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OECD Governments' Approaches to the Protection of Proprietary Rights and Confidential Business Information in Pesticide Registration

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Series on Pesticides No. 6

OECD Governments' Approaches to the Protection of Proprietary Rights and Confidential Business Information in Pesticide Registration

Environment Directorate

Organisation for Economic Co-operation and Development

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Also published in the Series on Pesticides:

No. 1, *Data Requirements for Pesticide Registration in OECD Member Countries: Survey Results* (1993)

No. 2, *Final Report on the OECD Pilot Project to Compare Pesticide Data Reviews* (1995)

No. 3, *Data Requirements for Biological Pesticides* (1996)

No. 4, *Activities to Reduce Pesticide Risks in OECD and Selected FAO Countries. Part I: Summary Report* (1996)

No. 5, *Activities to Reduce Pesticide Risks in OECD and Selected FAO Countries. Part II: Survey Responses* (1996)

Also Published Separately:

OECD Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances - Monograph Guidance

OECD Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances - Dossier Guidance

About the OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 29 industrialised countries in North America, Europe and the Pacific, as well as the European Commission, meet to co-ordinate and harmonize policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialized Committees and subsidiary groups composed of Member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's Workshops and other meetings. Committees and subsidiary groups are served by the OECD Secretariat, located in Paris, France, which is organised into Directorates and Divisions.

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

The OECD Environment Directorate began work on pesticides in 1992 to help countries:

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

The work on pesticides is directed by the Pesticide Forum, which is composed primarily of delegates from OECD Member countries. The Forum also includes representatives from the European Commission and from 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 non-governmental organisations.

This publication was produced within the framework of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC).

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.

FOREWORD

This report presents the results of a survey of OECD Member countries' approaches to the protection of proprietary rights and confidential business information (CBI) with respect to the registration and re-registration of pesticides. The survey was conducted by the OECD Pesticide Programme in 1996-1997. It collected information on:

- national legal instruments on proprietary rights and CBI relating to pesticides; and
- national procedures for releasing pesticide data review reports to foreign regulatory authorities and to the public.

The purpose of the survey was to identify procedures that will facilitate the exchange of pesticide data review reports among countries while ensuring appropriate protection of proprietary rights and CBI. The exchange of reports is essential to achieve one of the goals of the OECD Pesticide Programme: to help countries co-operate in the assessment of pesticides and share the burden of the registration and re-registration of pesticides.

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

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RÉSUMÉ

Le présent rapport contient les résultats d'une enquête menée en 1996-97 dans le cadre du Programme de l'OCDE sur les Pesticides, afin de recueillir des informations sur les dispositions prises par les gouvernements en matière de protection des droits de propriété et des informations relevant du secret industriel et commercial (ISIC) dans le domaine des pesticides. L'enquête demandait des informations sur :

- les instruments juridiques nationaux relatifs aux droits de propriété et aux ISIC ;
- les procédures nationales d'échange des rapports d'examen des données sur les pesticides avec les autorités réglementaires d'autres pays ; et
- les procédures nationales de diffusion des rapports d'examen des données sur les pesticides auprès du public.

Dans le cadre de ce rapport :

- ***les droits de propriété*** désignent les droits des détenteurs d'homologations sur les données concernant les pesticides (interdisant l'utilisation de ces données par une autre partie sans leur permission) ;
- ***les informations relevant du secret industriel et commercial*** (ISIC) sont les informations fournies par les détenteurs d'homologation et qui ne peuvent normalement pas être divulguées par un gouvernement à un tiers.

Vingt et un pays de l'OCDE, la Commission Européenne, et l'Organisation des Nations Unies pour l'alimentation et l'agriculture (FAO) ont pris part à l'enquête. Les informations recueillies serviront à identifier des procédures facilitant l'échange des rapports d'examen des données sur les pesticides entre les pays de l'OCDE, tout en assurant une protection adéquate des droits de propriété et des ISIC.

Ce rapport comprend deux sections :

- La première section présente les résultats de l'enquête, en suivant le format du questionnaire, c'est-à-dire :
  - Partie 1 : Droits de propriété ;
  - Partie 2 : Informations relevant du secret industriel et commercial ; et
  - Partie 3 : Rapports d'examen des données sur les pesticides.
- La seconde section (Annexes) est une compilation 'mot pour mot' des réponses des pays.

Un résumé des conclusions les plus intéressantes est donné ci-après :

Droits de propriété

- La plupart des pays possèdent des lois ou des réglementations nationales en matière de protection des données sur les pesticides. Dans l'ensemble, ces lois sont propres aux pesticides. Presque tous les pays appliquent les même types de lois ou réglementations aux données, qu'elles soient soumises pour une première homologation ou pour un renouvellement d'homologation.

- Dans la quasi totalité des pays, il existe une "période d'usage exclusif" pendant laquelle seul celui qui possède les données peut les utiliser. La durée de cette période diffère suivant les pays et varie de un an à une durée illimitée. Cependant, souvent, le détenteur, initial ou actuel, d'une homologation peut permettre que ses données soient utilisées au profit d'un autre demandeur d'homologation, cette permission n'étant pas toujours nécessaire pour l'utilisation de données ayant impliqué des essais sur animaux (cas de certains pays de l'Union Européenne).

- Dans la majorité des pays, la compensation d'une compagnie pour l'utilisation de ses données n'est pas encadrée juridiquement. Les parties intéressées peuvent s'arranger entre elles (par exemple financièrement).

- La Recommandation de l'OCDE C(83)96, relative à la protection des droits de propriété pour les données soumises lors de la notification de produits chimiques nouveaux, s'applique également aux pesticides dans presque tous les pays.

Informations relevant du secret industriel et commercial (ISIC)

- Aucun pays ayant répondu à l'enquête n'a donné de définition des ISIC. D'autres termes similaires sont cependant définis, tels que "informations confidentielles", "informations couvertes par le secret commercial", et "informations confidentielles complémentaires".

- La plupart des pays ont des lois et des réglementations pour protéger les ISIC sur les pesticides. En général, ces réglementations sont propres aux pesticides.

- Plus de la moitié des pays requièrent des demandeurs d'homologation qu'ils identifient, dans leurs soumissions de données, les informations confidentielles en les plaçant par exemple dans un classeur à part. Cependant, la plupart des pays n'acceptent pas automatiquement comme confidentiel ce que souhaitent les demandeurs, les autorités nationales ayant souvent besoin d'établir que les requêtes de ces derniers sont justifiées.

- La quantité et le type de données considérées comme confidentielles varient suivant les pays. Seules les informations sur les catégories de dangers, la nature des risques, les avertissements et les précautions à prendre, ainsi que les moyens pour rendre la substance inoffensive, sont communes à tous les pays et ne sont jamais considérées comme confidentielles. Pour de nombreux pays, il semble généralement plus facile d'indiquer ce qui n'est pas confidentiel que d'indiquer ce qui l'est.

- Seuls les États-Unis et le Canada ont établi un accord bilatéral concernant la protection des ISIC lors des échanges de rapports. Un accord semblable semble être en vigueur parmi les pays scandinaves.

- La Recommandation de l'OCDE C(83)98, sur les données non confidentielles sur les produits chimiques, est appliquée également aux pesticides dans presque tous les pays.

Rapports d'examen des données sur les pesticides – problèmes liés aux droits de propriété et aux ISIC

Structure des rapports

- Dans la plupart des pays, les ISIC sont conservées séparément du reste du rapport. Dans certains pays, les informations confidentielles ont été tenues séparées depuis plus de vingt ans, tandis qu'ailleurs, cette pratique est plus récente.

- Beaucoup de pays ont indiqué que séparer les informations confidentielles facilitait l'envoi de rapports à d'autres pays ou la diffusion de ces rapports auprès du public.

Échange des rapports entre gouvernements

- Presque tous les pays peuvent communiquer leurs rapports à des autorités réglementaires étrangères. Cependant, la plupart ont indiqué que ceci était possible sous certaines conditions.

- En ce qui concerne les ISIC contenues dans les rapports reçus de l'étranger, presque tous les pays ont indiqué qu'ils pouvaient seulement assurer le même niveau de protection que celui qui existe dans leur pays.

- Dans l'ensemble, on ne requiert pas l'accord des détenteurs d'homologation avant d'envoyer les rapports d'examen à d'autres pays.

Diffusion des rapports auprès du public

- Les rapports peuvent être diffusés auprès du public dans la plupart des pays, bien que cela soit souvent soumis à certaines conditions.

Procédure proposée par l'industrie pour protéger les droits de propriété lors des échanges de rapports

L'industrie des pesticides, via la GCPF (Global Crop Protection Federation), a proposé la procédure suivante pour protéger les droits de propriété lors des échanges de rapports d'examen des données sur les pesticides :

> *"Afin de garantir la protection des données, données résumées dans les rapports gouvernementaux au cours du processus d'évaluation réglementaire, lors d'un échange de rapports d'examen entre les gouvernements, un gouvernement ne peut pas accorder une homologation en utilisant les rapports d'autres gouvernements que s'il a reçu, soit une autorisation d'utilisation des droits de propriété*[*)] *de la part du détenteur des données (qu'il s'agisse du détenteur initial ou d'un détenteur secondaire), soit une autorisation d'utilisation du rapport d'examen de la part du détenteur des données."*

[*)] *Les droits de propriété sont les données qui appartiennent à la personne ou compagnie qui les a produites. La période de propriété est spécifiée par les réglementations nationales ou multinationales.*

La déclaration ci-dessus doit être considérée comme reflétant la position de la GCPF. De nombreux Pays membres ont indiqué que la procédure proposée était en accord avec leurs propres procédures en vigueur. Cependant, des pays ont indiqué qu'ils ne pouvaient pas accepter ou soutenir la position de l'industrie telle que représentée dans la déclaration.

SUMMARY

This report presents the results of a survey conducted by the OECD Pesticide Programme in 1996-97 to gather information on governments' approaches to the protection of proprietary rights and confidential business information (CBI) with respect to pesticides. The survey requested information on:

- national legal instruments concerning proprietary rights and CBI;
- national procedures for exchanging pesticide data review reports with regulatory bodies in other countries; and
- national procedures for releasing pesticide data review reports to the public.

In the context of this report:

- ***proprietary rights*** are the registrant's ownership rights over the pesticide data (prohibiting use of the data by another party without permission);
- ***confidential business information*** (CBI) is information provided by a pesticide registrant that cannot normally be disclosed by a government to a third party.

Twenty-one OECD countries, the European Commission, and the Food and Agriculture Organization (FAO) of the United Nations participated in the survey. The information collected will be used to identify procedures that will facilitate the exchange of pesticide data review reports among OECD countries, while ensuring appropriate protection of proprietary rights and CBI.

This report is divided into two main sections:

- The first section presents the survey results, following the format of the questionnaire, i.e:
  - Part 1: Proprietary rights;
  - Part 2: Confidential business information; and
  - Part 3: Pesticide data review reports.
- The second section (Annexes) is a verbatim compilation of countries' responses.

A summary of some of the major/most interesting findings is given below:

Proprietary rights

- Most of the countries have national laws or regulations to protect proprietary rights with regard to pesticide data. In most countries these are specific to pesticides. Almost all countries apply the same laws or regulations for first registration and for re-registration data.

- In most of the countries, there is an "exclusive use period" during which only the owner can use the data. The duration of this period differs among countries. It varies from one year to permanently. However, the first or current registrant can often give permission for this data to be used for the benefit of another registrant, although permission of the owner is not always necessary for the use of data involving animal testing (e.g. in some EU countries).

- In most of the countries, compensation for the use of another company's data is not legally set. Arrangements (e.g. financial) are left to the interested parties.

- OECD Recommendation C(83)96, concerning the protection of proprietary rights to data submitted in notification of new chemicals, is applied to pesticides in almost all the countries.

Confidential business information (CBI)

- No country responding to the survey provided a definition of CBI. However, other similar terms were defined, such as "confidential information", "confidential commercial information", and "confidential supporting information".

- Most of the countries have laws and regulations to protect CBI on pesticides. In general, these regulations are specific to pesticides.

- More than half of the countries require pesticide registrants to identify confidential information in their data submissions, e.g. by putting it in a separate volume. However, most of the countries do not automatically accept what the registrant wishes to be treated as confidential, since national authorities often need to establish that registrants' requests are warranted.

- The amount and type of data treated as confidential vary among countries. The only common finding is that information on hazard categories, the nature of the risks, relevant warnings, and precautions to be taken, as well as ways to render the substance harmless, are never treated as confidential. For many countries, it seems generally easier to indicate what is non-confidential than to indicate what is confidential.

- Only the United States and Canada had entered into a bilateral agreement regarding the protection of CBI during exchange of reports. A similar agreement seems to be in effect among Scandinavian countries.

- OECD Recommendation C(83)98, concerning non-confidential data on chemicals, is applied to pesticides in almost all the countries.

Pesticide data review reports – proprietary rights and CBI issues

Structure of reports

- In most of the countries, CBI is kept separate from the rest of the report. In some countries confidential information has been kept separate for more than 20 years, while in others this practice is more recent.

- Many countries reported that the separation of confidential information makes it easier to send reports to other countries, or to release these reports to the public.

Exchanging reports with other governments

- Almost all of the countries can release reports to the regulatory authorities of other countries. However, most indicated that this takes place only under certain conditions.

- With respect to CBI in reports received from other countries, almost all the countries indicated that they can ensure only the same level of protection as exists in their own country.

- In most of the countries, the consent of the pesticide registrant is not required before reports are sent to other countries.

Releasing reports to the public

- Reports can be released to the public in most of the countries, although often only under certain conditions.

Procedure proposed by industry to protect proprietary rights during exchange of reports

The pesticide industry, via the Global Crop Protection Federation (GCPF), has proposed the following procedure to protect proprietary rights during the exchange of pesticide data review reports:

> *"In order to respect the proprietary nature of the data which are summarised by governments in their regulatory process when there is an exchange of pesticide review reports between governments, a government should not grant a registration using reviews by other governments unless it has first received a submission of proprietary data*[*)] *on which the summaries are based, either from the owner of the data or from a second party who has authorised permission from the owner of the data or when the owner of the data has given the government permission to use the review."*
>
> [*)] *Proprietary data are data which are owned by the person or company that generated them. The period of ownership is specified by national or multi-national regulations.*

The above statement should be taken as the position of GCPF. Many Member countries indicated that the proposed procedure was in line with their existing procedures. However, some countries indicated that they are unable to accept or support industry's position as represented in the statement.

INTRODUCTION

This report presents the results of an OECD survey on proprietary rights and confidential business information (CBI) with respect to pesticides. The survey was carried out in 1996-97 by the OECD Pesticide Programme, in order to gain a better understanding of OECD Member countries' approaches to the protection of proprietary rights and CBI with respect to the registration and re-registration of pesticides.

In the context of this report:

- ***proprietary rights*** are the registrant's ownership rights over the pesticide data (prohibiting use of the data by another party without permission);

- ***confidential business information*** (CBI) is information provided by a pesticide registrant that cannot normally be disclosed by a government to a third party.

A major activity of the OECD Pesticide Programme is to help countries co-operate in the hazard assessment of pesticides, and thereby share the burden of the registration and re-registration of pesticides. Essential to this process is the sharing of pesticide data review reports among countries. Since the outcome of the Pilot Project to Compare Pesticide Data Reviews,[1] this sharing of reports has been taking place at a significant level (more than 300 reports have been exchanged since 1995); however, report exchange raises important issues with regard to the protection of industry rights over the data produced for registration and re-registration, and reviewed in countries' data review reports.

The information collected in the survey and presented here should be used to identify procedures that will facilitate the exchange of pesticide data review reports among OECD countries, while ensuring appropriate protection of proprietary rights and CBI.

Scope

The survey requested information on:

- national legal instruments concerning proprietary rights and CBI relating to pesticides;

- national procedures for exchanging pesticide data review reports with regulatory bodies in other countries;

- national procedures for releasing pesticide data review reports to the public.

1. See Series on Pesticides No. 2, *Final Report of the OECD Pilot Project to Compare Pesticide Data Reviews* (1995).

Responses received

Twenty-one countries and the European Commission (EC) responded to the survey. The responding countries were: Australia (AUS), Austria (AUT), Belgium (BEL), the Czech Republic (CZ), Denmark (DK), Finland (FIN), France (FR), Germany (GER), Greece (GR), Hungary (HUN), Japan (JP), the Netherlands (NL), New Zealand (NZ), Norway (NOR), Portugal (POR), Spain (SP), Sweden (SWE), Switzerland (SWI), Turkey (TK), the United Kingdom (UK) and the United States (US). Ireland indicated that it would leave the European Commission to respond on its behalf. The Food and Agriculture Organization of the United Nations (FAO) provided information on its position regarding the protection of proprietary rights. Canada preferred not to complete the questionnaire, as its legislation was in the process of being changed at the time the survey was conducted.

Structure of the report

This report is divided into two main sections:

- The first section presents an overview, with comments on the survey results;
- The second section (Annexes) is a *verbatim* compilation of countries' responses, following the format of the questionnaire:

  Annex 1: Proprietary rights: national laws, regulations and procedures;

  Annex 2: CBI: national laws, regulations and procedures;

  Annex 3: Pesticide data review reports: proprietary rights and CBI issues;

  Annex 4: Names of contacts.

Responses of the European Commission and Member States of the European Union are normally presented first, followed by those of the non-EU OECD countries.

The complete text of the survey questionnaire is included in **Annex 5**.

SURVEY RESULTS

Part 1: Proprietary Rights (Annex 1 – Tables A, B, C and D)

Definitions (Table A)

The survey first asked countries to provide their definitions of proprietary rights with respect to pesticides. Most countries reported that they did not have such a pesticide-specific definition. However, the principle of proprietary rights with respect to pesticides exists almost everywhere. Proprietary rights in general exist in many countries, sometimes together with a definition. Therefore, these countries simply apply the general principle to the particular case of pesticides.

Only Turkey and the FAO provided definitions:

- Turkey reported that proprietary rights apply to "*any information submitted by a registrant and which cannot be declared to others by the government.*"

- The FAO definition covers many aspects of the handling of registration data and suggests different reasons (e.g. financial, or to encourage research) such data should be treated as proprietary: "*All data submitted by a company in support of its request for registration of its product should be treated as proprietary and should neither be divulged nor used to evaluate a petition submitted by another applicant, unless by agreement with the owner of the data or unless a period of proprietary rights to the data has expired. The synthesis of new materials and procurement of data on safety and efficacy essential for registration will have taken commercial companies many years and will have been very expensive. The results obtained are as much the property of the company that produced them as is the plant used to manufacture the product. Therefore, it would be unjust for registration authorities to use, for the benefit of industrial competitors, data submitted to them in good faith. Each applicant should be required to produce full supporting data, either by doing the work himself or by licence from the owner of the data. Apart from the injustice of allowing competitors to benefit from the use of data to which they have no right, the consequences of such an action would be to discourage, because it is unrewarding, the research and development required for the production of new pesticides which are needed, for example, for the control of new or difficult pests or to overcome resistance.*" (*Addendum II to Guidelines for the Registration and Control of Pesticides*, FAO, Rome, 1988)

Australia and the United States cited some protection-related texts:

- In Australia, the term "proprietary rights" is not defined. Australia "*does not provide any form of proprietary rights to registration data.*" However, some data protection terms exist. For example, information is designated as "protected registration information" during a "protection period" if "*it is requested by the registration authority for the purpose of reconsidering the registration of a product. It means information that has been obtained because of trials or laboratory experiments and relates to the interaction between that product and the environment or living organisms or naturally occurring populations in ecosystems including human beings.*"

- In the United States, a document on *Procedures to Ensure Protection of Data Submitters' Rights* explains the types of rights which have been afforded to data submitters, and the conditions under which they are applied. It also specifies the obligations the government has assumed in order to protect those rights.

