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Persistent, Bioaccumulative and Toxic Pesticides in OECD Member Countries

Part A: Report and Annexes 1, 3 and 4

Part B: Contains Annex 2, which is available only on the Internet

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Series on Pesticides

No. 15

Persistent, Bioaccumulative, and Toxic Pesticides in OECD Member Countries

Results of Survey on Data Requirements and Risk Assessment Approaches

Part A: Report and Annexes 1, 3 and 4

(Part B contains Annex 2, which is available only on the Internet)

Environment Directorate
Organisation for Economic Co-operation and Development
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Report of the Pesticide Aquatic Risk Indicators Expert Group (2000)

ABOUT THE OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation composed of 30 industrialised countries in North America, Europe and the Pacific. The OECD works to co-ordinate and harmonise government policies, address issues of mutual concern, and respond to international problems.

The Pesticide Programme was created in 1992 within the OECD's Environmental Health and Safety Division to help OECD countries:

- harmonise their pesticide review procedures,
- share the work of evaluating pesticides, and
- reduce risks associated with pesticide use.

The Pesticide Programme is directed by the Working Group on Pesticides, composed primarily of delegates from OECD Member countries, but also including representatives from the European Commission and other international organisations (*e.g*. United Nations Food and Agriculture Organization, United Nations Environment Programme, World Health Organization, Council of Europe), and observers from the pesticide industry and public interest organisations (NGOs).

In addition to the **Series on Pesticides**, the Environment, Health and Safety (EHS) Division publishes documents in five other series: **Testing and Assessment**; **Good Laboratory Practice and Compliance Monitoring**; **Risk Management**; **Harmonization of Regulatory Oversight in Biotechnology**; and **Chemical Accidents**. More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (see next page).

This publication was produced within the framework of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC). It was approved for derestriction by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, the governing body of the Environment, Health and Safety Division.

The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) was established in 1995 by UNEP, ILO, FAO, WHO, UNIDO and the OECD (the Participating Organizations), following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. UNITAR joined the IOMC in 1997 to become the seventh Participating Organization. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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NOTE

- The Report and Annexes 1, 3 and 4 make up **Part A** of the document.
- Annex 2 - Individual Member Countries Responses to the Main Body of the Questionnaire is available only on the Internet. It makes up **Part B** of the document.

FORWARD

A survey on persistent, bioaccumulative, and toxic pesticides in OECD Member countries was conducted during 1999–2000. The primary objective of the survey was to develop a clear understanding of the information generally available to pesticide regulators that is relevant to risks associated with low-dose exposure to persistent, bioaccumulative, and toxic (PBT) pesticides and how this information is used. The survey was undertaken with a view to developing a harmonised OECD approach for assessing the risks associated with exposure to these low-level PBT pesticides in the environment.

PREFACE

This document presents the final report of the Organization for Economic Cooperation and Development (OECD) survey to collect information on member countries' data requirements for persistent, bioaccumulative, and toxic (PBT) pesticides and approaches to assessing such pesticides. The survey was initially distributed in August 1999 by Canada, the lead country on the project. Canada prepared a draft survey report in mid-2000 and circulated it to the responding countries at the end of 2000 in order to check that the original responses had been adequately captured and interpreted in the report. Additional comments were submitted by member countries in the fall of 2001 and the document was finalized in January 2002.

Twelve countries participated in the survey: Australia, Canada, Czech Republic, France, Germany, Greece, Hungary, Japan, Norway, Sweden, the United Kingdom and the United States.

The purpose of the survey was to provide a clear understanding of the data and information that are used by pesticide regulators to determine the risks associated with low-dose exposure to PBT pesticides. It was also undertaken with a view to developing a harmonised OECD approach for assessing such risks.

The survey questionnaire was intended to:

1. identify the data on persistence, bioaccumulation, and toxicity routinely available to pesticide regulators,

2. confirm the test guidelines accepted for generation of the data,

3. identify modelling and monitoring data considered, and

4. describe assumptions used in data interpretation.

The survey results are divided into two main parts:

- Part 1. Current Data Evaluation Practices

- Part 2. Data Gaps and Other Approaches

In addition, the following annexes are included:

- Annex 1 - Summary of Member Countries' Responses to the Questionnaire

- Annex 2 - Individual Member Countries' Responses to the Main Body of the Questionnaire

- Annex 3 - Contact Information

- Annex 4 - Appendix A on Definitions and Appendix B on Abbreviations

The Conclusion of the report identifies several areas needing further study or refinement, as far as the determination and assessment of both persistence and toxicity are concerned. It also recommends further harmonisation of data requirements and scientific approaches used in the assessment of PBT pesticides, to facilitate work sharing and (re-) registration.

Finally, as a next step of the project, the report suggests using a case study of a pesticide "to determine the differences and similarities in how exposure and toxicity data are synthesised in the preparation of risk assessments by OECD countries" (see Paragraph 7 of the report).

ACKNOWLEDGEMENT

The first draft of this document was prepared by the Pest Management Regulatory Agency, Ottawa, Canada, as part of an OECD project to collect information on data requirements and assessment of PBT pesticides. Subsequent draft incorporated amendments suggested by Member countries. The authors and those who provided comment and advice are thanked for their contribution to the development of the final manuscript.

Introduction

1. At the seventh session of the OECD Pesticide Forum in February 1998, Canada proposed that consideration be given to a project aimed at improving the ability to address matters related to low levels of persistent, bioaccumulative, and toxic (PBT) pesticides. As a result, a Steering Committee, led by Canada, was formed in March 1998 to expand on the proposal and report back to the OECD with a more concrete work plan. The work plan was approved at the eighth session of the OECD Pesticide Forum held in November 1998. A draft survey questionnaire on the risk assessment of PBT pesticides was produced and circulated in April 1999 to the Steering Committee members (Denmark, Germany, Japan, Mexico, Netherlands, Sweden, United Kingdom, and United States) for review and comment. The final version of the questionnaire was sent by the OECD Secretariat to all member countries in August 1999.

2. This report presents the results of this survey. The purpose of the survey was to provide a clear understanding of the data and information that are used by pesticide regulators to determine the risks associated with low-dose exposure to persistent, bioaccumulative, and toxic pesticides.

Survey Method

3. Responses to the questionnaire were analysed to confirm data requirements, to confirm how these data are actually used by pesticide regulators on a routine basis, to identify and describe computer models and post-registration monitoring programmes, and to describe the elements of data interpretation.

4. The questionnaire was divided into two major sections. The purpose of the first section, *Current Data Evaluation Practices*, was threefold:

- to confirm the data that are currently received and used for the evaluation of persistence, bioaccumulation, and environmental toxicity,
- to identify or confirm the standardized test guidelines used or required for generating data that are received by regulators, and
- to identify the models or monitoring data used in relation to persistence, bioaccumulation, and toxicity.

5. The focus of the second section, *Data Gaps and Other Approaches*, was to identify issues that may promote improvement of these processes.

6. For the purpose of this questionnaire, the evaluation of data referred to active ingredients. Specific questions on the metabolites (also called transformation products or degradation products by various countries) were also included. A summary of the responses received is presented in Annex 1. Responses from individual member countries are found in Annex 2. Contact information for regulatory bodies of each responding member country are presented in Annex 3. General definitions and

abbreviations were provided in Appendices A and B of the questionnaire, respectively, and are presented in Annex 4 of this report.

In the next stage of this project, a case study will be analysed by member countries to determine the differences and similarities in how exposure and toxicity data are synthesized in the preparation of risk assessments by OECD countries. Each country will be requested to complete a risk assessment using sample environmental data and information on the use pattern of a pesticide. From the risk assessments, comparisons will be made of the use of data endpoints, the terrestrial and aquatic risk scenarios, the safety factors calculated, and the recommended mitigative measures.

Responding Countries

7. Twelve countries completed the questionnaire with the final respondent replying in February 2000. Final comments on the draft report were received in the fall of 2001 and the final report was prepared in January 2002.The responding countries were Australia, Canada, Czech Republic, France, Germany, Greece, Hungary, Japan, Norway, Sweden, United Kingdom, and United States.

Survey Results

Part 1. Current Data Evaluation Practices

8. Part 1 of the survey was divided into three sections on persistence, bioaccumulation, and toxicity. Each section was further subdivided into questions on definitions, data requirements, endpoints, modelling, monitoring, data interpretation, and additional comments.

Persistence

Definitions

9. Persistence refers to the length of time a chemical can exist in the environment before being transformed or degraded by natural processes, however among member countries, there is a lack of a harmonized definition for the persistence of pest control products. Fundamental differences are present in defining persistence as either dissipation from a particular medium, e.g., soil, or resistance to degradation. The majority of responding countries associate dissipation time (DT50 and/or DT90) with the definition of persistence, although official definitions of persistence are non-existent in several countries. For the majority of countries, field data indicating a DT50 greater than three months and a DT90 greater than one year or laboratory data indicating a DT50 greater than six months are used to define persistence. Other criteria are also used by responding countries, such as a DT50 greater than six months in soil, sediment, or water and a half-life of two or more days in air. Some countries define persistence for soil only and several countries define persistence in relation to residence time in a compartment. Degradability and resistance to degradation in the environment, due to the intrinsic

properties of the pesticide, are also used in the definition of persistence. Also, in laboratory studies, a pesticide may be considered persistent when non-extractable residues are greater than 70% of the applied quantity of the active ingredient after 100 days with a mineralization rate of less than of 5% after 100 days.

10. Major metabolites are considered to be greater than or equal to 10% of the initial concentration in a particular compartment by all responding countries, however, some countries prefer to use the term “relevant metabolites”. Laboratory (metabolism) studies or soil degradation studies are preferred for such determination. There are variations on the “10%” definition. For example, Japan defines a major metabolite as a metabolite found in crops or soils (greater than or equal to 10%) or having a toxic concern. In addition, the United States reported that a metabolite present at very low levels (less than 10% applied) might be of concern if it is of human health or ecological concern.

Data Requirements

11. A summary of the specific data (study) requirements for the determination of persistence and the endpoints that would trigger additional studies are indicated in the responses to Questions 3 and 4, respectively, in Annex 1. The majority of responding countries (six or more countries) require data on solubility; vapour pressure; dissociation constant; octanol/water partition coefficients; hydrolysis; phototransformation on soil and in water; biotransformation in aerobic soil, in water, and in aerobic water/sediment; and adsorption/desorption. Terrestrial field studies of dissipation/accumulation are required by four countries and conditionally required by a further seven countries, whereas aquatic field studies are required by only one country (for paddy fields in Japan) and are conditionally required by three countries. In general, the scale of field studies (plot sizes) is not specified. Various additional studies are required or conditionally required by some countries to determine persistence.

12. Those studies required for determining the persistence of major and minor metabolites are summarized in the responses to Questions 5a and 5b, respectively, in Annex 1. Specific study requirements to determine the persistence of major metabolites were addressed by ten countries and those to determine the persistence of minor metabolites were addressed by three countries. Of the ten responding countries, the majority of these countries (five or more countries) indicated that studies of hydrolysis, biotransformation in aerobic and anaerobic soil, adsorption/desorption, and field studies of dissipation/accumulation are either required or conditionally required for the determination of persistence of major metabolites. Of the three countries determining the persistence of minor metabolites, two countries indicated that studies of biotransformation in aerobic soil are conditionally required.

13. For laboratory studies using soil, water, and sediment, there are approximately equal preferences among countries for using standard media, using the media from the proposed area of use, or using a natural source (although this does not necessarily have to originate from the proposed area of use of the pesticide). All but two countries indicated that they accept field trial data from studies conducted in other countries. Often there are stipulations for using data from out-of-country, including that climatic conditions are similar and that the types of soil, agricultural conditions, and conditions of use (or methods) are similar to the soil and conditions in the accepting country.

Endpoints

14. All but two of the responding countries use the same endpoints for the determination of the persistence of the active ingredient as they do for the determination of the persistence of the major metabolites. The United States responded that in the case of major metabolites that were significantly less toxic than the active ingredient, different endpoints are generally used, but did not elaborate on these differences.

15. In soil, DT50 is the common endpoint used to determine persistence by most countries, however, the values used to define the degree of persistence are variable among countries. Both "persistence" and "degradation" are used in various classification schemes. Separate field and laboratory criteria may be used to describe persistence. Most countries use the categories non-persistent, moderately persistent, and persistent with Canada including an additional category of slightly persistent. As the criteria for DT50s for each category are variable, please see Question 9a in Annex 1 for details.

16. Four countries use a classification scheme for persistence in water, while three use a classification scheme for sediment. These classification schemes may be identical to that used for soil. DT50 is the common endpoint that is used for the determination of persistence in water and sediment by most countries. The values used to define the degree of persistence in water and sediment are similar between Australia and Canada, while the cut-offs used by Greece are half the values used by Australia and Canada. Norway uses degradation, not persistence, in their classification scheme for both water and sediment. The persistence in both water and sediment is generally classified as non-persistent, moderately persistent, or persistent. As for soils, Canada includes an additional category of slightly persistent. See Questions 9b and 9c in Annex 1 for details.

17. Few classification systems exist for persistence in air. In several countries, a compound is considered to be persistent if the DT50 is greater than two days in air. Volatility may also be classified according to the vapour pressure of the compound. See Question 9d in Annex 1 for details.

Modelling

18. In general, modelling is not used to estimate persistence. One country (Czech Republic) stated that the results of models may be accepted for review if they are submitted by an applicant

Monitoring

19. Occasional monitoring for persistence is required by the majority of responding countries. One country (Czech Republic) stated that monitoring results might be accepted for review if submitted by the applicant. The monitoring of soil for persistence is slightly preferred over not monitoring this compartment. Surface water is monitored by all countries that conduct monitoring. The majority of these countries also monitor groundwater. In the United States, the monitoring of surface water and groundwater is requested on a case-by-case basis. The monitoring of sediment is generally not required, except if warranted by Australia or the Czech Republic. There are no requirements to monitor air in any country, however, the Czech Republic stated that air monitoring might

be performed, if required. With the exception of vegetation in Australia, responding countries do not monitor other compartments.

20. The need for post-registration monitoring is determined by expert scientific judgement of the regulatory body in each country, on a case-by-case, basis during the evaluation of the product (e.g., examining laboratory and field data from persistence studies, studies of mobility, looking at classification of persistence, examination of toxicity profile). Various other comments were noted on post-registration monitoring. These comments included the following: the criteria for determining the need for monitoring must be flexible; the variability of the behaviour of active ingredients in laboratory and field tests should be examined; and the risk, persistence, and mobility of pesticides should be examined. It was also noted that, in some countries, monitoring is the responsibility of the registrant or applicant.

Data Interpretation

21. The majority of responding countries determine the quantity of the active ingredient that partitions into soil, water, sediment, or air. This is accomplished by interpreting analytical data (e.g., measuring concentrations in each medium expressed as a percentage of the initial active ingredient), calculating predicted environmental concentrations (PEC), or by using fugacity models.

22. Most countries do not have a fixed criterion or any firm criteria for determining significant amounts of annual carryover of pesticide residues. In the four countries with a numerical criterion, various percentages of the initially applied amount are considered to be significant, however, there is no consensus; significant levels range from a minimum carryover of 10% to a carryover of at least 60%. In countries without a numerical criterion for carryover, other factors are used to indicate the significance of carryover. These include the phytotoxicity to succeeding crops, residues in succeeding crops, toxicity to organisms, and/or accumulation. In France, the level of residues is estimated and a determination of whether or not a “balance level” is reached is made. Transfer to the watershed, ecotoxicological properties, and phytotoxicity are then assessed.

23. The amount of carryover is used in risk assessments in a variety of ways. Carryover may be used to determine acceptability for, or conditions of, registration (e.g., frequency of use)or to determine the degree of persistence. Carryover may also be used to examine effects on successive crops and residues or pattern of rotation or to indicate the need for further field studies to assess whether continued use will result in accumulation in the environment. A model is used by Hungary (called “PELMO”) to estimate the predicted environmental concentrations, including the accumulation in soil. Predicted soil levels are compared to toxicity levels for soil-dwelling invertebrates and the toxicity exposure ratio (TER) is calculated. Carryover is also used by the United Kingdom to estimate environmental effects resulting from toxicity to soil or aquatic organisms.

Additional Comments

24. Various comments relevant to the evaluation of persistence data and the role of persistence in risk assessments were provided and are summarized here. Note that some of these comments are generalities that may apply to other countries.

25. Canada evaluates persistence in conjunction with the evaluation of data for toxicity and bioaccumulation. In addition, Canada may also conduct monitoring studies. Greece relies on field data for accurate determination of the persistence of a pesticide. In the United Kingdom, persistence is assessed with other criteria in the risk assessment, never in isolation, but only in relation to its likely effects on the overall risk assessment process. The United Kingdom does not use a cut-off criterion for persistence in soil.

26. Sweden stated that in evaluating persistent compounds, it is important to take all available information into consideration, noting that laboratory and field studies have various advantages and disadvantages. Swedish national data requirements are formulated in a general way, without detailed specifications: the areas to be covered are listed and it is the responsibility of the notifiers to address the requirements. The Swedish regulatory decision is then made based on the available data. The Swedish national approach will be replaced by the standards laid down in the "Uniform Principles" of Annex VI to Directive 91/414/EEC. This is the case for all Member States of the European Union.

27. Both Sweden and the United States stressed that dissipation observed in the field is not synonymous with degradation (transformation). The United States reported that it is important to distinguish between persistence in a single medium (air, water, soil, or sediment) and overall persistence in the environment. As outlined by the United States, in a single medium, persistence is controlled by transport of the pesticide to other media and transformation to other chemical species (i.e., dissipation). In the case of overall environmental persistence, the environment is perceived to behave as a set of interconnected media into which a pesticide will be distributed in accordance with its intrinsic (physical/chemical) properties and reactivity with only irreversible transformation (degradation) contributing to the net loss of the chemical.

28. A common measure of persistence in individual media is the half-life of a pesticide, which reflects the rate(s) of one or more transformation processes. Degradation half-lives depend on chemical properties, chemical structure, and characteristics of the surrounding environment. Thus, half-lives may have substantial spatial and temporal variability. Variability in the rates of biodegradation is important because biodegradation is the dominant transformation process in soil and water/sediment systems. Furthermore, the variability in biotic transformation processes tends to be less predictable than the variability in abiotic transformation processes.

Summary

29. Among member countries, there is a lack of a harmonized definition for the persistence of pest control products. This appears to stem from a fundamental difference in defining persistence as either dissipation from a particular medium, e.g., soil, or resistance to degradation. As a result, various numerical criteria are used to define persistence. For most countries, flexibility in data requirements as well as the use of expert judgement in the interpretation of results are the key elements for the evaluation of the persistence of a pest control product. The assessment of the risk from major and minor metabolites differs among responding countries, where such an assessment is carried out. The classification schemes used to assess persistence differ among countries. Persistence modelling is rarely used and monitoring for the persistence of pesticides is occasionally conducted on surface water, but less frequently on ground water.

Bioaccumulation

Definitions

30. Various definitions of bioaccumulation are used among countries. Although a formal regulatory definition does not exist in most countries, other (working) definitions of bioaccumulation may be adopted for use. The definitions may incorporate one or more of the following concepts: (1) the increase in the concentration of a substance in biota, (2) accumulation occurs over time, (3) a comparison is made to the surrounding media, (4) occurs in aquatic organisms, (5) occurs in fish, predators of fish, other aquatic organisms, and earthworms, (6) the propensity of a chemical to be retained in living organisms, and/or (7) the degree of bioaccumulation is a function of uptake, distribution, and elimination (metabolism and excretion) (i.e., intake exceeds depuration).

Data Requirements

31. A summary of the specific data (study) requirements for the determination of bioaccumulation and the endpoints that would trigger additional studies are indicated in the responses to Questions 23 and 24, respectively, in Annex 1. The majority of responding countries either require or conditionally require laboratory studies of bioaccumulation in fish, however, only two countries specified the species of fish to be used. Studies of bioaccumulation in earthworms are conditionally required by two countries, with one country identifying the species to be used for testing. Three countries conditionally require field studies of bioaccumulation. Additional studies of bioaccumulation, such as those with bivalves or crustaceans, birds, mammals, and *Collembola*, are also required or conditionally required by certain countries. Japan does not examine bioaccumulation. Responding countries provided various triggers for additional studies of bioaccumulation. These include a bioconcentration factor greater than 1000, a log P_{ow} (log K_{ow}) value greater than 3 combined with multiple applications, or a DT90 greater than a certain number of days in the field. See Question 24 in Annex 1 for details.

Endpoints

32. The majority of countries derive bioconcentration factors or bioaccumulation factors from studies of bioaccumulation. Additional endpoints are also derived including clearance time, depuration rate, plateau level, and/or concentration in tissues. See Question 25 in Annex 1 for details. Four of the responding countries use an elimination value of 95% within 14 days, which may or may not be recognized formally as the criterion for depuration. Also, clearance times (CT50 and CT90) may be used.

33. Bioaccumulation factors, bioconcentration factors, and/or octanol-water partition coefficients are used to classify the degree of bioaccumulation. Generally, a bioaccumulation factor or bioconcentration factor greater than 1000 or a log K_{ow} (log P_{ow}) greater than or equal to 3 are used to indicate bioaccumulation. Some countries have two numerical criteria depending on the biodegradability of the pesticide: a BCF greater than 100, if the pesticide is not readily biodegradable, and a BCF greater than 1000, if the pesticide is readily biodegradable. Other countries also use separate classifications

for different species. For example, in Greece, a BCF greater than 1 indicates the pesticide is bioaccumulative in birds, but for aquatic organisms, a BCF greater than 100 or greater than 1000 indicates bioaccumulation of non-readily or readily biodegradable pesticides, respectively. Norway classifies the potential for bioaccumulation using ranges of BCF values. In Sweden, a BCF greater than 2000 together with a DT50 greater than 1 month is considered to be an unacceptable degree of bioaccumulation.

Modelling

34. According to the survey, models are not currently used to determine bioaccumulation. Furthermore, Quantitative Structure-Activity Relationship (QSAR) values are generally not used to evaluate bioaccumulation. Of the three responding countries that do use QSAR, one country uses QSAR as a trigger for bioaccumulation studies and one country uses QSAR as a trigger or as a replacement for bioaccumulation studies (no comment from the third country). In all of the countries that examine bioaccumulation (i.e., all countries with the exception of Japan), octanol-water partition coefficients (K_{ow} or P_{ow}) are evaluated. Nine countries specified that they use partition coefficients as a trigger for bioaccumulation studies. One country indicated that partition coefficients are used as either a trigger or a replacement for bioaccumulation studies.

Monitoring

35. Post-registration monitoring for bioaccumulation is not conducted on a regular basis for new pesticides. Australia indicated that monitoringmight, however, be warranted by the properties of the pesticide and its exposure profile. Australia is currently working on developing dialysis bags as surrogates for monitoring the bioaccumulation of pesticides in fish.

