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DATA REQUIREMENTS FOR PESTICIDE REGISTRATION IN OECD MEMBER COUNTRIES: SURVEY RESULTS

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris 1994

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Environment Directorate

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Foreword

A survey of data requirements for pesticide registration in OECD countries was one of several projects carried out, as part of the work of the OECD Environment Programme, under a one-year Pesticide Project initiated in June 1992. Work on pesticides was expanded in 1994 with the establishment of a three-year Pesticide Programme that includes projects on data requirements for biological pesticides, test guidelines, hazard assessment, re-registration, and risk reduction.

The Joint Meeting of the Chemicals Group and Management Committee recommended that this report be derestricted. It has been made public under the authority of the Secretary-General.

Contents

Annexes

Résumé

Le présent rapport contient les résultats d'une enquête réalisée par l'OCDE en 1992-1993 sur les données requises pour l'homologation des pesticides. Cette enquête constituait l'un des divers projets réalisés dans le cadre du Programme de l'OCDE sur l'environnement au titre d'un projet d'un an sur les pesticides lançé en juin 1992. Des réponses ont été reçues de dix-sept pays Membres de l'OCDE, ainsi que de la Commission des Communautés européennes. Si cette enquête visait essentiellement les produits phytosanitaires classiques, elle portait également (mais de façon moins détaillée) sur les pesticides biologiques et autres, c'est-à-dire d'autres produits chimiques qui pourraient être considérés comme faisant fonction de pesticides mais qui peuvent ou pas être reconnus ou réglementés comme des pesticides.

L'enquête sur les données requises a été lancée à la demande de la Réunion conjointe du Groupe des produits chimiques et du Comité de gestion du Programme spécial sur le contrôle des produits chimiques, conformément à des recommandations formulées lors de précédentes réunions de l'OCDE et d'autres rencontres internationales. Ce projet visait à établir un inventaire des données actuellement requises au plan national concernant les pesticides dans la perspective d'une intensification de la coopération internationale en matière d'homologation et d'analyse des pesticides.

Les travaux dans ce domaine ont, en fin de compte, pour objectif de rendre les pays Membres de l'OCDE mieux à même d'accepter réciproquement des données et des analyses de données, ce qui leur permettrait de se répartir la charge de l'homologation des pesticides et de son renouvellement. Une plus grande harmonisation internationale des données requises sur les pesticides aurait, en outre, pour effet de réduire les doubles emplois dans les essais incombant à l'industrie, donc d'économiser les ressources et d'éviter le sacrifice inutile d'animaux, ainsi que de réduire les obstacles aux échanges.

Méthode de l'enquête

Le questionnaire a été conçu de façon à permettre aux pays Membres d'indiquer les données qu'ils demandent actuellement pour l'homologation des pesticides. Il comportait deux parties. La partie 1 demandait des informations générales telles que :

1) processus d'homologation (grandes lignes) ;
2) classification et étiquetage ;
3) essais séquentiels ;
4) dispense de fournir certaines données exigibles ;
5) pesticides biologiques et obtenus par des méthodes biologiques ;
6) ingrédients neutres ; et
7) produits utilisés comme pesticides autres que ceux qui servent à la protection des plantes cultivées (catégories de déclaration/agrément).

La deuxième partie du questionnaire comportait une liste précise de données requises sur les produits phytosanitaires. Les pays étaient invités à remplir une série de tableaux indiquant les données requises dans les catégories d'essais suivantes :

1) identité chimique ;
2) propriétés physico-chimiques ;
3) fonction, mode d'action, manutention ;
4) méthodes analytiques ;
5) efficacité ;
6) destination et comportement dans l'environnement ;
7) chimie des résidus ;
8) toxicologie et métabolisme ; et
9) écotoxicologie.

Après avoir rempli les tableaux de la partie 2, les pays étaient invités à indiquer pour chaque élément de données : 1) si la conformité aux Principes de bonnes pratiques de laboratoire (BPL) était requise et, 2) la fréquence avec laquelle l'élément de donnée considéré était demandé. Le questionnaire comportait une liste détaillée des éléments de données pouvant figurer dans chaque catégorie d'essai, et laissait aux pays Membres de la place pour ajouter des éléments complémentaires. Un espace était aussi réservé aux commentaires.

Réponses à l'enquête

Les réponses ont montré que les données requises et les méthodes d'homologation pour les produits phytosanitaires classiques dans les pays de l'OCDE et dans ceux de la CEE présentaient déjà un degré élevé de similitude. Dans la plupart des grandes catégories d'essais, on relevait d'importants points communs, tant dans les éléments de données eux-mêmes que dans la fréquence à laquelle ils étaient demandés. Les exigences des pays se ressemblaient aussi, s'agissant des éléments de données requis pour la matière active ou pour la préparation. Pour certaines catégories d'essais, les besoins étaient semblables, en ce sens qu'ils dépendaient du mode d'utilisation du pesticide : dans des locaux ou en plein air.

Il ressort également des réponses que de nombreux pays ont adopté des stratégies semblables dans la mise en oeuvre des exigences en matière de données requises pour l'homologation de produits phytosanitaires. Toutes les personnes qui ont répondu ont précisé que leur pays avait défini les données requises pour de nouvelles homologations. La plupart des pays disposaient, en outre, de programmes pour le renouvellement de l'homologation d'anciens produits pesticides, et exigeaient, dans la plupart de ces programmes, des données sur les ingrédients neutres du pesticide. La plupart des pays ont indiqué qu'ils répartissaient les données en séquences ; tous ont précisé qu'ils avaient la possibilité de renoncer à exiger certaines données.

Malgré ces recoupements notables des données requises et des méthodes générales d'homologation, l'enquête a également révélé d'importants domaines de divergence. Toutes les catégories d'essai présentaient des différences mineures, aussi bien dans la fréquence avec laquelle des essais étaient requis que dans les essais complémentaires exigés seulement par un pays ou quelques-uns. Deux catégories d'essais, efficacité et écotoxicologie, accusaient des différences assez marquées. Les deux domaines où l'on a constaté les plus fortes divergences sont : les données requises pour les pesticides biologiques, et les dispositifs réglementaires appliqués à des pesticides autres que des produits phytosanitaires.

Les réponses à la partie 1 du questionnaire figurent dans l'**Annexe 1**, à titre de référence, la partie 1 du questionnaire est reproduite à l'**Annexe 2.**

Les réponses à la partie 2 du questionnaire sont présentées dans deux ensembles de tableaux. Les tableaux de l'**Annexe 3** récapitulent les réponses des pays, le nombre de pays exigeant chaque élément de données étant indiqué en regard de celui-ci. Les tableaux de l'**Annexe 4** présentent les réponses de pays donnés.

Introduction

This report presents the results of an OECD survey conducted in 1992-1993 on data requirements for pesticide registration. Seventeen OECD Member countries and the Commission of the European Communities responded. While the survey focused principally on conventional plant protection products, it also addressed (but in less detail) biological pesticides and other pesticidal products, i.e. other chemicals that could be regarded as performing a pesticidal function but which may or may not be identified and regulated as pesticides.

The data requirements survey was initiated at the request of the Joint Meeting of the Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals, in keeping with recommendations of earlier OECD and other international meetings. The purpose of the project was to develop an inventory of current national data requirements for pesticides, in order to prepare the way for future efforts to increase international co-operation in pesticide registration and review.

The ultimate goal of work in this area is to increase OECD countries' ability to accept each other's data and data reviews, making it possible for them to share the burden of registration and re-registration of pesticides. Greater international harmonization of pesticide data requirements could also reduce the need for duplicative testing by industry, thereby saving resources and preventing unnecessary loss of animal life, and could help ease barriers to trade.

Survey Method

A questionnaire designed to allow OECD countries to identify their current pesticide data requirements was developed with assistance from the United States Environmental Protection Agency, which seconded a staff member to the OECD Secretariat to serve as consultant on the data requirements project. The questionnaire was also reviewed and approved by a Steering Committee composed of representatives from Germany, Sweden, the United States, the European Community, and the pesticide industry. The questionnaire was mailed to all OECD countries in August 1992. It was requested that questionnaires be completed and returned by 1 December 1992.

The questionnaire was divided into two parts. Part 1 requested general information on:

1) the registration process (overview);
2) classification and labelling;
3) tier testing;
4) waivers of certain data requirements;
5) biological and biologically derived pesticides;
6) inert ingredients; and
7) pesticidal products other than those used for plant protection (types of notification/ approval).

Part 2 of the questionnaire requested a specific listing of data requirements for plant protection products. Countries were asked to complete a series of matrices showing these requirements for the following test areas:

1) chemical identity;
2) physical-chemical properties;
3) function, mode of action, handling;
4) analytical methods;
5) efficacy;
6) fate and behaviour in the environment;
7) residue chemistry;
8) toxicology and metabolism; and
9) ecotoxicology.

When completing the Part 2 matrices, countries were asked to indicate for each data element: 1) whether compliance with principles of Good Laboratory Practice (GLP) was required; and 2) how often the data element was required, i.e. always, frequently (in more than 80 per cent of registration submissions), less frequently (in fewer than 80 per cent of registration submissions), or not required. The questionnaire contained an extensive listing of possible data elements in each test area, and provided space for countries to include additional elements. Space was also left for comments.

Summary of Responses

Seventeen Member countries and the Commission of the European Communities (CEC) completed the questionnaire. The countries were: Australia, Austria, Canada, Denmark, Finland, Germany, Italy, Japan, the Netherlands, New Zealand, Norway, Portugal, Sweden, Switzerland, Turkey, the United Kingdom and the United States. Belgium, France and Ireland did not complete the questionnaire, but indicated that the CEC replied on their behalf.

The responses indicated that there was already a high degree of similarity in the data required by OECD countries and by the CEC for registration of conventional plant protection products. In most major test areas, there was significant commonality both in the data elements themselves and in the frequency with which they were required. Countries' requirements were also similar in regard to whether the data element was required for the active ingredient or for the formulation. In certain test areas, their requirements were similar in being dependent on whether the pesticide was to be used indoors or outdoors.

The responses also indicated that many countries have adopted similar approaches to implementing their data requirements for registration of plant protection products. All respondants said their country had established data requirements for new registrations. Most countries also had re-registration programmes for old pesticide products, and most required data on pesticide inert ingredients. Most countries said they organised their data requirements in tiers; all said they had the flexibility to waive some data requirements.

Despite this substantial overlap in data requirements and general registration approaches, the survey also revealed some important areas of divergence. All test areas showed minor differences, both in the frequency with which tests were required and in the additional tests required by only one or by a few countries. Two test areas, efficacy and

ecotoxicology, showed fairly substantial differences. The two areas where countries diverged most sharply were: data requirements for biological pesticides; and regulatory approaches for pesticides other than plant protection products.

Survey Results: Part 1

Responses to Part 1 of the questionnaire are presented in **Annex 1**. Each table follows the format of the related section of the questionnaire (for example, "Table 1. Overview of the Registration Process" corresponds to the Questionnaire's "Part 1, Section 1. Overview of the Registration Process"). Where countries provided additional comments, they are indicated by notes to the tables [e.g. "(a)"]. These comments follow Table 8.

The summaries below were developed from Tables 1-8. They are intended to show where common practices and policies exist among countries. For reference, Part 1 of the questionnaire is included in **Annex 2**.

Overview of the Registration Process (Table 1)

The survey results showed that all responding countries had established data requirements for new pesticide registrations, and that most (all but three) had programmes for re-evaluating, or re-registering, plant protection products. (Many countries provided copies of registration forms, regulations and other documents. These are available from the OECD's Environmental Health and Safety Division.) A majority of the responding countries indicated that they offered different types of pesticide registrations other than full registration, such as research/development or experimental approval, emergency approval, or provisional/limited registration. Nearly all responding countries required reporting of other relevant information (such as adverse effects incident reports or epidemiological studies) either during the registration process or after registration was granted.

Classification and Labelling (Table 2)

The survey results showed that all responding countries had a system for classifying plant protection products for the purpose of label warnings/precautions. In addition, all countries indicated that they classified and labelled pesticide products both for acute hazards to humans and for other concerns, such as chronic human health hazard and environment effects. Most countries also used classification and labelling to limit pesticide use to trained personnel (for example, in the case of highly toxic chemicals). Although some countries said they used the same system for classifying/labelling pesticides and industrial chemicals, the majority indicated that their systems for the two types of products were different. Nearly all countries (all but one) indicated that they had a classification/labelling system for pesticide transport and shipping; most said this system was the same as that used for industrial chemicals.

Tier Testing (Table 3)

Tier testing refers to the use of a stepped testing sequence in which tests in higher tiers are required only if specified hazard levels or "triggers" are exceeded at earlier stages. The majority of non-EC OECD countries, as well as some EC countries, indicated that they organised their data requirements for plant protection products in tiers. In addition, the CEC indicated that it was discussing a proposal for tier testing. The survey results showed that tier structures were most frequently applied in the areas of ecotoxicology and environmental fate, and less frequently in those of toxicology and metabolism, residue chemistry, and efficacy. Several countries attached diagrams or other documents illustrating the structure of their tiered requirements. These documents are on file at the OECD's Environmental Health and Safety Division.

Waivers (Table 4)

All responding countries and the CEC indicated that they had the flexibility to waive certain data requirements. Only two countries said they used written criteria to evaluate waiver requests, although the CEC indicated that written criteria were currently under discussion. In most cases, countries said that waiver requests were evaluated on a case-by-case basis. The CEC and four non-EC OECD countries indicated that any of the six reasons listed in the questionnaire [physical form of the product, physical-chemical data, (eco)toxicological properties of similar chemicals, use pattern, similarity to an already registered pesticide, and economic grounds] might be used to justify a waiver request. Of these, use pattern was the reason cited by the largest number of countries (all but three) as a basis for waiving certain data requirements.

Biological and Biologically Derived Pesticides (Table 5)

The responses to Section 5 of the questionnaire showed some common trends, but also differences, in how OECD countries approach "biological" pesticides. In this section, countries were asked to define biological and biologically derived pesticides, to indicate whether or not they had developed data requirements in this area, and, if requirements had been developed, to explain how they differed from the requirements for conventional chemical pesticides.

The most common way to define biological/biologically derived pesticides was as microorganisms or microbial pest control agents such as viruses, bacteria, algae, fungi and protozoa. Ten countries and the CEC provided such a definition. Six countries went on to distinguish between microorganisms (as defined above) and biochemical pesticides, which were most often defined as pheromones. Several countries also identified biochemical pesticides as including, for example, natural insect and plant growth regulators, enzymes, and antiobiotics. Three countries added a third category – higher biocontrol agents, macroorganisms, or living biological organisms – consisting of, for example, predatory insects, mites and nemotodes. One country also identified genetically modifed organisms as a separate category. One country defined biological pesticides in terms of their modes of action,

and several indicated that the use rather than the nature of the product was most important for regulatory purposes.

Eight countries and the CEC indicated that they had developed draft or final data requirements/guidelines for biological pesticides. In some cases, countries indicated that these requirements were substantially similar to their requirements for conventional pesticides. Other countries identified the main areas of difference. Most of the countries that indicated they had developed draft or final data requirements attached regulatory documents or filled in the blank matrices supplied with the original questionnaire. These documents are available from the OECD's Environmental Health and Safety Division.

Inert Ingredients (Table 6)

All but one country indicated that specific data or information on the inert ingredients in pesticide formulations were required. Data were most often required in the area of chemical identity, followed by physical-chemical properties, function in formulation, and toxicology and metabolism. The majority of countries also required environmental fate data and analytical methods for inert ingredients.

Types of Notification or Approval for Other Pesticidal Products (Table 7)

The purpose of the final section of Part 1 of the data requirements questionnaire was to gather information on countries' regulatory schemes for other types of pesticides in addition to plant protection products, in order to prepare for future projects to examine data requirements for these pesticides. These other types of pesticides were grouped under four categories: disinfectants, biocides, preservatives, and public health products.

Table 7 shows the countries' responses, coded as follows:

1 = This type of product is subject to the *same registration process and data requirements as plant protection products*;

2 = This type of product is not registered/regulated like plant protection products, with corresponding data requirements, but is *covered by general chemical legislation/regulation, with a requirement for pre-manufacture notification*;

3 = This type of product is not registered/regulated like plant protection products, with corresponding data requirements, but is *covered by general chemical legislation/regulation, with a requirement for pre-market approval*;

4 = This type of product is registered/regulated in some *other* way. (Any explanatory comments supplied by responding countries are available in the original questionnaire responses, on file at the Environmental Health and Safety Division.)

Responses showed a considerable divergence in the regulatory treatment of the four categories of pesticides. No one product in any of the four categories was consistently marked as being regulated in one particular way by all responding countries. Moreover, none of the four categories taken as a whole received a consistent marking. Each of the four categories received a mix of "1's", "2's", "3's" and "4's", indicating that products in these categories are being regulated under different laws or regulations, presumably with different data requirements, in different countries. The public health products category came closest to consensus, with 72 "1's" marked out of a possible 108.

It should be noted that four countries (Australia, Italy, the Netherlands and the United States) and the CEC indicated that all or most products in all four categories were required to undergo registration similar to that required for plant protection products. Several other countries required all or most products in at least two of the four categories to undergo registration similar to that for plant protection products (e.g. Sweden requires this type of registration for biocides, preservatives and public health products; Denmark, for preservatives and public health products; Canada, for public health products, disinfectants and some biocides; Finland, for preservatives, public health products and some biocides).

The divergence in the remaining responses suggests that harmonization of data requirements for these four categories of pesticides could be a more complex task than harmonization of requirements for plant protection products. Although countries were not asked to describe their data requirements for these products, it seems fair to speculate that greater differences will be found than those identified in the case of plant protection products, where existing registration requirements already show considerable overlap.

Ministry Responsible for Reviewing Data Submitted to Support the Registration of Pesticide Products (Table 8)

Table 8 identifies the ministries in each responding country responsible for reviewing data submitted to support the registration of plant protection and other types of pesticide products. This table was developed both to show the areas of authority in each country and to provide contact points for future work on these products.

Survey Results: Part 2

Responses to Part 2 of the questionnaire are displayed in two sets of matrices. The matrices in **Annex 3** summarise countries' responses, with the number of countries requiring each data element indicated. Those in **Annex 4** show individual countries' responses. Each set of matrices follows the questionnaire's format, with separate matrices for each of the nine test areas and a comprehensive listing of data elements in each area. As on the questionnaire, the matrices distinguish between data requirements for the active ingredient vs. the formulation, for indoor uses vs. outdoor uses, and for food/feed uses vs. non-food/non-feed uses, where appropriate.

Countries were asked to indicate how frequently each data element was required during registration of plant protection products. The matrices in Annex 4 indicate *individual country responses for each data element* as follows:

A = this data element is *always* required;

F = this data element is *frequently* required, i.e. in more than 80 per cent of registration submissions;

L = this data element is *less* frequently required, i.e. in less than 80 per cent of registration submissions; and

NR = this data element is *not required*.

The matrices also indicate whether compliance with principles of GLP is required (indicated by "*****") and whether additional comments were provided (indicated by "**c**"). Owing to the extensive number and length of individual countries' comments, they have not been included in this report. However, these comments can be readily accessed in the original questionnaire responses on file at the Environmental Health and Safety Division.

Where a country did not respond (i.e. left the box blank), the corresponding box in the matrix is also left blank.

Responses from the Commission of the European Communities and EC Member States

The changing situation in the European Community with respect to pesticide data requirements presented a dilemma in analysing the survey results. As the CEC stated in its questionnaire response:

> "From the end of July 1993 the data requirements of Directive 91/414/EEC will be in force in all the Member States for active substances not yet placed on the market in the EEC at that time and for plant protection products containing such active substances. For active substances already on the market in the EEC at the end of July 1993 and for the plant protection products containing such active substances the Member States *may* continue to apply their previous national rules concerning data requirements as long as such active substances have not been reevaluated at Community level."

As indicated earlier, Belgium, France and Ireland did not complete the questionnaire, but indicated that they will follow the EEC Directive. For those EC countries responding (i.e. Denmark, Germany, Italy, the Netherlands, Portugal and the United Kingdom), the survey results indicated that some already follow the Directive closely while others have a number of data requirements that are different. Therefore, responses from the EC Member States, as well as the CEC, are shown in the matrices in Annex 4.

The summary matrices in Annex 3, however, are based on the CEC response rather than including individual EC countries' replies. CEC responses are therefore counted as 12 countries, while responses by the individual EC countries are not shown except in cases where a data element was added to the original list. (In the latter situation, responses are shown in parentheses.) This was done to reflect the anticipated compliance of all EC countries with the EEC Directive, and in view of the fact that harmonization of pesticide data requirements among OECD countries represents a task for the future.

Limitations of the Matrices

Several caveats should be kept in mind when reviewing the data requirements matrices.

First, it should be noted that there are inherent limitations associated with this type of questionnaire. For both scientific and practical reasons, most countries exercise some flexibility in their acceptance and assessment of pesticide data. For example, if a good scientific argument can be made for not submitting a data item, most regulatory agencies will take this into consideration. Similarly, if an old study does not comply fully with current principles of GLP but nevertheless meets key scientific criteria, the data may be accepted as valid. This type of flexibility, or "case-by-case" consideration of data, cannot be captured in a matrix box-ticking exercise. This is why space for comments was provided in the questionnaire, and no doubt it is why most countries commented frequently.

It also appeared that the structure of the matrices did not necessarily conform to the structure of individual countries' data requirements. In distinguishing between indoor vs. outdoor and food/feed vs. non-food/non-feed pesticide uses, the questionnaire assumed that certain data requirements might be use-dependent (e.g. environmental fate data would not normally be required for indoor uses) and that countries might have structured their data requirements accordingly. While countries' responses showed a link between requirements and use patterns, some respondants indicated that the distinction is not established in the structuring of the requirements but may be accomplished through the granting of waivers when a data element appears to be relevant. Thus, the questionnaire may not have captured the full extent to which data requirements are influenced by pesticide use patterns in actual practice.

It should also be noted that there may be some overlap between data elements listed in the questionnaire and those data elements added by countries. In most cases, this is likely to have occurred because of differences in terminology. In the toxicology and metabolism test area (Matrix 8), under Mutagenicity, a different problem arises where mutagenicity endpoints and the specific assays used to test them have been listed in different sections.

One further limitation of the survey derives from the fact that pesticide data requirements are not rigid, but are continually changing as the science progresses and as countries and international organisations revise their registration and assessment processes. The need to take into account responses from both the CEC and its Member States is an obvious example.

Summary of Part 2 Findings

The summary matrices in Annex 3 identify general patterns and similarities in pesticide data requirements among OECD countries. Responses showed that in many test areas there is a significant amount of similarity in pesticide data requirements (i.e. data always or frequently required). The greatest similarity occurred in the first four test areas: chemical identity (Matrix 1), physical-chemical properties (Matrix 2), function, mode of action and handling (Matrix 3), and analytical methods (Matrix 4). The greatest differences, and also the lowest occurrence of data elements always or frequently required, were in ecotoxicology (Matrix 9).

Results showed that data requirements are to some extent use-dependent in at least two test areas: fate and behaviour in the environment (Matrix 6) and ecotoxicology (Matrix 9). In these two areas, countries are more likely to require data for outdoor than for indoor uses of a pesticide. This distinction is not as strong in the toxicology and metabolism area (Matrix 8), which also allowed for use-dependent responses. Responses in the latter area show little difference in data requirements for food/feed and non-food/non-feed uses. It is possible, however, that data requirements are more use-dependent in practice than is reflected in this survey. It is likely that some countries follow the same approach as the CEC, which indicated that it currently makes no distinction between indoor and outdoor uses in its data requirements for fate and behaviour in the environment. In practice, countries generally have the authority to waive a requirement if it appears not to be relevant.

The survey also revealed a general pattern of similarity between countries in regard to whether data are required for the active ingredient or for the formulation. Moreover, the responses indicate that common data sets would be different for active ingredients than for formulations. For example, in some test areas, such as toxicology and metabolism (Matrix 8) and ecotoxicology (Matrix 9), data are mainly required for the active ingredient. In other test areas, such as function, mode of action and handling (Matrix 3), data are generally required for the formulation. In still other areas, such as physical-chemical properties (Matrix 2), certain data elements are required for the active ingredient while others are required for the formulation.

Finally, it should be noted that in every test area countries added further data elements to those listed in the questionnaire. A significant number of tests were added in all test areas except analytical methods (Matrix 4). In some cases, it is clear that these added tests reflect special national considerations (e.g. pesticide residues in wool, required in Australia, and toxicity to the silkworm of residues on foliage, required in Japan). In other cases, the added data appear to be required in order to test for the same endpoint as data elements listed in the questionnaire, but with differences in test details such as duration, test species, etc. Other tests added, such as distribution/dissipation in air, accumulation in soil, and run-off (fate and behaviour in the environment), and field tests on beneficial arthropods and honey bees (ecotoxicology), may indicate areas where some countries place more emphasis and require more data on certain effects than do others.

