourvoice/forms/dispatch?form=392&lang=EN

Adherence to a single marker residue has several advantages for food control authorities: (1) results on a single analytical method control, (2) allows more monitoring and surveillance of residues in vegetables and food animals, and (3) reduces the analytical uncertainties associated with residue analysis when compared with those situations in which more than one analysis may be required to determine compliance with an MRL.

B. HOW IS THIS INFORMATION FOUND

7. This information (i.e. the "product profile") is obtained from the molecule sponsor[3] who, in submitting an application, includes in the data studies of total residue depletion and metabolism studies with radiolabel compound in species for which approval is sought. The carryover to animal products is studied in eggs, milk, and target tissues (usually liver, kidney, or fat) because residues generally deplete from these tissues more slowly than from other. These data will remain the intellectual property of the submitter and be of confidential nature.

C. WHO IS HELD RESPONSIBLE FOR ACTIVE SUBSTANCE PRODUCED OUTSIDE THE EUROPEAN COMMUNITIES?

8. For an active substance produced outside the European Communities *"producer"* means the person established within the Community and designated by the manufacturer of an active substance as his sole representative or where no such person has been so designated, the importer into the European Communities of that active substance.[4]

D. HOW CAN A TRADING PARTNER FIND GUIDANCE DOCUMENTS FOR REGISTERING ACTIVE SUBSTANCES OR REQUESTING IMPORT TOLERANCES?

9. In the SANCO website described above, there is a specific page on GUIDANCE DOCUMENTS for the implementation of Council Directive 91/414/EEC (Plant Protection Products). Its internet address is:

http://europa.eu.int/comm/food/plant/protection/resources/publications_en.htm

10. Two documents have special relevance; one is document 7196/VI/9938 "Working document guidance notes on Import Tolerances". This document describes the current situation in the European Communities regarding situations, procedures, timetables, data requirements, and financial provisions related to the setting of import tolerances for pesticides residues in foodstuffs and agricultural commodities entering the European Communities. This document contains, among other information:

- a template to describe Good Agricultural Practice in support of an application for an import tolerance in the European Communities;
- a template to report results of supervised residue trials in support of an application for an import tolerance in the European Communities; and
- a summary data sheet to be included with an application for an import tolerance.

[3] "Producer" or "legal representative" if the producer is established outside the European Communities.

[4] Commission Regulation (EC) No 1896/2000 of 7 September 2000 on the first phase of the programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council on biocidal products.

II. THE FUTURE SYSTEM AS NOTIFIED IN G/SPS/N/EEC/196 (11 APRIL 2003)

11. The European Communities notified a proposal for a Regulation that will replace the four basic Council Directives on MRLs for PPP (i.e. Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC[5]) and will harmonize all MRLs through all EC member States after a transitional period. As of its enforcement MRLs will only be set at the EC level.

A. HOW WILL THE PROPOSAL AFFECT FEEDINGSTUFFS AND FOOD PRODUCE FROM OUTSIDE THE EUROPEAN COMMUNITIES?

12. It is a matter of fact that different Good Agricultural Practices (GAP) as regards the use of PPP may be legally applied by trade partners of the European Communities and that these GAP result in MRLs differing from those resulting from uses legally applied in the European Communities. A consequence of this is that to ensure trade as well as facilitate control purposes, there is a need to fix MRLs for imported products that take these GAP into consideration, provided these approved uses (and resulting MRLs) fulfil the same criteria as followed for European Communities. Article 29 of the proposal deals with the setting of *"import tolerances"*.

B. HOW ARE IMPORT TOLERANCES SET IN THE NEW PROPOSAL?

13. *Import tolerance* is defined as "a MRL based on a Codex 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 European Communities; or (b) an existing MRL is not sufficient to meet the needs of international trade".

C. WHO CAN APPLY FOR IMPORT TOLERANCES?

14. Applications for import tolerances may be made by the EC member States, interested parties, including manufacturers, growers, importers and producers of plant protection products applied outside the European Communities.