Data Interpretation

36. Bioconcentration is used to assess bioaccumulation in a variety of ways. For example, some countries use the BCF to indicate the potential for bioaccumulation, while other countries use the BCF in regulatory decisions. When used in the regulatory decision-making process, the BCF is used as a trigger for long-term toxicity tests or as a trigger for risk assessments on mammals and birds. The BCF may also be used in the refinement of exposure assessments and/or in the refinement of risk assessments.

37. Only one country (Greece) uses an endpoint (with an associated value) to trigger the need for an assessment of biomagnification. Greece uses the BCF and the assessment of persistence to make a case-by-case decision to examine biomagnification. France stated that, although not explicitly defined, biomagnification is considered by assessing secondary poisoning to non-target species. Responding countries were approximately evenly divided as to whether or not they assess the risk of biomagnification. In countries that do examine biomagnification, various approaches are used, such as assessing the risk for discontinued pesticides, using the BCF as a trigger for laboratory studies or as a potential for bioaccumulation/biomagnification, using modelling, and restricting use if bioaccumulation occurs. The majority of responding countries will use studies human toxicity studies to determine the potential for bioaccumulation in wildlife species. France

and the United Kingdom specified that they follow the general principles of evaluation in Directive 91/414/CEE, to assess biomagnification, Germany uses toxicokinetic (adsorption, distribution, metabolism, and excretion) studies in mammals and birds (rodents and livestock). Canada and Sweden also use metabolism/toxicokinetic studies with mammals and other livestock (e.g., poultry), as does Greece (although the species used were not specified). During the assessment of bioconcentration/bioaccumulation for the parent compound, the majority of responding countries also assess the bioaccumulation of metabolites.

Additional Comments

38. Various general comments relevant to the evaluation of bioaccumulation and its role in pesticide risk assessment were provided. France and Sweden commented that Member States of the European Union will eventually follow the standard laid down in Annex VI (Uniform Principles) to Directive 91/414/EEC, as active ingredients are successively being evaluated at the level of the European Union and included in Annex I of the directive. Once listed in Annex I, the criteria laid down in the Uniform Principles will apply as guidance for Member States in their decisions on the registration of plant protection products containing these active ingredients.

39. Greece stated that there is a difference in both the definitions and applicable compartments for bioconcentration factors (BCF) and bioaccumulation factors (BAF) with BCFs important in aquatic ecotoxicology and BAFs important in terrestrial ecotoxicology. Indicators of bioaccumulation are a low rate of metabolism, a high affinity to fat tissues, a long period to reach a plateau concentration in tissues, and a slow rate of elimination. If toxicokinetic studies involve feeding or multiple dosing such that the plateau concentration is reached, then a BAF (residue in tissue/residue in feed) may be derived from these studies.

40. Further improvements to the overall assessment of bioaccumulation were also suggested. For example, Hungary stated that bioaccumulation of pesticides should be tested in wildlife with a long life expectancy (e.g., deer, corvidae). Norway commented that more emphasis should be placed on bioaccumulation in their risk assessments in the future. The United Kingdom stated that the determination of appropriate BCF and clearance time (CT) values is fairly straight forward, however, there is a lack of guidance or information on how to interpret this information and how to use it appropriately in a risk assessment.

41. Finally, one country-specific comment on the assessment of bioaccumulative pest control products was presented. In considering the relevance of the rate of depuration, Sweden examines the length of the potential exposure period. For instance, the depuration rate in clean water is possibly less important to consider for a pesticide that is applied frequently within one season, as compared to a pesticide that is applied only once per season.

Summary

42. Almost all OECD countries examine bioaccumulation, however, the data are interpreted differently among countries. Bioconcentration factors, bioaccumulation factors, and

octanol-water partition coefficients are used as indicators of bioaccumulation. Modelling for bioaccumulation of pesticides is not performed and monitoring for bioaccumulation is not typically conducted by any of the responding countries. Where biomagnification of pest control products is examined, various methods are used to assess the risk of biomagnification. From the responses received, there appears to be a need for harmonizing the definition of bioaccumulation and the approaches used in the assessment of bioaccumulation.

Toxicity

Definitions

43. Half of the countries responding to the questionnaire use a formal definition for toxicity, while half do not. Generally, a pesticide is considered toxic if it produces an adverse effect(s) in an organism, their offspring, or an ecosystem. Dose-response relationships are considered in the definition of toxicity in some countries. Endpoints, such as LC50, LD50, NOEC, are also used to describe or define toxicity, which may be separately defined for different species (e.g., birds, fish, aquatic organisms, honey bees, and earthworms).

Data Requirements

44. A summary of the specific data (study) requirements for the determination of toxicity and the endpoints that would trigger additional studies are indicated in the responses to Questions 41 and 42, respectively, in Annex 1.

45. Acute toxicity studies with earthworms are required by all but three countries. The majority of responding countries either require or conditionally require acute contact and acute oral studies with bees. Hive studies are conditionally required by more than half of the responding countries, especially for insect growth regulators. Similarly, more than half of the responding countries either require or conditionally require toxicity studies with predators, parasites, and/or other terrestrial invertebrates.

46. Almost all countries require studies of the acute toxicity to *Daphnia* while the majority of responding countries require or conditionally require chronic toxicity studies with *Daphnia*. Toxicity studies with other freshwater invertebrates are conditionally required by over half of the responding countries, while only a few countries require toxicity studies with marine invertebrates. The majority of responding countries require acute toxicity studies with both coldwater and warmwater fish and conditionally require sublethal and chronic fish studies.

47. For birds, studies of acute oral toxicity are required by the majority of responding countries while studies of the acute dietary toxicity are required or conditionally required by half of the responding countries. Chronic toxicity studies with birds are conditionally required by the majority of countries and are required by only a few countries. Less than half of the responding countries require or conditionally require toxicity studies with wild mammals, freshwater algae, marine algae, or terrestrial vascular plants. If the pest

control product is a herbicide, studies of the toxicity to aquatic vascular plants are required or conditionally required by half of the responding countries.

48. Those studies required for determining the toxicity of major and minor metabolites are summarised in the responses to Questions 43a and 43b, respectively, in Annex 1. Seven countries responded with specific studies required to determine the toxicity of major metabolites. Of these countries, there were no clear trends in the types of studies required, however, at least four of the seven countries either require or conditionally require acute toxicity studies with earthworms, *Daphnia*, freshwater algae, and fish. Similarly, at least four of seven countries either require or conditionally require early life cycle toxicity studies with fish and chronic toxicity studies with *Daphnia*. Only one country (Greece) specified studies that are required to determine the toxicity of minor metabolites. Several countries determine the need for such studies based on a variety of factors, such as exposure to the compound, concerns identified by the applicant, or concerns arising from other submitted studies.

Endpoints

49. The NOEC, or an approximation thereof, is used in risk assessments by all countries with the exception of Japan. Measured values of the NOEC are required by the majority of responding countries, although measured values are conditionally required by Sweden and the United States. The United States further stated that measured values are required if the pesticide precipitates, otherwise, they are not required. NOEC values estimated from the LC50 are acceptable or conditionally acceptable by the majority of responding countries.

50. The classification systems described below are used to characterise the hazard, but are not necessarily used for labelling purposes. Various hazard classification systems are used for earthworms, bees, *Daphnia*, fish, birds, aquatic plants, terrestrial plants, and other organisms. Further details are provided in Annex 1.

51. For earthworms, most countries classify LC50 with various descriptions of the degree of toxicity according to the following ranges: <1; 1 to 10; 10 to 100; 100 to 1000; and >1000 mg/kg. The descriptors for these ranges (e.g., highly toxic, moderately toxic, slightly toxic) are variable among countries. See Question 46a in Annex 1 for details. Hungary unofficially uses a single criterion of 1000 mg/kg dried soil to indicate that the compound is non-toxic.

52. For bees, the ranges for the toxicity classification systems are generally similar among countries, although the descriptors for the ranges are variable. Several countries specified that their classification schemes were for acute oral exposure, acute contact exposure, or both. The Czech Republic and United Kingdom specified that they evaluate risk to bees. Furthermore, the United Kingdom specified that risk-based labelling is used with label statements dependent on the hazard quotient and results from field studies. Most countries classify toxicity according to the amount of product per bee. Various descriptions of the degree of toxicity (e.g., highly toxic, moderately toxic, practically non-toxic) are used depending on the location of the LD50 (µg/bee) within the following ranges: <0.1, 0.1 to 1, 1 to 10, 10 to 100, and >100. There are several variations on the number of ranges included in the classification system. Other classification systems also exist, such as classifying the LD50 within the ranges 0.001 to 1.99, 2.00 to 10.99, and

>10.99 μg/bee or within the ranges <3, 3 to 11, 11 to 100, and >100 μg/bee. See Question 46b in Annex 1 for details.

53. The same classification systems are used for *Daphnia* and fish within each responding member country. Some countries use separate classification schemes for acute toxicity and chronic toxicity/reproduction. The classification for acute toxicity is generally based on the LC50 or EC50 while the classification for chronic toxicity is based on the NOEC in two countries and based on the EC50 in one country. Most countries classify acute toxicity according to where the LC50 or EC50 falls within the following ranges: <0.1, 0.1 to 1, 1 to 10, 10 to 100, and >100 mg/L. Various descriptions of the degree of toxicity exist (e.g., highly toxic, moderately toxic, practically non-toxic). Despite most countries using these numerical criteria, there are also variations on the number of ranges used by member countries. Other distinct classification systems are also applied to *Daphnia* and fish. For example, Japan employs three toxicity classifications (Class A, B, or C) depending on the acute toxicity (LC50) to both *Daphnia* and the common carp. In Hungary, different ranges are used to classify the toxicity: <0.1, 0.1 to 5, 5 to 50, and >50 mg/L, while the United Kingdom uses the ranges <0.01, 0.01 to 1, and 1 to 100 mg/L. Three countries classify chronic toxicity according to the NOEC. See Questions 46c and 46d in Annex 1 for details on the classification systems for *Daphnia* and fish, respectively.

54. For birds, six countries provided classification schemes for acute dietary and acute oral studies. Most countries classify the acute *dietary* toxicity to birds according to where the LC50 (mg/kg food) falls within the following ranges: <50, 50 to 500, 500 to 1000, 1000 to 5000, and >5000. As with other classification schemes for other organisms, various descriptors of the degree of toxicity are used (e.g., highly toxic, moderately toxic, practically non-toxic).Similarly, there are also variations on the number of ranges. For example, Germany uses slightly different ranges and toxicity descriptors: <50, 50 to 200, >200 to 500, >500 to 1000, and >1000. Four countries classify the acute *oral* toxicity to birds according to where the LD50 (mg/kg bw) falls within the following ranges: <10, 10 to 50, 50 to 500, 500 to 2000, and >2000. Again, there are various descriptions of the degree of toxicity as well as differences in the number of ranges used. As for the classification of acute dietary toxicity, Germany also uses slightly different ranges for the description of acute oral toxicity to birds: <10, 10 to 50, >50 to 200, >200 to 1000, >1000 mg/kg body weight. Greece also uses a separate classification scheme with the following ranges: <5, >5 to <50, >50 to <500, and >500 mg/kg body weight. As expressed for the classification of toxicity to bees, the Czech Republic only evaluates risk and the United Kingdom has specific risk-based labelling. Hungary unofficially uses a single criterion for the classification of acute oral and dietary toxicity. See Question 46e in Annex 1 for details.

55. For aquatic plants, Germany and Greece apply separate classification systems for both acute and chronic (or reproductive) toxicity to aquatic plants. The classification system may, however, be similar to that used for other organisms (e.g., similar to that for fish in Germany, *Daphnia* in Greece, and algae in the Czech Republic, Greece, and Sweden). Several countries reported that they do not have a classification scheme for aquatic plants. Most countries classify acute toxicity according to where the LC50 or EC50 (mg/L) falls within the following ranges: <0.1, 0.1 to 1.0, >1 to <10, 10 to 100, and >100. As with other classification schemes, there are various descriptions of the degree of toxicity (e.g., highly toxic, moderately toxic, practically non-toxic) and the number of ranges used. Again, Hungary uses a separate classification system with different ranges:

<0.1, 0.1 to 5, 5 to 50, and >50. Germany and Greece classify the chronic toxicity to aquatic plants according to where the NOEC (mg/L) falls within the following ranges: <0.01, 0.01 to 0.1, >0.1 to 1.0, and >1.0. The United Kingdom uses broader ranges of <0.01, 0.01 to 1, and 1 to 100 mg/L to classify the toxicity to aquatic plants. See Question 46f in Annex 1 for details.

56. Only Germany has a classification system for acute toxicity to terrestrial plants using the following ranges (mg/kg substrate): <10 = highly toxic, 10 to 100 = toxic, >100 to 1000 = moderately toxic, >1000 = slightly toxic. Again, The Czech Republic stated that only risk to terrestrial plants is evaluated. See Question 46g in Annex 1 for details.

57. Four countries specified toxicity classification systems for other organisms: Czech Republic and France reported that they classify toxicity to non-target/beneficial arthropods; Norway classifies toxicity to soil microorganisms; and Sweden classifies the toxicity to additional terrestrial arthropods using the same classification system as used for bees. See Question 46h in Annex 1 for details.

Modelling

58. Modelling is not used to determine toxicity, with the exception of France.

Monitoring

59. Generally, post-registration monitoring for toxicity is not required by responding countries for new pesticides, however, it may be required under certain circumstances. The species used for monitoring depends on the situation. Hungary reported that when monitoring is implemented, pheasant, mallard duck, brown hare, fish, or bees are used.

Data Interpretation

60. Although several countries estimate exposure based on individual applications, the majority of responding countries use calculations and models that take into account multiple applications in one season when estimating exposure. France noted that the toxicity of a pesticide and its derivatives is of greater importance than multiple exposures to the pesticide.

61. Several countries responded that they do not consider or calculate the potential for biomagnification, or, that it is seldom done in the evaluation of toxicity. Different approaches were, however, reported by member countries. In Australia, when a potential for biomagnification occurs with a pesticide, a weight-of-evidence approach including field observations is followed. Canada notes the potential for biomagnification in their assessment, whereas France assesses the risk of biomagnification and secondary poisoning in birds and other terrestrial vertebrates. Germany uses residues in a particular trophic level as inputs in the exposure assessment conducted for higher trophic levels. Greece multiplies the BCF in fish by the long-term average PEC in seawater. For fish-eating birds, the NOEC is then divided by the above estimated value, whereas for earthworm-eating birds, the estimated BCF in earthworms, as calculated via models or measured residue from field studies, may be used. In addition, Greece may use the long-

term average PEC in soil in the toxicity/exposure ratio. In Hungary, biomagnification is taken into consideration when the use of any product is defined in the registration document (e.g., secondary toxicity on predatory birds). Sweden sets criteria for unacceptable levels of bioaccumulation, which are interpreted as an indication of a risk of biomagnification. Finally, the United States uses biomagnification in the characterization of risk, but it is not considered in actual risk determination.

62. All responding countries, with the exceptions of Japan and the United States, use studies from human toxicology in determining the toxicity to wildlife species.

Additional Comments

63. Various comments relevant to the evaluation of toxicity and its role in pesticide risk assessment were provided.

64. France reported that pesticides are assessed according their usage dose, while other chemicals are assessed according the quantity that is produced. Assessment according to the usage dose has "side-effects" on the risk assessment of pesticides and post-registration policy. First, products that are used on minor crops in France are assessed with the same set of studies as those used for the evaluation of large-scale products used on major crops. Secondly, some products that are considered "safe" when first approved for use on a small scale may reveal unpredicted adverse effects when used on a large scale. Hungary responded that, in some cases, indirect toxicity of pesticides on nidicoulus birds (birds reared for a time in a nest or sharing the nest of another type of animal) should be checked by examining the toxicity of crop milk (food from glands in parent birds) to hatchlings. Hungary also noted that there is no official method for this test. Improvements in interpretation of the relationship between toxicity and exposure (mode and time of application) are also required.

Summary

65. In general, the data requirements for the determination of toxicity are similar among the majority of responding countries with most countries requiring or conditionally requiring studies on earthworms, bees, *Daphnia*, freshwater algae, fish, and birds. Among responding countries, different classification schemes may be used to assess toxicity in the same class of organisms. Differences in the classification schemes include variations in the numerical endpoints of the ranges for a particular species, the number of ranges used, and/or the descriptions of the degree of toxicity. The same classification scheme is, however, used for *Daphnia* and fish within each responding country. In most countries, modelling is not used to determine toxicity and monitoring for toxicity is not required. The majority of responding countries use models or calculations that account for multiple applications when estimating exposure. Finally, various approaches are used to examine the potential for biomagnification.

Part 2. Data Gaps and Other Approaches

66. As for Part 1, Part 2 of the questionnaire was divided into three sections on persistence, bioaccumulation, and toxicity. The purpose of Part 2 was to identify issues that may help

to improve the regulatory processes (e.g., data received and utilized in the evaluation of pest control products, standardization of test guidelines, and the use of models and monitoring data) among responding countries.

Persistence

67. A small majority of responding countries stated that persistence should not be defined in relation to the life span of exposed indicator organisms or representative non-target organisms. Furthermore, the majority of responding countries expressed that there are circumstances under which the expected persistence of a compound could be considered of little or no concern. Numerous examples of such situations were presented including the use of termite bait blocks, the use of multiple applications of hybrids, or the use of products not intended for use on food or feed crops. Additional circumstances under which persistence would be considered of little or no concern include a lack of dissipation occurring from the treated area combined with a high effect threshold, indoor use patterns (including glasshouses), or use in non-crop areas (e.g., airports, railway stations) with deep underground water tables. Furthermore the use of a persistent product in a situation or manner which resulted in low environmental exposure (e.g., very restricted indoor or outdoor use) was considered to be of limited concern. Persistent products undergoing enhanced degradation in a specific use pattern (e.g., seed treatment) are also considered to be of limited concern as are cases of very low use of a minimally-toxic pesticide.

68. The majority of responding countries replied that the persistence of minor metabolites should be addressed in a manner different from that of major metabolites. The relevance, toxicity, quantity, and risk of the metabolite were considered to be more important than the designation of “major” or “minor” metabolite. The majority of countries suggested that more reliable methods of determining long-term exposure are needed. This includes using more realistic scenarios for risk assessments. Additional areas were suggested for improving the determination and/or assessment of persistence. These suggestions included unifying or harmonizing approaches to the classification of persistence; establishing clear criteria for defining persistence and using modelling and measurement. Additional suggestions included determining DT50 values, distinguishing between chemical persistence and biological persistence, and improving test methods. Further ideas included assessing persistence under country-specific climatic conditions, defining the role of bioavailability, developing methodology (exposure/risk assessment or toxicity tests) to assess the risk from prolonged exposure, and defining the contribution of metabolites to exposure.

Bioaccumulation

69. The majority of countries responded that studies on biomagnification or bioconcentration should be required for regulatory purposes. Fish were considered to be the best indicator organisms for studies on bioaccumulation, followed by birds and earthworms with only one species of each required for testing. Depuration was indicated by the majority of countries to be relevant to long-term exposure at low concentrations, however, Sweden noted that because the bioconcentration factor is the function of uptake, distribution, and elimination (metabolism and excretion), depuration is not relevant *per se* given that exposure is continuous. Responses were evenly divided on whether or not factors such as

age, sex, or nursing of young should be considered in bioaccumulation studies. Australia responded that such factors should be considered where biologically relevant and the United Kingdom stated that the need for further studies should depend on the proposed use pattern and the probability of exposure. Responding countries were divided as to whether or not life cycle studies on bioaccumulation should be conducted, with several countries indicating that these studies should be conducted in special circumstances, as determined on a case-by-case basis, or depending on the proposed use pattern and probability of exposure. The majority of countries responded that studies from human toxicology could be extrapolated to wildlife, although Germany and Sweden indicated that this should be extrapolated to mammalian wildlife only.

Toxicity

70. As for assessing persistence, the majority of countries responded that the toxicity of minor metabolites should be addressed in a manner different from that of major metabolites. Several countries stated that the relevance and risk of the metabolite are more important than the designation of "major" or "minor" metabolite. Many different aspects of determination or assessment of toxicity were suggested for improvement. These suggestions included the following: agreeing on and determining low level of effects concentrations (i.e., ECx), unifying and updating test methods, examining endocrine effects, examining chronic and/or population effects, and studying the teratogenicity of pesticides. Additional suggestions included examining long-term risk assessments for mammals and developing guidance regarding the selection of appropriate, ecologically-relevant endpoints from mammalian toxicity tests, harmonizing decision-making on hazard assessments, and examining the link between laboratory tests and field tests. A need for toxicological testing of additional species, such as amphibians and nidicoulus birds, was expressed. The specific test species and triggers for these studies should be determined on a case-by-case basis, with a possibility of extrapolating the results from the chosen test species to other species.

Additional Comments

71. Several countries provided additional comments on the evaluation of data and risk assessment approaches. Australia prefers a weight-of-evidence approach over a rigid, criteria-driven process. Germany commented that the suitability of bioaccumulation tests on further species for regulatory assessments should be explored. Japan is now considering whether or not to require bioconcentration factors in fish. Furthermore, Japan is considering new assessment methods using the toxicity data on fish, *Daphnia*, and algae to evaluate aquatic effects and using toxicity data on birds to evaluate terrestrial effects. In Sweden, there is a special concern for persistent and bioaccumulative substances. Criteria for unacceptable persistence and bioaccumulation have therefore been established. As in other countries, the overall aim is to protect the environment and non-target organisms from unacceptable toxic effects, however, several problems may arise in the control of persistent pesticides. For pesticides with low degradability, there is a limit beyond which it cannot be concluded with certainty that no unacceptable effects will occur. The reason for this is that the set of tests upon which Swedish decisions are made is very limited with respect to species and time-scales, and possible long-term effects may be difficult to identify in chronic laboratory toxicity tests, especially for persistent pesticides.

Summary

72. Although there are differences among responding countries in the types of data required and the approaches used to assess the submitted data, similar trends, viewpoints, and concerns were identified by the responding countries.

73. Similar concerns were identified among countries for the assessment of both the persistence and toxicity of pest control products. There was general agreement among countries that certain circumstances exist under which persistent compounds should not cause environmental concern. These circumstances include reduced exposure, low toxicity, or the proposed use pattern. Numerous countries indicated that the persistence and toxicity of minor metabolites should be addressed in separate manner from that of major metabolites, with relevance, toxicity, quantity, and risk being more important than the designation of "major" or "minor". Also, a need for improving or furthering the science used in the assessment of persistence and toxicity was stated. Overall, there was consensus that studies on bioconcentration, bioaccumulation, and biomagnification should be required for the assessment of pest control products, however, the approaches to such assessments and their interpretation differ among responding countries.

Conclusion

74. Among responding OECD member countries, there are many similarities in the data requirements and the method of scientific review of the data for persistent, bioaccumulative, and toxic pesticides, however, there are several areas of discrepancy in the interpretation of these data requirements. The ways in which these data are used and their interpretation differ as a result of the regulatory approaches and policies of each country. These differences may lead to unique regulatory actions in each country for the same pest control product. The inventory of current national data requirements for persistent, bioaccumulative, and toxic pesticides developed from this survey should enhance future efforts to increase the international harmonization of data requirements.