Legal instruments (Table A and Appendix 1.1)

All the countries except Australia reported that they have national laws or regulations to protect proprietary rights with regard to pesticide data. (There is a complete list of national texts in Appendix 1.1.) The European Commission and many European countries referred to Article 13 of Directive 91/414/EEC, which describes how registration data submitted by an applicant should be protected. (The procedure laid down in Article 13 is fully described in Annex 1, Table C, under European Commission.)

In Australia there are no legal instruments to protect proprietary rights. However, data protection, as distinct from proprietary rights, is provided in a limited form under the Agvet Code.

Some countries insisted on the fact that laws protecting registration data and those protecting patented substances are generally different. Two separate authorities normally deal with granting registrations (by reviewing data) and patents. In the case of a substance that is protected by a patent but not registered, no data need to be protected.

Are legal instruments specific to pesticides?

In most countries these laws or regulations are specific to pesticides, although in some cases (e.g. in Japan and Norway) protection of proprietary rights is covered by more general regulations.

Are the same legal instruments used for registration and re-registration?

All but two countries (Australia and New Zealand) reported that the same laws or regulations apply for first registration and re-registration data:

- In Australia, data protection laws and regulations apply only to certain data submitted, at the request of the registration authority, in relation to a product under *re-registration.* However, during 1997 the Australian Parliament was expected to consider a bill concerning the protection of data in relation to new active ingredients.

- In New Zealand, the Pesticides Amendment Act protects the data for the *first registration* only. The law does not provide any data protection for *re-registration*, although there may be an administrative policy in place to protect proprietary data submitted to satisfy a formal review.

Procedures for protecting proprietary rights (Tables B and C)

Countries were asked to describe, as far as possible, the different aspects of their national procedures for protecting proprietary rights. In particular, they were asked what data are protected, how long the protection period is, who can use the protected data, and under what conditions. A full summary of countries' responses is given in Table C.

What data are protected?

Generally speaking, countries appear to protect all data concerning the active ingredient(s), formulations and formulants.

How long is the protection period?

In almost all the countries, there is an "exclusive use period" during which only the owner can use the data. The length of this period differs greatly among countries. It varies from one year to permanently. Not surprisingly, the protection period is more harmonized in the European Union than among non-EU countries.

In the European Union:

Most EU countries referred to the rules laid down in Article 13 of Directive 91/414/EEC. That is, they protect data during a period of:

- ten years, for both the active substance and product-related data submitted for the first registration;

- five years, for the active substance-related data for re-registration or for supplementary information.

- The European Commission reported that, within the EU, there is complete harmonization with regard to the data protection period for new active substances[2] and products containing them, whereas the provisions for existing active substances and products containing them are not fully harmonized. The Directive will be fully functioning when active ingredients are entered in the EU list (Annex I of the Directive), and when registrations of products with those active substances are granted in Member States. Meanwhile, national rules should still be valid.

- According to Finnish and Swedish legislation, data protection lasts forever. However, after inclusion of active substances in Annex I and after registrations of products in Member States, Finland and Sweden will observe data protection periods of ten and five years, as stated in the Directive.

Some European countries (Austria, Belgium, Germany, the Netherlands, Spain) reported that the protection period for data involving animal testing may not be an "exclusive use period", i.e. a registration authority can use such data when reviewing a submission by another registrant without having to obtain

2. According to Directive 91/414/EEC, new active substances are those registered after 25 July 1993.

the consent of the owner of the data. (Compensation for use of the data may, however, be arranged during the protection period.)

- Austria and Germany indicated that if the owner of data involving animal testing does not wish this data to be used, an "exclusive use period" can be set (normally five years). However, if the new registrant considers this period too long, the duration can be shortened to the time needed to perform the study in question. For example, if a test took two years to perform, the owner might have the right to exclusive use for two years. For the eight (maximum) remaining years, this data could be used for the benefit of another registrant. The provisions for compensation would apply during these eight years.

In non-EU OECD countries:

In non-EU OECD countries, the data protection period lasts from two years (Turkey) to permanently (the Czech Republic, Japan, Norway, Switzerland). In Australia, the protection period for a piece of information ranges from two to seven years and generally reflects the expense involved in conducting the trials necessary to produce the data. A formula is used to determine its exact duration.

Access to protected data

Countries were asked to explain how the data protection period was applied and what it involved, particularly with regard to access to the protected data. Many countries reported that the protection period is not an "exclusive use" period, since the first applicant can often give permission for this data to be used for the benefit of another applicant. This is generally done by means of a written agreement between the two parties. However, as indicated by some EU countries, this agreement procedure is not always necessary for data involving animal testing (see above). This is in line with the Directive, which tends to make these data more accessible in order to avoid duplicative testing on vertebrate animals. Article 14 states that registration authorities should provide new applicants with the name and address of the holder(s) of previous relevant registration(s) (and vice versa). Both parties are encouraged to "*take reasonable steps to reach agreement on the sharing of such data.*" Switzerland also indicated that efforts should be made to avoid repetition of tests involving vertebrate animals.

Compensation

In the case of countries whose procedures allow protected data to be used, the survey attempted to determine whether compensation mechanisms exist. The majority of these countries have no formal arrangements for compensation. Apparently, national legislation in these countries establishes the rules for access to protected data, for example with the consent of the first or previous registrant. However, it does not go further and does not describe how the parties should proceed. The arrangements for compensation (financial or other) appear to be treated as a private matter between the two parties involved.

Several countries (Australia, Austria, Germany, the United States) do have compensation mechanisms, together with a compensation period:

- Australia has defined various aspects relating to the terms of compensation. For instance, the following points are described: in which case compensation is owed, how the primary and secondary applicants should negotiate terms for compensation, what happens if the primary registrant does not want this information used in relation to another product, who decides

how much compensation is to be paid, what happens if parties cannot arrive at a reasonable proposal for compensation, and what constitutes a reasonable proposal for compensation.

- In Austria and Germany, compensation is legally set only for data involving animal testing: if the authority has granted a registration on the basis of a previous applicant's data, the previous applicant is entitled to 50% of the costs of the study(ies). (As mentioned above, the owner's consent for the use of this data is not required.)

- In the United States, a company wishing to use another company's protected data must, prior to registration, certify to the EPA either that it has permission from the original data submitter to use the data, or that it has made an offer to pay compensation to the original data submitter. Disputes with regard to the value of data may be resolved through binding arbitration. The EPA may proceed with registration action prior to the fixing of compensation.

- In Addendum II to Guidelines for the Registration and Control of Pesticides, the FAO suggests adopting the following guiding principle with regard to compensation:

  "When instituting a procedure of safeguarding proprietary rights which includes a period during which payment for the use of the data is required, the principles to be followed in agreeing adequate payment should be established. The procedure should not place the regulatory authority in the position of having to arbitrate between the data owner(s) and subsequent petitioners. There is no single solution regarding payment for costs incurred in producing registration data. An important factor is the length of the period of exclusive use provided to the data owner. The longer this period, the more "scientifically" outdated the data become. Thus, with a relatively long exclusive use period the payment could consist of an equal sharing of the costs of the studies. If the exclusive use period is kept relatively short, the situation is more difficult. The data will still have their full scientific value and the original data owner has run a substantial risk in developing these data, which he legitimately wants to see reflected in a more substantial payment. In this case, it is particularly important that a definite system for agreeing on payment is instituted." (FAO, Rome, 1988)

Implementation of the OECD Recommendation on protection of proprietary rights (Table D)

In July 1983, the OECD Council adopted a Recommendation on the Protection of Proprietary Rights to Data Submitted in Notification of New Chemicals (Appendix 1.3). This Act recommends that authorities require each company wishing to notify a new chemical:

(1) to identify the laboratories which produced the data; or

(2) to provide certification of the right to use the data, if the laboratories are not owned by or affiliated with the notifier.

If the company cannot provide such certification, the OECD Recommendation states that the authorities should not accept these data.

Countries were asked whether they applied this Recommendation to pesticides. Almost all the countries replied that they did so. Hungary specified that the pesticide registration process follows the principles of this Recommendation in practice, although there is no written regulation.

Three countries (Australia, the Czech Republic, Finland) reported that they do not apply the Recommendation:

- Australia originally abstained from endorsing this Council Act. In response to the survey, it explained that *"it is considered the responsibility of the notifier to ensure there is no unauthorised access to their data outside the responsibilities of the registration authority. "*
- The Czech Republic reported that the principles of the Recommendation are used. In that country "*generally all data, submitted by the applicant are checked for their origin before the evaluation of them is started."*
- Finland does not implement the Recommendation.

Part 2: Confidential Business Information (Annex 2 – Tables E, F, G, H and I)

Definitions (Table E)

No country provided a definition of CBI. However, other similar terms are used. For example, several countries reported that they have definitions of "confidential commercial information" (Australia), "confidential information" (New Zealand, Spain, Turkey, the United Kingdom), "confidential" (Finland) or "confidential supporting information" (New Zealand).

- Australia has a quite comprehensive definition of CBI, which is referred as "confidential commercial information" under the Agvet Code. Such information "*in relation to an active constituent for a proposed or existing chemical product or in relation to a chemical product or a constituent of a chemical product means:*

  a) a trade secret relating to the constituent or product; or

  b) any other information relating to the constituent or product that has a commercial value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed; or

  c) information (other than trade secrets to which paragraph a) applies or information to which paragraph b) applies) that:

  i. concerns the lawful commercial or financial affairs of a person, organisation or undertaking; and

  ii. relates to the manufacture, distribution or supply of the constituent or product; and

  iii. if it were disclosed, could unreasonably affect the person, organisation or undertaking in an adverse manner."

- In Turkey and the United Kingdom, as a general rule "confidential information" relates to all information submitted by a registrant. Such information cannot be disclosed by the government. There are of course exceptions to this definition. Finland, New Zealand and Spain reported that "confidential information" deals with industrial or trade secret information having a commercial value that would be diminished by disclosure.

- In New Zealand, "confidential supporting information" means "*confidential information given in, or in relation to, a new pesticide application and about the pesticide that is or was, as the case may be, the subject of an application."*

Note: ***In view of the differing terms used by countries, in the rest of the text the abbreviation CBI is used with the general meaning of "confidential information". However, it should be kept in mind that in some countries (e.g. Canada and the United States) CBI may have a more restrictive sense: it could be a subset of confidential information and could relate to the very confidential information that registration authorities would never disclose.***

Legal instruments (Table E and Appendix 2.1)

All of the countries (except the Czech Republic and Hungary) have laws and regulations to protect CBI. (There is a complete list of national texts in Appendix 2.1.) The new Hungarian pesticide law, expected in 1998, will cover confidential information. Although the Czech Republic does not have specific legal instruments, protection of confidential information works in practice. Most regulations in EU countries concern the implementation of Directive 91/414/EEC. In particular, Article 14 of the Directive lays down principles for confidential and non-confidential treatment of registration information. (See the text of Article 14 in comments to Table G, under European Commission.)

Are legal instruments specific to pesticides?

In general, there are CBI regulations specific to pesticides. However, in some cases protection of CBI is covered by both a regulation specific to pesticides and legislation of a more general nature, i.e. laws on data protection in general or on administrative procedures.

Four countries (Germany, Japan, Norway, Sweden) reported that their legal instruments are not specific to pesticides and are more general.

Procedures regarding information the registrant identifies as confidential (Tables E and F)

Is the registrant required to identify confidential information?

Most EU countries require pesticide registrants to indicate the information they wish to be treated as confidential in their data submissions. Only Sweden and the United Kingdom do not proceed in this way. Three of the non-EU countries (Australia, Switzerland, the United States) also ask the registrant to identify confidential information, but Australia reported that this is optional for the registrant.

How does the registrant indicate what is confidential?

In some EU countries (Austria, Belgium, Denmark, Greece, the Netherlands) and in the United States, the registrant is requested to provide confidential information in a separate volume. In the United States, such separate documents are called "confidential attachments" and are study-specific. In Australia, France, Germany, Portugal, Spain and Switzerland, the registrant should identify this information by "designating" it. The Australian response specified that the registrant may indicate "*which information is confidential in a covering letter or by labelling the confidential pieces of information in his submission.*" Apparently, in those countries confidential information does not have to be separated from the rest.

Is the registrant's request automatically accepted?

Only Belgium, Finland, Hungary and Turkey automatically accept registrants' requests for confidentiality. The main reason given for not automatically accepting registrants' requests in this regard is that authorities need to establish that such requests are warranted. In particular, data which are of importance for health and environmental safety reasons will not be accepted as confidential. A similar decision would be taken in the case of types of information in national and international lists of non-confidential data, such as in Directive 91/414/EEC or the OECD Recommendation on non-confidential data (see below).

In addition:

- In Australia, only "confidential commercial information" under the Agvet Code (see first paragraph under ***Definitions*** above) is accepted as confidential.

- In Norway, only information which would be of competitive importance and which cannot be patented is kept secret.

- In the United States, information claimed as confidential is treated as such by the EPA until and unless the EPA, by formal process, determines that the information is not entitled to confidential treatment.

Switzerland and the United States reported that when the registration authority and the applicant disagree on what information is entitled to confidential treatment, the applicant is informed of the decision. In the United States, the applicant is given the opportunity to substantiate the confidentiality claim.

Information considered confidential by countries (Tables G and H)

The amount and type of data treated as confidential vary among countries and can also vary within a country. Some countries reported that the categories they designate as confidential (or non-confidential) may be subject to change, depending on whether the data contain information of toxicological or ecotoxicological importance.

The only common finding is that, in the case of both active ingredients and products, information on hazard categories, the nature of the risks, relevant warnings, and precautions to be taken, as well as ways to render the substance harmless, are never treated as confidential.

It is of interest that, in many countries, it appears easier to indicate what is non-confidential than what is confidential. Along the same lines, the European Commission preferred to indicate what would not be treated as confidential according to Article 14 of Directive 91/414/EEC. This Directive lists information to which confidentiality shall not apply (see the complete text of Article 14 in the comments to Table G, under EC).

Tables 1 and 2 provide an overview of the types of information countries treat as confidential, based on Tables G and H in Annex II.

Table 1: Active ingredient (Table G)

Data for the active ingredient	Confidential?
Identity	
• General information (e.g. name(s), formula(e), mass, CAS, EEC or CIPAC numbers)	No (in most countries)
• Purity	Yes (in half the countries)
• Internal code numbers (for the manufacturer or the applicant)	No (in most countries)
Isomers (identity and content)	Yes (in most countries)
Impurities (identity and content)	Yes (in most countries)
Analytical profiles of batches	Yes (in most countries)
Detailed description of the manufacturing process	Yes (in almost all countries)
Identity of the manufacturer(s)	Yes (in half the countries)
Physical and chemical properties	No (in most countries)
Complete results (raw data) of all tests	Yes (in most countries)
Summary results (*)	No (in most countries)

Table 2: Product - preparation/formulation (Table H)

Data for the product	Confidential?
Identity	
• General information (e.g. trade name, type of preparation)	No (in most countries)
• Internal code numbers (for the manufacturer or the applicant)	No (in most countries)
Composition	Yes (in most countries)
• Identity and content of active ingredients	No (in most countries)
• Isomers	Yes (in half the countries)
• Formulants	Yes (in most countries)
• Inert compounds	Yes (in almost all countries)
Identity of the manufacturer(s)	No (in most countries)
Physical and chemical properties	No (in most countries)
Complete results (raw data) of all tests	Yes (in most countries)
Summary results (*)	No (in most countries)

(*) The EU Directive states that the summary of the results of tests to establish the substance's or product's efficacy and its harmlessness to humans, animals, plants and the environment shall not be treated as confidential.

Bilateral agreements (Table E)

Countries were requested to indicate whether they had entered into bilateral agreements regarding the protection of CBI. Only the United States (EPA) and Canada (PMRA) had signed such an agreement. It has been effective since March 1996, along the following lines: *"The two agencies have agreed that data reviews which may contain CBI may be exchanged with the written permission of the registrant. The purpose of this agreement is to facilitate the exchange of data reviews, and to eliminate the burden of reviewing all of the documents and eliminating CBI prior to the exchange."*

Finland mentions the *"Nordic co-operation concerning the evaluation of health and environmental effects of active substances (old and new ones)"* under which pesticide review reports on active ingredients are normally exchanged among the Scandinavian authorities and also with the Netherlands.

Implementation of the OECD Recommendation on non-confidential data (Table I)

In 1982, the OECD Council adopted a Recommendation which lists a number of types of data on chemicals which should be non-confidential (Appendix 2.2). "Non-confidential" in this context means that no restrictions should be placed on the exchange of data between governments nor on their disclosure to the public. The list (which is not restrictive) concerns data which are of value for hazard assessment and for other purposes relating to the protection of man and the environment, i.e.:

- trade name;
- general data on uses;
- safe handling precautions for manufacture, storage, transport and use;
- recommended methods for disposal and elimination;
- safety measures in case of an accident;
- physical and chemical data (excluding those which would reveal a chemical's identity);
- summaries of health, safety and environmental data.

Countries were asked whether they applied this Recommendation to pesticide data. Almost all the countries do so. Some EU countries indicated that their "yes" answer was linked to the implementation of Directive 91/414/EEC. The Czech Republic reported that it applies the Recommendation with the exception of "summaries of health, safety, and environmental data including precise figures and interpretations," but that the problem posed by this exception is expected to be solved by the new law on chemicals.

Five countries (Australia, Finland, Hungary, Japan, Norway) do not apply the Recommendation:

- Australia originally abstained from voting in respect of this Council Act.
- Japan accepts most of the items on the OECD list. Regarding physical and chemical data and the summaries of health, safety and environmental data, the Japanese government recommends that industry consider them to be non-confidential.
- The Recommendation is not implemented in Finland.
- Norway considers the Recommendation too conservative.

Part 3: Pesticide Data Review Reports: Proprietary Rights and CBI Issues (Annex 3 – Tables J, K L and M)

Under the OECD Pesticide Programme, some countries have begun to exchange pesticide data review reports. This exchange process has, however, raised concerns among governments and industry, such as:

- How are industry rights over registration data protected?
- How is confidential information handled when review reports are sent to another country?
- Is confidential information removed before reports are sent to another country?
- How does the receiving authority keep the reports?
- How does the receiving authority handle confidential information?

With a view to alleviating these concerns and/or facilitating report exchanges in the future, the survey requested information on countries' current procedures, i.e. on how they deal with CBI in their own review reports, and on their procedures if they release reports to other governments and to the public.

Structure of the reports (Table J)

In most of the countries, CBI is kept separate from the rest of the data review report. Only Hungary, Japan and Turkey do not separate CBI. However, although it is kept separate, confidential information is not necessarily put together in an annex. As the United Kingdom stated, confidential information can simply be edited out of the review in consultation with the registrant.

