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OECD Survey on Integrity of Pesticides at the Manufacturing, Import and Distribution Stages: Survey Results

Series on Pesticides
No. 69

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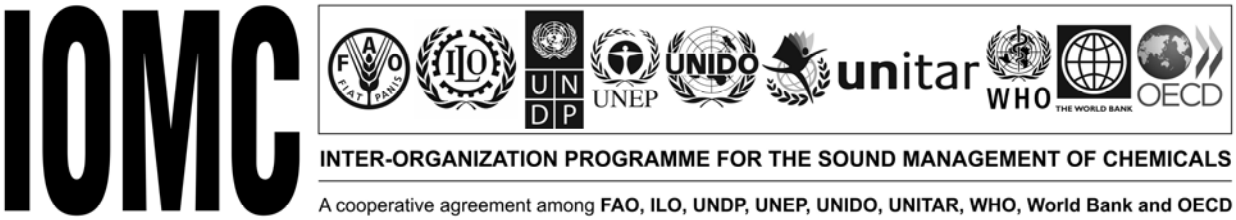

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OECD Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances-Dossier Guidance (1998, revised 2001, 2005)

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FOREWORD

This document provides the results of an **OECD Survey on Integrity of Pesticides at the Manufacturing, Import and Distribution Stages** that was carried out in 2009-2010 as part of the OECD pesticide risk reduction activities. The survey was conducted by Canada that also analysed the survey responses and prepared this survey report.

Maintaining integrity of pesticide products implies that the composition (formulation) that was assessed and registered by the regulatory authority remains within approved specifications throughout the entire product life cycle - from manufacture to distribution, sale and use. Increasingly, pesticide products available for sale in one country are packaged in another country, and consist of components manufactured in a third country. Unacceptable changes in composition could result in unknown risks to health or to the environment. Due to the globalization of the pesticide market, the pesticide regulatory authorities that are involved in the OECD Pesticides Programme therefore recommended that certain key stages (i.e. manufacture, import and distribution/sale) of the pesticide life cycle should be addressed by the survey as they could benefit from work at the international level by identifying opportunities for potential cooperation and for minimizing duplication.

The objectives of this survey were:

- to explore issues regarding product integrity at the manufacturing, import, distribution and sale stages, and

- to gather information on current regulatory practices and oversight mechanisms, in terms of regulatory and compliance best practices, that exist to mitigate risks and to address emerging issues.

Ensuring product integrity of pesticide products is consistent with the framework of the OECD pesticide risk reduction activities that promote risk reduction and create strategic opportunities to facilitate risk reduction internationally. Risk reduction can be obtained if, as a result of greater understanding of the current regulatory and non-regulatory gaps in the life cycle of pesticides, actions are taken to reduce these gaps and help ensure product integrity.

This survey report was approved out-of-session by the Working Group on Pesticides by written procedure that was finished on 20 February 2012.

This document is being published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, which has agreed that it be unclassified and made available to the public.

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BACKGROUND

In June 2008, Canada presented a Canadian Framework for the Life Cycle Management of Pesticides to the Risk Reduction Steering Group (RRSG) of OECD. The objective of the Framework was to provide an appropriate level of oversight through the entire life cycle of a pest control product using suitable instruments to mitigate risk. Due to the globalization of the pesticide market, it was recommended that certain stages (i.e. manufacture, import and distribution/sale) of the pesticide life cycle could benefit from work at the international level by identifying opportunities for potential cooperation and for minimizing duplication.

Increasingly, pesticide products available for sale in one country are packaged in another country, and consist of components manufactured in a third country.

Unacceptable changes in composition could result in unknown risks to health or to the environment. Regulators are continuing to look for opportunities to collaborate with international partners to identify areas for increasing efficiencies and to better manage the risks. These factors point to the potential for a global approach to managing pesticides and product integrity at key stages of the product life cycle.

The RRSG supported the development of an OECD survey to explore issues regarding product integrity at the import and manufacturing stages, and to gather information on current regulatory practices and oversight mechanisms that exist to address emerging issues.

In November 2008, a draft framework of the survey was presented to the Working Group on Pesticides (WPG) and received concept approval. In February 2009, the RRSG recommended distribution of the survey to Member countries and industry observers. In May 2010, at the WGP meeting, the Canadian delegation presented the first survey report that was circulated for comments. In October 2010, a revised version was presented and lastly in October 2011, the RRSG approved this document.

Ensuring product integrity of pesticide products is consistent with the RRSG mandate to promote risk reduction and to create strategic opportunities that facilitate risk reduction internationally. Risk reduction can be obtained if, as a result of greater understanding of the current regulatory and non-regulatory gaps in the life cycle of pesticides, actions are taken to reduce these gaps and help ensure product integrity.

ISSUES

Maintaining integrity of pesticide products implies that the composition (formulation) that was assessed and registered by the regulatory authority remains within approved specifications throughout the entire product life cycle - from manufacture to distribution, sale and use.

Increasingly, pesticide products available for sale in one country are packaged in another country, and consist of components manufactured in a third country. Unacceptable changes in composition could result in unknown risks to health or to the environment. Regulators are continuing to look for opportunities to collaborate with international partners to identify areas for increasing efficiencies and to better manage the risks. These factors point to the potential for a global approach to managing pesticides and product integrity at key stages of the product life cycle.

GOALS OF THE SURVEY

The goals of the survey were to:

- Gather information on the current level of oversight, in terms of regulatory and compliance best practices;
- Identify the nature and extent of product integrity issues at the manufacturing, import, distribution and sale stages;
- Determine instruments used to mitigate risks associated with product integrity; and
- Identify areas for collaboration among OECD Member countries.

OVERVIEW OF SURVEY

Questions were designed to identify current mechanisms for active prevention, targeted oversight and rapid response to address potential risks to health and the environment.

The survey was designed in two main parts:

- Part A - Manufacturing and
- Part B - Import and Distribution/Sale.

This structure is reflected in this survey report.

Countries were asked for details on:

- the requirements, strategies or processes used by regulators and/or industry to assure compliance with approved/registered specifications and to consider both regulated and illegal pesticides;

- regulatory and non-regulatory initiatives at country, region, international and industry levels (including any partnerships);
- current practices to target compliance oversight;
- criteria which determine when a response to non-conformity is necessary; and
- degree and capability for information sharing.

The survey was distributed to members of the WGP (composed of delegates from OECD Member countries, industry and NGO observers, and representatives of other intergovernmental organizations such as FAO, UNEP and WHO) in July 2009.

Appendix 1 of this report includes the survey questions.

REPORTING OF THE RESULTS

This report summarizes and analyzes the information obtained through the survey.

A compilation of individual country responses for each question is provided in Appendix 2.

SURVEY RESPONDENTS

Responses were received from national government pesticide regulatory authorities from the following countries:

- Australia
- Belgium
- Canada
- Germany
- Ireland
- Japan
- Mexico
- New Zealand
- Norway
- Slovak Republic
- Switzerland
- United Kingdom
- United States

SURVEY RESULTS

PART A. MANUFACTURING STAGE

In this part of the survey, countries were asked about the level of regulatory oversight, as part of pre-market assessment for product registration, and also on the level of compliance oversight on the manufacturing of pesticides. Information on active substances and end-use products were separated. Examples and actions taken on non-compliance or non-conformity and level of information sharing were also requested.