D. WHEN DO IMPORT TOLERANCES HAVE TO BE REQUESTED?

15. There are three cases where "import tolerances" would be required (Article 29 of proposal), namely if a trader wants to import a commodity:

(a) containing residues of a substance used in the European Communities but where the commodity is not produced in the European Communities e.g. papayas. In this case there would usually be expertise (Rapporteur member State);

(b) treated with a substance no longer or not yet used in the European Communities. In this case, there would normally not be expertise in the European Communities and full toxicological and residues data would be required. A significant workload would

[5] Council Directive 76/895/EEC of 23 November 1976, on the fixing of maximum levels for pesticide residues in and on fruit and vegetables. Official Journal L 340, 09/12/1976 pp.:26-31)

Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals (Official Journal L 221, 07/08/1986 pp.:37 -42)

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 (Official Journal L221, 07/08/1986 pp.:43 -47)

Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables (Official Journal L 350, 14/12/1990 pp.:71-79)

be expected for each individual evaluation - for which there could be many due to our withdrawal of numerous substances from the market[6];

(c) treated with a substance in use in the European Communities but where the foreign GAP allows higher residues than the European Communities' 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.

16. In all cases where a particular PPP is not authorized on a commodity or when no data are available to demonstrate that its residues do not endanger consumer health, no residues may be permitted on this commodity at levels higher than 0.01 mg/kg which is an enforceable default for zero.[7] Exceptions will be made for substances where a level of 0.01 mg/kg is not safe for the consumer by setting MRLs at a lower level.

E. WHY THE EUROPEAN COMMUNITIES CHOOSE 0.01 MG/KG AS A DEFAULT MRL FOR CONTROL PURPOSES ON NON AUTHORIZED SUBSTANCES

17. When a PPP is not authorized no residues may be permitted on any commodity at levels higher than 0.01 mg/kg. 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 control level is conventionally set at 0.01 mg/kg.*

18. 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 uncertainty increases as zero is approached, in fact, 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 of marker residues and agricultural produce. 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.

19. Secondly, for almost all pesticides in use, a MRL at 0.01 mg/kg protects sufficiently the consumer from misuses (excessive use) although in exceptional cases where this is not the case a lower level should be explicitly set.

20. Thirdly, monitoring laboratories do not have the resources to routinely examine every possible crop/substance combination and they have to prioritize 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 one run but multi-residue methods are not as sensitive as methods targeted to detect a specified marker residue at a time but at much lower levels. For verification of compliance it is considered that screening 50 different samples using a multi-residue method screening more than a hundred substances per sample is more protective for the consumer than spending the same time analyzing 10 samples for one substance.

[6] An exception would be for substances that had been evaluated at EC 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.

[7] This also applies to products used outside the European Communities and for which an import tolerance has not been requested.

F. WHAT IS THE MEANING OF SETTING A MRL AT THE LIMIT OF DETERMINATION (LOD)

21. 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 are not arbitrary. 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 the active substance is obsolete and no longer used anywhere although illegal uses and/or contamination cannot be excluded;

(b) No residue is expected and no residues are wanted: e.g. its residues are genotoxic, carcinogenic;

(c) No residues expected because of use pattern: the authorized uses of the substance do not leave residues in the harvested crop, e.g. it is used as a soil or seed dressing or any residues degrade quickly;

(d) No residues expected because the substance is not (yet) used on certain crops: particularly for new substances, in early years of use 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[8];

(e) No residue expected because no longer authorized for use in the European Communities: In 2003, about 400 substances will have been withdrawn from the market and most withdrawals will have been for economic reasons.[9] They might still be used by EC trade partners and residues could still be present on imported produce;

(f) New data indicates that a substance is not as safe as formerly thought and existing MRLs are possibly unsafe although lower levels would be acceptable. In these cases, the MRLs need to be reduced to safe levels. If a GAP exists - giving rise to the lower safe levels- then the MRL can be reduced. If not, the MRL is temporarily set at LOD until 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; and

[8] This will also be true in future for present-day substances because, with the loss of half of all existing substances in 2003, the others will find wider uses.

[9] Producing companies are not interested anymore in manufacturing the molecule because its use has declined or is being replaced by a new (more efficient) molecule often with less toxic residues. A consequence of the withdrawal is that the control authorities are left without a "standard" to calibrate the analytical method to be used in control of compliance.

(h) Insufficient data: Minimum data requirements to set a MRL are not met for a substance/crop combination.

G. DATA TO BE SUBMITTED FOR REGISTRATION OF MOLECULES

22. Since October 2001 the EC member States agreed that as from 31 December 2004, all dossiers submitted by notifiers wishing to have active substances included in Annex I to Directive 91/414/EEC (the Directive), or other interested parties wishing to have other information taken into account by the relevant regulatory authorities should be presented in OECD-format (see below for reference).