75. Several important issues were identified by member countries responding to the survey as areas requiring improvement, especially in light of the ongoing harmonization efforts. For the determination or assessment of persistence, the following issues were identified as areas needing further study or refinement:

(1) Agreement on a definition of persistence,

(2) Harmonization of approaches to the classification of persistence,

(3) Establishment of clear criteria for defining persistence,

(4) Use of modelling and measurement,

(5) Determination of DT50 values,

(6) Distinguishing between chemical persistence and biological persistence,

(7) Improvement of test methods,

(8) Assessment of persistence under the specific climatic conditions of each country,

(9) Defining the role of bioavailability,

(10) Development of methodology (exposure/risk assessment or toxicity tests) to assess the risk from prolonged exposure, and

(11) Defining the contribution of metabolites to exposure.

Regarding the bioconcentration/bioaccumulation of pest control products, there is a need to harmonize the definitions of bioconcentration/bioaccumulation and the approaches used in the assessment of these processes in risk assessments. Member countries also differ in their approaches to examining the potential for biomagnification.

76. For the determination or assessment of toxicity, the following issues were identified as areas requiring improvement:

(1) Agreement on and determination of low level of effects concentrations (i.e., ECx),

(2) Unification and updating of (test) methods,

(3) Endocrine effects,

(4) Chronic and/or population effects,

(5) Teratogenicity,

(6) Long-term risk assessment for mammals and guidance regarding the selection of the appropriate, ecologically-relevant endpoints from mammalian toxicity tests,

(7) Harmonization of decision making on hazard assessment,

(8) Examination of the link between laboratory tests and field tests.

77. Harmonization of data requirements and scientific approaches used in the assessment of pest control products will facilitate the exchange of pesticide evaluations among OECD member countries. Such efforts will reduce the amount of work required in the scientific review process, thus facilitating the registration and re-registration of pest control products. Furthermore, harmonization of data requirements and approaches will reduce trade barriers between countries, as well as reduce the need for duplicative testing of pesticides by industry.

ANNEX 1
Summary of Member Countries' Responses to the Questionnaire

Main body of questionnaire

Q #	Questionnaire	SUMMARY COMMENTS
	Part 1. CURRENT DATA EVALUATION PRACTICES	
	PERSISTENCE	
	Definitions	
1	What is the **definition of persistence** that is used in your regulatory system?	(1) Most countries associate dissipation time (DT50 and/or DT90) with the definition of persistence (Australia, Canada, Czech Republic, France, Germany, Hungary, Norway, United Kingdom, United States). (2) Generally DT50 >3 months in field and DT90 >1 year in field (Czech Republic, France, Germany, Norway, United Kingdom) or DT50 >6 months in lab (Norway). (3) Other responses included DT50 >6 months in soil and natural water (Australia, Canada) or unspecified media (Hungary). (4) Some countries define persistence for soil only (Czech Republic, France, United Kingdom). (5) Several countries define persistence in relation to residence time in a compartment --- the residence time of an active substance in a defined compartment of the environment as outlined in Annex VI of Council Directive 91/414/EEC (Greece) or a long-time residual property in succeeding crops and soil (Japan). (6) Resistance to degradation in the environment due to the chemical's intrinsic properties (Sweden). (7) Several countries do not have an official definition of persistence (Australia, Canada, Hungary, United Kingdom). (8) In laboratory studies, non-extractable residues >70% of the applied quantity of active ingredient per 100 days, with a mineralization rate of less than 5% per 100 days (Czech Republic). (9) A chemical's persistence refers to the length of time the chemical can exist in the environment before being destroyed (i.e., transformed) by natural processes (United States).
2	What is the **definition of a major metabolite** that your regulatory system uses (include the percent of initial concentration of active ingredient that is used to define a major metabolite)?	(1) Where a formal definition exists or where one is understood, major metabolites are considered to be >=10% of the initial concentration in a particular compartment (soil, water) (Australia, Canada, Czech Republic, France, Germany, Greece, Hungary, Japan, Norway, Sweden, United Kingdom, United States). (2) In some countries, the term "relevant metabolites" is used or preferred (Czech Republic, Sweden). (3) In countries using the cutoff of >=10% of the initial concentration, laboratory (metabolism) studies (France, Germany, Greece, United Kingdom) or soil degradation studies (Norway, United States) were specified as being used to measure the concentrations of metabolites. (4) Japan defines a major metabolite as [1] a metabolite found in crops or soils (>=10%) or [2] a metabolite that has a toxic concern. (5) There can be numerous exceptions to the 10% "rule". A metabolite present at very low levels (less than 10% applied) may be of concern if it is of human health or ecological concern (United States).
	Data Requirements	
3	For a pesticide that would be used on a terrestrial crop, indicate which of the **studies** listed in Table 1 are currently required by your regulatory authority **to determine persistence**? Indicate which studies are classified as Required (R), i.e., must be submitted to support the registration of a pesticide, and those that are classified as Conditional (C), i.e., requested on the basis of an endpoint from another study. Please provide answer in Table 1.	See separate table in Annex 1 for Question 3.
4	For the studies identified in Question 3, **specify the endpoints**, e.g., DT50, and the corresponding values, e.g., = 6 months, **that would trigger** a request for **additional studies**. Please provide answer in Table 1.	See separate table in Annex 1 for Question 4.
5	Indicate in Table 1 the **studies** you require **to determine persistence** of the: **(a) major metabolites (b) minor metabolites**. Please provide answers in Table 1.	See separate tables in Annex 1 for Questions 5a and 5b.

Q #	Questionnaire	SUMMARY COMMENTS
6	In laboratory studies to determine persistence, do you request that soil, water and sediment be **obtained from the proposed area of use or** that **a standard** be used. Area of Use - Standard - Other (specify)	See 6a, 6b, and 6c below.
6a	**SOIL** - obtained from proposed area of use or a standard?	(1) Approximately equal preference for standard soils and soils from the proposed area of use. (2) 5 Standard soil, 6 Area of Use, 1 Standard & Area of Use, 1 Other (3) Standard soil: Czech Republic, France, Germany, Hungary, Sweden. Soil from Area of Use: Australia (if necessary), Canada, Japan, Norway, United Kingdom, United States. Standard & Area of Use: Greece. Other: Australia (overseas).
6b	**WATER** - obtained from proposed area of use or a standard?	(1) Approximately equal preference for standard water and water from the proposed area of use with greater preference for other types of water. (2) 3 Standard water, 5 Area of Use, 6 Other, 1 No preference (3) Standard water: Czech Republic, Hungary, Sweden. Water from Area of Use: Australia (if necessary), Canada, Greece, Japan, United States. Other: Australia (overseas), France (from natural sources), Germany (systems must be representative), Greece (representative), United Kingdom (obtained according to draft OECD guideline), United States (natural water and buffer). No preference: Norway.
6c	**SEDIMENT** - obtained from proposed area of use or a standard?	(1) Approximately equal preference for standard sediment and sediment from the proposed area of use with greater preference for other types of sediment. (2) 3 Standard sediment, 5 Area of Use, 6 Other, 1 No preference (3) Standard sediment: Czech Republic, Hungary, Sweden. Sediment from Area of Use: Australia (if necessary), Canada, Greece, Japan, United States. Other: Australia (overseas), France (from natural sources), Germany (OECD recommendations), Greece (representative), United Kingdom (obtained according to draft OECD guideline), United States (natural sediment or surface soils). No preference: Norway.
7a	Do you accept **field trial data from studies** conducted **in other countries**? Yes/No	(1) 10 Yes, 2 No (2) Yes: Australia, Canada, Czech Republic, France, Germany, Greece, Hungary, Norway, Sweden, United Kingdom. No: Japan, United States.
7b	Comments	(1) Consensus among all countries responding yes to Question 7a that climatic conditions must be similar. (2) In addition, similar types of soil, agricultural conditions, and conditions of use (or methods) were also necessary by the majority of countries that accept data from other countries.
	Endpoints	
8a	Are the **same endpoints** used **for** the **active ingredient and** the **major metabolites**? Yes/No	(1) 10 Yes, 2 No (2) Yes: Australia, Canada, Czech Republic, Germany, Greece, Hungary, Japan, Norway, Sweden, United Kingdom. No: France, United States.
8b	If No, specify the differences:	(1) United States: For major metabolites that are significantly less toxic, different end-points are generally used. (2) No comment from France, who responded "No" to part 8a.
9	What **classification system** is used **for persistence**?, e.g., t1/2, DT90, or DT50 >x days indicates non-persistent; t1/2, DT90, or DT50 >y days indicates moderately persistent; t1/2, DT90, or DT50 >z days indicates persistent?	See 9a, 9b, 9c, and 9d below.
9a	**Classification system** for persistence in **SOIL**	(1) DT50 is the common endpoint used to determine persistence by most countries, however, the values used to define the degree of persistence are variable among countries. Japan uses "persistence". Norway and Sweden use "degradation" not persistence in their classification scheme. Czech Republic, France, and Germany use separate field criteria and laboratory criteria to describe persistence. (2) Most countries use the following categories: non-persistent, [slightly persistent included by Canada and United Kingdom], moderately persistent, persistent. DT50s for each are as follows (countries reporting in months have been converted to approximate number of days): Australia: <15 d, 45 to 180 d, >180 d; Canada: <15 d, [15 to 45 d], 45 to 180 d, >180 d; Greece: <20 d, 20 to 60 d, >60 d; Hungary: <30 d,>30 to <180 d,>180 d; United Kingdom: <5 d, [5 to 21 d], 22 to 60 d, >60 d ("very persistent"). (3) Germany uses <21 d to indicate non-persistent. (4) Japan: a compound is persist when DT50 >1 year or <1 year but toxicity concerns with residues to crops or to livestock. (5) Norway and Sweden use degradation, not persistence, with Norway using DT50 to classify rates of degradation: <1 d = very high, 1 to 10 d = high, 10 to 60 d = medium, 60 to 200 d = moderate, and >200 d = low. Sweden classifies the degradability property of the compound as "clearly unwanted" when DT50 >70 d (>10 weeks) and "particularly serious" when >182 d (>26 weeks). (6) Czech Republic, France, and Germany have separate field criteria and laboratory criteria. For the Czech Republic and France, a DT50 >3 months in laboratory studies indicates persistence. For Germany, a DT50 >3 months in field studies indicates persistence. For all three countries, a DT90 >1 year in the field indicates persistence. Czech Republic and France also use laboratory criteria to define persistence where the formation of non-extractable residues >70% of applied active ingredient after 100 d, with mineralization rate <5% in 100 d indicating that the compound is persistent. (7) The United States is currently evaluating persistence on a case-by-case basis.

Q #	Questionnaire	SUMMARY COMMENTS
9b	**Classification system** for persistence in **WATER**	(1) Four countries use a classification scheme for persistence in water (Australia, Canada, Greece, and Norway). The classification scheme may be identical to that used for soil and/or sediment. (2) DT50 is the common endpoint used to determine persistence by most countries. The values used to define the degree of persistence are similar between Australia and Canada, while the cut-off for persistence used by Greece is half that of Australia and Canada. Norway uses degradation not persistence in their classification scheme. (3) Most countries use the following categories: non-persistent, [slightly persistent included by Canada], moderately persistent, persistent. DT50s for each are as follows (countries reporting in months have been converted to approximate number of days): Australia (no formal criteria, but those for soil are used): <15 d, 45 to 180 d, >180 d; Canada: <15 d, [15 to 45 d], 45 to 180 d, >180 d; Greece - whole system (water/sediment): <20 d, 20 to 60 d, >60 d. (4) Norway uses degradation, not persistence, using DT50 to classify rates of degradation: <1 d = very high, 1 to 10 d = high, 10 to 60 d = medium, 60 to 200 d = moderate, and >200 d = low. (5) The United States is currently evaluating persistence on a case-by-case basis.
9c	**Classification system** for persistence in **SEDIMENT**	(1) Three countries use a classification scheme for persistence in sediment (Australia, Greece, and Norway). The classification scheme may be identical to that used for soil and/or sediment. In Canada, persistence in a water/sediment system would be classified as persistence in water. (2) DT50 is the common endpoint used to determine persistence by most countries. The values used to define the degree of persistence are similar between Australia and Canada, while the cut-off for persistence used by Greece is half that of Australia and Canada. Norway uses degradation not persistence in their classification scheme. (3) Most countries use the following categories: non-persistent, [slightly persistent included by Canada], moderately persistent, persistent. DT50s for each are as follows (countries reporting in months have been converted to approximate number of days): Australia (no formal criteria, but those for soil are used): <15 d, 45 to 180 d, >180 d; Canada - whole system (water/sediment): <15 d, [15 to 45 d], 45 to 180 d, >180 d; Greece - whole system (water/sediment): <20 d, 20 to 60 d, >60 d. (4) Canada is also following a new policy where a compound is persistent if the DT50 >1 year, which differs from the scheme presented here for whole water/sediment systems that is used for technical purposes. (5) Norway uses degradation, not persistence, using DT50 to classify rates of degradation: <1 d = very high, 1 to 10 d = high, 10 to 60 d = medium, 60 to 200 d = moderate, and >200 d = low. (6) The United States is currently evaluating persistence on a case-by-case basis.
9d	**Classification system** for persistence in **AIR**	(1) In general, few classification systems exist for air. (2) In several countries, a compound is persistent in air if DT50 >2 d in air (Australia, Canada, Germany). (3) Greece, and possibly other countries that did not include volatility in their response, classifies volatility: highly volatile when vapour pressure >100 Pa; volatile when vapour pressure = 1 to 100 Pa; moderately volatile when vapour pressure = 0.01 to 1 Pa; slightly volatile when vapour pressure = 0.0001 to 0.01 Pa. (4) The United States is currently evaluating persistence on a case-by-case basis.
	Modelling	
10	Is a **computer model used** to estimate persistence? Yes/No. If No, omit Questions 11 to 14.	(1) In general, modelling is not used. (2) Results of models may be accepted if submitted by an applicant (Czech Republic).
11	**Which** computer **model(s)** is (are) employed?	No models specified.
12	Is (Are) the **model(s) validated?** Yes/No	Not applicable.
13	Indicate the **endpoints** required **for input** into this (these) persistence model(s)? Please provide answer in Table 1.	See separate table in Annex 1 for Question 13.
14	Can the model(s) **determine persistence when multiple applications** are used in one growing season? Yes/No	Not applicable.
	Monitoring	
15	Is **post-registration monitoring for persistence** of new pesticides required? Routinely / Occasionally / Never	(1) In general, occasional (10 countries) monitoring for persistence is required. (2) Monitoring is never/seldom required by two countries (France, Sweden). (3) Monitoring results may be accepted if submitted by the applicant (Czech Republic).
16	If Yes to Question 15, indicate the environmental **compartment(s) for** which you currently request post-registration **monitoring**.	See 16a to 16f below.
16a	**SOIL** - monitoring compartment	(1) Slightly higher preference for monitoring soil than for not monitoring soil. (2) 5 Yes, 4 No (3) Yes: Australia, Germany, Greece, Hungary, United Kingdom. No: Canada, Japan, Norway, United States.
16b	**SURFACE WATER** - monitoring compartment	(1) Surface water is monitored by all countries that carry out monitoring with the United States indicating that this is done on a case-by-case basis.
16c	**GROUND WATER** - monitoring compartment	(1) Generally, ground water is monitored by countries that carry out monitoring, with the exception of several countries (Greece, Japan, United Kingdom). (2) The United States indicated that this is done on a case-by-case basis.
16d	**SEDIMENT** - monitoring compartment	(1) Monitoring of sediment is generally not required, except Australia or the Czech Republic, if warranted.
16e	**AIR** - monitoring compartment	(1) Air is not monitored by any country. (2) In the Czech Republic, monitoring of air may be performed, if required.

Q #	Questionnaire	SUMMARY COMMENTS
16f	**OTHER** - monitoring compartment	(1) In general, no other compartments are monitored, with the exception of vegetation in Australia.
17	What **criteria determine** the **need for** post-registration **monitoring** to examine persistence?	(1) The need for post-registration monitoring is determined by expert scientific judgement of the regulatory body in each country on a case-by-case basis during the evaluation of the product (e.g., examining laboratory and field data from persistence studies, studies of mobility, looking at classification of persistence, examination of toxicity profile). (2) Criteria must be flexible (Australia). (3) Examine the variability of the behaviour of active substances in laboratory and field tests (great differences between DT50 values from laboratory and field studies and vice-versa) (Greece). (4) Monitor pesticides that are both persistent and mobile (Hungary, Norway, United Kingdom, United States). (5) Monitoring is the responsibility of the registrant / applicant (Czech Republic, Japan).
	Data Interpretation	
18a	Do you **determine the quantity of** the active ingredient **that partitions** into soil, water, sediment or air: Yes/No	(1) Generally, yes (11countries). (2) Exception was Japan. (3) Yes: Australia, Canada, Czech Republic, France, Germany, Greece, Hungary (except in air), Norway, Sweden, United Kingdom, United States.
18b	If yes, specify **how**:	(1) In general, most countries (8 countries) interpret analytical data (e.g., percent of initial active ingredient, determining concentrations in the media of interest) (Australia, Canada, Czech Republic, Greece, Hungary, Norway, United Kingdom, United States). (2) Three countries calculate PEC (Czech Republic, France, Germany). (3) Two countries use fugacity models (Australia, Sweden).
19	Some pesticide residues can be detected in the soil in the spring of the following year (**carry-over**). What level, e.g., percent, of residues is considered to be **significant**?	(1) Most countries do not have a set level for carryover or any firm criteria (Australia, Czech Republic, France, Hungary, Norway, United Kingdom, United States). (2) For those countries with a limit, a minimum of 10% of the initial applied amount is considered to be significant carryover (Germany, Greece); 20% carryover in Canada; and 60% carryover in Sweden under Swedish climate (assumptions: first order kinetics; Q10 = 2; yearly mean temperature 5°C). (3) In countries without a numerical limit for carryover, concern is raised by examining phytotoxicity to succeeding crops, residues in succeeding crops, toxicity to organisms, and/or accumulation (Australia, Czech Republic, France, Hungary, Norway, United Kingdom, United States). (4) Criterion not used in this form. About 1%, but this criterion is not evaluated as "percent of residues". Phytotoxicity for succeeding crops depends sometimes much on the soil (e.g. pH) or climatologic parameters. (Czech Republic). (5) The level of residues is estimated and whether a balance level is reached, then transfer to the watershed, the ecotoxicological properties and phytotoxicity are assessed (France).
20	How is the **carry-over used** in the evaluation process?	(1) Variable responses. (2) Use carryover to determine acceptability for or conditions of registration (Canada). (5) Looking at effects on successive crops and residues (Canada, Czech Republic, United Kingdom) or pattern of rotation (Greece). (6) Indicates need for further field studies to assess whether continued use will result in accumulation in the environment (Australia, United States, Norway). (7) Case-by-case basis (Germany). (8) Using modelling - PELMO model can handle the carry over in the estimation of predicted environmental concentrations (Hungary). (9) Accumulation in soil is calculated, and the predicted soil levels are compared to toxicity levels for soil dwelling invertebrates, and TER is calculated. [TER = toxicity exposure ratio = toxicity endpoint / PEC] (Norway). (10) 60% carry-over at Swedish temperatures over the year corresponds to a DT50 of 6 months at 20°C, and, if the laboratory data on degradation in soil is supported by all other relevant data, this means that the substance has an unacceptable degree of persistence (Sweden). (11) Environmental effects due to ecotoxicity to soil or aquatic organisms (more concern if pesticide moves to water) (United Kingdom).
	Additional Comments	
21	Please provide any additional **comments** that you consider to be **relevant to** the **evaluation of data regarding persistence** in pesticide risk assessment.	(1) There is agreement by some countries that dissipation is not equivalent to degradation. Degradation depends on various transformation processes whereas dissipation in the environment reflects both transformation processes and transport. (2) Canada evaluates persistence with data for toxicity and bioaccumulation. Monitoring may also be conducted. (3) Greece relies on field data for accurate determination of the persistence of a chemical. (4) Sweden stated that in evaluating persistent compounds, it is important to take all available information into consideration noting that laboratory and field studies have different advantages and disadvantages. "Dissipation" observed in the field is not synonymous with "degradation". Swedish national data requirements are formulated in a general way, without detailed specifications. The areas to be covered are listed and it is up to the notifiers to address the requirements. A decision is made based on the available data. The Swedish national approach will be replaced by the standards laid down in the "Uniform Principles" of Annex VI to the directive 91/414/EEC. (5) In the United Kingdom, persistence is assessed with other criteria in the risk assessment, never in isolation, but only in relation to its likely effects on the overall risk assessment process. There are no cut-off criteria for soil persistence. (6) United States: Persistence in a single medium (air, water, soil, or sediment), which is controlled by transport of the chemical to other media and transformation to other chemical species, is different from overall environmental persistence, where the environment behaves as a set of interconnected media and a chemical will be distributed in these media in accordance with its intrinsic (physical/chemical) properties and reactivity. For overall persistence, only irreversible transformation contributes to net loss of a chemical. A common measure of persistence in individual media is a chemical's half-life, which reflects the rate(s) of one or more transformation processes. Degradation half-lives depend on chemical properties and structure and characteristics of the surrounding environment, thus, there is substantial spatial and temporal variability in half-lives. Variability in rates of biodegradation is important because this is the dominant transformation process in soil and water/sediment and this variability tends to be less predictable than the variability in abiotic transformation processes.
	BIOACCUMULATION	
	Definitions	