In some countries (Finland, Germany, the Netherlands, New Zealand, Portugal, Sweden, Switzerland) confidential information has been separated for more than 20 years, while in others this practice is more recent.

Many countries reported that the separation of confidential information makes it easier to send reports to other countries, or to release them to the public.

Exchanging reports with other governments (Table J)

With the exception of Japan, Switzerland and Turkey, where data review reports are treated in a confidential manner, all the countries can release reports to the regulatory authorities of other countries. However, most of the countries reported that this takes place only under certain conditions**.** In the case of Japan, the situation may change when the "Public Information Act" is established.

An important aspect of exchanging reports is the level of protection granted to CBI in reports received from other countries. Almost all countries can ensure only the same level of protection as in their own country. In the United Kingdom, data review reports sent by other regulatory agencies would be treated as confidential if requested by the transmitting country and are therefore not normally released. Only France and Hungary would protect CBI at the same level as in the transmitting country.

Countries' procedures (Table K)

Generally speaking, countries do not formally ensure that a request from another country for a data review report is bona fide. Australia ensures that requests are from a bona fide authority, from a known individual, and signed. In most countries, as long as there is no CBI in the report, the consent of the pesticide registrant does not have to be obtained before the report is released. Only two countries, Australia and Japan, would ask for the registrant's consent. In Australia, the registrant has 28 days to decide and/or comment on the intended disclosure of the CBI. If the registrant agrees, the report (CBI included) is sent out. Alternatively, if the registrant does not consent, the authority will consider the registrant's comments and decide whether to proceed with the intended release of CBI. The authority's decision can be appealed. In the end, the report is normally sent (with or without CBI, depending on the final decision). If CBI is not released, it is relocated to appendices.

Among the countries' responses, the following may be noted:

- In Portugal, releases are evaluated case by case.

- In Hungary, the exchange is possible only if the receiving country can ensure the same level of data protection as in Hungary.

- Australia and the United Kingdom reported that they maintain a list of requests. The list is publicly available in the UK.

At the EU level, there is no procedure yet. Therefore, five EU countries (Belgium, Denmark, Greece, the Netherlands, Spain) stated that they do no have formal procedures at the moment. In the future, they will probably will act according to the EU principles.

Releasing reports to the public (Table J)

Most of the countries can release reports to the public, although often only under certain conditions. Reports are not released to the public in Germany, Japan, Switzerland and Turkey. In the future, such releases may be possible in Germany (when it has implemented Directive 91/414/EEC) and in Japan (when the "Public Information Act" is established).

Countries' procedures (Table L)

Some countries (e.g. Belgium, the Netherlands, Portugal, the United Kingdom) have adopted the same process for releasing reports to the public as for releasing them to other countries.

New Zealand, Sweden the United Kingdom and the United States reported that they do not have to obtain consent from the pesticide registrant before releasing reports to the public. However, in the United States data submitters can object that public disclosure would cause competitive harm. The EPA then reviews the data submitter's argument and issues a final decision. In Australia, Hungary and Japan, consent from the registrant must be obtained before reports can be released. Australia reported that, if registrants agree, reports with CBI can be released domestically to the public. Otherwise, CBI is removed from the public version of the report.

In some cases, what is provided to the public may differ, strictly speaking, from the report itself without confidential information. For example, in Finland and Norway the public is given only summary information concerning health and environmental effects. In the Netherlands, only the common parts, i.e. the condensed overall conclusions for specific test areas, are publicly available.

At the EU level, there is as yet no procedure for releasing information to the public. Therefore, six EU countries (Austria, Belgium, Denmark, Germany, Greece, Spain) stated that they do no have such formal procedures at this time. In the future, such procedures will probably be established according to forthcoming EU rules.

Procedure proposed by industry to protect proprietary rights during exchange of reports (Table M)

The pesticide industry, via the Global Crop Protection Federation (GCPF), has proposed the following procedure to protect proprietary rights during the exchange of pesticide data review reports:

> *"In order to respect the proprietary nature of the data which are summarised by governments in their regulatory process when there is an exchange of pesticide review reports between governments, a government should not grant a registration using reviews by other governments unless it has first received a submission of proprietary data*[*)] *on which the summaries are based, either from the owner of the data or from a second party who has authorised permission from the owner of the data or when the owner of the data has given the government permission to use the review."*
>
> [*)] *Proprietary data are data which are owned by the person or company that generated them. The period of ownership is specified by national or multi-national regulations.*

The above statement should be taken as the position of GCPF. Many Member countries have indicated that the proposed GCPF procedure was in line with their existing procedures. However, some countries have expressed their inability to accept or support industry's position as represented in this statement. Comments were received from Australia, the United Kingdom and the United States as follows:

- Australia indicates that the proposed text is in line with its current procedures, but only in respect of the provision of data protection as distinct from proprietary rights, which that country does not provide. However, Australia has some concerns about the way the proposed GCPF procedure is written. In particular, the focus should be on data protection as distinct from protection of proprietary rights. Furthermore, Australia would not wish to be required to grant registration to a chemical product simply based on the views of other governments, without receiving and reviewing the applicable data as considered appropriate by the Australian Government.

- The United Kingdom commented on the definition of proprietary data. As the data may not be owned by the person/company that generated them, the UK suggested the alternative: *"Proprietary data are data which, for a period, may only be used in support of pesticide registrations with the permission of the person or company owning the data*."

- The United States did not fully accept the way the proposal is written. At present, as the proposal states, the US *"would not grant a registration by simply using the reviews of other*

governments without also receiving and reviewing the data from the prospective registrant." However, it *"would not want to be precluded from doing so in the future."* The US therefore considers that *"the GCPF proposal should focus more specifically on the issue of proprietary rights and compensation to data submitters, and ensuring that fairness and equity exist among different governments, and not the issue of how governments conduct their business in reviewing data submitted for registration purposes."*

- ANNEXES -

COMPILATION OF COUNTRIES' RESPONSES

Annex 1: **Proprietary rights**

Annex 2: **Confidential business information**

Annex 3: **Pesticide data review reports**

Annex 4: **Contact names**

Annex 5: **Text of the survey questionnaire**

- Annex 1 -

Proprietary rights

National laws, regulations and procedures

TABLE A - Proprietary rights: definitions and laws/regulations

Questions 1.1 to 1.4.

Questions	EC	AUT	BEL	DK	FIN	FR	GER	GR	NL	POR	SP	SWE	UK	AUS	CZ[1)]	HUN	JP	NZ	NOR	SWI	TK	US	FAO[9)]
Q.1.1 - Does your country have a definition of proprietary rights with respect to pesticides?	-	No	No	No	No	No	No	No	No	No	No	No	No	No[1)]	No[2)]	No[1)]	No	No	No	No	Yes[1)]	No	Yes
↳ Reference of documents in which the definition can be found		-	-	-	-	-		-	-	-	-	-	Yes[1)]	N/A	-	2)	Yes[1)]	-	-	-	Yes[2)]	Yes[1)]	-
Q.1.2 - Does your country have national instruments (e.g. laws/regulations) to protect proprietary rights with respect to pesticides? (Titles can be found in Appendix 1.1)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No[2)]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes[2)]	Yes
Q.1.3 - Are the laws/regulations specific to pesticides? (See Appendix 1.1)	Yes	Yes	Yes	Yes No	Yes		Yes	Yes	Yes	Yes	Yes	Yes No	Yes	Yes[3)]	Yes	Yes	No	Yes	No	Yes No	Yes	Yes	Yes
Q.1.4 - Do the same laws/regulations apply to first-registration and re-registration?	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	No[4)]	Yes	Yes	Yes	No[1)]	Yes	Yes	Yes	Yes	-

Note: See comments on next pages

Comments for Table A

EU countries

UK 1) Data protection policy under UK's existing national rules is described in the "Registration Handbook - Pesticides, Biocides, Plant protection products' issued jointly by the Pesticide Safety Directorate, an executive Agency of the Ministry of Agriculture, Fisheries and Food, and the Pesticides Registration Section of the Health and Safety Executive.

Non-EU countries

AUS 1) It should be noted that Australia provides a certain type of protection to certain review of registration data, however Australia does not provide any form of proprietary rights to registration data. Consequently Australia does not have a definition of the term 'proprietary rights'. The data protection terms used however, are defined under the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 as follows:

'**Protected chemical product**' means a registered chemical product to which both of the following paragraphs apply:
(a) the product is or includes an invention in respect of which letters of patent were granted under the Patents Act 1952 or the Patents Act 1990;
(b) the term of the letters patent (Including any extension of that term) has ended, or will end during the protection period that applies to protected registration information about that product;
but does not include chemical products for use on non-food producing animals.

'**Protected registration information',** in relation to a chemical product, means information that has been obtained because of trials or laboratory experiments and relates to the interaction between that product and:
(a) the environment, or
(b) living organisms or naturally occurring populations in ecosystems, including human beings; but does not include information obtained for the purposes of assessing the performance of the product in respect of its proposed use.

'**Protection period**' in relation to protected registration information of a particular kind, means:
(a) if a period is stated in, or worked out in accordance with, the regulations in relation to information of that kind for the purposes of Part 3 [Compensation for provider of certain information in respect of continued registration of certain products] -the period so stated or worked out, or
(b) otherwise - 7 years.

AUS 2) Data protection, as distinct from proprietary rights, is provided in a limited form in respect of certain review of registration information provided at the request of the NRA.

3) The data protection laws/regulations for pesticide products are covered by the Agvet Code and associated regulations, except those products used exclusively on non-food producing animals. In addition, data protection under the Agvet Code does not apply to efficacy data.

4) The laws/regulations only apply to certain data submitted at the request of the NRA in relation to a product under reconsideration (re-evaluation).

CZ 1) All answers in all parts of the questionnaire should be valid as the new Phytosanitary Care Act No. 147/1996 is valid since January 1. 1997.

2) There is none explicit definition of the term proprietary rights with respect to pesticides in any Czech law yet, though the principles are used.

HUN 1) Hungary has no written definition of proprietary rights with respect to pesticides. The principle of proprietary rights exists only in practice of pesticide registration, and in general regulations concerning data protection.

2) The principle of proprietary rights exists in a general regulation : 'Law on Protection of personal data and the publicity of data of public interest No. LXIII' - this came into force in 1992.

JP 1) The 'Unfair Competition Prevention Law' has a definition of proprietary rights in general.

NZ 1) The Amendment Act was solely a legislative measure to meet New Zealand's obligations under the GATT:TRIPS Agreement, i.e. to protect registration data for "New Chemical Entities".

TK 1) "Any information submitted by a registrant cannot be declared to the others by the government"

2) Reference: Regulation of Agriculturals Chemicals and Protection Tools (no: 11142)

US 1) Procedures to Ensure Protection of Data Submitters' Rights, published in 40 Code of Federal Regulations §152.80. This document explains the types of rights which have been afforded to data submitters, the conditions under which they are applied, and specifies the obligations that the government has assumed in order to protect those rights.

2) US laws and regulations apply to pesticide data. They do not necessarily apply to "pesticides", which implies authorities related to patents for products or active ingredients.

FAO 1) Extract from a FAO letter from Arpad Ambrus (Pesticide Group), dated 23/7/1996.

"FAO has long established a clear position concerning the proprietary rights of the manufacturers. It was specifically discussed in the FAO Addenda to Guidelines for the Registration and Control of Pesticides (Addendum II in Appendix 1.2), FAO Rome 1988. The International Code of Conduct on Distribution and Use of Pesticides, 1990, says in Article 6. "Governments should (6.1.3) protect the proprietary rights to use of data". Finally FAO and WHO JMPR Secretaries agreed to include in the JMPR Evaluations and Reports from 1996 the following statement:

"The summaries and evaluations contained in this report are, in most cases, based on unpublished proprietary data submitted for the purpose of the JMPR assessment. A regulatory authority should not grant a registration based on the evaluations unless it has first received authorization for its use from the owner that submitted data for the JMPR review or has received a submission of data on which the summaries are based, either from the owner of the data or from a second party that has obtained permission from the owner of the data for this purpose."

TABLE B - Countries' procedures for protecting proprietary rights with respect to pesticides

(summary table - see full description of countries' procedures in Table C)

Question(s) 1.6.

Questions	EC	AUT	BEL	DK	FIN	GER	GR[1]	NL	POR	SP	SWE	UK	AUS	CZ[1]	HUN	JP	NZ	NOR	SWI	TK	US	FAO
Q.1.6- Describe your country's procedure for protecting proprietary rights with respect to pesticides (see full description in Table C)																						
Q.1.6.1- Do you protect data for a.i., formulations and inert ingredients?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Table C	Yes	Yes		Yes	Yes	Yes	Yes	Yes	
Q.1.6.2- Do you have an 'exclusive use' period in which only the owner can use the data?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No[1]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
If so, how long is this period (years)?	5-10[1]	1-6[1]-10[2]	5-10[1]	5-10[1]	5-10 or perm[1]	1-6[1]-10[2]	5-10	5-10	5-10[1]	5-10[1]	5-10 or perm[1]	5-10[1]	-	10-perm.[2]	10	perm.	5-10[1]	perm.	perm.	2	10-13[1]	10-15[1]
Q.1.6.3- Do you have a period in which others can use the data but must compensate the owners?	No	Yes[1]	No	No	No	Yes	No	No[1]	No	No	No	No	Yes[2]	No[3]	No	No	No[1]	No	No	No	Yes[2]	Yes[2]
If so, how long is this period (years)?	-	1-6[1]	-	-	-	1-6[1]	-	-	-	-	-	-	2-7[3]	-	-	-			-	-	15[3]	10-15
Q.1.6.5- Are all data treated the same?	No[2]	No[1]	No[2]	Yes		No[1]	No	No[2]	Yes	No[2]	Yes	Yes	No[3]	Yes	Yes	Yes	Yes	Yes	Yes[1]	Yes	Yes	

perm.: permanent

Comments for Table B

EC and EU countries

EC 1) 10 years initial data.
5 years further data.

2) In the case of products containing an active substance listed in annex I of Directive 91/414/EEC, holders of authorisation and applicants must take all reasonable steps to reach agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals. In this regard, applicants for authorisation of plant protection products shall, before carrying out experiments involving vertebrate animals, enquire of the competent authority:
   - whether the plant protection product for which an application is to be made is the same as a plant protection product for which authorisation has been granted; and
   - as to the name and address of the holder or holders of the authorisations.

AUT 1) For data generated from animal testing, the 'exclusive use' period varies from 1 to 6 years, depending of the length of the study(ies) in question. The owner of the study(ies) is entitled by the Act to a compensation of 50% -of the cost of the study(ies).

2) For data which do not involve animal testing, the 'exclusive use' period is 10 years after the registration (or less if the first registrant gives his written consent to use of his data)

BEL 1) 10 years initial data.
5 years further data.

2) In the case of products containing an active substance listed in Annex I of Directive 91/414/EEC, holders of authorisation and applicants must take all reasonable steps to reach agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals. In this regard, applicants for authorisation of plant protection products shall, before carrying out experiments involving vertebrate animals, enquire of the competent authority:
   - whether the plant protection product for which an application is to be made is the same as a plant protection product for which authorisation has been granted; and
   - as to the name and address of the holder or holders of the authorisations.

DK 1) 10 years initial data.
5 years further data.

FIN 1) According to the Finnish legislation concerning pesticides, protection of data lasts forever.
The situation will change for plant protection products to 10 and 5 years respectively following the inclusion of active substances in Annex I of Directive 91/414/EEC and the authorizations of formulations with those active substances in Member States.

GER 1) For data generated from animal testing, the 'exclusive use' period varies from 1 to 6 years, depending of the length of the study(ies) in question. The owner of the study(ies) is entitled by the Act to a compensation of 50% -of the cost of the study(ies).
2) For data which do not involve animal testing, the 'exclusive use' period is 10 years after the registration (or less if the first registrant gives his written consent to use of his data)

GR 1) Reply of the European Commission.

NL 1) This "compensation period" is not regulated, but is practice (written consent) during protection period, unless animal testing is involved.
2) Not all data are treated the same. Data derived from animal testing may not be repeated.

POR 1) 10 years initial data.
5 years further data.

SP 1) 10 years initial data.
5 years further data.
2) The data from animal testing are used more easily, because they must be avoided to repeat tests with vert ebrates.

SWE 1) According to the Swedish legislation concerning pesticides, there is no time limit for protection of data.
However, the situation will change for plant protection products to 10 and 5 years respectively following the inclusion of active substances in Annex I of Directive 91/414/EEC and the authorizations of formulations with those active substances in Member States.

UK 1) - 10 years protection for both active ingredient and product-related data submitted in support of applications for the first commercial level of approval of a pesticide product.
- 5 years protection for active ingredient-related data subsequently required by the registration authority either to support the continuing approval of a product and its uses, or for the purposes of reviews (or until the expiry date of the protection period for the original data package, whichever is later).
(These periods of protection are similar to those which were expected to apply to pesticides under Directive 91/414/EEC.)

Non-EU countries

AUS 1) Unless the a.i. is under patent.

2) If the NRA proposes to use the same information to determine whether to register, or continue registration of another chemical product, the NRA must not use the information until agreement as to the terms for compensation is reached, unless the NRA is satisfied that it is in the public interest to use the information, or the protection period has expired.

3) The protection period generally reflects the expense involved in conducting the trials (depending on their extent and type) necessary to produce the data.

CZ 1) All answers in all parts of the questionnaire should be valid as the new Phytosanitary Care Act No. 147/1996 is valid since January 1. 1997.

2) - 10 years for active ingredients;
- "forever" for other data on formulated pesticide products (preparations);
- data on formulated pesticide product label are excluded from protection by the law No. 147/1996.

3) The principle of obligatory data compensation is not given in any Czech law, though there is the possibility for data compensation based on an agreement with data owner ("Letter of Access" for the national authority).

NZ 1) First registration

- There is an initial 5 year period from the time of data submission. During that time the respective applicant has 5 years to seek full clearance (registration).
  If such a clearance is determined within that 5 year period, the applicant is given a further 5 years of protection. If for whatever reason, a full clearance is determined after five years has elapsed from the time of data submission, then the second leg of 5 years protection is not given. The protection is afforded to all trade secret-or other proprietary data that is likely to be diminished by disclosure.
- There is no provision for compensation mechanisms

Re-Registration

There is no re-registration requirement for pesticides mandated in law, nor is there any data protection provisions mandated in law for proprietary data submitted to satisfy any review. If, though pesticides are formally reviewed because of say some adverse finding, then there is an administrative policy in place to protect proprietary data submitted to satisfy the formal review. The protection afforded is a period of 5 years during which the data will not be used to grant registrations for other proprietors, unless:

(i) The original proprietor agrees to the second registrant citing the data; or

(ii) The original proprietor seeks and obtains voluntary registration cancellation of the pesticide to which the data relates.

SWI 1) However, data derived from animal testing should be shared to avoid duplication of testing on animals.

US 1) - The exclusive use period is 10 years, granted from the date of registration. As a result of new legislation (Food Quality Protection Act of 1996), that period may be extended for up to an additional 3 years with the addition of minor uses to the registration.
In addition, the new legislation also provides that data submitted after the expiration of any period of exclusive use to support solely a new minor use are also entitled to 10 years of exclusive use treatment from the date of submission of the data.
- Exclusive use treatment applies to data submitted in support of the initial registration of a product containing a new active, and to data submitted in support of a new use.