23. Applicants and interested parties should use the OECD guidelines and criteria for industry for the preparation and presentation of complete dossiers and of summary dossiers for plant protection products and their active substances in support of regulatory Decisions in OECD countries (Revision 1 March 2001). For new active substances, dossiers in the OECD format are already acceptable. The OECD guidance document is based on and is consistent with the previous European Commission Guidance Document approved by the 11th meeting of the OECD Working Group on pesticides (November 2000).

24. To help industry and other interested parties understand any differences between the existing EC format and the OECD format, a document that compares the two numbering systems has been prepared as a background document to this guidance. This "Comparison List" is available from the SANCO home page[10] under "Guideline on the Preparation and Presentation of Complete Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), (doc. SANCO/10518/2004, 8 October 2004)".

25. This document provides guidance on the submission of dossiers to support the inclusion of an active substance in Annex I. In particular, this document provides guidance on the number and format of dossiers, addresses to which they should be submitted and general contact points. For guidance on the submission of dossiers to support national authorizations, prospective applicants should consult the competent authorities of the relevant EC member States. In preparing Annex III submissions, the OECD guidelines should be followed from 1 July 2006. This document has been conceived as an opinion of the Commission Services and elaborated in co-operation with the member States. The Commission also had comments received from the European Crop Protection Industry (ECPA). This document does not, however, produce legally binding effects and by its nature does not prejudice any measure taken by an EC member State, nor any case-law developed by the European Court of Justice with regard to the interpretation of Directive 91/414/EEC and the legislation made under it.

26. Article 8 (2) of the Directive provides that the Commission will set out all the provisions necessary for the implementation of the review programme for existing active substances. For new active substances it is also in the interest of all parties involved to provide similar guidance. Therefore the Commission and the member States expect that the approach proposed in this document will also be followed for new active substances. When preparing dossiers for submission, applicants and other interested parties are advised to consult the most recent texts of data requirements as set out in Annexes II and III of the Directive. These can be obtained from the SANCO home page under Guidance Documents for the implementation of Council Directive 91/414/EEC.

27. Where additional or more detailed guidance is required on technical points, applicants and other interested parties are advised to refer to the Guidance documents which can be obtained from the SANCO home page under Guidance Documents for the implementation of Council Directive

[10] http://europa.eu.int/comm/food/plant/protection/resources/publications_en.htm

91/414/EEC. If necessary, they should contact the designated authority of the EC member State to which the documentation is to be submitted.

Format

28. The OECD formatting guidelines are available on the OECD homepage.[11] The essential components of the application file[12] ("dossier") are described in Table 1.

CADDY-Format

29. Several EC member States, the European Food Safety Authority (EFSA) and the Commission request that dossiers be submitted in electronic form. Such dossiers will only be accepted if they are compiled in accordance with the Format Specification for CADDY Document Interchange Format for Pesticides Registration Applications.[13]

30. The RMS will check the format of electronic submissions to ensure that they comply with the CADDY format. Submissions in electronic form will *inter alia* reduce the number of paper copies to be submitted. Further information on CADDY is available from the CADDY website at:

http://caddy.ecpa.be

31. Dossiers for new and existing active substances should be submitted to the European Commission and to EFSA in the form of a signed covering letter plus an electronic version of the remainder of the dossier.

Number of dossiers to be submitted

32. Information on the number of copies of dossiers relating to existing and new active substances is available on the DG SANCO home page.

For new active substances:

http://europa.eu.int/comm/food/plant/protection/evaluation/nas_2004.pdf

For existing active substances:

http://europa.eu.int/comm/food/plant/protection/evaluation/eas_2004.pdf

[11] http://www1.oecd.org/ehs/pesticid.htm

[12] Advise on how a dossier should be compiled and structured is available in the OCDE guidance document (see address in footnote 3).

[13] CADDY is an electronic format for the exchange, archiving and evaluation of complex dossiers, developed jointly by industry and regulatory authorities. It was developed for the interchange of plant protection products dossiers, and is currently adopted by the European Commission and member States as the only electronic dossier interchange format. CADDY is a dynamic format; it is continuously improved to follow developments in the evaluation process. In order to harmonize the submissions and to avoid compatibility problems, it is recommended that the standard "table of contents" that is available on the CADDY website is used in all CADDY dossiers.