1.0 Information required by regulators prior to the manufacture or sale of a pesticide

All respondents require manufacturing information on both the active substance and end-use product prior to the manufacture and sale of a pesticide, as part of pre-market assessment for product registration.

For end-use product formulation, all respondents require a specification or declaration and the identity of active substance or source.

Table 1A

Number of respondents requiring specific manufacturing information on end-use products prior to registration

Type of information required	No. respondents
Specifications/ declaration of end-use product formulation	13
Identity of active substance (source) in the end-use product	13
Address of each formulating site	12
Storage Stability	12
Analytical method of the end-use product	11
Description of the formulating process	7
Expiry specification	7
Alternate formulations permitted with one registration number (same registrant)	7

Respondents mentioned other information required for end-use products. These include:

- batch analysis or formulation stability data;
- formulation composition;
- addition of marker substances for identification;

- certified limits for all ingredients of the formulation;
- identity and concentration of contaminants of concern;
- information on packaging, product label, material safety data sheets;
- release specifications; and
- information to show the distributor products match the primary registration.

Table 1B

Number of respondents requiring specific manufacturing information on active substances separately from the end-use product

Type of information required	No. respondents
Specification/declaration of active substance	13
Validated analytical method for the active substance	12
Locations of the manufacturing site	12
Analysis of a specified number of production /batches	12
Description of the Manufacturing Process	11
Storage Stability information	9
Sample of pure active substance for enforcement purposes	7

Other information required for active substances include:

- physical and chemical properties;
- analytical reference standards;
- information on stabilizing agents and additives added to the active substance;
- identity and concentration of contaminants of health and environmental concern;
- identity and concentration impurities at levels greater than 0.1% by weight within certified limits; and
- packaging and product labelling.

2.0 Information required by regulators in order to maintain registration

2.1 Application for changes in product chemistry

All respondents require an application to support a change in product chemistry for both the active substance and end-use product.

Table 2:

Changes in product chemistry of Active Substance which trigger a submission for application	**No. of respondents**
Change in manufacturing site	13
Change in specification /guarantee	12
Change in manufacturing process	10
Other: change in impurity profile	

Changes in product chemistry of End-use product which trigger a submission for application	**No. of respondents**
Change in form of active substance	12
Change in identity of formulants	12
Change in proportion of formulant	12
Change in formulation type	11
Change in guarantee	9
Other: change in formulator or formulation site; change in source of active or inert ingredients	

In most cases, the information is evaluated or assessed to approve and support the continued product registration with a range of objectives:

- to verify equivalence with previously approved specifications;
- to assess against a set of criteria and thresholds;
- to determine if the changes are significant enough to affect the original risk assessment;
- to insure that the product continues to be stable, effective and be safely used with minimum impact to the users, consumers, crops, the environment and trade; and
- to determine if the change is major or unacceptable, thus requiring re-evaluation or a submission for a new registration.

Information required to support changes to the chemistry of end-use product formulations and active substances varies among countries.

There was a range of information required to support the changes to the product chemistry or specifications:

- Mexico reported that only the change allowed is that of the manufacturing site of the active substance and that any other changes would require the same information as submitted for a new registration;
- Australia requires the same information as required prior to registration;
- the United States do not collect additional product chemistry information;
- the Slovak Republic reported that physical-chemical properties must conform with the Food and Agriculture Organization specifications;
- Canada requires new batch data to support product specifications and levels of contaminants of concern and method validation for any new enforcement analytical method;
- Ireland requires five batch analysis, synthetic pathway and methods of analyses;
- New Zealand's requirements depend on the proposed changes and must address the risk areas managed under the legislation;
- Belgium requires information (e.g. physical-chemical analysis) to demonstrate equivalence; and
- the United Kingdom requirements depend on degree of change--- i.e. storage stability data if minor and possibly efficacy and toxicology data if significant.

Where the amendments are possible or authorized, the type of data required is based on proposed change. For minor changes, a revised product specification form and batch data may be sufficient. For more significant changes, supporting chemistry, efficacy or toxicology data may be required.

The extent of the changes would determine whether or not the registration is maintained.

- The United Kingdom indicated that any change in manufacturing process resulting in new specification would require an application.
- In Japan, the decision to maintain the registration depends on the extent of changes from the original registration

2.2 Renewal, re-evaluation and other post-registration activities

All respondents conduct post-registration activities in the form of periodic renewal and/or re-evaluation of the products.

- Australia, Mexico and New Zealand conduct periodic renewal only.

- Germany, Japan, Norway, United Kingdom, and United States conduct re-evaluation only.
- Belgium, Canada, Ireland, Slovak Republic and Switzerland conduct both periodic renewal and re-evaluation.

Periodic Renewal

The renewal period ranges from three to five to ten years and the information regarding the product chemistry requested vary, and may range from administrative activity where no information required, to attestation or confirmation of update of product specifications, to chemistry review by the regulator.

- In Canada, the submitted updated specification form is verified by the regulator during renewal. It was found that 9% of renewals included specification form changes that required further applications for amendments.
- In New Zealand, changes to the specifications may trigger data review for compliance with the legislation.
- Mexico has not yet implemented their renewal process. Information requirements are still to be defined.

Re-evaluation

Re-evaluation or re-registration activities are conducted approximately every 15 years. The information regarding the product chemistry requested varies and may include:

- batch data supporting current active substance specifications;
- random sampling of products from the market place;
- levels of contaminants of concern in the technical grade active are validated;
- information as per Annex II of DIR 91/414/EEC;
- formulation details, including other physical, chemistry and storage stability data; and
- same information or data required as per submission for the original registration.

Data review against information on file will identify any outstanding deficiencies or changes, update registrations and confirms that the product continues to meet the stringent safety standards for continued registration.

Renewal and re-evaluation activities can contribute to product integrity in the following ways:

- Modern standards of assessment and updated scientific knowledge are applied to the review of the re-evaluated active, ensuring that all registered products are registered under the latest regulatory infrastructure.
- It allows the authority to confirm that the information provided for registration is still current and the commercialization of the product is safe for the public health.
- Registrant declares the product to be the same as when the last data assessment was made.
- It maintains biological efficacy, safe use and safety standards.
- This information will determine if the product meets the data requirements for approval.

Other post-registration activities

Product integrity for active substances and end-use products is also maintained through inspection and monitoring activities.

A range of compliance activities exists for active substances and end-use products, such as:

- site inspections, sample analysis (random or targeted) largely focused on compliance to guarantee, formulants or impurity or contaminant level;
- audits on Quality Assurance schemes to ensure conditions of registration are upheld;
- inspections into improper or manufacture as a result of complaints of wrong-doings, suspected non-compliance;
- analysis for specific parameters listed in FAO specifications; and
- inspections responding to incident reports.

In the United States, the results may trigger an evaluation of the product chemistry or toxicity, which provides opportunities to reassess the product integrity.