Q #	Questionnaire	SUMMARY COMMENTS
22	What is the **definition for bioaccumulation** that is used in your regulatory system?	(1) Variable or no formal regulatory definition in most (six) countries, although other definitions may be adopted for use (Australia, Canada, Hungary, Japan, Norway, United Kingdom). (2) Working definitions used by most countries, may incorporate one or more of the concepts indicated in points 3 through 9: (3) the increase in the concentration of a substance in biota (Australia, Canada, Czech Republic, Germany, Greece), (4) accumulation occurs over time (Australia, from acceptance of definition provided in Appendix A), (5) comparison is made to the surrounding media (Germany), (6) occurs in aquatic organisms (Canada, United States), (7) occurs in fish, fish predators, aquatic organisms, and earthworms (France), (8) the propensity of a chemical to be retained in living organisms (Sweden), (9) the degree of bioaccumulation is a function of uptake, distribution, and elimination (metabolism and excretion) (or intake exceeds depuration) (Canada, Greece, Sweden, United States).
	Data Requirements	
23	For a pesticide that would be used on a terrestrial crop, indicate which of the **studies** listed in Table 2 are currently required by your regulatory authority **to determine bioaccumulation**? Indicate which studies are classified as Required (R) and those that are classified as Conditional (C), i.e., requested on the basis of an endpoint from another study. Please provide answer in Table 2.	See separate table in Annex 1 for Question 23.
24	For the studies identified in Question 23, specify the **endpoints** and the corresponding values, e.g., DT50, = 6 months and BCF = 1000, that would **trigger** a request for **additional studies**. Please provide answer in Table 2.	See separate table in Annex 1 for Question 24.
	Endpoints	
25	What **endpoints** are **derived from the studies** in Question 23, e.g., bioaccumulation factor (BAF), etc.? Please provide answer in Table 2.	See separate table in Annex 1 for Question 25.
26	What **criteria** are used **for depuration** in the assessment of the potential for bioaccumulation, e.g., number of days to depurate to a specified concentration?	(1) Several countries use elimination value of 95% within 14 days, which may or may not be formally recognized (Australia, Germany, Greece, United Kingdom). (2) Also clearance time (CT50 and CT90) may be used (France). (3) Several countries have no formally defined criteria (Australia, Canada, Hungary, Norway, Sweden).
27	What **classification system** is used **for bioaccumulation**, e.g., Octanol/water partition coefficient >1000 = bioaccumulative; BCF >5000 = bioaccumulative	(1) BAF or BCF and/or octanol-water partition coefficient are used to classify the degree of bioaccumulation. (2) BAF (Australia) or BCF (United States) >1000 = bioaccumulation. (3) Log K_{ow} or log P_{ow} >=3 is a criterion for bioaccumulation (Canada, France, Greece, Hungary, United Kingdom, United States). (4) Log K_{ow} >=2 triggers study of bioconcentration in fish (Canada). (5) BCF or BAF >=5000 and/or log K_{ow} >=5 is a new policy criteria for bioaccumulation that is in the process of being implemented (Canada). (6) Some countries use two cut-off points depending on the biodegradability of the pesticide: BCF >100 if not readily biodegradable and BCF >1000 if readily biodegradable (Czech Republic, France, Germany, Greece, United Kingdom). (7) Some countries also use separate classifications for different species: for birds, BCF >1 = bioaccumulative, but for aquatic organisms, BCF >1000 if readily biodegradable or BCF >100 if not readily biodegradable (Greece) (8) potential for bioaccumulation can be classified using BCF values: BCF >1000 = very high potential for bioaccumulation, BCF 200 to 1000 = high potential for bioaccumulation, BCF 100 to 200 = medium potential for bioaccumulation, BCF 10 to 100 = moderate potential for bioaccumulation, BCF <10 = low potential for bioaccumulation (Norway). (9) BCF >500 in fish "clearly unwanted" property; substance unacceptable if at potential levels of exposure a not negligible risk of accumulation is posed (i.e., a further analysis of exposure is required). BCF >2000 in fish and DT50 in soil or water >1 month (at 20°C) is a "particularly serious" property; substance unacceptable (Sweden). (10) May cause long-term adverse effects in the aquatic environment if the substance is not ready biodegradable or if log K_{ow} is >3 unless bioconcentration factor <100 (France).
	Modelling	
28	Is a (Are) computer **model(s) used** in determining bioaccumulation? Yes/No	(1) 10 No, 1 Yes (2) No: Australia, Canada, Czech Republic, Germany, Greece, Hungary, Norway, Sweden, United Kingdom, United States. Yes: France.
29	If Yes to Question 28, **which model(s)** is (are) employed?	(1) France referred to OECD method No. 305E (Bioconcentration: Flow-through Fish Test: No. 305).
30a	Are **QSAR** values **used** for evaluation of bioaccumulation? Yes/No	(1) 6 No, 3 Yes (2) No: Canada, Czech Republic, Germany, Hungary, Norway, United Kingdom. Yes: Australia, France, Greece.
30b	Are **K_{ow}** values **used** for evaluation of bioaccumulation? Yes/No	(1) Yes by all countries that examine bioaccumulation (all countries with the exception of Japan).

Q #	Questionnaire	SUMMARY COMMENTS
31a	If Yes to Question 30a, is **QSAR** used **in place of bioaccumulation studies or as triggers** for bioaccumulation studies? Replacement/Trigger	(1) Of countries responding yes, one used QSAR as trigger/replacement (depending on the chemical, its properties and proposed use pattern) (Australia) and one used QSAR as a trigger (Greece). No comment from France.
31b	If Yes to Question 30b, is **K_{ow}** used **in place of bioaccumulation studies or as triggers** for bioaccumulation studies? Replacement/Trigger	(1) Of countries responding yes, one uses K_{ow} as trigger/replacement (Australia) and nine used K_{ow} as a trigger (Canada, Czech Republic, Germany, Greece, Hungary, Norway, Sweden, United Kingdom, United States). (2) No comment from France.
	Monitoring	
32a	Is **post-registration monitoring** for **bioaccumulation of new pesticides required**? Yes/No	(1) 10 No, 1 On occasion (2) No: Canada, Czech Republic, France, Germany, Greece, Hungary, Norway, Sweden, United Kingdom, United States. On Occasion: Australia. (3) In Australia, monitoring may be warranted by the properties of the chemical and its exposure profile.
32b	If Yes, what **species** are use in monitoring programmes?	(1) For Australia, there are no firm requirements. Dialysis bags are showing potential as surrogate fish, but need further development.
33	If Yes to Question 32, what are the **criteria which determine** the **necessity** for a monitoring programme.	(1) For Australia: significant aquatic exposure and demonstrated bioaccumulation potential.
	Data Interpretation	
34a	Is **bioconcentration** (see definition in Appendix A) **used** in your evaluations or risk assessments? Yes/No	(1) All countries that examine bioaccumulation (all with the exception of Japan) responded yes.
34b	If Yes, specify **how** it is used:	(1) In some countries, BCF is used to indicate potential for bioaccumulation (Australia, Canada, Norway, Sweden). (2) Several countries (e.g., Czech Republic, France, Greece, Hungary, Sweden) use the BCF in regulatory decisions. (3) Germany uses BCF as a trigger for long-term toxicity tests, refinement of exposure assessment, and refinement of risk assessment. (4) The half life for depuration is also used in the risk assessment (Norway). (5) United Kingdom uses BCF as a trigger for risk assessment on mammals and birds. (6) Bioconcentration is used as additional confirmatory information in ecological risk assessment (United States).
35a	Is there an **endpoint**, e.g., BCF, **and** a **value**, e.g., 2000, that are **used to trigger** the need for an **assessment for biomagnification**? Yes/No	(1) 10 No, 1 Yes (2) No: Australia, Canada, Czech Republic, France, Germany, Hungary, Norway, Sweden, United Kingdom, United States. Yes: Greece.
35b	If Yes, **specify**:	(1) Greece: BCF >1000 (for readily biodegradable a.s.) and/or BCF >100 (for not readily biodegradable a.s.) for aquatic organisms. Persistence (DT90 field >365 days) regardless of the number of applications. If DT90 is between 100 and 365 days and /or the number of applications is between 3 and 6, a case-by-case decision is made. Also chronic toxicity endpoints i.e. NOEC values are considered in chronic TER estimations. Essentially the behaviour of the active substance in a particular compartment is considered in detail. (2) France: biomagnification is not explicitly defined but it is assessed by assessing secondary poisoning to non-target species.
36a	Do you **assess** the **risk for** increasing bioaccumulation through the food chain (**biomagnification**)? Yes/No	(1) Variable responses among countries. (2) 6 Yes, 5 No (3) Yes: Australia, France, Germany, Greece, Hungary, Norway. No: Canada, Czech Republic, Sweden, United Kingdom, United States.
36b	If Yes, **specify**:	(1) Various approaches followed by different countries. (2) Australia uses risk of bioaccumulation for discontinued substances. (3) In some countries, BCF may be a trigger for laboratory studies. (3) May use modeling. (4) In Hungary, restrictions in pesticide use may be made in bioaccumulation occurs. (5) BCF may be an indicator of the potential for bioaccumulation / biomagnification.
37	Do you use studies submitted to support **human toxicology** requirements **in determining bioaccumulation in wildlife species**? Yes/No	(1) Variable responses among countries. (2) 7 Yes, 4 No (3) Yes: Canada, Czech Republic, Germany, Greece, Hungary, Sweden, United Kingdom. No: Australia, France, Norway, United States.
38	If Yes to Question 37, **what** are the studies used?	(1) France and the United Kingdom follow the general principles of evaluation in the 91/414/CEE directive. (2) Germany uses toxicokinetic (adsorption, distribution, metabolism, and excretion) studies in mammals and birds (rodents and livestock). (3) Canada and Sweden use metabolism/toxicokinetic studies with mammals. (4) Greece also uses metabolism/toxicokinetic studies, but species used were not specified. (5) Canada and Sweden also use studies on metabolism in other livestock (e.g., hen).
39	Do you consider the **bioaccumulation of metabolites** in the risk assessment? Yes/No	(1) 9 Yes, 2 No (2) Yes: Australia, Canada, Czech Republic, France, Germany, Greece, Hungary, Sweden, United Kingdom. No: Norway, United States.
	Additional Comments	

Q #	Questionnaire	SUMMARY COMMENTS
---	Please provide any additional **comments** that you consider to be **relevant to** the **evaluation of bioaccumulation** and its role in pesticide risk assessment.	(1) Comments were varied. (2) France and Sweden referred to (eventually) following the standard laid down in Annex VI (Uniform Principles) to directive 91/414/EEC, as active substances are successively being evaluated at the EU-level and included in Annex I to the directive. Once listed in Annex I, the criteria laid down in the Uniform Principles apply as guidance for Member States in their decisions on registration of plant protection products containing these active substances. (3) Greece stated that there is a difference between the definitions for BCF and BAF. Bioconcentration factors are important in the aquatic ecotoxicology and bioaccumulation factors are critical in terrestrial ecotoxicology. Indicators of bioaccumulation are a low metabolism rate, high affinity to fat tissues, long period to reach a plateau concentration in tissues or a slow elimination rate. If toxicokinetic studies involve feeding or multiple dosing such that the plateau concentration is reached then a bioaccumulation factor (residue in tissue / residue in feed) may be derived from these studies. (4) Hungary stated that bioaccumulation of pesticides should be tested in long life-cycle wildlife (deer, corvidae) [Corvidae = avian family of ravens, crows, jays, magpies, and others]. (5) Norway stated that bioaccumulation should be more emphasized in our risk assessments in the future. (6) Sweden had several comments: (A) Considering the relevance of the rate of depuration, we try to pay attention to the length of the potential exposure period. For instance, the depuration rate in clean water is possibly less important to consider for a substance which is applied frequently within one season, as compared to a substance which is applied only once. (B) Our national data requirements are formulated in a general way, without detailed specifications. Rather than listing specific studies, the areas which must be covered by the notifiers' dossiers are listed. Then, it is up to the notifiers to decide on how to address the requirements. Rather than wait for the dossiers to be complete, we try to make our decisions on the available data. (7) The United Kingdom stated that the determination of appropriate BCF and CT values is fairly straight forward, however, there is a lack of guidance or information on how to interpret this information and how to use it in an appropriate risk assessment.
	TOXICITY	
	Definitions	
40	What is the **definition for toxicity** that is used in your regulatory system?	(1) Countries may (Czech Republic, France, Germany, Greece, Japan, United States) or may not (Australia, Canada, Hungary, Norway, Sweden, United Kingdom) have a formal definition for toxicity. (2) Generally, a substance is considered toxic if it produces an adverse effect(s) in an organism (Australia, Czech Republic, France, Germany, Greece, Japan, United States), or their offspring (United States), or an ecosystem (Czech Republic). (3) Dose-response relationships are considered in the definition of toxicity in some countries (Germany, Greece, Japan). (4) Endpoints (such as LC50, LD50, NOEC) are also used to describe/define toxicity (e.g., Canada, Japan, United Kingdom, United States). (5) Toxicity may be separately defined for different species (e.g., humans, birds, fish, aquatic organisms, honey bees, and earthworms) (Hungary).
	Data Requirements	
41	For a pesticide that would be used on a terrestrial crop, indicate which of the **studies** listed in Table 3 are currently required by your regulatory authority **to determine toxicity**? Indicate which studies are classified as Required (R) and those that are classified as Conditional (C), i.e., requested on the basis of an endpoint from another study. Please provide answer in Table 3.	See separate table in Annex 1 for Question 41.
42	For **studies identified** in Question 41 that are **Conditional**, indicate the **criteria**, e.g., DT50, LC50, and the corresponding values, e.g., >6 months, <5 mg/L, **for conducting** these toxicity studies? Please provide answer in Table 3.	See separate table in Annex 1 for Question 42.
43	Indicate in Table 3 the **studies** you require **to determine toxicity of** the: (a) **Major metabolites** (b) **Minor metabolites**. Please provide answers in Table 3.	See separate tables in Annex 1 for Questions 43a and Q43b.
	Endpoints	
44	Is the **NOEC used** in your risk assessment? Yes/No	(1) 11 Yes, 1 No (2) Yes: Australia, Canada, Czech Republic, France, Germany, Greece, Hungary, Norway, Sweden, United Kingdom, United States. No: Japan. (3) Norway specified that the NOEC is the endpoint used in chronic risk assessment and the LC50 is used in acute risk assessment.
45a	If Yes to Question 44, are **measured values** required / not required?	(1) 8 Required, 2 Conditionally required, 1 Not required (2) Required: Canada, Czech Republic, France, Germany, Greece, Hungary, Norway, United Kingdom. Conditionally required: Sweden, United States. Not required: Australia. (3) United States requires measured values if the pesticide precipitates.

Q #	Questionnaire	SUMMARY COMMENTS
45b	If Yes to Question 44, are values estimated from the LC50 acceptable, e.g., one tenth the LC50? **Estimated Values** Acceptable/Not Acceptable	(1) 5 Acceptable, 2 Conditionally acceptable, 2 Not acceptable (2) Acceptable: Australia, Canada, Czech Republic, Hungary, United Kingdom. Conditionally acceptable: Sweden, United States. Not acceptable: Germany, Norway. (3) United States does not accept estimated values if the pesticide precipitates.
46	What **classification system** (e.g., <0.1 ppm very highly toxic, >0.1 <1 highly toxic, >1 <10 moderately toxic, >10 <100 slightly toxic, >100 practically non-toxic) is **used for toxicity**?	See 46a to 46h below.
46a	Classification system for toxicity to **EARTHWORMS**?	(1) Most countries classify LC50 with various descriptions of the degree of toxicity according to scheme: <1 mg/kg; 1 to 10 mg/kg; 10 to 100 mg/kg; 100 to 1000 mg/kg; >1000 mg/kg. The descriptors for these ranges are variable among countries --- for Australia and Sweden: very highly toxic, highly toxic, moderately toxic, slightly toxic, and practically non-toxic; for Germany: highly toxic, toxic, moderately toxic, slightly toxic, and practically non-toxic; for Greece, the same terms are used as for Germany, although there is no classification of practically non-toxic and an LC50 >100 mg/kg is defined as very slightly to slightly toxic; for Norway, extremely toxic, very toxic, toxic, moderately toxic, and low toxicity are used. (2) Hungary unofficially uses 1000 mg/kg dried soil = non-toxic. (3) Czech Republic only evaluates risk to earthworms.
46b	Classification system for toxicity to **BEES**?	(1) Classification schemes are generally similar, although the descriptors for the ranges are variable among countries. (2) Canada and the United States specified that their classification schemes were for acute oral and acute contact exposure. Norway had separate classification schemes for acute oral and acute contact exposure. (3) Czech Republic and United Kingdom evaluate risk and the United Kingdom uses risk-based labelling based on the hazard quotient and results from field studies. (4) For **acute oral** exposure, most countries classify toxicity according to amount per bee with various descriptions of the degree of toxicity according to scheme: <0.1 µg/bee; 0.1 to 1 µg/bee; 1 to 10 µg/bee; 10 to 100 µg/bee; >100 µg/bee. Australia and Sweden uses the terms very highly toxic, highly toxic, moderately toxic, slightly toxic, and practically non-toxic, which is also referred to as low toxicity in Sweden. Greece uses highly toxic, toxic, moderately toxic, slightly toxic, and very slightly toxic. Norway uses extremely toxic, very toxic, toxic, moderately toxic, and low toxicity. (5) For **acute contact** exposure, Norway uses the following ranges and descriptions: <1 µg/bee = extremely toxic, 1 to 10 = very toxic, 10 to 100 = toxic, 100 to 1000 = moderately toxic, and >1000 = low toxicity. (6) For both **acute oral and acute contact** exposure, Canada and the United States use LD50 0.001 to 1.99 µg/bee (<2 in US) = highly toxic, 2.00 to 10.99 µg/bee = moderately toxic, and >10.99 µg/bee = relatively non-toxic (nearly non-toxic in US). (7) Germany uses a distinct classification scheme where <3 µg/bee = highly toxic, 3 to 11 µg/bee = toxic, 11 to 100 µg/bee = moderately toxic, and >100 µg/bee = slightly toxic. (8) Hungary uses a separate classification scheme where <1 µg/bee = highly toxic, 1 to 100 µg/bee = moderately toxic, >100 µg/bee = practically non-toxic.
46c	Classification system for toxicity to ***DAPHNIA***?	(1) Classification schemes identical to those for fish. (2) Separate classification schemes exist for both acute and chronic/reproduction in some countries. (3) Acute classification based on LC50 or EC50, chronic classification based on NOEC (Germany and Greece) or EC50 (Norway). (4) Australia, Canada, Norway, Sweden, and United States: <0.1 mg/L = very highly toxic, 0.1 to 1 mg/L = highly toxic, 1 to 10 mg/L = moderately toxic, 10 to 100 mg/L = slightly toxic, and >100 mg/L = practically non-toxic (or low toxicity in Sweden). Descriptors for Norway: extremely toxic, very toxic, toxic, moderately toxic, and low toxicity, respectively. (5) Czech Republic & France: <1 mg/L = highly toxic/very toxic (CR/Fr), >1 to <10 mg/L = toxic, >10 to <100 mg/L = detrimental/harmful, >100 mg/L = relatively harmless (CR only). (6) Germany & Greece: <1 mg/L = highly toxic, >1 to <10 mg/L = toxic/moderately toxic (Ger/Gre), >10 to <100 mg/L = moderately toxic/slightly toxic. Germany: >100 to 1000 mg/L = slightly toxic, >1000 mg/L = practically non-toxic. Greece: >100 mg/L = very slightly toxic. (7) Classification in Japan depends on toxicity (LC50) to Daphnia and carp. Class A: Carp >10 mg/L and Daphnia >0.5 mg/L. Class B: 0.5 mg/L<Carp<=10 mg/L or Daphnia <=0.5 mg/L. Class C: Carp <=0.5 mg/L. (8) Hungary: <0.1 mg/L = highly toxic, 0.1 to 5 mg/L = moderately toxic, 5 to 50 mg/L = slightly toxic, >50 mg/L = practically non-toxic. (9) United Kingdom: <0.01 mg/L = extremely dangerous, 0.01 to 1 mg/L = dangerous, and 1 to 100 mg/L = harmful. (10) For CHRONIC toxicity, Germany & Greece (NOEC): <0.01 mg/L = highly toxic, 0.01 to 0.1 mg/L = toxic/moderately toxic (Ger/Gre), 0.1 to 1.0 mg/L = moderately toxic/slightly toxic, and >1.0 = slightly toxic/very slightly toxic. Norway (EC50): <0.001 mg/L = extremely toxic, 0.001 to 0.01 mg/L = very toxic, 0.01 to 0.1 mg/L = toxic, 0.1 to 1 mg/L = moderately toxic, and >1 mg/L = low toxicity.