Annexes

Annex 1

Tables Showing Individual Countries' Responses to Part 1 of the Questionnaire: The Registration Process

TABLE 1. OVERVIEW OF THE REGISTRATION PROCESS

Country	1. Established data requirements for new registrations	2. Re-registration (re-evaluation) programme for old products	4. Alternate types of registration				5. Other relevant information must be reported	
			Research/develop	Emergency	Provisional	Other	when applying for registration	after approval
CEC	yes	yes	yes	yes	yes		no	yes
Denmark	yes	yes	yes	yes	no		yes	yes
Germany	yes	yes(a)	yes	yes	no		yes	yes
Italy	yes	yes	yes	no	yes		no	yes
Netherlands	yes	yes	yes	yes	no		yes	yes
Portugal	yes	yes	yes	yes	yes		yes	yes
United Kingdom	yes	yes(b)	yes	yes	yes	only through the New Chemicals Notification Scheme under the EC Dangerous Substances Directive	yes(c)	yes(c)
Australia	yes	yes(d)	yes	yes	yes		yes(e)	yes(e)
Austria	yes	yes(f)	no	no	yes		yes	yes(g)
Canada	yes	yes(h)	yes	yes	yes	minor use registration	yes	yes
Finland	yes	yes(i)	yes	yes	no		yes(j)	yes
Japan	yes	no(k)	no	no	no		no	yes
New Zealand	yes	no(n)	yes	no	yes		no(o)	no
Norway	yes	yes(l)	no	yes	no		yes(m)	
Sweden	yes	yes(p)	yes	yes	no		(q)	
Switzerland	yes	yes(r)	yes	yes	yes		yes	yes(s)
Turkey	yes	no(t)	no	no	no		yes(u)	
United States	yes	yes(v)	yes	yes	yes	companies must submit pre-manf. notices under Toxic Substances Control Act for pesticide intermediates and inerts	yes (w)	yes (x)

TABLE 2. CLASSIFICATION AND LABELLING

Country	1. Class/label system to limit use to trained personnel	2. Class/label system for label warnings based on acute hazard	3. Class/label for other concerns, e.g. chronic health hazard, environmental effects	4. Class/label system same/ different as for industrial chemicals	5.1. Class/label system for transport and shipping	5.2. If yes to 5.1, is system same/different as for industrial chemicals?
CEC	no(a)	yes	yes	different	yes	same(b)
Denmark	yes	yes	yes(c)	same/different(d)	yes	same
Germany	yes(e)	yes	yes(f)	same/different(g)	yes	same
Italy	no	yes	yes(h)	same	yes	same
Netherlands	yes(i)	yes	yes(j)	different	yes	same
Portugal	no(k)	yes	yes(l)	different	yes	same
United Kingdom	yes(m)	yes(n)	yes(o)(p)	different(q)	yes(r)	same
Australia	yes	yes	yes(s)	different(t)	yes	same(u)
Austria	yes	yes	yes(v)	same(w)	yes	same
Canada	yes	yes	yes	same	yes	different
Finland	yes(x)	yes(y)	yes(z)	same	yes	same
Japan	yes	yes	yes(aa)	different	yes	same
New Zealand	yes	yes(ff)	yes(gg)	same	yes	same
Norway	(bb)	yes	yes(cc)	same(dd)	yes(ee)	same
Sweden	yes	yes	yes(hh)	same(ii)	yes	same
Switzerland	yes	yes	yes(jj)	different	yes	same
Turkey	no	yes	yes(kk)	different	no	
United States	yes	yes	yes(ll)	different	yes	same

TABLE 3. TIER TESTING

Country	1. Data requirements are organised in tiers	2a/b. Tier testing formalised or case-by-case in specific test areas											
		environmental fate		residue chemistry		tox & metabolism		ecotoxicology		efficacy		other	
		formalised	case-by-case	formalised	case-by-case	formalised	case-by-case	formalised	case-by-case	formalised	case-by-case	formalised	case-by-case
CEC	(a)												
Denmark	yes	X	X(b)		X(b)		X(b)	X	X(b)		X(b)		X(b)
Germany	yes	X			X		X	X(c)					
Italy	no												
Netherlands	yes	X		X		(X)	X(d)	X		X			X(e)
Portugal	no(f)												
United Kingdom	yes		X(g)					X	X(h)		X		
Australia	yes(i)		X(j)	X		X			X				
Austria	yes		X						X				
Canada	yes	X(k)						X(l)		X			
Finland	no												
Japan	no												
New Zealand	yes		X		X		X		X		X		
Norway	no												
Sweden	yes		X				X		X				
Switzerland	yes		X		X		X		X		X		
Turkey	no												
United States	yes					X		X				X(m)	

TABLE 4. WAIVERS

Country	1. Flexibility to waive certain data requirements based on:							2. Written criteria for waivers or case-by-case evaluation	
	physical form of the product	physical-chemical data	(eco)tox properties of similar chemicals	use pattern	similarity to already registered pesticide	economic grounds	other	written criteria	case-by-case evaluation
CEC	yes	yes	yes	yes	yes	yes		(a)	X
Denmark	yes	yes	no	yes	no	no			X
Germany	yes	no	no	yes	no	no		X	
Italy	yes	yes	yes	yes	yes	yes			X
The Netherlands	yes	no	yes	no(b)	yes	no		X	X(c)
Portugal	yes	yes	yes	yes	yes	yes			X
United Kingdom	no	no	yes	yes	yes	yes			X
Australia	yes	yes	yes(d)	yes	yes/no	yes(e)	Biological(d)		X
Austria	yes	yes	yes	yes(f)	yes(g)	no			X
Canada	yes	yes	no	yes(h)	yes	yes	Scientific grounds(i)		X
Finland	no	no	no	no	no	no			X
Japan	no	no	no	yes(j)	no	no			X
New Zealand	yes	yes	yes	yes	yes	yes			X
Norway	no	no	no	yes	no	yes			X
Sweden							Applicant's rationale/justification(k)		X
Switzerland	yes	yes	yes	yes	yes	yes			X
Turkey	no	no	no	no	yes	no			X
United States	yes	yes	yes	yes	yes	yes			X

TABLE 5. BIOLOGICAL AND BIOLOGICALLY DERIVED PESTICIDES

Country	1. Definition of biological/biologically derived pesticides	2. Data requirements developed	3. Difference between data requirements for biological pesticides and conventional pesticides
CEC	*Substances*: Chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process. *Active substances*: Substances or micro-organisms including viruses, having general or specific action: – against harmful organisms, or – on plants, parts of plants or plant products	yes	In principle, more or less the same data requirements apply, where necessary adapted to the biological nature of the plant protection product.
Denmark	There is no requirement for approval before marketing. Consequently, there is no definition other than §5 in the Chemicals Act.	no	
Germany	– Biological/biologically derived pesticides: products with micro-organisms or viruses as active ingredients – Biochemical pesticides: products with pheromones as active ingredients. These are not legal definitions but reflect current use.	yes	In general, requirements will be adjusted according to the type of biological pest control agent and the use pattern. (Matrices attached.)
Italy	Substances: Chemical elements and their compounds, including any impurity inevitable. Active substances: Substances or micro-organism (incl. viruses), having action against harmful organisms or on plants, parts of plants or plant-products. (Same definition as provided by CEC.)	yes	Ref. Ann II and III EC Directive 91/414, Requirements for Biological Pesticides
The Netherlands	We make no difference in the definition of biological and biologically derived pesticides. In due time we will have the EC definition in our pesticide law in relation to harmonisation (91/414).	yes	In principle, less data requirements apply, where necessary adapted to the biological nature of the plant protection product. A separate application form has been developed in the Netherlands.
Portugal	See EC Directive 91/414.	no(a)	
United Kingdom	Biological agents used as pesticides include naturally occurring bacteria, protozoa, fungi or viruses or their mutants for the control of invertebrate pests, weeds or microbial pathogens of crops (from Appendix 9 of COPR Data Requirements Book).	yes	See attached Appendix 9, Registration Criteria for Biological Agents Used as Pesticides, in COPR Data Requirements Book. Also see completed Matrix 7.

TABLE 5 (CONT). BIOLOGICAL AND BIOLOGICALLY DERIVED PESTICIDES

Country	1. Definition of biological/biologically derived pesticides	2. Data requirements developed	3. Difference between data requirements for biological pesticides and conventional pesticides
Australia	Biological and biologically derived pesticides are those that: destroy, stupefy, inhibit, attract or repel a pest in relation to a plant, a place or a thing; destroy a plant; modify the physiology of a plant so as to alter its natural development, productivity or reproductive capacity; or modify the effect of another agricultural chemical product.	no(b)	
Austria	"Biological pesticides" is not a technical term in Austrian Law – see definition chapter 1, section 1(1). Pheromones, hormones, natural insect and plant growth regulators as well as enzymes are dealt with in the same way as chemicals. Organisms are divided into macro-organisms (e.g. predatory insects), micro-organisms (e.g. bacteria, funghi, protozoa), and genetically modified organisms.	yes	Not yet legally fixed. Will be very similar to the requirements for micro-organisms and viruses as given in EC Directive 91/414. The matrices 1-7 for "biological pesticides" are not filled in because there are different requirements for the different types of organisms mentioned in definition.
Canada	a) microbial pest control agents, e.g. bacteria, algae, fungi, viruses, etc. b) higher biocontrol agents, e.g. insects, mites, nematodes c) pheromones	(c)	re: *Microbial pest control agents (draft guidelines)* – Normally, only environmental toxicology data are required. However, if these data indicate a concern, then environmental fate data will be required at the Tier II level. – The guidelines are at the draft stage and have not been finalised. – Identification, taxonomy data specific to microbials as are toxicology requirements, e.g. infectivity studies.
Finland	No official definition of biological pesticides (no separate legislation for those products either). In the pesticide law, however, it is the purpose of use which is the most essential point, not the nature of the "product". Thus the pesticide law is applied to some extent when registering biological pesticides. "Living biological organisms", for instance natural enemies, are not regulated at the moment.	no(d)	

TABLE 5 (CONT). BIOLOGICAL AND BIOLOGICALLY DERIVED PESTICIDES

Country	1. Definition of biological/biologically derived pesticides	2. Data requirements developed	3. Difference between data requirements for biological pesticides and conventional pesticides
Japan	– Biological pesticides mean natural enemies including microbial pest control agents, used for control of fungi, nematodes, mites, insects, rodents, or other animals and plants or viruses which are injurious to crops. – Biologically derived pesticides mean biochemical pest control agents, e.g. pheromones, hormones, natural insect and plant growth regulators, and antibiotics.	no	– These data requirements for biological pesticides are case-by-case now, and developed data requirements are being investigated. – In principle, these data requirements for biologically derived pesticides are not different from those for conventional chemical pesticides.
New Zealand	Substances or mixtures of substances that contain microbial pathogens (such as bacteria, fungi, nematodes, protozoa, Rickettsia, or viruses, or their mutants) *and* intended for use in controlling invertebrate pests, weeds or crop pathogens.	yes	Similar procedures and general requirements but less attention to chemistry and more on biological identity, purity and infectivity. (guidelines attached)
Norway	Biological pesticides include microbial pest control agents, e.g. bacteria, algae, fungi, viruses and protozoa. Biologically derived pesticides are defined as chemical pesticides.	no (e)	
Sweden	As stated in the Swedish Act on Pre-testing of Biological Pesticides, biological pesticides comprise micro-organisms (bacteria, fungi, algae), viruses, nematodes, insects and mites. As regards biochemical pest control agents, these are generally treated as chemical pesticides but are in specific cases subject to a lower level of test requirements (e.g. pheromones).	(f)	
Switzerland	Biological pesticides are living organisms. (regulatory document attached)	yes	(document attached)
Turkey	Biological and biologically derived pesticides include Microbial Pest Control Agents: pheromones, hormones, insect and plant growth regulators.	no	
United States	Microbial pest control agents are micro-organisms and include, but are not limited to, bacteria, fungi, viruses and protozoa. Biochemical pesticides generally fall into the following functional classes: semiochemicals, hormones, natural plant regulators, natural insect growth regulators and enzymes. They are naturally occurring and have modes of action that are non-toxic.	yes	Special requirements for Microbial pesticides are encoded at 40 CFR Part 158.740. Requirements for Biochemical pesticides are encoded at 40 CFR Part 158.690.

TABLE 6. INERT INGREDIENTS

Country	1. Specific data or information required on inert ingredients	2. Areas for which data are required								
		chemical identity	physical-chemical properties	function in formulation	analytical methods	environ-mental fate	residue chemistry	toxicology and metabolism	ecotox-icology	other
CEC	yes(a)	X	X	X	X	X	X	X	X	
Denmark	yes	X	X	X				(X)		
Germany	yes	X	X	X	X	X(b)	X(c)			
Italy	yes(a)	X	X	X	X	X	X	X	X	
The Netherlands	yes(a)	X	X	X	X	X	X	X	X	
Portugal	yes	X	X	X	X	X	X	X	X	
United Kingdom	yes	X		X						case-by-case basis
Australia	yes	X	X	X	X	X		X	X	
Austria	yes	X	X		X	X		X	X	
Canada	yes	X	X	X	X	X(d)		X(d)		
Finland	yes	X	X	X	X(e)	X(e)	X(e)	X(e)	X(e)	
Japan	yes	X	X	X	X			X		
New Zealand	yes	X	(g)	(g)	(g)	(g)	(g)	(g)	(g)	(g)
Norway	yes	X								X(f)
Sweden	(h)									X(h)
Switzerland	yes	X	X	X	X	X	X	X	X	
Turkey	no									
United States	yes(i)	X	X	X		X	X	X	X	

TABLE 7. TYPES OF NOTIFICATION OR APPROVAL FOR OTHER PESTICIDAL PRODUCTS

1 = Registration similar to plant protection products required
2 = Covered by general chemical legislation or regulation: pre-manufacture notification
3 = Covered by general chemical legislation or regulation: pre-market approval
4 = Other

Country	Disinfectants				Biocides					
	general	skin	swimming pool	food industry	general	sanitary	air conditioning	industrial	specialist	anti fouling
CEC	1(a)	1	1	1	1	1	1	1	1	1
Denmark	2	2	2	2	2	2	2	1, 2, 4	1, 2, 4	2
Germany	1, 4	1, 4	4	1, 4	4	4	4	4	4	4
Italy	1, 3	1, 3	1, 3	1, 3	1, 3	1,3	1, 3	1, 3	1, 3	1, 3
Netherlands	1	1, 4	1	1	1	1	1	1	1	1
Portugal	4	4	4	4	4	4	4	4	4	4
United Kingdom		1, 4	4		1, 2, 4	2, 4	2, 4	2, 4	2, 4	1
Australia			1	1	1		1	1	1	1
Austria	3, 4	1, 3, 4	3, 4	3, 4	3, 4	3, 4	3, 4	3, 4	3, 4	3, 4
Canada	1, 3	1	1, 3, 4	1	1, 3	1, 3, 4	1, 3, 4	3	3	3
Finland	4	3, 4	4	4	4	4	4	1, 3	4	1, 3
Japan	2	1	1		2	2, 3	2	2	2	2
New Zealand	2	1, 2, 3	2, 3	2, 3	2	2	2	2	2	1
Norway	1, 3, 4	1, 3, 4		4	4	4	4	4	4	4
Sweden	4	4	4	4	1	1	4	1, 4		1
Switzerland	3	3	3	3	3	3	3	3	3	1, 3
Turkey	2	2	2	2						
United States	1		1	1	1	1	1	1	1	1

TABLE 7 (CONT). TYPES OF NOTIFICATION OR APPROVAL FOR OTHER PESTICIDAL PRODUCTS

1 = Registration similar to plant protection products required
2 = Covered by general chemical legislation or regulation: pre-manufacture notification
3 = Covered by general chemical legislation or regulation: pre-market approval
4 = Other

Country	Preservatives				Public Health Products					
	wood	textile	masonry	consumer product	rodenticide	avicide	molluscicide	insecticide/acaricide	ectoparasite controls	mosquito repellant
CEC	1	1	1	1	1	1	1	1	1(b)	1
Denmark	1	1	2	2	1, 4	4	1	1	1, 4	1, 4
Germany	1, 3, 4	4	3, 4	4	1	4	1	1	4	4
Italy	1, 3	1, 3	1, 3	1, 3	1, 3	1, 3	1, 3	1, 3	1, 3	1, 3
Netherlands	1	1	1	1	1					
Portugal	1, 3, 4	4	4	4	1, 3, 4	1, 3, 4	1, 3, 4	4	4	4
United Kingdom					1	1	1	1	1	1
Australia	1	1			1	1	1	1	1, 4	1
Austria	3, 4	3, 4	3, 4	3, 4	3, 4			3, 4	1, 4	4
Canada	3	3	3	3	1, 3	1,3	1,3	1,3	1,3	1,3
Finland	1, 3	1, 3	1, 3	4	1, 3	1, 3	1, 3	1, 3	1, 3	1, 3
Japan	2, 3	2	2	2	1, 2, 3			1, 2, 3	1	1
New Zealand	1	3	2	2	1	1	1	1	1	2
Norway	4	4	4	4	4	4	4	4	4	4
Sweden	1	1	1	4	1	1	1	1	1, 4	1
Switzerland	1, 3	3	3	3	3	3	3	3	3	3
Turkey	2			2	1		1	1	1	1
United States	1	1	1	1	1	1	1	1	1(c)	1

TABLE 8. MINISTRY RESPONSIBLE FOR REVIEWING DATA SUBMITTED TO SUPPORT THE REGISTRATION OF PESTICIDE PRODUCTS (from questions 1.3 and 7)

Country	Responsible Ministry(ies)	
	Plant Protection Products	**Other Pesticidal Products**
CEC	Directorate-General for Agriculture, Standing Committee on Plant Health (12 Member States + Commission): active ingredient Individual Member States: formulation	Directorate-General for Environment, Nuclear Safety and Civil Protection
Denmark	Ministry of the Environment: responsible for approval Ministry of Agriculture: evaluates efficacy Ministry of Health: evaluates residues in food	(no ministry given)
Germany	Federal Biological Research Centre for Agriculture and Forestry (BBA): tests and authorizes plant protection products. BBA consults with the Federal Health Office (BGA) concerning health-related requirements for authorization, and with the Federal Environmental Office (UBA) concerning avoidance of damage through air and water pollution or pollution caused by plant protection product waste.	disinfectants, biocides, avicides, insecticides/acaricides, ectoparasite controls, mosquito repellants: Federal Health Office, Ministry for Health wood preservatives: Ministry for Economy, Institute of Stuctural Engineering masonry preservatives: Ministry for Economy rodenticides: Ministry of Food, Agriculture and Forestry (BBA); Federal Health Office molluscicides: Federal Biological Agency (BBA)
Italy	Ministero Sanitá – D.G.I.A.N. – Div. V (Fitofarmaci) (in the experts committee also Ministero Agricoltura, Ambiente, Lavoro e Industria) from 26/7/1993: Dir. 91/414/EEC	disinfectants, biocides, preservatives, public health products: Ministero Sanitá, D.G.S. Farmceutico

TABLE 8 (CONT). MINISTRY RESPONSIBLE FOR REVIEWING DATA SUBMITTED TO SUPPORT THE REGISTRATION OF PESTICIDE PRODUCTS (from questions 1.3 and 7)

Country	Responsible Ministry(ies)	
	Plant Protection Products	**Other Pesticidal Products**
The Netherlands	Commission Registration Pesticides, Pesticides Bureau	(registration similar to plant protection products; no other ministry listed)
Portugal	Centro Nacional de Protecçao Agricola, Ministério da Agricultura	disinfectants) biocides) Ministério da Sáude preservatives) public health products) rodenticides (non-ag)) avicides (as repulsives)) Ministério da Agricultura ectoparasite controls)
United Kingdom	Ministry of Agriculture (MAFF) Department of Health: toxicological aspects Department of the Environment) may consider certain aspects of data by Health and Safety Executive) area, e.g. worker safety	skin disinfectants: CSM/Dept of Health swimming pool disinfectants: Dept of the Environment (DWI) biocides: Dept of the Environment; Health and Safety Executive rodenticide: Dept of Agriculture (MAFF) ectoparasite controls: Health and Safety Executive/VMD mosquito repellants: Health and Safety Executive

TABLE 8 (CONT). MINISTRY RESPONSIBLE FOR REVIEWING DATA SUBMITTED TO SUPPORT THE REGISTRATION OF PESTICIDE PRODUCTS (from questions 1.3 and 7)

Country	Responsible Ministry(ies)	
	Plant Protection Products	**Other Pesticidal Products**
Australia	Commonwealth Environment Protection Agency: environmental hazard assessment Department of Health, Housing and Community Services: scheduling, first aid and safety direction, public health Worksafe Australia: occupational health and safety Department of Primary Industries and Energy: efficacy, chemistry, crop and animal safety National Registration Authority: registration of agricultural and veterinary chemicals	(registration similar to plant protection products; no other ministry listed)
Austria	Ministry of Agriculture and Forestry: biological efficacy, phytotoxicity, waiting intervals, analytical methods Ministry of Health: evaluates human health effects for users/consumers Ministry of Environment: ecotoxicity, fate and behaviour in the environment	disinfectants (general, skin, food industry)) ecotoparasite controls) Ministry of Health mosquito repellants) swimming pool disinfectants) biocides) preservatives) Health and Environment rodenticides) insecticides/acaricides)
Canada	Agriculture Canada: evaluates efficacy, performance, phytotoxicity data Health and Welfare Canada: evaluates toxicology data and data on occupational exposure; sets maximum residue limits Environment Canada: evaluates environmental fate and toxicology data	disinfectants (general, swimming pool)) biocides) Agriculture Canada, Health and preservatives) Welfare Canada and public health products) Environment Canada disinfectants (skin, food industry): Health and Welfare Canada mosquito repellants: Agriculture Canada and Health and Welfare Canada

TABLE 8 (CONT). MINISTRY RESPONSIBLE FOR REVIEWING DATA SUBMITTED TO SUPPORT THE REGISTRATION OF PESTICIDE PRODUCTS (from questions 1.3 and 7)

Country	Responsible Ministry(ies)	
	Plant Protection Products	**Other Pesticidal Products**
Finland	Agricultural Research Centre) evaluate efficacy and usefulness Forest Research Institute) Ministry of Social Affairs and Health: evaluates toxicity National Board of Water and Environment: evaluates ecotoxicity National Board of Labour Protection: evaluates harmful effects on work hygiene State Institute of Agricultural Chemistry: chemical and physical examination, determines residues in crops National Veterinary Institute: determines residues in products of animal origin National Board of Agriculture: co-ordinates review, registration process	skin disinfectants) Health authorities ectoparasite controls) biocides (industrial, anti fouling)) National Board of Water and preservatives (wood, textile, masonry))Environment public health products:) Pesticide Commission/ (rodenticide, molluscicide, Ministry of Agriculture and Forestry insecticide/acaricide, mosquito repellant)
Japan	Ministry of Agriculture, Forestry and Fisheries, co-operating with the Environmental Agency and the Ministry of Health and Welfare	general disinfectants) biocides) Ministry of Health and Welfare, MITI preservatives) skin disinfectants) swimming pool disinfectants) Ministry of Health and Welfare public health products:) (rodenticides, insecticides/ acaricides, ectoparasite controls, mosquito repellants)

TABLE 8 (CONT). MINISTRY RESPONSIBLE FOR REVIEWING DATA SUBMITTED TO SUPPORT THE REGISTRATION OF PESTICIDE PRODUCTS (from questions 1.3 and 7)

Country	Responsible Ministry(ies)	
	Plant Protection Products	**Other Pesticidal Products**
New Zealand	Ministry of Agriculture and Fisheries: chemistry, residues, toxicology, environment, efficacy Department of Health: sets maximum residue limits; audit role on toxicology	disinfectants (general, swimming pool)) biocides (except anti fouling)) Department of Health preservatives (masonry, consumer product)) mosquito repellants) disinfectants (skin, food industry): Department of Health, Ministry of Agriculture and Fisheries anti fouling biocides) wood preservatives) Pesticides Board (Ministry of Agriculture public health products) and Fisheries) textile preservatives: New Zealand Wool Board
Norway	The National Agricultural Inspection Service, Pesticides Division	disinfectants (general, skin): Norwegian Medicines Control Authority food industry disinfectant: Norwegian Food Control Authority biocides) preservatives) State Pollution Control Authority public health products)

TABLE 8 (CONT). MINISTRY RESPONSIBLE FOR REVIEWING DATA SUBMITTED TO SUPPORT THE REGISTRATION OF PESTICIDE PRODUCTS (from questions 1.3 and 7)

Country	Responsible Ministry(ies)	
	Plant Protection Products	**Other Pesticidal Products**
Sweden	Swedish National Chemicals Inspectorate: responsible for data reviewing as a whole and final decision to approve/reject a product Swedish National Food Administration: responsible for decisions on tolerance levels in edible crops	disinfectants (general, swimming pool) biocides preservatives public health products) National Chemicals Inspectorate (KemI) food industry disinfectant: National Food Administration
Switzerland	Swiss Federal Research Station for Fruit-Growing, Viticulture and Horticulture	disinfectants (general, swimming pool, food industry) biocides preservatives public health products) (BAG) Bundesamt für Gesundheitswesen skin disinfectants ectoparasite controls) (IKS) Interkantonale Kontrollstelle für Heitmittel anti fouling biocides wood preservatives) (BUWAL) Bundesamt für Umwelt, Wald und Landschaft/BAG

TABLE 8 (CONT). MINISTRY RESPONSIBLE FOR REVIEWING DATA SUBMITTED TO SUPPORT THE REGISTRATION OF PESTICIDE PRODUCTS (from questions 1.3 and 7)

Country	Responsible Ministry(ies)	
	Plant Protection Products	**Other Pesticidal Products**
Turkey	Ministry of Agriculture and Rural Affairs: responsible for registration of plant protection products. Data to support registration are studied by the commission which is formed by the General Direction for Protection and Control	disinfectants, wood preservatives, public health products) Ministry of Health consumer product preservatives: Ministry of Health, Ministry of Agriculture ectoparasite controls for animals: Ministry of Agriculture
United States	Environmental Protection Agency, Office of Pesticide Programs	disinfectants (general, swimming pool, food industry), biocides, preservatives, public health products (rodenticides, avicides, molluscicides, insecticides/acaricides, mosquito repellants)) Environmental Protection Agency Office of Pesticide Programs skin disinfectants, ectoparasite controls for humans) Food and Drug Administration

Notes to Tables 1-8

Table 1. Overview of the registration process

(a) The authorisation is granted for a maximum period of ten years. After this period the applicant can apply for a new authorisation.