3.0 Quality Assurance (QA) in manufacturing

Manufacturers must adhere to product specifications and maintain compliance. Some respondents indicated that QA practices were required by the regulating authority, mostly in the form of chemical analysis and batch analysis to be conducted under the Good Laboratory Practices (GLP).

- Australia's mandatory AgQA Scheme requires the registrant to show that the active substance and end-use product is compliant with their standards via the submission of batch analysis or batch manufacturing records.

- Through regulation and policy, the United States requires Good Manufacturing Practices (GMP) and GLP. These are reviewed annually.

Canada indicated that although no mandatory QA was in place, questions regarding QA practices are asked during inspections in order to identify the companies of greatest risk of non-compliance.

None of the respondents were aware of any QA practices required by industry associations. However in Belgium, manufacturers are required to set up a system of "auto-enforcement" to deal with safety and quality of their products. The national association for plant protection products (PPP) has developed a sectoral guide for the application of this initiative.

Quality Assurance practices, in the form of GLP or GMP, are conducted at the factory level in some countries, although the QA practices in overseas manufacturing sites is unknown.

- Australia and Japan conduct on-site inspections to confirm that quality control activities are performed at the (domestic) manufacturer.

4.0 Product integrity issues encountered for registered products

The survey asked countries about their use of laboratory facilities, the extent of monitoring for product integrity and to provide cases of non-conformity found as a result of their activities.

Belgium, Canada, Ireland, Japan, Slovak Republic, Switzerland and the United Kingdom conduct their chemical analysis in government laboratories. Australia and the United States use private laboratories.

4.1 Product integrity of active substances

The majority of respondents monitor for either changes to the active substance specifications or manufacturing process or for unacceptable variability in levels of contaminants of concern through targeted or random sampling, either ad hoc (after receiving intelligence on or suspicion of non-compliance) or as part of a regular national program.

Cases of non-conformity

Australia

- sourcing of active constituents (AC) from non-existent overseas manufacturing sites, cases of fraudulent documentation;
- AC imported into Australia which exceeds the concentration of toxicologically significant impurities.

Belgium

- presence of impurities

Canada

- High levels of compliance in 1998–2002 for guarantee and micro-contaminant resulted in discontinuing the monitoring program after 2004. In the late 1990-2000s:
  - 59 samples tested for hexachoro-dibenzo-p-dioxin with 6 samples testing positive for levels above the reporting level of 0.01 ppm (Compliance level of 89%.).
  - 21 samples were tested for presence of nitrosamines and all 21 samples were in compliance with their registration specifications.
  - micro-contaminant analysis was done for emana, folpet and N-nitrosodi-n-propylamine (NDPA). Small quantities of emana (0.067ppm) and folpet (0.002% based on Captan active content) were detected in the two products sampled.

Mexico

- Unlabeled product, damaged package, not in Spanish.
- Unregistered, false registration number, expired registration.
- Used in a different manner compared to the one authorized.

Slovak Republic

- Content of the active substance (2 cases in 2007, 6 cases in 2008).

United Kingdom

- Variation in levels of active substances in excess of FAO tolerances.

4.2 Product integrity of end-use product formulations

Through random, targeted or periodic sampling, the majority of respondents monitor for all or a combination of the following:

- a new source of active substance that has not been previously assessed;
- changes in end-use product guarantee (i.e., active content) that has not been previously assessed; or
- changes in the end-use product specifications (identity of formulants, proportion of formulants, formulation type) that have not been previously assessed.

Countries that do not monitor products as part of a regular national program, may respond to complaints or suspicion of non-compliance.

Cases of non-conformity

Canada

- 2003-2005: 6 out of 29 products were identified that did not meet the specified/ approved guarantee (compliance level of 79%).

Germany

- Content of the active substance, content of formulants, physical-chemical properties

Japan

- Change in guarantee (by one half) of registered product resulting in an invalid registration and product recall

United Kingdom

- Variation in levels of active substances/co-formulants in excess of FAO tolerances

United States

- A manufacturer (registrant) failing to inform the Environmental Protection Agency (EPA) that product had changed formulation and therefore did not have an approved product in marketplace.

- Failure of manufacturer to inform EPA of new source of active ingredient. Contained contaminants of toxic concern.

4.3 Regulation and oversight of formulating sites

Five respondents monitor for changes (e.g. process, location, starting material) in the formulating plant of the end-use product. Monitoring can consist of random, targetted or periodic on-site inspections, periodic monitoring during re-evaluation, tracking through the product specifications, or through discussions with the registrants.

Cases of non-conformity

Canada

2002: program was conducted to verify formulating site locations.

- Company mergers and lack of reporting site changes or incorrect listing of the registrant address instead of the formulating site on product specification forms on file lead to difficulties in confirming locations.

- Because there are no specific formulating/manufacturing requirements in place, other than adhering to product specifications and use directions for technical grade active ingredients and manufacturing concentrates, it is difficult to say switching to a new formulator is a concern although clearly some have better quality assurances in place than others.

Japan

- Change in guarantee (by one half) in a registered product resulted in an invalid registration and product recall.

Mexico

- Lack of sanitary license (registration).

- Factories established on residential, school, and hospital areas.

- Inadequate facilities; lack of safety and hygiene measures.

- Use of forbidden substances.

- Imminent harm to health.

Other product integrity issues that may result in unacceptable health or environmental risks include:

- Product and active substance instability resulting in development toxicologically significant impurities;
- Toxicologically significant impurities introduced into the formulation through poorly tested inert substances;
- Mistakes in packaging, labelling, storage, cleaning of tanks/product lines, of the pest control product;
- Level of contaminants, level of active substance;
- Storage or expiration of product;
- Emissions to the environment;
- Deficiencies in the control process and lack of quality monitoring;
- Packaging, labelling, cleaning of tanks; and
- Contaminants from a new unapproved source of active ingredient. The contaminant was a known carcinogen at levels of concern.

4.4 Enforcement responses to cases of non-conformity

- In the countries where monitoring or inspections occur, each has a range of responses available when non-conformities are discovered and it was indicated that more than one response could be actioned.
- The responses and the criteria for action are similar for both active substances and end-use products. Countries that monitor for changes in the formulating plants indicated fewer available responses.
- For active substances and end-use product non-conformity, the response actions are directed towards the product or the manufacturer.

Actions toward the product include:

- Stop importation supply, deny entry into the country;
- Product recall or removal;
- Detention or seizure;
- Forfeiture by consent or disposal;

- Limitation, suspension or prohibition of sales; and
- Suspension, invalidity, withdrawal or cancellation of registration or authorisation.

Actions toward the manufacturer or registrant include:

- Education: verbal or written;
- Requirement of additional information;
- Requirement to apply for authorization of changes in formulation;
- Order for compliance, testing or correction measures;
- Denying further authorizations (registrations);
- Order or request of report for internal investigation result and improvement;
- Levying fines, e.g. Administrative Monetary Penalties (AMPs); and
- Prosecution in court;

For example, the United Kingdom has a range of enforcement options and applies appropriate proportionate sanctions available under European Union and UK regulations (e.g. those set out under FEPA, COPR, PPPR, and PP(BC)R).

Respondents indicated a range of criteria used to determine the appropriate response, with the response escalating with the impact on health and environment, both potential or actual (e.g. crop failure, injury or death), the degree of non-compliance, and the compliance history of the person or company (i.e. repeat offence).