Q #	Questionnaire	SUMMARY COMMENTS
46d	Classification system for toxicity to **FISH**?	(1) Classification schemes identical to those for Daphnia. (2) Separate classification schemes exist for both acute and chronic/reproduction in some countries. (3) Acute classification based on LC50 or EC50, chronic classification based on NOEC (Germany and Greece) or LC50 (Norway). (4) Australia, Canada, Norway, Sweden and United States: <0.1 mg/L = very highly toxic, 0.1 to 1 mg/L = highly toxic, 1 to 10 mg/L = moderately toxic, 10 to 100 mg/L = slightly toxic, and >100 mg/L = practically non-toxic (or low toxicity in Sweden). Descriptors for Norway: extremely toxic, very toxic, toxic, moderately toxic, and low toxicity, respectively. (5) Czech Republic & France: <1 mg/L = highly toxic/very toxic (CR/Fr), >1 to <10 mg/L = toxic, >10 to <100 mg/L = detrimental/harmful, >100 mg/L = relatively harmless (CR only). (6) Germany & Greece: <1 mg/L = highly toxic, >1 to <10 mg/L = toxic/moderately toxic (Ger/Gre), >10 to <100 mg/L = moderately toxic/slightly toxic. Germany: >100 to 1000 mg/L = slightly toxic, >1000 mg/L = practically non-toxic. Greece: >100 mg/L = very slightly toxic. (7) Classification in Japan depends on toxicity (LC50) to Daphnia and carp. Class A: Carp >10 mg/L and Daphnia >0.5 mg/L. Class B: 0.5 mg/L<Carp<=10 mg/L or Daphnia <=0.5 mg/L. Class C: Carp <=0.5 mg/L. (8) Hungary: <0.1 mg/L = highly toxic, 0.1 to 5 mg/L = moderately toxic, 5 to 50 mg/L = slightly toxic, >50 mg/L = practically non-toxic. (9) United Kingdom: <0.01 mg/L = extremely dangerous, 0.01 to 1 mg/L = dangerous, and 1 to 100 mg/L = harmful. (10) For CHRONIC toxicity, Germany & Greece (NOEC): <0.01 mg/L = highly toxic, 0.01 to 0.1 mg/L = toxic/moderately toxic (Ger/Gre), 0.1 to 1.0 mg/L = moderately toxic/slightly toxic, and >1.0 = slightly toxic/very slightly toxic. Norway (LC50): <0.001 mg/L = extremely toxic, 0.001 to 0.01 mg/L = very toxic, 0.01 to 0.1 mg/L = toxic, 0.1 to 1 mg/L = moderately toxic, and >1 mg/L = low toxicity.
46e	Classification system for toxicity to **BIRDS**?	(1) Several countries provided classification schemes for acute oral and dietary studies (Canada, Germany, Hungary, Norway, Sweden, United States). (2) Czech Republic only evaluates risk and the United Kingdom has specific risk-based labelling. (3) Hungary unofficially uses a single criterion - Acute oral: LD50 >2000 mg/kg = non-toxic and Dietary LC50 >5000 mg/kg = non-toxic. (4) Dietary LC50 (mg/kg food) --- Australia, Canada, Norway, Sweden, United States: <50 = very highly toxic (Norway-extremely toxic), 50 to 500 = highly toxic (Norway-very toxic), 500 to 1000 = moderately toxic (Norway-toxic), 1000 to 5000 = slightly toxic (Norway-moderately toxic), >5000 = practically non-toxic (Norway and Sweden-low toxicity) Germany: <50 = highly toxic, 50 to 200 = toxic, >200 to 500 = moderately toxic, >500 to 1000 = slightly toxic, >1000 = practically non-toxic. (5) Acute oral LD50 (mg/kg bw) --- Canada, Norway, Sweden, and United States: <10 = very highly toxic (Norway-extremely toxic), 10 to 50 = highly toxic (Norway-very toxic), 50 to 500 = moderately toxic (Norway-toxic), 500 to 2000 = slightly toxic (Norway-moderately toxic), >2000 = practically non-toxic (Norway and Sweden-low toxicity) Germany: <10 = highly toxic, 10 to 50 = toxic, >50 to 200 = moderately toxic, >200 to 1000 = slightly toxic, >1000 = practically non-toxic Greece: <5 = highly toxic, >5 to <50 = toxic, >50 to <500 = moderately toxic, >500 = slightly toxic. (6) Australia states in Q46h that they follow US EPA guidelines.
46f	Classification system for toxicity to **AQUATIC PLANTS**?	(1) Separate classification schemes exist for both acute and chronic/reproduction in Germany and Greece. (2) Classification scheme may be similar to that used for other organisms e.g., fish (Germany) and Daphnia (Greece) and algae (Czech Republic, Greece, Sweden). (3) No classification by Canada, Japan, or United States. (4) Acute EC50 or LC50 (mg/L) -- Australia, Norway, Sweden generally <0.1 = very highly toxic (Norway-extremely toxic), 0.1 to 1.0 = highly toxic (Norway-very toxic), >1 to <10 = moderately toxic (Norway-toxic), 10 to 100 = slightly toxic (Norway-moderately toxic), >100 = practically non-toxic (Norway and Sweden-low toxicity). Czech Republic/France: <1 = highly toxic/very toxic, >1 to <10 = toxic, >10 to <100 = detrimental/harmful, >100 = relatively harmless (CR only). Germany: <1 = highly toxic, 1 to 10 = toxic, >10 to 100 = moderately toxic, >100 to 1000 = slightly toxic, >1000 = practically non-toxic. Greece: <1 = highly toxic, >1 to <10 = moderately toxic, >10 to <100 = slightly toxic, >100 = very slightly toxic. Hungary: <0.1 = highly toxic, 0.1 to 5 = moderately toxic, 5 to 50 = slightly toxic, >50 = practically non-toxic. (5) Chronic NOEC (mg/L) --Germany/Greece: <0.01 = highly toxic, 0.01 to 0.1 = toxic/moderately toxic, >0.1 to 1.0 = moderately toxic/slightly toxic, >1.0 = slightly toxic/very slightly toxic. (6) United Kingdom: <0.01 mg/L = extremely dangerous, 0.01 to 1 mg/L = dangerous, and 1 to 100 mg/L = harmful.
46g	Classification system for toxicity to **TERRESTRIAL PLANTS**?	(1) Only Germany has a classification system for acute toxicity using the following limits (mg/kg substrate): <10 = highly toxic, 10 to 100 = toxic, >100 to 1000 = moderately toxic, >1000 = slightly toxic. (2) Czech Republic evaluates only risk to plants.
46h	Classification system for toxicity to **OTHER** organisms?	(1) Four countries have toxicity classification systems for other organisms. (2) Czech Republic: beneficial arthropods: >75% = toxic, 50 to 75% = medium harmful, 25 to 50% = slightly harmful, <25% = relatively harmless. (3) France: non-target/beneficial arthropods: >99% of effects = harmful, 80 to 99% = moderately harmful, 30 to 80% = slightly harmful, <30% harmless. (4) Norway: Soil microorganisms: Irreversible effects = very toxic; Reversible effects = harmful; No effects. (5) Sweden: Other terrestrial arthropods than bees: same classification as bees.
	Modelling	
47	Do you **use** a computer **model(s)** in determining toxicity? Yes/No. If No, omit Questions 48 to 50.	(1) Generally no, except France.
48	**Which model(s)** do you use?	(1) France (no model specified)
49	Is (Are) the **model(s) validated**? Yes/No	(1) France: Yes.
50	Indicate the **studies** required **for input** into this (these) model(s)? Please provide answer in Table 3.	See separate table in Annex 1 for Question 50.
	Monitoring	

Q #	Questionnaire	SUMMARY COMMENTS
51	Is **post-registration monitoring for toxicity** of a new pesticide required? Yes/No	(1) Responses were variable. (2) 1 Yes, 6 No, 5 Where necessary (3) Yes: United Kingdom. No: Czech Republic, Greece, Japan, Norway, Sweden, United States. Where necessary: Australia, Canada, France, Germany, and Hungary.
52	If Yes to Question 51, what **species** are used in post-registration monitoring programmes conducted to examine toxicity, e.g., rainbow trout, mallard duck, etc.?	(1) Generally, species used depends on the situation. (2) When implemented in Hungary, pheasant, mallard duck, brown hare, fish or bees are used. (4) United Kingdom has a program set up (Wildlife Incident Investigation Scheme) to investigates the deaths of wildlife and companion animals [beneficial insects, pets and livestock (not fish)], where there is strong evidence that poisoning may have occurred.
	Data interpretation	
53	If **multiple applications** are used in one season, how is **exposure estimated**?	(1) Widely variable responses. (2) Most countries use calculations and models that (may) take multiple applications into account (Australia, Canada, Czech Republic, France, Germany, Greece, Sweden, United Kingdom, United States). (3) Some countries estimate exposure based individual applications (Hungary, Japan, Norway). (5) Note from France: toxicity of the substances and derivatives is viewed as of a greater importance than multiple exposure.
54	How is the **potential for** increasing bioaccumulation through the food chain (**biomagnification**) used in the evaluation of toxicity?	(1) Not considered or calculated in some countries or seldom done (Australia, Canada, Japan, Norway, Sweden, United Kingdom, United States). (2) Australia: Where such potential occurs, a weight of evidence approach including field observations is followed. (3) Canada: potential for biomagnification would be noted in the assessment. (4) Czech Republic and France: assess risk and secondary poisoning to birds (CR & France) and other terrestrial vertebrates (France only). (5) Germany: Residues in a trophic level are used as an input for the exposure assessment for higher trophic levels. (6) Greece: BCF in fish is multiplied by the PECsw long term (average). The NOEC is then divided by the above estimated value (i.e. for fish-eating birds). For earthworm-eating birds estimated BCF in earthworms via models or real residue from field studies may be used. Further the PEC soil long term average may be used in the toxicity/exposure ratio. (7) Hungary: taken into consideration when the use of any product is defined in the registration document (e.g., secondary toxicity on predatory birds). (8) Sweden: criteria for unacceptable level of bioaccumulation (BCF >2000 in fish and DT50 in soil or water >1 month at 20°C) has been interpreted as an indication of risk for bio-magnification. (9) United States: can be used in characterization of risk, but is not considered in actual risk determination.
55	Do you use **studies from human toxicology** in determining toxicity in wildlife species? Yes/No	(1) 10 Yes, 1 No, 1 No comment (2) Yes: all countries, except Japan (No) and United States (no comment).
	Additional Comments	
56	Please provide any additional **comments** that you consider to be **relevant to** the **evaluation of toxicity** and its role in pesticide risk assessment.	(1) France: Pesticides are assessed according their usage dose. Other chemicals are assessed according the quantity that is produced. This dose approach affects the risk assessment of pesticides and post-registration policy: Products that are used on minor crops are assessed with the same set of studies as large-scale products used on major crops. Some minor products considered safe at first time of approval may reveal adverse effects when used on a larger scale. (2) Hungary: In some cases, indirect toxicity of pesticides on nidicoulus birds [birds reared for a time in a nest or sharing the nest of another type of animal] should be checked, to have information on the toxicity to hatchlings through the crop milk. No official method. Improvement in interpretation of the relation toxicity and exposure (mode and time of application) is also required. (3) Sweden: National standard will be replaced by the standard in Annex VI (Uniform Principles) to directive 91/414/EEC, as active substances are successively being evaluated at the EU-level and included in Annex I to the directive. Swedish data requirements are formulated in a general way.
	Part 2. DATA GAPS AND OTHER APPROACHES	
	PERSISTENCE	
57	Should **persistence** be defined **in relation to life spans** of exposed indicator/representative non-target organisms? Yes/No	(1) 4 Yes, 7 No (2) Yes: France, Hungary, United Kingdom, United States. No: Australia, Canada, Czech Republic, Germany, Greece, Japan, Sweden.
58	Are there circumstances for which an **expected persistence** of a pesticide could be considered of **less or no concern**? Yes/No	(1) 10 Yes, 2 No (2) Yes: Australia, Czech Republic, France, Germany, Greece, Hungary, Japan, Norway, Sweden, United States. No: Canada, United Kingdom. (3) Canada: No. For example, even minor uses in Canada could cover a large area. And if a compound is very persistent, a restricted use could still expose the environment over time, and may cause specialized problems (e.g., persistent compounds in paint and painted objects or materials end up in land-fill where they could pose a problem). (4) Hungary: Yes, in case of special use or other parameters of the product.
59	If Yes to Question 58, give **examples**, e.g., minor use patterns.	(1) Use of termite bait blocks (Australia). (2) Multiple application of hybrids, products not intended as food or feed (Czech Republic). (3) Depends on quantities applied and surface (France). (4) No dissipation from treated area and high effect threshold; indoor uses (Germany). (5) Use in non-crop areas (airports, railway stations) with deep underground water table (Greece). (6) Indoor use (glasshouses), if low toxicity (Norway). (7) Where use results in low environmental exposure (e.g. very restricted indoor or outdoor use) or if an enhanced degradation occurs in a specific use pattern (e.g., seed treatment) (Sweden). (7) Use pattern limiting exposure (Japan, United Kingdom). (8) In case of very low use and minimally toxic chemical the expected persistence could be of no concern (United States).
60a	Should **minor metabolites** be **addressed** in a manner that is **different** from major metabolites? Yes/No	(1) Generally, yes (9 countries). (2) Yes: Canada, Czech Republic, Germany, Greece, Japan, Norway, Sweden, United Kingdom, United States. (3) France responded no and Australia had no firm views (depends on circumstances).

Q #	Questionnaire	SUMMARY COMMENTS
60b	Please provide the **rationale** for the above response.	(1) Relevance is more important (Czech Republic, France). (2) Depends on toxicity and/or quantity (Canada, Germany, Japan, Norway, Sweden-see also point 4 below). (3) Minor metabolites useful for understanding the metabolic pathway. In risk assessment, toxicity of active substance is most important (Greece). (4) Resources should be spent on areas of risk. "Minor" definition implies non-persistence (otherwise it would accumulate and be "major"), if formed from a significant degradation pathway. Minor metabolites where higher toxicity indicated than for parent or major metabolites may form an exception (Sweden). (5) Under 91/414/EC, we currently assess risk from 'major' metabolites only. If a metabolite occurs at <10% and is persistent or has some known biological activity or fate profile (e.g., highly mobile), then the risk is considered. From Q. 70, if a metabolite occurs at less than 10% it is considered not to be relevant by definition, unless there are reasons to be careful (e.g., intrinsic properties, etc.). Sometimes, based on expert judgement, these metabolites may need to be assessed (United Kingdom). (6) Minor metabolites could be insignificant when the application rates of the parent are extremely low or when the chemical is used as a minor use or when the minor metabolites are of low toxicity. However, minor metabolites of high toxicity could be considered significant and addressed in a manner similar to major metabolites (United States).
61	Is there a **need for more reliable methods of determining long-term exposure**? Yes/No	(1) Generally, yes (9 countries). (2) Yes: Canada, France, Germany, Greece, Hungary, Norway, Sweden, United Kingdom, United States. (3) A more refined assessment of long-term exposure other than using typical "worst case" scenarios would be useful, as would more realistic scenarios (Canada). (4) France also suggested using a scenario approach. (5) Czech Republic did not have a strong opinion.
62	**What aspects** of determination or assessment of persistence **need improvement**?	(1) Unification / harmonization of approaches or classification of persistence (Canada, Czech Republic, Hungary). (2) Establishment of clear criteria for defining persistence (United States). (3) Modelling and measurement (Germany). (4) Determination of DT50 values (Canada, Greece, United Kingdom). (5) Distinction between chemical persistence and biological persistence (Greece). (6) Test methods (Hungary). (7) Assessment of persistence under Norwegian climatic conditions (Norway). (8) The role of bioavailability (Sweden). (9) Currently no methodology (exposure / risk assessment or toxicity tests) to truly assess the risk from prolonged exposure (United Kingdom). (10) Contribution of metabolites to exposure (United States).
	BIOACCUMULATION	
63	If your regulatory authority does not currently require studies on **biomagnification** or **bioconcentration**, **should** they **be required**? Yes/No	(1) Generally, yes (8 Yes, 2 No). (2) Yes: Canada, Czech Republic, Germany, Greece, Hungary, Japan, Norway, United Kingdom No: France and Sweden. (3) Sweden: studies on bioaccumulation required if log K_{ow} >3. Studies on long-term biomagnification does not seem to be a possible option. Perhaps a better way is to collect information on substances which have been shown to biomagnify and compare their intrinsic properties and exposure pattern with those for which we have less information.
64	Of the following **studies** on bioaccumulation, which **should be required** (Yes/No)?	See 64a to 64g below.
64a	**BIRDS** - bioaccumulation study required?	(1) 3 Yes, 3 No (2) Yes: Czech Republic, France, Hungary. No: Canada, Germany, Greece. (3) Need for studies should be determined primarily by exposure considerations and/or proposed use patterns (Australia, United Kingdom).
64b	**AQUATIC INVERTEBRATES (LOTIC)** - bioaccumulation study required?	(1) 2 Yes, 3 No (2) Yes: Greece, Hungary. No: Canada, France, Germany. (3) Need for studies should be determined primarily by exposure considerations and/or proposed use patterns (Australia, United Kingdom).
64c	**AQUATIC INVERTEBRATES (BENTHIC)** - bioaccumulation study required?	(1) 2 Yes, 3 No (2) Yes: Greece, Hungary. No: Canada, France, Germany. (3) Need for studies should be determined primarily by exposure considerations and/or proposed use patterns (Australia, United Kingdom).
64d	**FISH** - bioaccumulation study required?	(1) Generally, yes (8 countries). (2) Yes: Canada, Czech Republic, France, Germany, Greece, Hungary, Japan, Norway. (3) Need for studies should be determined primarily by exposure considerations and/or proposed use patterns (Australia, United Kingdom).
64e	**EARTHWORMS** - bioaccumulation study required?	(1) 2 Yes, 3 No, 2 Possibly. (2) Yes: Greece, Hungary. No: Canada, France, Germany Possibly: Norway, Sweden. (3) Need for studies should be determined primarily by exposure considerations and/or proposed use patterns (Australia, United Kingdom).
64f	**AMPHIBIANS** – bioaccumulation study required?	(1) 2 Yes, 3 No (2) Yes: Greece, Hungary. No: Canada, France, Germany. (3) Need for studies should be determined primarily by exposure considerations and/or proposed use patterns (Australia, United Kingdom).
64g	**OTHER** (list) – bioaccumulation study required?	(1) 3 Yes (2) Yes: Czech Republic, France, Greece. (3) Need for studies should be determined primarily by exposure considerations and/or proposed use patterns (Australia, Germany, United Kingdom). (4) Examples provided included game and *Collembola* (a wingless insect, springtail).
65	For those studies indicated as Yes in Question 64, **should more than one species be tested?**	See 65a to 65g below.
65a	**BIRDS** - test more than one species?	(1) 5 No (2) Canada, France, Germany, Greece, Hungary. (3) Need for studies should be determined primarily by exposure considerations and/or proposed use patterns (Australia, United Kingdom).
65b	**AQUATIC INVERTEBRATES (LOTIC)** - test more than one species?	(1) 1 Yes, 3 No (2) Yes: Hungary. No: Canada, Germany, Greece. (3) Need for studies should be determined primarily by exposure considerations and/or proposed use patterns (Australia, United Kingdom).

Q #	Questionnaire	SUMMARY COMMENTS
65c	**AQUATIC INVERTEBRATES (BENTHIC)** - test more than one species?	(1) 4 No (2) Canada, Germany, Greece, Hungary. (3) Need for studies should be determined primarily by exposure considerations and/or proposed use patterns (Australia, United Kingdom).
65d	**FISH** - test more than one species?	(1) 1 Yes, 5 No (2) Yes: Hungary. No: Canada, France, Germany, Greece, Norway. (3) Need for studies should be determined primarily by exposure considerations and/or proposed use patterns (Australia, United Kingdom).
65e	**EARTHWORMS** - test more than one species?	(1) 5 No (2) Canada, Germany, Greece, Hungary, Norway. (3) Need for studies should be determined primarily by exposure considerations and/or proposed use patterns (Australia, United Kingdom).
65f	**AMPHIBIANS** - test more than one species?	(1) 4 No (2) Canada, Germany, Greece, Hungary. (3) Need for studies should be determined primarily by exposure considerations and/or proposed use patterns (Australia, United Kingdom).
65g	**OTHER** (list) - test more than one species?	(1) 3 No (2) France, Germany, Greece. (3) Need for studies should be determined primarily by exposure considerations and/or proposed use patterns (Australia, United Kingdom).
66	Is **depuration relevant to long-term exposure at low conc**entrations? Yes/No	(1) 5 Yes, 2 No (2) Yes: Canada, Czech Republic, France, Germany, Hungary. No: Norway, Sweden. (3) Swedish comment: since the BCF is the function of uptake, distribution and elimination (metabolism and excretion) depuration is not relevant per se given that exposure is continuous.
67	Should the following factors be **considered in bioaccumulation** studies? Yes/No	See 67a, 67b, 67c, and 67d below.
67a	Consider **age** in bioaccumulation studies?	(1) 3 Yes, 3 No (2) Yes: Czech Republic, Greece, Hungary. No: Canada, France, Germany. (3) Australia: where biologically relevant. (4) United Kingdom: the need for further studies should depend upon the proposed use pattern and the likely exposure scenarios.
67b	Consider **sex** in bioaccumulation studies?	(1) 3 Yes, 3 No (2) Yes: Canada, Czech Republic, Greece. No: France, Germany, Hungary. (3) Australia: where biologically relevant. (4) United Kingdom: the need for further studies should depend upon the proposed use pattern and the likely exposure scenarios.
67c	Consider **nursing of young** in bioaccumulation studies?	(1) 3 Yes, 3 No (5) Yes: Czech Republic, Greece, Hungary. No: Canada, France, Germany. (2) Australia: where biologically relevant. (3) United Kingdom: the need for further studies should depend upon the proposed use pattern and the likely exposure scenarios.
67d	Consider **other factors (list)** in bioaccumulation studies?	(1) Only two comments were received. (2) Australia: Such factors should be considered where biologically relevant. (3) United Kingdom: the need for further studies should depend upon the proposed use pattern and the likely exposure scenarios.
68	Should **life-cycle bioaccumulation studies** be conducted? Yes/No	(1) 2 Yes, 2 No, 4 In special circumstances (2) Yes: Czech Republic, Greece. No: France, Germany. In special circumstances: Australia, Canada, Hungary, United Kingdom. (3) United Kingdom: the need for further studies should depend upon the proposed use pattern and the likely exposure scenarios.
69	Can studies from **human toxicology** be used to **extrapolate to wildlife** species? Yes/No	(1) 9 Yes, 1 No (2) Yes: Australia, Canada, Czech Republic, France, Germany, Greece, Hungary, Norway, Sweden. No: Japan. (3) Germany and Sweden indicated extrapolation to mammalian wildlife only. (4) United Kingdom: the need for further studies should depend upon the proposed use pattern and the likely exposure scenarios.
	TOXICITY	
70a	Should **minor metabolites** be **addressed** in a manner that is **different** from major metabolites? Yes/No	(1) 8 Yes, 1 No (2) Yes: Canada, Czech Republic, Germany, Greece, Hungary, Norway, Sweden, United Kingdom. No: France
70b	Please provide the **rationale** for the above response.	(1) Relevance is more important (Czech Republic and France). (2) Minimal amounts, therefore, low toxicological concern, unless there is data (such as intrinsic properties, persistence, known biological activity, or fate profile) to indicate otherwise (Canada, United Kingdom). (3) Products of the slowest step in any degradation process are most important (Czech Republic). (4) Must exclude toxification reactions so that minor metabolites become relevant (Germany). (5) Minor metabolites may need to be assessed using the same approach as for major metabolites (Greece). (6) In case of indication (Hungary). (7) Quantity is important (Norway). (8) Resources should be spent on areas of risk. "Minor" definition implies non-persistence (otherwise it would accumulate and be "major"), if formed from a significant degradation pathway. Minor metabolites where higher toxicity indicated than for parent or major metabolites may form an exception (Sweden).
71	What **aspects of determination or assessment of toxicity need improvement**?	(1) Agreement on and determination of low level of effects concentrations (i.e., ECx) (Canada). (2) Unification and updating of (test) methods (Czech Republic, Hungary). (3) Endocrine effects (Germany, Sweden). (4) Chronic and/or population effects (Germany, Norway). (5) Teratogenicity (Germany). (6) Long-term risk assessment for mammals and guidance regarding the selection of the appropriate, ecologically relevant endpoints from mammalian toxicity tests (Greece). (7) Harmonization of decision making on hazard assessment (Hungary). (8) The link between laboratory tests and field test (United Kingdom).
72a	Should studies of **additional species** be required, e.g., amphibians. Yes/No	(1) 6 Yes, 1 No, 2 Perhaps (2) Yes: Canada, Germany, Greece, Hungary, Norway, United Kingdom. No: Czech Republic. Perhaps: Australia, France. (3) Australia: In cases of demonstrable exposure and hazard.

Q #	Questionnaire	SUMMARY COMMENTS
72b	If Yes, please specify **which species**, and the **triggers** for these studies:	(1) Several species mentioned by various countries: amphibians and nidicoulus birds [birds reared for a time in a nest or sharing the nest of another type of animal]. (2) Generally, the species is selected on a case-by-case basis. The selection of species should be based on factors such as degradation of the compound, bioaccumulation potential, toxicity to other species, potential for exposure, and life stage. (3) United Kingdom: need to look at new tests and data that could indicate if tests on other species are equivalent, for example can we extrapolate from fish to frogs?
	Additional Comments	
73	Please provide any **additional comments** that you consider to be **relevant to** the evaluation of data regarding **pesticides** which are expected to be persistent, bioaccumulative and toxic.	(1) Australia: Weight-of-evidence approach is preferred over rigid, criteria-driven process. (2) France: Significance of the impact of those pesticides and their derivatives should be assessed in order to improve risk assessment. (3) Germany: Suitability of bioaccumulation tests on further species for regulatory assessments should be explored. (4) Japan is now considering to require BCF in fish. Japan is considering new assessments methods using the toxicity data on fish, *Daphnia*, and algae to evaluate aquatic effects and toxicity data on birds to evaluate terrestrial effects as well. (5) Sweden: Overall aim of the assessments is to protect the environment and non-target organisms from unacceptable toxic effects from the use of pesticides. The set of tests upon which decisions are taken is very limited with respect to species and time-scales. Unpredicted effects may present themselves and long-term impact may be difficult to identify in chronic laboratory toxicity tests (especially for persistent substances). For substances with low degradability, there is a limit beyond which it cannot be concluded with certainty that no unacceptable effects will occur.