(b) Reviewed in the light of concerns: e.g. toxicological implications; environmental/wildlife implications; unacceptable residues (food, drinking water, etc.).

(c) The company should provide any data it considers relevant, in support of its application or to support its continued use. Epidemiological studies are often not considered of sufficient quality.

(d) The data requirements for the major toxicology and other endpoints are the same; however the programme recognises that the quality of some data may not meet current standards. In many cases this may be addressed by the provision of supplementary data (e.g. human exposure). Australia has chosen to adopt a flexible approach with regard to the review of existing chemicals.

(e) Companies are obligated to report any adverse environmental effects that come to their attention following registration. For OH + S, any additional information supplied to an overseas authority must be provided.

(f) The same data.

(g) See Sections 19 and 20 of the Federal Plant Protection Act.

(h) The data requirements are the same as those for initial registration. In addition, special reviews, which focus on specific areas of concern (teratogenicity, effects on avians, etc.), are underway for 17 active ingredients.

(i) The registration is valid for a maximum of 8 years at a time. Re-registration is possible upon application. There are problems with the time schedule concerning re-registration.

In principle, yes. Special attention is paid to ecotoxicology, because of the lack of relevant studies for many old products. All *new* studies have to be submitted when applying for re-registration at the latest.

(j) In the application scheme "other information" is asked for.

(k) – Term of validity of registration shall be three years.
– The data requirements for re-registering are the same as those for initial registration.
– If new data for that pesticide appears, those data shall also be required for re-registering.

(l) Basically, yes. However, the data requirements have been extended over the years, and in some cases the documentation for old substances has not been updated to the standard required today. In these cases, it is taken into account what kind of data is missing related to the actual use of the preparation, and a renewal of registration may be granted in spite of lacking data (case-by-case decision).

(m) It is included in the data requirements.

(n) No formal review programme, but ad hoc reviews are conducted where specific concerns arise.

(o) While not required, if such data are available they can be demanded.

(p) The data requirements are the same.

(q) The manufacturer of a plant protection product must not withhold data that in any respect could be relevant to the risk assessment of the product.

(r) During re-registration the complete data set is reconsidered.

(s) Toxicological, ecotoxicological, biological (e.g. resistance development) or any other adverse effects are monitored and reported.

(t) But in light of new scientific data, specific pesticides already registered could be re-evaluated.

(u) Findings in humans exposed to the product temporarily or for long periods of time are to be stated.

(v) Yes. In 1983, EPA promulgated 40 CFR Part 158, which systematically set forth rigorous data requirements for registration and tolerance setting of pesticides. These requirements are now being applied to pesticides (first registered before 1984) during re-registration.

(w) EPA regulations (40 CFR 152.50(f)3) require registration applicants to supply, with their application, "any factual information of which [they are] aware regarding unreasonable adverse effects of the pesticide on man or the environment....".

(x) Section 6(a)(2) of the federal pesticide law (FIFRA) and Environmental Protection Agency regulations (40 CFR 153 subpart D) state that "If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator [of EPA]." FIFRA 3(c)(2)(B) also gives EPA authority to demand additional data if EPA determines that such data are required to maintain an existing registration of a pesticide.

Table 2. Classification and labelling

(a) Under discussion.

(b) UN requirements.

(c) According to EEC rules for classification of general chemicals.

(d) I.e. additional options.

(e) Yes, in very special cases.

(f) – Chronic human health hazard; – toxicity to aquatic and terrestrial non-target organisms.

(g) Same: human health; different: environmental effects.

(h) For toxicity to fish: Directive 91/325/EEC.

(i) At present for specified products, in the future for all products.

(j) Human health: all relevant endpoints, using EC regulation on classification and labelling and information concerning exposure if applicable.

(k) Proposal in preparation.

(l) Adopted from Directive 67/547/EEC and amendments. For wildlife the danger classifications are adopted from UK (bees) and EPA (birds and fish).

(m) There is a category "for professional use only".

(n) Labelling may identify the need for personal protection equipment (PPE). Avoid contact with skin, eyes, etc. (may cause skin sensitisation). Avoid breathing dust.

(o) Various labels to avoid contamination of aquatic environment particularly.

(p) Harmful/Dangerous/V. dangerous to fish/aquatic life; Avoid overspray of pond, ditches, waterways; others (e.g. dangerous to bees/beneficials).

(q) But aquatic warnings similar.

(r) Also PIC procedures.

(s) Safety directions stating that the product may have cumulative effect on repeated exposure. Also carcinogenicity, teratogenicity, non-target species toxicity.

(t) Different applies to end-use product; however, same classification for the active constituent.

(u) Guidelines for transport of hazardous goods.

(v) Chemical Act and Chemical Ordinance classification and labelling criteria of the Austrian Chemicals Act are very similar to the criteria of the EC Directive on labelling and packaging of dangerous chemicals and preparations.

(w) Additional warnings and precautions in some special aspects concerning the special use of PPP's.

(x) There are special requirements for persons using very toxic products.

(y) Classification according to the EEC legislation (chemicals).

(z) Carcinogenicity; Irritation; Mutagenicity; Reproduction; Sensitisation; Teratogenicity; Toxicity to water organisms; Persistence in soil; Leaching in soil; Bee toxicity. The system for "environmental" classification is under development.

(aa) Toxicity to man, livestock and aquatic organisms; Crop Persistent Pesticides, Soil Persistent Pesticides, Water Polluting Pesticides.

(bb) All users of pesticides for professional purposes (farmers, etc.) have to be authorized. However, a few preparations are also available for others for use in gardens, etc.

(cc) Skin sensitisation, cancer, mutagenicity, teratogenicity, reproductive effects, allergic reactions, irritation, fish toxicity.

(dd) Except for acute toxicity.

(ee) But it is not administered by us.

(ff) Based on WHO classification.

(gg) Toxic to fish, birds, bees labelling. Human health hazards (other than acute hazard).

(hh) Chronic toxicity/carcinogenicity; Reproductive toxicity; Skin sensitisation; Hazards to fish and other aquatic organisms; Hazards to pollinating insects.

(ii) The system is basically the same, but may in special cases be more comprehensive, especially in the environmental hazard area.

(jj) See Attachment No. 5.

(kk) A notification is written on the label as "Poisonous for fish. Avoid contamination of water resources." Label should contain advice to protect the appliers, consumers, pets, wildlife and the environment.

(ll) Pesticides can be labelled for acute toxicity hazard to humans. They can also be labelled for hazard to non-target wildlife based on laboratory testing of acute toxicity to fish, birds and insects and/or incident reports which demonstrate fatality (40 CFR Part 156).

Table 3. Tier testing

(a) Proposal under discussion.

(b) If indicated, additional tests can always be required

(c) Not every part; not for aquatic organisms.

(d) Mostly case-by-case; these tests are organised in a waiver approach.

(e) Occupational exposure.

(f) At the moment, decision-making schemes considering the above subject are in discussion and some approved on an EPPO and Council of Europe Joint Group. Maybe in the near future and according to EEC approach, data requirements are to be organised in tiers.

(g) Further tests depending on results of initial tests – no formal diagrams at this stage.

(h) Mixture at present, moving towards formalised. We are about to test use of the CoE/EPPO schemes with a view to adopting them. They are pretty much a formalisation of what we already do. Note that consideration by the committee routes can overturn any structural approach we may have adopted. Uniform Principles will affect what we do next year. [See CoE/EPPO schemes: (1) current approaches – general, overspray, arthropod natural enemies, honeybees; (2) proposed future approaches – terrestrial vertebrates, aquatic organisms, earthworms, soil micro-organisms.]

(i) Tiered approach applies to genotoxicity, ectoparasitoids. Generally tiered approach not used. CEPA has adopted a very flexible approach based on exposure considerations but this is not a formal tier approach.

(j) Ectoparasitoids protocol covers both areas.

(k) Microbial pesticides (*draft* guidelines).

(l) Re microbial pesticides and non-target plant testing of chemical pesticides (both *draft* guidelines).

(m) Microbials, biochemicals.

Table 4. Waivers

(a) Under discussion.

(b) Waivers occur for biological pesticides and other incidental cases.

(c) Related to question application form for registration in the Netherlands (see Appendix 1).

(d) With respect to environmental requirements, approach is flexible depending on likely exposure. Requirements may be waived if notifier can show they are not relevant, and data on other chemicals may be used in other circumstances.

(e) Very conditional – only for existing chemicals with new minor use.

(f) E.g. ornamentals, greenhouse, provision preservation.

(g) For the same active ingredient with permission of the first applicant.

(h) (May be.)

(i) Omission of any "required" study must be justified on scientific grounds. Where the decision is made (on a case-by-case basis) to not conduct a laboratory study with a major transformation product, the applicant for registration must provide the rationale for not conducting the study.

(j) Pesticide which is not found as residues in food stuffs.

(k) To justify that data are waived in a specific test area, the applicant is obliged to provide his own rationale for why this specific investigation/data is not considered necessary for a reliable hazard/risk assessment of his product.

Table 5. Biological and biologically derived pesticides

(a) When applied, the requirements are, in principle, more or less the same as the other products.

(b) Development of data requirements has been identified as a high priority; they are expected to be drafted during 1993.

(c) Microbial pest control agents and pheromones: yes. These are at the draft guidelines state. Insects, mites, nematodes: not yet.

(d) Case-by-case consideration. In future, EEC registration requirements.

(e) Not formally yet. Case-by-case decision.

(f) In preparation.

Table 6. Inert ingredients

(a) In individual cases.

(b) Case-by-case.

(c) Only in exceptional cases.

(d) Sometimes.

(e) In some cases.

(f) Are additives listed in the list worked out by the product control authorities?

(g) May be requested if considered necessary.

(h) Basic data corresponding to those compiled in fact sheets for chemical in general.
Further data requirements: If the required toxicity data (LD50) and/or ecotoxicity data (acute and reproduction toxicity, daphnia) disclose an unexpected increase of the toxicity of the formulation compared to the active ingredient, this must be clarified by further test data on the inerts.

(i) The data required for inerts comprise a minimal base set which is a subset of the requirements for active ingredients.

Table 7. Types of notification or approval for other pesticidal products

(a) Development of medical devices directive.

(b) Directive 81/851/EEC on the approximation of the Laws of the Member States relating to veterinary medicine products.

(c) For humans, not animals.

Annex 2

Part 1 of the Questionnaire

Questionnaire on Data Requirements for Registering Plant Protection Products

Part 1: The Registration Process

***Please use the following definitions in completing this questionnaire*:**

Registration is a license to market a product for a specific purpose.

Active ingredient is any chemical substance that has general or specific action against harmful organisms or on plants, parts of plants or plant products.

Formulation is any product containing one or more active ingredients and formulated with any necessary inert ingredients so that it can be used against harmful organisms or on plants, plant parts or plant products.

1. Overview of the Registration Process

1) Does your country have established data requirements for registering new plant protection products?

yes___ no___

If yes, please attach a copy for reference purposes and indicate whether it is up-to-date, i.e. fully reflects current practice. Please note that provision of such a document is *not* a substitute for completing the questionnaire.

2) Does your country have a programme for re-evaluating, or re-registering, plant protection products at some time after their initial approval?

yes___ no___

If yes, are the data requirements the same as those for initial registration? If no, please explain how the data requirements differ.

3) What ministry or agency is responsible for reviewing data submitted to support the registration of plant protection products? If more than one ministry or agency is involved, please indicate how their responsibilities for reviewing pesticide data are divided.

4) Does your country offer different types of pesticide registrations or approvals, such as those listed below, in addition to full commercial registration?

		yes	no
a)	research and development or experimental approval (approval for *limited use* to collect data to register the product)	___	___
b)	emergency approval (*temporary* approval to address a pest emergency when registered alternatives are not available)	___	___
c)	provisional or limited registration (registration that is conditional on receiving further supporting data, often by a specific due date)	___	___
d)	*other* (e.g. pre-manufacture or pre-market notice, i.e. that a company intends to produce a chemical)		

5) In addition to the studies generated to fulfill specific data requirements, does your country also require manufacturers of plant protection products to report other relevant information (such as adverse effects incident reports or epidemiological studies) when applying for registration or after registration is obtained?

when applying	after approval
yes___ no___	yes___ no___

Explain if necessary.

2. Classification and Labelling

1) Does your country have a system for classifying plant protection products in order to limit their use to trained personnel?

yes ___ no ___

2) Do you have a system for classifying plant protection products for the purpose of label warnings or precautions, based on acute hazard to humans?

yes ___ no ___

3) Do you also classify/label plant protection products according to other specific concerns, such as chronic human health hazard or environmental effects (e.g. toxicity to fish)?

yes ___ no ___

If yes, please list the end points that may be the basis for classification/ labelling.

4) Is your system for classifying plant protection products for the purpose of label warnings or precautions the same as your classification/labelling system for industrial chemicals?

the same ___ different ___

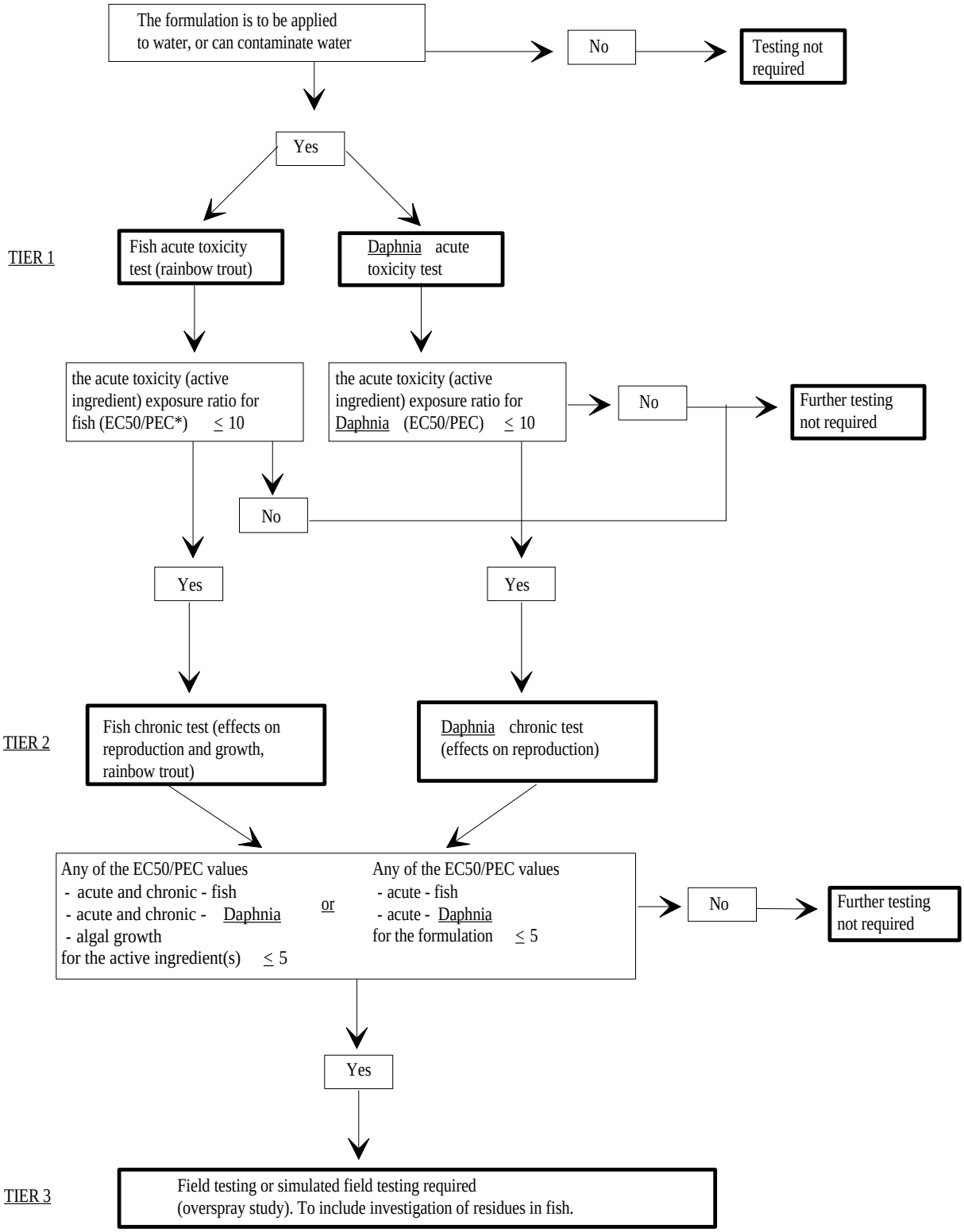
5) Do you have a system for classifying/labelling plant protection products for transport and shipping purposes?

yes ___ no ___

If yes, is this system the same as the system used for industrial chemicals?

the same ___ different ___

SAMPLE TIER TESTING DIAGRAM:
AQUATIC EFFECTS TESTING



*EC50 = concentration at which the effect occurs in 50% of test organisms
PEC = predicted environmental concentration

3. Tier Testing

1) Does your country organise its data requirements for plant protection products in tiers? The tier structure sets out a stepped sequence for testing pesticides, where tests in higher tiers are required only if triggers are met at earlier stages. Under a tiered structure, for example, data requirements might progress from a basic set of laboratory tests, to field studies under normal conditions of use (e.g. field trials, pond studies), to incident or field monitoring.

___ yes, some data requirements are organised in tiers

___ no, data requirements are not organised in tiers

2) If your data requirements for plant protection products are organised in tiers:

a) Please check those test areas that incorporate tier testing:

___ fate and behaviour in the environment

___ residue chemistry

___ toxicology and metabolism

___ ecotoxicology

___ efficacy

___ other (please specify)

b) Indicate whether the tier testing is formalised or case-by-case:

	formalised	case-by-case
• fate and behaviour in the environment	____	____
• residue chemistry	____	____
• toxicology and metabolism	____	____
• ecotoxicology	____	____
• efficacy	____	____
• other (please specify)	____	____

c) For those areas where tier testing is formalised, please attach a diagram of the tier structure, indicating which studies are included in the various tiers. Also indicate clearly those studies in basic tiers which are precursors of higher tier studies. In addition, please indicate, if possible, what criteria in one tier would trigger requirements for testing in the next tier. The following diagram for tiered testing of effects on aquatic organisms can serve as an example.

4. Waivers

1) Does your country have flexibility to waive certain mandatory or triggered data requirements based on one or more of the following?

	yes	no
• the physical form of the product	___	___
• physical-chemical data	___	___
• (eco)toxicological properties of chemicals with similar structure (structure/activity relationship)	___	___
• intended use pattern (e.g. low acreage or anticipated exposure)	___	___
• similarity to already registered pesticide	___	___
• economic grounds (e.g. important minor use crop)	___	___
• other (please specify)	___	___

2) Do you have written criteria for waiving or reducing data requirements, or do you evaluate data waivers on a case-by-case basis?

written criteria ___ case-by-case ___

5. Biological and Biologically Derived Pesticides

1) How does your country define biological and biologically derived pesticides? (For example, one Member country defines them as follows: Biological and biologically derived pesticides include microbial pest control agents, e.g. bacteria, algae, fungi, viruses, and protozoa; and *biochemical pest control agents*, e.g. pheromones, hormones, natural insect and plant growth regulators, and enzymes. Biological and biologically derived pesticides are typically naturally occurring, specific to the target species, and, in the case of biochemicals, typically have unique or non-toxic modes of action.) Please provide your country's definition in the space below.

2) Has your country developed data requirements for biological and biologically derived pesticides?

yes ___ no ___

3) If yes, please indicate generally how these requirements differ from those for conventional chemical pesticides. Alternatively, if convenient, please complete the separate blank matrices provided for this purpose.

6. Inert Ingredients

(Any substance other than an active ingredient which is intentionally included in a plant protection product)

1) Does your country require specific data or information on inert ingredients in addition to that for whole formulations?

yes ___ no ___

2) If yes, please check those areas for which you require data:

___ chemical identity

___ physical-chemical properties

___ function in the formulation

___ analytical methods

___ fate and behaviour in the environment

___ residue chemistry

___ toxicology and metabolism

___ ecotoxicology

___ other (please specify)

7. Other Pesticide Products

The OECD anticipates that future projects will examine data requirements for additional types of pesticides other than plant protection products. To help us direct such future efforts, we would like you to identify, in the attached matrix, the type of regulatory scheme your country applies to the product types listed below:

Product Type	Description of Use
Disinfectants	
general disinfectant	Disinfection of hard surfaces and articles intended to come into contact with the human body, such as medical devices
skin disinfectant	Disinfection of human or animal skin
swimming pool disinfectant	Disinfection of water used for public bathing
food industry disinfectant	Disinfection of containers, surfaces and pipework associated with the production of food and drink for humans and animals
Biocides	
general biocide	Control of harmful micro-organisms in premises, vehicles and areas used by human and animals
sanitary biocide	Control of harmful micro-organisms in sanitary conveniences and equipment, e.g. toilets
air conditioning systems biocide	Control of harmful organisms in air conditioning
industrial biocide	Control of harmful organisms affecting other industrial processes, e.g. slimicides in paper mills, biocides in cooling-water systems, oil recovery drilling muds

specialist biocide	Control of harmful organisms in connection with specific products, substances, materials, articles or areas not covered by other product types
anti fouling biocide	Control of fouling organisms on ships, boats, aquatic structures and articles
Preservatives	
wood preservative	Protection of sawn timber and timber products from harmful organisms
textile preservative	Protection of textiles from harmful organisms
masonry preservative	Protection of masonry and other construction materials (except wood) from harmful organisms
consumer product preservative	Protection of products marketed to the consumer, other than food, feed and cosmetics, from harmful organisms (e.g. paints)
Public Health Products	
rodenticide	Control of rats, mice or other rodents for purposes of public health and wellbeing
avicide	Control of birds for purposes of public health and wellbeing
molluscicide	Control of snails and other molluscs, both terrestrial and aquatic, for purposes of public health and wellbeing
insecticide/acaricide	Control of insects, mites and other arthropods for purposes of public health and wellbeing (includes repellants)
ectoparasite controls for humans and animals	Control of skin parasites for public health and for veterinary purposes
mosquito repellant	Control of mosquitos for public health purposes

7. Types of Notification or Approval for Other Pesticidal Products

Product type	Registration similar to plant protection products required	Covered by general chemical legislation or regulations		Other (please specify)	Responsible ministry/agency
		Pre-manufacture notification	Pre-market approval		
DISINFECTANTS					
general disinfectant					
skin disinfectant					
swimming pool disinfectant					
food industry disinfectant					
BIOCIDES					
general biocide					
sanitary biocide					
air conditioning biocide					
industrial biocide					

7. Types of Notification or Approval for Other Pesticidal Products (continued)

Product type	Registration similar to plant protection products required	Covered by general chemical legislation or regulations		Other (please specify)	Responsible ministry/agency
		Pre-manufacture notification	Pre-market approval		
specialist biocide					
anti fouling biocide					
PRESERVATIVES					
wood preservative					
textile preservative					
masonry preservative					
consumer product preservative					
PUBLIC HEALTH PRODUCTS					
rodenticide					
avicide					

7. Types of Notification or Approval for Other Pesticidal Products (continued)

Product type	Registration similar to plant protection products required	Covered by general chemical legislation or regulations		Other (please specify)	Responsible ministry/agency
		Pre-manufacture notification	Pre-market approval		
molluscicide					
insecticide/acaricide					
ectoparasite controls for humans and animals					
mosquito repellant					
OTHER (please specify)					

8. Contact Names

Please provide names, addresses, and telephone and fax numbers of persons we may contact in each ministry or agency if clarification of the information provided in Parts 1 and 2 of this questionnaire is necessary.

1) Area of questionnaire:

Name:

Address:

Tel:

Fax:

2) Area of questionnaire:

Name:

Address:

Tel:

Fax:

3) Area of questionnaire:

Name:

Address:

Tel:

Fax:

Annex 3

Summary of Responses to Part 2 of the Questionnaire: Number of Countries Requiring Each Data Element

Key to Symbols Used in the Matrices

A *Always required:* These data are always required for all plant protection products.

F *Frequently required:* These data are typically required in more than 80 per cent of registration submissions.

L *Less frequently required:* These data are typically required in less than 80 per cent of registration submissions.