Additional criteria include the following:

- loss of trade;
- risk-based analysis or evaluation for impact on human health, environment;
- impact to regulatory integrity;
- knowledge, will and ability of the person to comply;
- evidence, effectiveness and practicability of the corrective or improvement plan; and
- level of response needed to achieve/maintain compliance.

5.0 Regulation and oversight of manufacturing sites

All respondents, except Switzerland, have the authority to regulate the manufacture of pesticides and to keep records of active substance manufacturing sites and end-use product formulation sites.

The majority keep records of the manufacturing sites and formulation sites---both domestic and foreign, or domestic only. The type of information collected varies from just the name and location, to process and annual production data.

Five countries (Belgium, Japan, Mexico, Slovak Republic, and United States) indicated that the manufacturing or formulation sites were subject to national/federal licensing or approval. All countries, with the exception of the Slovak Republic, conduct on-site inspections. Only Mexico and Slovak Republic have the authority to share information.

Information gathered on manufacturing and formulation sites may be used for the following purposes:

- analysing trends;
- targeting surveillance, oversight or inspections;
- completing the registration dossier;
- verifying or confirming with the product specification form;
- inputting into regulatory decisions for pesticides with risk of concern; or
- using as reference if an issue should arise.

Table 3
Number of respondents with oversight on the manufacture of pesticides

	Number of Respondents
Authority to regulate manufacture of pesticides	12
Maintain records of active substance manufacture sites	2 (Domestic only) 8 + 1* (Domestic and Foreign) 1 (sites unspecified)*
Authorized to share information on manufacturing sites with other regulators	8
Maintain records of end-use product formulation sites	3 (Domestic only) 7+1** (Domestic and Foreign) 2 (sites unspecified)*
Authorized to share information on formulation sites with other regulators	6
Manufacturing or formulation sites subject to national/federal licensing or approval	5
Site inspections conducted	4 domestic only, 1 no inspections
Authorized to share licensing information	3

* respondents who indicated that information is collected but not tracked
** respondents who indicated no authority to regulate, but collected information.

Countries reported the following benefits of tracking activities in manufacturing and formulation sites**:**

- Information collected can assist in conducting inquiries domestically and overseas and provided a basis for targeted testing in QA schemes as well as to target products and determine where to divert resources for inspection activities.
- Information on process or site changes can be used to identify potential illegal products and determine where to conduct product recalls.
- Production information can be used in re-evaluation of those pesticides considered higher risk and concern and contribute to the assessment of potential benefits.

The United States indicated that inspections of national/federally licensed sites contributed to the identification of inconsistencies with GMP requirements and product integrity problems. Mexico found non-conformities such as unregistered products, misuse of substances, illegal entry of pesticides and use of banned substances.

PART B. IMPORTATION, SALE AND DISTRIBUTION STAGES

In this part of the survey, countries were asked about the level of regulatory and compliance oversight on products before importation, at the border and in the market place. Examples and actions taken on non-compliant products and level of information sharing were also requested.

6.0 Importation of pesticides manufactured in other countries

6.1 Types of information required prior to product importation

Five respondents indicated that all pesticide active substances were required to be registered before importation into their country.

The following cases are examples where registration is not required before importation:

- cases where registration is required for the end-use product only and not the active substance;
- for formulation into products registered outside the country;
- for formulation or manufacture of pesticides for export;
- for manufacturing into end-use formulations which do not require approval; and
- for use under permit (e.g. research) to generate data for registration.

Although not asked in the survey, respondents indicated the following:

- non-registered end-use products are permitted to be imported for the purpose of test research;
- special grower programs which allows importation for own use;
- pesticides imported for personal use, meeting specified small quantities and monetary value; and
- specific exemptions from registration exist because of coverage in another piece of legislation, or due to alternative method of regulating the product.

All respondents, except Belgium, have mechanisms to oversee importation and require some information to allow for import.

Table 4

Number of respondents requiring specific information for importation

Information required for importation	Number of Respondents
Product Name	12
Registration number	12 (if product is registered)
Country of origin	9
Destination	9
Active substance	8
Quantity of imported product or substance	8
Purpose for importation	8
Date of import	8
Point of entry	8

Other information required by some respondents:

- name and postal address of the shipper and importer
- quantity of the active in the end-use product
- for non-registered end-use products---the amount of import and the test research period

Examples of issues associated with the quality of imported active substances or end-use products include:

- Impurities and formulants above allowable standards;
- Contaminants of concern (e.g., nitrosamines, dioxins);
- Problems with guarantee;
- Unapproved or incorrect sources of actives;
- Composition of some parallel imported products are not identical to the reference product;
- Manufacture at fictitious sites.

The types of mechanisms in place to prevent issues or track incidents may include:

- QA Scheme;
- working with customs services ;
- border lookouts ;
- sample collection;
- liaison with foreign regulatory authorities;

- import declaration forms, import certificates;
- incident reporting database;
- industry monitoring activities related to their own product ;
- information from third parties: registrants, growers, industry; and
- requirement for a domestic representative for foreign-based registrants.

Verification of the information collected

Verification of the information varies between countries and may involve customs or border officials. The majority of the respondents do not conduct data analysis. Examples of verifications include:

- spot or random checks after incidents occur;
- comparison against the product registration file;
- examination of customs data, importer records, QA scheme records and records from foreign regulatory authorities;
- review at point of entry by customs officials;
- verification of information prior to importation; and
- contacting the country of export for details on the approved formulation, manufacturing site of the active substance and its purity and comparing the information to the domestically registered product.

6.2 Border monitoring activities

Not all respondent countries conduct border monitoring on a regular basis, although cooperation with customs services or audits conducted at the border have resulted in findings of actual or attempted illegal importations, importation of unregistered products, unapproved or illegal sources and counterfeit pesticides.

Countries were asked about their information sharing capabilities and activities with other regulators and jurisdictions.

Table 5

Number of respondents participating in information sharing activities

Information Sharing activities	Number of Respondents
with other regulators in same country	8
with other countries	7
among points of entry	6

Respondents indicated that the type of information shared may be all or a portion of information collected as a requirement for importation; suspicions about illegal products; or be determined case by case.

Information shared as a result of border activity includes:

- product name, registration number;
- active ingredient;
- importer and date of import;
- country of origin and exporter at origin; and
- import/export statistics.

The respondents that share information do so informally by e-mail, or more formally by official communications (e.g. memoranda of understanding, notification process) or through their annual publications.

7.0 Monitoring registered products

7.1 Activities to ensure product integrity

All respondents have enforcement legislation. The majority of respondents monitor and inspect at the point of importation, sale or distribution. Few do product tracking.

Table 6

Number of respondents with specific activities to ensure product integrity

Activities to ensure product integrity at importation, sale or distribution	Number of Respondents
Enforcement legislation	13
Inspection	11
Monitoring	10
Compliance Promotion	7
Product Tracking	2

Other activities, reported by respondents, include:

- investigation and enforcement action
- yearly random market control campaigns at sale points
- evaluating import requests to confirm registration, correct labelling and sourced from registered production establishment

Monitoring results are used mostly for program development and operational planning in the following ways:

- forming compliance history for future enforcement response;
- building a picture of the industry and individual trading units within the industry;
- assisting in decision making, e.g. approve or deny importation;
- improving enforcement targeting;
- assessing inspection needs at specific points of entry.