Addresses and contact points

33. The addresses to which the dossier(s) should be sent are available on the DG SANCO home page under "Contact Points":

http://europa.eu.int/comm/food/plant/protection/evaluation/index_en.htm

Completeness check

34. Electronic versions of the Completeness Check Forms are available on the DG SANCO home page. They should be used for new active substances as well as for dossiers of existing active substances. Link to completeness check evaluation forms at:

http://europa.eu.int/comm/food/plant/protection/evaluation/completeness_en.htm

TABLE I - ESSENTIAL COMPONENTS OF A DOSSIER

	Information requested
A	Statement of the context in which the dossier is submitted
B	Task force information: Where in the context of Article 8 (2) of Directive 91/414/EEC and Commission Regulations made pursuant to that Article, there is an obligation on notifiers of particular existing active substances to *take all reasonable steps to present collectively the dossiers* concerned and, where it is not possible to so present the dossiers - a claim that all reasonable steps were taken to present the dossiers collectively, and documentation to justify the claim made.
C	Where requested, copies of existing or proposed label(s) and where relevant leaflets (see Article 16 (2) of the Directive) for each of the preparations for which an Annex III dossier is submitted and in addition, labels and leaflets relevant to the uses on the basis of which import tolerances are supported or proposed. Where relevant, a translation of the texts of labels and leaflets submitted.
D1	Details of the intended uses (GAPs) (uses that are being supported by the applicant, for which data have been provided or for which data are to be provided by a specified date) and conditions of use (GAPs), on both food and feed crops and on non food and feed crops in the territory of the EU, supported in relation to the proposed inclusion of the active substance in Annex I.
D2	Details of registered uses (GAPs) in EU Member States and an indication of whether, or not, actually used. The listing provided should include those uses which are currently authorized but which are not being supported by the applicant. The information provided with respect to actual use, should identify those authorizations that are not currently availed of (some uses or all uses), and further should describe those instances where the rate and manner of use in practice is more restrictive than is provided for in the existing authorization (e.g. authorized uses of a plant protection product for which the product is not currently commercialized; uses for which the maximum authorized application rate is seldom if ever availed of).
D3	Details of supported uses (GAPs) in exporting countries (non-EU Member States) Details of the intended uses (GAPs) that are being supported by the applicant on both food and feed crops which are imported in significant quantities into the territory of the EU from non-EU Member States and for which import tolerances are required.
E1	Details of existing EU MRLs. Where relevant, details of MRLs established by Member States and details of MRLs established by the CAC or proposed by the CCPR, should also be provided.
E2	Where an import tolerance is required, a listing of the MRLs established for the active substance in countries that export the plants and plant products concerned and in addition, where relevant, a listing of MRLs and import tolerances established in non-EU OECD countries, should be provided.
F	Where relevant, in the case of existing active substances, a copy of each notification submitted to the Commission in the context of the programme of work undertaken for the examination of existing active substances pursuant to Article 8 (2) of the Directive.
G	Unless a dossier in accordance with Annex II is submitted for every formulant included in the preparation (ingredient other than active substance): A statement as to whether the substance is permitted in food, animal feeding stuffs, medicines or cosmetics in accordance with Community legislation.
H	Unless a dossier in accordance with Annex II is submitted for every formulant included in the preparation (ingredient other than active substance): A copy of the safety data sheet prepared in accordance with Directive 67/548/EEC.
I	Unless a dossier in accordance with Annex II is submitted for every formulant included in the preparation (ingredient other than active substance): Where requested, other available toxicological and environmental data.
J	Where relevant and desired, a statement to indicate the data and information involving industrial and commercial secrets for which confidentiality is requested, in accordance with Article 14 of Directive 91/414/EEC. To facilitate the secure handling of such information, it should be included in a separate file, where it is feasible to do so (e.g. details of manufacturing processes, detailed specifications of active substance and preparations and individual medical records). The file should be identified as containing industrial and commercial secrets.
K	Individual test and study reports in accordance with the requirements of 91/414/EEC. Separate dossiers should be provided for the active substance and formulated products. Where dossiers are submitted that concern more than one formulation, a separate Annex III dossier must be provided