NR *Not required:* These data are not required.

MATRIX 1. CHEMICAL IDENTITY
Summary of Responses

TYPE OF DATA/INFORMATION	A	F	L	NR
IDENTITY OF THE ACTIVE INGREDIENT				
Common name(s)	23			
Chemical name (IUPAC) nomenclature	23			
CAS and EEC numbers (if available)	22	1		
Empirical and structural formula and molecular mass	22	1		
Trade name(s)	9			2
Method of manufacture: reaction process	21			2
Method of manufacture: clean up steps	4		3	2
Specification of purity	23			
Impurities and additives – identity, formation and range of each	23			
Name of manufacturer	23			
Name of applicant	23			
ADDITIONAL DATA LISTED BY COUNTRIES				
Identity of isomers	12			
Quality control	2			
Name and address of manufacturing plant	2			
Molecular weight	1			
Wissvesser line notation	1			
Date of specification	1			
Patent status			1	
Microcontaminants (such as nitrosamines and dioxins) data and methodology			1	

MATRIX 1 (CONT). CHEMICAL IDENTITY
Summary of Responses

TYPE OF DATA/INFORMATION	A	F	L	NR
Samples	1			
Identity of the products of decomposition	1			
Certified limits	1			
Preliminary analysis			1	
IDENTITY OF THE FORMULATION				
Trade name	22			
Composition: names and amount of – active ingedient(s), adjuvants, inert components	23			
Physical state (emusifiable concentrate, wettable powder, solution, etc.)	23			
Name of manufacturer	23			
Name of applicant	23			
ADDITIONAL DATA LISTED BY COUNTRIES				
Chemical specification of composition				
Quality control	2			
Name and address of manufacturing plant	2			
Date of quality guarantee limit	1			
Name of the person responsible for manufacturing	1			
Authorization	1			
Manufacturing method			1	
Certified limits	1			
Preliminary analysis			1	

MATRIX 2. PHYSICAL-CHEMICAL PROPERTIES
Summary of Responses

TYPE OF DATA/INFORMATION	Active Ingredient				Formulation			
	A	F	L	NR	A	F	L	NR
Colour	22	1			17	1	1	3
Physical state	22	1			9	1		
Odour	21	1	1		14	2	3	3
pH	4	3		3	19	3	1	
Density	19	3		1	19	4		
UV-visible, IR, NMR, Mass Spectra	18	2		2	1		2	6
Melting point	21	1	1		1	1	2	6
Boiling point	21	2			1	1	2	6
Vapour pressure	22	1			3	1	2	4
Solubility in water	21	2			2		1	7
Solubility in organic solvents	21	1	1		2		1	7
Octanol-water partition coefficient as a function of pH	20	2			1			8
Dissociation constant in water	16	2	2	2			1	8
Thermal stability	20	2	1		4	2	1	3
Stability in air	14	1	3	4	1	1	2	5
Stability in presence of metal ions or sunlight as a function of temperature	18	1	2	2	1	1	2	6
Viscosity	2	1	3	4	14	2	2	3
Surface tension	16		1	5	12		3	6
Dielectric breakdown voltage			1	9			2	7
Oxidizing properties	17		3	2	14	1	3	4

MATRIX 2 (CONT). PHYSICAL-CHEMICAL PROPERTIES
Summary of Responses

TYPE OF DATA/INFORMATION	Active Ingredient				Formulation			
	A	F	L	NR	A	F	L	NR
Flammability	19		2	2	18	2	2	1
Explosive properties	16	1	2	4	17	2	3	1
Storage stability or stability in solvents used in formulation	5		1	5	20	2	1	
Corrosion characteristics	4		2	5	6	2		3
Reactivity toward container	15		1	7	4	1	2	4
Miscibility of the product with water and other solvents	2	1	1	6	3	2	1	5
Particle size distribution	1	1	1	7	18	3		2
Flash point	19		2	2	18	2	2	1
Wettability	2		1	7	16	1	1	5
Persistant foaming			1	9	13	2		7
Suspensibility and suspension stability	1	1	1	7	17	2	1	3
Wet sieve and dry sieve test	1	1	2	6	15	3	2	3
Emulsifiability, emulsion stability, re-emulsifiability	1	1	1	7	16	2	2	3
Flowability, pourability and dustability	1		1	7	15	2	2	3
ADDITIONAL DATA LISTED BY COUNTRIES								
Stability in organic solvents used in preparations	12							
Stability in water	12							
Attrition, friability			1		12	1		
Physical-chemical compatibility in mixes to be authorized					12			
Content of a.i. in or on bait particles, granules or treated seed					12			

MATRIX 2 (CONT). PHYSICAL-CHEMICAL PROPERTIES
Summary of Responses

TYPE OF DATA/INFORMATION	Active Ingredient				Formulation			
	A	F	L	NR	A	F	L	NR
Pourability					(1)			
Bulk density					(1)			
Ignition temperature of liquids and gases					(1)			
Autoignition temperature of solids					(1)			
Dust explosion limit					(1)			
Dust content of granules					(1)			
Attrition of granules						(1)		
Adhesion on seed of seed treatments					(1)			
Uniformity of distribution of seed treatments to cereal grains					(1)			
Condensation point (gasses)	1					1		
Refractive index	1	1	1			1		
X-ray defraction spectrum		1				1		
Fat solubility	2							
Henry's constent	1							
Fission and other reactions during combustion			1					
Drift index							1	
Disintegration in air and water							1	
Angle of repose							1	
Fuming test							1	
Miscibility with other pesticides or substances					1			
Combustion	1							
Submittal of samples for each active ingredient (technical grade)	1						1	

MATRIX 3. FUNCTION, MODE OF ACTION AND HANDLING
Summary of Responses

TYPE OF DATA/INFORMATION	Active Ingredient				Formulation			
	A	F	L	NR	A	F	L	NR
Function (e.g. fungicide, herbicide, insecticide, repellant, growth regulator, etc.)	19			4	23			
Mode of action on target organisms (e.g. contact poison, inhalation poison, stomach poison fungitoxic, fungistatic systemic or not in plants)	18	1		4	19	2		2
Field of use (e.g. terrestrial field, greenhouse, food crop)	17			5	23			
Pests controlled	17			5	23			
Plants or products to be protected	17			5	22			1
Application rate per unit treated acre, row-foot etc.					23			
Concentration of active ingredient in material used (e.g. in the diluted spray, treated seed etc.)	1				23			
Number and timing of applications and duration of protection					22	1		
Re-entry intervals					13	2	6	2
Pre-harvest intervals					19	3		1
Proposed instructions for use	1				22			1
Method of application					23			
Type of packaging					22			1
Procedures for cleaning application equipment					15	1	4	2
Possible occurrence of development of resistance and appropriate management strategies	15		2	5	14		5	3
Recommended methods and precauations for handling, storage, transport or fire (including reaction products)	18	1		3	22	1		
Emergency measures in case of accidents	17	2		3	21	2		

MATRIX 3 (CONT). FUNCTION, MODE OF ACTION AND HANDLING
Summary of Responses

TYPE OF DATA/INFORMATION	Active Ingredient				Formulation			
	A	F	L	NR	A	F	L	NR
ADDITIONAL DATA LISTED BY COUNTRIES								
In case of fire: nature of reaction product, combustion gases, etc.	12				12			
Conditions (agricultural, plant health and/or environmental) under which not to be used	12				12			
Necessary waiting period or other precautions to avoid phytotoxic effects on succeeding crops					12			
Methods of safe disposal, destruction	1				3			
Disposal methods for empty containers					1			
Registration in other countries					1			

MATRIX 4. ANALYTICAL METHODS
Summary of Responses

METHOD FOR DETERMINATION OF	Active Ingredient				Formulation			
	A	F	L	NR	A	F	L	NR
Pure active ingredients and isomers, impurities and addivities of the technical grade of the active ingredient or formulation	23				9		2	
Active ingredients in food or feed (multiresidue methods)	18	2		3	5		1	4
Composition of formulated product					19		3	1
Residues in treated plants, foods or feed	20		1	2	15	1		4
Residues in animal tissues	18	2	1	2	15			5
Pesticide in soil	18	3	1	1	14	1	1	5
Pesticide in water, including potable water	18	1	2	2	13	2	2	4
Pesticide in air	16		3	4	13		2	6
Residues in human body fluids	13		3	5	13		1	6
Relevant breakdown products	19	2	1	1	3		1	5
ADDITIONAL DATA LISTED BY COUNTRIES								
Freezer storage stability						1		

MATRIX 5. EFFICACY OF FORMULATIONS
Summary of Responses

TYPE OF DATA/INFORMATION	A	F	L	NR
Preliminary range-finding tests	15	1		7
Field experimentation	21	1		1
Information on possible occurrence of resistance	18	1	2	1
Effects on quality and yield	18	1	2	2
Dose/efficacy relationships	7		2	2
ADDITIONAL DATA LISTED BY COUNTRIES				
Phytotoxicity	13			
Undesirable or unintended effects	12			
Effects on following crops			(1)	
Risks to adjacent/nearby crops			(1)	
Risk of phytotoxicity from carry-over in straw, etc.			(1)	
Safety to organisms used in biological control/compatibility with integrated pest management			(1)	
Effect on germination	1			
Compatibility/Formulation mixes		1		
Efficacy tests for non-public health uses of pesticides			1	

MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT
Summary of Responses

TYPE OF DATA/INFORMATION	Indoor Uses								Outdoor Uses							
	Active Ingredient				Formulation				Active Ingredient				Formulation			
	A	F	L	NR	A	F	L	NR	A	F	L	NR	A	F	L	NR
LABORATORY STUDIES																
Hydrolysis rate including identification of metabolites and breakdown products	19		1	1					21	2						
Photodegradation in water including identification of metabolites and breakdown products	16		2	3			1		17	4	1	1			1	
Photodegradation on soil including identification of metabolites and breakdown products	2	1	4	2					5	3	2	1	1			
Rate and route of photochemical degradation in air, identification of breakdown products	13		6	2					13	1	6	2				
Soil metabolism, aerobic and anaerobic, to determine rate and route of degradation in representative soil types including metabolites and breakdown products	15		4	2					19	3			1			
Biodegradation in aquatic systems, aerobic and anaerobic, including identification of breakdown products and metabolites	15		4	2					17	2	2	1			1	
Mobility/leaching in representative soil types and mobility of metabolites and breakdown products	15		4	2					19	1	1	1	1			
Adsorption/desorption in representative soil types including metabolites and breakdown products	15		4	2					20	2			1			
Extent and nature of bound residues in soil	14	1	4	2					18	3	1	1	1			
Laboratory volatility	13		5	3					15	1	4	1			1	
Spray droplet size spectrum					2		1	6					2	1	2	6
ADDITIONAL DATA LISTED BY COUNTRIES																
Adsorption/desorption in water	12								12							
Leaching: Lysimeter experiment (comment only)																
Degradation and distribution in water – sediment – system			1							1						
FIELD STUDIES																
Terrestrial field dissipation, distribution and dissipation in soil					12	1	2	6	1				14	3	4	1
Aquatic (sediment) field dissipation; distribution and dissipation in water					12		3	6	1				13	2	6	1
Forestry field dissipation							2	6			1		1		6	2
Long-term field dissipation							3	6	1					1	7	2
High tier field studies with emphasis on potential to leach and contaminate ground water							3	6							6	4
Spray drift field deposition							3	6							7	3

MATRIX 6 (CONT). FATE AND BEHAVIOUR IN THE ENVIRONMENT
Summary of Responses

TYPE OF DATA/INFORMATION	Indoor Uses								Outdoor Uses							
	Active Ingredient				Formulation				Active Ingredient				Formulation			
	A	F	L	NR	A	F	L	NR	A	F	L	NR	A	F	L	NR
ADDITIONAL DATA LISTED BY COUNTRIES																
Distribution/dissipation in air					12								12			
Accumulation in soil											(1)				(1)	
Run-off											(1)				(1)	
OTHER REQUIREMENTS																
Accumulation in fish	14		2	5			1	8	15	4	1	2		1	1	8
Accumulation in other aquatic non-target organisms			1	8			1	8	1	1	2	5			1	8
APPLICATION AND RE-ENTRY EXPOSURE																
Wetting, adherence and distribution to target plants					12		4	5					12		4	6
Foliar dissipation							6	3							7	3
Dermal exposure					2	2	2	3					2	1	3	4
Inhalation exposure					2	2	2	3					2	1	3	4
Indoor surface dissipation	1					2	3	4							3	7
Likely exposure to applicator under field conditions, detailed use information, timing and number of treatments per season per year for private and professional handlers etc.					16		3	2					15		4	2
Dermal penetration					13	1	3	4					13		4	5
ADDITIONAL DATA SUBMITTED BY COUNTRIES																
Rainfall and arid conditions to be checked (comment only)																

MATRIX 7. RESIDUE CHEMISTRY
Summary of Responses

TYPE OF DATA/INFORMATION (for food/feed uses only)		Active Ingredient				Formulation			
		A	F	L	NR	A	F	L	NR
IDENTIFICATION OF BREAKDOWN PRODUCTS AND METABOLITES									
Nature of the residue in plants		21	1		1	3		1	4
Nature of the residue in livestock if residues remain in or on crop used for feed		18	1	3	1	2		2	4
ADDITIONAL DATA LISTED BY COUNTRIES									
Behaviour of residue from application until harvest		12							
Overall material balance		12							
Estimation of exposure		12							
Nature of residues in livestock if the product is applied directly or indirectly		1						1	
MAGNITUDE OF THE RESIDUE									
Crops from the field		7	1	1	2	16	1	2	2
Meat, milk, poultry and eggs		4	3	2	1	13	1	3	3
Processed food/feed		14	1	4	3	12	2	4	2
Potable water		2		4	4		1	3	4
Fish		1		6	3			16	4
Irrigated crops		1		2	5	13		3	4
Food handling				4	5			4	4
Tobacco		1		1	7	13		1	6
Freezer or storage stability tests for any of the above magnitude of the residue tests		2	1	2	4	3		2	3
ADDITIONAL DATA LISTED BY COUNTRIES									
Post harvest use						(1)			
Quantification of metabolites in plants		(1)							
Animal Fibres (e.g. wool)				1					
Reduction of residue								1	
OTHER REQUIREMENTS									
Proposed tolerance or maximum residue levels		6	1		4	13		2	6
Residue data in succeeding or rotational crops	Laboratory or greenhouse study	2	2	3	4	12		5	3
	Field study	2	1	3	5	12		6	2
Effects of household preparation, e.g. cooking, on residues		1	1	6	3	12		5	3
Effects on odor, taste and quality of food due to residues		1		3	6	14	1	3	3
ADDITIONAL DATA LISTED BY COUNTRIES									
Proposed preharvest intervals or witholding periods or storage periods						12			
Effect of industrial processing on residues/wool residues			1				1		
Submittal of analytical reference standard		1							

MATRIX 8. TOXICOLOGY AND METABOLISM STUDIES
Summary of Responses

TYPE OF DATA/INFORMATION	Food/Feed								Non-food/Non-feed							
	Active Ingredient				Formulation				Active Ingredient				Formulation			
	A	F	L	NR	A	F	L	NR	A	F	L	NR	A	F	L	NR
ACUTE TESTING																
Acute oral	23				19	2			23				19	2		
Acute dermal	23				19	2			23				19	2		
Acute inhalation	19	4			15	5		1	19	4			15	5		1
Acute dermal irritation	21	1		1	19	2			21	1		1	19	2		
Acute eye irritation	21	1		1	19	2			21	1		1	19	2		
Skin sensitization	21	1		1	18	2	1		21	1		1	18	2	1	
Acute intraperitoneal toxicity	13	2	1	7				9	13	2	1	7	12			9
Potentiation/interactions of multiple active ingredients or products	2	1	2	6	2	2	2	3	2		3	6	2	1	3	3
ADDITIONAL DATA LISTED BY COUNTRIES																
Acute oral toxicity (second mammal species)	1								1							
SUBCHRONIC TESTING																
Repeated dose oral – 28 day	13	1	2	6			1	8	13	1	2	6			1	8
Repeated dose inhalation – 28 day		1	4	5			1	8		1	4	5			1	8
Subchronic oral rat – 90 day	22		1					9	21		2					9
Subchronic oral non-rodent – 90 day	20	1	1	1				9	17	1	2	3				9
Subchronic dermal – 90 day			6	4			1	8			6	4			1	8
Subchronic inhalation – 90 day			5	5			1	8			5	5			1	8
ADDITIONAL DATA LISTED BY COUNTRIES																
Other routes (inhalation, percutaneous as appropriate)	12								12							
Repeated dose dermal (21-28 days)		(1)	2, (1)				1, (2)			(1)	2, (1)				1, (2)	
Repeated dose/28 day		1								1						
DEVELOPMENTAL TOXICITY AND REPRODUCTIVE STUDIES																
Teratogenicity rodent	22							9	21		1					9
Teratogenicity – second species	20	1		1				9	19		2	1				9
Multi-generation reproduction	21							8	17	1	3					8

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES
Summary of Responses

TYPE OF DATA/INFORMATION		Food/Feed								Non-food/Non-feed							
		Active Ingredient				Formulation				Active Ingredient				Formulation			
		A	F	L	NR	A	F	L	NR	A	F	L	NR	A	F	L	NR
ADDITIONAL DATA LISTED BY COUNTRIES																	
Teratogenicity rodent – dermal				(1)								(1)					
Teratogenicity second species – dermal				(1)								(1)					
METABOLISM TESTING																	
Toxicokinetics	absorption, distribution, excretion	22	1					1	8	20	1	2				1	8
	metabolic pathways	21	2					1	8	19	2	2				1	8
ADDITIONAL DATA LISTED BY COUNTRIES																	
Animal transfer studies			1				1										
Dermal penetration				1				1				1				1	
Human toxico-kinetics study				1								1					
CHRONIC TESTING																	
Chronic toxicity rodent		22							9	17	1	3					8
Chronic toxicity non-rodent		18	1		3				9	14	1	3	3				8
Carcinogenicity – rat		21	1						9	16	2	3					8
Carcinogenicity – second species		20	2						9	16	2	3					8
ADDITIONAL DATA LISTED BY COUNTRIES																	
Subchronic oral non-rodent (dog) – 1 year			1														
Combined carcinogenicity and chronic studies			1														
MUTAGENICITY – Testing for specific endpoints (listed by countries)																	
Gene mutations		16							2	16							2
Chromosomal damage		19							5	19							5
DNA aberrations/genetic damage		13		1					1	13		1					1
Gene toxicity in vitro and in vivo		1							1	1							1
Induction of point mutation in microbial assay (e.g. salmonella)		2							2	2							2
Production of cytogenetic damage in bone marrow or other proliferative cells, in vivo (e.g. micronucleus assay)			1						1		1						1
Genetic damage other than cytogenetic end points (e.g. unscheduled DNA synthesis)			1						1		1						1
DNA synthesis/repair		2							2	2							2

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES
Summary of Responses

TYPE OF DATA/INFORMATION	Food/Feed								Non-food/Non-feed							
	Active Ingredient				Formulation				Active Ingredient				Formulation			
	A	F	L	NR	A	F	L	NR	A	F	L	NR	A	F	L	NR
MUTAGENICITY – Specific mutagenicity assays																
Salmonella typhimurium	7							5	7							5
Escherichia coli	3			1				4	4			1				4
Mammalian cytogenetics, in vitro	7							5	6							5
Mammalian cytogenetics, in vivo	3	1	2	1				5	3	1	2	1				5
Micronucleus test	2	1	3					5	2	1	3					5
Mammalian cell gene mutation, in vitro	2	1	1	2				5	2	1	1	2				5
Drosophila melanogaster, sex-linked recessive lethal test	1		2	2				4	1		2	2				4
Dominant lethal test, rodent	1	1	3					4	1	1	3					4
Sister chromatid exchange, mammalian cells in vitro	1		2	2				4	1		2	2				4
Saccharomyces cerevisiae, gene mutation	1		2	2				4	1		2	2				4
Mouse spot	1			3				4	1			3				4
Heritable translocation, mouse	1			3				4	1			3				4
NEUROTOXICITY TESTING																
Acute neurotoxicity – rat	13	1	3	3				8	13	1	3	3				8
Acute delayed neurotoxicity of organophosphates – hen	2	1	6					8	1	1	6					8
28 day delayed neurotoxicity			6	2				6			6	2				8
Subchronic neurotoxicity – rat – 90 day	1		2	5				8	1		2	5				8
Subchronic delayed neurotoxicity of organophosphates – hen			3	4				7			3	4				7
Postnatal developmental neurotoxicity		1	1	6				8			2	6				8

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES
Summary of Responses

TYPE OF DATA/INFORMATION	Food/Feed								Non-food/Non-feed							
	Active Ingredient				Formulation				Active Ingredient				Formulation			
	A	F	L	NR	A	F	L	NR	A	F	L	NR	A	F	L	NR
ADDITIONAL DATA LISTED BY COUNTRIES																
Cholinesterase inhibition	(1)								(1)							
OTHER TESTING																
Visual systems studies		1	1	7				9		1	1	7				9
Toxic effects in livestock and pets	13		2	6			2	6	13		2	6			2	6
Antidote	4		2	5	2	2		5	4		2	5	2	2		5
ADDITIONAL DATA LISTED BY COUNTRIES																
Toxic effects of metabolites from treated plants in cases where different from those identified in animal studies	12															
Any mechanistic studies needed to clarify effects reported in toxicity studies	12								12							
Pharmacological study	1								1							
MEDICAL DATA																
Medical surveillance of manufacturing plant personnel	13	1	4	3		1	4	4	13	1	4	3		1	4	4
Clinical cases and poisoning incidents	15	1	3	2	2	1	3	3	15	1	3	2	2	1	3	3
Health records from industry and agriculture	13		4	4			4	5	13		4	4			4	5
Observations of exposure of the general population or epidemiological studies	14		2	3	1		3	4	14		2	3	1		3	4
ADDITIONAL DATA LISTED BY COUNTRIES																
Diagnosis of poisoning	12								12							
Specific signs of poisoning clinical tests	12								12							
Sensitization/allergenicity observations, proposed treatment, prognosis of expected effects of poisoning, summary of mammalian toxicology and conclusions (NOAEL, NOEL, ADI)	12								12							
Ongoing updates of exposure and monitoring data, MSDS, toxicology and epidemiology data, where available	1				1				1				1			

MATRIX 9. ECOTOXICOLOGY
Summary of Responses

TYPE OF DATA/INFORMATION	Indoor Uses								Outdoor Uses							
	Active Ingredient				Formulation				Active Ingredient				Formulation			
	A	F	L	NR	A	F	L	NR	A	F	L	NR	A	F	L	NR
AVIAN TESTING																
Avian acute oral LD50	1	1	2	4			3	5	20	1		1	13		6	2
Avian dietary toxicity LC50 – terrestrial bird (short-term toxicity)	1		2	5			2	6	20	1		1			6	3
Avian dietary toxicity LC50 – aquatic bird (short-term)			2	6			2	6	16	2	1	2			6	3
Avian reproduction test – terrestrial bird			2	6			2	6	12	3	4	2			5	4
Avian reproduction test – aquatic bird			2	6			2	6	12	3	4	2			5	4
Avian field testing							1	6					12		6	2
Acceptance of bait, treated seeds by birds			1	6			1	6			1	7	1		15	4
ADDITIONAL DATA LISTED BY COUNTRIES																
Trials and observations on birds and other wild animals (comment only)																
AQUATIC TESTING																
Fish acute toxicity LC50, freshwater: warm-water species	1		4	3			4	4	17	1	2	1	13		6	2
Fish acute toxicity LC50, freshwater: cold-water species	3	1	2	3	1	1	3	4	17	3	1	1	13	1	6	2
Daphnia acute immobilization test	3	1	2	3	2	1	3	3	20	2			15	1	6	
Marine or estuarine fish acute toxicity LC50/EC50			3	6			3	6	12	1	3	6	12		4	6
Daphnia life-cycle	1		3	5	1		2	6	15	2	3	2	1	1	16	4
Fish reproduction and growth rate			3	5			1	7	12	1	5	3			15	6
Fish life-cycle			3	5			1	7			7	2			3	6
Chronic toxicity to fish or fish early life stage			3	5			1	7	13	1	6	2			15	6
Aquatic field testing							1	7			4	5			16	5
Aquatic bioavailability/biomagnification/bioaccumulation	2		2	4	1		1	6	15	2	3	2			14	7
ADDITIONAL DATA LISTED BY COUNTRIES																
Particular studies with fish and other aquatic organisms															12	
Chronic toxicity and reproduction with benthic organisms like Chironomus											(1)				(1)	
Daphnia reproduction (21 days)										(1)					(1)	
Fish prolonged toxicity (21 days)										(1)					(1)	

MATRIX 9 (CONT). ECOTOXICOLOGY
Summary of Responses

TYPE OF DATA/INFORMATION	Indoor Uses								Outdoor Uses							
	Active Ingredient				Formulation				Active Ingredient				Formulation			
	A	F	L	NR	A	F	L	NR	A	F	L	NR	A	F	L	NR
BENEFICIAL INSECTS																
Acute toxicity to honey bees LD50	3		1	5	2	1	2	4	18	3	1	1	15	2	3	2
Toxicity of residues on foliage to honeybees			3	6			3	6		2	2	6		2	4	4
Acute toxicity to predatory/parasitic insects	1	1	2	5	1	1	3	4	14	2	5	2	13	1	6	2
Field testing for pollinators							3	6		1	5	4	12		7	3
ADDITIONAL DATA LISTED BY COUNTRIES																
Semi-field test on honey bees (mortality) (tier test)															(1)	
Field tests on beneficial arthropods (reproduction, mortality, beneficial capacity) (tier test)															(1)	
Toxicity of residues on foliage to silkworm															1	
TERRESTRIAL VERTEBRATES																
Effects on terrestrial vertebrates other than birds			1	8			1	8	1	2	5	3	12		5	5
Mammalian field testing							1	8			4	6			5	5
TESTING ON OTHER NON-TARGET SPECIES																
Earthworm, acute toxicity test	1		3	5			1	8	15	3	2	2	1	1	3	5
Effects on soil micro-organisms	1		4	4			2	7	16	3	1	2	13	2	3	4
Activated sludge, respiration inhibition test			3	6			1	8	13		3	5			2	7
ADDITIONAL DATA LISTED BY COUNTRIES																
Available data from biological primary screening													12			
Earthworm, reproduction study (tier study)															(1)	
Accumulation in earthworm											(1)					

MATRIX 9 (CONT). ECOTOXICOLOGY
Summary of Responses

TYPE OF DATA/INFORMATION	Indoor Uses								Outdoor Uses							
	Active Ingredient				Formulation				Active Ingredient				Formulation			
	A	F	L	NR	A	F	L	NR	A	F	L	NR	A	F	L	NR
PHYTOTOXICITY TO NON-TARGET PLANTS – Laboratory testing																
Algae, growth inhibition	2		2	5			3	6	16	2	2	2	1	1	16	4
Seed germination			1	7	1		2	6		1	2	6	1		5	4
Vegetative vigour			1	7	1		1	7		1	3	5	1	1	4	4
Aquatic plant growth			2	7			1	8			6	4			3	7
PHTOTOXICITY TO NON-TARGET PLANTS – Field Testing																
Terrestrial field testing					1		1	7			3	6	1		6	3
Aquatic field testing							1	7			3	6			6	3
ADDITIONAL DATA LISTED BY COUNTRIES																
Effects on flora and fauna believed to be at risk											12					
Bacteria (aquatic) (comment only)																

Annex 4

Individual Countries' Responses to Part 2 of the Questionnaire

Key to Symbols Used in the Matrices

A	*Always required:* These data are always required for all plant protection products.
F	*Frequently required:* These data are typically required in more than 80 per cent of registration submissions.
L	*Less frequently required:* These data are typically required in less than 80 per cent of registration submissions.
NR	*Not required:* These data are not required.
AI	*Active ingredient:* These data are required in order to support the active ingredient.
FM	*Formulation:* These data are required in order to support the formulation.
*	*Good Laboratory Practice* is required.
c	*A comment was provided* in the country's questionnaire response.