Response to non-compliance and the criteria for response are similar to those listed under Part 4 Product Integrity.

7.2 Incidents related to importation, distribution or sale of registered products

Belgium

- Through a sampling and analyses program in the market, non-compliance results included problems with amounts of impurities, amounts of active substances (insufficient or excessive), excessive foaming and problems with insufficient amounts of active in anti-slug products.

Germany

- Permissions for the importation of products have been withdrawn

Ireland

- 2008: A consignment of unregistered products was seized by the Pesticide Control Service . Due to being the first offence, the company was afforded the opportunity to return the product to the supplier in the UK, at companies own expense. Any subsequent issues with this company will result in legal proceedings.

Japan

- Pesticide manufacturers voluntarily reported the information of complaints drawn by pesticide users to the Ministry of Agriculture, Forestry and Fisheries (MAFF), e.g. misprint of expiry date on a pesticide label; leak from a pesticide container; different description on a pesticide label from registered contents.

- In response to these cases, MAFF requested manufacturers to conduct internal investigation and develop improvement.

Slovak Republic

- National inspection program has determined several infringements during last years concerning unauthorised product; unauthorised sale; labelling; content of active substances.

- Each infringement is connected with appropriate action of phytosanitary inspection according to the National phytosanitary law.

United Kingdom

- Sale and Supply of registered product after date of revocation (following Annex 1 inclusion) by two major companies.

- Alleged breach was reported by competitor. The affected product subject to enforcement notice and the product was eventually recalled and exported outside the European Union. Response was determined in consultation with legal advisors and reflected lack of a safety concern.

United States

- The Environmental Protection Agency (EPA) settled an administrative penalty case against “Company A” and “Company B” for violations of the Federal Insecticide, Fungicide, and

Rodenticide Act (FIFRA). According to the terms of the settlement, Companies A and B collectively will pay a total civil penalty of more than $800,000, and will undertake corrective actions to ensure that the violations do not recur. “A” and “B” manufacture, market, and sell a variety of pesticide products within US.

- Through importation records reviews and inspections, EPA determined that Companies A and B had been importing a registered pesticide active ingredient from a non-approved manufacturing facility in China, and that the composition of the ingredient differed from the composition specified in the statement of formula set out in the registration. As a result, the composition of two end-use products manufactured by the companies, “Product X” and “Product Y”, differed from the compositions specified in EPA’s approved registrations for those products. The original registrant, Company B, began importing the active ingredient from the unapproved facility in 1994. In 1997, Company A and Company B formed “Company C” and in 2003, Company A acquired 100% interest in Company C. Both Company C and Company A continued the practice of importing the ingredient from the unapproved source in China.

Containers of pesticide ingredient imported from China were misbranded in that they stated the incorrect percentage of the active ingredient contained in the product. The analytical results from samples of the two end-use products showed that they contained the pesticide ingredient in concentrations exceeding the allowable certified limits specified in their registrations. After EPA notification in April 2005 that it was in violation of FIFRA, Company A filed a registration amendment for the active ingredient to indicate the new source and to revise the formulation. Company A recently sold the registrations for these products to another company.

8.0 Monitoring of illegal pesticides available for sale on the market

For the purposes of this survey, illegal products refer to unregistered products, counterfeit products and products which have been changed from approved/registered specification without amending or notifying regulatory authorities.

8.1 Activities to prevent illegal pesticides

All respondents have enforcement legislation. All respondents conduct some activity to actively prevent and monitor the presence of illegal pesticides on the market, either at the regulatory, industry or other government level.

Table 7

Number of respondents who conduct active prevention at the regulatory level

Activities at the Regulatory level to actively prevent and monitor the presence of illegal pesticides on the market	Number of Respondents
Enforcement legislation	13
Inspection	12
Monitoring	10
Compliance Promotion	8
Product Tracking	2

Other activities, reported by respondents, include:

- responding to complaints
- yearly market control campaigns at sales point
- QA scheme
- requesting public involvement in providing information

At the industry level, respondents reported activities initiated or implemented by either the regulator or industry. These activities include:

- Product compliance promotion and monitoring imported products;
- End user, retail and wholesale inspection programme;
- Cooperation with industry – identification of counterfeits;
- Market monitoring by several companies; and
- Incentives for self-policing.

Activities at other government levels vary. Some specific examples are listed.

- Canada: Provincial and municipal limitations imposed on sale of products and inspections carried out in this regard.
- Germany: The enforcement authorities are independent from the regulation authority.
- Japan: When the products alleged to be illegal are discovered by inspection of local governments, they promptly share the information with the Ministry of Agriculture, Forestry and Fisheries, who then determines the appropriate responses to the case.
- Mexico: Communications between the regulatory agencies.
- Slovak Republic: Cooperation of customers and pesticide regulators.
- Switzerland: Random control of imported products is conducted by customs. Market control is covered by the cantons.

8.2 Range of regulatory or compliance responses

In all cases, a tiered response is used. The enforcement tools available and the criteria which are implemented are similar to those already listed in previous sections of this report.

The decision for response can depend on factors including:

- the results of a risk based analysis: degree of harm or impact to health and to environment;
- impact to regulatory integrity;
- compliance history of the contravener or company and number of offences;
- analysis of the cause of the incident;
- effectiveness of submitted improvement or corrective plans; and
- the level of response needed to achieve compliance.

The monitoring results are used in the following manner:

- for operational planning of QA program activities and permits audits;
- for monitoring and inspection program development;
- to provide compliance history for future enforcement responses;
- to improve enforcement targeting; and

- to assess inspection needs at specific ports of entry.

8.3 Incidents related to illegal pesticides

Note that the following are incidents not previously reported in other sections of this document.

Belgium

- Presence of products authorised in other European Union countries but not authorised in Belgium. There was no danger to public health. Products were seized and destroyed.

Canada

- 2006: Unregistered Glyphosate from China was imported and resold for personal profit. The Pest Management Regulatory Agency (PMRA) became aware of this illegal activity from industry complaints. The import admitted to the import and resale, including to a retailer, of illegal Glyphosate. The product was detained. A Compliance Order was issued ordering the return of this product to the original distributor in China and three Notices of Violation with Penalty for the import and sale of an unregistered product were issued. The importer paid the monetary fines, but did not take the required steps to dispose of the illegal product as defined in the compliance order. After lengthy correspondence with the importer, preparations were made to confiscate the product and arrange for its disposal. Before PMRA could confiscate the product, the importer reported it as stolen from the storage facility. The entire investigation was turned over to the police. International counterparts were notified.

Germany

- Illegal importations were discovered due to information from customs offices, industry or
- consumers. Some permissions for the importation of plant protection products were withdrawn due to the findings of the monitoring programme. The enforcement authorities imposed fines.
- In the case of outright illegal importations, criminal investigations are carried out.