2) The compensation period applies to data submitted to support an application for registration, to add additional uses, to support an experimental use permit, to support or maintain an existing registration, or to support reregistration.

3) 15 years after the date of submission of the data.

FAO 1) See Appendix 1.2 - FAO documentation - 13.3/§2

2) See Appendix 1.2 - FAO documentation - 13.3/§2, 3, 4, 5

TABLE C - Full description of countries' procedures for protecting proprietary rights with respect to pesticides

Country/ Organization	Procedures for protecting proprietary rights with respect to pesticides
European Commission	All data to be submitted by applicants when applying for an authorization are protected. The exclusive use period is described in article 13 par. 3 and 4 of Directive 91/414/EEC which states that in granting authorizations, Member States shall not make use of the information for the benefits of other applicants unless except in certain cases. A differentiation is made between information on the active substance and information on the plant protection product; in addition there is a complete harmonisation for new active substances and plant protection products containing new active substances while the provisions for existing active substances and plant protection products containing existing active substances are not fully harmonised. The following applies: 1. For Annex II information (data for the active substance) 1.1 Plant protection products containing new active substances (those not on the market on 25th July 1993 (that is two years after the date of notification of the Directive)) In granting authorizations, Member States shall not make use of the information for the benefits of other applicants: a. unless the applicant has agreed with the first applicant that use may be made of such information; or b. for a period of 10 years from the first inclusion in Annex I of an active substance not on the market two years after the date of notification of the Directive; and c. for a period of 5 years from the date of a decision, following receipt of further information necessary for first inclusion in Annex I, or to vary the conditions for, or to maintain the inclusion of an active substance in Annex I, which has been taken either to vary the conditions for, or to maintain, the inclusion of an active substance in Annex I, unless the 5 year period expires before the period provided in (b) in which case the period of 5 years shall be extended so as to expire on the same date as those periods. (To be continued)

Country/ Organization	Procedures for protecting proprietary rights with respect to pesticides
European Commission (continued)	1.2 Plant protection products containing existing active substances In granting authorizations, Member States shall not make use of the information for the benefits of other applicants: a. unless the applicant has agreed with the first applicant that use may be made of such information; or b. for periods not exceeding 10 years from the date of the decision in each Member State and provided for in existing national rules, concerning an active substance on the market two years after the date of notification of this Directive; c. for a period of 5 years from the date of decision, following receipt of further information necessary for first inclusion in Annex I, or to vary the conditions for, or to maintain the inclusion of an active substance in Annex I, which has been taken either to vary the conditions for, or to maintain, the inclusion of an active substance in Annex I, unless the 5 year period expires before the period provided in (b) in which case the period of 5 years shall be extended so as to expire on the same date as those periods. 2. Annex III information (data for the plant protection product) 2.1 Plant protection products authorized after inclusion in Annex I of any active substance contained in the product In granting authorizations, Member States shall not make use of the information for the benefits of other applicants: a. unless the applicant has agreed with the first applicant that use may be made of such information. b. for a period of 10 years from first authorization of the plant protection product in any Member State, where authorization follows inclusion in Annex I of any active substance contained in the product. 2.2 Plant protection products authorized before inclusion in Annex I of any active substance contained in the product In granting authorizations, Member States shall not make use of the information for the benefits of other applicants: a. unless the applicant has agreed with the first applicant that use may be made of such information. b. for periods not exceeding 10 years and provided for in existing national rules after the first authorization of the plant protection product in each Member State, where that authorization precedes inclusion in Annex I of any active substance contained in that product. (To be continued)

Country/ Organization	Procedures for protecting proprietary rights with respect to pesticides
European Commission (continued)	- *Compensation:* There is no general system of obligatory sharing of data subject to compensation. - In the framework of the review of existing active substances companies are encouraged to share data and have to do all reasonable steps to achieve this with a view to limiting the duplication of testing on vertebrate animals. - Article 13.7 of Directive 91/414/EEC provides that applicants for authorization of plant protection products shall, before carrying out experiments involving vertebrate animals, enquire of the competent authority whether the plant protection product for which an application is to be made is the same as a plant protection product for which authorization has been granted. - The holder or holders of previous authorizations and the applicant shall take all reasonable steps to reach agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals. - If nevertheless, the applicant and holders of previous authorizations of the same product can still not reach an agreement on the sharing of data, Member States may introduce national measures obliging the applicant and holders of previous authorizations located within their territory to share the data with a view to avoiding duplicative testing on vertebrate animals and determine both the procedure for utilising information, and the reasonable balance of the interests of the parties concerned.
Austria	- Data for a.i., formulations and inert ingredients are protected. - For data which do not involve animal testing, the 'exclusive use' period is 10 years after the registration (or less if the first registrant gives his written consent to use of his data) - For data generated from animal testing, the 'exclusive use' period varies from 1 to 6 years, depending of the length of the study(ies) in question. The owner of the study(ies) is entitled by the Act to a compensation of 50% -of the cost of the study(ies).
Belgium	1) The enquiry shall be supported by evidence that the prospective applicant intends to apply for authorisation on his own behalf and that the other information necessary to obtain the authorisation is available. The competent authority, if satisfied that the applicant intends to apply, will provide the name and address of the holder or holders of previous relevant authorisations and will at the time inform the holders of the authorisations of the name and address of the applicant. (To be continued)

Country/ Organization	Procedures for protecting proprietary rights with respect to pesticides
Belgium (continued)	2) Several cases must be considered: 1. Formulation containing an active substance listed in Annex I of Directive 91/414/CEE concerning the placing of plant protection products on the market 1.1. the data for formulation are protected for a ten year period from the first authorisation of the product in any Member State of the EU, where authorisation follows the inclusion of the active substance in Annex I; 1.2. the data for the active substance are protected for: 1.2.1. a period of ten years from first inclusion in Annex I of an active substance not on the market of the EU on 25/7/1993; 1.2.2. a period of five years from the date of a decision, following receipt of further information necessary for first inclusion in Annex I, or to vary the conditions for, or to maintain the inclusion of an active substance in Annex I, unless the five year period expires before the period provided for under 2.2.1. and 2.2.2., in which cases the period of five years shall be extended so as to expire on the same date as those periods; 2. Formulation containing an active substance not listed in Annex I 2.1. no protection of the data for the formulation, 2.2. the data for the active substance are protected for: 2.2.1. a period of ten years from first authorisation in Belgium; 2.2.2. a period of five years from the date of a decision following receipt of further information necessary to maintain the active substance on the Belgian market. *Compensation:* The Belgian legislation does not provide for any rules about the use of protected data with compensation for the owner. However, in the case of products containing an active substance listed in Annex I, holders of authorisation and applicants must take all reasonable steps to reach agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals. In this regard, applicants for authorisation of plant protection products shall, before carrying out experiments involving vertebrate animals, enquire of the competent authority: - whether the plant protection product for which an application is to be made is the same as a plant protection product for which authorisation has been granted; and - as to the name and address of the holder or holders of the authorisations.

Country/ Organization	Procedures for protecting proprietary rights with respect to pesticides
Denmark	- Data about the synthesis, the degree of purity, impurity of the substances, formulations and inert ingredients are to be kept confidential. Other data for a certain substance can be used by the competent authority for other relevant applications containing this certain substance. - For plant protection products the EU-directive 91/414 lays down rules on data protection in article 13. These rules are implemented in the Danish Chemical Substances and Products Act, section 35a, and take effect when active ingredients - new and old - are entered on the EU list. The main rules are thus: • For plant protection products, as regards new active ingredients (i.e. active ingredients marketed in EU after July 26, 1993), a 10 year protection period applies as a main rule. • For plant protection products, as regards old active ingredients (active ingredients marketed before July 26, 1993), no EU data protection applies to the active ingredient; however, supplementary documentation submitted in connection with inclusion in the EU list may be given a 5-year protection period, related, however, to previous national legislation in the field. The Commission is at present preparing guidelines to assist member states in the administration of these rules. • For new products containing old active ingredients, documentation of the product will be protected for 10 years following inclusion of the active ingredient in the EU list.
Finland	For plant protection products, Finland has implemented directive 91/414/EEC. - Data protection concerns a.i., formulations and inert ingredients. - In the national Finnish legislation, data protection lasts "forever". This means that the documentation presented in a registration application for pesticides may not be used for the benefit of other applicants unless the owner of the documentation has given his permission. Thus in Finland, "pooling" has never been allowed. This legislation is still valid as long as the Plant Protection Product directive is not functioning and no active substances are in Annex I nor any authorizations have been granted in Member States. After the inclusion of active substances in Annex I of Directive 91/414/EEC and the authorizations of formulations with those active substances in Member States, we will of course follow the data protection periods of 10 and 5 years respectively for those substances/products as stated in the Directive. According to the Finnish legislation, there are also pesticide groups to which the Directive does not apply. For those products we will use our national data protection rules also in the future.

Country/ Organization	Procedures for protecting proprietary rights with respect to pesticides
Germany	- Data for a.i., formulations and inert ingredients are protected. - For data which do not involve animal testing, the 'exclusive use' period is 10 years after the registration (or less if the first registrant gives his written consent to use of his data) - For data generated from animal testing, the 'exclusive use' period varies from 1 to 6 years, depending of the length of the study(ies) in question. *Compensation:* The owner of the study(ies) is entitled by the Act to a compensation of 50% -of the cost of the study(ies).
Greece	See reply of the European Commission.
Netherlands	- Data for a.i., formulations and inert ingredients are protected. - There is an "exclusive use" period of 5/10 years: - *Compensation:* This is not regulated, but is practice (written consent) during protection period, unless animal testing is involved. - Normally new data are given a protection period of five years, starting at the moment the authorization is renewed - Not all data are treated the same. Data derived from animal testing may not be repeated.

Portugal	- Data for a.i., formulations and inert ingredients are protected.
	- There is an "exclusive use" period:
	  - 10 years initial data.
	  - 5 years further data.
	The 'exclusive use' period applies to data on toxicology, ecotoxicology, fate and behaviour in the environment and residues.
	- Compensation: There is no period in which others can use the data but compensate the owners.
	- Further data will be protected for 5 years after decision considering this new data.
	- All data are treated the same.

Country/ Organization	Procedures for protecting proprietary rights with respect to pesticides

Spain	- Data for a.i., formulations and inert ingredients are protected, according to Directive 91/414/EEC.
	- There is an "exclusive use" period:
	  - 10 years initial data.
	  - 5 years further data. (according to Directive 91/414/EEC).
	This applies to all data.
	- The secondary applicant must have a permission from the owner in order to use the confidential data.
	- The data from animal testing are used more easily, because it must be avoided to repeat tests with vertebrates.

Sweden	- Data for a.i., formulations and inert ingredients are protected.
	- In the past, there was no "exclusive use" period. However, the situation will change to:
	  - 10 years initial data
	  - 5 years further data,
	following the inclusion of active substances in Annex I of Directive 91/414/EEC and the authorizations of formulations with those active substances in Member states.
	- *Compensation:* There is no period in which others can use can use the data but compensate the owners.
	- All data are treated the same.
	
	National Chemicals Inspectorate always require written agreement from the company that owns the data before the registrant can use it for an application of the pesticide product.

United Kingdom	- Data for a.i., formulations and inert ingredients are protected.
	- There is an "exclusive use" period:
	  - 10 years protection for both active ingredient and product-related data submitted in support of applications for the first commercial level of approval of a pesticide product.
	  - 5 years protection for active ingredient-related data subsequently required by the registration authority either to support the continuing approval of a product and its uses, or for the purposes of reviews (or until the expiry date of the protection period for the original data package, whichever is later).
	(These periods of protection are similar to which were expected to apply to agricultural pesticides under Directive 91/414/EEC.)
	
	(To be continued)

Country/ Organization	Procedures for protecting proprietary rights with respect to pesticides
United Kingdom (continued)	- *Compensation:* No formal compensation arrangements. Use of protected data only by agreement between parties concerned. Data owners may give permission for their data to be used by the registration authorities for the benefit of another company, by means of a letter authorising access to their data before the expiry of the protection period. - New data submitted in support of applications for changes in approval for any product and/or its uses are not given any additional separate period of protection, but are protected until the expiry date of the original product data protection. - All data are treated the same.
Australia	- Under the data protection provisions described earlier, certain information is designated as 'protected registration information' for a 'protection period' (up to seven years) if it is requested by the NRA for the purposes of reconsidering (re-evaluating) the registration of a registered product and it relates to the interaction between the product and the environment or living organisms or naturally occurring populations in ecosystems including human beings. The data protection provisions do not apply to a chemical product which is registered for use only in relation to a particular class of animals that are not a food-producing species. Note: The Australian Government plans to introduce a Bill to Parliament during 1997 which, if enacted, will provide 5 years data protection for new active constituents (ie new chemical entities) in respect of agricultural and veterinary chemical products. - There is no 'exclusive use' period for the protected data owner, but if the NRA proposes to use protected registration information to determine whether to register, or continue registration of another chemical product, the NRA must not use that information until agreement as to the terms for *compensation* is reached, unless the NRA is satisfied that it is in the public interest to use the information, or the protection period has expired. - Protected registration information is not treated uniformly with respect to the protection period. The protection period for a piece of information ranges from two to seven years and generally reflects the expense involved in conducting the trials necessary to produce the information. - The protection period begins on the date the data are received by the NRA. If new data are submitted after the initial submission is received, and they are deemed protected, the protection period begins on the date of submission of the additional data, not the date of the original submission.

Country/ Organization	Procedures for protecting proprietary rights with respect to pesticides

Czech Republic	- Data for a.i., formulations and inert ingredients are protected.
	- There is an “exclusive use” period
	  - 10 years for active ingredients;
	  - "forever" for other data on formulated pesticide products (preparations);
	  - data on formulated pesticide product label are excluded from protection by the law No. 147/1996.
	- *Compensation:* There is no period in which others can use can use the data but compensate the owners. The principle of obligatory data compensation is not given in any Czech law, though there is the possibility for data compensation based on an agreement with data owner ("Letter of Access" for the national authority).
	- New data on the active ingredient/s submitted during period of valid registration are protected for the remaining x - years only; but when submitted at the re-registration procedure they will be fully protected for 10 years.
	- All data are treated the same.

Country/ Organization	Procedures for protecting proprietary rights with respect to pesticides
Hungary	- Data protection cover both active ingredients and formulation. - According to the Ministerial Order on Plant Protection, No.: 5/1988, Article 36: "The submitted documents supporting the application for registration cannot be handed over to other person, and the data cannot be used for at least 10 years (or until expiry date of licence) for the registration of other products without written permission of the owner. - Law No.LXIII of 1992, Section III, Publicity of Data of Public Interest - Article 9 (1) Any responsible body and person providing state or local government tasks (hereinafter: body) is obliged to contribute to reliable and rapid information of general public on any matter of his competence, including economic matters. (3) Those mentioned under paragraph (1) may allow that data of public interest available for them may be known by anybody, except, if data are declared state or service secret by the competent body pursuant to legislation. - The Ministerial Order No.: 2/1996 (I.9.) FM - Article 2 The list of service secret of the Ministry of Agriculture is specified in Annex to this Order: Annex to Order No. 2/1996 (I.9.) FM (2) Data submitted for registration of pesticides for max. 10 years. - It means that all data submitted for pesticide registration should be considered confidential for max. 10 years. It is not really clarified but distinguish could be made between the data submitted by registrant and the final conclusion of the authorities drawn from the submitted information. Such data are for example the content of registration documents (see Question 2.6). - *Compensation:* No compensation system for data use is operating, but the possibility of the implementation of US like regulation is being checked. The above mentioned 10 years data protection is also concerning to the submitted new documents and all data treated the same. - We know that more sophisticated regulation would be necessary for pesticides, it will be done during the elaboration of the new pesticide law, expected for approval in 1998.
Japan	- Japan protects permanent exclusive proprietary rights for owners concerning all data. The owners have the right to decide whether they use the data exclusively or they allow others to use data but must *compensate* the owners. - New data are also given permanent proprietary rights protection. - All data are treated the same.

Country/ Organization	Procedures for protecting proprietary rights with respect to pesticides
New Zealand	First registration - Data for a.i., formulations and inert ingredients are protected. - There is an initial 5 year period from the time of data submission. During that time the respective applicant has 5 years to seek full clearance (registration). If such a clearance is determined within that 5 year period, the applicant is given a further 5 years of protection. If for whatever reason, a full clearance is determined after 5 years has elapsed from the time of data submission, then the second leg of 5 years protection is not given. The protection is afforded to all trade secret or other proprietary data that is likely to be diminished by disclosure. - *Compensation:* There is no provision for compensation mechanisms - There is no provision for any additional data to be protected once the pesticide is in the second leg of protection. - All proprietary test data are treated the same. - Other relevant information. - The protection afforded also includes backdating provisions to give cognisance to an administrative policy on proprietary data protection that was in place prior to commencement of the Pesticides Amendment Act 1994. Data protection for relevant pesticides does not extend beyond 1 January 2000. - There is no linkage of data protection to patents. Re-Registration There is no re-registration requirement for pesticides mandated in law, nor is there any data protection provisions mandated in law for proprietary data submitted to satisfy any review. If, though pesticides are formally reviewed because of say some adverse finding, then there is an administrative policy in place to protect proprietary data submitted to satisfy the formal review. The protection afforded is a period of 5 years during which the data will not be used to grant registrations for other proprietors, unless: (i) The original proprietor agrees to the second registrant citing the data; or (ii) The original proprietor seeks and obtains voluntary registration cancellation of the pesticide to which the data relates.
Norway	- Data for a.i., formulations and inert ingredients are protected. - The "exclusive use" period is permanent. - *Compensation:* There is no period in which others can use the data but compensate the owners. Norway requires that all applicants submit dossier with its own documentation. An alternative would be to send a statement which shows that they are covered by/or co-operates with another companies documentation. - New data are protected in the same way as for first registration. - All data are treated the same.

Country/ Organization	Procedures for protecting proprietary rights with respect to pesticides
Switzerland	- Data for a.i., formulations and inert ingredients are protected. - The "exclusive use" period is permanent. However, during or after the period of patent protection, a second applicant may obtain registration without having to submit a full registration file of his own, provided he may procure an authorisation to do so of the first registrant, i.e. the legal owner of the registration file. *(Implementing Order on Plant Protection Products, RS 916.161, Para 13, al. 2a).* (This is a private matter and is probably subject to compensation). - *Compensation:* There is no compensation period as such. Arrangements for compensation are left entirely to the concerned parties - All data are treated the same. However, data derived from animal testing should be shared to avoid duplication of testing on animals Note: The proprietary rights on the actual documents submitted by a registrant in support of his pesticide registration request is guaranteed. The Swiss pesticide regulatory authorities, however, do not *ex* officio investigate the patent status of the product to be registered. Violation of patent rights have to be sued by the patent owner. Patent: A patent is only granted to a substance. Formulated products hardly ever get a patent. The patent protection lasts for 20 years. A Supplementary Protection Certificate, extending the protection period for a maximum of 5 years, is under consideration for pesticides. It would be along the same lines as in the European Union. Once patent protection has ended a follower applicant may obtain a registration in his own rights - without to having to submit a registration file of his own, provided he can prove his product to be factually identical with that of the first applicant, condition which is considered as complied with in cases of parallel imports, *(Implementing Order on Plant Protection Products, RS 916.161, Para 13, al. 2b).* - with a limited - case-wise defined - registration file, provided: - he can prove his product to be technically identical with that of the first applicant. and provided: - the poison classification of the product, - the crop tolerances, have already been established. *(Directives pour le dépôt des demandes. FAW, autumn 1994)*

Country/ Organization	Procedures for protecting proprietary rights with respect to pesticides
Turkey	- Data for a.i., formulations and inert ingredients are protected. - The "exclusive use" period is of 2 years. - *Compensation:* There is no period in which others can use the data but compensate the owners. After 2 years, others can automatically use the data. - New data are given proprietary rights protection for the remaining period of time. - All data are treated the same.