MATRIX 1. CHEMICAL IDENTITY

TYPE OF DATA/INFORMATION	CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
IDENTITY OF THE ACTIVE INGREDIENT																		
Common name(s)	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Chemical name (IUPAC) nomenclature	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
CAS and EEC numbers (if available)	A	A	A	A	A	A	A	A	A	A	A	A	A	F	A	A	A	A
Empirical and structural formula and molecular mass	A	A	A	A	A	A	A	A	A	A	A	A	A	F	A	A	A	A
Trade name(s)		A	A		NR		A	A	A	A	A	A	A	NR	A	NR	A	A
Method of manufacture: reaction process	A	A	A	A_c	NR	A_c	A	A	A	A	A_c	A	A	NR	A	NR	A	A
Method of manufacture: clean up steps		A	L		NR		A	A	A	L_c	L_c	A		NR	L	NR		A
Specification of purity	A	A	A*	A	A	A	A	A	A	A_c	A	A	A	A	A	A	A	A*
Impurities and additives – identity, formation and range of each	A	A	A*	A	A	A	A	A	A	A_c	A	A	A	A	A	A	A	A*
Name of manufacturer	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Name of applicant	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
ADDITIONAL DATA LISTED BY COUNTRIES																		
Identity of isomers [CEC, POR]	A					A												
Quality control [AUS]								A										A*
Address of manufacturing plant [AUS, JAP]								A				A						
Molecular weight [FIN]											A							
Wissvesser line notation [CAN]										A_c								
Date of specification [CAN]										A								
Patent status [CAN]										L								
Microcontaminants (such as nitrosamines and dioxins) data and methodology [CAN]										L								
Samples [CAN]										A_c								
Identity of the products of decomposition [AUT]									A									
Certified limits [USA]																		A^*_c
Preliminary analysis [USA]																		L*

MATRIX 1 (CONT). CHEMICAL IDENTITY

TYPE OF DATA/INFORMATION	CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
IDENTITY OF THE FORMULATION																		
Trade name	A	A	A	A_c	A	A_c	A	A	A	A	A	A	A	A	A	A	A	
Composition: names and amount of – active ingedient(s), adjuvants, inert components	A	A	A	A	A	A	A	A	A_c	A	A	A	A	A	A	A	A	A*
Physical state (emusifiable concentrate, wettable powder, solution, etc.)	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A*
Name of manufacturer	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Name of applicant	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
ADDITIONAL DATA LISTED BY COUNTRIES																		
Chemical specification of composition [NL]					A													
Quality control [AUS]								A										A*
Address of manufacturing plant [AUS, JAP]								A				A						
Date of quality guarantee limit [JAP]												A						
Name of the person responsible for manufacturing [JAP]												A						
Authorization [FIN]											A							
Manufacturing method [CAN]										L_c								
Certified limits [USA]																		A*
Preliminary analysis [USA]																		L^*_c

MATRIX 2. PHYSICAL-CHEMICAL PROPERTIES

TYPE OF DATA/INFORMATION		CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Colour	AI	A	A	A	A	NR	A	A*	A	A_c	A	A	A	A	A	A	F	A	A*
	FM	A	NR	NR	A	NR	A	A*	A	A_c	NR	L	A	NR	A		F	A	NR
Physical state	AI	A	A	A	A	A	A	A*	A	A_c	A	A	A	A	A	A	F	A	A*
	FM		A	A		A		A*	A	A_c	A	A	A	A	A		F	A	A*
Odour	AI	A	A	A	A	NR	A	A*	A	A_c	A	A	A_c	A	L	A	F	A	A*
	FM	A	NR	NR	A	NR	A	A*	F	A_c	NR	L	L_c	NR	L		F	A	NR
pH	AI		A	NR		NR		A*	A	NR	NR	NR	A		F	A	F	A	F*$_c$
	FM	A	A	A	A	A_c	A	A*	F	A	L	A	A	A	A	A	F	A	F*$_c$
Density	AI	A_c	A	A*	A	NR	A_c	A*	A	NR	F_c	A*	A	A	F_c	A	F	A	A*
	FM	A_c	F/L_c	A	A	A_c	A_c	A*	F	A	F_c	A*	A	A	F_c	A	F	A	A*
UV-visible, IR, NMR, Mass Spectra	AI	A	A	A*	A	F	A	A*	A	A_c	F_c	A*	A	A	NR	A_c	F		NR
	FM		NR	A*		F		NR	L	A_c	NR	NR	NR	NR	NR		L		NR
Melting point	AI	A	A	A*	A	F	A	A*	A	A_c	A_c	A*$_c$	A	A	A	A	F	A	L*$_c$
	FM		NR	NR		NR		NR	F	NR	NR	NR	NR	NR	L		L	A	NR
Boiling point	AI	A	A	A*	A	F	A	A*	A	A_c	A_c	A*	A	A	A	A	F	A	F*$_c$
	FM		NR	NR		NR		NR	F	NR	NR	NR	NR	NR	L		L	A	NR
Vapour pressure	AI	A	A	A*	A	A	A	A*	A	A_c	A_c	A*	A	A	A	A	F	A	A*
	FM		A	NR		NR		NR	F	NR	NR	A*	NR	A	L		L	A	NR
Solubility in water	AI	A_c	A	A*	A_c	L	A_c	A*	A	A_c	A	A*	A	A	F	A	F	A	A*$_c$
	FM		NR	NR		NR		NR	A	NR	NR	NR	NR	NR	L		NR	A	NR
Solubility in organic solvents	AI	A_c	A	A*	A_c	A	A_c	A*	A	A_c	A	A*	A	A	L	A	F	A	A*
	FM		NR	NR		NR		NR	A	NR	NR	NR	NR	NR	L		NR	A	NR
Octanol-water partition coefficient as a function of pH	AI	A	A	A*$_c$	A	A_c	A	A*	A	A_c	A_c	A*	A	A	A	A_c	F		F*$_c$
	FM		NR	NR		NR		NR	A	NR	NR	NR	NR	NR	NR		NR		NR
Dissociation constant in water	AI	A	A	A*	A	A	A	A*	L	A_c	L	A*	A	NR	F	NR	F		A*
	FM		NR	NR		NR		NR	L	NR	NR	NR	NR	NR	NR		NR		NR
Thermal stability	AI	A_c	A	A	A_c	A	A_c	A*	A	A_c	F	A*	A	A	L	A	F	A	A*
	FM		NR	A		NR		NR	F	A	NR	A*	A	NR	L		F	A	NR

MATRIX 2 (CONT). PHYSICAL-CHEMICAL PROPERTIES

TYPE OF DATA/INFORMATION		CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Stability in air	AI	A_c	A	A	A_c	NR	A_c	A*	A	L_c	L	NR*$_c$	A	NR	L	NR	F		NR
	FM		NR	NR		NR		NR	A	L	NR	NR*$_c$	NR	NR	L		F		NR
Stability in presence of metal ions or sunlight as a function of temperature	AI	A_c	NR	NR	A_c	NR	A_c	NR	L	L_c	NR	A*$_c$	A	A	NR	A_c	F	A	A*$_c$
	FM		NR	NR		NR		NR	L	L	NR	NR	NR	NR	NR		F	A	NR
Viscosity	AI		A	NR		NR		NR	A	NR	L	NR$_c$	A_c	NR	L	NR	L		F*$_c$
	FM	A	NR	A	A	A	A	NR	A	A	NR	NR$_c$	L_c	NR	L		F		F*$_c$
Surface tension	AI	A	A	NR	A	NR	A	NR	L	A_c	NR	A*	NR	A	NR	A	NR		NR
	FM	A	NR	NR	A	A	A	NR	L	NR	NR	NR	L_c	NR	NR		L		NR
Dielectric breakdown voltage	AI		NR	NR		NR		NR	NR	NR	NR	NR	NR	NR	NR	NR	L		NR
	FM		NR	NR		NR		NR	NR	NR	NR	NR	NR	NR	NR		L		L*$_c$
Oxidizing properties	AI	A	NR	L	A	L	A	A*	A		NR	A	L_c	A	NR	A	L	A	L*$_c$
	FM	A	A	NR	A	A	A	NR	A		NR	NR	L_c	NR	L	NR	F	A	L*
Flammability	AI	A	A	NR	A	NR	A	A*	A	A_c	NR	A	A_c	A	NR	A	L	A	L*$_c$
	FM	A	A	A*	A	A_c	A	NR	A	A	NR	A	L_c	A	F	A	F	A	L*
Explosive properties	AI	A	A	NR	A	NR	A	A*	F	A_c	NR	A	A_c	NR	NR	NR	L	A	L*$_c$
	FM	A	A	NR	A	L	A	NR	F	A	NR	A	L_c	A	L	A	F	A	L*
Storage stability or stability in solvents used in formulation	AI		NR	NR		NR		A*	A	NR	A	NR	NR	NR	NR	A	L	A	A*$_c$
	FM	A	A	A	A	NR	A	A*	A	A	A	A	A	A	F	A	F	A	L*
Corrosion characteristics	AI		NR	NR		NR		A*	A	NR	NR	NR	L	NR	NR	A	L	A	A*$_c$
	FM		A	L		F		F*	A	NR	NR	A	NR	A	F	A	F	A	A*
Reactivity toward container	AI	A	NR	NR	A	NR	A	NR	A	NR	NR	NR$_c$	NR	NR	NR	NR	L	A	A*$_c$
	FM		NR	L		F		F*	A	L	NR	NR$_c$	A	NR	L	NR	F	A	A*$_c$
Miscibility of the product with water and other solvents	AI		NR	NR		NR		NR	A	NR	NR$_c$		NR	NR	NR	NR	L	A	F*$_c$
	FM		NR	A	A			NR	A	NR	NR$_c$	A	NR	NR	L	NR	F	A	F*
Particle size distribution	AI		NR	NR		NR		NR	F	NR	NR		NR	NR	NR	NR	L	A	NR
	FM	A_c	A_c	A	A	A	A_c	L*	A	A	NR	A*$_c$	F_c	A	F	A	F	A	NR
Flash point	AI	A	A	NR	A	NR	A	A*	A	A_c	NR	A	A_c	A	NR	A	L	A	L*$_c$
	FM	A	A	A*	A	A_c	A	L*	A	A	NR	A	L_c	A	F	A	F	A	L*

MATRIX 2 (CONT). PHYSICAL-CHEMICAL PROPERTIES

TYPE OF DATA/INFORMATION		CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Wettability	AI		NR	NR		NR		NR	A	NR	NR		NR	NR	NR	NR	L	A	NR
	FM	A	NR	A	A	A_c	A	L*	A	A	NR	A_c	L_c	NR	NR	NR	F	A	NR
Persistant foaming	AI		NR	NR				NR	NR	NR	NR	NR	NR	NR	NR	NR	L		NR
	FM	A	NR	A	A	A	A	F*	F	A	NR	NR	NR	NR	NR	NR	F		NR
Suspensibility and suspension stability	AI		NR	NR				NR	F	NR	NR		NR	NR	NR	NR	L	A_c	NR
	FM	A	A	A	A	A	A	F*	A	A	NR	A	L_c	NR	F	A	F	A_c	NR
Wet sieve and dry sieve test	AI		NR	NR				NR	F	NR	NR		NR	NR	L	NR	L	A_c	NR
	FM	A	A	A	A	A	A	L*	F	A	NR	L	F_c	NR	L	A	F	A_c	NR
Emulsifiability, emulsion stability, re-emulsifiability	AI		NR	NR				NR	F	NR	NR		NR	NR	NR	NR	L	A_c	NR
	FM	A	A	A	A	A	A	L*	F	A	NR	A_c	L_c	NR	L	A	F	A_c	NR
Flowability, pourability and dustability	AI		NR	NR				NR		NR	NR		NR	NR	NR	NR	L	A_c	NR
	FM	A	NR	A	A	A	A	F*	F	A	NR	A_c	L_c	NR	L		F	A_c	NR
ADDITIONAL DATA LISTED BY COUNTRIES																			
Stability in organic solvents used in preparations [CEC, ITA, POR]	AI	A			A		A												
	FM																		
Stability in water [CEC, ITA, NL, POR]	AI	A			A	A													
	FM						A												
Attrition, friability [CEC, NL, POR, SWI]	AI																L		
	FM	A				A_c	A										F		
Physical-chemical compatibility in mixes to be authorized [CEC, NL, POR]	AI																		
	FM	A				A	A												
Content of a.i. in or on bait particles, granules or treated seed [CEC, POR]	AI																		
	FM	A					A												
Pourability [GER]	AI			NR															
	FM			A															

MATRIX 2 (CONT). PHYSICAL-CHEMICAL PROPERTIES

TYPE OF DATA/INFORMATION		CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Bulk density [GER]	AI			NR															
	FM			A															
Ignition temperature of liquids and gases [GER]	AI			NR															
	FM			A															
Autoignition temperature of solids [GER]	AI			NR															
	FM			A															
Dust explosion limit [GER]	AI			NR															
	FM			A*															
Dust content of granules [GER]	AI			NR															
	FM			A															
Attrition of granules [GER]	AI			NR															
	FM			F_c															
Adhesion on seed of seed treatments [GER]	AI			NR															
	FM			A															
Uniformity of distribution of seed treatments to cereal grains [GER]	AI			NR															
	FM			A															
Condensation point (gasses) [AUS]	AI								A										
	FM								F										
Refractive index [AUS, AUT, FIN]	AI								F	A_c		L							
	FM								F	NR									
X-ray defraction spectrum [AUS]	AI								F										
	FM								F										
Fat solubility [FIN, AUT]	AI									A^*_c		A^*_c							
	FM									NR									
Henry's constent [AUT]	AI									A_c									
	FM									NR									

MATRIX 2 (CONT). PHYSICAL-CHEMICAL PROPERTIES

TYPE OF DATA/INFORMATION		CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Fission and other reactions during combustion [FIN]	AI											L_c							
	FM																		

MATRIX 2 (CONT). PHYSICAL-CHEMICAL PROPERTIES

TYPE OF DATA/INFORMATION		CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Drift index [JAP]	AI												NR						
	FM												L_c						
Disintegration in air and water [JAP]	AI												NR						
	FM												L_c						
Angle of repose [JAP]	AI												NR						
	FM												L_c						
Fuming test [JAP]	AI												NR						
	FM												L_c						
Miscibility with other pesticides or substances [SWE]	AI															NR			
	FM															A			
Combustion [SWE]	AI															A			
	FM															NR			
Other chemical and/or physical data [SWE]	AI															c			
	FM															c			
Submittal of samples for each active ingredient (technical grade) [USA]	AI																		A*
	FM																		L*

MATRIX 3. FUNCTION, MODE OF ACTION AND HANDLING

TYPE OF DATA/INFORMATION		CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Function (e.g. fungicide, herbicide, insecticide, repellant, growth regulator, etc.)	AI	A	A	A_c	A	A	A	A	A	A	A	A	NR	NR	NR	NR	A	A	A
	FM	A	A	A_c	A	A		A	A	A	A	A	A	A	A	A	A	A	A
Mode of action on target organisms (e.g. contact poison, inhalation poison, stomach poison fungitoxic, fungistatic systemic or not in plants)	AI	A	A	A_c	A	A	A	F	A	A	A	A	A	NR	NR	NR	F	A	NR
	FM	A	A	NR	A	A		F	A	A	A	A	NR	A	F	A	F	A	NR
Field of use (e.g. terrestrial field, greenhouse, food crop)	AI	A		NR	A	A	A	NR	A_c	NR	A		NR	NR	NR	NR	A	A	A
	FM	A	A_c	A	A	A		A	A_c	A	A	A	A	A	A	A	A	A	A
Pests controlled	AI	A		NR	A	A	A	NR	A	NR	A		NR	NR	NR	NR	A	A	A
	FM	A	A_c	A	A	A		A	A	A	A	A	A	A	A	A	A	A	A
Plants or products to be protected	AI	A		NR	A	A	A	NR	A	NR	A		NR	NR	NR	NR	A	A	A
	FM	A	A_c	A	A	A		F	A	A	A	A	A	A	A	A	A	A	NR
Application rate per unit treated acre, row-foot, etc.	AI																		
	FM	A	A	A	A	A	A	F	A	A	A	A	A	A	A	A	A	A	A*
Concentration of active ingredient in material used (e.g. in the diluted spray, treated seed, etc.)	AI																		A_c
	FM	A	A	L_c	A	A	A	F	A	A	A	A	A	A	A	A	A	A	A_c
Number and timing of applications and duration of protection	AI																		
	FM	A	A	A	A	A	A	F	A	A	A	A	A	A	A	A	F	A	A*
Re-entry intervals	AI																		
	FM	A	A_c	L^*_c	A	A		L_c	F^*_c	L	L	L	NR	NR	L	L	L	A	F*
Pre-harvest intervals	AI																		
	FM	A	A_c	A_c	A	A	A	F	F	A	A	A_c	A	NR	F_c	A	A	A	F^*_c
Proposed instructions for use	AI																		A_c
	FM	A	A	A	A	A	NR	A	A	A	A	A	NR	A	A	A	A	A	A
Method of application	AI																		
	FM	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A

MATRIX 3 (CONT). FUNCTION, MODE OF ACTION AND HANDLING

TYPE OF DATA/INFORMATION		CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Type of packaging	AI																		
	FM	A_c	A	A	A_c	A	A	A	A	A	A	A	A	A	A	A	A	A	NR_c
Procedures for cleaning application equipment	AI																		
	FM	A	A	A	A	NR	NR	F	A	A	L	L	F	NR	L	A_c	L		NR
Possible occurrence of development of resistance and appropriate management strategies	AI	A	L_c		A	L		L_c	L	A	NR	NR	NR	A	NR	A	L		NR
	FM	A_c	NR		A	L		L_c	L	NR	L	NR	L	A	L	A	L		NR
Recommended methods and precauations for handling, storage, transport or fire (including reaction products)	AI	A	NR		A	NR		NR	A_c	NR	NR		NR	A	F	A	A	A	A_c
	FM	A	A	L	A	A	L	A	A_c	A	A	A	A	A	F	A	A	A	A_c
Emergency measures in case of accidents	AI	A	NR		A	NR		NR	A	NR	NR		NR	A	F	A	A	A	F*
	FM	A	A	NR	A	A	L	A	A	A	A	A_c	A	A	F	A	A	A	F*
ADDITIONAL DATA LISTED BY COUNTRIES																			
In case of fire: nature of reaction product, combustion gases, etc. [CEC, ITA]	AI	A			A														
	FM	A			A														
Conditions (agricultural, plant health and/or environmental) under which not to be used [CEC, ITA, NL]	AI	A			A	NR													
	FM	A			A	A													
Necessary waiting period or other precautions to avoid phytotoxic effects on succeeding crops [CEC, ITA, NL]	AI					NR													
	FM	A			A	A													
Methods of safe disposal, destruction [AUT, FIN, SWE]	AI									NR						A			
	FM									A		A				A			
Disposal methods for empty containers [NZ]	AI																		
	FM														A				
Registration in other countries [FIN]	AI																		
	FM											A							

MATRIX 4. ANALYTICAL METHODS

METHOD FOR DETERMINATION OF		CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Pure active ingredients and isomers, impurities and addivities of the technical grade of the active ingredient or formulation	AI	A	A	A	A	F	A	A*	A	A_c	A_c	A	A	A	A	A	A	A	A*
	FM		A	A		F	A	NR	A	A_c	A_c	L	A	A	L	A	A	A	A*
Active ingredients in food or feed (multiresidue methods)	AI	A	A	A	A	F		NR	F	A	NR	A	NR	NR	F_c	A	A	A	A*
	FM		A			NR		NR	A	NR	A_c		NR	NR	L_c	A	A_c	A	NR*
Composition of formulated product	AI																		
	FM	A	A	A	A	A	A	A*	A	L	A	L_c	A	A	A	NR	A	A	L*$_c$
Residues in treated plants, foods or feed	AI	A	A		A	F		L*	A	A	NR	A*	NR	A	A_c	A	A	A	L*$_c$
	FM	A	A	A*	A	NR	A	NR	A	NR	A_c		F	NR	NR	NR	A_c		
Residues in animal tissues	AI	A	A		A	F		L*	F	A	NR	A*	NR	A	F_c	A	A	A	L*$_c$
	FM	A	A	A*	A	NR	L_c	NR	A	NR	A_c		NR	NR	NR	NR	A_c		
Pesticide in soil	AI	A	A	A*	A	NR	A	A*	F	A	F	A	F	A	L	A	A	A	NR
	FM	A	NR	A*	A	NR		NR	A	NR	L		F	NR	NR	NR	A_c		NR
Pesticide in water, including potable water	AI	A	A	A*	A	A	L	A*	F	A	L	A	NR	A	L	A	A	A	NR
	FM	A	NR	A*	A	NR		NR	F	NR	L		F	NR	NR	NR	A_c		L*$_c$
Pesticide in air	AI	A		A*	A	NR	NR	NR	L_c	A	L	L	NR	A	NR	NR	A	A	NR
	FM	A		A*	A	NR		NR	L	NR	L		NR	NR	NR	NR	A_c		NR
Residues in human body fluids	AI	A	A	F*	A	L_c	A	L*	L_c	NR	NR	L	NR		L	NR	A		NR
	FM	A	NR		A	NR		NR	L	NR	NR		NR		NR	NR	A_c		NR
Relevant breakdown products	AI	A	A	A*	A	F	A	A*	A	A	NR	A	A	F	F	A	A	A	L*
	FM		A	A*		F		NR	A	NR	A_c		NR	NR	L	NR	A_c		NR*
ADDITIONAL DATA LISTED BY COUNTRIES																			
Freezer storage stability [CAN]	AI																		
	FM										F_c								

MATRIX 5. EFFICACY OF FORMULATIONS

TYPE OF DATA/INFORMATION	CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Preliminary range-finding tests	A	NR	A	A	A	A	L	A	A	NR	NR	NR	NR	F	NR	NR	A	NR
Field experimentation	A	A	A	A	A	A_c	F	A	A	A	A^*_c	A	A	F	A	A	A	NR
Information on possible occurrence of resistance	A	A	L_c	A	L	A_c	L_c	A	A	F		L_c	A	L	A	A	A	NR
Effects on quality and yield	A	A	L_c	A	A	A	L_c	A	L	A	A	A	NR	F	L	A	A	NR
Dose/efficacy relationships		A	NR			A_c	A/L_c	A	L	A	A	A_c	NR	A	L	A	A	NR
ADDITIONAL DATA LISTED BY COUNTRIES																		
Phytotoxicity to target plants [CEC, ITA, POR, NL, CAN]	A			A	A	A_c				A_c								
Undesirable or unintended effects [CEC, ITA, NL, POR]	A			A	A	A_c												
Effects on following crops [UK]							L_c											
Risks to adjacent/nearby crops [UK]							L_c											
Risk of phytotoxicity from carry-over in straw, etc. [UK]							L_c											
Safety to organisms used in biological control/compatibility with integrated pest management [UK]							L_c											
Effect on germination [CAN]										A_c								
Compatibility/formulation mixes [CAN]										F_c								
Efficacy tests for non-public health uses of pesticides [USA]																		L*

MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT

DATA REQUIRED			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
LABORATORY STUDIES																				
Hydrolysis rate including identification of metabolites and breakdown products	Indoor Uses	AI	A	NR	NR	A	A	F	F*$_c$	L	A*	A	A		A*	NR	A	A		A*
		FM																		
	Outdoor Uses	AI	A	A	F*$_c$	A	c	F	A*$_c$	A	A*	A	A	F	A*	F	A	A	A	A*
		FM																		
Photodegradation in water including identification of metabolites and breakdown products	Indoor Uses	AI	A	NR	NR	A	L$_c$	F	NR	L	A*	A	A		NR	NR	A$_c$	L		NR
		FM								L										
	Outdoor Uses	AI	A	A	F*$_c$	A	F$_c$	F	F*	F	A*	A	A	F	NR	F	A$_c$	L	A	F*$_c$
		FM								L										
Photodegradation on soil including identification of metabolites and breakdown products	Indoor Uses	AI		NR	NR	L	NR	F	NR	L	L*	A	L		F	NR	A$_c$	L		NR
		FM																		
	Outdoor Uses	AI		A	NR	L	NR	F	F*	A	L*	A	A	NR	F	F	A$_c$	L	A	F*$_c$
		FM								A										
Rate and route of photochemical degradation in air, identification of breakdown products	Indoor Uses	AI	A	NR	NR	A	NR	NR	NR	L	L*	L$_c$	L		NR	L	A$_c$	L		NR
		FM																		
	Outdoor Uses	AI	A	NR	L*$_c$	A	NR	NR	L*	L	L*	L$_c$	L	NR	NR	F	A$_c$	L		L*$_c$
		FM																		
Soil metabolism, aerobic and anaerobic, to determine rate and route of degradation in representative soil types including metabolites and breakdown products	Indoor Uses	AI	A	A$_c$	NR	A	L$_c$	A	F*$_c$	L	L	A$_c$	L		L*	NR	A	A		NR
		FM																		
	Outdoor Uses	AI	A	A	F*	A	L$_c$	A	A*$_c$	A	A	A$_c$	A	F	A*	F	A	A		F*$_c$
		FM								A										
Biodegradation in aquatic systems, aerobic and anaerobic, including identification of breakdown products and metabolites	Indoor Uses	AI	A	NR	NR	A	F	L$_c$	NR	L	L*	A	A		L*	NR	A	L		NR
		FM																		
	Outdoor Uses	AI	A	A	F*	A	F	L$_c$	F*$_c$	F	A*	A	A	NR	A*	F	A	L		L*$_c$
		FM								L										

MATRIX 6 (CONT). FATE AND BEHAVIOUR IN THE ENVIRONMENT

DATA REQUIRED			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Mobility/leaching in representative soil types and mobility of metabolites and breakdown products	Indoor Uses	AI	A	NR	NR	A	A	A	NR	L	L	A	L		L*	NR	A	A		NR
		FM																		
	Outdoor Uses	AI	A	A	F*$_c$	A	A	A	A*$_c$	A	A	A	A	NR	A*	F	A	A		L*$_c$
		FM			F*$_c$					A										
Adsorption/desorption in representative soil types including metabolites and breakdown products	Indoor Uses	AI	A	A	NR	A	A	A	F*$_c$	L	L	A	L		L*	NR	A	A		NR
		FM																		
	Outdoor Uses	AI	A	A	F*	A	A	A	A*$_c$	A	A	A	A	F	A*	F	A	A		A*$_c$
		FM								A										
Extent and nature of bound residues in soil	Indoor Uses	AI	A	NR	NR	A	F	A	NR	L	L	A	L		L	NR	A	F		NR
		FM																		
	Outdoor Uses	AI	A	A	F*	A	F	A	F*$_c$	A	A	A	A	NR	F	F	A	F		L*/A*$_c$
		FM								A										
Laboratory volatility	Indoor Uses	AI	A	A$_c$	F*	A	NR	L	NR	L	L	L	A		NR	NR	L$_c$	L		NR
		FM																		
	Outdoor Uses	AI	A	A$_c$	F*	A	NR	L	L*$_c$	F	A	L	A	A	NR	L	L$_c$	L		
		FM																		L*$_c$
Spray droplet size spectrum	Indoor Uses	AI																		
		FM		NR	NR				NR		A	L$_c$	NR		NR	NR	NR	NR	A	NR
	Outdoor Uses	AI																		
		FM		NR	NR				NR	F	A	L$_c$	NR	NR	NR	NR	NR	NR	A	L*$_c$
ADDITIONAL DATA LISTED BY COUNTRIES																				
Adsorption/desorption in water [CEC, ITA]	Indoor Uses	AI	A			A														
		FM																		
	Outdoor Uses	AI	A			A														
		FM																		
Leaching: Lysimeter experiment [DEN]	Indoor Uses	AI																		
		FM																		
	Outdoor Uses	AI		c																
		FM		c																
Degradation and distribution in water – sediment – system [AUT]	Indoor Uses	AI									L									
		FM									NR									
	Outdoor Uses	AI									F									
		FM									NR									

MATRIX 6 (CONT). FATE AND BEHAVIOUR IN THE ENVIRONMENT

DATA REQUIRED			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
FIELD STUDIES																				
Terrestrial field dissipation, distribution and dissipation in soil	Indoor Uses	AI																		
		FM	A	NR	NR	A	NR	F	NR	L	NR	NR	NR		NR	NR	L_c	F		NR
	Outdoor Uses	AI								A										
		FM	A	A_c	L*	A	L	F	A*$_c$	A	L	A	L	F	NR	L_c	L_c	F		F*$_c$
Aquatic (sediment) field dissipation; distribution and dissipation in water	Indoor Uses	AI																		
		FM	A	NR	NR	A	NR	L_c	NR	L	NR	NR	NR		NR	NR	L_c	L		NR
	Outdoor Uses	AI								A										
		FM	A	A_c	NR	A	NR	L_c	L*	F	A	L	L	F	NR	L_c	L_c	L		L*$_c$
Forestry field dissipation	Indoor Uses	AI																		
		FM	c	NR	NR		NR	L_c	NR	L	NR	NR	NR		NR	NR	L_c			NR
	Outdoor Uses	AI								L										
		FM	c	NR	NR		NR	L_c	L*	L	L	A	L	NR	NR	L_c	L_c			L*
Long term field dissipation	Indoor Uses	AI																		
		FM	c	NR	NR		NR	NR	NR	L	NR	NR	NR		NR	NR	L_c	L		NR
	Outdoor Uses	AI			L*					A										
		FM	c	A_c	L*		NR	L_c	F*$_c$	F	L	L_c	L	NR	NR	L_c	L_c	L		L*$_c$
High tier field studies with empahsis on potential to leach and contaminate ground water	Indoor Uses	AI																		
		FM	c	NR	NR		NR	L_c	NR	L	NR	NR	NR		NR	NR	L_c	L		NR
	Outdoor Uses	AI			L_c															
		FM	c	A_c	L*$_c$		NR	L_c	F*$_c$	L	L	NR	NR	NR	NR	L_c	L_c	L		L*
Spray drift field deposition	Indoor Uses	AI																		
		FM	c	NR	NR		NR	L_c	NR	L	NR	NR	NR		NR	NR	L_c	L		NR
	Outdoor Uses	AI																		
		FM	c	NR	NR$_c$		NR	L_c	NR	L	L	L	NR$_c$	NR	NR	L_c	L_c	L		L*
ADDITIONAL DATA LISTED BY COUNTRIES																				
Distribution/dissipation in air [CEC, ITA]	Indoor Uses	AI																		
		FM	A			A														
	Outdoor Uses	AI																		
		FM	A			A														
Accumulation in soil [GER]	Indoor Uses	AI																		
		FM																		
	Outdoor Uses	AI			L*															
		FM			L*															

MATRIX 6 (CONT). FATE AND BEHAVIOUR IN THE ENVIRONMENT

DATA REQUIRED			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Run-off [GER]	Indoor Uses	AI																		
		FM																		
	Outdoor Uses	AI			L															
		FM			L															
OTHER REQUIREMENTS																				
Accumulation in fish	Indoor Uses	AI	A	NR	L^*_c	A	L	NR	NR	L	L	NR	A_c		NR	NR	A_c	NR		NR
		FM		NR	NR			NR	NR	L	NR	NR	NR		NR	NR	NR	NR		NR
	Outdoor Uses	AI	A	L_c	L^*_c	A	L	L	F^*_c	F	F	F	A_c	NR	A*	F_c	A_c	NR		L*
		FM		L_c	NR			L	NR	F	NR	NR	NR	NR	NR	L_c	NR	NR		NR
Accumulation in other aquatic non-target organisms	Indoor Uses	AI		NR	NR		NR	NR	NR	L	NR	NR	NR		NR	NR	NR	NR		NR
		FM		NR	NR			NR	NR	L	NR	NR	NR		NR	NR	NR	NR		NR
	Outdoor Uses	AI		NR	L^*_c		NR	L	NR		L	NR	NR	NR	A*	F_c	NR	NR		L*
		FM		NR	NR			L	NR		NR	NR	NR	NR	NR	L_c	NR	NR		NR
APPLICATION AND RE-ENTRY EXPOSURE																				
Wetting, adherence and distribution to target plants	Indoor Uses	AI																		
		FM	A		L	A			NR	L*	NR	NR	NR		NR	L_c	NR	L		L*
	Outdoor Uses	AI																		
		FM	A		L	A			NR	L*	NR	NR	NR	NR	NR	L^c	NR	L		L*
Foliar dissipation	Indoor Uses	AI																		
		FM	c	L	L				NR	L*	L	NR_c	NR		NR	L_c	L	L		L^*_c
	Outdoor Uses	AI																		
		FM	c	L	L				NR	L*	L	L	NR	NR	NR	L_c	L	L		L^*_c
Dermal exposure	Indoor Uses	AI			A*															
		FM	c	NR	A*		A	L	NR	F^*_c	A	A	F		NR	L_c	NR	NR		L^*_c
	Outdoor Uses	AI			A*															
		FM	c	NR	A*		A	L	NR	L^*_c	A	A	F	NR	NR	L_c	NR	NR		L^*_c
Inhalation exposure	Indoor Uses	AI			A*															
		FM	c	NR	A*		L	L	NR	F^*_c	A	A	F		NR	L_c	NR	NR		L^*_c
	Outdoor Uses	AI			A*															
		FM	c	NR	A*		L	L	NR	L^*_c	A	A	F	NR	NR	L_c	NR	NR		L^*_c

MATRIX 6 (CONT). FATE AND BEHAVIOUR IN THE ENVIRONMENT

DATA REQUIRED			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Indoor surface dissipation	Indoor Uses	AI			A*					A*										
		FM	c	NR	A*		L	NR	NR	F*	NR	F	L		NR	L_c	NR	NR		L^*_c
	Outdoor Uses	AI			A*															
		FM	c	NR	A*		NR	NR	NR	L*	NR	NR	L	NR	NR	NR	NR	NR		L^*_c
Likely exposure to applicator under field conditions, detailed use information, timing and number of treatments per season per year for private and professional handlers etc.	Indoor Uses	AI			NR															
		FM	A	NR	A*	A	L	L	NR	A*	A	A	A		NR	L_c	NR	L		L
	Outdoor Uses	AI			NR															
		FM	A	NR	A*	A	L	L	NR	L*	A	A	A	NR	NR	L_c		L		L
Dermal penetration	Indoor Uses	AI			A*															
		FM	A	NR	A*	A	L	L	NR	F*	NR	L	A_c		NR	L_c	NR	NR		L*
	Outdoor Uses	AI			A*															
		FM	A	NR	A*	A	L	L	NR	L*	NR	L	A_c	NR	NR	L_c	NR	NR		L*
ADDITIONAL DATA LISTED BY COUNTRIES																				
Rainfall and arid conditions to be checked [AUS]	Indoor Uses	AI																		
		FM																		
	Outdoor Uses	AI																		
		FM								c										

MATRIX 7. RESIDUE CHEMISTRY

TYPE OF DATA/INFORMATION (for food/feed uses only)		CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
IDENTIFICATION OF BREAKDOWN PRODUCTS AND METABOLITES																			
Nature of the residue in plants	AI	A	A	A*	A	A	A	F*	A	A*	A	A	NR	A*	A	F_c	A	A	A*
	FM		NR					NR	A	NR	L		A	NR		NR	A		NR
Nature of the residue in livestock if residues remain in or on crop used for feed	AI	A	A	A*	A	A	A	A*	A	A	A	A	NR	L	A	L	L	A	F^*_c
	FM		NR					NR	A	NR	L		A	NR		NR	L		NR
ADDITIONAL DATA LISTED BY COUNTRIES																			
Behaviour of residue from application until harvest [CEC, ITA, NL]	AI	A			A	A													
	FM																		
Overall material balance [CEC, ITA, NL]	AI	A			A	A													
	FM																		
Estimation of exposure [CEC, ITA, NL]	AI	A			A	A													
	FM																		
Nature of residues in livestock if the product is applied directly or indirectly [CAN]	AI										A								
	FM										L								
MAGNITUDE OF THE RESIDUE																			
Crops from the field	AI		A					F*	L	A	A_c	A	NR	A*	F	A_c	A	A	NR
	FM	A	NR	A*	A	A	A	F*	A	NR	L_c		A	NR	L	F_c	A		A^*_c
Meat, milk, poultry and eggs	AI		A	L*			A_c	L*	L	A	F_c	A_c	NR	L	F	A_c	c	A	F^*_c
	FM	A	A		A	A_c		NR	A	NR	L_c		L_c	NR	L	F_c	c		NR

MATRIX 7. RESIDUE CHEMISTRY

TYPE OF DATA/INFORMATION (for food/feed uses only)		CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Processed food/feed	AI	A	NR		A	A		L*	L	A	F_c	L	NR	NR	L	L	c	A	NR
	FM	A	NR	L*	A	A	F	NR	F	NR	L_c		L_c	NR	L	L	c		F^*_c

MATRIX 7 (CONT). RESIDUE CHEMISTRY

TYPE OF DATA/INFORMATION (for food/feed uses only)		CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Potable water	AI		NR				NR	NR	L	A	L	L	NR	NR	L	NR	c	A	NR
	FM		NR	NR		NR		NR	F	NR	L		NR	NR	L	NR	c		L^*_c
Fish	AI		NR	L*			L_c	L*	L	L	L	L	NR	L	L	NR	c	A	NR
	FM	L_c	NR		L_c	NR		NR	L	NR	L		NR	NR	L	NR	c		L^*_c
Irrigated crops	AI		NR				L	NR	A	NR	L		NR	NR	L	NR	c		NR
	FM	A	NR	NR	A	A		NR	A	NR	L		NR	NR	L	NR	c		L^*_c
Food handling	AI		NR				NR	NR	L	NR	L	L	NR	NR	L	NR	c		NR
	FM	c	NR	NR		L		NR	L	NR	L		NR	NR	L	NR	c		L^*_c
Tobacco	AI		NR					NR	L	A	NR	NR	NR	NR	NR	NR	c		NR
	FM	A	NR	F*	A	A	A	NR	A	NR	NR		NR	NR	NR	NR	c		L^*_c
Freezer or storage stability tests for any of the above magnitude of the residue tests	AI		NR	F*			NR	A*	L	NR	A	NR	NR	NR	F	L	c		A^*_c
	FM		NR					A*	A	NR	A		NR	NR	L	L	c		A^*_c
ADDITIONAL DATA LISTED BY COUNTRIES																			
Post harvest use [GER]	AI																		
	FM			A*															
Quantification of metabolites in plants [POR]	AI						A												
	FM																		
Animal fibres (e.g. wool) [AUS]	AI								L_c										
	FM																		
Reduction of residue [USA]	AI																		NR
	FM																		L^*_c

MATRIX 7 (CONT). RESIDUE CHEMISTRY

TYPE OF DATA/INFORMATION (for food/feed uses only)			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
OTHER REQUIREMENTS																				
Proposed tolerance or maximum residue levels		AI		NR	A	A	A		F*	A	A	A	NR	NR	NR	F	NR	A	A	A*$_c$
		FM	A	NR			L		F*	NR	NR	L		NR	NR	L	NR	A		NR
Residue data in succeeding or rotational crops	Laboratory or greenhouse study	AI		L	NR	A	L		F*	L	A	F	NR	NR	NR	L	L	NR	A	F*$_c$
		FM	A$_c$	L	L*		NR	L	NR	L	NR	L		L	NR	L	L			NR
	Field study	AI		L	NR	A	L		L*	L	A	F	NR	NR	NR	L	L	NR	A	NR
		FM	A$_c$	L	L*		NR	L	NR	L	NR	L		L	NR	L	L			L*$_c$
Effects of household preparation, e.g. cooking, on residues		AI		NR	NR	A	L		L*	L	L	F	L	NR	NR	L	L	L	A	NR
		FM	A	NR	L*		NR	L	L*	L	NR	L		NR	NR	L	L			L*$_c$
Effects on odour, taste and quality of food due to residues		AI		NR	NR	A	L		L$_c$	L	NR	L	NR	NR	NR	L	NR	A		NR
		FM	A	NR	L$_c$		NR	NR	L$_c$	A	F	L		L$_c$	NR	L	NR	A		NR
ADDITIONAL DATA LISTED BY COUNTRIES																				
Proposed preharvest intervals or witholding periods or storage periods [CEC, ITA, NL]		AI				A														
		FM	A				A													
Effect of industrial processing on residues/wool residues [AUS]		AI								F$_c$										
		FM								F										
Analytical reference standard [USA]		AI																		A$_c$
		FM																		NR

MATRIX 8. TOXICOLOGY AND METABOLISM STUDIES

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
ACUTE TESTING																				
Acute oral	Food/feed	AI	A	A	A*	A	A*	A	F*	A^*_c	A*	A*	A*	A*	A*	A*	A	A	A	A*
		FM	A	A	A*	A	A*	A	F*	A^*_c	A*	A*	A*	A*	A*	F*	A			F^*_c
	Non-food/ Non-feed	AI	A	A	A*	A	A*	A	F*	A^*_c	A*	A*	A*	A*	A*	A*	A	A	A	A*
		FM	A	A	A*	A	A*	A	F*	A^*_c	A*	A*	A*	A*	A*	F*	A			F^*_c
Acute dermal	Food/feed	AI	A	A	A*	A	F*	A	F*	A^*_c	A*	A*	A*	A*	A*	A*	A	A	A	A*
		FM	A_c	A	A*	A	F*	A	F*	A^*_c	A*	A*	A/F*	A*	A*	F*	A			F^*_c
	Non-food/ Non-feed	AI	A	A	A*	A	F*	A	F*	A^*_c	A*	A*	A*	A*	A*	A*	A	A	A	A*
		FM	A_c	A	A*	A	F*	A	F*	A^*_c	A*	A*	A/F*	A*	A*	F*	A			F^*_c
Acute inhalation	Food/feed	AI	A	A	A*	A	NR	A	L*	F^*_c	F*	F*	A^*_c	F^*_c	A*	A*	A_c	A	A	A*
		FM	A	L	A*	A	L*	A	L*	F^*_c	F*	F*	A/F^*_c	F^*_c	A*	NR	A_c			F^*_c
	Non-food/ Non-feed	AI	A	A	A*	A	NR	A	L*	F^*_c	F*	F*	A^*_c	F^*_c	A*	A*	A_c	A	A	A*
		FM	A	L	A*	A	L*	A	L*	F^*_c	F*	F*	A/F^*_c	F^*_c	A*	NR	A_c			F^*_c
Acute dermal irritation	Food/feed	AI	A	A	A*	A	F*	A	F*	A*	A*	F*	A*	NR	A*	A*	A	A	A	A*
		FM	A_c	A	A*	A	F*	A	F*	A*	A*	F*	A*	A*	A*	A*	A			F^*_c
	Non-food/ Non-feed	AI	A	A	A*	A	F*	A	F*	A*	A*	F*	A*	NR	A*	A*	A	A	A	A*
		FM	A_c	A	A*	A	F*	A	F*	A*	A*	F*	A*	A*	A*	A*	A			F^*_c

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Acute eye irritation	Food/feed	AI	A	A	A*	A	F*	A	F*	A*	A*	F*	A*	NR	A*	A*	A_c	A	A	A*
		FM	A_c	A	A*	A	F*	A	F*	A*	A*	F*	A*	A*	A*	A*	A_c			F^*_c
	Non-food/ Non-feed	AI	A	A	A*	A	F*	A	F*	A*	A*	F*	A*	NR	A*	A*	A_c	A	A	A*
		FM	A_c	A	A*	A	F*	A	F*	A*	A*	F*	A*	A*	A*	A*	A_c			F^*_c
Skin sensitization	Food/feed	AI	A	A	A*	A	A*	F	F*	A*	A*	F*	A^*_c	NR	A*	A*	A	A	A	A*
		FM	A	NR	A*	A	L*	L	F*	A*	A*	F*	L^*_c	A*	A*	A*	A			F*
	Non-food/ Non-feed	AI	A	A	A*	A	A*	F	F*	A*	A*	F*	A^*_c	NR	A*	A*	A	A	A	A*
		FM	A	NR	A*	A	L*	L	F*	A*	A*	F*	L^*_c	A*	A*	A*	A			F*
Acute intraperitoneal toxicity	Food/feed	AI	A	N R	A*	A	NR	NR	L*	NR	NR	NR	L*	NR	F	NR	NR	F	A	NR
		FM		NR	NR		NR	NR	L*	NR	NR	NR	NR	NR	NR	NR	NR			NR
	Non-food/ Non-feed	AI	A	NR	A*		NR	NR	L*	NR	NR	NR	L*	NR	F	NR	NR	F	A	NR
		FM	A	NR	NR	A	NR	NR	L*	NR	NR	NR	NR	NR	NR	NR	NR			NR
Potentiation/interactions of multiple active ingredients or products	Food/feed	AI		NR	L*		NR	NR	L*	F^*_c	NR	NR	L*	NR	NR	L^*_c	A	NR	A	NR
		FM		NR	L*	L_c	NR	NR	L*	F^*_c	NR	F*	L*	A*	NR	L^*_c	A			NR
	Non-food/ Non-feed	AI		NR	L*		NR	NR	L*	L^*_c	NR	NR	L*	NR	NR	L^*_c	A	NR	A	NR
		FM		NR	L*	L_c	NR	NR	L*	L^*_c	NR	F*	L*	A*	NR	L^*_c	A			NR

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
ADDITIONAL DATA LISTED BY COUNTRIES																				
Acute oral toxicity (second mammal species) [AUT]	Food/feed	AI									A*									
		FM									NR									
	Non-food/ Non-feed	AI									A*									
		FM									NR									
SUBCHRONIC TESTING																				
Repeated dose oral – 28 day	Food/feed	AI	A	NR	A*	A	NR	NR	F*	F_c	NR	NR	A*	NR	NR	L*	NR_c	L		NR
		FM		NR	L*		NR	NR	NR	NR	NR	NR	L*	NR	NR	NR	NR			NR
	Non-food/ Non-feed	AI	A	NR	A*	A	NR	NR	F*	F_c	NR	NR	A*	NR	NR	L*	NR	L		NR
		FM		NR	L*		NR	NR	NR	NR	NR	NR	L*	NR	NR	NR	NR			NR
Repeated dose inhalation – 28 day	Food/feed	AI		NR	L*		NR	L_c	L*	L_c	F*	L*	L*	NR	NR	NR	NR	L		NR
		FM		NR	L*		NR	NR	NR	NR	NR	L*	NR	NR	NR	NR	NR			NR
	Non-food/ Non-feed	AI		NR	L*		NR	L_c	L*	L_c	F*	L*	L*	NR	NR	NR	NR	L		NR
		FM		NR	L*		NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR			NR
Subchronic oral rat – 90 day	Food/feed	AI	A	A	A*	A	A*	A	F*	$A*_c$	A*	$A*_c$	A*	A*	A*	$A*_c$	A	A	A	L*
		FM		NR	L*		NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR			NR
	Non-food/ Non-feed	AI	A	A	A*	A	F*	A	F*	$A*_c$	A*	$A*_c$	A*	A*	A*	$A*_c$	A	L	A	L*
		FM		NR	L*		NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR			NR

