

**DATA REQUIREMENTS FOR REGISTRATION OF BIOPESTICIDES IN OECD MEMBER
COUNTRIES: SURVEY RESULTS**

OECD ENVIRONMENT MONOGRAPH No. 106

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris 1996

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Environment Directorate

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Foreword

This Environment Monograph presents the results of a survey of data requirements for the registration of biological pesticides (or "biopesticides") in OECD Member countries. The survey was conducted as part of the OECD Pesticide Programme in 1993-1994. It focused primarily on specific testing requirements for micro-organisms used for plant protection, including organisms that have been genetically modified (GMOs). The survey also collected information on countries' overall regulatory approach to other types and uses of biopesticides.

The purpose of the survey was to develop an inventory of current national data requirements for biopesticides, in order to prepare for future efforts to increase the international harmonization of these requirements. The long-term goal is to enhance Member countries' ability to use each other's evaluations of pesticide data, so that they can share the work of registration and re-registration. Greater international harmonization of data requirements will also reduce trade barriers between countries, as well as reducing duplicative chemicals testing by industry.

The Joint Meeting of the Chemicals Group and the Management Committee of the Special Programme on the Control of Chemicals recommended that this document be derestricted. It is being published on the responsibility of the Secretary-General of the OECD.

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Résumé

Introduction

Le présent rapport contient les résultats d'une enquête de l'OCDE dans ses pays Membres sur les données requises pour l'homologation des pesticides biologiques ou «biopesticides». L'enquête portait principalement sur les essais spécifiques requis pour les micro-organismes à usage phytosanitaire, y compris les organismes génétiquement modifiés (OGM). L'enquête a également recueilli des informations sur l'approche réglementaire générale des pays concernant les autres types de biopesticides et leurs utilisations.

Cette enquête a été menée en 1993-1994 dans le cadre du Programme de l'OCDE sur les Pesticides. Il s'agissait de répertorier les données requises pour l'homologation des biopesticides dans chaque pays, afin de préparer les futurs efforts d'harmonisation des données requises au niveau international. L'objectif à long terme consiste à augmenter la capacité des pays de l'OCDE à utiliser de manière réciproque les évaluations des données ; cela leur permettra de se répartir la charge de l'homologation des pesticides et de son renouvellement. Une plus grande harmonisation internationale des données requises réduira également les obstacles aux échanges entre les pays et la duplication des essais (*double emplois dans les essais*) sur les produits chimiques réalisés par l'industrie pour être en conformité avec les diverses exigences des pays.

Méthode de l'enquête

L'enquête s'est appuyée sur un questionnaire conçu par le Secrétariat de l'OCDE avec l'aide d'un comité consultatif composé de représentants de l'Allemagne, de la Suède, de la Commission Européenne (CE) et de l'industrie des pesticides. Des experts des Etats-Unis, du Canada et du Programme de l'OCDE sur la Biotechnologie ont également révisé le questionnaire.

Le questionnaire comportait deux parties. La partie 1 concernait tous les types et usages des biopesticides, usages phytosanitaires (agriculture, horticulture, forêts, ...) et autres usages (usages domestiques, santé publique, contrôle professionnel des insectes et animaux nuisibles, ...). La partie 1 s'intéressait à l'approche réglementaire générale des pays concernant sept catégories de pesticides pouvant être considérés comme «biologiques» parce que remplissant l'un des deux critères suivants : (1) ils sont vivants, ou (2) ils existent naturellement. Les pesticides concernés étaient les :

- **micro-organismes** tels que les bactéries, les algues, les fungi, les virus et les protozoaires ;
- **phéromones** ;
- **régulateurs de croissance des insectes** ;
- **régulateurs de croissance des plantes** ;
- **extraits de plantes** ; • **macro-organismes** tels que les nématodes, les acariens et les insectes prédateurs ; et
- **plantes transgéniques**, modifiées pour avoir des propriétés pesticides.

Dans la partie 1, il était également demandé aux pays de fournir des informations générales sur :

- les données requises pour les OGM, les ingrédients neutres et les organismes non-indigènes ;
- l'utilisation des essais séquentiels ; et
- les politiques d'encouragement au développement et/ou à l'utilisation des biopesticides.

En dernier lieu, la partie 1 demandait aux pays de fournir une liste de tous les biopesticides homologués et de soumettre des copies des données requises et des lignes directrices publiées.

La partie 2 du questionnaire s'intéressait exclusivement aux **usages phytosanitaires des micro-organismes**. Il était demandé de fournir une liste spécifique des données requises pour l'homologation des micro-organismes, y compris les OGM, pour les usages phytosanitaires. Les pays devaient compléter des séries de tableaux concernant les données requises pour les domaines d'essai suivants :

- identité et propriétés biologiques ;
- fonction, mode d'action et manutention ;
- propriétés physico-chimiques ;
- fabrication, contrôle qualité et méthodes analytiques ;
- résidus ;
- efficacité ;
- toxicologie, pathogénicité et infectivité ;
- écotoxicologie ; et
- devenir dans l'environnement.

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, (2) si des conseils pour mener les études étaient disponibles, et (3) la fréquence avec laquelle l'élément de données considéré était demandé. Le questionnaire comportait une liste détaillée des éléments de données pouvant figurer dans chaque domaine d'essai, et laissait aux pays la possibilité d'ajouter d'autres éléments.

Pays ayant répondu à l'enquête

Le questionnaire a été envoyé à tous les pays Membres de l'OCDE et à la CE en septembre 1993. Quatorze pays Membres, la Hongrie (pays en voie de transition économique à l'OCDE) et la CE ont complété le questionnaire. Les pays Membres ayant répondu sont les suivants : Allemagne, Australie, Autriche, Canada, Danemark, Etats-Unis, Finlande, Italie, Japon, Norvège, Nouvelle-Zélande, Pays-Bas, Suède et Royaume-Uni. Deux autres pays Membres, la France et la Suisse, n'ont pas complété le questionnaire mais ont fourni des documents réglementaires et des listes de biopesticides homologués. Le Portugal a également envoyé une liste de micro-organismes homologués pour un usage phytosanitaire.

Réponses à l'enquête : Partie 1

Les réponses des pays à la partie 1 du questionnaire sont présentées dans les tableaux A-F en Annexe 1.

Produits identifiés comme biopesticides (Tableau A)

Les 15 pays qui ont répondu à l'enquête et la CE ont tous indiqué qu'ils identifiaient les micro-organismes comme des biopesticides. Onze d'entre eux ont également désigné les macro-organismes et trois pays les plantes transgéniques. Quatre pays ont identifié les phéromones, les régulateurs de croissance et les extraits de plantes comme des biopesticides. Enfin, plusieurs pays ont fait remarquer qu'un pesticide devait être un organisme vivant pour être «biologique». Certains pays et la CE ont déclaré que leur législation et/ou réglementation n'utilise pas le terme de «pesticide biologique».

Données requises pour les produits phytosanitaires (Tableau B)

En dépit de ces différences de terminologie, les pays tendent à aborder les données requises pour l'homologation des biopesticides de façon similaire, c'est-à-dire sous la réglementation des pesticides, en particulier pour les micro-organismes, les régulateurs de croissance, les extraits de plantes et, dans une certaine mesure, pour les phéromones. La situation est plus contrastée pour les macro-organismes et les plantes transgéniques.

L'enquête montre également que la plupart des pays différencient les organismes vivants des organismes non-vivants pour les données d'essai, ces dernières étant similaires ou différentes des données requises pour homologuer les pesticides chimiques. Tous ont répondu que des données étaient requises sur les ingrédients neutres des biopesticides.

Données requises pour les produits à usages autres que phytosanitaires (Tableau C)

L'approche réglementaire des pays concernant les biopesticides pour les usages autres que phytosanitaires est plus divergente ; cette conclusion n'est pas surprenante dans la mesure où la même divergence existe dans le cas des pesticides chimiques conventionnels.

Là encore, comme pour les produits phytosanitaires, les pays tendent à différencier les produits vivants des produits non-vivants pour les données requises pour les homologations. Tous requièrent également des données sur les ingrédients neutres.

Essais séquentiels sur les micro-organismes (Tableau D)

La plupart des réponses montrent que les pays appliquent des essais séquentiels soit de façon formelle, soit au cas par cas, dans les domaines de la toxicologie, pathogénicité, infectivité, écotoxicologie et du devenir environnemental. Seuls six pays utilisent les essais séquentiels pour la mesure des résidus.

Données supplémentaires requises pour les organismes non-indigènes et les organismes génétiquement modifiés (OGM) (Tableaux E et F)

Dix pays requièrent, de façon générale ou au cas par cas, des informations supplémentaires sur les organismes non-indigènes (par exemple le devenir et le comportement dans l'environnement, les effets écotoxicologiques), informations qui ne sont normalement pas demandées pour les organismes indigènes. Dix pays et la CE requièrent également des données supplémentaires pour l'homologation des OGM (par rapport aux organismes qui existent naturellement).

Politiques et programmes pour promouvoir les biopesticides

La quasi-totalité des pays qui ont répondu à l'enquête ont déclaré avoir des programmes ou politiques, en sus du développement de nouvelles données requises pour l'homologation, destinés à encourager le développement et l'utilisation des biopesticides. Des programmes de promotion de la gestion de protection intégrée dans l'agriculture et/ou les forêts semblent être l'approche la plus largement utilisée.

Réponses à l'enquête : Partie 2

Les réponses des pays à la partie 2 du questionnaire sont présentées dans deux séries de tableaux en Annexes 3 et 4. Le cas échéant, les tableaux font la distinction entre les données requises pour la substance active ou la formulation, pour les usages extérieurs ou intérieurs et pour les usages alimentaires ou non-alimentaires.

Les tableaux en Annexe 3 présentent les réponses individuelles des pays. Les tableaux en Annexe 4 proposent un résumé de ces réponses.

Résumé des conclusions de la Partie 2

Les réponses à l'enquête suggèrent que de nombreux pays ont adopté une approche similaire pour organiser les données requises pour les micro-organismes, et qu'ils tendent s'intéresser aux mêmes domaines d'essai ou catégories d'étude. L'enquête révèle des différences pour les données requises dans certains domaines d'essai, en particulier les propriétés physico-chimiques, l'écotoxicologie et le devenir dans l'environnement. L'enquête souligne également le fait que les pays n'ont pas tous la même approche pour l'homologation des OGM.

L'enquête a également mis en évidence des différences fondamentales entre les données requises pour les micro-organismes et celles requises pour les pesticides chimiques traditionnels.

Conclusion

L'enquête a montré que l'homologation de différents types de biopesticides est en cours dans les pays Membres de l'OCDE. Un nombre substantiel de biopesticides ont été homologués pour les produits phytosanitaires et un nombre plus restreint pour les produits autres que ceux qui servent à la protection des plantes. La plupart des pays qui ont répondu ont établi des données requises pour les micro-organismes, et certains l'ont également fait pour d'autres types de biopesticides. Beaucoup ont déclaré que l'établissement de données requises différentes était l'un des éléments de leur programme national pour promouvoir l'homologation et l'utilisation des biopesticides.

Les résultats de l'enquête suggèrent qu'un noyau commun de données minimum pourrait être proposé pour les micro-organismes, en s'appuyant sur le recoupement déjà existant dans les données requises de chaque pays. Les réponses ont également suggéré le besoin de travailler pour harmoniser les données requises pour les phéromones, pour lesquelles les pays semblent adopter des approches différentes.

Introduction

This report presents the results of an OECD survey of Member countries' data requirements for the registration of biological pesticides, or "biopesticides". The survey focused principally on specific testing requirements for micro-organisms used for plant protection, including organisms that have been genetically modified (GMOs). The survey also collected information about countries' overall regulatory approach to other types and uses of biopesticides.

This survey was conducted as part of the OECD Pesticide Programme during 1993-1994. Its purpose was to develop an inventory of current national data requirements for biopesticides, in order to prepare for future efforts to increase international harmonization of these requirements. The long-term goal of OECD work on pesticides is to increase Member countries' ability to use each other's evaluations of pesticide data, so that they can share the work of registration and re-registration. Greater international harmonization of data requirements will also reduce trade barriers between countries, as well as duplicative testing of chemicals by industry to comply with diverse national regulatory requirements.

Survey Method

The survey was based on a questionnaire designed by the OECD Secretariat with the assistance of an advisory committee composed of representatives from Germany, Sweden, the European Commission (EC), and the pesticide industry. Experts from Canada, the United States, and the OECD Secretariat also reviewed drafts of the questionnaire.

The questionnaire was divided into two parts. Part 1 covered all biopesticide types and uses, i.e. both plant protection (e.g. agriculture, horticulture and forestry) and non-plant protection (e.g. household, public health, and professional pest control). Part 1 asked about countries' regulatory approach to seven categories of pesticides that could be considered biological because they are alive and/or naturally occurring. These included:

- **micro-organisms** such as bacteria, algae, fungi, viruses and protozoa;
- **pheromones**;
- **insect growth regulators**;
- **plant growth regulators**;
- **plant extracts**;
- **macro-organisms** such as nematodes, mites and predatory insects; and
- **transgenic plants** that have been modified to have pesticidal properties.

Part 1 also requested general information on:

- requirements for GMOs, inert ingredients, and non-indigenous organisms;
- use of tier testing; and
- policies to encourage the development and/or use of biopesticides.

Finally, Part 1 asked countries to list all biopesticides they have registered, and to submit copies of published data requirements and guidelines.

Part 2 of the questionnaire focused exclusively on **plant protection uses of micro-organisms**. Part 2 requested a specific listing of data requirements for registration of micro-organisms, including GMOs, for plant protection uses. Countries were asked to complete a series of matrices showing their requirements in the following test areas:

- identity and biological properties;
- function, mode of action, and handling;
- physical-chemical properties;
- manufacturing, quality control, and analytical methods;
- residues;
- efficacy;
- toxicology, pathogenicity, and infectivity;
- ecotoxicology; and
- environmental fate.

When completing the Part 2 matrices, countries were asked to indicate for each data element: (1) whether compliance with principles of Good Laboratory Practice was required, (2) whether guidance for conducting the study was available, and (3) whether the data element was *always*, *frequently* (in more than 80 per cent of registration submissions), *less frequently* (in fewer than 80 per cent of registration submissions), or *never* required. The questionnaire contained an extensive listing of possible data elements in each test area, and provided space for countries to include additional elements.

Responding Countries

The questionnaire was sent to all OECD Member countries and the EC in September 1993. Fifteen Member countries and the EC, as well as Hungary (an OECD Partner-In-Transition), completed it. The Member countries were: Australia, Austria, Canada, Denmark, Finland, France, Germany, Italy, Japan, the Netherlands, New Zealand, Norway, Sweden, the United Kingdom, and the United States. Switzerland submitted regulatory documents and lists of biopesticides registered, but did not complete the questionnaire. Portugal also submitted a list of micro-organisms registered for plant protection uses.

Survey Results: Part 1

Countries' responses to Part 1 of the questionnaire are presented in Tables A-F in Annex 1. The summaries below (both the text and Tables 1-8) were developed from these tables.

Products Identified as Biopesticides (Table A)

The survey began by asking countries to list categories of products they identified as biopesticides. All 16 countries and the EC indicated that they identified micro-organisms as biopesticides. Eleven countries also listed macro-organisms (of these, one country noted that only products for public health use were regulated, and another said that nematodes were the only macro-organism regulated); three countries listed transgenic plants. Four countries also identified pheromones, growth regulators, and plant extracts as biopesticides. Several countries noted that, to be "biological", a pesticide must be a living organism. A number of countries, as well as the EC, stated that their laws and/or regulations did not apply the term "biological pesticide".

Requirements for Plant Protection Products (Table B)

Despite these differences in terminology, survey respondents tended to approach biopesticide registration and data requirements similarly, especially for plant protection uses. As shown in **Table 1** below, all 17 survey respondents said they required micro-organisms, growth regulators, and plant extracts used for plant protection to be registered under pesticide law. Fourteen required or would in future require the registration of pheromones for pest control (uses other than monitoring). Six countries also required or would require registration of pheromones for monitoring and forecasting, while eight countries and the EC did not (in practice, however, one respondent noted that pheromones used for monitoring were also used for mating disruption and other pest control measures and therefore would be registered). By contrast, only six of the respondents said they required or would require macro-organisms and transgenic plants to be registered under pesticide law.

The survey responses showed a clear trend for countries to differentiate, in their testing requirements for plant protection products, between living and non-living organisms. Most respondents said they applied the same data requirements used for chemical pesticides to growth regulators and plant extracts. Data requirements for viable micro-organisms, macro-organisms and transgenic plants were generally different, although many respondents said they were often based on requirements for chemicals. Approximately half the respondents said they used chemical data requirements for pheromones and non-viable micro-organisms; the other half said their requirements were different. All responding countries said they required data on inert ingredients in biopesticides, and approximately half had established data requirements for pre-registration field testing.

Table 1
Registration of Biopesticides for Plant Protection
(Number of Countries with Requirement)

pesticide type		registration required by pesticide law	review required under other law or programme	registration not required	registration not now required but will be in future	data requirements for registration are <i>the same</i> as or <i>different</i> from those for chemical pesticides		data requirements established for pre-registration field testing
						same	different	
micro-organisms								
naturally occurring	viable	17					17	8
	non-viable	17				7	10	8
genetically modified	viable	17	10				15	10
	non-viable	17	6			5	11	10
other								
pheromones	monitoring	6		8	1	6	3	4
	other uses	14		3	1	8	5	5
insect growth regulators		17				16	1	7
plant growth regulators		17				16	1	7
plant extracts		17				17		7
macro-organisms		5	2	8	1		7	4
transgenic plants		3	10	3	3		8	7

Requirements for Non-plant Protection Products (Table C)

Countries' regulatory approaches to biopesticides for non-plant protection uses were more divergent than their approaches to plant protection products, a finding that was not surprising since the same pattern occurred in the case of chemical pesticides. The most important difference was in the requirement to register products. As shown in **Table 2** below, just ten of the survey respondents currently required registration, under national pesticide law, of growth regulators, plant extracts, and non-viable naturally occurring micro-organisms. Still fewer countries required such registration of pheromones, viable naturally occurring micro-organisms, and GMOs. The remaining countries either regulated the products under another law, did not require them to be registered, or might require registration in the future. By comparison, all 17 survey respondents required registration of products in these five categories for plant protection use.

As was seen with plant protection products, countries treated living and non-living products differently in setting data requirements for registration. Table 2 shows that the majority of the countries responding to this question said their requirements for non-plant protection uses of growth regulators and plant extracts were the same as their requirements for chemical pesticides, while their requirements for viable micro-organisms were different. Countries diverged most sharply in their approach to pheromones and non-viable micro-

organisms: some treated them like chemicals, applying the same data requirements for registration, and others established separate requirements. Fewer than half the responding countries had established pre-registration field testing requirements for the various types of biopesticides, but all respondents said they required data on inert ingredients.

Table 2
Registration of Biopesticides for Non-plant Protection Uses
(Number of Countries with Requirement)

pesticide type		registration required by pesticide law	review required under other law or programme	registration not required	registration not currently required but will be in future	data requirements for registration are <i>the same as or different from</i> those for chemical pesticides		data requirements are established for pre-registration field testing
						same	different	
micro-organisms								
naturally occurring	viable	9	4	1	3	1	11	4
	non-viable	10	4	1	2	6	8	5
genetically modified	viable	8	10	1	2	0	13	8
	non-viable	9	8	1	2	4	9	8
other								
pheromones	monitoring	3	1	7	1	5	3	4
	other uses	7	2	5	2	7	4	5
insect growth regulators		10	2	2	2	10	3	5
plant extracts		10	3	1	3	10	3	4

An issue which arose during the course of the survey was only partially dealt with in countries' responses, but it raises some interesting questions. This concerns the relationship between countries' data requirements for biopesticides registered for plant protection, and their requirements for the same pesticides when they are registered for non-plant protection uses. The survey found three overall approaches. First, there were countries which did not require registration of biopesticides for non-plant protection uses, and which therefore had "different" data requirements for the different uses. Second, there were examples like the EC, which had developed separate data requirements for plant protection products (whether chemical or biological), for biocides (chemical or biological), and for micro-organisms. However, it should be noted that these "different" sets of data requirements were likely to overlap in at least some study areas. Finally, there were countries which used the same basic set of data requirements for all product uses, but which tailored the requirements to the particular use undergoing registration. A key question not answered by the survey – which would be important for future work on harmonized data sets – is the extent to which general data requirements tailored to specific uses were substantially different from

requirements developed separately for separate uses. A second unanswered question concerns the way the data requirements were implemented, the circumstances under which some were waived, and how this contributed to the creation of distinct sets of requirements for different use patterns.

Tier Testing of Micro-organisms (Table D)

The questionnaire asked countries to indicate whether they used tier testing in their data requirements for micro-organisms on a formal or case-by-case basis. (Tier testing refers to the use of a stepped testing sequence, in which tests in higher tiers are required only if specified hazard levels were exceeded at earlier stages.) As seen in **Table 3**, most survey respondents said they applied tier testing on either a formal or case-by-case basis to determine toxicity, pathogenicity, infectivity, ecotoxicity and environmental fate. However, just seven countries used tier testing for residues. A total of six countries had developed or were in the process of developing formal testing tiers.