Question 3

R = Required data, C = Conditional data

Q. 3 - From Table 1: Persistence	SUMMARY
For a pesticide that would be used on a terrestrial crop, indicate which of the **studies** listed in Table 1 are currently required by your regulatory authority **to determine persistence**? Indicate which studies are classified as Required (R), i.e., must be submitted to support the registration of a pesticide, and those that are classified as Conditional (C), i.e., requested on the basis of an endpoint from another study.	(1) Australia: This question is difficult to answer unequivocally, e.g., normally soil metabolism data is required, however, in exceptional cases, such a requirement could be considered unreasonable. Australian data requirements in respect of environmental fate may include any of the items listed, but applicants can request a waiver for specific items based on scientific argument. Information on all aspects would generally be required for terrestrial crops. Copies of current requirements for agricultural and veterinary products were attached and Internet addresses provided. (2) Canada: Canada has defined 33 use site categories for pesticides, each with a unique set of data requirements. This survey was answered based on the use site categories for terrestrial food and feed crops, which have the most extensive data requirements. A request for a waiver of a particular study, based on a scientific rationale, may be submitted.
ENVIRONMENTAL FATE	
Solubility	(1) 8 R, 1 C (2) R: Canada, France, Germany, Hungary, Japan, Norway, Sweden, United States. C: Greece.
Vapour Pressure	(1) 8 R, 1 C (2) R: Canada, France, Germany, Hungary, Japan, Norway, Sweden, United States. C: Greece.
Dissociation Constant	(1) 6 R, 2 C (2) R: Canada, France, Germany, Hungary, Japan, United States. C: Greece, Sweden.
Octanol/Water Partition Coefficient	(1) 7 R, 2 C (2) R: Canada, France, Germany, Hungary, Japan, Norway, Sweden. C: Greece, United States.
UV/Visible Absorption Spectra	(1) 3 R (2) R: Canada, Japan, Sweden.
Hydrolysis	(1) 9 R, 1 C (2) R: Canada, France, Germany, Hungary, Japan, Norway, Sweden, United Kingdom, United States. C: Greece.
Phototransformation	(1) 5 R, 4 R&C, 1 C (2) R: France, Germany, Japan, Norway, United Kingdom. R&C: Canada, Hungary, Sweden, United States. C: Greece.
Soil	(1) 7 R, 2 C (2) R: Canada, France, Germany, Hungary, Norway, Sweden, United Kingdom. C: Greece, United States.
Water	(1) 8 R, 2 C (2) R: Canada, France, Germany, Japan, Norway, Sweden, United Kingdom, United States. C: Greece, Hungary.
Air	(1) 1 R, 5 C (2) R: Germany. C: Canada, Greece, Hungary, Sweden, United States.
Biotransformation in Soil	(1) 4 R, 6 R&C, 1 C (2) R: Canada, Hungary, Norway, United States. R&C: France, Germany, Greece, Japan, Sweden, United Kingdom. C: Czech Republic.

Q. 3 - From Table 1: Persistence	SUMMARY
Aerobic (20-30°C)	(1) 10 R, 1 C (2) R: Canada, France, Germany, Greece, Hungary, Japan, Norway, Sweden, United Kingdom, United States. C: Czech Republic. (3) 20°C specified by 2 countries: France (3 soils), Germany.
Aerobic (3-8°C)	(1) 2 R, 1 R/C, 2 C (2) R: France, Norway. R/C: Greece. C: Germany, Sweden. (3) 10°C specified by 2 countries: France (one soil), Germany.
Anaerobic (20-30°C)	(1) 5 R, 1 R/C, 4 C (2) R: Canada, France, Hungary, Norway, Sweden. R/C: Greece. C: Czech Republic, Germany, Japan, United Kingdom. (3) Flooded soil used by Canada. (4) 20°C specified by France. (5) 10°C specified by Germany.
Anaerobic (3-8°C)	(1) 1 R/C, 3 C (2) R/C: Greece. C: France, Germany, Sweden. (3) 10°C specified by Germany (as above).
Biotransformation in Water	(1) 6 R, 1 R/C (2) R: Canada, France, Germany, Hungary, Japan, Norway. R/C: Greece. (3) Sublevels not provided by France or Japan.
Aerobic (20-30°C)	(1) 5 R (2) R: Canada, Germany, Greece, Hungary, Norway.
Aerobic (3-8°C)	(1) 1 R/C (2) R/C: Greece.
Biotransformation in Water/Sediment	(1) 5 R, 2 R/C, 1 C (2) R: France, Germany, Hungary, Sweden, United Kingdom. R/C: Greece, Norway. C: Canada.
Aerobic (20-30°C)	(1) 7 R, 1 C (2) R: France, Germany, Greece, Hungary, Norway, Sweden, United Kingdom. C: Canada.
Anaerobic (3-8°C)	(1) 1 R/C (2) R/C: Greece.
Anaerobic (20-30°C)	(1) 1 R/C, 2 C (2) R/C: Greece. C: Canada, Norway.
Adsorption/Desorption	(1) 9 R, 1 C (2) R: Canada, France, Germany, Hungary, Japan, Norway, Sweden, United Kingdom, United States. C: Greece.
Soil Column Leaching	(1) 1 R, 3 R&C, 2 C (2) R: Canada. R&C: France, Hungary, Norway. C: Germany, Greece.
Unaged Soil	(1) 2 R, 3 C (2) R: Hungary, Norway. C: France, Germany, Greece.
Aged Soil	(1) 1 R, 3 C (2) R: France. C: Germany, Greece, Norway.
Soil TLC Leaching	(1) 2 C (2) C: Greece, Hungary.
Volatilization	(1) 2 R, 3 C (2) R: Hungary, United States. C: Canada, Germany, Greece.
Field Studies of Dissipation/ Accumulation	(1) 3 R, 1 R&C, 7 C (2) R: Japan, United Kingdom, United States. R&C: Canada. C: Czech Republic, France, Germany, Greece, Hungary, Norway, Sweden.
Small Scale	
Terrestrial	(1) 4 R, 7 C (2) R: Canada, Japan, United Kingdom, United States. C: Czech Republic, France, Germany, Greece, Hungary, Norway, Sweden. (3) No plot size requirements specified with the exception of Canada. (4) Either large- or small-scaled field studies are required by Canada.
Aquatic	(1) 1 R, 3 C (2) R: Japan (for paddy fields). C: Canada, Germany, Hungary.
Large Scale	
Terrestrial	(1) 1 R, 4 C (2) R: Canada. C: Czech Republic, France, Greece, Hungary. (3) Either large- or small-scaled field studies are required by Canada.
Aquatic	(1) 0 R, 2 C (2) C: Canada, Hungary.
Other Studies:	(1) Identification if relevant for (eco)toxicity [class not given] (France). (2) Soil residues studies [class not given] (France). (3) Field leaching studies: C (France). (4) Lysimeter studies: C (France, Germany, Greece). (5) Study of accumulation: C (Norway).

Question 4

Q. 4 - From Table 1: Persistence	SUMMARY
For the studies identified in Question 3, **specify the endpoints**, e.g., DT50, and the corresponding values, e.g., = 6 months, **that would trigger** a request for **additional studies**.	(1) It was assumed that no response indicated that these studies were not required or that there were no triggers for additional studies. The specific endpoint was not always identified by the responding country. (2) Additional data requirements are determined on a case-by-case basis using expert judgement. Factors such as exposure, intended use pattern, or concerns with a formulation may trigger the need for further data (Australia, Canada).
ENVIRONMENTAL FATE	
Solubility	(1) One country indicated that this study could trigger additional studies (1 Yes). (2) Yes: Norway.
Vapour Pressure	(1) 1 Yes. (2) Norway.
Dissociation Constant	no comments
Octanol/Water Partition Coefficient	no comments
UV/Visible Absorption Spectra	no comments
Hydrolysis	(1) 1 Yes. (2) Norway.
Phototransformation	no comments
Soil	(1) 1 Yes. (2) Norway.
Water	(1) 1 Yes. (2) Norway.
Air	no comments
Biotransformation in Soil	(1) No precise trigger for further studies but for restrictions in use at a certain degree of persistence (see Q.9); often the response to this is to submit higher tier data, like field studies (Sweden).
Aerobic (20-30°C)	(1) 6 Yes. (2) Czech Republic, France, Greece, Hungary, Norway, United Kingdom. (3) From Q.3 - aerobic metabolism in soil must be specified if soil contamination cannot be excluded (Czech Republic). (4) Non-extractable residues >70% and CO_2 <5% in 100 days (France). (5) DT50 >2 months (Greece). (6) DT50, DT90 in 3 soils (Norway). (7) $DT50_{lab}$ (@20°C) >60 days (United Kingdom).
Aerobic (3-8°C)	(1) 3 Yes. (2) France, Greece, Norway (3) $DT50_{lab}$ >60 d (@20°C), $DT50_{lab}$ >90 d (@10°C) (France). (4) DT50 >3 months (Greece). (5) DT50, DT90 in 1 soil (Norway). (6) No precise trigger for further studies but for restrictions in use at a certain degree of persistence (see Q.9); often the response to this is to submit higher tier data, like field studies (Sweden).
Anaerobic (20-30°C)	(1) 4 Yes. (2) Czech Republic, Hungary, Norway, United Kingdom. (3) From Q.3 - anaerobic metabolism in soil must be specified if anaerobic conditions cannot be excluded (Czech Republic). (4) DT50, DT90 (Norway). (5) Conditional on use pattern (United Kingdom).
Anaerobic (3-8°C)	(1) No precise trigger for further studies but for restrictions in use at a certain degree of persistence (see Q.9); often the response to this is to submit higher tier data, like field studies (Sweden).
Biotransformation in Water	(1) 2 Yes. (2) France, Norway. (3) >70% or >60% (France). (4) Readily biodegradable (Norway).
Aerobic (20-30°C)	(1) 1 Yes. (2) Norway. (3) Readily biodegradable (Norway).
Aerobic (3-8°C)	no comments
Biotransformation in Water/Sediment	(1) 1 Yes. (2) Norway.
Aerobic (20-30°C)	(1) 1 Yes. (2) Norway.
Anaerobic (3-8°C)	no comments
Anaerobic (20-30°C)	(1) 1 Yes. (2) Norway.
Adsorption/Desorption	(1) 1 Yes. (2) Norway. (3) Kd, Koc for 4 soils (Norway).
Soil Column Leaching	(1) 1 Yes. (2) Norway. (3) % radioactivity in leachate (Norway).
Unaged Soil	(1) 1 Yes. (2) Norway. (3) % radioactivity in leachate (Norway).
Aged Soil	(1) 1 Yes. (2) Norway. (3) % radioactivity in leachate. R if specific adsorption/ desorption studies have not been conducted on the metabolites (Norway).
Soil TLC Leaching	no comments
Volatilization	no comments

Q. 4 - From Table 1: Persistence	SUMMARY
Field Studies of Dissipation/ Accumulation	(1) 8 Yes. (2) Czech Republic, France, Germany, Greece, Hungary, Japan, Norway, United Kingdom. (3) From Q.3 – terrestrial field studies necessary if $DT90_{lab}$ >100 days (Czech Republic, Hungary). (4) Required when $DT50_{lab}$ >60 days (@20°C) or $DT50_{lab}$ >90 days (@10°C) (Czech Republic, Germany, Greece). (5) Terrestrial Dissipation - $DT50_{lab}$ @10°C >90 days (France). (5) Terrestrial Accumulation - $DT90_{field}$ >1 year (France, Germany, United Kingdom). (6) DT50 >1 year (Japan). (7) Terrestrial - DT50, DT90, usually for 4 soils if $DT50_{lab}$ >60 d or if $DT50_{lab}$ @ 10°C >90 d (Norway).
Small Scale	
Terrestrial	(1) 5 Yes. (2) Czech Republic, Greece, Hungary, Japan, United Kingdom. (3) 100 m^2 (Greece). (4) DT50 >1 year or longer (Japan). (5) $DT90_{field}$ >1 year (United Kingdom).
Aquatic	(1) 2 Yes. (2) Greece, Japan. (3) 1 m^2 x 0.30 m (Greece). (4) DT50 >1 year or longer in soil (for paddy fields) (Japan).
Large Scale	
Terrestrial	(1) 2 Yes. (2) Czech Republic, Hungary.
Aquatic	no comments
Other Studies:	(1) Field leaching studies and lysimeter studies: expert judgement (France). (2) Hungary (studies not specified). (3) Study of Accumulation: In two fields if $DT90_{field}$ >1 year (Norway).

Question 5a

R = Required data, C = Conditional data

Q. 5a - From Table 1: Persistence	SUMMARY
Indicate in Table 1 the **studies** you require **to determine persistence** of the: **(a) major metabolites.**	(1) Specific study requirements submitted by 10 countries: Czech Republic, France, Germany, Greece, Hungary, Japan, Norway, Sweden, United Kingdom, United States. (2) Other comments from Australia, Canada, and Czech Republic. (3) No formal requirements. Persistence is assessed on a case-by-case basis, depending on various factors, using expert judgement (Australia, Canada). (4) "Major" and "minor" are understood as "relevant" and "irrelevant", respectively (Czech Republic).
ENVIRONMENTAL FATE	
Solubility	(1) 1 C (2) Japan.
Vapour Pressure	(1) 2 C (2) Japan, United States.
Dissociation Constant	(1) 1 C (2) United States.
Octanol/Water Partition Coefficient	(1) 2 C (2) Japan, United States.
UV/Visible Absorption Spectra	no comments
Hydrolysis	(1) 3 Yes, 1 R, 2C (2) Yes: Norway, Sweden, United Kingdom. R: Germany. C: Japan, United States.
Phototransformation	(1) 3 Yes, 1 C (2) Yes: France, Japan, Norway. C: United States.
Soil	(2) 2 Yes, 1 C (2) Yes: France, Norway. C: United States.
Water	(1) 2 Yes, 1 C (2) Yes: Japan, Norway. C: United States.
Air	(1) 1 C (2) C: United States.
Biotransformation in Soil	(1) 9 Yes, 1 C (2) Yes: Czech Republic, France, Germany, Greece, Hungary, Japan, Norway, Sweden, United Kingdom. C: United States.
Aerobic (20-30°C)	(1) 5 Yes, 4 C, 1 R (2) Yes: Czech Republic, Norway, Sweden, United Kingdom, France @ 20°C. R: Greece, Hungary, Japan, Germany @ 20°C. C: United States
Aerobic (3-8°C)	(1) 1 Yes, 1 R/C (2) Yes: France specified 10°C. R/C: Greece
Anaerobic (20-30°C)	(1) 2 Yes, 1 R, 1 C, 1 R/C. (2) Yes: Czech Republic, France @ 20°C. R: Hungary. C: Japan. R/C: Greece.
Anaerobic (3-8°C)	(1) 1 R/C. (2) R/C: Greece.
Biotransformation in Water	(1) 1 R, 1 C, 1R/C. (2) R: Greece. C: Japan. R/C: Greece.
Aerobic (20-30°C)	(1) 1 R (2) R: Greece.
Aerobic (3-8°C)	(1) 1 R/C (2) R/C: Greece.
Biotransformation in Water/Sediment	(1) 2 R, 1 C, 1 R/C. (2) R: Germany, Greece. C: United States. R/C: Greece.

Q. 5a - From Table 1: Persistence	SUMMARY
Aerobic (20-30°C)	(1) 2 R, 1C. (2) R: Germany, Greece. C: United States.
Anaerobic (3-8°C)	(1) 1 R/C, 1 C (2) R/C: Greece. C: United States.
Anaerobic (20-30°C)	(1) 1 R/C (2) R/C: Greece.
Adsorption/Desorption	(1) 3 Yes, 1 R, 3 C (2) Yes: Norway (3 soils), Sweden, United Kingdom. R: United States. C: Greece, Hungary, Japan.
Soil Column Leaching	(1) 1 R, 1 C (2) R: United States. C: Greece.
Unaged Soil	(1) 1 R, 1 C (2) R: United States. C: Greece.
Aged Soil	(1) 1 R, 1 C (2) R: United States. C: Greece.
Soil TLC Leaching	(1) 1 C (2) C: Greece.
Volatilization	(1) 2 C (2) C: Greece, United States.
Field Studies of Dissipation/ Accumulation	(1) 3 Yes, 1 R, 1C (2) Yes: Czech Republic, Norway (terrestrial studies only), United Kingdom. R: Japan. C: Germany.
Small Scale	
Terrestrial	(1) 1 Yes, 1 R, 1C (2) Yes: United Kingdom. R: Japan. C: Germany (no size specified).
Aquatic	(1) 1 R, 1 C (2) R: Japan (for paddy fields). C: Germany (no size specified).
Large Scale	
Terrestrial	no comments
Aquatic	no comments
Other Studies:	(1) 1 C (2) C: Germany (outdoor lysimeter studies)**.**

Question 5b

R = Required data, C = Conditional data

Q. 5b - From Table 1: Persistence	SUMMARY
Indicate in Table 1 the **studies** you require **to determine persistence** of the: **(b) minor metabolites**.	(1) Specific study requirements submitted by France, Germany, and United States. (2) Other comments from Australia, Canada, and Czech Republic. (3) No formal requirements. Metabolite persistence is assessed on a case by case basis, depending on various factors including mobility, toxicity and bioaccumulation potential (Australia). (4) Additional studies are not requested unless a concern is identified by the applicant or from other submitted studies. Therefore, there are no formal data requirements, but additional studies may be requested if minor transformation products are identified to be of toxicological concern (Canada). (5) "Major" and "minor" are understood as "relevant" and "irrelevant", respectively (Czech Republic).
ENVIRONMENTAL FATE	
Solubility	
Vapour Pressure	(1) 1 C (2) C: United States.
Dissociation Constant	(1) 1 C (2) C: United States.
Octanol/Water Partition Coefficient	(1) 1 C (2) C: United States.
UV/Visible Absorption Spectra	
Hydrolysis	(1) 1 C (2) C: United States.
Phototransformation	(1) 1 C (2) C: United States.
Soil	(1) 1 C (2) C: United States.
Water	(1) 1 C (2) C: United States.
Air	(1) 1 C (2) C: United States.
Biotransformation in Soil	(1) 2 C (2) C: Germany, United States.
Aerobic (20-30°C)	(1) 2 C (2) C: Germany @20°C, United States.
Aerobic (3-8°C)	
Anaerobic (20-30°C)	

Q. 5b - From Table 1: Persistence	SUMMARY
Anaerobic (3-8°C)	
Biotransformation in Water	
Aerobic (20-30°C)	
Aerobic (3-8°C)	
Biotransformation in Water/Sediment	(1) 1 C (2) C: United States.
Aerobic (20-30°C)	(1) 1 C (2) C: United States.
Anaerobic (3-8°C)	(1) 1 C (2) C: United States.
Anaerobic (20-30°C)	
Adsorption/Desorption	(1) 1 C (2) C: United States.
Soil Column Leaching	(1) 1 C (2) C: United States.
Unaged Soil	(1) 1 C (2) C: United States.
Aged Soil	
Soil TLC Leaching	
Volatilization	(1) 1 C (2) C: United States.
Field Studies of Dissipation/ Accumulation	
Small Scale	
Terrestrial	
Aquatic	
Large Scale	
Terrestrial	
Aquatic	
Other Studies:	(1) Identification if relevant for (eco)toxicity (France).

Question 13

Q. 13 - From Table 1: Persistence	SUMMARY
Indicate the **endpoints** required **for input** into this (these) persistence model(s)?	(1) Comments from Czech Republic only. (2) All data, including those concerning persistence, must be supported by the applicant. The results of computer models are accepted [no other comment] (Czech Republic).
ENVIRONMENTAL FATE	
Solubility	
Vapour Pressure	
Dissociation Constant	
Octanol/Water Partition Coefficient	
UV/Visible Absorption Spectra	
Hydrolysis	
Phototransformation	
Soil	
Water	
Air	
Biotransformation in Soil	
Aerobic (20-30°C)	
Aerobic (3-8°C)	

Q. 13 - From Table 1: Persistence	SUMMARY
Anaerobic (20-30°C)	
Anaerobic (3-8°C)	
Biotransformation in Water	
Aerobic (20-30°C)	
Aerobic (3-8°C)	
Biotransformation in Water/Sediment	
Aerobic (20-30°C)	
Anaerobic (3-8°C)	
Anaerobic (20-30°C)	
Adsorption/Desorption	
Soil Column Leaching	
Unaged Soil	
Aged Soil	
Soil TLC Leaching	
Volatilization	
Field Studies of Dissipation/ Accumulation	
Small Scale	
Terrestrial	
Aquatic	
Large Scale	
Terrestrial	
Aquatic	
Other Studies:	

Question 23

R = Required data, C = Conditional data

Q. 23 - From Table 2: Bioaccumulation	SUMMARY
For a pesticide that would be used on a terrestrial crop, indicate which of the **studies** listed in Table 2 are currently required by your regulatory authority **to determine bioaccumulation**? Indicate which studies are classified as Required (R) and those that are classified as Conditional (C), i.e., requested on the basis of an endpoint from another study.	(1) Australia: The only study required at this time is bioaccumulation in fish, but this may be waived for an obviously low risk substance. Other studies could be requested on a case by case basis.
BIOACCUMULATION STUDIES	
Laboratory Studies	
Fish (specify species)	(1) 2 R, 1 R/C, 7 C (2) R: Australia, France. R/C: Norway. C: Canada, Czech Republic, Germany, Greece, Sweden, United Kingdom, United States. (3) Species not specified by most countries, with the exception of *Lepomis macrochirus* / Bluegill sunfish by Greece and United States.
Earthworms (specify species)	(1) 2 C (2) C: Greece, United Kingdom. (3) *Eisenia foetida* specified by Greece. (4) species not specified by United Kingdom.
Field Studies (specify species studies)	(1) 3 C (2) C: Greece, United Kingdom, United States. (3) Greece conditionally requires studies with soil organisms and organic matter breakdown. (4) Species not specified by United Kingdom or United States.
Other studies:	(1) Bivalve or crustacean: C (Canada). (2) Birds: R (France, Germany - toxicokinetic studies). (3) Mammals - toxicokinetic studies: R (Germany). (4) Laboratory test on *Collembola* reproduction: C (Greece).