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Subchronic oral non-rodent – 90 day	Food/feed	AI	A	A	A*	A	L*	A	F*	A^*_c	A*	A^*_c	NR	A*	A*	F^*_c	A	A	A	L*
		FM		NR	NR		NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR			NR
	Non-food/ Non-feed	AI	A	A	A*	A	F*	A	F*	A^*_c	A*	NR	NR	NR	A*	F^*_c	A	L	A	L*
		FM		NR	NR		NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR			NR
Subchronic dermal – 90 day	Food/feed	AI		NR	L*		NR	NR	L*	NR	NR	L*	L*	L^*_c	NR	L*	NR	L		L*
		FM		NR	L*		NR	NR	NR	NR	NR	L*	NR	NR	NR	NR	NR			NR
	Non-food/ Non-feed	AI		NR	L*		NR	NR	L*	NR	NR	L*	L*	L^*_c	NR	L*	NR	L		L*
		FM		NR	L*		NR	NR	NR	NR	NR	L*	NR	NR	NR	NR	NR			NR
Subchronic inhalation – 90 day	Food/feed	AI		NR	L*		L*	L_c	L*	L^*_c	NR	L*	NR	L^*_c	NR	NR	NR	L		L*
		FM		NR	L*		NR	NR	NR	NR	NR	L*	NR	NR	NR	NR	NR			NR
	Non-food/ Non-feed	AI		NR	L*		L*	L_c	L*	L^*_c	NR	L*	NR	L^*_c	NR	NR	NR	L		L*
		FM		NR	L*		NR	NR	NR	NR	NR	L*	NR	NR	NR	NR	NR			NR
ADDITIONAL DATA LISTED BY COUNTRIES																				
Other routes (inhalation, percutaneous as appropriate) [CEC, ITA]	Food/feed	AI	A			A														
		FM																		
	Non-food/ Non-feed	AI	A			A														
		FM																		

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Repeated dose dermal (21-28 days) [GER, POR, AUS, USA]	Food/feed	AI			L*			F		L^*_c										L*
		FM			L*			L		NR										L*
	Non-food/ Non-feed	AI			L*			F		L^*_c										L*
		FM			L*			L		NR										L*
Repeated dose/28 day [AUT]	Food/feed	AI									F*									
		FM									NR									
	Non-food/ Non-feed	AI									F*									
		FM									NR									
DEVELOPMENTAL TOXICITY AND REPRODUCTIVE STUDIES																				
Teratogenicity rodent	Food/feed	AI	A	A	A*	A	A*	A	F*	A^*_c	A*	A^*_c	A*	A*	A*	A^*_c	A	A	c	A*
		FM		NR	NR		NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR			NR
	Non-food/ Non-feed	AI	A	A	A*	A	A*	A	F*	A^*_c	A*	A^*_c	A*	A*	A*	A^*_c	A	L	c	A^*_c
		FM		NR	NR		NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR			NR
Teratogenicity – second species	Food/feed	AI	A	A	A*	A	L*	A	F*	A^*_c	A*	A^*_c	A*	A*	A*	A^*_c	NR	F	c	A*
		FM		NR	NR		NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR			NR
	Non-food/ Non-feed	AI	A	A	A*	A	L*	A	F*	A^*_c	A*	A^*_c	A*	A*	A*	A^*_c	NR	L	c	L^*_c
		FM		NR	NR		NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR			NR

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Multi-generation reproduction	Food/feed	AI	A	A	A*	A	A*	A	F*	A^*_c	A*	A^*_c	A*	A^*_c	A*		A	A	c	A*
		FM		NR	NR		NR	NR	NR	NR	NR	NR	NR	NR	NR		NR			NR
	Non-food/ Non-feed	AI	A	A	A*	A	A*	A	F*	A^*_c	F*	A^*_c	A*	L*	A*		A	L	c	L^*_c
		FM		NR	NR		NR	NR	NR	NR	NR	NR	NR	NR	NR		NR			NR
ADDITIONAL DATA LISTED BY COUNTRIES																				
Teratogenicity rodent – dermal [GER]	Food/feed	AI			L*															
		FM			NR															
	Non-food/ Non-feed	AI			L*															
		FM			NR															
Teratogenicity second species – dermal [GER]	Food/feed	AI			L*															
		FM			NR															
	Non-food/ Non-feed	AI			L*															
		FM			NR															

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES

TYPE OF DATA/INFORMATION				CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
METABOLISM TESTING																					
Toxico-kinetics	absorption, distribution, excretion	Food/feed	AI	A	A	A*	A	A^*_c	A	F*	A	A*	A*	A*	A	A*	A*	A_c	A	A	F*
			FM		NR	NR		NR	NR	NR	L	NR	NR	NR	NR	NR	NR	NR			NR
		Non-food/ Non-feed	AI	A	A	A*	A	A^*_c	A	F*	A	F*	A*	A*	A	A*	A*	A_c	L	A	L*
			FM		NR	NR		NR	NR	NR	L	NR	NR	NR	NR	NR	NR	NR			NR
	metabolic pathways	Food/feed	AI	A	A	A*	A	A^*_c	A	F*	A	A*	A*	A*	A	A*	F*	A	A	A	F*
			FM		NR	NR		NR	NR	NR	L	NR	NR	NR	NR	NR	NR	NR			NR
		Non-food/ Non-feed	AI	A	A	A*	A	A^*_c	A	F*	A	F*	A*	A*	A	A*	F*	A	L	A	L*
			FM		NR	NR		NR	NR	NR	L	NR	NR	NR	NR	NR	NR	NR			NR
ADDITIONAL DATA LISTED BY COUNTRIES																					
Animal transfer studies [AUS]		Food/feed	AI								F										
			FM								F										
		Non-food/ Non-feed	AI								NR										
			FM								NR										
Dermal penetration [USA]		Food/feed	AI																		L*
			FM																		L*
		Non-food/ Non-feed	AI																		L*
			FM																		L*

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Human toxicokinetics study [FIN]	Food/feed	AI											L*							
		FM																		
	Non-food/ Non-feed	AI											L*							
		FM																		
CHRONIC TESTING																				
Chronic toxicity rodent	Food/feed	AI	A	A	A*	A	F*	A	F	A*$_c$	A*	A*$_c$	A*	A*	A*	A*$_c$	A	A	c	A*
		FM		NR	NR		NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR			NR
	Non-food/ Non-feed	AI	A	NR	L*	A	NR	L	F	c	A*	A*$_c$	F*$_c$	L*$_c$	A*	A*$_c$	A	L	c	L*
		FM		NR	NR		NR	NR	NR	c	NR	NR	NR	NR	NR	NR	NR			NR
Chronic toxicity non-rodent	Food/feed	AI	A	A$_c$	L*	A	NR	A	F	A*$_c$	NR	NR	A*	A*	NR	A*$_c$	A	F	c	A*
		FM		NR	NR		NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR			NR
	Non-food/ Non-feed	AI	A	NR	L*	A	NR	L	F	c	NR	NR	F*$_c$	L*$_c$	NR	A*$_c$	A	L	c	L*
		FM		NR	NR		NR	NR	NR	c	NR	NR	NR	NR	NR	NR	NR			NR
Carcinogenicity – rat	Food/feed	AI	A	A	A*	A	L*	A	F	A*$_c$	A*	A*	A*	A*	A*	F*$_c$	A	A	c	A*
		FM		NR	NR		NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR			NR
	Non-food/ Non-feed	AI	A	A	L*	A	L*	A	F	c	A*	A*	F*$_c$	L*$_c$	A*	F*$_c$	A	L	c	L*
		FM		NR	NR		NR	NR	NR	c	NR	NR	NR	NR	NR	NR	NR			NR

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Carcinogenicity – second species	Food/feed	AI	A	A	A*	A	L*	A	F	A*	A*	A*$_c$	A*	A*	A*	F*$_c$	A	F	c	A*
		FM		NR	NR		NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR			NR
	Non-food/ Non-feed	AI	A	A	L*	A	L*	A	F	c	A*	A*$_c$	F*$_c$	L*$_c$	A*	F*$_c$	A	L	c	L*
		FM		NR	NR		NR	NR	NR	c	NR	NR	NR	NR	NR	NR	NR			NR
ADDITIONAL DATA LISTED BY COUNTRIES																				
Subchronic oral non-rodent (dog) – one year [CAN]	Food/feed	AI										F*								
		FM										NR								
	Non-food/ Non-feed	AI										NR								
		FM										NR								
Combined carcinogenicity and chronic studies [AUS]	Food/feed	AI								F$_c$										
		FM								NR										
	Non-food/ Non-feed	AI								c										
		FM								c										
MUTAGENICITY – Testing for specific endpoints (listed by countries)																				
Gene mutations	Food/feed	AI	A	A	A*	A							A	A*	A*		A			
		FM			NR									NR	NR					
	Non-food/ Non-feed	AI	A	A	A*	A							A	A*	A*		A			
		FM			NR									NR	NR					

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Chromosomal damage	Food/feed	AI	A	A	A*	A				A*	A*	A*$_c$	A	A*	A*		A			
		FM			NR					NR	NR	NR		NR	NR					
	Non-food/ Non-feed	AI	A	A	A*	A				A*	A*	A*$_c$	A	A*	A*		A			
		FM			NR					NR	NR	NR		NR	NR					
DNA aberrations/genetic damage	Food/feed	AI	A	F	A*	A							c	A*			L_c			
		FM			NR									NR						
	Non-food/ Non-feed	AI	A	F	A*	A							c	A*			L_c			
		FM			NR									NR						
Gene toxicity in vitro and in vivo	Food/feed	AI									A*									
		FM									NR									
	Non-food/ Non-feed	AI									A*									
		FM									NR									
Induction of point mutation in microbial assay (e.g. salmonella)	Food/feed	AI								A*		A*$_c$								
		FM								NR		NR								
	Non-food/ Non-feed	AI								A*		A*								
		FM								NR		NR								
Production of cytogenetic damage in bone marrow or other proliferative cells, in vivo (e.g. micronucleus assay)	Food-feed	AI								F*$_c$										
		FM								NR										
	Non-food/ Non-feed	AI								F*$_c$										
		FM								NR										

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Genetic damage other than cytogenetic end points (e.g. unscheduled DNA synthesis)	Food/feed	AI								F*$_c$										
		FM								NR										
	Non-food/ Non-feed	AI								F*$_c$										
		FM								NR										
DNA synthesis/repair	Food/feed	AI									A*	A/F*$_c$								
		FM									NR	NR								
	Non-food/ Non-feed	AI									A*	A/F*$_c$								
		FM									NR	NR								
MUTAGENICITY – Specific mutagenicity assays																				
Salmonella typhimurium	Food/feed	AI			A*		A*$_c$	F	F*		A*$_c$	A		A*	A*	A*	A	c	c	A*
		FM			NR		NR	NR	NR		NR			NR	NR	NR				NR
	Non-food/ Non/feed	AI			A*		A*$_c$	L	F*		A*$_c$	A		A*	A*	A*	A	c	c	A*
		FM			NR		NR	NR	NR		NR			NR	NR	NR				NR
Escherichia coli	Food/feed	AI			L*		A*$_c$	F	NR		A*$_c$	c		A*	NR	A*		c	c	
		FM			NR		NR	NR	NR		NR			NR	NR	NR				
	Non-food/ Non-feed	AI			L*		A*$_c$	L	NR		A*$_c$	c		A*	NR	A*	A	c	c	
		FM			NR		NR	NR	NR		NR			NR	NR	NR				

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Mammalian cytogenetics, in vitro	Food/feed	AI			A*			F	F*		A^*_c	A		A*	A*	A*	A_c	c	c	A*
		FM			NR			NR	NR		NR			NR	NR	NR				NR
	Non-food/ Non-feed	AI			A*			L	F*		A^*_c	A		A*	A*	A*		c	c	A*
		FM			NR			NR	NR		NR			NR	NR	NR				NR
Mammalian cytogenetics, in vivo	Food/feed	AI			F*			A			A^*_c	A		L^*_c	NR	F*	L_c	c	c	A^*_c
		FM			NR			NR			NR			NR	NR	NR				NR
	Non-food/ Non-feed	AI			F*			L			A^*_c	A		L^*_c	NR	F*	L_c	c	c	A^*_c
		FM			NR			NR			NR			NR	NR	NR				NR
Micronucleus test	Food/feed	AI			A*			A	F*		A^*_c	c		L^*_c	L*	F*	L_c	c	c	A^*_c
		FM			NR			NR	NR		NR			NR	NR	NR				NR
	Non-food/ Non-feed	AI			A*			L	F*		A^*_c	c		L^*_c	L*	F*	L_c	c	c	A^*_c
		FM			NR			NR	NR		NR			NR	NR	NR				NR
Mammalian cell gene mutation, in vitro	Food/feed	AI			F*			F	F*		A^*_c	c		NR	NR	F*	L_c	c	c	A^*_c
		FM			NR			NR	NR		NR			NR	NR	NR				NR
	Non-food/ Non-feed	AI			F*			L	F*		A^*_c	c		NR	NR	F*	L_c	c	c	A^*_c
		FM			NR			NR	NR		NR			NR	NR	NR				NR
Drosophila melanogaster, sex-linked recessive lethal test	Food/feed	AI			L*			F	NR		A^*_c	c		L^*_c	NR	L*	NR	c	c	
		FM			NR			NR	NR		NR			NR	NR	NR				
	Non-food/ Non-feed	AI			L*			L	NR		A^*_c	c		L^*_c	NR	L*	NR	c	c	
		FM			NR			NR	NR		NR			NR	NR	NR				

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Dominant lethal test, rodent	Food/feed	AI			L*			F	NR		A*$_c$	c		L*$_c$	L*$_c$	F*	L$_c$	c	c	
		FM			NR			NR	NR		NR			NR	NR	NR				
	Non-food/ Non-feed	AI			L*			L	NR		A*$_c$	c		L*$_c$	L*$_c$	F*	L$_c$	c	c	
		FM			NR			NR	NR		NR			NR	NR	NR				
Sister chromatid exchange, mammalian cells in vitro	Food/feed	AI			L*			L	F*		A*$_c$	c		NR	NR	L*	L	c	c	
		FM			NR			NR	NR		NR			NR	NR	NR				
	Non-food/ Non-feed	AI			L*			L	F*		A*$_c$	c		NR	NR	L*	L	c	c	
		FM			NR			NR	NR		NR			NR	NR	NR				
Saccharomyces cerevisiae, gene mutation	Food/feed	AI			L*			L	NR		A*$_c$	c		NR	NR	L*	L$_c$	c	c	
		FM			NR			NR	NR		NR			NR	NR	NR				
	Non-food/ Non-feed	AI			L*			L	NR		A*$_c$	c		NR	NR	L*	L$_c$	c	c	
		FM			NR			NR	NR		NR			NR	NR	NR				
Mouse spot	Food/feed	AI			L*			NR	NR		A*$_c$	c		NR	NR	NR	c	c	c	
		FM			NR			NR	NR		NR			NR	NR	NR				
	Non-food/ Non-feed	AI			L*			NR	NR		A*$_c$	c		NR	NR	NR	c	c	c	
		FM			NR			NR	NR		NR			NR	NR	NR				
Heritable translocation, mouse	Food/feed	AI			L*			L	NR		A*$_c$	c		NR	NR	NR	c	c	c	
		FM			NR			NR	NR		NR			NR	NR	NR				
	Non-food/ Non-feed	AI			L*			L	NR		A*$_c$	c		NR	NR	NR	c	c	c	
		FM			NR			NR	NR		NR			NR	NR	NR				
NEUROTOXICITY TESTING																				
Acute neurotoxicity – rat	Food/feed	AI	A$_c$	NR	L*	A		L$_c$	NR	c	F*	NR$_c$	L*$_c$	NR	NR	L*$_c$	A	c		L*
		FM		NR	NR			NR	NR	c	NR	NR$_c$	NR	NR	NR	NR	NR	c		NR
	Non-food/ Non-feed	AI	A$_c$	NR	L*	A		L$_c$	NR	c	F*	NR$_c$	L*$_c$	NR	NR	L*$_c$	A	c		L*
		FM		NR	NR			NR	NR	c	NR	NR$_c$	NR	NR	NR	NR	NR	c		NR
Acute delayed neurotoxicity of organophosphates – hen	Food/feed	AI		A$_c$	L*		A*$_c$	A	F*$_c$	A$_c$	L*	L$_c$*	A*	L*$_c$	F*	L*$_c$	L	c		L*$_c$
		FM		NR	NR		NR	NR	NR	c	NR	NR	NR	NR	NR	NR	NR	c		NR
	Non-food/ Non-feed	AI		A$_c$	L*		L*$_c$	A	F*$_c$	c	L*	L$_c$*	A*	L*$_c$	F*	L*$_c$	L	c		L*$_c$
		FM		NR	NR		NR	NR	NR	c	NR	NR	NR	NR	NR	NR	NR	c		NR

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
28 day delayed neurotoxicity	Food/feed	AI		NR	L*		A*	L	L^*_c	c	L*	L_c*	L*	NR	NR	L^*_c	L	c		L^*_c
		FM		NR	NR		NR	NR	NR	c	NR	NR	NR	NR	NR	NR	NR	c		NR
	Non-food/ Non-feed	AI		NR	L*		A*	L	L^*_c	c	L*	L_c*	L*	NR	NR	L^*_c	L	c		L^*_c
		FM		NR	NR		NR	NR	NR	c	NR	NR	NR	NR	NR	NR	NR	c		NR
Subchronic neurotoxicity – rat – 90 day	Food/feed	AI		NR	L*			L	NR	c	L*	NR_c	NR	NR	NR	NR	A	c		L*
		FM		NR	NR			NR	NR	c	NR	NR_c	NR	NR	NR	NR	NR	c		NR
	Non-food/ Non-feed	AI		NR	L*			L	NR	c	L*	NR_c	NR	NR	NR	NR	A	c		L*
		FM		NR	NR			NR	NR	c	NR	NR_c	NR	NR	NR	NR	NR	c		NR
Subchronic delayed neurotoxicity of organophosphates – hen	Food/feed	AI		NR	L*			A	L*	c	L*	NR	NR	L^*_c	NR	NR	L	c		c
		FM		NR	NR			NR	NR	c	NR	NR	NR	NR	NR	NR	NR	c		c
	Non-food/ Non-feed	AI		NR	L*			A	L^*_c	c	L*	NR	NR	L^*_c	NR	NR	L	c		c
		FM		NR	NR			NR	NR	c	NR	NR	NR	NR	NR	NR	NR	c		c
Postnatal developmental neurotoxicity	Food/feed	AI		NR	NR			NR	NR	c	F*	NR_c	NR	NR	NR	NR	NR	c		L*
		FM		NR	NR			NR	NR	c	NR	NR_c	NR	NR	NR	NR	NR	c		NR
	Non-food/ Non-feed	AI		NR	NR			NR	NR	c	L*	NR_c	NR	NR	NR	NR	NR	c		L*
		FM		NR	NR			NR	NR	c	NR	NR_c	NR	NR	NR	NR	NR	c		NR
ADDITIONAL DATA LISTED BY COUNTRIES																				
Cholinesterase inhibition [NL]	Food/feed	AI					A^*_c													
		FM					NR													
	Non-food/ Non-feed	AI					A^*_c													
		FM					NR													

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
OTHER TESTING																				
Visual systems studies	Food/feed	AI		NR	L*		A	L	NR	F*$_c$	NR	NR	NR	NR	NR	NR	NR			L*
		FM		NR	NR		NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR			NR
	Non-food/ Non-feed	AI		NR	L*		L	L	NR	F*$_c$	NR	NR	NR	NR	NR	NR	NR			L*
		FM		NR	NR		NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR			NR
Toxic effects in livestock and pets	Food/feed	AI	A	A	L*	A	NR	NR	NR		NR	NR	L	NR	NR	NR	NR		A	L*
		FM		NR	NR		NR	NR	NR		NR	NR	L	NR	NR	NR	NR			L*
	Non-food/ Non-feed	AI	A	A	L*	A	NR	NR	NR		NR	NR	L	NR	NR	NR	NR		A	L*
		FM		NR	NR		NR	NR	NR		NR	NR	L	NR	NR	NR	NR			L*
Antidote	Food/feed	AI		NR	L*		A	L	L	NR	A	NR/L$_c$	A	NR	A	NR	NR$_c$	L$_c$	A	NR
		FM		NR	NR		A	NR	NR	F*$_c$	A	NR	NR	F	A	NR	NR$_c$			NR
	Non-food/ Non-feed	AI		NR	L*		A	L	L	NR	A	NR/L$_c$	A	NR	A	NR	NR$_c$	L$_c$	A	NR
		FM		NR	NR		A	NR	NR	F*$_c$	A	NR	NR	F	A	NR	NR$_c$			NR
ADDITIONAL DATA LISTED BY COUNTRIES																				
Toxic effects of metabolites from treated plants in cases where different from those identified in animal studies [CEC, ITA]	Food/feed	AI	A			A														
		FM																		
	Non-food/ Non-feed	AI																		
		FM																		

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Any mechanistic studies needed to clarify effects reported in toxicity studies [CEC, ITA]	Food/feed	AI	A			A														
		FM																		
	Non-food/ Non-feed	AI	A																	
		FM																		
Pharmacological study [JAP]	Food/feed	AI												A						
		FM												NR						
	Non-food/ Non-feed	AI												A						
		FM												NR						
MEDICAL DATA																				
Medical surveillance of manufacturing plant personnel	Food/feed	AI	A	c	A	A	A*	NR	F_c	L*	A	NR_c	L	NR	NR	L_c	c	F	c	L_c
		FM		c	A		A*	NR	F_c	L*	NR	NR_c	L	NR	NR	L_c	c	F	c	L_c
	Non-food/ Non-feed	AI	A	c	A	A	A*	NR	F_c	L*	A	NR_c	L	NR	NR	L_c	c	F	c	L_c
		FM		c	A		A*	NR	F_c	L*	NR	NR_c	L	NR	NR	L_c	c	F	c	L_c
Clinical cases and poisoning incidents	Food/feed	AI	A	c	A	A	A*	NR	F_c	$L*_c$	A	NR_c	A	NR	A	L_c	c	F	c	L_c
		FM		c	A		A*	A	F_c	$L*_c$	NR	NR_c	A	NR	A	L_c	c	F	c	L_c
	Non-food/ Non-feed	AI	A	c	A	A	A*	NR	F_c	$L*_c$	A	NR_c	A	NR	A	L_c	c	F	c	L_c
		FM		c	A		A*	A	F_c	$L*_c$	NR	NR_c	A	NR	A	L_c	c	F	c	L_c
Health records from industry and agriculture	Food/feed	AI	A	c	A	A	A*	NR	F_c	L*	A	NR_c	L	NR	NR	NR	c	L	c	L_c
		FM		c	A		A*	L	F_c	L*	NR	NR_c	L	NR	NR	NR	c	L	c	L_c
	Non-food/ Non-feed	AI	A	c	A	A	A*	NR	F_c	L*	A	NR_c	L	NR	NR	NR	c	L	c	L_c
		FM		c	A		A*	L	F_c	L*	NR	NR_c	L	NR	NR	NR	c	L	c	L_c
Observations of exposure of the general population or epidemiological studies	Food/feed	AI	A	c	A	A	A*	NR	F_c	$L*_c$	A	NR_c		NR	A	NR	c		c	$L*_c$
		FM		c	A		A*	L	F_c	$L*_c$	NR	NR_c	L	NR	A	NR	c		c	$L*_c$
	Non-food/ Non-feed	AI	A	c	A	A	A*	NR	F_c	$L*_c$	A	NR_c		NR	A	NR	c		c	$L*_c$
		FM		c	A		A*	L	F_c	$L*_c$	NR	NR_c	L	NR	A	NR	c		c	$L*_c$

MATRIX 8 (CONT). TOXICOLOGY AND METABOLISM STUDIES

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
ADDITIONAL DATA LISTED BY COUNTRIES																				
Diagnosis of poisoning [CEC, ITA]	Food/feed	AI	A			A														
		FM																		
	Non-food/ Non-feed	AI	A			A														
		FM																		
Specific signs of poisoning: clinical tests [CEC, ITA]	Food/feed	AI	A			A														
		FM																		
	Non-food/ Non-feed	AI	A			A														
		FM																		
Sensitization/allergenicity observations, proposed treatment, prognosis of expected effects of poisoning, summary of mammalian toxicology and conclusions (NOAEL, NOEL, ADI) [CEC]	Food/feed	AI	A																	
		FM																		
	Non-food/ Non-feed	AI	A																	
		FM																		
Ongoing updates of exposure and monitoring data, MSDS, toxicology and epidemiology data, where available [AUS]	Food/feed	AI								A_c										
		FM								A_c										
	Non-food/ Non-feed	AI								A_c										
		FM								A_c										