Table 3
Tier Testing of Micro-organisms (Number of Countries Using Tiers)

test area	formal tiers	case-by-case
residues	1	6
toxicity	4	9
pathogenicity	2	10
infectivity	2	10
ecotoxicity	5	9
environmental fate	4	9

Supplemental Requirements for Non-indigenous and Genetically-engineered Organisms (Tables E and F)

The survey found that ten countries required, either generally or on a case-by-case basis, information on non-indigenous organisms that was not normally required for indigenous organisms. The supplemental information generally concerned fate and behaviour in the environment or ecotoxicological effects. Eleven respondents including the EC had additional policies or registration requirements, not normally required for naturally occurring organisms, for GMOs.

Status of Data Requirements (Table A)

The questionnaire asked countries to submit copies of data requirements developed separately for biopesticides, along with guidelines and other supporting documents. As seen in **Table 4**, the responses showed that several countries had developed data requirements and/or guidelines for registration of one or more categories of biopesticide.

Table 4
Availability of Data Requirements and/or Guidelines

final data requirements or guidelines are available for:			
micro-organisms	macro-organisms	pheromones	other biopesticides
EC Austria France Hungary Italy The Netherlands New Zealand United Kingdom United States	Hungary New Zealand (nematodes)	Hungary United States	Hungary United States
draft data requirements or guidelines are available for:			
micro-organisms	macro-organisms	pheromones	other biopesticides
Australia Canada Sweden	Canada Sweden	Australia Canada	Australia

Policies and Programmes to Promote Biopesticides

Nearly all the countries responding to the survey said they had some kind of programme or policy, apart from development of separate data requirements, intended to encourage the development and use of biopesticides. These included research and development of biological controls, activities to promote their use in agriculture and forestry, and measures to facilitate registration of biopesticides, such as lower fees or faster registration processes. Countries' programmes to promote integrated pest management can also result in increased use of biological controls. **Table 5** gives an overview of the different types of programmes and policies that were being carried out by the survey respondents.

Table 5
Policies and Programmes to Promote Biopesticides

programmes and policies to promote biological pesticides	countries
shorter registration process	France, United States
priority for registration	United States
reduced registration fees	United Kingdom
government initiatives to promote use of biological controls and integrated pest management in agriculture and/or forestry, including: • research/development of new products and methods • development of guidelines for integrated pest management • extension, training, and subsidies to assist the transition from conventional to biodynamic and ecological farming • laws requiring farmers to limit the use of chemical pesticides, increase use of integrated pest management methods • systems to provide farmers with information on integrated pest management methods	Australia, Austria, Canada, Finland, France, Germany, Italy, Japan, the Netherlands, Sweden, United Kingdom

Registered Products

Nearly all the countries responding to the survey provided a list of biopesticides registered, or in the registration process, for plant protection or other uses. These sometimes lengthy lists confirmed that registration of biopesticides – particularly micro-organisms and pheromones – was actively underway in OECD Member countries. A compilation of the individual country lists, organised by biopesticide type and use, is provided in Annex 2. **Table 6** gives an overview of the number of countries with registrations of different types of products.

Table 6
Types of Biopesticides Registered

type of biopesticide	use pattern	number of countries with registered products
micro-organism	plant protection	17
	non-plant protection	11
pheromone	plant protection	9
	non-plant protection	3
growth regulator	plant protection	6
	non-plant protection	3
plant extract	plant protection	8
macro-organism	non-plant protection	5

Survey Results: Part 2

Responses to Part 2 of the questionnaire, focusing on data requirements for registration of micro-organisms for plant protection, are displayed in two sets of matrices in Annexes 3 and 4. The matrices follow the questionnaire's format, with a separate matrix for each of the nine test areas and a comprehensive list of data elements in each area. Where appropriate, 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.

The matrices also indicate:

- how often each data element is required during registration;
- whether compliance with principles of Good Laboratory Practice is required;
- whether test guidelines for specific data elements were available; and
- whether additional comments were provided by the country.

(Owing to the number and length of individual countries' comments, they have not been included in this document; they are, however, available on request from the OECD Secretariat at the address shown on page 5.)

The matrices in Annex 3 show individual countries' responses. The matrices in Annex 4 summarise those responses by indicating the number of countries that required each data element.

Responses from the European Commission and EU Member States

The changing situation in the European Union (EU) with respect to pesticide data requirements complicated the analysis of the survey results. As the EC explained, variable data requirements will operate in the EU until the year 2003, with:

- new active substances, re-evaluated old active substances, and products containing them covered by the requirements of Directive 91/414/EEC; and
- national data requirements *or* Directive 91/414/EEC covering old active substances not yet re-evaluated and plant protection products containing them.

Responses from both the EU Member States and the EC are shown in the matrices in Annex 3. The summary matrices in Annex 4, however, include only the responses from the EC and do not show individual EU countries' replies except in those cases where a country specifically added a data element to the original list. (In the latter situation, responses are shown in parentheses.) EC responses are counted as 12, to reflect the anticipated compliance of EU countries with the EEC Directive. The responses of Austria, Finland and Sweden are listed with those of the non-European Union countries, because they had not yet joined the EU at the time of the survey.

Limitations of the Matrices

The limitations inherent in this type of survey should be kept in mind when reviewing the data requirement matrices. The box-ticking approach can provide a useful overview of data requirements and a starting point for future work, but it cannot capture the complexity of pesticide testing and the use of judgment that accompanies countries' implementation of their data requirements. For both scientific and practical reasons, most countries exercise some flexibility in their acceptance of pesticide data and in their waiving of certain requirements in certain cases. Moreover, registration of micro-organisms is a relatively new exercise, and some countries found it difficult to complete the matrices because they had registered only a handful of products and therefore could not say with certainty how often a data element was required.

In an effort to reflect the complexity and uncertainty of the situation, most countries added comments to the matrices. These comments, noted in the matrices with a "c", were too numerous to include in this report but are available on request from the OECD Secretariat. Other countries and the EC simply marked data elements with an "X" rather than indicating whether they were always, frequently, or less frequently required. It should thus be kept in mind that the matrices are intended only to provide an overview and starting point for harmonization, and not to serve as a definitive description of the registration of micro-organisms.

Summary of Part 2 Findings

The survey responses suggest that many countries had adopted a similar approach to structuring their data requirements for micro-organisms, and that they tended to emphasize the same test areas or study categories. The survey reveals some differences in requirements in certain test areas, most notably physical-chemical properties, ecotoxicology and environmental fate. It also underscores the fact that not all countries were taking the same approach to registration of GMOs. An overview of the survey findings for each study area is presented in **Table 7**.

The survey also highlights the key differences between data requirements for micro-organisms and requirements for traditional chemical pesticides, as shown in **Table 8**.

Conclusion

The survey found that registration of various types of biopesticides was well underway in OECD Member countries. Respondents had registered a considerable number of biopesticides for plant protection and a smaller number for non-plant protection uses. Most had established separate data requirements for micro-organisms, and some had done so for other biopesticide types. Many respondents said the establishment of separate data requirements was one element of their country's programme to promote registration and use of biopesticides.

The survey found that many countries had adopted a similar approach to structuring their data requirements for micro-organisms, and that they tended to emphasize the same test areas or study categories. Nevertheless, the survey revealed some differences in requirements in certain test areas, most notably physical-chemical properties, ecotoxicology and environmental fate. It also showed that some countries required additional tests or additional review (e.g. under a second law or by a second regulatory body) for GMOs.

The survey results suggest that a minimum "common core data set" could be proposed for micro-organisms, based on the overlap that already exists in countries' requirements. The results also suggest a need for work towards harmonization of requirements for pheromones, where countries appear to be adopting differing approaches.

Table 7
Summary and Comparison of Countries' Data Requirements

test area	summary and comparison of data requirements
identity and biological properties	Survey respondents generally required the same information on identity and biological properties of <i>naturally occurring</i> micro-organisms, e.g.: • scientific name, common name, subspecies, strain, serotype; • history of the organism, relationship to known pathogens, natural occurrence and geographic distribution, genetic stability, survivability. For <i>genetically modified</i> organisms, the EC and several non-European countries required additional information not required by others on the donor organism, genetic material, vector, gene control region, modification technique, and site of new material in recipient.
physical-chemical properties	Survey respondents required only a few data elements on physical-chemical properties, and the elements they required were often different. The only elements required by all or most respondents were storage stability, physical state, and appearance.
function, mode of action and handling	Survey respondents' requirements were very similar in this area, which includes information ranging from application rate to pre-harvest intervals to product packaging and storage.
manufacturing, quality control and analytical methods	All or most survey respondents required information on manufacturing, quality control, and methods to show microbiological purity. Greater difference was seen in requirements for methods to detect and quantify residues in various media.
residues	Survey responses were very similar in this test area. All respondents but one required information on the persistence, nature and magnitude of residues in/on crops or food; all required a summary and evaluation of residue behaviour and proposed maximum residue levels; and nearly all (but not the EC) required information on the effects of processing or cooking on residues.
efficacy	Survey responses were very similar in this test area except in the case of requirements for data on dose-efficacy relationships and on use of the product in integrated pest management systems. These data elements were listed by most or all non-European Union respondents, but not by the EC.
toxicology, pathogenicity and infectivity	Respondents took a similar approach to data requirements throughout this test area. Most or all required basic acute toxicity tests (oral, dermal, inhalation) as well as skin and eye irritation/sensitivity for all registration submissions. Most or all required subchronic tests on a less frequent basis (for fewer than 20% of registration submissions). Several countries and the EC required medical data (e.g. on applicator exposure, hypersensitivity/allergenicity incidents). Five to eight countries required data on genetic toxicity, dermal penetration, and estimates of occupational exposure. The EC and a small number of countries sometimes required information on: neurotoxicity, metabolism, oncogenicity, long-term toxicity, developmental and reproductive effects, immunotoxicity and allergenicity/hypersensitivity.
ecotoxicology	Ecotoxicology data were somewhat less rigorously required than toxicology data. The EC and most non-European Union respondents required basic acute toxicity, pathogenicity and infectivity tests (bird, honey bee, freshwater fish, freshwater invertebrate), but half the countries said the tests were required frequently (i.e. for 80-99% of registration submissions) rather than always. Acute tests on other organisms such as earthworm, algae, wild mammal, estuarine and marine animal were seldom required. Long-term studies and field tests were seldom or never required.
environmental fate	Requirements for information on environmental fate showed a pattern similar to that seen in ecotoxicology. Six non-European Union respondents and the EC required laboratory/microcosm testing on environmental fate (spread, mobility, multiplication and persistence) in soil, water and air; but only half the countries said they always required such data. The same number of countries but not the EC required data on gene-transfer rates/competitiveness in the environment for GMOs. Only a few non-European countries and the EC said they required, even on an occasional basis, greenhouse or field studies.

Table 8
Comparison of Data Requirements for Micro-organisms, Chemical Pesticides

test area	requirements for micro-organisms	requirements for chemicals
identity/biological properties physical-chemical properties	focus on identity and biological properties	focus on physical-chemical properties
toxicology	focus on hypersensitivity, allergenicity and genetic toxicity	greater focus on chronic, developmental and reproductive effects
environmental fate	focus on multiplication in the environment, competitiveness with other organisms	focus on photodegradation in various media
ecotoxicology	fewer tests required overall than for chemicals, but some countries emphasize testing of effects on non-target organisms	
efficacy	all countries required data in this area; some countries required extra tests not required for chemicals	not all countries required efficacy testing

Annex 1

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

TABLE A
STATUS OF DATA REQUIREMENTS AND PRODUCTS COVERED

Country	Products identified as biological pesticides	Status of data requirements
EC	products containing micro-organisms or viruses	Directive 91/414/EEC which defines the requirements for authorization of plant protection products became operational on 25 July 1993. A proposed Council Directive concerning authorization, placing on the market, use and control within the Community of biocides, i.e. pesticides other than plant protection products, has been adopted by the Commission and will soon be considered by the European Parliament, the European Economic and Social Committee and the Council of the European Communities. Both Directives distinguish between chemical pesticides and pesticides containing micro-organisms or viruses.
Australia	1) biologically derived chemicals - direct toxicity - indirect toxicity semiochemicals (pheromones) hormones growth regulators enzymes/proteins plant and animal extracts 2) microbials 3) other living organisms	"Guidelines for Registration of Biological Products" (October 1994) have been prepared and circulated for use as a working document. A case-by-case approach will be taken in determining the appropriateness of certain data and exemptions will be granted when necessary.
Austria	micro- and macro-organisms <i>Comments:</i> The Austrian legislation doesn't use the term "biological pesticides"	Details of the data requirements are not yet legally fixed, but practically they are in use.

Country	Products identified as biological pesticides	Status of data requirements
Canada	1) microbial pest control agents 2) macro-organisms <i>Comments:</i> Macro-organisms do not yet require registration, but guidelines for registration of biological control agents (insects, mites and nematodes) are being developed. Pheromones, plant extracts, and insect and plant growth regulators are not identified as biological pesticides and require registration as chemical pesticides. Transgenic plants with pesticidal properties are regulated as varieties under the Seeds Act and by Health Canada as novel foods.	<u>Micro-organisms</u> Current data requirements are published in Research Permit Guidelines for Microbial Pest Control Agents (PRO-93-05), and Registration Guidelines for Microbial Pest Control Agents (PRO-93-04). These are under review and may be further revised. <u>Pheromones</u> Draft Guidelines for the Regulation of Pheromones and Other Semiochemicals have been prepared but not yet circulated for review. It is proposed that the data requirements for registration of many pheromone products be less than those for traditional chemicals, and that some pheromone products be exempted from registration altogether. <u>Macro-organisms</u> Draft Guidelines for the Introduction and Release of Invertebrate Biological Control Agents (Insects, Mites and Nematodes) are under interdepartmental review and may be revised. <u>Insect and plant growth regulators and plant extracts</u> are regulated in the same way as other chemical pesticides.
Denmark	1) micro-organisms 2) macro-organisms 3) transgenic plants <i>Comments:</i> Biological pesticides include only pesticides which consist of living organisms. Pheromones, insect and plant growth regulators, and plant extracts are regarded as chemical pesticides.	Data requirements for microbiological plant protection products are those listed in EEC directive 91/414/EEC. Detailed regulations are established in Statutory Order from the Ministry of the Environment No. 584 of 9 July 1993 on Pesticides. Draft guidelines for implementing the requirements are published in 1993.

Country	Products identified as biological pesticides	Status of data requirements
Finland	<u>Comments:</u> Biological pesticides are not mentioned separately in the Finnish legislation nor are they grouped in different categories. Use has been the decisive factor, i.e. if the product is intended for use against insects, plant diseases, weeds, etc. it has been regulated as a pesticide whether or not the product is a chemical or biological one. Macro-organisms and transgenic plants are not considered to be pesticides at all. Since becoming a member of the EU in 1995, Finland has implemented directive 91/414/EEC, meaning that products containing micro-organisms or viruses are controlled as biopesticides.	No specific legislation and no specific data requirements. Requirements are set on a case-by-case basis, e.g.: 1) <i>Phlebia gigantea</i> – no toxin – no studies required. 2) <i>Streptomyces griseoviridis</i> – documentation required. a) For <u>plant extracts</u>, the requirements are the same as for synthesized pesticides. These products are not considered biological pesticides, but pesticides in general. b) For <u>micro-organisms</u>, the contentional study requirements are not so strict as for chemical substances. The requirements are not officially stated, however, since there have been only a few applications and the decisions are made on a case-by-case basis in tiers. c) Requirements for <u>macro-organisms</u> or <u>transgenic plants</u> have not been considered, since these are not classified as pesticides. The same is true for some uses of pheromones, e.g. for monitoring purposes. The Finnish Pesticide Act was amended in Jan 1995 to comply with the general regulations of 91/414/EEC, but the more specific test requirements for biopesticides will be established in the future by the Ministry of Agriculture and Forestry. (General data requirements for micro-organisms and viruses are set in the annexes of 91/414/EEC and draft Biocide Directive)
France	<u>Comments:</u> France follows the principles of the EC	see EC response
Germany	for plant protection: micro-organisms and viruses for public health: micro- and macro-organisms are considered biological pesticides; pheromones, plant extracts and insect growth regulators are biochemicals	No separate data requirements are published for biological pesticides, because the German Plant Protection Act makes no distinction between biological and chemical substances. Nevertheless, the competent German authority recognizes that different approaches are required to evaluate biological vs. chemical active ingredients, and different approaches are therefore used. For public health pesticides, it is common practice to summarize micro- and macro-organisms as biological pesticides, and pheromones, plant extracts and insect growth regulators as biochemicals. However, this is not a definition by any law or directive. Data requirements are based on those for chemical pesticides.

Country	Products identified as biological pesticides	Status of data requirements
Hungary	1) living organisms suitable for biological control - micro-organisms (viruses, virus-like organisms, bacteria, protozoa, fungi, algae) - macro-organisms (nematodes, parasitic and predatory insects, transgenic plants) 2) living organisms other than those used for control (pollinating insect) 3) chemicals of biological origin (biochemicals) - insect growth regulators - pheromones - plant growth regulators - plant extracts - metabolites produced by micro-organisms (antibiotics) - toxins produced by animals	Data requirements for registration of biological pesticides, including requirements for field trials, are contained in the Plant Protection Law of 1988.
Italy	1) micro-organisms 2) pheromones 3) insect growth regulators 4) plant growth regulators 5) plant extracts 6) macro-organisms 7) transgenic plants	Data requirements available (based on EC Directives) for micro-organisms for plant protection uses, genetically modified pesticides, and micro-organisms for household uses.
Japan	1) micro-organisms 2) macro-organisms <u>Comments:</u> Pheromones, insect and plant growth regulators, and plant extracts are defined as chemical pesticides. Transgenic plants are defined as seeds or seedlings, not as pesticides.	The data requirements for micro-organisms, pheromones and macro-organisms are to be provided on a case-by-case basis. The data requirements for registration of insect and plant growth regulators and plant extracts are not different from those for conventional pesticides. MAFF and EA are currently investigating development of data requirements for microbial pest control agents.

Country	Products identified as biological pesticides	Status of data requirements
The Netherlands	1) micro-organisms 2) viruses <u>Comments:</u> Pheromones, insect growth regulators, plant growth regulators and plant extracts are identified as chemical pesticides. Macro-organisms and transgenic plants are not included in the Pesticides Act 1962.	Data requirements for biological pesticides (application form and data requirements, June 1991?) and guidelines (June 1992) are available. The explanatory notes are under revision.
New Zealand	1) micro-organisms (bacteria, protozoa, rickettsia, fungi, viruses) 2) nematodes <u>Comments:</u> • pheromones are not considered to be pesticides, and therefore do not require registration • transgenic plants have not yet been considered, and the question of whether they require registration will be addressed as the need arises. • macro-organisms other than nematodes do not require registration	Data requirements and guidelines are published in Guidelines for the Registration of Biological Pesticides and (for all pesticides) Procedures for Registration and Experimental Use Permits.
Norway	micro-organisms such as bacteria, fungi and viruses <u>Comments:</u> The Norwegian legislation does not use the term biological pesticides, but rather the general terms "ingredient" and "preparation."	Data requirements are in principal the same as those for chemical pesticides, although in practice they are different. Requirements are set on a case-by-case basis.
Sweden	1) micro-organisms 2) viruses 3) nematodes 4) insects 5) <i>Arachnida</i> <u>Comments:</u> Only living organisms are regarded as biological pesticides.	Until the end of 1994, a biological pesticide could be offered for sale and used if the Chemicals Inspectorate decided to grant an exemption from the requirement of approval for the preparation. As of 1 January 1995, a biological pesticide can be offered for sale and used only if it is approved under the Act on Preliminary Examination of Biological Pesticides. A draft application form for approval of biological pesticides is available (including data requirements), as well as guidance for filling in the form (one guidance for micro-organisms and viruses; one for nematodes, insects and arachnida).

Country	Products identified as biological pesticides	Status of data requirements
United Kingdom	micro-organisms only	Micro-organisms are regulated under the Control of Pesticides Regulations to be amended in Spring 1994 to comply with 91/414/EEC (Appendix 9 of CPR contains registration criteria for biological agents used as pesticides). Genetically modified micro-organisms are also regulated under The Genetically Modified Organisms (Deliberate Release) Regulations 1992. Macro-organisms are considered in terms of "release" under the Wildlife and Countryside Act (1981) although in some cases, e.g. use in glasshouses, macro-organisms can be used without approval. Other "biological pesticides" fall outside scope of UK regulations. UK government departments are currently considering biological pesticides other than microbials, to see if a more comprehensive assessment system is required.
United States	1) microbial pesticides (micro-organisms) 2) biochemicals including: - pheromones, insect growth regulators and plant growth regulators, provided they: (1) are naturally occurring or, if synthesized, are substantially similar in chemical structure and functionally identical to the natural substance, (2) have a nontoxic mode of action to the target pest - plant extracts, if they meet the above two criteria. 3) macro-organisms 4) transgenic plants <i>Comments:</i> Naturally occurring substances that don't meet criteria for designation as biological pesticide are regulated like conventional pesticides but receive special consideration for data waivers. Macro-organisms do not require EPA registration. Transgenic plants (plant pesticides) are currently subject to regulation under federal food safety law; registration under federal pesticide law will be required in the future.	Data requirements for biological pesticides are contained in Subdivision M and 40 Code of Federal Regulations Part 158.