Ireland

- 2008: consignment of unregistered plant protection products was seized by the Pesticide Control Service and as it was the companies first offence, the company was afforded the opportunity to return the product to the supplier in the UK, at companies own expense. The consignment was seized as a result of complaints from industry. There were no negative health implications associated with the issue. Any subsequent issues with this company will result in legal proceedings.

United Kingdom

- Sale of unapproved product reported by industry, follow up investigation identified counterfeit product, which was seized and has been disposed. Response was determined by nature of breach including origin of counterfeit, active and scale of operation.

United States

- Company C paid a $1.4 million civil administrative penalty to Environmental Protection Agency (EPA) for importing, selling and distributing seed that contained an unregistered genetically engineered pesticide. EPA also issued a Stop Sale, Use, or Removal Order specific to all quantities of violative seed within the company's control. The company then disclosed to EPA that it may have distributed the seed to the United States, Europe, and South America. Immediately following the disclosure, U.S. Department of Agriculture (USDA), the U.S. Food and Drug Administration (FDA) and EPA began an investigation and evaluation that confirmed the distribution of unregistered seed on over 1000 occasions. A penalty was also assessed by USDA and the company destroyed all the affected seed under USDA supervision.

9.0 Sharing information when incidents of non-compliance are found

The sharing of information on non-compliance with other regulators or countries varies among the countries. There was no information to confirm whether it was due to the lack of authorization to share, or a function of the regulators' common practice. The countries who share, indicated the exclusion of confidential business information. Most of the sharing is linked to requests for information or seeking assistance from other regulators. Typical information includes:

- product details (i.e., product name, product type, quantifies);
- information on the contravener (e.g. importer name, supplier, manufacturer etc.); and
- the nature of the non-compliance.

Information sharing between countries may occur at the international level (e.g. OECD), informally, or as requested by another country.

Information sharing among different levels of government within the country and among other national or federal/regional government jurisdictions within the country as appropriate (e.g. for border control) also varies. Sharing occurs as part of cooperation and collaboration with other jurisdictions to address mutual concerns; as a result of requests; or simply as regulatory updates and other information on the website.

Sharing of information between government and industry takes place though different methods including:

- stakeholder meetings and technical committees;
- formal information exchange;
- sharing with only the relevant industry (e.g. registrant, importer, supplier) or on specific issues (e.g. counterfeits); and
- website postings, media coverage or incident databases.

Respondents identified different mechanisms to assist in collaboration and intelligence sharing and include:

- Strengthening the existing mechanism and ensure the effectiveness;
- Improving and formalizing cooperation arrangements with foreign regulatory authorities;
- Requiring mandatory QA and record keeping for product formulation;
- Implementing conditional licensing of manufacturers, formulators and importers;
- Developing bilateral working agreements with other agencies;

- Publishing program results and notification of where to find these documents through regulatory fora;

- Increasing international border control;

- Increasing communication between authorities in different jurisdictions and internationally when incidents of non-compliance occur;

- Identifying contact persons and developing a rapid alert system, databases and web sites on monitoring results; and

- Developing a European Union database of approved products and formulations.

Specific initiatives underway include the following:

- Switzerland is currently discussing the possibility of a free trade treaty on agricultural products with the European Union, which would greatly influence the exchange of data with the EU.

- The United States is integrating the Notice of Arrival (EPA Form 3540-1) into Automated Commercial Environment/Import Tracking Data System (custom's automated data exchange). This computer database tracking system integrates databases about a wide range of products (chemicals and non-chemicals) from US regulatory agencies into one system. For pesticide products, this enables United States authorities for imports to easily and quickly determine whether a product should be imported and more quickly enter into US commerce or not.

- Canada plans to include inspection reports on the Pest Management Regulatory Agency website.

APPENDIX 1: SURVEY QUESTIONS

PART A. MANUFACTURING

1) Information required by regulators prior to manufacture or sale of a pesticide:

(a) In addition to the data requirements for the registration of chemical pesticides, do regulators require information regarding the manufacturing of end-use product formulations?
☐YES ☐NO

If 'YES, please check all information required by regulators regarding the manufacturing of end use product formulations:

- ☐ Specifications / declaration of end-use product formulation
- ☐ Identity of active substance (source) used in the end-use product
- ☐ Address of each formulating site
- ☐ Description of the formulating process
- ☐ Analytical method of the end-use product
- ☐ Storage Stability
- ☐ Expiry Specification
- ☐ Alternate formulations permitted with one registration number (same registrant)
- ☐ Other: (provide details)

(b) In addition to the data requirements for the registration of chemical pesticides, do regulators require information regarding the manufacture of the active substance, separately from the end use product?
☐YES ☐NO

If 'YES', please check all information required by regulators regarding the manufacture of the active substance:

- ☐ Specification / declaration of active substance (purity, impurities, contaminants)
- ☐ Validated analytical method for the active substance
- ☐ Sample of pure active substance for enforcement purposes
- ☐ Storage stability information
- ☐ Location of manufacturing site
- ☐ Analysis of a specified number of production / batches
- ☐ Description of the manufacturing process
- ☐ Other: (provide details)

2) Information required by regulators in order to maintain registration.

(a) Do you require registrants to submit an application for changes in the chemistry of the product?
☐YES ☐NO
If 'YES':

i) From the list below, identify when regulatory approval is required:

Active Substance

☐ Changes in manufacturing site
☐ Changes in specifications / guarantee
☐ Changes in manufacturing process
☐ Other:

End Use Product Formulations

☐ Changes in guarantee
☐ Changes in form of active substance
☐ Changes in identity of formulants
☐ Changes in proportion of formulants
☐ Changes in formulation type
☐ Other: (please describe)

ii) What information is required to support changes to the product chemistry/ specifications?

iii) How is this information used to approve continued registration/approval?

(b) Do you conduct the following post-registration activities?
Periodic Renewal ☐YES ☐NO
Re-evaluation / re-registration ☐YES ☐NO

If 'YES' to either:

i) At what frequency are these post-registration activities conducted?

ii) What information do you collect regarding the product chemistry/specifications?

iii) How is this information used to approve continued registration?

iv) How does this activity contribute to ensuring product integrity?

(c) Describe other post-regulatory activities that contribute to product integrity (consistency with approved/registered specifications):

3) Quality Assurance in Manufacturing

(a) Are Quality Assurance Practices conducted at the factory level?
☐YES ☐NO ☐UNKNOWN

If 'YES', please describe the practices:

(b) Are Quality Assurance Practices required by industry associations?
☐YES ☐NO ☐UNKNOWN

If 'YES', please describe the practices:

(c) Are Quality Assurance Practices required by pesticide regulators or another regulating authority?
☐YES ☐NO ☐UNKNOWN

If 'YES', please describe the practices:

4) Product integrity issues encountered for registered products

Active Substances
(a) Do you monitor for changes to the active substance specifications or manufacturing process?
☐YES ☐NO

(b) Do you monitor for unacceptable variability in levels of contaminants of concern
☐YES ☐NO

If 'YES' to either 4(a) or 4(b):

i) Describe the monitoring activities and indicate the approach (e.g., targeted, random, periodical) or triggers.

ii) Identify the types of responses available when cases of non-conformity are discovered:

iii) What criteria are used to determine the appropriate response?

iv) Describe cases of non-conformity that have occurred in the last 5 years:

End-Use Product Formulations
(c) Do you monitor for a new source of active substance that has not been previously assessed?
☐YES ☐NO

(d) Do you monitor for changes in end-use product guarantee (i.e., active content) that has not been previously assessed?
☐YES ☐NO

(e) Do you monitor for changes in the end-use product specifications (identity of formulants, proportion of formulants, formulation type) that have not been previously assessed?
☐YES ☐NO

If 'YES' for 4(c), 4(d) or 4(e):

i) Describe the monitoring activities and indicate the approach (e.g., targeted, random, periodical) or triggers.

ii) Identify the types of responses available when cases of non-conformity are discovered:

iii) What criteria are used to determine the appropriate response?

iv) Describe cases of non-conformity that have occurred in the last 5 years.