Question 24

Q. 24 - From Table 2: Bioaccumulation	SUMMARY
For the studies identified in Question 23, specify the **endpoints** and the corresponding values, e.g., DT50, = 6 months and BCF = 1000, that would **trigger** a request for **additional studies**.	(1) There are no formal trigger criteria. Exposure is a key consideration in determining the need for additional data (Australia). (2) No criteria have been established to trigger the need for additional data beyond the initial study. This would be decided case by case, based on other data and expert judgement (Canada). (3) Bioaccumulation is not officially defined yet. In accordance with the new Plant Protection Regulation the pesticide is qualified bioaccumulative if the DT50 >=6 month and P_{ow} >=1000 (Hungary).
BIOACCUMULATION STUDIES	
Laboratory Studies	
Fish (specify species)	(1) BCF >1000 combined with toxicity / exposure ratios (France). (2) Log P_{ow} >= 3, DT90 >100 days, multiple applications - short interval (Greece). (3) Log P_{ow} >= 3 (Czech Republic, Norway, Sweden). (4) Depends on log K_{ow} (United Kingdom). (5) No species specified.
Earthworms (specify species)	(1) $DT90_{field}$ >365 days, Number of applications >6 (Greece). (2) Depends on risk assessment and profile of the compound (United Kingdom). (3) No species identified.
Field Studies (specify species studies)	(1) Soil organisms: $DT90_{field}$ >365 days, BCF >1000 (Greece). (2) Organic matter breakdown: $DT90_{field}$ >365 days (Greece). (3) Depends on risk assessment and profile of the compound (United Kingdom). (4) No species identified.
Other studies:	(1) Birds: BCF >1 combined with toxicity / exposure ratios (France). (2) Laboratory test on *Collembola* reproduction (in case-by-case decision): not yet specified - draft guideline edited by ISO (Greece).

Question 25

Q. 25 - From Table 2: Bioaccumulation	SUMMARY
What **endpoints** are **derived from the studies** in Question 23, e.g., bioaccumulation factor (BAF), etc.?	
BIOACCUMULATION STUDIES	
Laboratory Studies	
Fish (specify species)	(1) BCF (Canada, Czech Republic, Germany, Greece, Norway, Sweden, United Kingdom, United States). (2) Rate of depuration (Canada, United States). (3) Clearance time (Germany, United Kingdom). (3) DT50 for depuration (Norway). (4) Depuration time and plateau level (United Kingdom). (5) Concentration in tissues (United States).
Earthworms (specify species)	(1) Evaluate effects in field conditions or could use models (case-by-case) (Greece). (2) Concentration in earthworms (United Kingdom).
Field Studies (specify species studies)	(1) Depends on the species or concern (United Kingdom).
Other studies:	no comments

Question 41

R = Required data, C = Conditional data

Q. 41 - From Table 3: Toxicity	SUMMARY
For a pesticide that would be used on a terrestrial crop, indicate which of the **studies** listed in Table 3 are currently required by your regulatory authority **to determine toxicity**? Indicate which studies are classified as Required (R) and those that are classified as Conditional (C), i.e., requested on the basis of an endpoint from another study.	(1) Table 3 is consistent with Australian data requirements. Requirements are flexible, depending on the exposure profile and other factors (Australia). (2) The need for certain studies and the associate criteria are closely related to the use of the product, its toxicity, and the potential exposure of non-target organisms. The criteria are all outline in Annex II and III of 91/414/EC. This is also true for data on major metabolites, however, regarding minor metabolites, no data are generally required, unless information from other parts of the dossier indicate that it may be highly toxic, etc. (United Kingdom).
ENVIRONMENTAL TOXICOLOGY	
Earthworm Acute Toxicity (specify species)	(1) Earthworm acute toxicity study is R by all countries, except Australia, Japan, and United States. (2) Species not usually identified although *Eisenia foetida* specified by 2 countries (Czech Republic, Hungary). (3) Earthworm sublethal is C by France. (4) Earthworm reproduction is C by Germany.
Bees/Pollinators	(1) 2 R, 3 C, 5 R&C (2) R: Japan, Sweden. C: Canada, United Kingdom, United States. R&C: Czech Republic, Germany, Greece, Hungary, Norway.
Acute Contact	(1) 7 R, 3 C (2) R: Czech Republic, Germany, Greece, Hungary, Japan, Norway, Sweden. C: Canada, United Kingdom, United States.
Acute Oral	(1) 7 R, 2 C (2) R: Czech Republic, Germany, Greece, Hungary, Japan, Norway, Sweden. C: Canada, United Kingdom.
Hive Study (including brood)	(1) 1 R, 7 C (2) R: Japan. C: Canada, Czech Republic, Germany, Greece, Hungary, Norway, United Kingdom.
Predators (if specific species required, please list)	(1) 7 R, 2 C (2) R: Czech Republic, France, Germany, Greece, Hungary, Japan, Norway. C: Canada, United Kingdom. (3) Predatory mite is specified for Czech Republic, Germany, Greece, Norway, with Germany and Greece specifying *Typhlodromus pyri*. (4) "Spider, etc." specified by Japan.
Parasites (if specific species required, please list)	(1) 5 R, 2 C (2) R: France, Germany, Greece, Norway. C: Canada, United Kingdom. (3) Parasitoid wasp (Czech Republic, Norway). (4) *Aphidius rhopalosiphi* (Germany). (5) *A. rhopalosiphi* (Greece).
Other Terrestrial Invertebrates (please list)	(1) 3 R, 4 C (2) R: Czech Republic, Greece, Norway. C: Canada, Germany, Sweden, United Kingdom. (3) Two additional beneficial arthropod species relevant to the intended use of product (Czech Republic). (4) R: Ground dwelling predators (i.e., *P. cupreus, A. bilineata*) (Greece). (4) R: Foliage dwelling predators (i.e., *E. baleatus, C. septempunctata*) (Greece). (5) R: 2 additional arthropod species relevant to the area of use (Norway). (6) R: soil microorganisms (Norway). (7) C: two other species, *e.g., Coccinella septempunctata, Chrysoperla carnea, Trichogramma cacoeciae, Aleochara bilineata, Peocilus cupreus* (Germany).
***Daphnia* sp.** Acute	(1) 10 R, 1 C (2) R: Canada, Czech Republic, France, Germany, Greece, Japan, Norway, Sweden, United Kingdom, United States. C: Hungary. (3) France requires substance + preparation.
***Daphnia* sp.** Chronic (Life-Cycle)	(1) 5 R, 4 C (2) R: Czech Republic, Germany, Greece, Norway, Sweden. C: Canada, Hungary, United Kingdom, United States.
Other Aquatic Invertebrates (please list)	(1) 7 C (2) C: Canada, Czech Republic, Germany, Greece, Hungary, Norway, United Kingdom. (3) C: Sediment dwellers (Czech Republic, Germany, Norway), specifically *Chironomus riparius* (Greece). (4) C: *Gammarus* sp. (Germany). (5) C: *Thamnocephalus* sp. (Hungary).
Non-target Marine Invertebrates	(1) 2 C (2) C: Canada, Greece.
Acute (Crustacean)	(1) 2 C (2) C: Canada, Greece.
Mollusk embryo larvae	(1) 2 C (2) C: Canada, Greece.
Mollusk shell deposition	(1) 3 C (2) C: Canada, Greece, United States.
Chronic (Mollusk or Crustacean)	(1) 2 C (2) C: Canada, Greece.
Bioconcentration/ Depuration (Bivalve or Crustacean)	(1) 2 C (2) C: Canada, Greece.
Acute Fish Studies	(1) 7 R, 2 R&C, 1 R/C, 1 R and no classification (2) R: Czech Republic, Germany, Greece, Japan, Norway, Sweden, United Kingdom. R&C: Canada, United States. R/C: Hungary. R and no classification: France.
Cold Water (*Onchorynchus mykiss*)	(1) 8 R, 1 R/C (2) R: Canada, Czech Republic, France, Germany, Greece, Norway, United Kingdom, United States. R/C: Hungary. (3) France requires substance + preparation.

Q. 41 - From Table 3: Toxicity	SUMMARY
Other cold water (specify species)	no comments
Warm Water (*Lepomis macrochirus*)	(1) 7 R (2) R: Canada, Czech Republic, France, Germany, Greece, United Kingdom, United States. (3) *L. macrochirus* or *Cyprinus carpio* (Czech Republic). (4) R for substance (France).
Other warm water (specify species)	(1) 2 R, 1 R/C, species indicated but no classification by France (2) R: Czech Republic, Japan. R/C: Hungary. (3) *Cyprinus carpio* (Czech Republic, Hungary, Japan). (4) Bluegill (France).
Marine/Estuarine Fish (specify species)	(1) 2 C (2) C: Canada, United States. (3) Species not provided.
Other fish species (please list)	(1) 1 C, 1 R/C (2) C: Canada. R/C: Hungary. (3) *Brachidanio rerio* (Hungary).
Salinity Challenge (species used)	(1) 1 C (2) C: Canada. (3) Species not provided.
Sublethal and Chronic Fish Studies	(1) 1 R, 8 C (2) R: Greece. C: Canada, Czech Republic, France, Germany, Norway, Sweden, United Kingdom, United States.
Early Life Cycle Toxicity Test	(1) 8 C (2) C: Canada, Czech Republic, France, Germany, Greece, Norway, United Kingdom, United States.
Life Cycle Toxicity Test	(1) 8 C (2) C: Canada, Czech Republic, France, Germany, Greece, Norway, United Kingdom, United States.
Acute Bird Studies	(1) 7 R, 1 C, 1 R and C, 1 No classification (2) R: Czech Republic, Germany, Greece, Hungary, Norway, Sweden, United Kingdom, United States. C: Canada. R and C: Hungary. No classification: France.
Oral (LD50)	(1) 8 R, 1 C, 1 No classification (2) R: Czech Republic, Germany, Greece, Hungary, Norway, Sweden, United Kingdom, United Kingdom. C: Canada. No classification: France. (3) *Anas platyrhynchos* or *Colinus virginianus* (Norway).
Anas platyrhynchos	(1) 6 R (2) R: Canada, Czech Republic, Germany, Greece, Hungary, Norway. (3) May be replaced by study with *Colinus virginianus* (Canada, Czech Republic, Norway).
Colinus virginianus	(1) 5 R (2) R: Canada, Czech Republic, Germany, Greece, Norway. (3) May be replaced by study with *Anas platyrhnchos* (Canada, Czech Republic, Norway).
Other (specify)	(1) 1 C, 1 R/C, 1 No classification (2) C: Canada. R/C: Hungary. No classification: France. (3) *Colinus coturnix* (France). (4) *Coturnix coturnic, Phasianus* (Hungary).
Dietary (LC50)	(1) 4 R, 3 C, 2 R&C (2) R: Greece, Norway, United Kingdom, United Kingdom. C: Czech Republic, Hungary, Sweden. R&C: Canada, Germany. (3) *Anas platyrhynchos* or *Colinus virginianus* (Norway).
Anas platyrhynchos	(1) 3 R, 3 C (2) R: Canada, Greece, Norway. C: Czech Republic, Germany, Hungary. (3) May be replaced by study with *Colinus virginianus* (Czech Republic, Norway).
Colinus virginianus	(1) 4 R, 1 C (2) R: Canada, Germany, Greece, Norway. C: Czech Republic. (3) May be replaced by study with *Anas platyrhnchos* (Czech Republic, Norway).
Other (specify)	(1) 2 C (2) C: Canada, Hungary. (3) *Coturnix coturnic, Phasianus* (Hungary).
Chronic Bird Studies	(1) 2 R, 7 C, 1 R/C (2) R: Canada, Greece. C: Czech Republic, France, Germany, Norway, Sweden, United Kingdom, United States. R/C: Hungary.
Avian Reproduction (specify species)	(1) 2 R, 6 C, 1 R/C (2) R: Canada, Greece. C: France, Germany, Norway, Sweden, United Kingdom, United States. R/C: Hungary. (3) On the more sensitive species in acute studies (France). (4) *Anas, Coturnix, Phasianus* (Hungary).
Wild mammals (specify species)	(1) 1 C, 3 based on human toxicity studies (2) C: Czech Republic. Based on human toxicity studies: Canada, France, Hungary. (3) *Lepus europeus* (Hungary).
Freshwater Algae Acute Toxicity	(1) 6 R, 1 C, 3 R&C (2) R: Czech Republic, France, Norway, Sweden, United Kingdom, United States. C: Hungary. R&C: Canada, Germany, Greece. (3) Sweden does not specify the particular species to be tested.
Selenastrum capricornutum	(1) 5 R, 1 C (2) R: Canada, Czech Republic, France, Germany, Greece. C: Hungary. (3) France requires substance + preparation. (4) Canada accepts other species of green algae. (5) *Scenedesmus subspicatus* is alternate species (Czech Republic).
Anabaena flos-aquae	(1) 1 R, 3 C (2) R: Canada. C: Germany, Greece, Hungary. (3) Canada accepts other species of blue-green algae.
Navicula pelliculosa	(1) 1 R, 2 C (2) R: Canada. C: Germany, Greece. (3) Canada accepts other diatom species.
Other (if specific species required, please list)	(1) 2 R, 2 C (2) R: Czech Republic, France. C: Canada, Hungary. (3) *Scenedesmus subspicatus* (Czech Republic, France) or *Scenedesmus* sp. (Hungary). (4) Czech Republic accepts *S. subspicatus* or *Selenastrum capricornutum.* (5) France requires substance + preparation.

Q. 41 - From Table 3: Toxicity	SUMMARY
Marine Algae (if specific species required, please list)	(1) 1 C (2) C: Canada.
Terrestrial Vascular Plants	(1) 3 R, 2 C (2) R: Canada, United Kingdom, United States. C: Germany, Greece.
Vegetative vigour	(1) 1 R, 1 C (2) R: Canada C: Greece.
Seedling emergence	(1) 1 R (2) R: Canada.
Aquatic Vascular Plants Acute Toxicity	(1) 2 R, 7 C (2) R: Canada, United States. C: France, Germany, Greece, Hungary, Norway, Sweden, United Kingdom.
Lemna gibba	(1) 1 R, 6 C (2) R: Canada. C: Czech Republic, France, Germany, Greece, Hungary, Sweden. (3) No particular species requirement (Canada). (4) For herbicides only (France).
Other (if specific species required, please list)	
Field Studies	(1) 3 C, 1 R/C (2) C: Canada, Germany, United Kingdom. R/C: Hungary. (3) Studies with bees (Hungary).
Other Studies	(1) 4 C, 1 No classification (2) C: Canada, Czech Republic, Germany, Sweden. No classification: France. (3) C: Field studies with bees and/or other pollinators (Czech Republic, France, Sweden). (4) C: Micro-, Mesocosms (Czech Republic, Germany, Sweden). (5) C: Other extended lab studies (Germany).

Question 42

Q. 42 - From Table 3: Toxicity	SUMMARY
For **studies identified** in Question 41 that are **Conditional**, indicate the **criteria**, e.g., DT50, LC50, and the corresponding values, e.g., >6 months, <5 mg/L, **for conducting** these toxicity studies?	(1) Specific criteria were not identified by each responding country. (2) Rigid criteria have not been established and are not favoured (Australia). (3) No strict criteria are used. Studies are, generally, conditionally required based on toxicological concerns from other studies and the potential for exposure (Canada). (4) The need for certain studies and the associate criteria are closely related to the use of the product, its toxicity and the potential exposure of non-target organisms. The criteria are all outline in Annex II and III of 91/414/EC (United Kingdom).
ENVIRONMENTAL TOXICOLOGY	
Earthworm Acute Toxicity (specify species)	(1) 2 responses: France, Hungary. (2) Not required if toxicity can be extrapolated from the study on the substance (France). (3) LC50 (*Eisenia foetida*) (Hungary).
Bees/Pollinators	
Acute Contact	(1) 3 responses: Hungary, United Kingdom, United States. (2) LD50 (Hungary). (3) Depends on the usage of the product and the likelihood of exposure, see Annex II of 91/414 for areas where data are not required (United Kingdom). (4) Possible exposure (United States).
Acute Oral	(1) 2 responses: Hungary, United Kingdom. (2) LD50 (Hungary). (3) Depends on the usage of the product and the likelihood of exposure, see Annex II of 91/414 for areas where data are not required (United Kingdom).
Hive Study (including brood)	(1) 6 responses: Czech Republic, Germany, Greece, Hungary, Norway, United Kingdom. (2) For insect growth regulators (Czech Republic, Germany, Greece, Hungary, Norway). (3) Colony life conditions (Hungary). (4) Depends on exposure as well as whether the compound is an insect growth regulator (United Kingdom).
Predators (if specific species required, please list)	no comments
Parasites (if specific species required, please list)	no comments
Other Terrestrial Invertebrates (please list)	(1) 1 response: Sweden. (2) When laboratory studies on bees indicate high risk (Sweden).
***Daphnia* sp.** Acute	(1) 1 response: Hungary. (2) LC50 48 h (Hungary).
***Daphnia* sp.** Chronic (Life-Cycle)	(1) 3 responses: Hungary, United Kingdom, United States. (2) EC50 21 d (Hungary). (3) DT50 >2 days from a sediment water study (United Kingdom). (4) LC50 <1 ppm, persistent (United States).

Q. 42 - From Table 3: Toxicity	SUMMARY
Other Aquatic Invertebrates (please list)	(1) 6 responses: Czech Republic, Germany, Greece, Hungary, Norway, United Kingdom. (2) Sediment dwellers - if (a) the product is to be used direct in water, (b) a.i. is persistent in water or sediment, (c) a.i. is of high toxicity to daphnids (NOEC <0.1 mg/L) (Czech Republic). (3) Sediment dwellers: >10% ads. to sediment (14 d) + NOEC Daphnia <0.1 mg/L (Germany). (4) Sediment/ water study day 14 >10% (Greece). (5) *Chironomus riparius*: NOEC <0.1 mg/L in chronic Daphnia test of TER based risk assessment (Greece). (6) LC50 24 h (*Thamnocephalus* sp.) (Hungary). (7) Sediment dwelling organisms: if it is likely that the substance partitions into sediment and is persistent in sediment. EC50 (Norway). (8) Further data may be required if the product is to be used in or near water - see Annex II 8.2.4 of 91/414 for further details (United Kingdom).
Non-target Marine Invertebrates	(1) 1 response: Greece. (2) When use directly on surface water (Greece).
Acute (Crustacean)	(1) 1 response: Greece. (2) When use directly on surface water (Greece).
Mollusk embryo larvae	(1) 1 response: Greece. (2) When use directly on surface water (Greece).
Mollusk shell deposition	(1) 2 responses: Greece, United States. (2) When use directly on surface water (Greece).(3) Possible marine exposure (United States).
Chronic (Mollusk or Crustacean)	(1) 1 response: Greece. (2) When use directly on surface water (Greece).
Bioconcentration/ Depuration (Bivalve or Crustacean)	(1) 1 response: Greece. (2) When use directly on surface water (Greece).
Acute Fish Studies	
Cold Water (*Onchorynchus mykiss*)	(1) 1 response: Hungary. (2) LC50 96 h (Hungary).
Other cold water (specify species)	no comments
Warm Water (*Lepomis macrochirus*)	no comments
Other warm water (specify species)	(1) 1 response: Hungary. (2) LC50 96 h (*Cyprinus carpio*) (Hungary).
Marine/Estuarine Fish (specify species)	(1) 1 response: United States. (2) Possible marine exposure - no species provided (United States).
Other fish species (please list)	(1) 1 response: Hungary. (2) LC50 96 h (*Brachidanio rerio*) (Hungary).
Salinity Challenge (species used)	no comments
Sublethal and Chronic Fish Studies	(1) 7 responses: France, Czech Republic, Germany, Greece, Norway, Sweden, United Kingdom. (2) Expert judgement (France). (3) Various endpoints (Czech Republic, Germany, Greece). (4) If continuous or repeated exposure is likely, or if micro- or macrocosm studies are not available (Norway). (5) Case-by-case basis depending on exposure and ecotoxicological risk profile (Sweden). (6) Data on the chronic toxicity to fish is dependent upon the fate profile (see reply for *Daphnia*). Further information is provided in Annex II point 8.2.2 of 91/414 (United Kingdom).
Early Life Cycle Toxicity Test	(1) 6 responses: Czech Republic, France, Germany, Greece, Norway, United States. (2) log Pow >3, LC50 <0.1 mg/L (Czech Republic). (3) Expert judgement (France). (4) BCF >100 or EC50 <0.1 mg/L (Germany). (5) Chronic test on juvenile fish. LC50 acute <0.1 mg/L (Greece). (6) Suitable when BCF is 100 to 1000, and when EC50 is <0.1 mg/L (Norway). (7) LC50 <1 ppm, possible exposure (United States).
Life Cycle Toxicity Test	(1) 6 responses: Czech Republic, France, Germany, Greece, Norway, United States. (2) log Pow >3, DT90 in water or sediment >100 days (Czech Republic). (3) Expert judgement (France). (4) BCF >1000 and ct95 >14 d, DT90 >100 d + EC50 <0.1 mg/L (Germany). (5) BCF >1000, 14 day depuration <95%, DT90 >100 days (Greece). (6) BCF >1000 and depuration in 14 days is less than 95%, or when DT90 >100 d in water or sediment (Norway). (7) LC50 <1 ppm, possible exposure (United States).
Acute Bird Studies	(1) 3 responses: Hungary, Sweden, United Kingdom. (2) In case repeated exposure may occur in the field (Sweden). (3) Depends on exposure during the breeding season (United Kingdom).
Oral (LD50)	no comments
Anas platyrhynchos	(no comments
Colinus virginianus	no comments
Other (specify)	(no comments
Dietary (LC50)	(1) 3 responses: Hungary, Sweden, United Kingdom. (2) When high toxicity is indicated in other toxicity studies (Hungary). (3) In case repeated exposure may occur in the field (Sweden). (4) Depends on exposure during the breeding season (United Kingdom).
Anas platyrhynchos	(1) 1 response: Hungary. (2) When high toxicity is indicated in other toxicity studies (Hungary).
Colinus virginianus	no comments

Q. 42 - From Table 3: Toxicity	SUMMARY
Other (specify)	(1) 1 response: Hungary. (2) *Phasianus* when high toxicity is indicated in other toxicity studies (Hungary).
Chronic Bird Studies	(1) 4 responses: Germany, Hungary, Norway, Sweden. (2) In case repeated exposure may occur in the field (Germany, Norway, Sweden). (3) Hungary - study indicated, but no criteria identified.
Avian Reproduction (specify species)	(1) 4 responses: Germany, Hungary, Norway, Sweden. (2) In case repeated exposure may occur in the field (Germany, Norway, Sweden). (3) *Anas*, *Coturnix*, and *Phasianus* (Hungary).
Wild mammals (specify species)	(1) 1 response: Hungary. (2) *Lepus europeus* (Hungary).
Freshwater Algae Acute Toxicity	(1) 4 responses: Germany, Greece, Hungary, United Kingdom. (2) If herbicides are involved (Germany, Greece, United Kingdom). (3) EC50 72 h (Hungary). (4) Two species of alga are required if the compound is a herbicide (United Kingdom).
Selenastrum capricornutum	(1) 1 response: Hungary. (2) EC50 72 h (Hungary).
Anabaena flos-aquae	(1) 3 responses: Germany, Greece, Hungary. (2) If herbicides are involved (Germany, Greece). (3) EC50 72 h (Hungary).
Navicula pelliculosa	(1) 2 responses: Germany, Greece. (2) If herbicides are involved (Germany, Greece).
Other (if specific species required, please list)	(1) 1 response: Hungary. (2) EC50 72 h (*Scenedesmus* sp.) (Hungary).
Marine Algae (if specific species required, please list)	no comments
Terrestrial Vascular Plants	(1) 2 responses: France, Greece. (2) [From Q. 41 - No] but can be derived from efficacy studies (France). (3) If herbicides are involved (Greece).
Vegetative vigour	(1) 1 response: Greece. (2) If herbicides are involved (Greece).
Seedling emergence	no comments
Aquatic Vascular Plants Acute Toxicity	(1) 8 responses: Czech Republic, France, Germany, Greece, Hungary, Norway, Sweden, United Kingdom. (2) Applies to herbicides only (Czech Republic, France, Germany, Greece, Norway, Sweden, United Kingdom). (3) If plant growth regulator (Greece). (4) EC50 7d (Hungary).
Lemna gibba	(1) 6 responses: Czech Republic, France, Germany, Greece, Hungary, Sweden. (2) Applies to herbicides only (Czech Republic, France, Germany, Greece, Sweden). (3) If plant growth regulator (Greece). (4) EC50 7d (Hungary).
Other (if specific species required, please list)	no comments
Field Studies	(1) 2 responses: Hungary, United Kingdom. (2) Bees (Hungary). (3) Field studies are only requested depending upon the risk (United Kingdom).
Other Studies	(1) 2 responses: Czech Republic, Sweden. (2) Bees: when hazard quotient >50, cage or field studies are required. Arthropods other than bees: when mortality >30%, semi-field or field studies are required (Czech Republic). (3) Field studies on bees or other important pollinators: when laboratory studies indicate a high risk to bees (Sweden).