United States	- Data for active ingredients, formulations and inert ingredients are protected.
	- There is an "exclusive use" period in which only the owner can use the data.
	  - The exclusive use period is 10 years, granted from the date of registration.. As a result of new legislation, (Food Quality Protection Act of 1996), that period may be extended for up to an additional three years with the addition of minor uses to the registration.
	  - Exclusive use treatment applies to data submitted in support of the initial registration of a product containing a new active, and to data submitted in support of a new use.
	  - In addition, the new legislation also provides that data submitted after the expiration of any period of exclusive use to support solely a new minor use are also entitled to ten years of exclusive use treatment from the date of submission of the data.
	- Compensation: The period of time for compensation is 15 years from the date of submission of the data. This applies to data submitted to support an application for registration, to add additional uses, to support an experimental use permit, to support or maintain an existing registration, or to support reregistration.
	The company wishing to use the data must, prior to registration, certify to the U.S. EPA that either it has permission from the original data submitter to use the data, or that it has made an offer to pay compensation to the original data submitter. Disputes about the value of data may be resolved through binding arbitration. Provided the certification referred to above (affirming multinational pesticide producer status) has been submitted to EPA, EPA may proceed with registration action prior to the fixing of compensation.
	
	(To be continued)

Country/ Organization	Procedures for protecting proprietary rights with respect to pesticides
United States (continued)	- All data are treated the same. If a registrant submits data to add a new use to the registration within the original ten-year period of exclusive use, such data are entitled to exclusive use treatment for the remainder of the original exclusive use period. As noted above, the original period of exclusive use may be extended up to an additional three years if the registrant adds new minor uses to the registration. After the expiration of the exclusive use period, such data would still be subject to compensation for any period remaining to the 15-year compensation period. That period is measured from the date of submission of the data. Thus, if data were submitted in 1985 to support a product also registered in 1985, the exclusive use period would have expired in 1995, but the data submitter would still possess compensation rights for the data until 2000. As noted above, new legislation provides that data submitted to support a new minor use also receive exclusive use protection for ten years if any previous period of exclusive use applicable to data submitted to support the registration has expired. Other data (e.g., data submitted to support reregistration) are subject to compensation for a period of 15 years from the date of submission of the data.
FAO	See Appendix 1.2

TABLE D - Application of the OECD Recommendation of the Council C(83)96

Question 1.5.

Does your country apply the OECD Recommendation concerning the Protection of Proprietary Rights to Data Submitted in Notification of New Chemicals (see Appendix 1.3) to pesticides?

Note: Australia abstained from endorsing this recommendation.

Responses	Countries	* Additional information
YES	EC Austria Belgium Denmark France Germany Greece Netherlands Portugal* Spain* Sweden UK* ---------- Hungary* Japan New Zealand Norway Switzerland Turkey US*	Portugal: We adopt the EU model. Spain: Applying the Directive 91/414/EEC. UK: De facto implementation via the UK's national rules for pesticides. ---------- Hungary: There is no written regulation to apply the OECD Recommendation, but the practice of the pesticide registration follows points 1 and 2 of the mentioned Recommendation. US: The US do comply with the OECD recommendation. To clarify: we are able to share the results of physical and chemical data studies, but we are not able to share the data itself. Further, we are limited by FIFRA Section 10(g) in releasing information to multinational pesticide producers, or persons or governments who intend to release such information to multinational pesticide producers. When complying with a request for information, the EPA is obligated to first obtain a statement signed by the requester, indicating that the requester is not a representative of a multinational pesticide producer, and does not intend to release the information to such a producer.

(To be continued)

(continued)

Responses	Countries	* Additional information
NO	Finland* --- Australia* Czech Rep.*	Finland: Not implemented. --- Australia: It is considered the responsibility of the notifier to ensure there is no unauthorised access to their data outside the responsibilities of the NRA. Czech Rep.: Due to the fact that the law on chemicals exists only in an early stage draft. The principles of this OECD Recommendation C(83)96 are used by the pesticides registration national authority of the Czech Republic in the registration procedure. Generally all data, submitted by the applicant are checked for their origin before the evaluation of them is started.

APPENDIX 1.1

Titles of national instruments (e.g. laws/regulations) to protect Proprietary Rights with respect to pesticides

Country/ Organization	Titles	Specific to pesticides?
European Commission	Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market.	Yes
Austria	"Pflanzenschutzmittelgesetz 1997" (will come into force in 1997).	Yes
Belgium	Art. 13 of the 'Arrêté royal du 28/02/1994 relatif à la conservation, à la mise sur le marché et à l'utilisation des pesticides à usage agricole'	Yes
Denmark	- Biocides: Act No. 572, 19 Dec. 1985. The Danish Access to Public Administration Files Act.	No
	- Plant Protection Products: Dir 91/414/EEC - implementation in the Danish Act on Chemical Substances (consolidated Act no 21 of 16 January 1996).	Yes
Finland	- Pesticides Act (327/69, last amendment 1204/94) § 9a. - Pesticides Decree (792/95) §19 and §20	Yes
Germany	Plant Protection Act (Pflanzenschutzgesetz)	Yes
Greece	- Council directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. - National Law 721/77	Yes
Netherlands	- Bestrijdingsmiddelenwet 1962 ("Pesticide Law"). - Regeling toelating bestrijdingsmiddelen 1995 ("Regulations for permitting pesticides").	Yes
Portugal	- Regulation 106/89, Republic Diary nr. 265, I Série, of 17 November 1989. - Law 563/95, Republic Diary nr. 135/95, I Série, of 12 June 1995.	Yes
Spain	- Real Decreto 3349/1983, of 30 November, adopting the Technical Sanitary reglementation for the manufacturing, marketing and use of pesticides. - Real Decreto 2163/1994, of 4 November, adopting the harmonized communitary system relating to the marketing and use of pesticides (Directive 91/414/EEC)	Yes
Sweden	- Pesticides Ordinance (SFS 1985:836 as amended SFS 1996:821): implementation of the Council Directive 91/414/EEC of 15 July 1991)	Yes
	- Rules in the Swedish constitution cover all types of proprietary rights. They are applicable for the protection of proprietary rights with respect to pesticides (ref. 2:18, 2:20 and 2:22)	No
United Kingdom	The Food and Environment Protection Act 1985, the Control of Pesticides Regulations 1986 and related statutory instruments give legal validity to the administrative procedures, or requirements, of the 'Registration Handbook' (PSD-HSE).	Yes
Australia	*The following address data protection (distinct from proprietary rights): The 'Agricultural and Veterinary Chemicals Code Act', 1994 (Agvet Code) and associated regulations.*	*(Yes)*

Country/ Organization	Titles	Specific to pesticides?
Czech Republic	Phytosanitary Care Act No. 147/1996 from April 24, 1996 (approved by Czech Parliament). This Act is valid since January 1, 1997.	Yes
Hungary	- Order No.5/1988 (IV. 26.) MéM of the Ministry of Agriculture and Food on the Enforcement of the Statutory Law No.2 of 1988 on Plant Protection (amended by the Ministerial Order No.9/1993 (I. 30.) FM) - Order No. 2/1996 (I. 9.) FM of the Ministry of Agriculture on the Statement of Service Secrets of the Ministry of Agriculture	Yes
Japan	- The 'Unfair Competition Prevention Law': it covers CBI. - The 'Government Official Act': it stipulates that government officials shall not release confidential information which they can obtain thorough their work. - The Patent Law	No
New Zealand	The Pesticides Amendment Act 1994.	Yes
Norway	The Public Administration Act	No
Switzerland	- Implementing Order on Plant Protection Products: 'Ordonnance sur la mise dans le commerce des produits de traitement des plantes et de protection des récoltes. (Ordonnance sur les produits de traitement des plantes)' du 26 janvier 1994 - RS 916.161	Yes
	- Patent Law: 'Loi fédérale sur les brevets d'invention' du 25 juin 1954 (Etat le ler janvier 1996) - RS 232.14 - Implementing Order on Patents: 'Ordonnance relative aux brevets d'invention' (Ordonnance sur les brevets) du 19 octobre 1977 (Etat le 1er janvier 1996) - RS 232.141	No
Turkey	- Law 6968: "Agricultural Protection and Quarantine". - Regulations no. 11142: "Regulation of Agricultural Chemicals and Protection Tools" (article 29).	Yes
United States	- Law: Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 10(g): -- legislative authority for protection of Confidential Business Information (CBI): prevents a "person" from obtaining data generated at another "person's" expense and then using the data to obtain approval of another country's government to manufacture or sell a product, or use the data in support of another product's registration. - Regulation: 40 Code of Federal Regulations (CFR) 152.80 - 152.99 - Legal interpretation: class determination 3-85, 40 CFR 2.207	Yes
FAO	- FAO Addendum II to Guidelines for the Registration and Control of Pesticides, FAO Rome 1988 (see text in Appendix 1.2). - Article 6 of the International Code of Conduct on Distribution and Use of Pesticides, 1990: "Governments should (6.1.3) protect the proprietary rights to use of data".	Yes

APPENDIX 1.2

FAO documentation

ADDENDUM II
to Guidelines for the Registration and Control of Pesticides, FAO Rome 1988

PROPRIETARY RIGHTS TO DATA

The text below is to replace the text on pages 38 and 39 para 13.3 of the Guidelines for the Registration and Control of Pesticides.

13.3 Proprietary Rights to Data

All data submitted by a company in support of its request for registration of its product should be treated as proprietary and should neither be divulged nor used to evaluate a petition submitted by another applicant, unless by agreement with the owner of the data or unless a period of proprietary rights to the data has expired. The synthesis of new materials and procurement of data on safety and efficacy essential for registration will have taken commercial companies many years and will have been very expensive. The results obtained are as much the property of the company that produced them as is the plant used to manufacture the product. Therefore, it would be unjust for registration authorities to use, for the benefit of industrial competitors, data submitted to them in good faith. Each applicant should be required to produce full supporting data, either by doing the work himself or by licence from the owner of the data.

Apart from the injustice of allowing competitors to benefit from the use of data to which they have no right, the consequences of such an action would be to discourage, because it is unrewarding, the research and development required for the production of new pesticides which are needed, for example, for the control of new or difficult pests or to overcome resistance.

The following guiding principles are suggested when developing procedures to safeguard proprietary rights on registration data:

1. Authorities should request from new petitioners for an already registered product the same data as they have requested from those who already hold such a registration. They should request original data rather than a summary monograph. This will help the authority in making a judgement on the ownership of the data.

2. Authorities should provide a significant period of exclusive use to the registrant who generates the registration data. Many countries already protect the proprietary data supporting registration by this means. The period of protection varies from country to country depending on its own circumstance. In most instances, this exclusive use period runs for 10 to 15 years. In those cases where the exclusive use period is stipulated as 10 years, it is usually coupled with compensation payment for the use of data for a further 5 year period. This is seen as a compromise between the rights of the original data submitter and the interest of new petitioners.

3. For follow-up data which have been submitted to the authorities during the exclusive use period and are less than 10 years old, new petitioners should be requested to submit a written permission from the data owner(s) that the authorities may use these data for the registration of their product.

4. After the exclusive use period since the first registration in a given country any new petitioner should be entitled to obtain the permission for using data submitted less than 10 years ago upon agreeing to the sharing of the costs incurred in generating the data.

5. When instituting a procedure of safeguarding proprietary rights which includes a period during which payment for the use of the data is required, the principles to be followed in agreeing adequate payment should be established. The procedure should not place the regulatory authority in the position of having to arbitrate between the data owner(s) and subsequent petitioners. There is no single solution regarding payment for costs incurred in producing registration data. An important factor is the length of the period of exclusive use provided to the data owner. The longer this period, the more "scientifically" outdated the data become. Thus, with a relatively long exclusive use period the payment could consist of an equal sharing of the costs of the studies. If the exclusive use period is kept relatively short, the situation is more difficult. The data will still have their full scientific value and the original data owner has run a substantial risk in developing these data, which he legitimately wants to see reflected in a more substantial payment. In this case, it is particularly important that a definite system for agreeing on payment is instituted.

6. The maintenance of a registration and any further follow-up data needed to affect this should be the responsibility of all registration holders once the period of exclusive use to the registrant who generated the original data, has elapsed. Any requests by the regulatory authorities for further data should therefore be addressed to both the original data owner(s) as well as new and subsequent petitioners.

During the Second Government Consultation on International Harmonization of Pesticide Registration Requirements (Rome, 1982), GIFAP expressed the opinion that there are no objections concerning public access to health and safety data submitted in support of pesticide registrations as long as this public access does not include the right to copy that proprietary data.

APPENDIX 1.3

RECOMMENDATION OF THE COUNCIL

concerning the Protection of Proprietary Rights to Data submitted in Notifications of New Chemicals (*)

26th July 1983 - C(83)96(Final)

The Council,

Having regard to Articles 2 a), 2 b), 2 d), 3 and 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14th December 1960;

Having regard to the Recommendation of the Council of 14th November 1974, on the Assessment of the Potential Environmental Effects of Chemicals [C(74)215];

Having regard to the Recommendation of the Council of 7th July 1977, Establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment [C(77)97(Final)];

Having regard to the Decision of the Council of 21st September 1978, concerning a Special Programme on the Control of Chemicals and the Programme of Work established therein and the extension of the duration of the Programme by Council on 12th May 1981 [C(78)127(Final) and C/M(81)7(Final), Item 86];

Having regard to the conclusions of the First High-Level Meeting of the Chemicals Group of May 1980, concerning the confidentiality of data [ENV/CHEM/HLM/80.M/1];

Having regard to the conclusions of the Second High-Level Meeting of the Chemicals Group of November 1982, on proprietary rights [ENV/CHEM/HLM/M/82.1];

Considering the importance of production and international trade in chemicals and the mutual economic and trade advantages which accrue to OECD Member countries from harmonization of policies for chemicals control;

Considering the economic value of certain data on chemicals, in particular health, safety, and environmental data, and the possible adverse effects of the disclosure of these data on the competitive position of the person or company who developed the data;

Considering therefore the need to protect data from unauthorised use in notifications of new chemicals;

On the proposal of the Second High-Level Meeting of the Chemicals Group, endorsed by the Environment Committee;

1. RECOMMENDS that authorities responsible in Member countries for receiving notifications of new chemicals require each notifier to identify the laboratories which produced each of the health, safety, and environmental data in the notification and, if the laboratories are not owned or otherwise affiliated with the notifier, to provide certification of the right to use the data.

2. RECOMMENDS that authorities responsible in Member countries for receiving notifications of new chemicals not accept from a notifier health, safety, and environmental data for which the notifier cannot provide a certification of the right of use, if the laboratories are not owned or otherwise affiliated with the notifier.

3. INVITES Member countries to report to the Organisation on measures taken to implement this Recommendation.

4. INSTRUCTS the Environment Committee and the Management Committee of the Special Programme on the Control of Chemicals to review actions taken by Member countries in pursuance of this Recommendation and report thereon to the Council.

* Australia abstained

- Annex 2 -

CBI

National laws, regulations and procedures

TABLE E - CBI: definitions, laws/regulations and agreements

Questions 2.1, 2.2, 2.3, 2.5, 2.7.

Questions	EC	AUT	BEL	DK	FIN	FR	GER	GR	NL	POR	SP	SWE	UK	AUS	CZ	HUN	JP	NZ	NOR	SWI	TK	US
Q2.1 - Does your country have a definition of CBI with respect with pesticides?	No	No	No	No	No[1)]	No[1)]	No[1)]	No	No	No	Yes[1)]	No	No[1)]	Yes[1)]	No[1)]	No	No	Yes[1)]	No	No	Yes[1)]	No
↳ Reference of documents in which the definition can be found	-	-		-	Yes[2)]	-	-	-	-	1)	Yes[2)]	-	Yes[2)]	Yes[2)]	-	-	-	No	-	-	Yes[2)]	Yes[1)]
Q2.2 - Does your country have national instruments to protect CBI for pesticides? (Titles can be found in Appendix 2.1)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes[3)]	No[2)]	No[1)2)]	Yes	Yes	Yes	Yes	Yes	Yes
Q2.3 - Are the laws/regulations specific to pesticides? (See Appendix 2.1)	Yes No	Yes No	Yes	Yes	Yes	Yes	No	Yes	Yes No	No?	Yes	No	Yes	Yes	Yes		No	Yes	No	Yes No	Yes	Yes No
Q2.5 - Note: Detailed answers to this question are shown in Table F - The two following rows show only a summary of the answers																						
Q2.5 - Does your country require the pesticide registrant to identify information he wishes to be treated as confidential in his data submission?	No	Yes	Yes	Yes[1)] No	Yes	Yes	Yes[2)]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No	No	No	Yes	No	Yes
Q2.5b) - Do you automatically accept it as confidential?	No	No	Yes	No	Yes	No	No	No	No	No	No	No	-	No	-	Yes	-	-	No	No	Yes	No
Q2.7 - Has your country entered any bilateral agreements regarding the protection of CBI?	No	No	No	No	Yes[3)]	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes[2)]

Comments for Table E

EU countries

DK 1) Yes for plant protection products covered by Directive 91/414/EEC
No (in other cases??)

FIN 1) Finland does not have any special definition of CBI. However, the Pesticides Act § 9a defines what is confidential:
"Documents issued or drafted for processing of a pesticide registration application which contain information concerning a private or professional secret shall remain confidential".
2) - Pesticides Act (327/69, last amendment 1204/94) § 9a.
- Pesticides Decree (792/95) §19 and §20.
3) Nordic co-operation concerning evaluation of health and environmental effects of active substances (old and new ones).

FR 1) We use the term 'confidential data' as defined in article 14 of Directive 91/414/EEC.

GER 1) No legal definition but there are some specific addressed items which cannot be disclosed without authorization, for instance personal or business matters.
2) In future according to Directive 91/414/EEC.

POR 1) We use the concepts of the 91/414/EEC Directive.