(f) Do you monitor for changes in the formulating plant of the end-use product (process, location, starting material, etc.)?
☐YES ☐NO

If 'YES':

i) Describe the monitoring activities and indicate the approach (e.g., targeted, random, periodical) or triggers.

ii) Identify the types of responses available when cases of non-conformity are discovered:

iii) What criteria are used to determine the appropriate response?

iv) Describe cases of non-conformity that have occurred in the last 5 years.

(g) Describe other product integrity issues that may result in unacceptable health or environmental risks:

(h) As part of your monitoring program, are chemical analysis conducted at a:
☐ Government laboratory
☐ Private laboratory

5) Manufacturing Sites

(a) As regulator, do you have the authority to regulate the manufacture of pesticides (technical and/ or end-use)?
☐YES ☐NO

(b) Do you keep records of Active Substance manufacturing sites?
☐YES ☐NO

If 'YES':

i) Do you track: ☐ domestic sites ☐ foreign sites

ii) What information do you collect?

iii) How is this information used? (e.g., trend analysis, targeted oversight, active prevention)

iv) Are you authorized to share this information with other regulators?
☐YES ☐NO

v) Describe any findings as a result of your tracking activities of the past 5 years.

(c) Do you keep records of end-use product formulation sites?
☐YES ☐NO

If 'YES':
i) Do you track: ☐ domestic sites ☐ foreign sites
ii) What information do you collect?

iii) How is this information used? (e.g., trend analysis, targeted oversight, active prevention)

iv) Are you authorized to share this information with other regulators?
☐YES ☐NO

v) Describe any findings as a result of your tracking activities of the past 5 years.

(d) Are active substance manufacturing sites and/or end-use product formulation sites subject to federal licensing or approval**?**
☐YES ☐NO

If 'YES':
i) What information do you collect?

ii) Are site inspections conducted?
☐YES ☐NO

iii) Are foreign sites included?
☐YES ☐NO

iv) Are you authorized to share this information with other regulators?
☐YES ☐NO

v) Please describe any findings as a result of your licensing activities of the past 5 years:

PART B. IMPORTATION, SALE AND DISTRIBUTION

6) Importation of pesticides manufactured in other countries

(a) Is registration required for all pesticide active substances imported into your country?
☐YES ☐NO

If "NO", describe cases where registration is not required:

(b) Have you identified issues associated with the quality of imported active substances or end-use products?
☐YES ☐NO

If 'YES':

i) Describe the issues related to the quality of imported products:

ii) Describe any mechanisms that are in place to actively prevent issues, or to track incidents. Mechanisms may include government or industry initiatives.

(c) Are there mechanisms to oversee the importation of pesticide products into your country?
☐YES ☐NO

If 'YES':

i) Identify what information is required to import pesticides into your country:

- ☐ Name of the product
- ☐ Registration number
- ☐ Active substance(s) / active ingredient(s)
- ☐ Quantity of imported product / substance
- ☐ Purpose for importation
- ☐ Destination
- ☐ Date of import
- ☐ Point of entry
- ☐ Country of origin
- ☐ Other:

ii) Describe how this information is verified:

iii) Is data analysis conducted? If yes, please describe any trends or issues related to importation of pesticides.

iv) Describe any findings as a result of border monitoring activities in the last five years.

(d) Is information shared among different points of entry (e.g., shipments denied entry at one point may attempt entry at another)?
☐YES ☐NO

(e) Is information shared with other regulators in your country?
☐YES ☐NO

(f) Is information shared with other countries?
☐YES ☐NO

If 'YES' for 6(d), 6(e) or 6(f):

i) What type of information is shared, and at what frequency?

ii) How is this information shared?

7) Monitoring Registered Products

(a) Identify activities that are in place to ensure product integrity of registered products at importation, sale or distribution. Activities may include:

- ☐ Monitoring at point of importation, sale or distribution
- ☐ Product tracking
- ☐ Inspection at point of importation, sale or distribution
- ☐ Enforcement legislation
- ☐ Compliance promotion
- ☐ Other:

(b) Describe the range of regulatory/ compliance responses available in your jurisdiction, and when they may be applied.

(c) Describe the criteria for selecting the appropriate regulatory/compliance response.

(d) How are the monitoring results used? (e.g.: contribute to operational planning, program development).

(e) Describe any incident related to the importation, distribution or sale of registered products within the last 5 years. How was each incident detected? What was the regulatory/compliance response? How was the appropriate response determined?

8) Monitoring of illegal pesticides available for sale on the market.
Note: For the purpose of this survey, illegal products refer to unregistered products, counterfeit products and products which have been changed from approved/registered specifications without amending or notifying regulatory authorities.

(a) Identify activities that are in place to actively prevent and monitor the presence of illegal pesticides on the market at the:

i) Regulatory Level
☐ Monitoring at point of importation, sale or distribution
☐ Product tracking
☐ Inspection at point of importation, sale or distribution
☐ Enforcement legislation
☐ Compliance promotion
☐ Other:

ii) Industry Level

iii) Other levels of government / state

(b) Describe the range of regulatory/ compliance responses available in your jurisdiction, and when they may be applied.

(c) Describe the criteria for selecting the appropriate regulatory/ compliance response.

(d) How are the monitoring results used?

(e) Describe any incident related to the importation, distribution or sale of illegal pesticides within the last 5 years. How was each incident detected? What was the regulatory/compliance response? How was the appropriate response determined?

9) Sharing information when incidents of non-compliance are found

(a) When incidents of non-compliance are found, do you share information with other countries or regulators?
☐YES ☐NO

If 'YES',
(i) Describe what information is shared:

(ii) Describe how information is shared (if applicable):

- Among different levels of government (e.g. federal and provincial/state)

- Among different parts of the federal government (e.g. border control and pesticide regulators)

- Between industry and government

- Between countries

(b) In the future, what additional mechanisms could help collaboration and intelligence sharing with regards to non-compliance?

APPENDIX 2: COMPILATION OF RESPONSES

Integrity of Pesticides at the Manufacturing, Import and Distribution Stages
Report on the OECD Survey
Compilation of Submitted Information

- This document is a compilation of countries' responses to each survey question, in tabulated form.
- The question precedes the countries' responses.
- The submitted information is not edited except for minor typographical changes. However, where practical, the information is combined or summarized as a statement.
- Blank areas indicate "no response" submitted.
- Where Yes/No questions are followed by *If 'yes"* examples or explanations, blanks may be interpreted as *No* answers, with no further examples or explanations.