TABLE B: REGISTRATION OF BIOPESTICIDES FOR PLANT PROTECTION

pesticide type	registration required under pesticide law (biological or chemical)	review required under other law or programme	registration not required	registration not currently required but will be in future	data requirements for registration are <i>the same as or different</i> from those for chemical pesticides:		data requirements established for pre-registration field testing
					same	different	
micro-organisms							
naturally occurring	viable	Aus, Aut, Can, Den, Fin, Fra, Ger, Hun, Ita, Jap, Nth, Nor, NZ, Swe, UK, US, EC				Aus, Aut, Can, Den, Fin, Fra, Ger, Hun, Ita, Jap, Nth, Nor, NZ, Swe, UK, US, EC	Can, Den, Fra, Hun, Ita, Nth, NZ, US
	non-viable	Aus, Aut, Can, Den, Fin, Fra, Ger, Hun, Ita, Jap, Nth, Nor, NZ, Swe, UK, US, EC			Den, Ger, Jap, Nor, Swe, UK, US	Aus, Aut, Can, Fin, Fra, Hun, Ita, Nth, NZ, EC	Can, Den, Fra, Hun, Ita, Nth, NZ, US
genetically modified	viable	Aus, Aut, Can, Den, Fin, Fra, Ger, Hun, Ita, Jap, Nth, Nor, NZ, Swe, UK, US, EC	Den, Fra, Ger, Ita, Jap, Nth, Nor, NZ, UK, EC			Aus, Aut, Can, Den, Fin, Fra, Ger, Hun, Ita, Nth, NZ, Swe, UK, US, EC	Can, Den, Fra, Hun, Ita, Nth, Nor, NZ, US, EC
	non-viable	Aus, Aut, Can, Den, Fin, Fra, Ger, Hun, Ita, Jap, Nth, Nor, NZ, Swe, UK, US, EC	Ger, Ita, Jap, Nth, Nor, NZ		Den, Ger, Swe, UK, US	Aus, Aut, Can, Fin, Fra, Ger, Hun, Nth, NZ, EC	Can, Den, Fra, Hun, Ita, Nth, Nor, NZ, US, EC

pesticide type	registration required under pesticide law (biological or chemical)	review required under other law or programme	registration not required	registration not currently required but will be in future	data requirements for registration are <i>the same</i> as or <i>different from</i> those for chemical pesticides:		data requirements established for pre-registration field testing
					same	different	
other							
pheromones	Den, Fra, Hun, Jap, Swe, US		Aus, Aut, Fin, Ger, Nth, Nor, NZ, UK, EC	Ita	Den, Fra, Jap, Nth, Swe, UK	Aut, Hun, US	Den, Hun, Nth, US
	other uses		Fin, Nor, NZ	Ita	Den, Fra, Ger, Jap, Nth, Swe, UK, EC	Aus, Aut, Can, Hun, US	Can, Den, Hun, Nth, US
insect growth regulators	Aus, Aut, Can, Den, Fin, Fra, Ger, Hun, Ita, Jap, Nth, Nor, NZ, Swe, UK, US, EC				Aus, Aut, Can, Den, Fin, Fra, Ger, Hun, Ita, Jap, Nth, Nor, NZ, Swe, UK, EC	US	Can, Den, Hun, Ita, Nth, NZ, US
					Aus, Aut, Can, Den, Fin, Fra, Ger, Hun, Ita, Jap, Nth, Nor, NZ, Swe, UK, EC	US	Can, Den, Hun, Ita, Nth, NZ, US
plant growth regulators	Aus, Aut, Can, Den, Fin, Fra, Ger, Hun, Ita, Jap, Nth, Nor, NZ, Swe, UK, US, EC				Aus, Aut, Can, Den, Fin, Fra, Ger, Hun, Ita, Jap, Nth, Nor, NZ, Swe, UK, EC	US	Can, Den, Hun, Ita, Nth, NZ, US
plant extracts	Aus, Aut, Can, Den, Fin, Fra, Ger, Hun, Ita, Jap, Nth, Nor, NZ, Swe, UK, US, EC				Aus, Aut, Can, Den, Fin, Fra, Ger, Hun, Ita, Jap, Nth, Nor, NZ, Swe, UK, US, EC		Can, Den, Hun, Ita, Nth, NZ, US

pesticide type	registration required under pesticide law (biological or chemical)	review required under other law or programme	registration not required	registration not currently required but will be in future	data requirements for registration as or <i>different from</i> those for chemical pesticides:		data requirements established for pre-registration field testing
					same	different	
macro-organisms	Aus, Aut, Hun, Jap, Swe	Fin, Nor	Den, Ger, Ita, Nth, Nor, NZ, US, EC*	Can		Aus, Aut, Can, Hun, Jap, Swe, EC*	Can, Hun, Nor, EC*
transgenic plants	Aus, Den, Hun	Aut, Can, Den, Fin, Fra, Ger, Ita, Nth, Nor, Swe	Ger, Nth, Nor	Aut, NZ, US		Aus, Can, Den, Fra, Ger, Hun, Ita, EC	Den, Fra, Hun, Ita, Nor, US, EC
additional types listed by countries							
metabolites of micro-organisms	Hun				Hun		Hun
animal toxins	Hun				Hun		Hun
living organisms for other than control (pollinating insects)	Hun					Hun	Hun
nematodes (but not other macro-organisms)	Fra, NZ					Fra, NZ	NZ

*Registration is required only if organisms are genetically modified.

TABLE C: REGISTRATION OF BIOPESTICIDES FOR NON-PLANT PROTECTION USES*
(HOUSEHOLD, PUBLIC HEALTH AND/OR PROFESSIONAL PEST CONTROL)

pesticide type	registration required under pesticide law (biological or chemical)	review required under other law or programme	registration not required	registration not currently required but will be in future	data requirements for registration are <i>the same as</i> or <i>different from</i> those for chemical pesticides		data requirements established for pre-registration field testing
					same	different	
micro-organisms							
	naturally occurring	viable	Aus, Can, Fin, Fra, Nth, NZ, Swe, UK, US	Ger, Hun, Ita, Nor	Aut	Den, Ger, EC	
		non-viable	Aus, Can, Den, Fin, Fra, Nth, NZ, Swe, UK, US	Ger, Hun, Ita, Nor	Aut	Ger, EC	
genetically modified		viable	Aus, Can, Fin, Fra, Nth, NZ, Swe, US	Aus, Den, Fra, Ger, Hun, Ita, Nth, Nor, NZ, EC	Aut	Den, Ger	
		non-viable	Aus, Can, Den, Fin, Fra, Nth, NZ, Swe, US	Aus, Fra, Ger, Hun, Ita, Nth, Nor, NZ	Aut	Ger, EC	
					Ita	Aus, Fin, Fra, Ger, Hun, Nth, Nor, NZ, Swe, US, EC	Fra, Hun, Nth, US
					Den, Ger, Ita, Swe, UK, US	Aus, Fin, Fra, Hun, Nth, Nor, NZ, EC	Den, Hun, Nth, UK, US
						Aus, Den, Fin, Fra, Ger, Hun, Ita, Nth, Nor, NZ, Swe, US, EC	Den, Fra, Hun, Ita, Nth, Nor, US, EC
					Den, Swe, US, EC	Aus, Fin, Fra, Ger, Hun, Ita, Nth, Nor, NZ	Den, Fra, Hun, Ita, Nth, Nor, US, EC

pesticide type	registration required under pesticide law (biological or chemical)	review required under other law or programme	registration not required	registration not currently required but will be in future	data requirements for registration as or different from those for chemical pesticides		data requirements established for pre-registration field testing
					same	different	
other							
pheromones	Den, Swe, US	Hun	Aut, Fin, Ger, Ita, Nth, NZ, UK	EC	Den, Ger, Nth, Swe, EC	Hun, Nor, US	Den, Hun, Nth, US
monitoring							
other uses	Aus, Can, Den, Fra, Nth, Swe, US	Ger, Hun	Aut, Fin, Ita, NZ, UK	Ger, EC	Aus, Den, Fra, Ger, Nth, Swe, EC	Can, Hun, Nor, US	Can, Den, Hun, Nth, US
insect growth regulators	Aus, Can, Den, Fin, Fra, Nth, NZ, Swe, UK, US	Ger, Hun	Aut, Ita	Ger, EC	Aus, Den, Fra, Ger, Nth, NZ, Swe, UK, EC	Hun, Nor, US	Den, Hun, Nth, UK, US
plant extracts	Aus, Can, Den, Fin, Fra, Nth, NZ, Swe, UK, US	Ger, Hun, Ita	Aut	Nor, Ger, EC	Aus, Den, Fin, Fra, Ger, Ita, Nth, NZ, Swe, EC	Hun, Nor, US	Den, Hun, Nth, US

pesticide type	registration required under pesticide law (biological or chemical)	review required under other law or programme	registration not required	registration not currently required but will be in future	data requirements for registration are <i>the same</i> as or <i>different from</i> those for chemical pesticides		data requirements established for pre-registration field testing
					same	different	
additional types listed by countries							
other living organisms, e.g. nematodes	Aus, Fra					Fra	
macro-organisms	Fra			Ger		Fra	
preservatives for products				EC			
preservatives for processes				EC			
antifouling products				EC			

* The original questionnaire requested information separately for each of the three uses: household, public health and professional pest control. This table combines the three groups because countries' responses are identical for all three in nearly all cases. Exceptions are as follows:

- Hungary's response applies only to public health uses;
- Norway's response regarding requirements for field testing applies only to public health and professional pest control uses;
- The UK's requirements are usually, but not always, consistent across the three categories.

TABLE D
USE OF TIER TESTING IN DATA REQUIREMENTS FOR MICRO-ORGANISMS*

Country	Tier testing is formal (F), case-by-case (C), or not applied (N)					
	residues	toxicity	pathogenicity	infectivity	ecotoxicity	environmental fate
Australia	C	C	C	C	C	C
Austria	C	C	C	C	C	C
Canada	N	N	N	N	F	F
Denmark	N	F	F	F	F	F
Finland	N	C	C	C	C	C
France	N	C	C	C	C	C
Germany	N ₁	C ₁	C ₁	C ₁	C ₁	C ₁
Hungary	N	F	C	C	F	N
Italy	N	N	N	N	N	N
Japan	N	N	N	N	N	N
Netherlands	F ₂	F ₂	F ₂	F ₂	F ₂	F ₂
New Zealand	C	C	C	C	C	C
Norway	C	C	C	C	C	C
Sweden	C	F ₁ C	F ₁ C	F ₁ C	F ₁ C	F ₁ C
UK	C	C	C	C	C	C
US		F			F	F

* The EC did not answer this question, since implementation of requirements has not yet been specified.

¹ refers only to biopesticides authorised up to now

² formal tiers are under development

TABLE E
POLICIES, REQUIREMENTS FOR NON-INDIGENOUS ORGANISMS

Country	Definition of Indigenous/Non-indigenous	Special Policies or Requirements
EC	none	none
Australia	none	
Austria	none	yes – decision case-by-case
Canada	A micro-organism is considered indigenous if it has been isolated from or previously used in the ecozone of intended use. It is currently proposed that any genetically modified organism be considered non-indigenous for environmental review purposes. Definitions and special requirements for indigenous/non-indigenous macro-organisms are under development.	Environmental fate data are required for all organisms if tier I environmental toxicology effects are unacceptable. Life cycle (tier III) studies are required for non-indigenous organisms if tier II environmental toxicology effects are unacceptable.
Denmark	none	More comprehensive requirements for data on ability of non-indigenous organisms to survive, spread and establish in the environment.
Finland	Definitions of indigenous/non-indigenous organisms are not given in legislation.	Stricter handling takes place for micro-organisms from outside the Finnish environment. More comprehensive data are requested on environmental fate of the non-indigenous organisms
France	none	none
Germany	indigenous organisms are those that occur naturally in the area of use, especially in Germany and the neighbouring countries	no additional policies or requirements
Hungary	A non-indigenous micro-organism is one that has not been detected in the country or, if it occurs, for which the circumstances of its intended introduction are known (date, place, mode, spread, etc.) If accidental introduction is suspected, indirect evidences (origin of imported plant, plant material ecology and biology of the micro-organism, host-species) are used for deciding whether the micro-organism is foreign and what its origin is.	Further data requirements are ordered case by case by the ministries participating in the registration procedure: Ministry of Agriculture, Ministry of Welfare, Ministry of Environmental Protection and Regional Development.

Country	Definition of Indigenous/Non-indigenous	Special Policies or Requirements
Italy	none	Greater attention on studies about environmental distribution and environmental fate.
Japan	currently under investigation	currently under investigation
Netherlands	none	see appendices 2 & 3 (in Dutch)
New Zealand	no definition	Non-indigenous organisms that are pathogenic to or are pests of animals, plants or insects must receive, in addition to registration, clearance from the Ministry of Agriculture and Fisheries, before they can be imported.
Norway	none	If non-indigenous, Norway will require clear statements of the potential for spread in the environment.
Sweden	An indigenous organism is one that occurs naturally in that particular ecological system where it may be used as a biological pesticide. A non-indigenous organism is one that does not occur naturally in that particular ecological system where it may be used as a biological pesticide.	Information according to Tier 2, concerning effects on the environment, are mandatory for non-indigenous organisms. For indigenous organisms, Tier 1 information may be sufficient.
UK	–	Non-indigenous plants and animals are covered by the Wildlife and Countryside Act (1981). Applications are assessed on a case-by-case basis.
US	An organism is considered indigenous if it occurs in: a) the continental U.S. including Alaska, and the immediately adjoining countries, i.e. Canada and Mexico, b) the Hawaiian islands, or c) the Caribbean Islands including Puerto Rico and the U.S. Virgin Islands.	Notification prior to small-scale (non-contained) testing is required for non-indigenous microbial pesticides that have not been acted upon by the US Department of Agriculture.

TABLE F
POLICIES AND REQUIREMENTS FOR GENETICALLY MODIFIED ORGANISMS

Country	Policies, requirements for GMOs
EC	For plant protection products consisting of or containing GMOs, data requirements of Directive 90/220/EEC currently apply in addition to those of Directive 91/414/EEC. Directive 91/414/EEC will be adapted in the future to cover those aspects now covered in 90/220/EEC. For non-plant protection products consisting of or containing GMOs, data requirements of Directive 90/220/EEC apply in addition to those required at the national level by Member states.
Australia	GMOs are currently assessed by the Genetic Manipulation Advisory Committee prior to consideration by registration authorities. However, arrangements for consideration of GMOs are being refined, and it is likely that GMAC will be replaced by a new body.
Austria	Additional requirements very similar to Directive 90/220/EEC.
Canada	Aim is to regulate products rather than processes. However, the method of production is considered, and if it involved GMOs or their products, this would have to be cited in the application, and any change in properties or potential hazards of the product would be assessed.
Denmark	Genetically modified biological pesticides are covered by the Danish Act no. 356 of 6 June 1991 on environment and genetic engineering and by the statutory order no. 1098 of 11 December 1992 on the approval of experimental release and marketing of GMOs, which contains data requirements as laid down in the EEC Directive 90/220/EEC. GMO pesticides must be registered in accordance with this regulation as well as in accordance with the pesticide regulation.
Finland	The new Gene Technology Act came into force 1 June 1995 and it contains regulations and policies as laid down in the EEC directives 90/220/EEC and 90/219/EEC. According to 91/414/EEC and the Finnish Pesticide Act, 90/220/EEC applies also to genetically modified biopesticides. GMOs need two separate reviews and approvals, if they are going to be used as pesticides. The Committee on Gene Technology reviews any release of GMOs and processes of genetic engineering, as the Committee on Pesticides reviews the acceptability of a product to be placed on the market as a pesticide. The Ministry of Social Affairs and Health is preparing a decision concerning data requirements for GMOs. The information is not yet available, and cannot be taken into account in more detail in the survey.
France	In France the dossier for registration of a microbial preparation voluntarily released in the environment is reviewed by three committees as follows: 1. CGB (Commission du Génie Biomoléculaire) analyses the risks linked to the introduction of an heterologous gene (vector, gene, markers, recombination, gene diffusion, etc) 2. GEODE (Groupe d'Etude des Organismes disséminés dans l'environnement). This group is included in the "Commission d'étude de la toxicité des produits antiparasitaires à usage agricole" which is responsible for the toxicological classification of all phytosanitary and fertilizing products. 3. Comité d'homologation which rules on the efficacy of the product.

Country	Policies, requirements for GMOs
Germany	Genetically modified organisms for plant protection, like all genetically modified organisms, are subject to the prescriptions of the "Gentechnikgesetz" (Gene Technology Act). Thus, any release of a GMO for field tests (e.g. for efficacy testing) is regulated by the Gentechnikgesetz. The placing on the market of a product containing a GMO, however, is subject to both Gentechnikgesetz and Plant Protection Act.
Hungary	In Hungary no GMOs are registered. Thus the Ministry of Agriculture, involving the Ministry of Welfare and Ministry of Environmental Protection and Regional Development, decides on special requirements in every case.
Italy	All categories of biological pesticides that are genetically modified are regulated by the d.lgs of the 3/3/93 n. 92 in realization of the directive 90/220/CEE.
Japan	Any GMOs intended for use as pesticides are controlled under "the Guidelines for Application of Recombinant DNA Organisms in Agriculture, Forestry, Fisheries, the Food Industry and Other Related Industries."
Netherlands	GMOs must first be approved for release to the environment by the VCOGEM, a Dutch organisation responsible for evaluating risks of environmental release. Authorization must then be granted under the Pesticide Act.
New Zealand	Any genetically modified organisms intended for use as pesticides must first be cleared by an interdepartmental scientific "Interim Assessment Group" before being considered for registration.
Norway	Different requirements apply to genetically modified organisms, and they are harmonized with the EC.
Sweden	Additional information is required about the genetic modification. In all other respects, a GMO is treated the same way as a non-GMO. This policy applies to all organisms named in the Act on Preliminary Examination of Biological Pesticides (micro-organisms, viruses, nematodes, insects or <i>Arachnida</i>).
UK	GMOs and transgenic plants are covered by the Genetically Modified Organisms (deliberate release) Regulations 1992.
US	There are no specific differences in policies or data requirements for registration and large scale testing (Experimental Use Permit scale) between naturally occurring and genetically modified pesticides. Any additional data requirements which might be needed for genetically modified products would be determined on a case-specific basis. A pre-experimental use permit notification rule is in place which requires that EPA be notified before small-scale (uncontained) testing is performed with a microbial pesticide whose pesticidal properties have been imparted or enhanced by the addition of genetic material that has been deliberately modified. The requirement also applies to non-indigenous microbial pesticides that are not acted on by the US Department of Agriculture. EPA is currently developing a policy and associated regulations for the oversight of plant pesticides, including those that have been developed through genetic engineering. Because these documents are still in the formative stages, it is not possible to specify any distinctions made for plant pesticides that have been genetically modified.

Annex 2

Biopesticides Registered in OECD Countries for Plant Protection and Other Uses

Note: This annex lists different types of biopesticides registered for use in OECD countries and Hungary. It should be noted that some of the categories included – namely plant/insect growth regulators and plant extracts – are not considered to be biopesticides by some countries (see Table A, page 32 ff). These countries therefore did not list products in these categories, although they may indeed have registered such products, as chemical pests.