SP 1) All the documentation that could reveal industrial or commercial secrets are considered "confidential information".
2) Real Decreto 2163/1994, of 4 November, adopting the harmonized communitary system relating to the marketing and use of pesticides (Directive 91/414/EEC)

UK 1) The term "confidential information" is used:
"As a general rule all information, correspondence and other documents concerning pesticide approval applications are treated as confidential and cannot be disclosed."
2) More information is given in the "Registration Handbook" (PSD - HSE), Part I: Pesticides Policy and Controls, Section G: Access to information

Non-EU countries

AUS 1) '**Confidential commercial information**' in relation to an active constituent for a proposed or existing chemical product or in relation to a chemical product or a constituent of a chemical product means:
(a) a trade secret relating to the constituent or product; or
(b) any other information relating to the constituent or product that has a commercial value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed; or
(c) information (other than trade secrets to which paragraph (a) applies or information to which paragraph (b) applies) that:
(i) concerns the lawful commercial or financial affairs of a person, organisation or undertaking; and
(ii) relates to the manufacture, distribution or supply of the constituent or product; and
(iii) if it were disclosed, could unreasonably affect the person, organisation or undertaking in an adverse manner.

2) The AgVet Code.

3) Yes. Except in the performance of functions or duties, or the exercise of powers (as specified in the Agvet Code) persons employed or appointed (current or past) by the NRA under the Code's provisions, must not intentionally or recklessly disclose, directly or indirectly, to another person any information about an active constituent for a proposed or existing chemical product, about a chemical product or any of its constituents, or about a label for container for a chemical product, that:
(a) the person knows to be confidential commercial information, and
(b) was acquired by the person in the performance of such functions or duties or the exercise of such powers.
The Freedom of Information Act 1982 also applies.

CZ 1) There is none explicit definition of the term "CBI" with respect to pesticides in any Czech law yet. Any other term for CBI is not used.

2) All data submitted by the pesticide registrant are considered to be confidential with the exception of the data used for product labelling according to the Phytosanitary Care Act No. 147/1996.

HUN 1) The protection of CBI works only **in practice**. The pesticide registration authorities consider as CBI all information which is **asked to be confidential** by the owner of the data or, without special request, all submitted data **except** those which were officially published (registration document, official journal).

2) Law/regulation to protect CBI for pesticides is under preparation. It will be incorporated in the new pesticide law.

NZ 1) The relevant term are "confidential information" and "confidential supporting information".
- "Confidential Information" is trade secret information and information that has a commercial value that would be, or would likely to be, diminished by disclosure;
- "Confidential Supporting Information" means confidential information given in, or in relation to, an innovative pesticide application and about the pesticide that is or was, as the case may be, the subject of an application.

TK 1) “Any information by a registrant cannot be declared to the others by the government”.
2) Reference: Regulation of Agriculturals Chemicals and Protection Tools (no: 11142).

US 1) - FIFRA §10(b), 7 U.S.C. §136h(b), provides that EPA may not disclose to the public "commercial or financial information obtained from a person and privileged or confidential."
- Exemption 4 of the Freedom of Information Act (FOIA) similarly exempts from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential."
- 5 U.S.C. §552(b)(4). EPA analyzes FIFRA CBI claims according to the law interpreting FOIA exemption 4, and relevant provisions in FIFRA.

Although FOIA Exemption 4 includes several grounds for according confidential treatment to business information, the chief rationale applicable to FIFRA submissions is where disclosure of the information is likely to cause substantial harm to the competitive position of the person from whom the information was obtained. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974).

FIFRA §10(d)(1) provides that certain safety and efficacy information may not be treated as confidential. (See answer to question 2.4 for more information)

2) The U.S. Environmental Protection Agency's Office of Pesticide Programs and the Canadian Pest Management Regulatory Agency exchanged formal letters on March 27, 1996. The two agencies have agreed that data reviews which may contain CBI may be exchanged with the written permission of the registrant. The purpose of this agreement was to facilitate the exchange of data reviews, and to eliminate the burden of reviewing all of the documents and eliminating CBI prior to the exchange.

TABLE F - Information the registrant wishes to be treated as confidential

Question 2.5

Does your country require the pesticide registrant to identify information he wishes to be treated as confidential in his data submission?

a) Please explain how should the registrant do this?

b) Do you automatically accept as confidential the information identified by the registrant?

Country/ Organization	Countries' answers to questions 2.5, 2.5.a) and 2.5.b)
European Commission	Yes a) The applicant has to provide confidential information in a separate volume. b) No - Information involving industrial and commercial secrets is treated as confidential if the applicant requests so and if the Member State concerned or the Commission accept that the applicant's request is warranted.
Austria	Yes a) The applicant has to provide confidential information in a separate volume. b) No - Information involving industrial and commercial secrets is treated as confidential if the applicant requests so and if th e Member State or the Commission accept that the applicant's request is warranted.
Belgium	Yes a) The applicant must request the confidential treatment of the submitted data. Together with his application, he must submit a separate dossier containing all information that cannot be considered as confidential. This dossier can freely be consulted by the public. b) Yes - The information identified by the registrant is automatically accepted as confidential, unless it cannot be considered as confidential according to art. 37 of the arrêté royal of 28/02/94.
Denmark	Yes for plant protection products covered by Directive 91/414/EEC. No (in other cases??) a) The applicant has to provide confidential information in a separate volume. b) No (for plant protection products covered by Directive 91/414/EEC).

Country/ Organization	Countries' answers to questions 2.5, 2.5.a) and 2.5.b)
Finland	Yes a) In Finland, the main rule of data protection is that, during the handling of an application for the registration of a pesticides, all information which a company sends to the authorities is confidential and authorities do not use the information in benefit of other companies without consent. When the decision on approval has been taken, some information becomes public as shown in the answer to question 2.4. b) Yes
France	Yes a) The notifier lists data he wishes to protect. b) No. Two scenarios: - for <u>new products</u>: the list is accepted as proposed by the notifier. - for products already authorised in France, new studies (e.g. done to obtain registration in another country) may or may not be protected, based on the competent authorities' judgement.
Germany	Yes (in the future) / No (at the moment) a)b) Information submitted by applicants involving industrial and commercial secrets is treated as confidential if the applicant so request, and if it is accepted that the applicant's request is warranted.
Greece	Yes a) The applicant has to provide confidential information in a separate volume. b) No - Information involving industrial and commercial secrets is treated as confidential if the applicant requests so and if the our Department or the Commission accept that the applicant's request is warranted.
Netherlands	Yes a) The applicant has to provide confidential information in a separate volume. Identification in request to government. b) No - Information involving industrial and commercial secrets is treated as confidential if the applicant requests so and if the government accepts that the applicant's request is warranted.
Portugal	Yes a) The registrant should claim to the data concerned. b) No - We check with the existing data in other dossiers.

Country/ Organization	Countries' answers to questions 2.5, 2.5.a) and 2.5.b)
Spain	Yes a) The applicant can ask the confidentiality for some data, except the ones on the article 32 (Real Decreto 2163/1994), if he considers necessary. b) No - It is necessary to establish if it is justified.
Sweden	No a) - b) No - The Swedish Constitution states the freedom of information (or the principle of public access to official records) as a rule. The Official Secrets Act is an exception from the Swedish Constitution. Further, the data a registrant claims to be confidential can be important from health/environmental risks and can therefore not always be handled as confidential.
United Kingdom	No
Australia	No. The interested person (registrant) has the option to identify CBI. a) The interested person (registrant) may do this by indicating which information is confidential commercial information in a covering letter or by labelling the confidential pieces of information in his/her application. b) No - Only the information considered as "confidential commercial information" under the Agvet Code or the Freedom of Information Act is accepted as confidential.
Czech Republic	No
Hungary	No a) - b) Yes.
Japan	No
New Zealand	No
Norway	No a) - b) No - Only information which would be of competitive importance and which cannot be patented is kept secret.

Country/ Organization	Countries' answers to questions 2.5, 2.5.a) and 2.5.b)
Switzerland	Yes (according to the *Implementing Order on Environmentally Dangerous Substances: 'Ordonnance sur les substances dangereuses pour l'environnement.(Ordonnance sur les substances, Osubst)' du 9 juin 1986 (Etat le ler juillet 1995) - RS 8140.13*) a) Whoever provides documents to the authorities will himself designate the information which must be kept secret. b) No - If an authority wishes not to treat in a confidential manner information for which secrecy has been requested, the authority will consider whether the information truly warrants protection. If there is a contradiction between the judgement of the authority and the request of the interested party, the authority will communicate to the party, as a (regulatory) decision which pieces of information are considered not to warrant protection. The authority does not have the right to publish the information concerned until the decision is in force. *(Unofficial translation)*
Turkey	No a) - b) Yes.
United States	Yes a) Per PR Notice 86-5, by confidentiality statement, with confidential attachments. b) No - Information claimed as confidential is treated as such by EPA until and unless the Agency, by formal process, determines that the information is not entitled to confidential treatment. Normally the registrant is given an opportunity to substantiate its confidentiality claim, and is always given advance notice in the event that the Agency determines the information not to be entitled to confidential treatment.

TABLE G - For active ingredient: which of the following does your country treat as confidential (✓) ?
Question 2.4

Active ingredient	EC*	AUT	BEL	DK*	FIN	FR	GER	GR	NL	POR*	SP	SWE	UK	AUS	CZ*	HUN*	JP	NZ	NOR	SWI	TK	US*
Identity		✓[1]																				
• common name, synonyms																						
• chemical name																						
• CAS, EEC or CIPAC numbers																						
• internal code numbers (manufacturer✓, applicant✓)									✓					✓✓						✓✓		
• molecular formula																						
• structural formula																						
• molecular mass						✓																
• purity of the a.i.		✓	✓			✓			✓					✓	✓	✓	✓	✓		✓		
Identity of isomers		✓[2]				✓	✓	✓	✓		✓		✓	✓	✓	✓	✓	✓				
Content of isomers		✓[2]				✓	✓	✓	✓		✓		✓	✓	✓	✓	✓	✓				
Identity of impurities		✓[2]	✓	✓		✓	✓	✓	✓		✓	✓[1]	✓	✓	✓	✓	✓	✓		✓		✓[1]
Content of impurities		✓[2]	✓	✓		✓	✓	✓	✓		✓	✓[1]	✓	✓	✓	✓	✓	✓		✓		✓[1]
Analytical profiles of batches			✓	✓		✓		✓	✓		✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	
Detailed description of the manufacturing process		✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Manufacturer(s)			✓	(✓)		✓	✓		✓				✓		✓			✓			✓	✓
Physical and chemical properties							✓								✓						✓	
Summary results of all tests (all test areas)									✓				✓[1]		✓	✓	✓[1]				✓	
Complete results (raw data) of tests (all test areas)		✓	✓		✓	✓	✓		✓		✓		✓[2]	✓	✓	✓	✓[1]	✓		✓	✓	✓[2]
Complete results (raw data) for specific test areas (please specify areas)		✓			✓	✓			✓								✓[1]	(✓)		✓	✓	
Summary results for specific test areas (please specify areas)					✓				✓[1]								✓[1]			✓[1]	✓	
Information on hazard categories, nature of the risks, relevant warnings & precautions to be taken																						
Ways to render substance harmless																						
Others (please list)														✓[1]								

Comments for Table G

EC and EU countries

EC *) *Article 14 of Directive 91/414/EEC*

"Member States and the Commission shall, without prejudice to Council Directive 90/313/EEC of 7 June 1990 on the freedom of access to information on the environment (OJ No L 158, 23. 6. 1990, p.56.), ensure that information submitted by applicants involving industrial and commercial secrets is treated as confidential if the applicant wishing to have an active substance included in Annex I or the the applicant for authorization of a plant protection product so requests, and if the Member State or the Commission accepts that the applicant's request is warranted.

Confidentiality shall not apply to:

- the names and content of the active substance or substances and the name of the plant protection product,
- the name of other substances which are regarded as dangerous under Directives 67/548/EEC and 78/631/EEC,
- physico-chemical data concerning the active substance and plant protection product,
- any ways of rendering the active substance or plant protection product harmless,
- a summary of the results of the tests to establish the substance's or product's efficacy and harmless to humans, animals, plants and the environment,
- recommended methods and precautions to reduce handling, storage, transport, fire or other hazards,
- methods of analysis to determine:
    - the nature and quantity of the active substance and, where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants,
    - residues of the active substance resulting from authorized uses and which are of toxicological or environmental significance,
- methods of disposal of the product and of its packaging,
- decontamination procedures to be followed in the case of accidental spillage or leakage,
- first aid and medical treatment to be given in the case of injury to persons.

If the applicant subsequently discloses previously confidential information, he shall be required to inform the competent authority accordingly."

AUT	1)	Partly.
	2)	Except if toxicological or ecotoxicological relevant.
DK	*)	Refer to Directive 91/414 article 14 for what is not confidential.
NL	1)	Not confidential: efficacy, damage to: humans, animals, plants, environment.
POR	*)	Follows the rules established by 91/414/EC Directive.
SWE	1)	Exception from this when a substance (impurity) is classified as dangerous and the product will be labelled as such.
UK	1)	Available on request - See Table L.
	2)	Available on request - Request has to be granted - See Table L.

Non-EU countries

AUS	1)	Compositional analytical methods (as distinct from residue detection analytical methods).
CZ	*)	There are only the formulated pesticide products (preparations) registered in the Czech Republic, not the active ingredients. Thus the confidentiality of data on active ingredients is not defined in any law yet, but the ticked data in this part of the table are treated as confidential. It is expected this problem to be solved generally by the above mentioned new law on chemicals.
HUN	*)	Without written regulation, in the practice of registration
JP	1)	In Japan, we regard the results of tests as the issue of proprietary rights. Whether they are treated as confidential or not depends on the decision of the owner of the data. Moreover it is not clear what the word "summary" includes in this context. Therefore, Japan would like to reserve the answer.
SWI	1)	Except information in respect to damage to the environment, to human health and to animals which can be given to medical professions (Article 38 Annexe 2.2 of *the Implementing Order on Environmentally Dangerous Substances - 'Ordonnance sur les substances dangereuses pour l'environnement. (Ordonnance sur les substances, Osubst)' du 9 juin 1986 (Etat le ler juillet 1995). - RS 8140.13)*
US	*)	Where a category is checked, it means that the information is potentially entitled to confidential treatment. The actual eligibility for confidential treatment depends upon the applicability of the factors discussed in question 2.1, above to the specific information in question.
	1)	in as much as this info could reveal manufacturing process information
	2)	Such information is subject to FIFRA section 10(g), and as such cannot be released to multinational pesticide producers or individuals or governments who intend to release the information to multinational pesticide producers.

TABLE H - For preparation/formulation: which of the following does your country treat as confidential (✓) ?

Question 2.4

Preparation/formulation	EC	AUT	BEL	DK*	FIN	FR	GER	GR	NL	POR*	SP	SWE	UK	AUS	CZ	HUN*	JP	NZ	NOR	SWI	TK	US*
Identity																						
• trade name(s)																						
• internal code numbers (manufacturer✓, applicant✓)									✓					✓✓						✓✓		
• type of preparation																					✓	
Composition		✓			✓		✓	✓			✓	✓	✓				✓	✓	✓	✓	✓	✓[1)]
• identity and content of active ingredients							✓				✓	✓					✓					
• isomers		✓[1)]				✓	✓	✓	✓		✓	✓	✓		✓[1)]	✓	✓					✓[1)]
• formulants		✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓[1)]	✓[1)]		✓[1)]
• inert compounds		✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓[1)]		✓
Manufacturer(s)			✓				✓		✓				✓					✓			✓	✓[1)]
Physical and chemical properties														✓	✓						✓	
Summary results of tests (all areas)									✓				✓[1)]		✓	✓	✓[1)]				✓	
Complete results (raw data) of tests (all test areas)		✓	✓		✓	✓	✓		✓		✓		✓[2)]	✓	✓	✓	✓[1)]	✓		✓	✓	✓[2)]
Complete results (raw data) for specific test areas (please specify areas)		✓			✓	✓			✓								✓[1)]	(✓)		✓	✓	
Summary results for specific test areas (please specify areas)					✓				✓[1)]								✓[1)]			✓[2)]	✓	
Information on hazard categories, nature of the risks, relevant warnings & precautions to be taken																						
Ways to render substance harmless																						
Others (please list)									✓[2)]					✓[1)]	✓[2)]							

Comments for Table H

EC and EU countries

EC	1)	See text of *Article 14 of Directive 91/414/EEC* in the section titled "Comments for Table G".
AUT	1)	Except if toxicological or ecotoxicological relevant.
DK	*)	Refer to Directive 91/414 article 14 for what is not confidential.
NL	1)	Not confidential: efficacy, damage to: humans, animals, plants, environment.
	2)	Not confidential: first aid and medical device in case of accidents, decontamination measures, methods for disposal of packaging, analytical methods.
POR	*)	Follows the rules established by 91/414/EC Directive.
UK	1)	Available on request - See Table L.
	2)	Available on request - Request has to be granted - See Table L.

Non-EU countries

AUS	1)	Compositional analytical methods (as distinct from residue detection analytical methods).
CZ	1)	For new ones only
	2)	Directions for use (application)
HUN	*)	Without written regulation, in the practice of registration
JP	1)	In Japan, we regard the results of tests as the issue of proprietary rights. Whether they are treated as confidential or not depends on the decision of the owner of the data. Moreover it is not clear what the word "summary" includes in this context. Therefore, Japan would like to reserve the answer.
NOR	1)	Non hazardous

SWI 1) Except if the formulants and the inert compounds are toxic.

2) Except information in respect to damage to the environment, to human health and to animals which can be given to medical professions (Article 38 Annexe 2.3 of *the Implementing Order on Environmentally Dangerous Substances - 'Ordonnance sur les substances dangereuses pour l'environnement. (Ordonnance sur les substances, Osubst)' du 9 juin 1986 (Etat le ler juillet 1995). - RS 8140.13)*

US *) Where a category is checked, it means that the information is potentially entitled to confidential treatment. The actual eligibility for confidential treatment depends upon the applicability of the factors discussed in question 2.1, above to the specific information in question.

1) Of inerts

2) Such information is subject to FIFRA section 10(g), and as such cannot be released to multinational pesticide producers or individuals or governments who intend to release the information to multinational pesticide producers.

TABLE I - Application of the OECD Recommendation of the Council C(83)98

Question 2.6.
Does your country apply the OECD Recommendation concerning the OECD List of Non-Confidential Data on Chemicals (see Appendix 2.2) to pesticides?

Responses	Countries	* Additional information
YES	EC* Austria Belgium Denmark* France Germany Greece Netherlands* Portugal* Spain* Sweden UK* ---------- Czech Rep.* New Zealand Switzerland Turkey US	EC: More details in Article 14 of Directive 91/414/EEC (See text of *Article 14* in the section titled "Comments for Table F"). Denmark: With reference to EC answer concerning Article 14 of Directive 91/414/EEC. Netherlands: More details in Article 14 of Directive 91/414/EEC. Portugal: We follow 91/414/EC Directive. Spain: If that coincides with the Directive 91/414/EEC. UK: De facto implementation via the UK's national rules for pesticides. ---------- Czech Rep.: With the exception on "Summaries of health, safety, and environmental data including precise figures and interpretations". It is expected this exception to be solved generally by the above mentioned new law on chemicals.