	Information requested
	for each plant protection product. Dossiers for additional plant protection products should be identified and numbered as indicated below. - KIIA Individual test and study reports for the active substance - KIIIA1 Individual test and study reports for the 1st formulated product - KIIIA2[14] Individual test and study reports for the 2nd formulated product **Note:** Dossiers containing from supervised residue trials data (Annex point IIA 6.3) for more than one crop, it is recommended that the data are organized as follows: - IIA 6.3.1 Crop 1 (e.g. wheat) - IIA 6.3.2 Crop 2(e.g. oilseed rape) - IIA 6.3.3 Crop 3 - IIA 6.3.4 Crop 4, etc.
L-N	A summary, evaluation and assessment of the dossier of data submitted by the applicant, prepared in accordance with the tiered structure outlined below: Where dossiers are submitted that concern more than one formulation, a separate Annex III dossier must be provided for each plant protection product. Dossiers for additional plant protection products should be identified and numbered as indicated below.
L	Reports (Tier 1 Summaries) as to the quality of the individual tests and studies submitted and a list of study reports and documents submitted. - LIIA Tier 1 Summaries for the active substance - LIIIA1 Tier 1 Summaries for the 1st formulated product - LIIIA2* Tier 1 Summaries for the 2nd formulated product Reference lists for the active substance, 1st formulated product and from 2nd formulated product* (sorted according annex points and authors)
M	Tier 2 summaries. Comprehensive summaries and assessments of individual tests and studies' and groups of tests and studies, as appropriate, in the light of relevant evaluative and decision making criteria. - MIIA - Tier 2 Summaries for the active substance - MIIIA1 - Tier 2 Summaries for the 1st formulated product - MIIIA2* - Tier 2 Summaries for the 2nd formulated product
N	Tier 3 Summary. An overall summary and assessment of the application in the light of relevant evaluative and decision making criteria, the conclusion reached by the applicant on the basis of the data and information submitted. This summary should include a complete list of regulatory end points and a key to the metabolites and breakdown products identified in animal metabolism studies, crop metabolism studies and appropriate studies conducted with soil, water, sediment etc.
O	A completed set of the forms for checking the completeness of the dossier. 1. for Doc. A – J 2. for Doc. L – N (for active and formulated products together, possibility to include more than one FL is already included) 3. for Doc. KIIA (for active substance 4. for Doc. KIIIA1 (for 1st formulated product) for Doc. KIIIA2* (for 2nd formulated product)

[14] Where a data package contains more than one Annex III dossier.

TEMPLATE TO DESCRIBE GOOD AGRICULTURAL PRACTICE IN SUPPORT OF AN APPLICATION FOR AN IMPORT TOLERANCE IN THE EUROPEAN COMMUNITY

Crop and/ or situation (a)	**Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	Growth Stage & season (j)	Number Min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		

Remarks: (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soilborne insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench etc.
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Template to report results of supervised residue trials in support of an application for an import tolerance in the European Community

Active substance (common name) :
Crop/crop group :
Responsible body for reporting (name, address) :
Country :
Content of active substance (g/kg or g/L) :
Formulation (*e.g.* WP) :
Commercial Product (name) :
Producer of commercial product :
Indoor/Glasshouse/Outdoor :
Other active substance in the formulation (common name and content):
Residues calculated as :

1	2	3	4	5			6	7	8	9	10	11
Report No. Location (region)	Commodity/ Variety	Date of 1. Sowing or Planting 2. Flowering 3. Harvest	Method of treatment	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Remarks:
	(a)	(b)	(c)	kg as/hL	Water (L/ha)	kg as/ha	(d)	(e)	(a)		(f)	(g)

(a) According to EEC and Codex classifications (both) should be used
(b) Only if relevant
(c) High or low volume spaying, spreading, dusting *etc.*, overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4),
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
(g) Remarks may include: Climatic conditions; Reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

Note: All entries to be filled as appropriate

SUMMARY DATA SHEET TO BE INCLUDED WITH AN APPLICATION FOR AN IMPORT TOLERANCE

Active substance:
Residue definition:
Commodity for which MRL to be set:
The requested import tolerance is:
The (proposed) ADI is:
The (proposed) ARfD is:

Existing data

There is no/an EC MRL (value = mg/kg; fixed in Directive)

The ADI for this substance of mg/kg bw/day was fixed in 19 by .

The ARfD for this substance of mg/kg bw was fixed in 19 by .

Implication of granting import tolerance

Granting this import tolerance: % ADI (adult) based on and
% ADI (infant/child) based on .

and: % ARfD (adult) based on and
% ARfD (infant/child) based on .

Supporting data provided

1. Residue definition and analytical methods ☐
2. Description of GAP ☐
3. Supervised trials data ☐
4. Residue behaviour data ☐
5. Proposed import tolerance/MRL ☐
6. Toxicological summaries/full data package ☐
7. Consumer intake assessments (adult and children) ☐
8. Other information ☐

Background to the request

Additional information

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