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MICRO-ORGANISMS REGISTERED FOR PLANT PROTECTION USES

Active ingredient	Registered uses (pest and/or crop)	Country
BACTERIA		
<i>Agrobacterium radiobacter</i>	root dip against crown gall disease in non fruit-bearing plants	Canada
	rose seedling	Japan
	seedling dip for prevention of crown gall in peaches, bush fruit, kiwifruit, roses	New Zealand
	crown gall disease	US
<i>Agrobacterium radiobacter</i> Strain k1026	against crown gall disease on almond, peach, rose, stone fruit, walnut	Australia
<i>Bacillus popilliae</i> + <i>B.lentimorbus</i>	Japanese beetle larvae	US
<i>Bacillus pumilis</i>	lucerne hay inoculant	Australia
<i>Bacillus subtilis</i>	damping off disease; seed treatment protection from <i>Fusarium</i> , <i>Rhizoctonia</i> , <i>Alternaria</i> , and <i>Aspergillus</i> ; and for use as a manufacturing-use product	US
<i>Bacillus thuringiensis</i>	vegetable, maize, viticulture	Austria
	fruit crops	Austria, Netherlands
	cabbage	Netherlands, UK
	crops, vegetables that are botanically grown	Netherlands
	ornamental plants	Netherlands, UK
	forestry	Netherlands
	foliar insecticide for caterpillars in horticulture	New Zealand
		Norway ^(*)
	lepidopteran larvae in: cabbages, cauliflower, tomato, vine, olive tree, pine tree, <i>Quercus</i> sp.	
	forestry, viticulture (caterpillars)	Switzerland
	brussels sprout, cauliflower, calabrese, broccoli, lettuce, French bean, pea, tomato, cucumber, pepper, strawberry, raspberry, apple, pear, cherry, vine	UK
<i>B. thuringiensis</i> and δ -endotoxin	vegetable, tea, apple, cherry	Japan
<i>B. thuringiensis</i> serotype 1 + piperonyl butoxyde + pyrethrines	amateur gardens, treatments of aerial parts; insecticides	France

Active ingredient	Registered uses (pest and/or crop)	Country
<i>B. thuringiensis</i> serotype 3	general treatments, treatments of aerial parts, moths, olive tree, olive moth, apple tree, <i>Capua</i> , <i>Pandemis</i> , vine, <i>Cochylis</i> , <i>Eudemis</i> , <i>Eulia</i> , conifers, pine processionary caterpillar, broad-leaved trees, bombyx, seed treatments, soya, cabbage, tomatoes, amateur gardens; insecticides	France
<i>B. thuringiensis</i> serotype 3 + piperonyl butoxyde + pyrethrines	amateur gardens, treatments of aerial parts; insecticides	France
<i>B. thuringiensis</i> subsp. <i>aizawai</i>	lepidopteran larvae	US
	against <i>Lobesia botrana</i> and <i>Eupoecilia ambiguella</i> (viticulture); against <i>Hibernia defoliara</i> (<i>Erannis defoliara</i>) (horticulture)	Germany
<i>B. thuringiensis</i> subsp. <i>aizawai</i> strain GC-91	lepidopteran larvae	US
<i>B. thuringiensis</i> subsp. <i>aizawai</i> x <i>kurstaki</i>	cabbage butterfly (<i>Pieris brassicae</i> , <i>P rapae</i>), diamondback moth (<i>Plutella xylostella</i>)	Sweden
<i>B. thuringiensis</i> subsp. <i>kurstaki</i>	cabbage moth, cabbage white butterfly on brassica spp. or cole crop, broccoli, brussels sprout, cabbage and cauliflower. Light brown apple moth on fruit crop or tree, grapevine, kiwi fruit and ornamental plant or annual. Grapevine moth on grape and grapevine. Cabbage moth and cabbage white butterfly on ornamentals. Looper on ornamental plant or annual. Tobacco looper or looper caterpillar on tobacco. Cotton.	Australia
	lepidopteran larvae	Canada, US
	<i>Hyphantria</i> , <i>Lymantria</i> in forestry; <i>Ostrinia nubilalis</i> on maize	France, Hungary
	lepidoptera in agriculture (<i>Ostrinia nubilalis</i>), viticulture (<i>Lobesia botrana</i> , <i>Eupoecilia ambiguella</i>), ornamentals (e.g. <i>Euproctis chrysorrhoea</i> , <i>Lymantria dispar</i>), horticulture (e.g. <i>Pieris brassicae</i> , <i>Plutella</i> sp.), fruit-growing (e.g. <i>L. dispar</i> , <i>C. chrysorrhoea</i>), forestry	Germany
	insecticide	Italy
δ -endotoxin of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i>	hairy and hairless, free living butterfly caterpillars (lepidopteran pests), larva of european corn borer (<i>Ostrinia nubilalis</i>), Grape Berry Moth on viticulture, leaf rollers on fruit, white butterfly (cabbage-white) on vegetables, cabbage moth caterpillars on vegetables	Austria

Active ingredient	Registered uses (pest and/or crop)	Country
<i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> vegetative cells and spores	hairy and hairless, free living butterfly caterpillars (lepidopteran pests), larva of european corn borer (<i>Ostrinia nubilalis</i>), Grape Berry Moth on viticulture, leaf rollers on fruit, white butterfly (cabbage-white) on vegetables, cabbage moth caterpillars on vegetables	Austria
<i>B. thuringiensis</i> subsp. <i>tenebrionis</i> (= <i>B. thuringiensis</i> var. <i>san diego</i>)	Colorado potato beetle on potatoes and tomatoes - <i>Leptinotarsa decemlineata</i>	Canada, Germany, Hungary
	coleopteran larvae	US
<i>B. thuringiensis</i> var. <i>tenebrionis</i>		Austria
	insecticide	France, Italy
<i>Lactobacillus casei</i> + <i>Lactobacillus plantarum</i> + hemicellulase + amylase + <i>Pediococcus pentosaceus</i>	silage inoculant: maize	France
<i>Lactobacillus plantarum</i>	silage inoculant: maize	France
<i>Lactobacillus plantarum</i> + <i>Pediococcus acidilactici</i>	silage inoculant: maize	France
<i>Lactobacillus plantarum</i> + <i>Pediococcus pentosaceus</i>	silage inoculant: maize	France
<i>Lactobacillus plantarum</i> + <i>Streptococcus faecium</i>	silage inoculant: maize	France
<i>Lactobacillus plantarum</i> + cellulase + <i>Pediococcus acidilactici</i>	silage inoculant: maize	France
<i>Lactobacillus plantarum</i> + enzymes + <i>Streptococcus faecium</i>	silage inoculant: maize	France
<i>Lactobacillus plantarum</i> + <i>Streptococcus faecium</i> + <i>Pediococcus acidilactici</i>	silage inoculant: maize	France
<i>Lactobacillus plantarum</i> + hemicellulase + amylase + <i>Lactobacillus casei</i> + <i>Pediococcus pentosaceus</i>	silage inoculant: maize	France
<i>Pediococcus acidilactici</i> + <i>Lactobacillus plantarum</i>	silage inoculant: maize	France
<i>Pediococcus acidilactici</i> + cellulase + <i>Lactobacillus plantarum</i>	silage inoculant: maize	France
<i>Pediococcus acidilactici</i> + <i>Lactobacillus plantarum</i> + <i>Streptococcus faecium</i>	silage inoculant: maize	France
<i>Pediococcus pentosaceus</i>	silage inoculant: maize	France

Active ingredient	Registered uses (pest and/or crop)	Country
<i>Pediococcus pentosaceus</i> + <i>Lactobacillus plantarum</i>	silage inoculant: maize	France
<i>Pediococcus pentosaceus</i> + <i>Lactobacillus plantarum</i> + hemicellulase + amylase + <i>Lactobacillus casei</i>	silage inoculant: maize	France
<i>Pseudomonas fluorescens</i>	against bacterial spot/blotch on mushroom	Australia
	antagonist to mushroom blotch in mushroom beds	New Zealand
<i>Pseudomonas fluorescens</i> EG1053	<i>Pythium</i> , <i>Rhizoctonia</i> seedling disease complex	US
<i>Pseudomonas fluorescens</i> A 506	frost inhibition by competition	US
<i>Pseudomonas fluorescens</i> 162RS	frost inhibition by competition	US
<i>Pseudomonas syringae</i> 742RS	frost inhibition by competition	US
<i>Pseudomonas cepacia</i> type Wisconsin	damping off disease, and nematodes	US
<i>Rhizobium japonicum</i>	silage inoculant: soya, seed treatment	France
<i>Rhizobium meliloti</i>	silage inoculant: leguminous fodder plant, seed treatments	France
<i>Serratia entomophila</i>	soil applied insecticide for grass grub in pasture	New Zealand
<i>Streptococcus faecium</i> + <i>Lactobacillus plantarum</i>	silage inoculant: maize	France
<i>Streptococcus faecium</i> + <i>Lactobacillus plantarum</i> + enzymes	silage inoculant: maize	France
<i>Streptococcus faecium</i> + <i>Lactobacillus plantarum</i> + <i>Pediococcus acidilactici</i>	silage inoculant: maize	France

Active ingredient	Registered uses (pest and/or crop)	Country
PROTOZOA		
<i>Nosema locustae</i> (protozoa)	grasshoppers	US
VIRUSES		
Apfelwicklergranulosevirus (CPGV) (<i>Cydia-pomonella-granulosis-virus</i>)	apple tree, treatments of aerial parts, apples, pears <i>Cydia pomonella</i>	France
	<i>Cydia pomonella</i> , apples, pears	Germany, Switzerland
<i>Borrelinavirus diprionis</i>	in forestry against <i>neodiprion sertifer</i>	Finland
Dendrolimus Cytoplasmic-polyhedrois Virus (DCV)	pine tree	Japan
Nuclear polyhedrosis virus (<i>Mamestra brassicae</i>)	cabbage, treatment of aerial parts, defoliating moths	France
Polyhedral inclusion bodies of Douglas fir tussock moth nuclear polyhedrosis virus (NPV)	Douglas fir tussock moth	Canada, US
Polyhedral inclusion bodies of pine sawfly NPV	pine sawfly in forests	Canada, US
Polyhedral inclusion bodies of <i>Heliothis</i> NPV	cotton bollworm, budworm	US
Polyhedral inclusion bodies of gypsy moth NPV	gypsy moth larvae	US
Polyhedral inclusion bodies of the beet armyworm NPV	Beet armyworm larvae	US
Polyhedral inclusion bodies of <i>Autographa californica</i> (Alfalfa looper)	Alfalfa looper larvae	US
Schalenwicklergranulose virus (<i>Capua granulosis virus</i>)		Switzerland
<i>Spodoptora exigua</i> nuclear polyhedrosis virus	against <i>Spodoptora exigua</i> on flower crops under glass	Netherlands
FUNGI		
<i>Achersonia aleyrodus</i>	White flies (<i>Trialeurodes vaporariorum</i> , <i>Beisa tabaci</i>)	Sweden
<i>Beauveria brongniartii</i>	cockchafer May beetle grub	Switzerland
<i>Colletotrichum gloeosporioides</i>	control of round leaf mallow (herbicide)	Canada
<i>Colletotrichum gloeosporioides</i> f. sp. <i>aeschynomene</i> ATCC 203 58	northern joint vetch	US
<i>Endothia parasitica</i> strains	chestnut tree, treatment of aerial parts, bark canker	France
<i>Gliocladium virens</i> G-21	<i>Pythium</i> , <i>Phizoctonia</i>	US
<i>Metarhizium anisopliae</i>	<i>Otiorhynchus sulcatus</i> , <i>Hepialus</i> sp.	Germany
<i>Monacrosporium phymatopagum</i>	tobacco	Japan

Active ingredient	Registered uses (pest and/or crop)	Country
<i>Paecilomyces fumosoroseus</i>	white flies (<i>Trialeurodes vaporariorum</i> , <i>Beisa tabaci</i>)	Sweden
<i>Phlebia gigantea</i>	forestry, against <i>Fomes annosus</i>	Finland
		Norway ^(*)
	rot: Pine tree and spruce	Sweden
<i>Phytophthora citrophthora</i> Strangler vine race	citrus strangler vine	US
<i>Puccinia canaliculate</i> (Schweinitz) Langerheim	yellow nutsedge control	US
Spores of <i>Beauveria bassiana</i> 147	maize, treatments of aerial parts, pyrale	France
Spores of <i>Beauveria tenella</i> 96	general treatments, soil treatment, May beetle grub (<i>Hoplochelus marginalis</i>), sugar cane; insecticide	France
<i>Streptomyces</i> sp.	soilborne diseases in ornamental	Sweden
<i>Streptomyces griseoviridis</i>	seed treatment in horticulture; spray treatment for ornamentals and cucumber	Finland
	<i>Fusarium</i> on carnation, gerbera, potted/cut flowers	Hungary
		Norway ^(*)
	withered state of cyclamen, gerbera, carnation	Switzerland
	control of <i>Fusarium</i> , <i>Alternaria</i> , <i>Phemopsis</i> and suppression of <i>Botrytis</i> , <i>Pythium</i> , and <i>Phytophthora</i>	US
<i>Trichoderma</i> sp	soil borne fungal diseases	Sweden
<i>Trichoderma harzianum</i> (ATCC 20476) (always sold and used with <i>Trichoderma polysporum</i>)	tree wound decay	France, US
	soil borne fungal diseases	Sweden
<i>Trichoderma polysporum</i> (ATCC 20475) (always sold and used with <i>Trichoderma harzianum</i>)	wood rot	US
<i>Trichoderma harzianum</i> Rifai strain KRL-AG2	damping off disease	US
<i>Trichoderma lignorum</i>	tobacco	Japan
<i>Trichoderma viride</i>	antagonist to silverleaf in pip and stonefruit	New Zealand
	plum, apple, pear, cherry, forestry	UK

Active ingredient	Registered uses (pest and/or crop)	Country
<i>Verticillium lecanii</i>	insects on tomatoes, cucumbers	Netherlands, Switzerland
	aphids, mites	Norway
	aphids (<i>Macrosiphum euphorbiae</i> , <i>Aulacothum solani</i>)	Sweden
	thrips of tobacco, aphids, <i>T. urticae</i>	Switzerland
	ornamental, flower(cut), cucumber, pepper, aubergine, lettuce, bean	UK
<i>Verticillium dahliae</i>	against elm disease on elms	Netherlands
weak stem of the tomatomozaik virus	on tomato plants for protection against mozaikvirus	Netherlands
NON-VIABLE MICROBIAL PESTICIDES		
<i>B. thuringiensis</i> toxin	vine, treatment of aerial parts, <i>Cochylis</i> , <i>Eudemis</i> , <i>Eulia</i> , conifers, pine processionary caterpillar	France
Delta endotoxin of <i>Bacillus thuringiensis</i> var <i>kurstaki</i> encapsulated in killed <i>Pseudomonas fluorescens</i>	leptidopteran larvae	US
Delta endotoxin of <i>Bacillus thuringiensis</i> var <i>San Diego</i> encapsulated in killed <i>Pseudomonas fluorescens</i>	coleopteran larvae	US

^(*) Not approved yet

MICRO-ORGANISMS REGISTERED
FOR USES OTHER THAN PLANT PROTECTION

Active ingredient	Registered uses (pest and/or crop)	Country
BACTERIA		
<i>Bacillus licheniformis</i>	products against microorganisms in chemical toilets	Sweden
<i>Bacillus sphaericus</i>	mosquitoes, larvae	France
	dipteran larvae control	US
<i>Bacillus subtilis</i>	products against microorganisms in chemical toilets	Sweden
<i>B. thuringiensis</i> subsp. <i>aizawai</i>	pet housing; insecticide; storage premises	France
<i>B. thuringiensis</i> subsp. <i>israelensis</i>	mosquito control in fresh and salt water: brown house mosquito, common Australian mosquito, common banded mosquito, saltmarsh mosquito	Australia
	control of mosquito and blackfly larvae in ponds, lakes and rivers	Canada
	against flies in different places	Finland
	public health: vs larvae of mosquitoes	France, Germany
	dipteran larvae (blackflies and mosquitoes near water)	France, US
	mosquito control	Hungary
	household insecticide	Italy
	against larvae of mosquitoes in crawlspaces under buildings	Netherlands
	fungus gnats (<i>Bradysia</i> spp)	Sweden
	control of blackfly / flies in sewage treatment works beehive (empty brood and honeycombs)	UK
	dipteran larvae control	US
VIRUSES		
FUNGI		
<i>Lagenidium giganteum</i>	dipteran (mosquito) larvae control	US
<i>Metarhizium anisopliae</i> strain ESF1	fly + cockroach control	US

PHEROMONES REGISTERED FOR PLANT PROTECTION USES

Active ingredient (trade/common name)	Target Pest	Uses	Country
ALCOHOLS (only)			
(E,E)-8,10-dodecadien-1-ol (Australia: <i>Cydia pomonella</i> pheromone) (Austria: Codlemon)	<i>Cydia pomonella</i>		Hungary
	<i>Cydia pomonella</i>	on apple and pear	Australia
		fruit growing	Austria
1-tetradecanol; (E,E)-8,10-dodecadien-1-ol; 1-dodecanol (US: Isomate C)	Codling Moth	in apple and pear orchards: control by mating disruption	Canada, US
3,7,11-trimethyl-2,6,10-dodecatriene-1-ol (Farnesol)	Tetranychid mite		US
3,7,11-trimethyl-1,6,10-dodecatriene-3-ol (Nerolidol)	Tetranychid mite		US
ESTER ACETATES			
[10, 1x=] Decen- acetates			
(E)-5-decen-1-ol acetate; (E)-5-decen-1-ol	<i>Anarsia lineatella</i>		Hungary
[12, 1x=] Dodecen- acetates			
(Z)-8-dodecen-1-ol acetate	<i>Cydia molesta</i>		Hungary
(E)-8-dodecen-1-ol acetate; (Z)-8-dodecen-1-ol acetate (Rak-5)	Oriental Fruit Moth	on peach trees	France
(E)-8-dodecen-1-ol acetate / 96.5%; (Z)-8-dodecen-1-ol acetate / 3.5%	<i>Cydia funebrana</i>		Hungary
(E)-8-dodecen-1-yl acetate; (Z)-8-dodecen-1-yl acetate; (Z)-8-dodecen-1-ol (US: Isomate M) (France: Confusaline) (Australia: Oriental fruit moth pheromone)	Oriental Fruit Moth	on peach trees	Australia, France, US
(E)-8-dodecenyl acetate; (Z)-8-dodecenyl acetate; (Z)-8-dodecen-1-ol (Checkmate OFM)	Oriental Fruit Moth		US
(Z,E)-8-dodecen-1-ol acetate; (Z,E)-9-dodecen-1-ol acetate	<i>Enarmonia formosana</i>		Hungary
(E)-9-dodecenyl acetate	Grape Berry Moth		US
(Z)-9-dodecenyl acetate (Switz.: Bocep Viti)	<i>Eupoecilia ambiguella</i>	viticulture	Germany, Switzerland

Active ingredient (trade/common name)	Target Pest	Uses	Country
(Z)-9-dodecenyl acetate		viticulture	Austria
	Grape Berry Moth, <i>Endopiza viteana</i>	in vineyards: control by mating disruption	Canada, US
(Z)-9-dodecen-1-ol acetate	<i>Eupoecilia ambiguella</i>		Hungary
(E,Z)-9-dodecen-1-ol acetate	Western Pine Shoot Borer		US
(E)-9-dodecen-1-ol acetate / 80-90%; (E)-9-dodecen-1-ol / 10-20%	<i>Sparganothis pilleriana</i> ; <i>Leucoptera malifoliella</i>		Hungary
[13, 1x=] Tridecen- acetates			
(E)-4-tridecen-1-yl acetate	Tomato Pinworm		US
(Z)-4-tridecen-1-yl acetate	Tomato Pinworm		US
[14, 1x=] Tetradecen- acetates			
(E)-11-tetradecenyl acetate	Grape Berry Moth; Tufted Apple Budmoth		US
(Z)-9-tetradecen-1-ol acetate; (Z)-11-tetradecen-1-ol acetate	<i>Adoxophyes reticulana, orana</i>		Hungary
[16, 1x=] Hexadecen- acetates			
(E)-11-hexadecen-1-ol acetate; (Z)-11-hexadecen-1-ol acetate; (Z)-11-hexadecen-1-ol;	<i>Plutella xylostella</i>		Hungary
[12, 2x=] Dodecadien- acetates			
(E)-7-(Z)-9-dodecadienylacetate	<i>Lobesia botrana</i>	viticulture	Germany
(Z,E)-7,9-dodecadien-1-ol acetate	<i>Lobesia botrana</i>		Hungary

Active ingredient (trade/common name)	Target Pest	Uses	Country
[16, 2x=] Hexadecadien- acetates			
(Z,E)-7-11-hexadecadien-1-yl acetate; (Z,Z)-7-11-hexadecadien-1-yl acetate (MEC Gossyplure)	Pink Bollworm		US
[18, 2x=] Octadecadien- acetates			
(E,Z)-3,13-octadecadien-1-ol acetate; (Z,Z)-3,13-octadecadien-1-ol acetate	Peachtree Borer		US
ESTER FORMATES			
[10, 2x=] Decadien- formates			
Decadienoic acid, methyl ester	<i>Pityogenes chalcographus</i>	monitoring and control in forestry	Switzerland
[12, 3x=] Dodecatrien-yl formates			
(Z,E)-7,9,11-dodecatrien-1-yl formate (Ectomyform)	Carob Moth		US
UNSATURATED COMPOUNDS			
7-11-dimethyl-3-methylene-1-(E)- 6,10-dodecatriene (β -Farnesene)	Aphid		US
2,6,6-trimethylbicyclo[3.1.1]-hept-2- ene (α -Pinene or Pinene); 5-cis-verbenol (Lineatin); (Linoprax Agro)	<i>Trypodendron lineatum</i>	monitoring and control in forestry	Switzerland
ALDEHYDES (also in mixtures)			
(Z)-9-tetradecenal	Tomato Budworm, Cotton Bollworm		US
(Z)-11-hexadecenal	Artichoke Plume Moth		US
(Z)-2-(3,3- dimethylcyclohexylidene) ethanol; (E)-(3,3-dimethylcyclohexylidene) acetaldehyde; (Z)-(3,3-dimethylcyclohexylidene) acetaldehyde; (1R-Cis)-1-methyl-2- (1-methylethenyl)cyclo butane ethanol; ("Grandlure")	Cotton boll weevil		US

Active ingredient (trade/common name)	Target Pest	Uses	Country
EPOXY			
Cis-7,8-epoxy-2-methyl octadecane	Gypsy Moth		US
(Z)-7,8-epoxy-2-methyloctadien	<i>Lymatria dispar</i>		Hungary
HETEROCYCLIC COMPOUNDS			
(R,Z)-5-(1-decenyl)dihydro-2-(3)-furanone (Nuranone Japonilure)	Japanese Beetle		US
OTHERS (unclassified)			
Ips dianol			Switzerland

Notes:

- Chemicals are arranged in ascending order of carbon chain and number of double bonds of the first ingredient
[length of the carbon chain, nb. of double bonds]

PHEROMONES REGISTERED FOR USES OTHER THAN PLANT PROTECTION

Active ingredient (trade/common name)	Registered uses (pest and/or crop)	Country
(Z)-9-tricosene (Canada: Muscalure) (Hungary: Muscamone)	fly attractant in farm buildings	US, Canada
	housefly control	Hungary
[1R-(1R), 2R, 5S, 6E, 10R]-(+)-8-methylene-5-(1-methylethyl)spiro [11-oxabicyclo [8.1.0] undec-6-ene-2,2-oxiran]-3-one (Periplanone B)	American cockroach	US