MATRIX 9. ECOTOXICOLOGY

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
AVIAN TESTING																				
Avian acute oral LD50	Indoor Uses	AI		NR	A*	A	NR	L	L*$_c$	L	L*	NR	NR		NR	NR	F$_c$	c		A*
		FM		NR	L*	A	NR	L	NR	L	L*	NR	NR		NR	NR	L$_c$	c		NR
	Outdoor Uses	AI	A	A$_c$	A*	A	L*	A	A*$_c$	A$_c$	A*	A$_c$	A	NR	A*	F	A$_c$	c	A	A*
		FM	A	NR	L*	A		L	L*$_c$	L	A*	L$_c$	L	L$_c$	NR	L	L$_c$	c		NR
Avian dietary toxicity LC50 – terrestrial bird (short-term toxicity)	Indoor Uses	AI		NR	L*	A		L	NR	L	NR	NR	NR		NR	NR	L$_c$	c		A*
		FM		NR	L*			L	NR	L	NR	NR	NR		NR	NR	L$_c$	c		NR
	Outdoor Uses	AI	A$_c$	A$_c$	F*	A		A	A*$_c$	A	A*	A	A$_c$	NR	A*	F	A$_c$	c	A	A*
		FM		NR	L*			L	L*$_c$	L	L*	L	L$_c$	NR	NR	L	L$_c$	c		NR
Avian dietary toxicity LC50 – aquatic bird (short-term)	Indoor Uses	AI		NR	L*			NR	NR	L	NR	NR	NR		NR	NR	L$_c$	c		NR
		FM		NR	NR			NR	NR	L	NR	NR	NR		NR	NR	L$_c$	c		NR
	Outdoor Uses	AI	A$_c$	A$_c$	F*			NR	L*	L	F*	A	A$_c$	NR	NR	F	A$_c$	c		A*
		FM		NR	NR			NR	NR	L	L*	L	L$_c$	NR	NR	L	L$_c$	c		NR
Avian reproduction test – terrestrial bird	Indoor Uses	AI		NR	NR	A		NR	NR	L	NR	NR	NR		NR	NR	L$_c$	c		NR
		FM		NR	NR			NR	NR	L	NR	NR	NR		NR	NR	L$_c$	c		NR
	Outdoor Uses	AI	A$_c$	A$_c$	L*	A		L	L*	L	L*	F	F$_c$	NR	NR	L	L$_c$	c		F*
		FM		NR	NR			NR	NR	L	L*	L	NR	NR	NR	L	L$_c$	c		NR
Avian reproduction test – aquatic bird	Indoor Uses	AI		NR	NR	A		NR	NR	L	NR	NR	NR		NR	NR	L$_c$	c		NR
		FM		NR	NR			NR	NR	L	NR	NR	NR		NR	NR	L$_c$	c		NR
	Outdoor Uses	AI	A$_c$	NR	L*	A		NR	L*	L	L*	F	F$_c$	NR	NR	L	L$_c$	c		F*
		FM		NR	NR			NR	NR	L	L*	L	NR	NR	NR	L	L$_c$	c		NR
Avian field testing	Indoor Uses	AI																		
		FM		L$_c$	NR	A		NR	NR	L	NR	NR	NR		NR	NR		c		NR
	Outdoor Uses	AI																		
		FM	A	L$_c$	L*	A		L	L	L	L	L	L	NR	NR	L		c		L*$_c$

MATRIX 9 (CONT). ECOTOXICOLOGY

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Acceptance of bait, treated seeds by birds	Indoor Uses	AI		NR	NR			NR	NR	L	NR	NR	NR		NR	NR				NR
		FM		NR	NR	L		NR	NR	L	NR	NR	NR		NR	NR		c		NR
	Outdoor Uses	AI		NR	NR		NR	F	NR	L	NR	NR	NR	NR	NR	NR				NR
		FM	L	NR	L*	L	L*	F	L	L	A_c	L	NR	NR	NR	L		c		NR
ADDITIONAL DATA LISTED BY COUNTRIES																				
Trials and observations on birds and other wild animals [TUR]	Indoor Uses	AI																		
		FM																	c	
	Outdoor Uses	AI																		
		FM																	c	
AQUATIC TESTING																				
Fish acute toxicity LC50, freshwater: warm-water species	Indoor Uses	AI		NR	NR_c	A	F_c	A	NR	L	NR	L	NR			NR	A_c	L		L^*_c
		FM		NR	NR_c	A	NR		NR	L	NR	L_c	NR			NR	NR	L		L^*_c
	Outdoor Uses	AI	A_c	A	NR_c	A	F_c	A	NR	A	NR	A	L*	A_c		F	A_c	L		A*
		FM	A_c	NR	NR_c	A		L	NR	L	NR	L_c	L*	A_c		L	NR	L		L^*_c
Fish acute toxicity LC50, freshwater: cold-water species	Indoor Uses	AI		NR	A^*_c	A	F_c	A	L*	L	A*	L	NR		NR	NR	A_c	F		A*
		FM		NR	L^*_c	A		NR	NR	L	A*	L_c	NR		NR	NR	NR	F		L^*_c
	Outdoor Uses	AI	A_c	A	A^*_c	A	F_c	A	A*	F	A*	A	L*	NR	A*	F	A_c	F		A*
		FM	A_c	NR	L^*_c	A		L	F*	L	A*	L_c	L*	NR	L*	L	NR	F		L^*_c
Daphnia acute immobilization test	Indoor Uses	AI		NR	A*	A	F	A	L*	L	A*	L	NR		NR	NR	A	F		A*
		FM		NR	L*	A		NR	NR	L	A*	L	NR		NR	NR	A	F		L^*_c
	Outdoor Uses	AI	A	A	A*	A	F	A	A*	A	A*	A	A	A	A*	F	A	F		A*
		FM	A	NR	L*	A		L	F*	L	A*	L	L	A	L*	L	A	F		L^*_c

MATRIX 9 (CONT). ECOTOXICOLOGY

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Marine or estuarine fish acute toxicity LC50/EC50	Indoor Uses	AI		NR	NR		NR	L	NR	L	NR	L_c	NR		NR	NR	NR	NR		L^*_c
		FM		NR	NR			NR	NR	L	NR	L_c	NR		NR	NR	NR	NR		L^*_c
	Outdoor Uses	AI	A_c	NR	NR		NR	F	NR	L	NR	L_c	NR	NR	NR	F	NR	NR		L^*_c
		FM	A_c	NR	NR			L	NR	L	NR	L_c	NR	NR	NR	L	NR	NR		L^*_c
Daphnia life-cycle	Indoor Uses	AI		NR	NR	A	L_c	NR	NR	L	NR	L_c	NR		NR	NR	A	L		NR
		FM		NR	NR	L		NR	NR	L	NR	NR	NR		NR	NR	A	L		NR
	Outdoor Uses	AI	A	A	NR	A	L	L	L*	F	A*	L	L	NR	NR	F	A	L		A*
		FM	L	NR	NR	L		NR	NR	L	F*	NR	L	NR	NR	L	A	L		NR
Fish reproduction and growth rate	Indoor Uses	AI		NR	NR	A		NR	NR	L	NR	L	NR		NR	NR	L_c	c		NR
		FM		NR	NR	L		NR	NR	L	NR	NR	NR		NR	NR	NR	c		NR
	Outdoor Uses	AI	A	NR	NR_c	A		L	L*	L	L*	L	L	NR	NR	F	L_c	c		NR
		FM	L_c	NR	NR_c	L		NR	NR	L	NR	NR	L	NR	NR	L	NR	c		NR
Fish life-cycle	Indoor Uses	AI		NR	NR			NR	NR	L	NR	L	NR		NR	NR	L_c	c		NR
		FM		NR	NR			NR	NR	L	NR	NR	NR		NR	NR	NR	c		NR
	Outdoor Uses	AI		NR	NR_c			L	L*	L	L*	L	L	NR	NR	L	L_c	c		L*
		FM		NR	NR_c			NR	NR	L	NR	NR	L	NR	NR	L	NR	c		NR
Chronic toxicity to fish or fish early life stage	Indoor Uses	AI		NR	NR	A		NR	NR	L	NR	L	NR		NR	NR	L_c	c		NR
		FM		NR	NR	L		NR	NR	L	NR	NR	NR		NR	NR	NR	c		NR
	Outdoor Uses	AI	A	NR	L^*_c	A		L	L*	L	L*	L	L	NR	NR	L	L_c	c	A	F*
		FM	L_c	NR	L^*_c	L		NR	NR	L	NR	NR	L	NR	NR	L	NR	c		NR
Aquatic field testing	Indoor Uses	AI																		
		FM		NR	NR	L		NR	NR	L	NR	NR	NR		NR	NR	NR	c		NR
	Outdoor Uses	AI		NR	NR			L	L	L	L	L	NR	NR	NR	L	NR	c		NR
		FM	L_c	NR	NR_c	L		L	NR	L	NR	L	NR	NR	NR	L	NR	c		L^*_c

MATRIX 9 (CONT). ECOTOXICOLOGY

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Aquatic bioavailability/biomagnification/ bioaccumulation	Indoor Uses	AI		NR	NR	A		NR	NR	L	NR	L_c	A_c		NR	NR	A_c	c		NR
		FM		NR	NR	L		NR	NR	L	NR	NR	NR		A*	NR	NR	c		NR
	Outdoor Uses	AI	A_c	A_c	L^*_c	A		F	L*	L	F	F_c	A_c	NR	NR	L	A_c	c	A	L*
		FM	L_c	NR	NR	L		L	NR	L	NR	NR	NR	NR	NR	L	NR	c		NR
ADDITIONAL DATA LISTED BY COUNTRIES																				
Particular studies with fish and other aquatic organisms [CEC, ITA]	Indoor Uses	AI																		
		FM				L														
	Outdoor Uses	AI																		
		FM	L_c			L														
Chronic toxicity and reproduction with benthic organisms like Chironomus [GER]	Indoor Uses	AI			NR															
		FM			NR															
	Outdoor Uses	AI			L^*_c															
		FM			L^*_c															
Daphnia reproduction (21 days) [GER]	Indoor Uses	AI			NR															
		FM			NR															
	Outdoor Uses	AI			F*															
		FM			L*															
Fish prolonged toxicity (21 days) [GER]	Indoor Uses	AI			NR															
		FM			NR															
	Outdoor Uses	AI			F*															
		FM			L*															

MATRIX 9 (CONT). ECOTOXICOLOGY

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
BENEFICIAL INSECTS																				
Acute toxicity to honey bees LD50	Indoor Uses	AI		L	NR	A	F_c	A	NR	L	A*	NR	NR		NR	NR	A	A_c		NR
		FM			L_c	F	NR	L	NR	L	A*	NR	L_c		NR	NR	F	A_c		NR
	Outdoor Uses	AI	A_c	A	NR	A	F_c	A	A*	F	A*	F	A	NR	A_*	F	A	A_c	A	L*
		FM	A_c		F_c	F	NR	L	L*	F	A*	NR	A	L_c	L*	L	F	A_c		NR
Toxicity of residues on foliage to honeybees	Indoor Uses	AI		L	NR		NR	L	NR	L	L	NR	NR		NR	NR	NR	L		NR
		FM			L		L	NR	NR	L	L	NR	NR		NR	NR	NR	L		NR
	Outdoor Uses	AI		A	NR		NR	L	NR	L	F	NR	NR	NR	NR	F	NR	L		NR
		FM			F		L	F	NR	L	F	F	NR	NR	NR	L	NR	L		L*
Acute toxicity to predatory/parasitic insects	Indoor Uses	AI		L_c	NR	A	L		NR	L	A	NR	NR		NR	NR	L_c	F_c		NR
		FM		NR	A_c	A	NR		NR	L	A	NR	L_c		NR	NR	L_c	F_c		NR
	Outdoor Uses	AI	A	NR	NR	A	L		NR	L	A	L	L	NR	L	F	L_c	F_c	A	NR
		FM	A	NR	F_c	A			A*	L	A	L	L	L_c	NR	L	L_c	F_c		NR
Field testing for pollinators	Indoor Uses	AI																		
		FM		NR	NR	A	L	L	NR	L	L	NR	NR		NR	NR	NR	L		NR
	Outdoor Uses	AI		NR	NR		L	L	NR	L	L	NR	L	NR	F*	L	NR	L		NR
		FM	A	L	L_c	A	L	F	L	L	L	L	L	NR	NR	L	NR	L		L*
ADDITIONAL DATA LISTED BY COUNTRIES																				
Semi-field test on honey bees (mortality) (tier test) [GER]	Indoor Uses	AI			NR															
		FM			NR															
	Outdoor Uses	AI			NR															
		FM			L_c															
Field tests on beneficial arthropods (reproduction, mortality, beneficial capacity) (tier test) [GER]	Indoor Uses	AI			NR															
		FM			NR															
	Outdoor Uses	AI			NR															
		FM			L_c															
Toxicity of residues on foliage to silkworm [JAP]	Indoor Uses	AI																		
		FM																		
	Outdoor Uses	AI												NR						
		FM												L_c						

MATRIX 9 (CONT). ECOTOXICOLOGY

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
TERRESTRIAL VERTEBRATES																				
Effects on terrestrial vertebrates other than birds	Indoor Uses	AI		NR	A*	A		NR	NR	L	NR	NR	NR		NR	NR	NR	NR		NR
		FM		NR	L*$_c$	L$_c$		NR	NR	L	NR	NR	NR		NR	NR	NR	NR		NR
	Outdoor Uses	AI		NR$_c$	A*	A		L	L*	L	F	NR	NR	NR	L	F	L	L	A	L*
		FM	A	NR$_c$	L*$_c$	L$_c$		NR	NR	L	L	NR	NR	NR	NR	L	L	L		NR
Mammalian field testing	Indoor Uses	AI																		
		FM		NR	NR			NR	NR	L	NR	NR	NR		NR	NR	NR	NR		NR
	Outdoor Uses	AI		NR	NR			L	NR	L	L	NR	NR	NR	L	NR	NR	L		NR
		FM		NR	L*			NR	L	L	L	NR	NR	NR	NR	L	NR	L		L*$_c$
TESTING ON OTHER NON-TARGET SPECIES																				
Earthworm, acute toxicity test	Indoor Uses	AI		NR	NR	A	A*	A	NR	L	L*	NR	L$_c$		NR	NR	A	NR		NR
		FM		NR	NR	L$_c$	NR	L	NR	L	NR	NR	NR		NR	NR	NR	NR		NR
	Outdoor Uses	AI	A	A	NR	A	A*	A	F*	F	A*	A	L	NR	F	F	A	L		NR
		FM		NR	A*	L$_c$	NR	L	NR	L	A*	F	NR	NR	NR	L	NR	L		NR
Effects on soil micro-organisms	Indoor Uses	AI		NR	NR	A	L*	A	NR	L	L*	NR	L$_c$		NR	NR	A	L		NR
		FM		NR	NR	A	NR	L	NR	L	NR	NR	NR		NR	NR	NR	L		NR
	Outdoor Uses	AI	A	A	NR	A	L*	A	L*	F	A*	A	A	NR	F	F	A	L		NR
		FM	A	NR	A*	A	NR	L	L*	L	F*	F	A	NR	NR	L	NR	L		NR
Activated sludge, respiration inhibition test	Indoor Uses	AI		NR	NR	A	L$_c$	NR	NR	L	L*	NR	NR		NR	NR	L	NR		NR
		FM		NR	NR			NR	NR	L	NR	NR	NR		NR	NR	NR	NR		NR
	Outdoor Uses	AI	A$_c$	NR	NR	A	L$_c$	L	NR	L	A*		NR	NR	NR	L	L	NR		NR
		FM		NR	NR			NR	NR	L	NR		NR	NR	NR	L	NR	NR		NR
ADDITIONAL DATA LISTED BY COUNTRIES																				
Available data from biological primary screening [CEC, ITA]	Indoor Uses	AI																		
		FM				A														
	Outdoor Uses	AI																		
		FM	A			A														

MATRIX 9 (CONT). ECOTOXICOLOGY

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Earthworm, reproduction study (tier study) [GER]	Indoor Uses	AI			NR															
		FM			NR															
	Outdoor Uses	AI			NR															
		FM			L*															
Accumulation in earthworm [DEN]	Indoor Uses	AI																		
		FM																		
	Outdoor Uses	AI		L																
		FM																		
PHYTOTOXICITY TO NON-TARGET PLANT – Laboratory Testing																				
Algae, growth inhibition	Indoor Uses	AI		NR	A*	A	F*$_c$	NR	NR	L	A*	NR	NR		NR	NR	A	L		NR
		FM		NR	NR	L		NR	NR	L	L*	NR	NR		NR	NR	NR	L		NR
	Outdoor Uses	AI	A	A	A*	A	F*$_c$	L	F*	F	A*	F	A	NR	A	NR	A	L		L*
		FM	L	NR	L*	L	L*$_c$	NR	NR	L	A*	L	NR	NR	F	L	NR	L		NR
Seed germination	Indoor Uses	AI		NR	NR				NR	L	NR	NR	NR		NR	NR	NR			NR
		FM		NR	NR				NR	L	L	NR	NR		NR	NR	NR	A$_c$		NR
	Outdoor Uses	AI		NR	NR				NR	L	NR	F	NR	NR	NR	NR	NR			L*
		FM		NR	NR				NR	L	L	L	NR	L$_c$	NR	L	NR	A$_c$		NR
Vegetative vigour	Indoor Uses	AI		NR	NR				NR	L	NR	NR	NR		NR	NR	NR			NR
		FM		NR	NR				NR	L	NR	NR	NR		NR	NR	NR	A		NR
	Outdoor Uses	AI		NR	NR				NR	L	NR	F	L	NR	NR	NR	NR			L*
		FM		NR	NR				NR	L	NR	L	L	F	NR	L	NR	A		NR
Aquatic plant growth	Indoor Uses	AI		NR	NR				NR	L	NR	NR	NR		NR	NR	L$_c$	NR		NR
		FM		NR	NR				NR	L	NR	NR	NR		NR	NR	NR	NR		NR
	Outdoor Uses	AI		NR	NR				F*	L	NR	L	L	NR	L	NR	L$_c$	NR		L*
		FM		NR	NR				NR	L	NR	L	NR	NR	NR	L	NR	NR		NR

MATRIX 9 (CONT). ECOTOXICOLOGY

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
PHTOTOXICITY TO NON-TARGET PLANTS – Field Testing																				
Terrestrial field testing	Indoor Uses	AI																		
		FM		NR				NR	NR	L	NR	NR	NR		NR	NR	NR	A		NR
	Outdoor Uses	AI		L_c				NR	NR	L	L	NR	L	NR	NR	NR	NR			NR
		FM		NR	L_c			L	L	L	L	L	L	NR	NR	L	NR	A		L*
Aquatic field testing	Indoor Uses	AI																		
		FM		NR	NR			NR	NR	L	NR	NR	NR		NR	NR	NR			NR
	Outdoor Uses	AI		L_c	NR			NR	NR	L	L	NR	L	NR	NR	NR	NR			NR
		FM		NR	NR_c			L	L	L	L	L	L	NR	NR	L	NR			L*
ADDITIONAL DATA LISTED BY COUNTRIES																				
Effects on flora and fauna believed to be at risk [CEC, ITA]	Indoor Uses	AI				L														
		FM																		
	Outdoor Uses	AI	L			L														
		FM																		
Bacteria (aquatic) [GER]	Indoor Uses	AI		c	NR															
		FM		c	NR															
	Outdoor Uses	AI		c	NR_c															
		FM		c	NR_c															

MATRIX 9 (CONT). ECOTOXICOLOGY

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
TERRESTRIAL VERTEBRATES																				
Effects on terrestrial vertebrates other than birds	Indoor Uses	AI		NR	A*	A		NR	NR	L	NR	NR	NR		NR	NR	NR	NR		NR
		FM		NR	L^*_c	L_c		NR	NR	L	NR	NR	NR		NR	NR	NR	NR		NR
	Outdoor Uses	AI		NR_c	A*	A		L	L*	L	F	NR	NR	NR	L	F	L	L	A	L*
		FM	A	NR_c	L^*_c	L_c		NR	NR	L	L	NR	NR	NR	NR	L	L	L		NR
Mammalian field testing	Indoor Uses	AI																		
		FM		NR	NR			NR	NR	L	NR	NR	NR		NR	NR	NR	NR		NR
	Outdoor Uses	AI		NR	NR			L	NR	L	L	NR	NR	NR	L	NR	NR	L		NR
		FM		NR	L*			NR	L	L	L	NR	NR	NR	NR	L	NR	L		L^*_c
TESTING ON OTHER NON-TARGET SPECIES																				
Earthworm, acute toxicity test	Indoor Uses	AI		NR	NR	A	A*	A	NR	L	L*	NR	L_c		NR	NR	A	NR		NR
		FM		NR	NR	L_c	NR	L	NR	L	NR	NR	NR		NR	NR	NR	NR		NR
	Outdoor Uses	AI	A	A	NR	A	A*	A	F*	F	A*	A	L	NR	F	F	A	L		NR
		FM		NR	A*	L_c	NR	L	NR	L	A*	F	NR	NR	NR	L	NR	L		NR
Effects on soil micro-organisms	Indoor Uses	AI		NR	NR	A	L*	A	NR	L	L*	NR	L_c		NR	NR	A	L		NR
		FM		NR	NR	A	NR	L	NR	L	NR	NR	NR		NR	NR	NR	L		NR
	Outdoor Uses	AI	A	A	NR	A	L*	A	L*	F	A*	A	A	NR	F	F	A	L		NR
		FM	A	NR	A*	A	NR	L	L*	L	F*	F	A	NR	NR	L	NR	L		NR
Activated sludge, respiration inhibition test	Indoor Uses	AI		NR	NR	A	L_c	NR	NR	L	L*	NR	NR		NR	NR	L	NR		NR
		FM		NR	NR			NR	NR	L	NR	NR	NR		NR	NR	NR	NR		NR
	Outdoor Uses	AI	A_c	NR	NR	A	L_c	L	NR	L	A*		NR	NR	NR	L	L	NR		NR
		FM		NR	NR			NR	NR	L	NR		NR	NR	NR	L	NR	NR		NR
ADDITIONAL DATA LISTED BY COUNTRIES																				
Available data from biological primary screening [CEC, ITA]	Indoor Uses	AI																		
		FM				A														
	Outdoor Uses	AI																		
		FM	A			A														

MATRIX 9 (CONT). ECOTOXICOLOGY

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
Earthworm, reproduction study (tier study) [GER]	Indoor Uses	AI			NR															
		FM			NR															
	Outdoor Uses	AI			NR															
		FM			L*															
Accumulation in earthworm [DEN]	Indoor Uses	AI																		
		FM																		
	Outdoor Uses	AI		L																
		FM																		
PHYTOTOXICITY TO NON-TARGET PLANT – Laboratory Testing																				
Algae, growth inhibition	Indoor Uses	AI		NR	A*	A	F^*_c	NR	NR	L	A*	NR	NR		NR	NR	A	L		NR
		FM		NR	NR	L		NR	NR	L	L*	NR	NR		NR	NR	NR	L		NR
	Outdoor Uses	AI	A	A	A*	A	F^*_c	L	F*	F	A*	F	A	NR	A	NR	A	L		L*
		FM	L	NR	L*	L	L^*_c	NR	NR	L	A*	L	NR	NR	F	L	NR	L		NR
Seed germination	Indoor Uses	AI		NR	NR				NR	L	NR	NR	NR		NR	NR	NR			NR
		FM		NR	NR				NR	L	L	NR	NR		NR	NR	NR	A_c		NR
	Outdoor Uses	AI		NR	NR				NR	L	NR	F	NR	NR	NR	NR	NR			L*
		FM		NR	NR				NR	L	L	L	NR	L_c	NR	L	NR	A_c		NR
Vegetative vigour	Indoor Uses	AI		NR	NR				NR	L	NR	NR	NR		NR	NR	NR			NR
		FM		NR	NR				NR	L	NR	NR	NR		NR	NR	NR	A		NR
	Outdoor Uses	AI		NR	NR				NR	L	NR	F	L	NR	NR	NR	NR			L*
		FM		NR	NR				NR	L	NR	L	L	F	NR	L	NR	A		NR
Aquatic plant growth	Indoor Uses	AI		NR	NR				NR	L	NR	NR	NR		NR	NR	L_c	NR		NR
		FM		NR	NR				NR	L	NR	NR	NR		NR	NR	NR	NR		NR
	Outdoor Uses	AI		NR	NR				F*	L	NR	L	L	NR	L	NR	L_c	NR		L*
		FM		NR	NR				NR	L	NR	L	NR	NR	NR	L	NR	NR		NR

MATRIX 9 (CONT). ECOTOXICOLOGY

TYPE OF DATA/INFORMATION			CEC	DEN	GER	ITA	NL	POR	UK	AUS	AUT	CAN	FIN	JAP	NOR	NZ	SWE	SWI	TUR	USA
PHTOTOXICITY TO NON-TARGET PLANTS – Field Testing																				
Terrestrial field testing	Indoor Uses	AI																		
		FM		NR				NR	NR	L	NR	NR	NR		NR	NR	NR	A		NR
	Outdoor Uses	AI		L_c				NR	NR	L	L	NR	L	NR	NR	NR	NR			NR
		FM		NR	L_c			L	L	L	L	L	L	NR	NR	L	NR	A		L*
Aquatic field testing	Indoor Uses	AI																		
		FM		NR	NR			NR	NR	L	NR	NR	NR		NR	NR	NR			NR
	Outdoor Uses	AI		L_c	NR			NR	NR	L	L	NR	L	NR	NR	NR	NR			NR
		FM		NR	NR_c			L	L	L	L	L	L	NR	NR	L	NR			L*
ADDITIONAL DATA LISTED BY COUNTRIES																				
Effects on flora and fauna believed to be at risk [CEC, ITA]	Indoor Uses	AI				L														
		FM																		
	Outdoor Uses	AI	L			L														
		FM																		
Bacteria (aquatic) [GER]	Indoor Uses	AI		c	NR															
		FM		c	NR															
	Outdoor Uses	AI		c	NR_c															
		FM		c	NR_c															