(To be continued)

(continued)

Responses	Countries	* Additional information
NO	Finland* ---------- Australia* Hungary* Japan* Norway*	Finland: Not implemented. ---------- Australia: Australia abstained from voting in respect of C(83)98 Final. Hungary: We consider non confidential data all the information published in the registration document of each formulation, namely: 1/ Name, address of producer (or the owner of registration), 2/ Type of product, 3/ Name and concentration of active ingredient(s), 4/ Use (crop, disease, pest, rate of use), 5/ Poisoning category, hazard category, fish and bee tox. Category, 6/ Precautions, protective cloth and equipment, first aid, 9/ Marketing category, 10/ Re-entry time, 11/ Residue, pre-harvest interval, 12/ Flammability, 13/ Shelf life time, 14/ Application method, 15/ Aerial application, 16/ p.o. LD, irritation Japan: Japan opens most of the items in the OECD List. Regarding the physical-chemical data, the health, safety and environmental data, Japanese Government recommends industries to open them. Norway: It is too conservative.

APPENDIX 2.1

Titles of national instruments (e.g. laws/regulations) to protect CBI with respect to pesticides

Country/ Organization	Titles	Specific to pesticides?
European Commission	Directive 91/414/EEC concerning the placing of plant protection products on the market	Yes
Austria	- Pflanzenschutzmittelgesetz 1997;	Yes
	- Datenschutzgesetz, Bundesverfassungsgesetz.	No
Belgium	Art. 37 of the 'Arrêté royal du 28/02/1994 relatif à la conservation, à la mise sur le marché et à l'utilisation des pesticides à usage agricole' indicates which information cannot be considered as confidential.	Yes
Denmark	Danish Chemical Substances and Product Act (implementation of Directive 91/14/EEC for plant protection products)	Yes
Finland	- Pesticides Act (327/69, last amendment 1204/94) § 9a. - Pesticides Decree (792/95) §19 and §20.	Yes
France	Décret d'application no. 94/359 de la Directive 91/414/EEC.	Yes
Germany	"Verwaltungsverfahrensgesetz" (Administration Procedure Act) covers all administrative CBI.	No
Greece	- Council directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. - National Law 721/77.	Yes
Netherlands	(- Directive 91/414/EEC) - Bestrijdingsmiddelenwet 1962 (Pesticide Law).	Yes
	- Algemene wet bestuursrecht (General law on legal administrative procedures). - Wet openbaarheid van bestuur (General law on the right-to-know). These two general laws are specific to disclosing of government information.	No
Portugal	Law 563/95, In Republic Diary nr.135/95, I Série B, of June 1995.	No
Spain	Real Decreto 2163/1994, of 4 November, adopting the harmonized communitary system relating to the marketing and use of pesticides (Directive 91/414/EEC).	Yes
Sweden	The "Official Secrets Act 1980:100" is applicable if it can be assumed that it may cause harm to an individual if the information is revealed.	No
United Kingdom	The Food and Environment Protection Act 1985, the Control of Pesticides Regulations 1986 and related statutory instruments give legal validity to the administrative procedures, or requirements, of the 'Registration Handbook' (PSD-HSE).	Yes
Australia	- The Agvet Code 1994;	Yes
	- The Freedom of Information Act 1982.	No
Czech Republic	-	
Hungary	Law/regulation to protect CBI for pesticides is under preparation. It will be incorporated in the new pesticide law, expected in 1998.	

Country/ Organization	Titles	Specific to pesticides?
Japan	- The "Unfair Competition Prevention Law" covers CBI in general. - The "Government Official Act" stipulates that government officials shall not release confidential information which they can obtain thorough their work. - The Patent Law.	No
New Zealand	The Pesticides Amendment Act 1994.	Yes
Norway	The Public Administration Act.	No
Switzerland	- Implementing Order on Plant Protection Products: 'Ordonnance sur la mise dans le commerce des produits de traitement des plantes et de protection des récoltes. (Ordonnance sur les produits de traitement des plantes)' du 26 janvier 1994 - RS 916.161	Yes
	- Implementing Order on Toxic Materials: 'Ordonnance sur les toxiques, Otox'' du 19 septembre 1983 - RS 814.801 - Implementing Order on Environmentally Dangerous Substances: 'Ordonnance sur les substances dangereuses pour l'environnement. (Ordonnance sur les substances, Osubst)' du 9 juin 1986 (Etat le ler juillet 1995) - RS 814.013 - Law on the Status of Swiss Federal Government Officials: 'Statut des fonctionnaires, (StF)' du 30 juin 1927 (Etat le ler janvier 1995) - RS 172.211 10 - Swiss Penal Code: 'Code pénal suisse' du 21 décembre 1937 (Etat le ler octobre 1995) - RS 311.0 - Patent Law: 'Loi fédérale sur les brevets d'invention' du 25 juin 1954 (Etat le ler janvier 1996) - RS 232.14 - Implementing Order on Patents: 'Ordonnance relative aux brevets d'invention' (Ordonnance sur les brevets) du 19 octobre 1977 (Etat le 1er janvier 1996) - RS 232.141	No
Turkey	- Law 6968: "Agricultural Protection and Quarantine". - Regulations no. 11142: "Regulation of Agricultural Chemicals and Protection Tools" (article 29).	Yes
United States	- FIFRA Sections 7, 10 and 12; - 40 CFR Section 152, et seq;	Yes
	- 40 CFR part 2, subpart B.	No

APPENDIX 2.2

RECOMMENDATION OF THE COUNCIL

concerning the OECD List of Non-Confidential Data on Chemicals*

C(83)98(Final)

The Council,

Having regard to Articles 2 a), 2 b), 2 d), 3, and 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14th December 1960;

Having regard to the Recommendation of the Council of 7th July 1977, Establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment [C(77)97(Final)];

Having regard to the Decision of the Council of 21st September 1978, concerning a Special Programme on the Control of Chemicals and the Programme of Work established therein and the extension of the duration of the Programme by the Council of 12th May 1981 [C(78)127(Final) and C/M(81)7(Final), Item 86];

Having regard to the Decision of the Council of 12th May 1981, concerning the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final)] and Addendum 1 to that Decision [C/M(82)22(Final), Item 215] ;

Having regard to the Decision of the Council of 8th December 1982, concerning the Minimum Pre-marketing Set of Data in the Assessment of Chemicals [C(82)196(Final)];

Having regard to the Recommendation of the Council of 26th July 1983, concerning the Protection of Proprietary Rights to Data Submitted in Notifications of New Chemicals [C(83)96(Final)];

Having regard to the conclusions of the First High-Level Meeting of the Chemicals Group of May 1980, concerning the confidentiality of data [ENV/CHEM/HLM/80.M/1];

Having regard to the conclusions of the Second High-Level Meeting of the Chemicals Group of November 1982, on non-confidential data [ENV/CHEM/HLM/M/82.1];

Considering the need to avoid unnecessary duplication of effort in developing data on chemicals, to make better use of existing data, to utilise more effectively scarce specialist manpower and test facilities, and to reduce the number of animals used in testing;

Considering the need of governments to inform the public and the need to disclose certain data related to the assessment of chemicals or to other purposes connected with the protection of man and the environment;

On the proposal of the Second High-Level Meeting of the Chemicals Group, endorsed by the Environment Committee;

1. RECOMMENDS that Member countries, for purposes of assessment and for other uses relating to protection of man and the environment, facilitate the disclosure and exchange of data belonging to the OECD List of Non-Confidential Data, set out in the Appendix hereto, which is an integral part of this Recommendation, and other data which may be deemed by the Member country concerned to be non-confidential.

2. INSTRUCTS the Environment Committee and the Management Committee of the Special Programme on the Control of Chemicals to review actions taken by Member countries in pursuance of this Recommendation and report thereon to the Council.

APPENDIX

THE OECD LIST OF NON-CONFIDENTIAL DATA ON CHEMICALS

Certain data, of value for hazard assessment of chemicals and for other purposes connected with the protection of man and the environment, may be termed non-confidential.

In this context, "non-confidential" means that no restrictions should be put on the exchange of the data between governments nor on the disclosure of such data to the public. Proprietary Rights to data are not affected by the non-confidential status of such data. Data should be exchanged between governments on request and not as a matter of routine.

The following list is not restrictive. It is recognised, on the contrary, that in some circumstances there may be other data which are considered non-confidential both by the government and the submitter and that if these are useful for hazard assessment of chemicals, they should also be exchanged. The list below is inspired by the OECD Minimum Pre-marketing Set of Data, but is not meant to be restricted to information on new chemicals. Non-confidentiality, as defined above, applies to all chemicals.

- trade name(s) or name(s) commonly used (in the United States of America, trade names or names commonly used may mean a generic name of a chemical substance);
- general data on uses (the uses need to be described only broadly, like: closed or open system, agriculture, domestic use, etc.);
- safe handling precautions to be observed in the manufacture, storage, transport and use of the chemical;
- recommended methods for disposal and elimination;
- safety measures in case of an accident;
- physical and chemical data with the exception of data revealing the chemicals identity (e.g. spectra). If the physical and chemical data make it possible to deduce therefrom the chemical identity only ranges of values need be given;
- summaries of health, safety, and environmental data including precise figures and interpretations. (The submitter of the health, safety, and environmental data should participate in the preparation of the summaries.)

* Australia abstained

- Annex 3 -

Pesticide data review reports

Proprietary rights and CBI issues

TABLE J - Pesticide data review reports: Structure, Exchange with other countries and Release to the public

Questions 3.1, 3.2, 3.4 and to 3.5.

Questions	EC	AUT	BEL	DK	FIN	FR	GER	GR	NL	POR	SP	SWE	UK[1]	AUS	CZ[1]	HUN	JP	NZ	NOR	SWI	TK	US
Structure of Pesticide Data Review Reports																						
Q.3.1 - Does your country keep CBI separate from the rest of the report?	Yes	Yes	Yes	Yes[1] No[2]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes[1]	Yes	Yes		No	No	Yes	Yes	Yes	No	Yes[1]
Q.3.1.a) - Since when?	New	New	07/93	-	A	1994	05/68	New	A	1967	07/93	A	10/86	1994		-	-	A	A	A	-	New[1]
Q.3.1.b) -Could this separate section/annex be easily separated before sending it to another country or to the public?	Yes	Yes	Yes	-	Yes	Yes	Yes	Yes	Yes[1]	Yes	Yes	N/A[1]	N/A[2]	Yes		-	-	Yes	Yes	-	-	Yes
Q.3.1.c) -Does this separate section/annex make it easier to exchange reports?	Yes	Yes	Yes	-	Yes	Yes	Yes	Yes	Yes[1]	Yes	Yes	N/A[1]	N/A[2]	Yes		-	-	Yes	Yes	-	-	Yes
Exchanging pesticide data review reports with other governments (Description of countries' entire procedures in Table K)																						
Q.3.2 - Can your country release reports to the regulatory authorities of other countries?	-	Yes, but	Yes	Yes	Yes, but[1]	Yes	Yes, but	Yes, but	Yes, but	Yes, but	Yes, but	Yes	Yes, but	Yes		Yes, but	No[1]	Yes	Yes, but	No	No[1]	Yes, but
Q.3.4 - To what extent can your country protect CBI contained in reports sent to you by another country?	SO	SO	SO	SO	SO	ST	SO	SO	SO	SO	SO	SO	Other[3]	SO		ST	SO	SO	SO	SO[1]	SO	SO[2]
Releasing pesticide data review reports to the public (Description of countries' entire procedures in Table L)																						
Q.3.5 - Can your country release reports to the public?	Yes	Yes, but	Yes	Yes	Yes, but[2]	Yes	No[1]	Yes	Yes	Yes, but	Yes, but	Yes	Yes, but	Yes		Yes, but	No[1]	Yes	Yes[1]	No[2]	No[2]	Yes, but

A: **A**lways - **SO**: **S**ame level of protection that in **o**wn country - **ST**: **S**ame level of protection than in **t**ransmitting country

Comments for Table J

EU countries

DK 1) Yes - refer to answer given by Directive 91/414/EEC.
2) No - according to Act no. 572 19 Dec 1985 the Danish Access to Public Administration Files, data has to be examined for confidential information. Only non-confidential information will be published.

FIN 1) Normally the pesticide review reports on active ingredients have been sent to the Swedish, Danish and Norwegian authorities, and sometimes to the Dutch authorities too. This is a part of the Nordic co-operation in the field of pesticides.
2) The public report version contains information in a very common level i.e. summary information mainly concerning health and environmental effects.

GER 1) There is no legal basis. Up to now only a describing list of authorized plant protection products with summarized data is published. After implementation of Directive 91/414/EEC in national legislation the release of data review reports will be in accordance with Art. 14 of the Directive.

NL 1) The format is not established now: at this moment we only have available to the public a part of the summaries. The big summary of all studies is not available: only condensed overall conclusions for the several aspects are available.

SWE 1) CBI is not included in the data review.

UK 1) At present we only exchange our public disclosure documents. For the most part these documents are comprehensive.
- For new active substances and non-agricultural pesticides the recently produced documents contain a full evaluation of the studies and the risk assessment/regulatory decisions.
- For reviews of existing agricultural pesticides, for historical reasons rather than reasons of confidentiality, the documents do not generally contain full details of the risk assessment or full details of the regulatory measures taken.

2) The confidential information is edited out in consultation with the data owner/registrant. No separate document, such as an annex, exists.
3) Reports sent by other regulatory authorities are not normally released. The complete report is treated as confidential if this is a request by the transmitting country.

Non-EU countries

CZ 1) Pesticide regulatory authorities were not preparing the "Pesticide Data Review Reports" as such in the past. It is expected to start with the work in this field and to harmonize step by step also this part of pesticide regulation scheme by January 1, 1997 (the new law, the Phytosanitary Care Act, is valid since this date).

JP 1) Because data review reports are treated as confidential at present in Japan. However, there is a movement toward the establishment of the "Public Information Act" in Japan, and the situation may change in the future.

NOR 1) CBI is removed from the report.

SWI 1) Monographs received by Swiss regulatory authorities from other countries will, as any other information/ documents, be treated as strictly confidential, except such documents which are expressly declared or evidently recognizable e.g. published documents as non-confidential.
2) Only the "Fiches techniques de sécurité" for the substances and the products are available to the public.

TK 1) Because of privacy of a registrant.
2) Because of Law 6968.

US 1) It is now the policy to segregate information in reviews which contain CBI. However, its implementation is being accomplished in stages, and different branches within the science divisions may actually document the reviews in different ways. So, there is not a specific date upon which the policy was initiated. In addition, historically, the CBI was imbedded in the reviews, and the program has not returned to the old reviews in order to segregate the CBI according to the current policy.
2) However, that if the information pertains to a pesticide which is not yet registered in the U.S., the mandatory disclosure requirements of Section 10(d)(1) do not apply.

TABLE K - Countries' procedures to release pesticide data review reports to the regulatory authorities of other countries

Question 3.3
If your country can release pesticide data review reports to the regulatory authorities of other countries, please describe your entire procedure.

Country/ Organization	Procedure
European Commission	Procedure still to be established.
Austria	- No substantiation is required (to know whether it is a bona fide request). - No consent is to be obtained (from the pesticide registrant before releasing the report). - All information listed in the table (see Question 2.4) is removed.
Belgium	No procedures have been laid down for the release of pesticide data review reports. The section containing CBI will not be sent to another country. (This response must be considered as provisional, as it is possible that the European Commission will establish rules on how to release the monographs when the first monographs are accepted)
Denmark	Procedure still to be established at Community level.
Finland	Normally the pesticide review reports on active ingredients have been sent to the Swedish, Danish and Norwegian authorities, and sometimes to the Dutch authorities too. This is a part of the Nordic co-operation in the field of pesticides.
Germany	- No substantiation is required (to know whether it is a bona fide request). - No consent is to be obtained (from the pesticide registrant before releasing the report). - All information listed in the table (see Question 2.4) is removed.
Greece	Procedure still to be established at Community level.
Netherlands	Procedure still to be established for release to regulatory bodies within EU as well as to bodies outside EU (according to Directive 91/414/EEC). The common parts, i.e. the condensed overall conclusions for specific test areas, are available to the public, so also to other bodies.
Portugal	It is evaluated case by case.
Spain	According to European Reglement 3600/92 and to Directive 91/414/EEC.
Sweden	- No steps must be taken to substantiate whether it is a bonafide request. - No consent must be obtained from the pesticide registrant before releasing the report.

Country/ Organization	Procedure
United Kingdom	Evaluation documents are produced by the Advisory Committee on Pesticides (ACP) for newly approved and reviewed (older) pesticides. National legislation allows copies of such reports to be publicly disclosed. Full details of this procedure are given in Table L. These evaluation (or public disclosure documents) are made available to the regulatory authorities of other countries under the OECD exchange programme. Requests are co-ordinated by the External Relations Branch of the Pesticides Safety Directorate. A list of all requests received and dispatched is maintained.
Australia	- All requests from other authorities for pesticide data review reports are made to the designated contact in Australia, curren tly the Executive Manager, Policy and Public Affairs of the NRA. - The Executive Manager ensures the requests are from a *bone fide* authority, from a known individual and are signed. - The NRA writes to the interested person (generally known as the registrant) notifying that the NRA has decided that it intends to disclose CBI and seeking the interested person's consent and any relevant comments to the intended disclosure within 28 days. - If the interested person's consent is obtained, the CBI can be release d immediately. - Alternatively, if the interested person's consent is not obtained and 28 days have elapsed, the NRA may consider any comments provided by the interested person, and decide whether or not to proceed with the intended release of CBI. The NRA's decision is appealable to the Administrative Appeals Tribunal (AAT). The interested person may also obtain a stay order from the AAT. Any CBI in the requested data review report may be re-located, if necessary, to appendices and the report released by the NRA with or without the appendices depending on the decision of the NRA. - The OECD is notified of the exchange. - The NRA maintains a list of all requests and their outcomes.
Czech Republic	<N/A. No “pesticide data review reports” prepared as such in the past>
Hungary	We have no such a regulation, but our approach is: The release of pesticide data review report to the regulatory authorities of other countries could be considered to be free, if the receiving country could ensure the same level of data protection as it is in the donor country. The registrant should be informed subsequently on the exchange of reports.
Japan	At the moment, Japan cannot release reports to other countries as they are treated as confidential. - Japanese Government must obtain consent from the pesticide registrant before releasing the report. - Japanese Government removes CBI in the table of Question 2.4.

Country/ Organization	
New Zealand	There are no confidentiality considerations on the review reports per se hence there are no limitations on their release.
Norway	- No steps related to bonafide request. - No steps related to consent from the registrant. - Remove CBI (ref. Tables B and H)
Switzerland	- The Swiss federal legislation assure strict confidentiality of any documentation submitted by a registrant to the Swiss regulatory authorities in support of his pesticide registration request. - These rules preclude Swiss regulatory authorities from the exchange of such documents, notably e.g. pesticide monographs with regulatory authorities of other countries unless Switzerland would have concluded with the receiving country/countries a bilateral and/ or multilateral agreement.
Turkey	Turkey cannot release pesticide data review reports to the regulatory authorities of other countries because of privacy of a registrant.
United States	Reviews can be released to the public and other countries without the consent of the data submitter as long as CBI and information of more than a summary nature is removed. Under Class Determination 3-85, reviews can be released to the public, and to other countries, as long as information of more than a summary nature (e.g., specific data from tests) is removed. Additionally, the information can be exchanged with the Canadian government, with the written permission of the data submitter.

TABLE L - Countries' procedures to release pesticide data review reports to the public

Question 3.6.
If your country can release pesticide data review reports to the public, please describe your entire procedure.