**PLANT GROWTH REGULATORS REGISTERED
FOR PLANT PROTECTION USES**

Active ingredient	Registered uses (pest and/or crop)	Country
ALCOHOLS		
n-decanol	Tobacco sucker inhibition	Hungary
ALCENES		
Ethylene	Fruit trees: hastens fruit ripening and maturity, enhances color, loosens nut hulls, and is a floral stimulant Controls witch weed	US
ACIDS		
Indole acetic acid (IAA) + naphthylacetic acid	Acceleration of root development growth and rooting induction (bowling green, cutting, golf course/green turf, lawn, sugar cane)	Australia
Indole acetic acid + Gibberellic acid + Zeatins (Biozyme: Nat. plant Ext.)	Not specified	US
4-indol-3-yl butanoic acid		Australia
	Root promotion in plant cuttings	Hungary New Zealand
Indole-3-butanoic acid	Assists fruit set, is a root stimulant, hastens maturity, increases fruit set, size, yield, vegetative growth and sugar content, stimulates germination and is a fruit abscission retardant Controls fungal rot, decay and fungi	US
Gibberellic acid (GA)	Currant grape and Sultana grape for drying: bunch elongation, fruit thinning, fruit size increasing, fruit maturity promotion or delay; Navel orange: advance or delay maturity, storage quality; Malting barley: germination period reduction; Mandarin: fruit quality improvement	Australia
	Cherry: spur and fruit development; Rhubarb: breaking dormancy	Canada
	Fruit russet, general plant growth regulator	US
Gibberellic acid + Gibberellin A4/A7	Growth promotants for pipfruit, stonefruit, citrus	New Zealand
	General	US
Gibberellic acid + boronacid (chemical)	Wheat, barley, sugar beet: enhancement of germination	Hungary

Active ingredient	Registered uses (pest and/or crop)	Country
Gibberellic acid, monopotassium salt	General	US
Gibberellic acid + naphthoxy-acetic acid (chemical)	Cherry, sour cherry: fruit setting	Hungary
PURINES		
Benzyladenine (also called: N-6-Benzyladenine or 6-benzylaminopurine) (US: Cytokinin B)	Apple, pear: budding and shooting promotion	Hungary
	Bud breaking in cherries and fruit elongation in apples	New Zealand
	General	US
Benzyladenine + Gibberellins A4/A7	Enhancing fruit shape of Delicious apples	Canada
6-furfural(amino)purine; 1H-purin-6-amine; N-(2-furanylmethyl)-(9CI) (US: Cytokinin)	General	US
Purine related derivative (US: Keatine)		US
OTHERS		
1,4-dimethylnaphthalene	Sprout inhibitor	US
Aminoethoxy Vinyl Glycine (AVG - Streptomyces product)	Ornamental plants (apples)	US
Na-nitrophenolate; Na-nitroguajacolate	Tomato, pepper: yield enhancement	Hungary
Na-nitrophenolate; Na-nitroguajacolate; Na-naphthylacetate	Apple, plum: dropping inhibition	Hungary
5-nitroguaiacolate; ortho-nitrophenol; para-nitrophenol (US: Atonik)	Not specified	US

INSECT GROWTH REGULATORS REGISTERED
FOR PLANT PROTECTION USES

Active ingredient	Registered uses (pest and/or crop)	Country
Trimethyl-dodecadien-		
Isopropyl (2E,4E)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate (Methoprene)	fly control on mushrooms	Canada
2-propynyl(S-(E,E))-3,7,1-trimethyl-2,4-dodecadienate (US: S-kinoprene)	gnats, aphids (fungus)	US
2-propynyl(S-(E,E))-3,7,1-trimethyl-2,4-dodecadienoate (Kinoprene)	insect control for ornamental plants grown in greenhouses	Canada
		US
OTHERS		
1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl) urea (diflubenzuron, Dimilin)	Gypsy moth larvae on forest lands	Canada
Azadirachtin (Neem seed extract)		US
Tetraazadirachtin		US

INSECT GROWTH REGULATORS REGISTERED
FOR USES OTHER THAN PLANT PROTECTION

Active ingredient	Registered uses (pest and/or crop)	Country
Trimethyl-dodecadienoates		
Ethyl(2E,4E)-3,7,11-trimethyl-2,4-dodecadienoate (Hydroprene) (*) + S-ethyl(2E,4E)-3,7,11-trimethyl-2,4-dodecadienoate (S-hydroprene)	roaches	New Zealand US
2-propynyl(S-(E,E))-3,7,1-trimethyl-2,4-dodecadienoate (Kinoprene)		US
Isopropyl (2E,4E)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate (Methoprene) (*)	mosquito larvicide; insect control in stored tobacco	Canada
	flea control in houses, buildings	Canada New Zealand
Isopropyl (2E,4E)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate (Methoprene) (*) + Isopropyl (2E,4E, 7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate (S-Methoprene) (*)	dipteran larvae, fleas, mosquitoes	New Zealand US
OTHERS		
1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl) urea (diflubenzuron, Dimilin)	control of mosquito larvae	Canada
	insecticide in public health and professional pest control	Germany

(*) Not considered to be "biological pesticides" in New Zealand

MACRO-ORGANISMS REGISTERED FOR PLANT PROTECTION USES

Active ingredient	Registered uses (pest and/or crop)	Country
INSECTS		
<i>Aphelinus abdominalis</i>	Aphids (<i>Macrosiphum euphorbiae</i> , <i>Aulacothum solani</i>) on vegetables under glass	Austria, Sweden
	Greenhouse: aphids on potatoes, tomatoes, green pepper, aubergines	Switzerland
<i>Aphidius colemani</i>	Aphids (except <i>Macrosiphum</i> sp.), on vegetables under glass	Austria
	Aphids (<i>Macrosiphum euphorbiae</i> , <i>Aulacothum solani</i>)	Sweden
<i>Aphidius matricariae</i>	Aphids (except <i>Macrosiphum</i> sp.), on vegetables under glass	Austria
	Aphids on peach trees and melon	Switzerland
<i>Aphidoletes aphidimyza</i>	Aphids (<i>Macrosiphum euphorbiae</i> , <i>Aulacothum solani</i>) on vegetables (e.g. cucumbers, tomatoes, pepperonis, aubergines)	Austria, Sweden, Switzerland
<i>Chrysoperla carnea</i>	Sucking insects and spider mites on vegetables and ornamentals under glass; mealybugs on ornamentals under glass	Austria
<i>Cryptolaemus montrouzieri</i>	Mealy bug, scale insects (<i>Coccoidea</i>) on ornamentals	Austria, Sweden
	Pseudococines	Switzerland
<i>Dacnusa sibirica</i>	Borer; diptera	France, Switzerland
	Leafminers (<i>Liriomyza pusilla</i>)	Sweden
<i>Dacnusa</i> + <i>Diglyphus</i>	Borer	Switzerland
<i>Diglyphus isaea</i>	Borer; diptera	France, Switzerland
	Leafminers (<i>Agromyzidae</i> e.g. <i>Liriomyza pusilla</i> , <i>Phytomyza</i>) on vegetables under glass	Austria, Sweden
<i>Encarsia formosa</i>	White flies (<i>Trialeurodes vaporariorum</i> , <i>Bemisia tabaci</i>) on vegetables and ornamentals under glass	Austria, Sweden
	Tomato, treatment of aerial parts	France
	Vegetables, ornamentals under glass: <i>Trialeurodes vapor</i>	Hungary
		Switzerland
<i>Leptomastidea abnormis</i>	Mealybugs (<i>Planococcus citri</i>) on ornamentals under glass	Austria
<i>Leptomastix dactylopii</i>	Mealybugs (<i>Planococcus citri</i>) on ornamentals under glass and ornamentals	Austria
<i>Orius insidiosus</i>	California thrips, tobacco thrips on paprika	Switzerland

Active ingredient	Registered uses (pest and/or crop)	Country
<i>Orius laevigatus</i>	Thrips (<i>Trips tabaci</i> , <i>Franklinella occidentalis</i>)	Sweden
	California thrips, tobacco thrips on paprika	Switzerland
<i>Orius majusculus</i>	Thrips (<i>Trips tabaci</i> , <i>Franklinella occidentalis</i>) on vegetables and ornamentals under glass	Austria
	California thrips, tobacco thrips on paprika Acarid: <i>T. urticae</i>	Switzerland
<i>Trichogramma</i>	Maize, treatment of aerial parts,	France
<i>Trichogramma brassicae</i>	Maize	Switzerland
<i>Trichogramma maidis</i>		France
<i>Typhlodromus pyri</i> Scheuten (Mikulov)	Red spider mite on fruit and viticulture, acarinoses of vine, apple rust mite on fruit farming	Austria
NEMATODES		
<i>Heterorhabditis</i> spp.	Otiorynchus spec. (broad-nosed weevils)	Germany
	Larvae on strawberry plant, fruit tree, vine	Switzerland
<i>Heterorhabditis bacteriophora</i>	Weevil larvae on ornamental plants	New Zealand
<i>Steinernema</i> spp.	Scaria spec. (moth fly in greenhouses)	Germany
<i>Steinernema carpocapsae</i>	Otiorynchus spec. (broad-nosed weevils)	Germany
	insecticide on turf	Japan
	Weevils (<i>Othiorynchus sulcatus</i>)	Sweden
	Larvae on strawberry plant, fruit tree, vine	Switzerland
<i>Steinernema feltiae</i>	Fungus gnats (<i>Bradysia</i> spp) Weevils (<i>Othiorynchus sulcatus</i> , <i>Othio. singularis</i>)	Sweden
SPIDERS/MITES		
<i>Amblyseius cucumeris</i>	Thrips (<i>Trips tabaci</i> , <i>Franklinella occidentalis</i>) on vegetables and ornamentals under glass	Austria, Sweden
<i>Amblyseius cucumeris</i> + <i>Amblyseius barkeri</i>	Tobacco thrips, California thrips on cucumbers, tomatoes, pepperonis and aubergines under glass Onion thrips	Switzerland
<i>Amblyseius mackenziei</i>	Tobacco thrips, California thrips on cucumbers, tomatoes, pepperonis and aubergines (under glass)	Switzerland
<i>Hypoaspis miles</i>	Fungus gnats (<i>Bradysia</i> spp)	Sweden
<i>Phytoseiulus persimilis</i>	Vegetables, berries, ornamentals under glass: spinning mites (<i>Tetranychus urticae</i>)	Austria, France, Hungary, Sweden, Switzerland

PLANT EXTRACTS REGISTERED FOR PLANT PROTECTION USES

Active ingredient	Registered uses (pest and/or crop)	Country
Abamectin		Switzerland
<i>Artemisia vulgaris</i> + <i>Pastinaca sativa</i> + <i>Solidago gigantea</i>	orchid, vegetables, ornamentals: <i>Aphididae</i>	Hungary
Capsicum (pepper)	insect, dog, bird	US
Castor oil	attractant/repellant (moles, dogs, cats)	US
Cedar leaf oil	attractant/repellant (blowflies, screw-worm)	US
Cedar wood oil	attractant/repellant (fleas, moths)	US
Cinnamaldehyde + Indole + Benzenepropanol + 3-phenyl-2-propenol + 4-methoxybenzenethanol + 3-(4-methoxyphenyl)2-propenal + 1,2,4-trimethoxybenzene	Corn Rootworm	US
Cinnamon	roaches	US
Corn Rootworm Bait	diabroticine beetle	US
Eugenol	Japanese Beetle	US
Garlic extract	birds	US
Garlic oil/Pyrethrin extract	fruit tree, indoor plants, vegetables	Australia
Geraniol	Japanese beetle	US
Marigold extract (<i>calendula officinalis</i>)	insects	US
Methyl Anthranilate	birds	US
Nicotine		Switzerland
2-phenylethyl propionate	Japanese Beetle	US
Pyrethrins/pip. butoxide	vegetables, citrus, fruit tree, indoor plants, ornamental plants	Australia
Pyrethrin (*)	agriculture	Finland, Norway

Active ingredient	Registered uses (pest and/or crop)	Country
Pyrethrum	insect control on ornamentals, fruit growing, vegetables	Austria Canada
	insecticide	Germany
	foliar insecticide for aphids and caterpillars in horticulture	New Zealand
Quassia tree extract		Switzerland
Rape seed oil	ornamental plants; horticulture (against spider mites)	Germany
		Switzerland
Rotenone	<u>against:</u> aphid, cabbage moth, cabbage white butterfly, cutworm, European earwig, jassid or leafhopper, rutherghlen bug, thrip, vegetable weevil <u>on:</u> broccoli, Brussels sprout, cabbage, cauliflower, turnip	Australia
	fruit growing	Austria
	insect control on vegetable, berry and ornamental crops	Canada
	foliar insecticide for caterpillars in horticulture	New Zealand
		Switzerland
Urtica extract + farnezen	tomato, paprika, ornamentals: <i>Aphididae</i>	Hungary

PLANT EXTRACTS REGISTERED FOR USES OTHER THAN PLANT PROTECTION

Active ingredient	Registered uses (pest and/or crop)	Country
Cinnamon	Cockroach control (repellent)	US
Citronella oil (*)	Topical and candle insect repellent (for humans and horses); Dog and cat repellent	US
	Mosquito repellent	Finland
Cedarwood oil	Flea and moth repellent	US
Garlic extract	Bird and insect repellent	US
Geraniol	Dog and cat repellent	US
Grapefruit seed extract	House dust mite control	New Zealand
Nicotine (*)	Non-agriculture	Finland
Pyrethrin (*)	Personal insect repellent	Australia
	Against insects indoors	Finland
Pyrethrum	Control of many insects (e.g.: home and garden, commercial livestock and pet care products)	Canada
	Insect control	Hungary
	Public health and professional pest control under the Federal Epidemics Act	Germany
Rotenone	Insect control on livestock; control of unwanted fishes in lakes and rivers	Canada
Soybean lecithin	Public health and professional pest control under the Federal Epidemics Act	Germany

(*) Considered and handled as chemical pesticides in Finland

OTHER BIOPESTICIDES REGISTERED

Active ingredient	Registered uses (pest and/or crop)	Country
Diallyl disulfide + N-propyl disulfide	fungicide	US
Dried blood	rabbit, dog and deer repellent	US
Grapefruit seed extract	control of dust mites in carpets	New Zealand
Neem oil (free fatty acid, glycerides)	insects	US
Nicotine (*)	non-agriculture	Finland
Phosphoric acid	fungicide	US
Polyoxins B	grape, raspberry, strawberry: Botrytis cinerea	Hungary
Putrescent whole egg solids	deer and big game repellent	US
Repellent oil Daphne (*)	game repellent	Finland
Sodium carboxymethylcellulose	insects, mites	US
Soybean oil	miticide	US
Traps for insects	aphids, caterpillar	Switzerland

(*) Considered and handled as chemical pesticides in Finland

Annex 3

Individual Countries' Responses to Part 2 of the Questionnaire

Key to Abbreviations Used

- | | |
|----|--|
| A | <i>Always required</i> for registration of plant protection products. |
| F | <i>Frequently required:</i> These data are required in more than 80 per cent of registration submissions. |
| L | <i>Less frequently required:</i> These data are required in less than 80 per cent of registration submissions. |
| X | <i>Required at an unknown rate:</i> These data are required in an undetermined number of cases. |
| AI | <i>Active ingredient</i> |
| FM | <i>Formulation</i> |
| * | <i>Good Laboratory Practice</i> is required. |
| g | <i>Guidance</i> for the study is available. |
| c | <i>A comment</i> was provided in the country's questionnaire response. |

MATRIX 1. IDENTITY AND BIOLOGICAL PROPERTIES

TYPE OF DATA/INFORMATION		EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
GENERAL INFORMATION																	
Applicant (name, address, etc.)	AI	X	A	A	A	A			A		A _g	A		A			A
	FM	X	A	A	A	A	A	A _g	A	A	A _g	A	A	A	A _c	A _g	A
Manufacturer (name, address, facility location)	AI	X	A	A	A	A	A	A _g	A	A	A _g	A	A	A			A
	FM	X	A	A	A	A	A	A _g	A	A	A _g	A	A	A	A	A _g	A
ADDITIONAL DATA LISTED BY COUNTRIES																	
Way of production	AI			A	A		A				A						
	FM										A						
Name of product	AI																
	FM			A	A		A										
Purpose of submission	AI								A								
	FM				A				A								
Claims for use	AI																
	FM				A												
Draft label and/or use pattern	AI								A		A						
	FM				A						A						
Formulating plant	AI				A												
	FM				A						A _g						
Patent status and number	AI										A _c						
	FM										A _c						
Source of active ingredient	AI				A						A						
	FM			A							A				A		
IDENTITY OF MICRO-ORGANISM (both naturally occurring and genetically modified)																	
Scientific name	AI	X	A	A	A	A	A	A _g	A _c	A	A _g	A	A	A		A _g	A
	FM					A					A _g	A			A	A _g	

TYPE OF DATA/INFORMATION		EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
Common name	AI	X _c	A		A	A	A	A _g	A _c	A	A _g	A	A	A		A	A
	FM					A					A _g	A			F		
Synonyms	AI	X	A	A	L	A	A	A _g	A _c	A	A _g	A	A	A		A	A
	FM					A					A _g	A			L		
Subspecies	AI	X	A	A	A	A	A	A _g	A _c	A	A _g	A	A	A		A	A*
	FM					A					A _g				A		
Strain	AI	X _c	A	A	A	A	A	A _g	A _c	A	A _g	A	A	A		A	A*
	FM					A					A _g				A		
Serotype	AI		L	A _c	A	A	A	A _g	A _c	A	A _{og}	A	F	A		A	L*
	FM					A					A _{og}				F		
For genetically modified organisms only:																	
Information on the donor organism(s): scientific name, subspecies, strain, etc.	AI	X	A	A	A	A	c	X?c	c	A	A _g	c	A _c	X _c		A _c	A
	FM					A	c				A _g				A		
Information on the inserted genetic material	AI	X	A	A	A	A	c	X?	c	A	A _g	c	A	X _c		c	A*
	FM					A					A _g				A		
	AI	X _c	A	A	A	A	c	X?	c	A	A _g	c	A	X _c		c	A*
	FM					A					A _g				A		
	AI	X _c	A	A	A	A	c	X?	c	A	A _g	c	A	X _c		A	A*
	FM					A					A _g				A		
	AI	X _c	A	A	A	A	c	X?	c	A	A _g	c	A	X _c		A	A*
	FM					A					A _g				A		
Information on the vector(s)	AI	X	A	A	A	A	c	X?	c	A	A _g	c	A	X _c		A	A*
	FM					A					A _g				A		
	AI	X _c	A	A	A	A	c	X?	c	A	A _g	c	A	X _c		A	A*
	FM					A					A _g				A		

TYPE OF DATA/INFORMATION			EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
Information on the host	Name	AI	X	A	A	A	A	c	X?	c	A	A _g	c	A	X _c		A	A*
		FM				A	A					A _g		A		A		
	Taxonomic position	AI	X	A	A	A	A	c	X?		A	A _g	c	A	X _c		A	A*
		FM				A	A					A _g		A		A		
Information on the genetically modified organism itself	Modification technique	AI	X	A	A	A	A	c	X?	c	A	A _g	c	A	X _c			A*
		FM				A	A					A _g				A		
	Site of new genetic material	AI		A	A	A	A	c	X?	c	A	A _g	c	A				A*
		FM					A					A _g				A		
ADDITIONAL DATA LISTED BY COUNTRIES																		
Collection and culture reference number where the culture is deposited		AI	X		A							L						
		FM										L						
	Test procedures and criteria for identification (e.g. morphology, biochemistry, serology)	AI	X		A							A						
		FM										A						
What kind of genetic modification has been made? Has any genetic material been removed or added, etc.?		AI			A							A					A	
		FM										A						
BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM																		
For naturally occurring organisms only:																		
History of the organism and its uses		AI	X	A	A _c	A	A		A		A	A _g	A	A	A		A	A _c
		FM				A						A _g	A			A		
Relationships to known plant or mammalian pathogens		AI	X _c	A	A _c	A	F		A		A	A _g	A	A	A		A	A*
		FM				A						A _g		A		F		
Natural occurrence and geographic distribution of the organism		AI	X	A	A _c	F	A	A	A		A	A _g	A	A	A		A	A*
		FM				F						A _g				A		
Information on biological properties and host specificity range		AI	X	A	A _c	F	A	A	A		A	A _{agg}	A	A	A		A _g	A*
		FM				F						A _{agg}				A	A _g	
Genetic stability and factors affecting it		AI	X _c	L	A _c	F	A	A	A		A	F _g	L	A	A		A	A _c
		FM				F						F _g	L			F		