Question 43a

R = Required data, C = Conditional data

Q. 43a - From Table 3: Toxicity	SUMMARY
Indicate in Table 3 the **studies** you require **to determine toxicity** of the: (a) **Major metabolites**.	(1) Some countries have specific required or conditionally required studies (see below). (2) For the Czech Republic, major is interpreted as relevant. (3) Need for studies on the major metabolite depends on factors such as exposure (Australia). (4) The request for additional studies is determined on a case by case basis, based on its mode of action, toxicological concerns, persistence, and the potential for exposure. In cases where several forms of an active ingredient may be involved (e.g., an ester form which transforms to an acid form, and both have similar toxicological properties), partially due to formulation properties, a full data package would be required for each compound (Canada). (5) In general, the same set of toxicity test[s] should be submitted as for an active substance. However, if acute tests with a.i. shows that one taxonomic group is clearly the most sensitive, testing on the metabolite can be restricted to that group (Norway). (6) The need for certain studies and the associate criteria are closely related to the use of the product, its toxicity and the potential exposure of non-target organisms. The criteria are all outlined in Annex II and III of 91/414/EC. This is also true for data on major metabolites (United Kingdom).

Q. 43a - From Table 3: Toxicity	SUMMARY
ENVIRONMENTAL TOXICOLOGY	
Earthworm Acute Toxicity (specify species)	(1) 5 Yes, 2 C. (2) Yes: Czech Republic (Eisenia foetida), Germany, Greece, Norway, United Kingdom. C: Germany, United Kingdom.
Bees/Pollinators	
Acute Contact	
Acute Oral	
Hive Study (including brood)	
Predators (if specific species required, please list)	
Parasites (if specific species required, please list)	
Other Terrestrial Invertebrates (please list)	(1) 2 Yes. (2) Yes: Greece (for ground dwelling predators), Norway (soil microorganisms).
***Daphnia* sp.** Acute	(1) 6 Yes, 2 C. (2) Yes: Czech Republic, Germany, Norway, Sweden, United Kingdom, United States. C: Germany, United Kingdom.
***Daphnia* sp.** Chronic (Life-Cycle)	(1) 4 Yes, 2 C. (2) Yes: Czech Republic, Germany, Norway, United Kingdom. C: Germany, United Kingdom.
Other Aquatic Invertebrates (please list)	(1) 4 Yes, 1 C. (2) Yes: Norway (sediment dwelling organisms), Greece (no species provided), Germany (sediment dwellers, *Gammarus* sp.), United Kingdom (no species provided). C: Germany, United Kingdom.
Non-target Marine Invertebrates	
Acute (Crustacean)	
Mollusk embryo larvae	
Mollusk shell deposition	
Chronic (Mollusk or Crustacean)	
Bioconcentration/ Depuration (Bivalve or Crustacean)	
Acute Fish Studies	(1) 5 Yes, 2 C. (2) Yes: Czech Republic, Germany, Greece, Sweden, United Kingdom. C: Germany, United Kingdom.
Cold Water (*Onchorynchus mykiss*)	(1) 4 Yes, 2 C. (2) Yes: Czech Republic, Germany, Greece, United Kingdom. C: Germany, United Kingdom.
Other cold water (specify species)	(1) 1 C (2) C: United Kingdom (no species provided).
Warm Water (*Lepomis macrochirus*)	(1) 4 Yes, 2 C. (2) Yes:: Czech Republic (or *Cyprinus carpio*), Germany, Greece, United Kingdom. C: Germany, United Kingdom.
Other warm water (specify species)	(1) 1 Yes. (2) Yes: Czech Republic (*Cyprinus carpio* or *Lepomis macrochirus*).
Marine/Estuarine Fish (specify species)	(1) 1 Yes. (2) Yes: United States (no species provided).
Other fish species (please list)	
Salinity Challenge (species used)	
Sublethal and Chronic Fish Studies	(1) 4 Yes, 3 C. (2) Yes: Czech Republic, Germany, United Kingdom, United States. C: Czech Republic, Germany, United Kingdom.
Early Life Cycle Toxicity Test	(1) 4 Yes, 3 C. (2) Yes: Czech Republic, Germany, United Kingdom, United States. C: Czech Republic, Germany, United Kingdom.
Life Cycle Toxicity Test	(1) 2 C (2) C: Czech Republic, Germany.
Acute Bird Studies	(1) 2 Yes, 1 C. (2) Yes: Czech Republic, United Kingdom. C: United Kingdom.
Oral (LD50)	(1) 2 Yes, 1 C. (2) Yes: Czech Republic, United Kingdom. C: United Kingdom. (3) Species not provided for United Kingdom.
Anas platyrhynchos	(1) 1 Yes. (2) Yes: Czech Republic (or *Colinus virginianus*).
Colinus virginianus	(1) 1 Yes. (2) Yes: Czech Republic (or *Anas platyrhnchos*).
Other (specify)	

Q. 43a - From Table 3: Toxicity	SUMMARY
Dietary (LC50)	(1) 2 Yes, 1 C. (2) Yes: Czech Republic, United Kingdom. C: United Kingdom. (3) Species not provided for United Kingdom.
Anas platyrhynchos	(1) 1 Yes. (2) Yes: Czech Republic (or *Colinus virginianus*).
Colinus virginianus	(1) 1 Yes. (2) Yes: Czech Republic (or *Anas platyrhnchos*).
Other (specify)	
Chronic Bird Studies	(1) 2 Yes, 1 C. (2) Yes: Czech Republic, United Kingdom. C: United Kingdom. (3) No further details provided.
Avian Reproduction (specify species)	
Wild mammals (specify species)	(1) 1 Yes. (2) Yes: Czech Republic.
Freshwater Algae Acute Toxicity	(1) 4 Yes, 1 C. (2) Yes: Czech Republic, Greece, Sweden, United Kingdom. C: United Kingdom.
Selenastrum capricornutum	(1) 1 Yes. (2) Yes: Czech Republic (or *Scenedesmus subspicatus*).
Anabaena flos-aquae	
Navicula pelliculosa	
Other (if specific species required, please list)	(1) 1 Yes. (2) Yes: Czech Republic (or *Selenastrum capricornutum*).
Marine Algae (if specific species required, please list)	
Terrestrial Vascular Plants	
Vegetative vigour	
Seedling emergence	
Aquatic Vascular Plants Acute Toxicity	(1) 1 C (2) C: United Kingdom.
Lemna gibba	(1) 1 C (2) C: United Kingdom.
Other (if specific species required, please list)	
Field Studies	(1) 1 C (2) C: United Kingdom.
Other Studies	(1) 1 C (2) C: United Kingdom (studies not provided).

Question 43b

Q. 43b - From Table 3: Toxicity	SUMMARY
Indicate in Table 3 the **studies** you require **to determine toxicity of** the: (b) **Minor metabolites**.	(1) Only Greece requires specific studies (see below). (2) Need for studies with the minor metabolites depends on factors such as exposure (Australia), or if a concern is identified by the applicant or from other submitted studies (Canada, United Kingdom).
ENVIRONMENTAL TOXICOLOGY	
Earthworm Acute Toxicity (specify species)	Greece
Bees/Pollinators	
Acute Contact	
Acute Oral	
Hive Study (including brood)	
Predators (if specific species required, please list)	
Parasites (if specific species required, please list)	
Other Terrestrial Invertebrates (please list)	Greece (for ground dwelling predators)
***Daphnia* sp.** Acute	
***Daphnia* sp.** Chronic (Life-Cycle)	

Q. 43b - From Table 3: Toxicity	SUMMARY
Other Aquatic Invertebrates (please list)	Greece
Non-target Marine Invertebrates	
Acute (Crustacean)	
Mollusk embryo larvae	
Mollusk shell deposition	
Chronic (Mollusk or Crustacean)	
Bioconcentration/ Depuration (Bivalve or Crustacean)	
Acute Fish Studies	Greece
Cold Water (*Onchorynchus mykiss*)	Greece
Other cold water (specify species)	
Warm Water (*Lepomis macrochirus*)	Greece
Other warm water (specify species)	
Marine/Estuarine Fish (specify species)	
Other fish species (please list)	
Salinity Challenge (species used)	
Sublethal and Chronic Fish Studies	
Early Life Cycle Toxicity Test	
Life Cycle Toxicity Test	
Acute Bird Studies	
Oral (LD50)	
Anas platyrhynchos	
Colinus virginianus	
Other (specify)	
Dietary (LC50)	
Anas platyrhynchos	
Colinus virginianus	
Other (specify)	
Chronic Bird Studies	
Avian Reproduction (specify species)	
Wild mammals (specify species)	
Freshwater Algae Acute Toxicity	Greece
Selenastrum capricornutum	
Anabaena flos-aquae	
Navicula pelliculosa	
Other (if specific species required, please list)	
Marine Algae (if specific species required, please list)	
Terrestrial Vascular Plants	
Vegetative vigour	
Seedling emergence	

Q. 43b - From Table 3: Toxicity	SUMMARY
Aquatic Vascular Plants Acute Toxicity	
Lemna gibba	
Other (if specific species required, please list)	
Field Studies	
Other Studies	

Question 50

Q. 50 - From Table 3: Toxicity	SUMMARY
Indicate the **studies** required **for input** into this (these) model(s)?	France was the only country that indicated yes to modelling for toxicity, but did not comment.
ENVIRONMENTAL TOXICOLOGY	
Earthworm Acute Toxicity (specify species)	
Bees/Pollinators	
Acute Contact	
Acute Oral	
Hive Study (including brood)	
Predators (if specific species required, please list)	
Parasites (if specific species required, please list)	
Other Terrestrial Invertebrates (please list)	
***Daphnia* sp.** Acute	
***Daphnia* sp.** Chronic (Life-Cycle)	
Other Aquatic Invertebrates (please list)	
Non-target Marine Invertebrates	
Acute (Crustacean)	
Mollusk embryo larvae	
Mollusk shell deposition	
Chronic (Mollusk or Crustacean)	
Bioconcentration/ Depuration (Bivalve or Crustacean)	
Acute Fish Studies	
Cold Water (*Onchorynchus mykiss*)	
Other cold water (specify species)	
Warm Water (*Lepomis macrochirus*)	
Other warm water (specify species)	
Marine/Estuarine Fish (specify species)	
Other fish species (please list)	
Salinity Challenge (species used)	
Sublethal and Chronic Fish Studies	
Early Life Cycle Toxicity Test	

Q. 50 - From Table 3: Toxicity	SUMMARY
Life Cycle Toxicity Test	
Acute Bird Studies	
Oral (LD50)	
Anas platyrhynchos	
Colinus virginianus	
Other (specify)	
Dietary (LC50)	
Anas platyrhynchos	
Colinus virginianus	
Other (specify)	
Chronic Bird Studies	
Avian Reproduction (specify species)	
Wild mammals (specify species)	
Freshwater Algae Acute Toxicity	
Selenastrum capricornutum	
Anabaena flos-aquae	
Navicula pelliculosa	
Other (if specific species required, please list)	
Marine Algae (if specific species required, please list)	
Terrestrial Vascular Plants	
Vegetative vigour	
Seedling emergence	
Aquatic Vascular Plants Acute Toxicity	
Lemna gibba	
Other (if specific species required, please list)	
Field Studies	
Other Studies	

ANNEX 3
Contact Information

Questionnaire	Australia	Belgium	Canada
Regulatory Agency(ies)	Department of the Environment and Heritage	**Did not answer questions**	Pest Management Regulatory Agency, Health Canada, 2250 Riverside Drive, Ottawa, Ontario K1A 0K9 Canada
Contact Person(s)	Dr. Jack Holland, Manager, Risk Assessment and Policy Section	Herman Fontier	[1] Ted Kuchnicki [2] Valerie Hodge (both with the Environmental Assessment Division)
Telephone	(61-2) 6250 7519		[1] 613-736-3733 [2] 613-736-3719
Fax	(61-2) 6250 0387		[1 and 2] 613-736-3710
E-mail	[1] jack.holland@ea.gov.au [2] ian.pitt@ea.gov.au	herman.fontier@cmlag.fgov.be	[1] ted_kuchnicki@hc-sc.gc.ca [2] valerie_hodge@hc-sc.gc.ca
Date received	Not provided		06-Jan-00
Date completed	October 1999		21-Jan-00
E-mail comments	Donna Bond: A small number of the questions have not been answered because Australia does not have a firm view on the particular topic.	Herman Fontier: Due to lack of time, Belgium will not be able to answer the questionnaire on PBT pesticides.	No comments

Annex 3. Contact Information

Questionnaire	Czech Republic	France	Germany
Regulatory Agency(ies)	State Phytosanitary Administration, Zemedelska 1a, 61300 Brno, Czech Republic	[1] Ministère de l'agriculture et de la pêche [2] Institut National de la Recherche Agronomique / Structure scientique mixte [3] Ministère de l'aménagement du territoire et de l'environnement	[1] Federal Biological Research Centre for Agriculture and Forestry [2] Federal Environmental Agency
Contact Person(s)	[1] Rndr. Milan Matousek (Fate in Environment) [2] Rndr. Libuse Rauscherova (Ecotoxicity)	[1] Sylvie Malezieux [2] Paul Gaillardon (environment fate and behavior) and Jean-Louis Rivière (ecotoxicity) [3] Mario Nichelatti (pesticides and Environment, ecotoxicity, OECD Pesticides Working Group)	[1] Gerhard Joermann [2] Bernd Stein
Telephone	[1] 00420-5-45137008 [2] 00420-5-45137004	[1] 33(0)1.49.55.81.85 [2] PG: 33(0)130833174 and JLR: 33(0)130833133 [3] 33(1)42191545	[1] +49-531-2993613 [2]+49-30-89033131
Fax	[1 and 2] 00420-5-45211078	[1] 33(0)1.49.55.59.49 [2] PG: 33(0)130833149 and JLR: 33(0)130833149 [3] 33(1)42191468	[1] +49-531-2993005 [2] +49-30-89033138
E-mail	none listed	[1] sylvie.malezieux @agriculture.gouv.fr [2] paul.gaillardon@versailles.inra.fr jean-louis.riviere@versailles.inra.fr [3] mario.nichelatti @environnement.gouv.fr	[1] g.joermann@bba.de [2] bernd.stein@uba.de
Date received	27-Aug-99	18-Aug-99	29-Sep-99
Date completed	26-Nov-99	06-Dec-99	04-Nov-99
E-mail comments	Milan Matousek: [The questionnaire] is an interesting material and it has forced me to think about [these] things. It's a pity that we cannot discuss some of the problems personally, it would require some time. e.g., I do not suppose that the term "major metabolite" is optimal. I thought that [what is] important is the relevancy. Sometimes there is [no] relevant metabolite despite the fact that one of them is "major". [There] can be also two metabolites of comparable relevancy, etc. Another problem: the task of the registration (evaluation) authority should be (as I suppose) the evaluation, not production of the data; they should be supplied by the producer. So if the producer uses some modelling for persistence prediction, we of course accept it, but if the modelling is used - this question should be given to the producer [whether or not modelling is appropriate is up to the producer] (normally the PEC - predicted environmental concentrations - are specified on the basis of computer models, estimated on the usual way). Despite it I hope that the activities like this will contribute to make things more standard in the future.	No comments	No comments

Annex 3. Contact Information

Questionnaire	Greece	Hungary	Japan
Regulatory Agency(ies)	Ministry of Agriculture, General Directorate of Plant Produce, Department of Pesticides	[1] Ministry of Agriculture and Regional Development Plant [2] Plant Protection and Soil Conservation Service of Zala County	Agricultural Materials Division, Ministry of Agriculture, Forestry and Fisheries
Contact Person(s)	J. Karanikolou; S. Loutseti and L. Protopapadaki (Ecotoxicology); A. Lachlou and P. Lolos (Fate and Behaviour)	[1] Mr. Zoltán Ocskó [2] Ms. Judit Ferenczi	Mr. Takehiko Yokoyama
Telephone	[1] 00301-3637457 [2] 00301-5291413 [3] 00301-6840333	[1] 36-1- 301 4248 [2] 36-92-550 165	81-3-3502-0124
Fax	[1] 00301-3617103 [2] 00301-6845870	[1] 36-1- 301 4644 [2] 36-92 311 054	61-3-3502-5302
E-mail	[1] j. karanikolou@minagr.gr [2] s.loutseti@minagr.gr [3] L.protopapadaki@minagr.gr [4] pesticide@nagref.gr	[1] zoltan.ocsko@fvm.hu [2] jferenczi@fki.gov.hu	takehiko_yokoyama@nm.maff.go.jp
Date received	07-Sep-99	Aug-99	24-Aug-99
Date completed	18-Oct-99	Dec-99 Additional comments received by the author 03-Oct-01.	27-Dec-99 Additional comments received by the author 19-Sep-01.
E-mail comments	No comments	Sorry for the long delay, but we could not really fulfill the questionnaire, although it seemed to be quite easy at the beginning, but became more and more difficult when we wanted to give proper answers. May be one of our problem[s] was, that we have not enough experiences in this field. In any case attached please find our (preliminary) response which we may modify soon. We should deal with this topic in detail in the future, regarding especially to the legal background.	No comments

Annex 3. Contact Information

Questionnaire	Netherlands	Norway	Sweden
Regulatory Agency(ies)	**Did not answer questions -** College voor de Toelating van Bestrijdingsmiddelen (CTB)	Norwegian Agricultural Inspection Service	National Chemicals Inspectorate (KemI)
Contact Person(s)	Mevr. dr.ir. M.C. Lans	[1] Terje Haraldsen [2] Reidunn Stokke	[1] Sylvia Karlsson [2] Vibeke Bernson
Telephone	0317-471819	+ 4764944400	[1] +46 8 783 1214 [2] +46 8 783 1139
Fax	0317-471899	+4764944410	+ 46 8 735 7698
E-mail	m.c.Lans@ctb.agro.NL	[1] terje.haraldsen@landbrukstilsynet.dep.no [2] reidunn.stokke@landbrukstilsynet.dep.no	[1] sylviak@kemi.se [2] vibekeb@kemi.se
Date received		Not provided	Aug-99
Date completed		20-Dec-99	29-Oct-99 Additional comments received by the author 02-Oct-01.
E-mail comments	M.C. Lans: Due to the increasing delay in work at the Board on the authorozation of Pesticides in the Netherlands, we were not able to fill in your questionnaire on the assessment of PBT's. It is in our interest to contribute to OECD developments, within the restrictions of time available.	No comments	No comments

Annex 3. Contact Information

Questionnaire	United Kingdom	United States of America
Regulatory Agency(ies)	Pesticides Safety Directorate (MAFF), Mallard House, Kings Pool, York, YO1 7PX, UK	Office of Pesticide Programs, United States Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460, USA
Contact Person(s)	Dr. Andrew Craven, Head, Environmental Fate Branch	[1] Policy issues: Janice Jensen, Field and External Affairs Division (7056C) [2] Environmental fate issues: Dr. James Hetrick, Environmental Fate and Effects Division (7507C) [3] Ecological issues: Dr. Richard Lee, Environmental Fate and Effects Division (7507C)
Telephone	44 - 1904 455913	[1] 703-305-7706 [2] 703-305-5237 [3] 703-305-5577
Fax	44 - 1904 455711	[1] 703-308-1850 [2&3] 703-305-6309
E-mail	a.c.c.craven@psd.maff.gov.uk	[1] jensen.janice@epa.gov [2] hetrick.james@epa.gov [3] lee.richard@epa.gov
Date received	19-Aug-99	NA
Date completed	20-Sep-99	23-Feb-00
E-mail comments	No comments	No comments

ANNEX 4
Appendices A and B to the Questionnaire

APPENDIX A - DEFINITIONS	
active ingredient	the ingredient(s) of a pest control product to which the effects of the pest control product are attributed, including a synergist, but does not include a solvent, diluent, emulsifier or component that by itself is not primarily responsible for the effect of the product.
bioaccumulation	an increase in the concentration or amount of a compound in a non-target organisms over time
bioconcentration	the uptake of a compound from the environment into an organism
biomagnification	an increase in the concentration of a compound in an organism through the food chain
carry-over	the amount of pesticide that remains in the soil in the season following application
cut-off value	an endpoint value that determines if a pest control product can be used safely
degradation = transformation	a chemical or configurational change of a compound in water, soil, sediment or air
depuration	the degradation or excretion a compound taken up by an organism
DT50	time required for 50% decline of the initial concentration of a compound
DT90	time required for 90% decline of initial concentration of a compound
endpoint	a property of a compound that can be quantified by the use of empirical data or by theoretical calculations (e.g., DT50)
metabolite = transformation product	compound that is produced as the result of the degradation (transformation) of another compound or an isomer of that compound
persistence	retention of the chemical integrity of a compound in the environment or in a particular compartment of the environment
transformation = degradation	a chemical or configurational change of a compound in water, soil, sediment or air
trigger value	an endpoint value that was obtained from study that would indicate the need for an additional study or studies to be conducted

APPENDIX B	
BAF	bioaccumulation factor
BCF	bioconcentration factor
C	Conditional Data
K_d	adsorption coefficient
K_{ow}	octanol-water partition coefficient (also referred to as P_{ow})
mol wt	molecular weight
NA	Not Applicable
pKa	dissociation constant
R	Required Data
sol	solubility in water
t1/2	half-life
TLC	thin layer chromatography
vp	vapour pressure

Abbreviations in responses of member countries to the questionnaire

CT	clearance time
PEC	predicted environmental concentrations
TER	toxicity exposure ratio = toxicity endpoint / PEC