Country/ Organization	Procedure
European Commission	Procedure still to be established.
Austria	No release to the public yet. After implementation of Dir. 91/414/EEC in national legislation, the release of reports will be in accordance with Art. 14 of the Directive.
Belgium	No procedures have been laid down for the release of pesticide data review reports to the public. In practice, these reports, with the exception of the section containing CBI, will be available to the public for consultation. (This response must be considered as provisional, as it is possible that the European Commission will establish rules on how to release the monographs when the first monographs are accepted)
Denmark	Procedure still to be established at Community level.
Finland	The public report version contains information in a very common level i.e. summary information mainly concerning health and environmental effects.
France	A database "AGRITOX" on toxicological data of authorised active substances is available on Minitel (via France Telecom) for public consultation. For each active substance, the origin of the data is given (either the name of the data owner, or bibliographical references).
Germany	<No release to the public yet. After implementation of Dir. 91/414/EEC in national legislation, the release of reports will be in accordance with Art. 14 of the Directive.>
Greece	Procedure still to be established at Community level.
Netherlands	The common parts, i.e. the condensed overall conclusions for specific test areas, are available to the public. Evaluation reports containing no CBI are available to public for consultation.
Portugal	It is evaluated case by case.
Spain	According to European Reglement 3600/92 and to Directive 91/414/EEC.
Sweden	No consent must be obtained from the pesticide registrant before releasing the reports, as there is no confidential information included in the reports.

Country/ Organization	Procedure
United Kingdom	Extract from the "Pesticide Handbook" - Public Access to Information on Pesticides (G1) G1.1 As a general rule all information, correspondence and other documents concerning pesticide approval applications are treated as confidential and cannot be disclosed. However the Regulations provide certain exceptions (Ministers are empowered to provide copies of evaluation reports and to make available for public inspection any information held in support of such applications.) - Evaluations G1.2 Evaluation documents are produced by the Advisory Committee on Pesticides (ACP) for newly approved and reviewed pesticides. A list of evaluation documents currently available (..) may be obtained by writing to the ACP Secretariat G1.3 Requests for evaluations should be made in writing stating name, name of company, address, and occupation and the product or active ingredient of interest. Standing orders may be arranged on request. Recipients are advised that: a) Commercial use of the evaluation must not be made either in the UK or overseas; b) No part of the evaluation may be published without the written permission of Ministers, nor may the document be passed to any other person; c) Any breach of these conditions would be a criminal offence. The Secretariat keeps a publicly available register of names and addresses of applicants for evaluations, and the documents issued. - Supporting data G1.4 If recipients of evaluation documents find them insufficient for their purposes applications may be made for access to the supporting data held by the Registration Authorities. Individuals wishing to apply for access to inspect study reports should write to the appropriate authority (External Relations Section - Pesticides Safety Directorate and Pesticide Registration Section - Health and Safety Executive) G1.5 A form must be filled in and returned for an application to inspect data. G1.6 If the request is granted, access will be given for inspection of the study report(s). Access is provided by a reading room facility at MAFF (York) or HSE (Bootle). Note taking is permitted but copying is not allowed. In order to protect the commercial interests of the data owner the following categories of information are excluded from the disclosure arrangements: - active ingredient and formulation specification and composition; - production methods, - names and addresses of laboratories, sites and personnel- individual medical details. (To be continued)

Country/ Organization	Procedure
United Kingdom (continued)	G1.7 Before access is granted, the enquirer is required to sign an undertaking that they will not: - make commercial use of the data - publish any part of it without the written permission of the Ministers. Any breach of this undertaking would be a criminal offence. Owners are advised that access has been granted to their data and of the name and address of the enquirer. A register of the study reports which are accessed and of the names and addresses of enquirers is publicly available.
Australia	- Pesticide data review reports containing CBI can be released domestically to the public with the consent of the interested person. In that case, CBI is retained in the public version of the report. - If the interested person does not consent, CBI may be relocated to appendices of the report which are not publicly released or the relevant CBI portions of the report are removed from the public version of the report. The Agvet Code provides for the NRA to release CBI in a summary of the assessment report without the interested person's consent. Note: The NRA's powers for the **domestic release** of pesticide data review reports containing CBI are **different** to those powers for the **release of such reports to overseas regulatory authorities** having similar functions to the NRA. As noted in response to question 3.3 (see Table K), in relation to the release of CBI contained in assessment reports to overseas regulatory authorities, the NRA is required to notify the interested person seeking consent for such intended release of CBI to an international regulatory body, but the NRA is not obligated to obtain the interested person's consent.
Czech Republic	<N/A. No “pesticide data review reports” prepared as such in the past>
Hungary	We have no such a regulation but our approach is: Decision of experts on the necessity of releasing of data review reports to the public. Obtain consent from the pesticide registrant: - if yes: the information could be published; - if no: decision of a competent international or national expert body could be required.
Japan	At the moment, Japan cannot release reports to the public as they are treated as confidential. - Japanese Government must obtain consent from the pesticide registrant before releasing the report. - Japanese Government removes CBI in the table of Question 2.4.
New Zealand	The review reports can be released to the public without any limitations.

Country/ Organization	Procedure
Norway	The report released to the public is a summary document related to health and environment.
Switzerland	The Swiss federal legislation assure strict confidentiality of any documentation submitted by a registrant to the Swiss regulatory authorities in support of his pesticide registration request. These rules imply that said regulatory authoritftes/officials are not allowed to divulge/release any information/documentation handed over to them to any other natural or juridical person, with the exception provided for by the law, i.e. the medical profession may be given in emergency cases, pertinent toxicological substance/product data on a confidential basis by the intermediary of the Swiss Toxicological Information Center, Zuerich. (The medical profession is bound to their own confidentiality rules.) No such information/document or any information/document developed in the process of registration - such as e.g. summary reports, monographs - may in part or in full be made available/distributed to media or the press for publication. Exempt from these confidentiality rules are only those substance/product data - study end-points - which are of importance for the substance/product risk assessment, i.e. required for ensuring the safety of man and/ or the environment in handling, transporting, storing and using such materials.(as defined in the Implementing Order of Substances *(RS 814.013, para 38, Annexe 2.2.: Fiche technique de sécurité pour les substances, Annexe 2.3.: Fiche technique de sécurité pour les produits)* Furthermore, exempt from these confidentiality rules are the published public Registration Decrees: *'List of Plant Protection Products Authorized for use', 'Product Label' (*name of the manufacturer, of the Swiss domiciled distributor, substance common and chemical name, content of active ingredient and of hazardous auxiliary matters in the formulation, range and concentration of usage, safety and precautionary measures in respect of the user, the consumer and the environment - e.g. information in respect of the bee- and fish-toxicity, agronomical and environmental use restrictions, e.g. prohibition of use in ground-water protection zones.), the poison classifications of the substances and the products (*Implementing Order on Toxic Substances, RS 814.801, para 3, Poison Lists),* the maximum concentrations - as tolerance and limit values - of residues in/ on food items (according to the stipulations of the *Implementing Order on Foreign and Natural Substances in on Food, RS 817.021.23, para 2, al. 6: Tolerance Lists).*
Turkey	Turkey cannot release pesticide data review reports to the public because of Law 6968.

Country/ Organization	Procedure
United States	Prior to the public release, the reviews on registered or previously registered pesticides are screened and any CBI is removed (actually, physically cut out of the document, and when photocopied appears that it is blacked out on the copy that is released.) No data submitter consultation or notification is required - disclosure of health and safety data reviews on registered or previously registered pesticides is mandatory under FIFRA Section 10(d)(1) and implemented by class determination 85-3. Since these mandatory disclosure provisions do not apply to data reviews on unregistered (pending or never registered) pesticides, data submitters must be afforded an opportunity to assert that public disclosure would cause competitive harm. Any such assertion must be based on criteria established at 40 CFR 2.208. If an objection to disclosure is filed, the EPA Office of General Counsel (OGC) will review the data submitter's argument and issue a final determination. Pending the outcome of this legal review, disclosure will be initially denied by the Agency. If OGC rules in favor of the data submitter, any request for public disclosure will be denied. If OGC rules in favor of disclosure, the data submitter will be given written notice to that effect and be allowed 10-15 business days to enjoin disclosure in Federal Court.

TABLE M - Exchange of pesticide data review reports and protection of proprietary rights GCPF Procedure

Question 3.7:
Is the proposed GCPF (Global Crop Protection Federation) procedure (below) to protect proprietary rights during the exchange of reports in line with your country's existing procedure?

> "In order to respect the proprietary nature of the data which is summarised by governments in their regulatory process when there is an exchange of pesticide review reports between governments, a government should not grant a registration using reviews by other governments unless it has first received a submission of proprietary data[1)] on which the summaries are based, either from the owner of the data or from a second party who has authorised permission from the owner of the data or when the owner of the data has given the government permission to use the review".
>
> [1)] proprietary data are data which are owned by the person or company that generated them. The period of ownership is specified by national or multi-national regulations.

Responses	Countries	Additional information
YES	EC Austria Belgium Denmark Finland Germany Greece Netherlands Portugal Spain Sweden Switzerland UK* ---------- Australia* Czech Rep.* Hungary Japan New Zealand* Norway Turkey US*	UK: As the data may not be owned by the person/company that generated them, UK suggests the alternative for the footnote: "proprietary data are data which, for a period, may only be used in support of pesticides registrations with the permission of the person or company owning the data". ---------- Australia: Yes, it is in line, but only in respect of the provision of data protection as distinct from proprietary rights which Australia does not provide. However, Australia has some concerns with the way in which the proposed GCPF procedure is written. In particular, the focus should be on data protection as distinct from protection of proprietary rights. Furthermore, Australia would not wish to be required to grant registration to a chemical product simply on the views of other governments, without receiving and reviewing the applicable data as considered appropriate by the Australian Government. (To be continued)

(continued)

Responses	Countries	Additional information
YES (cont'ed)		Czech Rep.: Though the "Pesticide Data Review Reports" are not issued in the Czech Republic yet, the Czech pesticide regulation authority is fully supporting the given GCPF proposal. There was never authorised for use a pesticide product in the Czech Republic based only on data submitted by anybody other than given in the GIFAP proposal. Submitted data are checked for their ownership in any case. New Zealand: The "Owner of the Data" for the purpose of adjudicating on proprietary rights in New Zealand would be the original NZ proprietor who gained the first registration for a pesticide containing an innovative pesticide active ingredient. It is that organisation/person who would authorise the use of the review report for the purpose of a secondary clearance. US: BUT--the U.S. has concerns with the way in which this statement is written. Basically, it does describe our current procedure. At the moment, we would not grant a registration by simply using the reviews of other governments without also receiving and reviewing the data from the prospective registrant. However, we would not want to be precluded from doing so in the future. Therefore, we believe that the GCPF proposal should focus more specifically on the issue of proprietary rights and compensation to data submitters, and ensuring that fairness and equity exist among different governments, and not to the issue of how governments conduct their business in reviewing data submitted for registration purposes.

- Annex 4 -

Contact names

for proprietary rights and CBI with respect to pesticides

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Area of survey: Plant Protection Products

- Annex 5 -

Text of the survey questionnaire

OECD Survey of Government Approaches to the Protection of Proprietary Rights and Confidential Business Information with respect to the Registration of Pesticides

PART 1
NATIONAL LAWS/REGULATIONS AND PROCEDURES ON PROPRIETARY RIGHTS

1.1 If your country has a definition of proprietary rights with respect to pesticides, please provide it together with the reference of the document in which the definition can be found.

1.2 Does your country have national instruments (e.g. laws/regulations etc.) to protect proprietary rights with respect to pesticides?

____ yes _____ no

If yes, please give the titles of all relevant laws/regulations.

If you have laws/regulations to protect proprietary rights for pesticides, please answer the following:

1.3 Are the laws/regulations specific to pesticides?

____ yes _____ no

If no, please list what they cover.

1.4 Do the same laws/regulations apply to first registration and re-registration (re-evaluation)?

____ yes _____ no

If no, please explain.

1.5 Does your country apply the OECD Recommendation concerning the Protection of Proprietary Rights to Data Submitted in Notification of New Chemicals to pesticides?

____ yes _____ no

If not, why not?

1.6 Please describe your country's procedure for protecting proprietary rights with respect to pesticides. If your procedures for first registration differ from those for re-registration, please describe both. In doing so, please address all the following questions plus other relevant information:

- do you protect data for active ingredients, formulations and inert ingredients?
- do you have an "exclusive use" period in which only the owner can use the data? If so, how long is this period? To which data does this apply?
- do you have a period in which others can use the data but must compensate the owners? If so, how long is this period? To which data does this apply? What arrangements have to be made with the owner of the data, and when?
- how are data protected when they are submitted after the first registration (e.g. for re-registration, special review, new use, etc.)? For example, if new data are submitted 2 years in to a 5-year period of 'exclusive use', are the new data given proprietary rights protection for the remaining 3 years or for 5 years?
- are all data treated the same? For example, can data derived from animal testing be used more easily by others than data which did not involve animal testing?

1.7 Given the relatively recent passage of GATT, and the TRIPS agreement within GATT (i.e. Trade Related Intellectual Properties Section) - which essentially requires at least 5 years protection of agricultural chemicals after first registration - please explain, if possible, how your country plans to implement TRIPS with respect to pesticides.

OECD Secretariat comment:

This question was found to be incorrect. The minimal protection period of 5 years is not a GATT:TRIPS requirement but a NAFTA (North America Free Trade Association) one. The question was then irrelevant for the majority of OECD countries. Responses to this question have not been included in the Annexes to this report.

PART 2
NATIONAL LAWS/REGULATIONS AND PROCEDURES ON CONFIDENTIAL BUSINESS INFORMATION (CBI)

2.1 If your country has a definition of CBI with respect to pesticides, please provide it together with the reference of the document in which the definition can be found. (If your country uses another term, such as "confidential information" or "third party information", please provide the term you use and the definition.).

2.2 Does your country have laws/regulations regarding the protection of CBI for pesticides?

____ yes _____ no

If yes, please give the titles of all relevant laws/regulations

If you have laws/regulations to protect CBI for pesticides, please answer the following:

2.3 Are the laws/regulations specific to pesticides?

____ yes _____ no

If no, please list what they cover.

2.4 Which of the following does your country treat as confidential? Please tick (✓) those which apply. If necessary, provide additional information on a separate sheet.

Active ingredient	***Preparation/formulation***
___ identity ___ common name, synonyms ___ chemical name ___ CAS, EEC or CIPAC numbers ___ internal code numbers (manufacturer, applicant) ___ molecular formula ___ structural formula ___ molecular mass ___ purity of the a.i. ___ identity of isomers ___ content of isomers ___ identity of impurities ___ content of impurities ___ analytical profiles of batches ___ detailed description of the manufacturing process ___ manufacturer(s) ___ physical and chemical properties ___ summary results of all tests (all test areas) ___ complete results (raw data) of tests (all test areas) ___ complete results (raw data) for specific test areas (please specify areas): ___ summary results for specific test areas (pleasespecify areas): ___ information on hazard categories, nature of the risks, relevant warnings & precautions to be taken ___ ways to render substance harmless ___ others (please list)	___ identity ___ trade name(s) ___ internal code numbers (manufacturer, applicant) ___ type of preparation ___ composition ___ identity and content of active ingredients ___ isomers ___ formulants ___ inert compounds ___ manufacturer(s) ___ physical and chemical properties ___ summary results of tests (all areas) ___ complete results (raw data) of tests (all test areas) ___ complete results (raw data) for specific test areas (please specify areas): ___ summary results for specific test areas (please specify areas): ___ information on hazard categories, nature of the risks, relevant warnings & precautions to be taken ___ ways to render substance harmless ___ others (please list)

2.5 Does your country require the pesticide registrant to identify information he wishes to be treated as confidential in his data submission?

_____ yes _____ no

If yes,

a) please explain how should the registrant do this?

b) do you automatically accept as confidential the information identified by the registrant?

_____ yes _____ no

If no, please explain.

2.6 Does your country apply the OECD Recommendation concerning the OECD List of Non-Confidential Data on Chemicals to pesticides?

____ yes _____ no

If not, why not?

2.7 Has your country entered into any bilateral agreements regarding the protection of CBI

____ yes _____ no

If yes, please provide details, including the country(ies) involved.

PART 3
PROTECTION OF PROPRIETARY RIGHTS AND CBI WITH RESPECT TO PESTICIDE DATA REVIEW REPORTS

Structure of Pesticide Data Review Reports

3.1 Does your country keep CBI information separate from the rest of the data review report (e.g. in an annex)?

____ yes _____ no

If yes,

a) since when have you been doing this? ___ month ___ year

b) could this separate section/annex be easily separated from the main report before sending it to another country or to the public?

____ yes _____ no

c) does this separate section/annex make it easier for you to exchange pesticide data review reports?

____ yes _____ no

if no, please explain.

Exchanging pesticide data review reports with other governments

3.2 Can your country release pesticide data review reports to the regulatory authorities of other countries?

____ yes ____ yes, but under certain conditions (list under 3.3) _____ no

If not, why not?

3.3 If your country can release pesticide data review reports to the regulatory authorities of other countries, please describe your entire procedure, including for example:

- whether steps must be taken to substantiate whether it is a bonafide request
- whether you must obtain consent from the pesticide registrant before releasing the report
- whether you remove any CBI, and if so, what information you remove and how you do it (Note: a copy of the table in Q2.4 could be used to indicate what CBI you remove)
- etc.

3.4 To what extent can your country protect CBI contained in pesticide data review reports sent to you by a regulatory authority in another country?

____ same level of protection as in transmitting country

____ same level as in own country

____ other (please explain)

Releasing pesticide data review reports to the public

3.5 Can your country release pesticide data review reports to the public?

____ yes ____ yes, but under certain conditions (list under 3.6) _____ no

If not, why not?

3.6 If your country can release pesticide data review reports to the public, please describe your entire procedure, including for example:

- whether you must obtain consent from the pesticide registrant before releasing the report
- whether you remove any CBI, and if so, what information you remove and how you do it. (Note: a copy of the table in Q2.4 could be used to indicate what CBI you remove)
- etc.

Exchange of pesticide data review reports and protection of proprietary rights

3.7 The pesticide industry (GCPF, formerly GIFAP) has proposed the following procedure to protect proprietary rights during the exchange of pesticide data review reports:

"In order to respect the proprietary nature of the data which is summarised by governments in their regulatory process when there is an exchange of pesticide review reports between governments, a government should not grant a registration using reviews by other governments unless it has first received a submission of proprietary data[3] on which the summaries are based, either from the owner of the data or from a second party who has authorised permission from the owner of the data or when the owner of the data has given the government permission to use the review".

Is this in line with your existing procedures?

____ Yes ____ No

If not, where not?

3. proprietary data are data which are owned by the person or company that generated them. The period of ownership is specified by national or multi-national regulations.

PART 4

CONTACT NAMES

Please provide names, addresses, telephone, fax and Email addresses of persons who can be contacted if we need to clarify any of your responses.

1) Name .....
Address .....
.....
.....
.....

Tel: .....
Fax: .....
Email: .....

Area of survey.....

2) Name .....
Address .....
.....
.....
.....

Tel: .....
Fax: .....
Email: .....

Area of survey.....