TYPE OF DATA/INFORMATION			EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
General information on survivability, physical stability	AI		X _c	A	A	A	A		A	A	A	F _g	A	A	A		A	
	FM				A							F _g	A	A		A		
ADDITIONAL DATA LISTED BY COUNTRIES																		
Effects on non-target species	AI		X _c		A							A						
	FM											A						
Presence, absence or production of toxins (nature, identity, chemical structure (if appropriate) and stability)	AI		X	A			A					A					A	
	FM																	
Identification test for micro-organism	AI				A		A											
	FM																	
Selection and mutation; state if the active organism was selected or was mutated	AI																A	
	FM																	
Methods to prevent the active organism from losing its ability to eliminate the target organism	AI																A	
	FM																	
Description of the life cycle of the active organism	AI				A												A	
	FM																	
Competitors and natural enemies of the active organism	AI																A	
	FM																	
Extent to which vector or modified genes may be transferred among or incorporated by other organisms	AI																A	
	FM																	
For genetically modified organisms only.																		
History and uses of the parent organism(s) including both donor and host	AI		X	c	A	c	A	c	X _c	c	A	A _g	c	A	X _c		c	A _c
	FM						A									A		
Relationship of the parent organism(s) to any plant pathogens or to pathogens of vertebrate species	AI		X	c	A	c	A	c	X _c	c	A	A _g	c	A	X _c		c	A [*]
	FM						A									F		
Natural occurrence and geographic distribution of the parent organism(s)	AI		X	c	A	c	A	c	X _c	c	A	A _g	c	A	X _c		c	A [*]
	FM						A									A		
Pathogenicity	AI		X	c		c	A	c	X _c	c	A	A _g	c	A	X _c		c	A [*]
	FM						A									A		
Properties of parent organism(s)	AI		X	c		c	A	c	X _c	c	A		c	A	X _c		c	A [*]
	FM						A									A		
Toxicity, including allergenicity	AI		X	c		c	A	c	X _c	c	A		c	A	X _c		c	A [*]
	FM						A									A		
Information on biological properties and host specificity range of the parent organism(s)	AI		X	c		c		c	X _c	c	A	A _g	c	A	X _c		c	A [*]
	FM															A		

TYPE OF DATA/INFORMATION		EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
Genetic stability of the parent organism(s) and factors affecting it	AI	X	c	L	c	A	c	X?		A			A	X _c		A	
	FM					A									A		
	AI	X	c		c	A	c	X?		A	F _g		A	X _c			
	FM					A							A		A		
ADDITIONAL DATA LISTED BY COUNTRIES																	
Potential of modified organism to transfer genetic material to other organisms	AI			A				X?								A	A*
	FM																
Relative environmental competitiveness of modified organism	AI			L												A	A*
	FM																
PURITY																	
Microbiological purity	AI	X _c	A	A	A _c	A	A	A _g	A	A	A _g	A	A	A	A	A _g	A*
	FM		A	A _g	A _c			A _g	A		A _g	A	A	A	A	A _g	A*
	AI	X _c	A		A _c	A	A	A _g	A	A	A _g	A	A	A		A _g	A*
	FM		A		A _c						A _g	A	A	A	A	A _g	A*
IDENTITY OF FORMULATION																	
Trade name and manufacturer's development code number	AI				A				A _c								
	FM	L _c	A	A	A	A	A	A	A _c	A	A _g	A	A	A	A	A _g	A*
	AI				A				A _c				A				
	FM	X	A	A	A	A	A	A	A _c	A	A	A	A	A	A	A _g	A*
Identity of toxic by-products, allergens, or other impurities produced by the micro-organism or in the incubation or manufacturing process; information on the nature and properties of such impurities	AI				A				A _c				A			A _g	
	FM	X _c	A		A	A		A	A _c	A	A _g	A	A	A	A	A _g	A*
Nature of the product (e.g. emulsifiable concentrate, wettable powder, etc.)	AI																
	FM	X	A	A	A	A	A	A	A _c	A	A _g	A	A	A	A	A _g	A

TYPE OF DATA/INFORMATION		EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
ADDITIONAL DATA LISTED BY COUNTRIES																	
Specific gravity/density	AI																
	FM										A _g						
Rheological properties (suspendability, wettability, etc.)	AI				A												
	FM				A						A _g						
Identity and purpose of non-active ingredients	AI																
	FM				A										A _c		
Relevant phase of development of active organism when the product is sold (e.g. spores)	AI																
	FM															A	

MATRIX 2. FUNCTION, MODE OF ACTION AND HANDLING

TYPE OF DATA/INFORMATION		EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
Function (e.g. fungicide, herbicide, insecticide, repellent, growth regulator, anti-viral agent)	AI	X		A		A		A		A	A _g		A	A		A _{cg}	A
	FM	X	A	A	A	A	A	A		A	A _g	A	A	A	A	A _c	A
Mode of action to target pest, infective dose, transmissibility	AI	X _c		A	F	A	A	A		A	A _{cg}		A	A		A _c	A
	FM		A	A				A		A	A _{cg}	A		A	A		A
Field of use (e.g. field, glasshouse, food crop)	AI	X				A			A _{cg}		A _g						A
	FM	X	A	A	A	A	A	A	A _{cg}	A	A _g	A	A	A	A	A _{cg}	A
Details of intended use (e.g. target organism and plants or plant products to be protected)	AI	X				A			A _g		A _g						A
	FM	X	A	A	A	A	A	A	A _g	A	A _g	A	A	A	A	A _{cg}	A
Application rate	AI							A	A _{cg}	A	A _g						A
	FM	X	A	A	A	A	A	A	A _{cg}	A	A _g	A	A	A	A	A _{cg}	A
Conditions under which the substance may not be used (agricultural, plant health or environmental)	AI	X						c	A _{cg}		A _g						
	FM	X	A		A		A		A _{cg}	A	A _g	A	A	A	A	A _{cg}	
Method of application	AI								A _{cg}		A _g						A
	FM	X	A	A	A	A	A	A	A _{cg}	A	A _g	A	A	A	A	A _{cg}	A
Number and timing of applications	AI								A _{cg}		A _g						A
	FM	X	A	A	A	A	A	A	A _{cg}	A	A _g	A	A	A	A	A _{cg}	A
Proposed instructions for use	AI								A _g		A _g						A
	FM	X	A	A	A	A	A	A	A _g	A	A _g	A	A	A	A	A _{cg}	A
Re-entry intervals	AI										A _g						A
	FM	X	A		A	A	A	L	F _c	A	A _g	L _c	A	A			A
Pre-harvest intervals (waiting period between last treatment and harvest or consumption)	AI										A _g					A _{cg}	A
	FM	X	A		A	A	A	L	F _{cg}	A	A _g	A _c	A	A	A _c		A
Type of packaging	AI								A _{cg}		A _g						A
	FM	X _c	A		A	A	A	A	A _g	A	A _g	A	A	A	A	A _{cg}	A
Procedures for cleaning application equipment	AI										A _g						
	FM	X	A		L	A	A	L	F _{cg}	A	A _g	L _c	A	A		A _{cg}	

TYPE OF DATA/INFORMATION		EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
Procedures for destruction or decontamination of the product and its packaging	AI								F _{cg}		A _g						
	FM	X	A	A	A	A	A	L	F _g	A	A _g	A	A	A	F	A _{cg}	
	AI	X				A			A _{cg}		A _g						
	FM	X _c	A	A	A	A	A	L	A _g	A	A _g	A	A	A	F	A _{cg}	
Emergency measures in case of an accident	AI								A _{cg}		A _g						
	FM	X	A	A	L	A	A	L	A _g	A	A _g	A	A	A	F	A _{cg}	
Methods to prevent loss of viability of seed stock	AI	X	A				F	A _g	L	A	A _{cg}	A _c					
	FM							A _g	L	A		A _c	A	A		A _{cg}	
ADDITIONAL DATA LISTED BY COUNTRIES																	
Possibility of rendering the organisms uninfected or non-infected	AI	X				L											
	FM																
Methods to prevent loss of virulence	AI					L											
	FM																
Selectivity of action	AI						A										
	FM																
End-use product: stability, maintenance of purity and potency	AI																
	FM			A							A _{cg}						
Withholding or storage periods in the case of post-harvest use (could substitute for pre-harvest intervals)	AI																
	FM	X															

MATRIX 3. PHYSICAL-CHEMICAL PROPERTIES

TYPE OF DATA/INFORMATION		EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
Appearance	AI				A			A _g *	A	A	A _g	A _c		A			
	FM	X	A	A	A	A _c *		A _g *		A	A _g	A _c	A _c	A	L	A _g	
Physical state	AI				A			A _g *	A	A	A _g	A		A			A*
	FM	X	A	A	A	A*		A _g *		A	A _g	A	A _c	A	L	A _g	A*
Density	AI				L			F _g *	A		A _g		L _c	A			A*
	FM				A	A*		F _g *	A	A	A _g	(F)	L _c	A	L	A _g	A*
pH	AI							F _g *	F				L _c	A			A*
	FM				A			F _g *	L	A		A	L _c	A	L	A _g	A*
Stability when used according to proposed method (e.g effects of sunlight, water, changes in pH and temperature)	AI	X			F		A	A _g *		A		A	L _c	A			A*
	FM		A			A*		A _g *	F	A		A	A _c	A	F		
Storage stability	AI									A	A _g	A	L _c	A			A*
	FM	X _c	A	A	A	A*	A	A _g *	A	A	A _g	A	A _c	A	A	A _g	A*
Suspendability and suspension stability	AI								L								
	FM		A		A	F*		F _g *	L	A		F	A _c	A	L	A _g	
Size distribution of the organism	AI							A _g *				F		A			
	FM		A		F	L*		A _g *		F		F	L _c	A	L		
Content of active ingredient in or on bait particles, granules or treated seed	AI							F _g *			A _g	A					A _c
	FM		A	A	L	L*		F _g *	L	A	A _g		L _c	A	A	A _g	A _c
Flowability, pourability, dustability	AI							F _g *			A _g			L			
	FM		L		A	F*		F _g *	L	F	A _g	A	A _c	A	L	A _g	
ADDITIONAL DATA LISTED BY COUNTRIES																	
Methods for establishing storage and shelf-life stability	AI																
	FM	X			A												
Technical characteristics of the preparation	AI																
	FM	X _c			A												
Physical and chemical compatibility with other products including plant protection products whose use is to be authorised	AI																
	FM	X			A												

TYPE OF DATA/INFORMATION		EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
Wetting, adherence and distribution to target plants	AI																
	FM	X			A												
Compatability with other products	AI																
	FM				A	A*											
Sample for analysis	AI						A										
	FM				A		A										
Miscibility	AI																
	FM										A _g						A*
Odour	AI										A _g						
	FM										A _g						
Corrosive character	AI										A _g						
	FM										A _g						A*
Colour	AI																
	FM															A _g	
Formation of aerosols	AI																
	FM															A	
Viscosity	AI																
	FM				A												A*

MATRIX 4. MANUFACTURING, QUALITY CONTROL AND ANALYTICAL METHODS

TYPE OF DATA/INFORMATION		EC	DEN	FR	GER	ITA	NL	UK	AU	CAN	FIN	HUN	NOR	NZ	SWE	US
Method of production: description of techniques used to ensure a uniform product and assay methods for standardization	AI	X _c		A _g	L	A*	A	A _g *	A	A _{og}	A	A _c	A		A _g	A _c
	FM	X	A	A _g		A*		A _g *	A	A _{og}	A	F _c	A	A	A _g	A _c
Methods to establish the identity and purity of seed stock from which batches are produced and results obtained, including information on variability	AI	X		A _g	F	F*	A	A _g *	F	A _{og}	A	A _c	A		A _g	A*
	FM		A	A _g					F	A _{og}	A		A	F	A _g	A*
Methods to show microbiological purity, including variability and levels of contaminants	AI	X		A _g	A	A*	A	A _g *	F	A _{og}	A	A _c	A		A _g	A*
	FM	X	A	A _g	F	A*		A _g *	A	A _{og}	A	A _c	A	A	A _g	A*
Methods to show there are no known human or other mammalian pathogens as contaminants	AI	X _c		A _g	A	A*	A	A _g *	A _c	A _{og}	A	A _c	A		c	A*
	FM	X _c	A	A _g		A*		A _g *	A	A _{og}	A	A _c	A	F	c	A*
Methods to detect and quantify residues in or on treated plants, products, food, feed, animal and human body fluids and tissues, soil, water and air	AI	X				A*	A	A _g *		A _{og}	A				A _c	L _c *
	FM	X _c	A		A	A*	A		F	A _{og}	A	A _c	A	F _c		
	AI	X				A*	A	A _g *		A _{og}	A				A _c	L _c *
	FM	X _c	A		A	A*	A		F	A _{og}	A	A _c	A	F _c		
	AI	X				A*	A	A _g *		A _{og}	A				A _c	L _c *
	FM	X _c	A		A	A*	A		L	A _{og}	A	A _c	A	F		
Methods to detect the organism in the environment	AI				A	A _c		A _g *		L _{cog}	A				A	
	FM		A							L _{cog}	A	A _c	A	F		
Methods for determining the composition of the formulation	AI															
	FM	X	A		A	A*	A	A _g *	L	A _{cog}	A	A _c		F		A*
For genetically modified organisms: methods to detect the inserted genetic material	AI	X			A	A*		X?		F _c			X _c		A	
	FM					A*		X?		F _c		A _c		A		

MATRIX 5. RESIDUES

TYPE OF DATA/INFORMATION		EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US	
GENERAL																		
	Likelihood of multiplication or persistence of the active substance in/on crops or food	MO	A		A	A	A	A _g	F _c	A	A _{cg}	A	A	A	A	F _c	A	A
		MT		A		A	A	A	A _g	F _c	A	A _{cg}	A	A	A	F _c	A	A
NATURE OF THE MATERIAL...																		
In/on treated plants or products	MO	X _c			A	A	A	A _g	F	A	A _c	A	A	A	F _c	A	L*	
	MT	X _c			A	A	A	A _g	F	A	A _c	A	A	A	F _c	A	L*	
	MO				F _c	F		A _g	F	A	A _c	A	A	L	F _c	A	L*	
	MT				F _c	F		A _g	F	A	A _c	A	A	A	F _c	A	L*	
PRESENCE & MAGNITUDE OF THE MATERIAL IN...																		
Food crops	MO		A		F	A	A	A _g	F	A	A _c	A	A	A	F _c	A	L*	
	MT		A		F	A	A	A _g	F	A	A _c	A	A	A	F _c	A	L*	
Meat, dairy products, poultry, eggs	MO		A		F _c	F		A _g	F	A	A _c	A	L	L	F	A	L*	
	MT	L _c	A		F _c	F		A _g	F	A	A _c	A	A	L	F	A	L*	
Processed food/feed	MO		A		L			A _g	F	F	A _c	L _c	L		F	A	L*	
	MT	L _c	A		L			A _g	F	F	A _c	L _c	A		F	A	L*	
Potable water	MO		A		A			A _g	F _c	F			A	L	F	A	L*	
	MT		A		A			A _g	F _c	F			A	L	F	A	L*	
Fish	MO		A		L		L	L _g	F _c	F			L		F	A	L*	
	MT		A		L		L	L _g	F _c	F			A		F	A	L*	
ADDITIONAL COUNTRIES LISTED BY COUNTRIES																		
Birds and rats	MO									F								
	MT									F								
OTHER REQUIREMENTS																		
Effects of processing or cooking on residues	MO		F/L		L	L		A _g	L	L	A _{cg}	L	L			A	L*	
	MT		F/L		L	L		A _g	L	F	A _{cg}	L	A			A	L*	
Proposed maximum residue levels	MO		A			A	A _c	A _g	A	A	A _{cg}	(A)F _c	F	F _c		A	L*	
	MT	X _c	A		L	A	A _c	A _g	A	A	A _{cg}	(A)F _c	F	F _c	A _c	A	L*	

TYPE OF DATA/INFORMATION		EC	DEN	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
Summary and evaluation of residue behaviour	MO	X	A	A	A		A _{cg}	F	A	A _{cg}	A	A	F	F	A _c	L*
	MT	X	A	A	A		A _g	F	A	A _{cg}	A	A	F	F	A _c	L*
ADDITIONAL DATA LISTED BY COUNTRIES																
Effects on colour, smell, taste and other quality aspects	MO															
	MT	X(L)													A	
Residue data in succeeding or rotational crops	MO														A	
	MT	X													A	
Residues in animals that come in contact with treated crop material	MO														A	
	MT														A	
Freezer stability (storage before analysis)	MO									A _{cg}						
	MT									A _{cg}						
Metabolism	MO									L _c						
	MT									L _c						

MATRIX 6. EFFICACY

TYPE OF DATA/INFORMATION		EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
Preliminary range-finding tests	AI									A							
	FM	X	A	A	A	A	F		L	A	F _{cg}	A	A _{cg}	F	L	A _y	A*
Field tests	AI																
	FM	X	A		A	A	A	A _{cg}	A	A	A _{cg}	A	A _{cg}	A _c	A	A _y	A*
Dose/efficacy relationships	AI										F _{cg}						
	FM		A	A	L			A _c	A	A	F _{cg}	A	A _c	A	F	A _y	A*
Use in integrated pest management systems	AI																
	FM			F			A	F _c	F	A	F _{cg}	A	A _c	F	F	A _y	
Information on the possible development of resistance and appropriate management strategies	AI							A _c					A _c				
	FM	X _c	A	L		A		A _c	F	A	L _{cg}	A		A	L	A _y	
Effects on quality and yield of treated plants	AI																
	FM	X	A	A	L	A	A	A _c	F	L	A _{cg}	A	F _c	A	A	A _y	A*
Effects on quality of treated plant products	AI																
	FM	X	A	A	A	A	A	F _c	L	L	A _{cg}	A	A _c	A	A	A _y	A*
Phytotoxicity to target plants	AI												L _c				
	FM	X _c	A	F	L	A	A	A _c	A	A	A _{cg}	A	A _c	A	A	A _y	
Phytotoxicity to rotational crops	AI												L _c				
	FM		A	F		F	L	F _c	L	A	A _{cg}	A	A _c	F	F	A _y	
Observations of undesirable or unintended side effects	AI												L _c				
	FM	X	A			A	A	A _c	A	A	A _{cg}	A	A _c	F	A	A _c	A*
ADDITIONAL DATA LISTED BY COUNTRIES																	
Summary and evaluation	AI																
	FM	X															
Methods, timing and equipment for application	AI																
	FM										A _y						
Value assessment	AI																
	FM										A _{cg}						
State elements which could affect efficacy, such as other pesticides, resistance formation, and climate conditions	AI																
	FM															A	
Phytopathogenicity	AI																
	FM	X															

MATRIX 7. TOXICOLOGY, PATHOGENICITY AND INFECTIVITY

TYPE OF DATA/INFORMATION		EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
ACUTE TOXICITY TESTING																	
Oral	AI	X _c	A _g [*]	A _g	A [*]	A [*]	A _g [*]	F _g [*]	A	A	A _{cg} [*]	A _c	A _g	A [*]	A _c [*]	A _g	
	FM	X _c	A _g [*]	A	A [*]	A [*]	L _g [*]	F _g [*]	A	A	A _{cg} [*]	A _c	A _g	A [*]		A _g	A [*]
Dermal	AI	X _c		A _g	F [*]	A [*]	L _g [*]	F _g [*]	A	A	A _{cg} [*]	A _c	A _g	A [*]			
	FM	X _c	A _g [*]	F	F [*]	A [*]	L _g [*]	F _g [*]	A	A	A _{cg} [*]	A _c	A _g	A [*]	A _c [*]	A _g	A [*]
Inhalation	AI	X _c	A _g [*]	A _g	F [*]	A [*]		L _g [*]	A	A	A _{cg} [*]	A _c	L _g	A [*]	A _c [*]	A _g	
	FM	X _c	A _g [*]	F	F [*]	A [*]	F _g [*]	L _g [*]	A	A	A _{cg} [*]	A _c		A [*]		A _g	A [*]
Eye irritation	AI	L	L _g [*]	A _g	A [*]	A [*]	F _{cg} [*]	L _g [*]	A	A		A _c	F _g	A [*]		(A) _c	
	FM	L	A _g [*]	F	A [*]	A [*]	F _{cg} [*]	F _g [*]	A	A	A _{cg} [*]	A _c	A _g	A [*]	A _c [*]	A _c	A [*]
Skin irritation	AI	X	L _g [*]	A _g	A [*]	A [*]	A _{cg} [*]	L _g [*]	A	A		A _c	F _g	A [*]		(A) _c	
	FM	X	A _g [*]	F	A [*]	A [*]	A _{cg} [*]	F _g [*]	A	A	A _{cg} [*]	A _c	A _g	A [*]		A _c	A [*]
Skin sensitization	AI	X	L _g [*]	A _g	A [*]	A [*]	A _g [*]	L _g [*]		A		A _c	F _g	A [*]		A _c	
	FM	X	A _g [*]	F	A [*]	A [*]		F _g [*]	A _c	A	A _{cg} [*]	A _c	A _g	A [*]	A _c [*]	A _c	A [*]
Intraperitoneal or intravenous	AI	X _c	A _{cg} [*]	A _g	L [*]	A [*]	A _g [*]	L _g [*]	C		A _{cg} [*]	A _c	L _g	F [*]	A _c [*]	A _c	
	FM			F				L _g [*]				A _c	L _g			A _c	
ADDITIONAL DATA LISTED BY COUNTRIES																	
Range finding test for cases where a single dose is not appropriate to assess pathogenicity	AI	X		L													
	FM																
Available toxicological data relating to non-active substances	AI															X	
	FM	X		F												X	
Intracerebral tests for neurotropic agents	AI								C		A _{cg} [*]						
	FM								C								
State any additional studies performed	AI			L												X	
	FM															X	
Tissue culture; applies mainly to virus	AI			A												X	
	FM															X	

TYPE OF DATA/INFORMATION		EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
Summary	AI															X	
	FM															X	
REPEATED DOSE TOXICITY, PATHOGENICITY AND INFECTIVITY (studies less than one month)																	
Oral	AI		F/L _g		A _c		L _{cg} [*]	F _g [*]	C	L	L _{cg} [*]	C			L _c [*]		A [*]
	FM				L _c		F _{cg} [*]	L _g [*]	C			C					
Dermal	AI				L _c		L _{cg} [*]	L _g [*]	C	L		C			L _c [*]		A [*]
	FM				L _c		F _{cg} [*]	L _g [*]	C			C					
Inhalation	AI		F/L _g [*]		L _c			L _g [*]	C	L		C			L _c [*]		A [*]
	FM				L _c		F _g [*]	L _g [*]	C			C					
Intraperitoneal	AI							L _g [*]	C			C					A [*]
Intravenous	AI							L _g [*]	C			C					
	FM							L _g [*]	C	L		C					A [*]
ADDITIONAL DATA LISTED BY COUNTRIES																	
Pathogenicity	AI				A [*]			F _g [*]	C	A		A			L _c [*]		
	FM				L [*]			L _g [*]	C			A					
Infectivity	AI		F/L _g [*]		A [*]		A	F _g [*]	C	A		A			F _c		
	FM				L [*]			L _g [*]	C			A					
SUBCHRONIC TOXICITY (studies longer than one month)																	
Oral	AI	X _c	F/L	F	A _c [*]	A [*]		F _g [*]	L _c	A	L _{cg}	L _c	A _g	F _c [*]	L _c [*]	X _c	L _c [*]
	FM						L				L _{cg}	C	A _g				
Dermal	AI	X _c			L _c [*]	A [*]		L _g [*]	L _c	L	L _{cg}	C	A _g			X _c	L _c [*]
	FM						L	L _g [*]			L _{cg}	C	A _g				
Inhalation	AI	X _c	F/L		L _c [*]	A [*]		L _g [*]	L _c	L	L _g	C				X _c	L _c [*]
	FM						L	L _g [*]			L _g	C					
GENETIC TOXICITY																	
Gene mutation	AI	X	A	F	F [*]	A [*]	L _c	L _g [*]	A _c	A _c	F _{cg}	F _c	A _g	A [*]	A _c [*]	X _c	
	FM							L _g [*]				F _c					
Chromosomal aberrations/cytotoxicity	AI	X	A	F	F [*]	A [*]	L _c	L _g [*]	A _c	A _c	F _{cg}	C	A _g	A [*]		X _c	
	FM							L _g [*]				C					

TYPE OF DATA/INFORMATION		EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
DNA alterations/genetic damage	AI	X	F/L	F	F*	A*	L _c	L _g *	A _c			c	A _g	F/L		X _c	
	FM							L _g *				c					
ADDITIONAL STUDIES																	
Oncogenicity	AI		L _g *		L _c *		L _{cg} *	L _g *	F			c	A _g			A	L _c *
	FM						L _{cg} *					c					
Long-term toxicity (≥ six months)	AI	X _c	L _g *		L _c *	A*		L _g *	F			c	A _g		L _c *	A	
	FM						L _c					c					
Developmental toxicity	AI	X _c	L _g *		L _c *		L _{cg} *	L _g *	F			c	A _g		L _c *	c	
	FM						L _{cg} *					c					
Fertility/reproduction	AI		L _g *		L _c *	A*	L _{cg} *	L _g *	F			c	A _g		L _c *	A	L _c *
	FM						L _{cg} *					c					
Dermal penetration/percutaneous absorption	AI				L _c *		L _{cg} *	L _g *		L		L	L _g				
	FM	X				A*	L	L*				L					
Immunotoxicity	AI	X			F*	A*	L _{cg} *	L*	F			F	L _g			A	L _c
	FM						L _{cg} *					F					
Allergenicity	AI	X	L _g *		F*	A*	L _c *	L*	F			A	L _g		A _c *	A	
	FM		A _g				L _c *					A					
Primate infectivity	AI					A*		L*		L		A					
	FM						L					A					
Cell or tissue culture (viruses only)	AI	X _c	A _g *		F _c *	A*	A _c *	L*		F	A				A _c *	A	L*
	FM						L _c *										
Hypersensitivity – laboratory tests	AI			L	F _c *			L*		F		A					
	FM		A _{cg} *				L				A _c	A					
Estimates of occupational exposure	AI				F*			L*	A _c	A		F				A	
	FM	X	A _g *				L	L*	A _c		A	F	F _g				
ADDITIONAL DATA LISTED BY COUNTRIES																	
Metabolic studies – absorption, distribution and excretion in mammals including elucidation of metabolic pathways	AI	X			X												
	FM																
Neurotoxicity studies including where appropriate delayed neurotoxicity testing in adult hens	AI	X			L _c *											X	
	FM																

TYPE OF DATA/INFORMATION		EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
Pathogenicity and infectivity under immunosuppression	AI	X			X											X	
	FM																
	AI															X	
	FM																
MEDICAL DATA																	
Applicator exposure	AI	X _c	A	L	F	A	A _c	F	F _c	A	A [*]	F	A			A _g	
	FM				F	A	A _c	F	F _c	A	A [*]	F		F	L	A _g	
Hypersensitivity/allergenicity incidents	AI	L _c	A	L	F _c	L	A _c	F	F _c	A	A [*]	A	A			A _g	A
	FM				F _c		A _c	F	F _c	A	A [*]	A		F	L	A _g	
Health records from industry, agriculture	AI	X _c	A	L	A _c	F	A _c	F	F _c	A	A [*]	L	A			A _g	
	FM				A _c		A _c	F	F _c	A	A [*]	L	A	F	L	A _g	
First aid treatments	AI	L _c	A	L	L	A	A	F	A		A _{cg}	A				A _g	
	FM				L		A	F	A		A _{cg}		A _g	A	L		
ADDITIONAL DATA LISTED BY COUNTRIES																	
Observations on exposure of the general population and epidemiological data, if appropriate	AI	X							F _c								
	FM								F _c								
Diagnosis of poisoning, specific signs of poisoning, chemical tests, if appropriate	AI	X				A											
	FM																
Prognosis of expected effects of poisoning, if appropriate	AI	X															
	FM																
Viruses: toxic effects on livestock and pets	AI	X			X												
	FM																
Operator protection	AI																
	FM																
Summary and evaluation of mammalian toxicology and conclusions	AI	X							A _c							X	
	FM								A _c								
TESTING OF MICROBIAL TOXINS																	
Do you require separate data/information on microbial toxins?	YES		X _c		X _c		X	X _c	X	X	X _c	X _c		X	X	X _c	
	NO	X				X	X						X				X
Are data requirements similar to those for conventional chemical pesticides	YES	X			X _c	X	X	X _c	X _c	X			X	X	X _c	X	
	NO		X						X _c		X						

MATRIX 8. ECOTOXICOLOGY

TYPE OF DATA/INFORMATION		EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
ACUTE TOXICITY, PATHOGENICITY, INFECTIVITY																	
Bird oral – species 1	AI	X	F _{cg} [*]	A	A _c [*]	A _c [*]	F _{cg} [*]	F _{cg} [*]	F _c	F		A _c		L	C	A _c	A [*]
	FM		cg [*]		L _c [*]	A _c [*]	L _{cg} [*]			A	A/F _c	A _c	A _{cg}		C		
Bird oral – species 2	AI		L _c [*]		L _c [*]	F _c [*]	F _{cg} [*]	F _{cg} [*]	F _c	F				L	C		A [*]
	FM		c [*]		L _c [*]	F _c [*]	L _{cg} [*]			A	A/F _c		A _{cg}		C		
Wild mammal	AI		L _c		A _c [*]				L _c	F				L	C		L [*]
	FM		C		L [*]					A	C		L _{cg}		C		
Honey bee	AI	X	F _c	A		A _c [*]	F _{cg} [*]	F _{cg}	F _c	F		A _c		L	C	A	A [*]
	FM	L	C		A _c [*]	A _c [*]	L _{cg} [*]			A	F _c	A _c	F _{cg}		C		
Other beneficial insects	AI		C	F		F _c [*]	F _{cg} [*]	F _{cg} [*]	L _c	F		F _c		L	C	A	A [*]
	FM	X	C		A _c [*]	F _c [*]	L _{cg} [*]	L _{cg} [*]		A	F _c	F _c	L _{cg}		C		
Earthworm	AI	X	C	F		A _c [*]	L _{cg} [*]	F _{cg} [*]	F _c	F		A _c		L	C		
	FM	X	C		F _c [*]	A _c [*]	L _{cg} [*]			A	L _c	A _c	L _{cg}		C		
Other soil fauna	AI		C			L [*]		L _{cg} [*]	L _c	F				L	C		
	FM	X	C			L [*]				A	L _c				C		
Other non-target organisms believed to be at risk	AI	X	C			L [*]		L _c [*]	L _c	F		L _c			C	A _c	L [*]
	FM	X	C			L [*]				A	A _c	L _c			C		
Extent of indirect contamination of adjacent non-target crops, wild plants, soil and water	AI	X	C	L			F [*]	L _c [*]	L _c	F		L _c			C	A _c	
	FM		C					L _c [*]		A		L _c			C		
Freshwater fish – species 1	AI	X _c	F _c	A	L [*]	A _c [*]	F _{cg} [*]	F _{cg} [*]	F _c	F		A _c		L		A _c	A
	FM	X _c	C		F _c [*]	A _c [*]	L _{cg} [*]	F _{cg} [*]		A	A _c	A _c					
Freshwater fish – species 2	AI		L		L [*]	F _c [*]	F _{cg} [*]	L _{cg} [*]	F _c	F				L			A
	FM		C		F _c [*]	F _c [*]	L _{cg} [*]	L _{cg} [*]		A	A _c						
Freshwater invertebrate	AI	X	F _c	A		A _c [*]	F _{cg} [*]	F _{cg} [*]	F _c	F		A _c		L		A _c	A
	FM	X	C		A _c [*]	A _c [*]	L _{cg} [*]	F _{cg} [*]		A	F _c	A _c					
Estuarine and marine animal	AI		L	L				L _{cg} [*]	L _c					L			L [*]
	FM		C					L _{cg} [*]			C						
Effects on algal growth	AI	X	L _c	L		A [*]	F _{cg} [*]	L _{cg} [*]	L _c	F		A _c		L		A _c	L [*]
	FM	X	C		L [*]		L _{cg} [*]			A	F _c	A _c					

TYPE OF DATA/INFORMATION		EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
ADDITIONAL DATA LISTED BY COUNTRIES																	
Important parasites and predators of target species; acute toxicity and/or pathogenicity and infectivity	AI	X		A	X _c												
	FM				X _c						F _c						
Summary and evaluation	AI	X			X _c												
	FM	X			X _c												
Non-target plants	AI																L*
	FM										F _c						
LONG-TERM STUDIES																	
Avian chronic reproduction	AI	X _c	C		L _c	A*		L _{cg} *	L	L				C	C	C	L*
	FM		C							L			L _{cg}	C	C	C	
Aquatic invertebrate range testing	AI		C			A*		F _{cg} *	L					C	C	C	L*
	FM		C		F									C	C	C	
Fish life cycle	AI		C		L*	A*		L _{cg} *	L	L				C	C	C	L*
	FM		C		L*					L	L _c			C	C	C	
Aquatic ecosystem	AI	X _c	C						L					C	C	C	L*
	FM		C		L*					L			L _c	C	C	C	
Non-target plants	AI	X	C		L	F*		L _c	L					C	C	C	L*
	FM		C		L	F*					L _c			C	C	C	
Micro-organisms, including soil or aquatic microflora	AI	X _c	C		L _c	A*			L	L		A _c		C	C		
	FM	X _c	C		L _c	A*				L		A _c		C	C		
ADDITIONAL DATA LISTED BY COUNTRIES																	
More extensive aquatic studies in cases where toxins are produced	AI	X															
	FM																
Fish chronic toxicity	AI							L _{cg} *									
	FM							L _{cg} *									
Bee/beneficial reproduction, bee brood test	AI							L _{cg} *									
	FM												L _{cg}				
Infectivity of micro-organisms to birds, fish, bees, earthworms and other beneficial organisms	AI							A									
	FM							L									
FIELD TESTS - SIMULATED OR ACTUAL																	
Terrestrial species	AI	X _c	C						L			C		L	C	C	L*
	FM		C		L*			L _c *		L	L _c	C	L _{cg}		C	C	
Aquatic species	AI	X _c	C						L			C		L	C	C	L*
	FM		C		L*			L _{cg} *		L	L _c	C			C	C	

TYPE OF DATA/INFORMATION		EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
Pollinators	AI	X _c	C						L			C		L	C	C	L*
	FM		C	L	L*			L _{cg}		L		C	L _c		C	C	
	AI	X _c	C						L			C		L	C	C	L*
	FM		C	L	L*			L _{cg}		L	L _c	C	L		C	C	
ADDITIONAL DATA LISTED BY COUNTRIES																	
Earthworms	AI																
	FM							L _{cg}									
Fish	AI																
	FM										L _c						
Secunder toxicity test	AI																
	FM													L _{cg}			
TESTING OF MICROBIAL TOXINS															C		
Do you require separate data/information on microbial toxins?	YES		X _c			X	X	X	X _c	X		X _c		X	X _c	X _c	X
	NO	X	X	X							X		X				
Are data requirements similar to those for conventional chemical pesticides	YES	X	X _c		X	X	X	X	X	X			X	X	X _c	X	
	NO																

MATRIX 9. ENVIRONMENTAL FATE

TYPE OF DATA/INFORMATION			EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
LABORATORY/MICROCOSM TESTING																		
Spread, mobility, multiplication and persistence in the environment	Soil	AI	X _c	(F) _c	L	A*	A _c *	F _{cp} *	A _g *	F	F		A _c	A	A _c	c	c	L*
		FM	X _c			L _c *						L _c	A _c					
		Water	X _c	(F) _c	L	A*	A _c *	F _{cp} *	A _g *	F	F		A _c	A	A _c	c	c	L*
	Air	AI	X _c	(F) _c	L	A*	A _c *	L _{cp} *	A _g *	L	F	L _c	A _c	L	A _c	c	c	L*
		FM	X _c			L _c *					A		A _c					
			X _c		A		A _c *			F	A			A	c	c	c	A*
	If genetically modified: gene-transfer rates											L _c						
	Soil	AI		c	A	A*	A _c *	c		F	A			A	c	c	c	A*
		FM																
		Water		c	L	A*	A _c *	c		F	A			A	c	c	c	A*
Information concerning possible fate in food chains	Air	AI		c	L	A*	A _c *	c		F	F			L	c	c	c	A*
		FM																
			X			L	L _c *	L _{cp} *	A _g	L	A			A		c		
	Additional data listed by countries																	
	Pure culture testing	AI																
		FM										L _c						
		Concluding evaluation of the product's effects on the environment															X _c	
	GREENHOUSE TESTING																	
	Spread, mobility, multiplication and persistence in the environment	AI	X _c	L		c			A _g *	L	L		c	L	F	c	c	
		FM																
		Water	X _c	L		c			A _g *	L	L		c		F	c	c	
	Air	AI	X _c	L		c			A _g *	L	L		c	L	F	c	c	
		FM																

TYPE OF DATA/INFORMATION			EC	DEN	FR	GER	ITA	NL	UK	AUS	AUT	CAN	FIN	HUN	NOR	NZ	SWE	US
<i>If genetically modified: gene-transfer rates</i>		AI	X _c							F	A		C	L			C	
		FM																
		AI	X	C		C				F	A		C	L	C	C	C	
		FM																
<i>If genetically modified: competitiveness relative to parental strains, in...</i>	Soil	AI																
		FM																
		AI	X	C		C				F	A		C	L	C	C	C	
		FM																
	Water	AI																
		FM																
		AI	X	C		C				F	L		C	L	C	C	C	
		FM																
	Air	AI																
		FM																
		AI							A _g	L	L		C	L	C		C	
		FM																
Information concerning possible fate in food chains										L	L		C	L	C		C	

Annex 4

Summary of Responses to Part 2 of the Questionnaire

Key to Abbreviations Used

- A *Always required* for registration of plant protection products.
- F *Frequently required:* These data are required in more than 80 per cent of registration submissions.
- L *Less frequently required:* These data are required in less than 80 per cent of registration submissions.
- X *Required at an unknown rate:* These data are required in an undetermined number of cases.
- AI *Active ingredient*
- FM *Formulation*
- () Numbers in *parentheses* (below double lines) refer to number of EU Member countries who listed the corresponding data element.

SUMMARY MATRIX 1. IDENTITY AND BIOLOGICAL PROPERTIES

TYPE OF DATA/INFORMATION		Active Ingredient				Formulation			
		A	F	L	X	A	F	L	X
GENERAL INFORMATION									
Applicant (name, address, etc.)		5			12	9			12
Manufacturer (name, address, facility location)		7			12	9			12
ADDITIONAL DATA LISTED BY COUNTRIES									
Way of production		1(3)				1			
Name of product						(3)			
Purpose of submission		1				1(1)			
Claims for use						1(2)			
Draft label and/or use pattern		1				2(1)			
Formulating plant		(1)				1(1)			
Patent status and number		1				1			
Source of active ingredient		1(1)				2(1)			
IDENTITY OF MICRO-ORGANISM (both naturally occurring and genetically modified)									
Scientific name		8			12	4			
Common name		8			12	2	1		
Synonyms		8			12	2		1	
Subspecies		8			12	2			
Strain		8			12	2			
Serotype		6	1	1		1	1		
For genetically modified organisms only:									
Information on the donor organism(s): scientific name, subspecies, strain, etc.		5			13	2			
Information on the inserted genetic material	Description of inserted material	4			13	2			
	Gene control region(s)	4			13	2			
	Silent genetic material	5			13	2			
	Phenotypic traits gained or lost	5			13	2			
Information on the vector(s)	Identity	5			13	3			
	Properties	5			13	3			

TYPE OF DATA/INFORMATION		Active Ingredient					Formulation				
		A	F	L	X	A	F	L	X		
Information on the host	Name	5			13	3					
	Taxonomic position	5			13	3					
	Modification technique	4			13	2					
	Site of new genetic material	4				2					
ADDITIONAL DATA LISTED BY COUNTRIES											
Collection and culture reference number where the culture is deposited		(1)		1	12			1			
Test procedures and criteria for identification (e.g. morphology, biochemistry, serology)		1(1)			12	1					
What kind of genetic modification has been made? Has any genetic material been removed or added, etc?		2(1)				1					
BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM											
<i>For naturally occurring organisms only:</i>											
History of the organism and its uses		7			12	3					
Relationships to known plant or mammalian pathogens		8			12	2	1				
Natural occurrence and geographic distribution of the organism		8			12	2					
Information on biological properties and host specificity range		8			12	3					
Genetic stability and factors affecting it		5	1	1	12		2	1			
General information on survivability, physical stability		6	1		12	4	1				
ADDITIONAL DATA LISTED BY COUNTRIES											
Effects on non-target species		1(1)			12	1					
Presence, absence or production of toxins (nature, identity, chemical structure (if appropriate) and stability)		2(2)			12						
Identification test for micro-organism		(2)									
Selection and mutation; state if the active organism was selected or was mutated		1									
Methods to prevent the active organism from losing its ability to eliminate the target organism		1									
Description of the life cycle of the active organism		1(1)									
Competitors and natural enemies of the active organism		1									
Extent to which vector or modified genes may be transferred among or incorporated by other organisms		1									
<i>For genetically modified organisms only:</i>											
History and uses of the donor organism(s)		4			13	1					
Relationship of the donor organism(s) to any plant pathogens or to pathogens of vertebrate species		4			13		1				

TYPE OF DATA/INFORMATION		Active Ingredient				Formulation			
		A	F	L	X	A	F	L	X
Natural occurrence and geographic distribution of the donor organism(s)		4			13	1			
	Pathogenicity	4			13	1			
	Infectivity	3			13	1			
Properties of donor organism(s)	Toxicity, including allergenicity	3			13	2			
	Information on biological properties and host specificity range of the donor organism(s)	4			13	1			
Genetic stability of the donor organism(s) and factors affecting it		3			13	1			
General information of survivability of the donor organism(s), physical stability		2	1		13	2			
ADDITIONAL DATA LISTED BY COUNTRIES									
Potential of modified organism to transfer genetic material to other organisms		2(1)			(1)?				
Relative environmental competitiveness of modified organisms		2		(1)					
PURITY									
Microbiological purity		8			12	8			
Identity of any unintended toxic by-products, allergens, or impurities produced by the micro-organism or in the incubation process; information on the nature and properties of such impurities		8			12	7			
IDENTITY OF FORMULATION									
Trade name and manufacturer's development code number		2				9		12	
Composition of the product: identity and concentration of active organism(s), inert components, extraneous organisms, etc.		2				9			12
Identity of toxic by-products, allergens, or other impurities produced by the micro-organism or in the incubation or manufacturing process; information on the nature and properties of such impurities		3				9			12
Nature of the product (e.g. emulsifiable concentrate, wettable powder, etc.)						9			12
ADDITIONAL DATA LISTED BY COUNTRIES									
Specific gravity/density						1(1)			
Rheological properties (suspendability, wettability, etc.)						1(1)			
Identity and purpose of non-active ingredients						1(1)			
Relevant phase of development of active organism when the product is sold (e.g. spores)						1			

SUMMARY MATRIX 2. FUNCTION, MODE OF ACTION AND HANDLING

TYPE OF DATA/INFORMATION	Active Ingredient				Formulation			
	A	F	L	X	A	F	L	X
Function (e.g. fungicide, herbicide, insecticide, repellent, growth regulator, anti-viral agent)	6			12	8			12
Mode of action to target pest, infective dose, transmissibility	6			12	6			
Field of use (e.g. field, glasshouse, food crop)	3			12	9			12
Details of intended use, e.g. target organism and plants or plant products to be protected	3			12	9			12
Application rate	4				9			12
Conditions under which the substance may not be used (agricultural, plant health or environmental)	2			12	8			12
Method of application	3				9			12
Number and timing of applications	3				9			12
Proposed instructions for use	3				9			12
Re-entry intervals	2				5	1	1	12
Pre-harvest intervals (waiting period between last treatment and harvest or consumption)	3				7	1		12
Type of packaging	3				9			12
Procedures for cleaning application equipment	1				5	1	1	12
Procedures for destruction or decontamination of the product and its packaging	1	1			6	2		12
Recommended methods and precautions concerning handling, storage, transport or fire	2			12	7	1		12
Emergency measures in case of an accident	2				7	1		12
Methods to prevent loss of viability of seed stock	3		1	12	5		1	
ADDITIONAL DATA LISTED BY COUNTRIES								
Possibility of rendering the organisms non-infective or non-infected			(1)	12				
Methods to prevent loss of virulence			(1)					
Selectivity of action	(1)							
End-use product: stability, maintenance of purity and potency					1(1)			
Withholding or storage periods in the case of post-harvest use (could substitute for pre-harvest intervals)								12

SUMMARY MATRIX 3. PHYSICAL-CHEMICAL PROPERTIES

TYPE OF DATA/INFORMATION	Active Ingredients					Formulation				
	A	F	L	X		A	F	L	X	
Appearance	5					6		1	12	
Physical state	6					7		1	12	
Density	4		1			6	1	2		
pH	2	1	1			5		3		
Stability when used according to proposed method (e.g. effects of sunlight, water, changes in pH and temperature)	4		1	12		4	2			
Storage stability	5		1			9			12	
Suspendability and suspension stability			1			4	1	2		
Size distribution of the organism	1	1				1	2	2		
Content of active ingredient in or on bait particles, granules or treated seed	3					6		2		
Flowability, pourability, dustability	1		1			5	1	2		
ADDITIONAL DATA LISTED BY COUNTRIES										
Methods for establishing storage and shelf-life stability									12	
Technical characteristics of the preparation									12	
Physical and chemical compatibility with other products including plant protection products whose use is to be authorised									12	
Wetting, adherence and distribution to target plants									12	
Compatibility with other products						(2)				
Sample for analysis	(1)					(2)				
Miscibility	1					2				
Odour	1					1				
Corrosive character	1					2				
Colour						1				
Formation of aerosols						1				
Viscosity						1(1)				

SUMMARY MATRIX 4. MANUFACTURING, QUALITY CONTROL AND ANALYTICAL METHODS

TYPE OF DATA/INFORMATION	Active Ingredient				Formulation			
	A	F	L	X	A	F	L	X
Method of production: description of techniques used to ensure a uniform product and assay methods for standardization	8			12	8	1		12
Methods to establish the identity and purity of seed stock from which batches are produced and results obtained, including information on variability	7	1		12	6	2		
Methods to show microbiological purity, including variability and levels of contaminants	7	1		12	9			12
Methods to show there are no known human or other mammalian pathogens as contaminants	7			12	7	1		12
Methods to detect and quantify residues in or on treated plants, products, food, feed, animal and human body fluids and tissues, soil, water and air	4		1	12	4	2		12
	4		1	12	4	2		12
	4		1	12	4	1	1	12
Methods to detect the organism in the environment	3		1		3	1	1	
Methods for determining the composition of the formulation					4	1	2	12
For genetically modified organisms: methods to detect the inserted genetic material	2	1		12	2	1		

SUMMARY MATRIX 5. RESIDUES

TYPE OF DATA/INFORMATION	Micro-organism				Microbial Toxin			
	A	F	L	X	A	F	L	X
GENERAL								
Likelihood of multiplication or persistence of the active substance in/on crops or food	7	2		12	7	2		
NATURE OF THE MATERIAL...								
In/on treated plants or products	6	2	1	12	6	2	1	12
In livestock, if residues remain on crop used for feed	5	2	2		6	2	1	
PRESENCE & MAGNITUDE OF THE MATERIAL IN...								
Food crops	6	2	1		6	2	1	
Meat, dairy products, poultry, eggs	4	2	3		5	2	14	
Processed food/feed	2	3	3		3	3	2	
Potable water	2	3	2		2	3	2	
Fish	1	3	2		2	3	1	
ADDITIONAL DATA LISTED BY COUNTRIES								
Birds and rats		1				1		
OTHER REQUIREMENTS								
Effects of processing or cooking on residues	2		5		3	1	3	
Proposed maximum residue levels	4	3	1		5	3	1	12
Summary and evaluation of residue behaviour	5	3	1	12	5	3	1	12
ADDITIONAL DATA LISTED BY COUNTRIES								
Effects on colour, smell, taste and other quality aspects	1				1			12
Residue data in succeeding or rotational crops	1				1			12
Residues in animals that come in contact with treated crop material	1				1			
Freezer stability (storage before analysis)	1				1			
Metabolism			1				1	

SUMMARY MATRIX 6. EFFICACY

TYPE OF DATA/INFORMATION	Active Ingredient				Formulation			
	A	F	L	X	A	F	L	X
Preliminary range-finding tests	1				5	2	2	12
Field tests					9			12
Dose/efficacy relationships		1			7	2		
Use in integrated pest management systems					4	4		
Information on the possible development of resistance and appropriate management strategies	1				4	1	2	12
Effects on quality and yield of treated plants					6	2	1	12
Effects on quality of treated plant products					7		2	12
Phytotoxicity to target plants			1		8			12
Phytotoxicity to rotational crops	1		1		5	2	1	
Observations of undesirable or unintended side effects			1		8	1		12
ADDITIONAL DATA LISTED BY COUNTRIES								
Summary and evaluation								12
Methods, timing and equipment for application					1			
Value assessment					1			
State elements which could affect efficacy, such as other pesticides, resistance formation, and climate conditions					1			
Phytopathogenicity								12

SUMMARY MATRIX 7. TOXICOLOGY, PATHOGENICITY AND INFECTIVITY

TYPE OF DATA/INFORMATION	Active Ingredient				Formulation			
	A	F	L	X	A	F	L	X
ACUTE TOXICITY TESTING								
Oral	8			12	8			12
Dermal	6			12	9	2		12
Inhalation	7		1	12	7			12
Eye irritation	5	1	12	12	9		12	
Skin irritation	5	1		12	8			12
Skin sensitization	4	1		12	9			12
Intraperitoneal or intravenous	4	1	1	12	2		1	
ADDITIONAL DATA LISTED BY COUNTRIES								
Range finding test for cases where a single dose is not appropriate to assess pathogenicity			(1)	12				
Available toxicological data relating to non-active substances				1		(1)		13
Intracerebral tests for neurotropic agents	1							
State any additional studies performed			(1)	1				1
Tissue culture; applies mainly to virus	(1)			1				1
Summary				1				1
REPEATED DOSE TOXICITY, PATHOGENICITY AND INFECTIVITY (studies less than 1 month)								
Oral	1		3					
Dermal	1		2					
Inhalation	1		2					
Intraperitoneal	1							
Intravenous	1		1					
ADDITIONAL DATA LISTED BY COUNTRIES								
Pathogenicity	2(1)	(1)	1		1		(2)	
Infectivity	2(2)	1(2)	1		1		(2)	
SUBCHRONIC TOXICITY (studies longer than 1 month)								
Oral	2	1	5	13	1		1	
Dermal	1		4	13	1		1	
Inhalation			4	13			1	

TYPE OF DATA/INFORMATION	Active Ingredient				Formulation			
	A	F	L	X	A	F	L	X
GENETIC TOXICITY								
Gene mutation	5	2		13		1		
Chromosomal aberrations/cytotoxicity	4	1		13				
DNA alterations/genetic damage	3	1	1	13				
ADDITIONAL STUDIES								
Oncogenicity	2	1	1					
Long-term toxicity (≥ six months)	2	1	1	12				
Developmental toxicity	1	1	1	12				
Fertility/reproduction	2	1	2	12				
Dermal penetration/percutaneous absorption			3	12			1	12
Immunotoxicity	1	2	2	12		1		
Allergenicity	3	1	1	12	1			
Primate infectivity	1	1	3		1			
Cell or tissue culture (viruses only)	3	1	1	12				
Hypersensitivity – laboratory tests	1	1			2			
Estimates of occupational exposure	3	1			2	2		12
ADDITIONAL DATA LISTED BY COUNTRIES								
Metabolic studies – absorption, distribution and excretion in mammals including elucidation of metabolic pathways				12(1)				
Neurotoxicity studies including where appropriate delayed neurotoxicity testing in adult hens			(1)	13				
Pathogenicity and infectivity under immunosuppression				13(1)				
Toxicokinetics to be studied in case of oncogenicity, genotoxicity, or reproductive effects caused by toxins				1				
MEDICAL DATA								
Applicator exposure	4	2		12	3	3	1	
Hypersensitivity/allergenicity incidents	6	1	12		4	2	1	
Health records from industry, agriculture	4	1	1	12	4	2	2	
First aid treatments	4		12		5		1	

TYPE OF DATA/INFORMATION	Active Ingredient				Formulation			
	A	F	L	X	A	F	L	X
ADDITIONAL DATA LISTED BY COUNTRIES								
Observations on exposure of the general population and epidemiological data, if appropriate		1		12		1		
Diagnosis of poisoning, specific signs of poisoning, chemical tests, if appropriate	(1)			12				
Prognosis of expected effects of poisoning, if appropriate				12				
Viruses: toxic effects on livestock and pets				12(1)				
Operator protection	1		(1)		1(1)			
Summary and evaluation of mammalian toxicology and conclusions				13				
TESTING OF MICROBIAL TOXINS	YES	NO						
Do you require separate data/information on microbial toxins?	7	14						
Are data requirements similar for conventional chemical pesticides?	18	2						

SUMMARY MATRIX 8. ECOTOXICOLOGY

TYPE OF DATA/INFORMATION	Active Ingredient				Formulation			
	A	F	L	X	A	F	L	X
ACUTE TOXICITY, PATHOGENICITY, INFECTIVITY								
Bird oral – species 1	3	2	1	12	3	1		
Bird oral – species 2	1	2	1		2	1		
Wild mammal		1	3		1		1	
Honey bee	3	2	1	12	2	2	12	
Other beneficial insects	2	2	2		1	2	1	12
Earthworm	1	2	1	12	2		2	12
Other soil fauna		1	2		1		2	12
Other non-target organisms believed to be at risk	1	1	3	12	2		2	12
Extent of indirect contamination of adjacent non-target crops, wild plants, soil and water	1	1	2	12	1		1	
Freshwater fish – species 1	3	2	1	12	3			12
Freshwater fish – species 2	1	2	1		2			
Freshwater invertebrate	3	2	1	12	2	1		12
Estuarine and marine animal			3					
Effects on algal growth	2	1	3	12	2	1		12
ADDITIONAL DATA LISTED BY COUNTRIES								
Important parasites and predators of target species; acute toxicity and/or pathogenicity and infectivity	(1)			12(1)		1		(1)
Summary and evaluation				12(1)				12(1)
Non-target plants			1			1		
LONG-TERM STUDIES								
Avian chronic reproduction			3	12			2	
Aquatic invertebrate range testing			2		1			
Fish life cycle			3				2	
Aquatic ecosystem			2	12			2	
Non-target plants			2	12			1	
Micro-organisms, including soil or aquatic microflora	1		2	12	1		1	12

TYPE OF DATA/INFORMATION	Active Ingredient				Formulation			
	A	F	L	X	A	F	L	X
ADDITIONAL DATA LISTED BY COUNTRIES								
More extensive aquatic studies in cases where toxins are produced				12				
Fish chronic toxicity			(1)				(1)	
Bee/beneficial reproduction, bee brood test			(1)				1(1)	
Infectivity of micro-organisms to birds, fish, bees, earthworms and other beneficial organisms	(1)						(1)	
FIELD TESTS – SIMULATED OR ACTUAL								
Terrestrial species			3	12			3	
Aquatic species			3	12			2	
Pollinators			3	12			2	
Beneficial insects			3	12			3	
ADDITIONAL DATA LISTED BY COUNTRIES								
Earthworms							(1)	
Fish							1	
Secunder toxicity test							1	
TESTING OF MICROBIAL TOXINS	YES	NO						
Do you require separate data/information on microbial toxins?	6	15						
Are data requirements similar to those for conventional chemical pesticides?	18							

SUMMARY MATRIX 9. ENVIRONMENTAL FATE

TYPE OF DATA/INFORMATION		Active Ingredient				Formulation			
		A	F	L	X	A	F	L	X
LABORATORY/MICROCOSM TESTING									
Spread, mobility, multiplication and persistence in the environment	Soil	3	2	1	12	2		1	12
	Water	3	2	1	12	2		1	12
	Air	2	1	3	12	2			12
<i>If genetically modified: gene-transfer rates</i>		3	1		12			1	
<i>If genetically modified: competitiveness relative to parental strains, in...</i>	Soil	3	1						
	Water	3	1						
	Air	1	2	1					
Information concerning possible fate in food chains		2		1	12				
ADDITIONAL DATA LISTED BY COUNTRIES									
Pure culture testing								1	
Concluding evaluation of the product's effects on the environment					1				1
GREENHOUSE TESTING									
Spread, mobility, multiplication and persistence in the environment	Soil		1	3	12			1	
	Water		1	2	12			1	
	Air		1	3	12				
<i>If genetically modified: gene-transfer rates</i>		1	1	1	12				
<i>If genetically modified: competitiveness relative to parental strains, in...</i>	Soil	1	1	1	12				
	Water	1	1	1	12				
	Air		1	2	12				
Information concerning possible fate in food chains				3					
FIELD TESTING									
Spread, mobility, multiplication and persistence in the environment	Soil		1	4	12			1	
	Water		1	4	12			1	
	Air		1	4	12				
<i>If genetically modified: competitiveness relative to parental strains in...</i>	Soil	1	1	2	12				
	Water	1	1	2	12				
	Air		1	3	12				

TYPE OF DATA/INFORMATION	Active Ingredient				Formulation			
	A	F	L	X	A	F	L	X
TESTING OF MICROBIAL TOXINS	YES	NO						
Do you require separate data/information on microbial toxins?	4	3						
Are data requirements similar to those for conventional chemical pesticides?	16							
Summary and evaluation	12							

PUBLICATIONS LIST

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^F following a title indicates that the entire publication is available from the OECD in a separate French translation. The other publications listed are available in English only, but they normally contain a French summary.

^{GLP} following a title indicates that the publication is part of the OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring. Translations of this series into Russian, Polish, Czech, Slovak, Hebrew, Spanish and Italian either exist or are planned. For more information, please contact the Environmental Health and Safety Division.

OECD Environment Monographs:

The OECD Environment Monograph Series is designed to make technical documents prepared by the OECD Environment Directorate available to the public. The Environment Monographs on this list were prepared by the Environmental Health and Safety Division. Copies are available at no charge in limited quantities.

No. 14, *Final Report of the Expert Group on Model Forms of Agreement for the Exchange of Confidential Data on Chemicals* (1988)^F

No. 15, *Final Report of the Working Group on Mutual Recognition of Compliance with Good Laboratory Practice* (1988)^F

No. 17, *The Use of Industry Category Documents in Source Assessment of Chemicals* (1989)^F

No. 24, *Accidents Involving Hazardous Substances* (1989)^F

No. 25, *A Survey of Information Systems in OECD Member Countries Covering Accidents Involving Hazardous Substances* (1989)^F

[superseded by the *Users Guide to Information Systems Useful to Emergency Planners and Responders Available in OECD Member Countries* (1991)]

No. 26, *Report of the OECD Workshop on Ecological Effects Assessment* (1989)^F

No. 27, *Compendium of Environmental Exposure Assessment Methods for Chemicals* (1989)^F

No. 28, *Workshop on Prevention of Accidents Involving Hazardous Substances: Good Management Practice* (1990)^F

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No. 36, *Scientific Criteria for Validation of In Vitro Toxicity Tests* (1990)^F

No. 39, *International Survey on Biotechnology Use and Regulations* (1990)^F

Users Guide to Hazardous Substance Data Banks Available in OECD Member Countries, OCDE/GD(91)102 (1991)^F

[Also translated into Spanish by the United Nations Environment Programme's Industry and Environment Office (UNEP IE).]

Users Guide to Information Systems Useful to Emergency Planners and Responders Available in OECD Member Countries, OCDE/GD(91)103 (1991)^F

[Also translated into Spanish by UNEP IE.]

No. 43, *International Directory of Emergency Response Centres* (1992)^F

[The International Directory is a co-operative project of OECD and UNEP IE. The emergency response centres listed in this Directory are located in both OECD and non-OECD countries.]

No. 44, *Workshop on Prevention of Accidents Involving Hazardous Substances: The Role of the Human Factor in Plant Operations* (1992)

No. 45, *The OECD Principles of Good Laboratory Practice* (1992)^{F, GLP}

No. 46, *Guides for Compliance Monitoring Procedures for Good Laboratory Practice* (1992)^{F, GLP}

[superseded by No. 110, *Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice* (1995)]

No. 47, *Guidance for the Conduct of Laboratory Inspections and Study Audits* (1992)^{F, GLP}

[superseded by No. 111, *Revised Guidance for the Conduct of Laboratory Inspections and Study Audits* (1995)]

No. 48, *Quality Assurance and GLP* (1992)^{F, GLP}

No. 49, *Compliance of Laboratory Suppliers with GLP Principles* (1992)^{F, GLP}

No. 50, *The Application of the GLP Principles to Field Studies* (1992)^{F, GLP}

No. 51, *Guiding Principles for Chemical Accident Prevention, Preparedness and Response: Guidance for Public Authorities, Industry, Labour and Others for the Establishment of Programmes and Policies related to Prevention of, Preparedness for, and Response to Accidents Involving Hazardous Substances* (1992)^F

[The Guiding Principles are also available in Russian. They are being translated into Spanish, and may also be translated into other languages. For more information, please contact the Environmental Health and Safety Division.]

No. 52, *Report of the OECD Workshop on Monitoring of Organisms Introduced into the Environment* (1992)

No. 58, *Report of the OECD Workshop on Quantitative Structure Activity Relationships (QSARS) in Aquatic Effects Assessment* (1992)

No. 59, *Report of the OECD Workshop on the Extrapolation of Laboratory Aquatic Toxicity Data to the Real Environment* (1992)

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[The OECD's Chemical Accidents Programme and Road Transport Research Programme co-operated in organising this workshop.]

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No. 77, *Data Requirements for Pesticide Registration in OECD Member Countries: Survey Results* (1993)

No. 81, *Health Aspects of Chemical Accidents: Guidance on Chemical Accident Awareness, Preparedness and Response for Health Professionals and Emergency Responders* (1994)^F

[Four international organisations collaborated in the preparation of this publication: the International Programme on Chemical Safety (IPCS), OECD, UNEP IE, and the World Health Organization – European Centre for Environment and Health (WHO-ECEH).]

No. 88, *US EPA/EC Joint Project on the Evaluation of (Quantitative) Structure Activity Relationships* (1994)

No. 90: *Ottawa '92: The OECD Workshop on Methods for Monitoring Organisms in the Environment* (1994)*

No. 91: *Compendium of Methods for Monitoring Organisms in the Environment* (1994)*

[*Monographs No. 90 and 91 are companion documents.]

No. 92, *Guidance Document for Aquatic Effects Assessment* (1995)

No. 93, *Report of the OECD Workshop on Chemical Safety in Port Areas* (1994)

[This Workshop was co-sponsored by OECD, the International Maritime Organization (IMO) and UNEP.]

No. 94, *Report of the OECD Special Session on Chemical Accident Prevention, Preparedness and Response at Transport Interfaces* (1995)

No. 95, *Report of the OECD Workshop on Small and Medium-sized Enterprises in Relation to Chemical Accident Prevention, Preparedness and Response* (1995)

No. 98, *OECD Series on the Test Guidelines Programme No. 2: Detailed Review Paper on Biodegradability Testing* (1995)

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No. 100, *Analysis of Information Elements Used in the Assessment of Certain Products of Modern Biotechnology* (1995)

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No. 103, *Risk Reduction Monograph No. 4: Mercury* (1994)

No. 104, *Risk Reduction Monograph No. 5: Cadmium* (1994)

No. 105, *Report of the OECD Workshop on Environmental Hazard/Risk Assessment* (1995)

No. 106, *Data Requirements for Biological Pesticides* (1996)

No. 107, *Report of the OECD Workshop on the Commercialisation of Agricultural Products Derived through Modern Biotechnology* (1995)

No. 108, *Final Report on the OECD Pilot Project to Compare Pesticide Data Reviews* (1995)

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No. 115, *Guidance for the Preparation of GLP Inspection Reports* (1995)^{F, GLP}

No. 116, *The Application of the Principles of GLP to Computerised Systems* (1995)^{F, GLP}

No. 117, *Industrial Products of Modern Biotechnology Intended for Release to the Environment: The Proceedings of the Fribourg Workshop* (1996)

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[Prepared in collaboration with the OECD Directorate for Science, Technology and Industry.]

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