PART A. MANUFACTURING

1) Information required by regulators prior to manufacture or sale of a pesticide:

(a) In addition to the data requirements for the registration of chemical pesticides, do regulators require information regarding the manufacturing of end-use product formulations?
YES NO

If 'YES', please check all information required by regulators regarding the manufacturing of end use product formulations:
Specifications / declaration of end-use product formulation
Identity of active substance (source) used in the end-use product
Address of each formulating site
Description of the formulating process
Analytical method of the end-use product
Storage Stability
Expiry Specification
Alternate formulations permitted with one registration number (same registrant)
Other: (provide details)

End Use: All respondents answered "yes" to 1 (a): require information regarding the manufacturing of end-use product formulations

	Specifications / declaration of end-use product formulation	Identity of active substance (source) used in end-use product	Address of each formulating site	Description of formulating process	Analytical method of end-use product	Storage Stability	Expiry Specification	Alternate formulations permitted with one registration number	Other
AUSTRALIA	x	x	x	x	x	x	x		see below
BELGIUM	x	x	x	x	x	x	x	x	see below

	Specifications / declaration of end-use product formulation	Identity of active substance (source) used in end-use product	Address of each formulating site	Description of formulating process	Analytical method of end-use product	Storage Stability	Expiry Specification	Alternate formulations permitted with one registration number	Other
CANADA	x	x	x	x	x	x		x	see below
GERMANY	x	x	x		x	x	x	x	see below
IRELAND	x	x	x	x	x	x		x	see below
JAPAN	x	x	x	x	x	x	x	x	
MEXICO	x	x	x						
NEW ZEALAND	x	x	x	x	x	x	x	x	
NORWAY	x	x			x	x	x		
SLOVAK REPUBLIC	x	x	x		x	x	x		see below
SWITZERLAND	x	x	x		x	x			
UNITED KINGDOM	x	x	x			x			
UNITED STATES	x	x	x	x	x	x		x	see below

OTHER:
AUSTRALIA:
Formulation stability data
Batch analysis data
Formulation composition
Packaging

BELGIUM: Only one formulation permitted per registration number

CANADA:
Product label
Certified limits for all ingredients of formulator
Identity and concentration of contaminants of health and environmental concern arising from the formulants at any level, if they must be risk-managed under Canadian legislation

GERMANY: Addition of marker substances for the identification of plant protection products (PPP's)

IRELAND: Product Label and MSDS

NEW ZEALAND: Release specifications

SLOVAK REPUBLIC: Product label; Package (compatibility, neutralisation of product, cleaning of package.)

UNITED STATES: Distributor products must match the primary registration

(b) In addition to the data requirements for the registration of chemical pesticides, do regulators require information regarding the manufacture of the active substance, separately from the end use product?
YES NO

If 'YES', please check all information required by regulators regarding the manufacture of the active substance:
Specification / declaration of active substance (purity, impurities, contaminants)
Validated analytical method for the active substance
Sample of pure active substance for enforcement purposes
Storage stability information
Location of manufacturing site
Analysis of a specified number of production / batches
Description of the manufacturing process
Other: (provide details)

Active: All respondents answered "yes" to 1 (b): require information regarding the manufacturing of the active substance separately from the end-use product

	Specifications / declaration of active	Validated analytical method for active	Sample of pure active	Storage stability	Location of manufacturing site	Analysis of specified no. of production/ batches	Description of manufacturing process	Other
AUSTRALIA	x	x	x	x	x	x	x	see below
BELGIUM	x	x	x		x	x	x	
CANADA	x	x	x	x1	x	x	x	see below
GERMANY	x	x		x	x	x	x	see below
IRELAND	x	x	x	x	x	x	x	
JAPAN	x	x		x	x	x	x	
MEXICO	x	x		x	x	x	x	
NEW ZEALAND	x				x	x	x optional requirement	
NORWAY	x	x		x				
SLOVAK REPUBLIC	x	x	x		x	x	x	
SWITZERLAND	x	x	x	x	x	x		
UNITED KINGDOM	x	x			x	x	x	
UNITED STATES	x	x	x	x	x	x	x	

OTHER

AUSTRALIA:
Physical and chemical properties
Analytical reference standards
Packaging

CANADA: 1 Storage stability: only for reaction mixtures (also known as Integrated System Products)
Product label
Concentration of active ingredient within certified limits
Identity and concentration of impurities at levels >0.1% by wt within certified limits
Identity and concentration of contaminants of health and environmental concern arising from the manufacture of the technical grade of active ingredient at any level, if they must be risk-managed under Canadian legislation

GERMANY: Information about stabilising agents or other additives that are added to the active substance prior to the formulation of the PPP

2) Information required by regulators in order to maintain registration.

(a) Do you require registrants to submit an application for changes in the chemistry of the product?
YES NO
If 'YES':
i) From the list below, identify when regulatory approval is required:
Active Substance
Changes in manufacturing site
Changes in specifications / guarantee
Changes in manufacturing process
Other:

End Use Product Formulations
Changes in guarantee
Changes in form of active substance
Changes in identity of formulants
Changes in proportion of formulants
Changes in formulation type
Other: (please describe)

All respondents answered "yes" to 2 (a): require registrants to submit an application for changes in the chemistry of the product.

	Active				End-Use					
	Manuf. site	Specification/ guarantee	Manuf. process	Other	Guarantee	Form of active	Identity of formulant	Proportion of formulant	Formulation type	Other
AUSTRALIA	x	x	x		x	x	x	x	x	see below
BELGIUM	x	x	x		x	x	x	x	x	
CANADA	x	x	x		x	x	x	x	x	
GERMANY	x	x	x		x	x	x	x	x	
IRELAND	x	x	x		x	x	x	x	x	

	Active				End-Use					
	Manuf. site	Specification/ guarantee	Manuf. process	Other	Guarantee	Form of active	Identity of formulant	Proportion of formulant	Formulation type	Other
JAPAN	x	x	x		x	x	x	x		see below
MEXICO	x									
NEW ZEALAND	x	x	x		x1	x	x	x	x	
NORWAY		x				x	x	x	x	
SLOVAK REPUBLIC	x	x			x	x	x	x	x	
SWITZERLAND	x	x	x			x	x	x	x	
UNITED KINGDOM	x	x	x	see below		x	x	x	x	
UNITED STATES	x	x	x	see below	x	x	x	x	x	see below

1 if guarantee is equivalent to specifications

OTHER

AUSTRALIA:
End-use: Change in formulator or formulation site

JAPAN:
End-use: Note: Determining whether the registration is maintained or not is depend on the extent of the changes from the original registration.

UNITED KINGDOM:
Active: If change in manufacturing process leads to new specification we require an application

UNITED STATES:
Active: Impurity profile change. End-use: Change in sources of active and/or inert ingredients

ii) What information is required to support changes to the product chemistry/ specifications?

iii) How is this information used to approve continued registration/approval?

	Information required to support changes to the product chemistry / specifications?	**How information used to approve continued registration/approval**
AUSTRALIA	Same as information set out in 1(a)	Evaluation process to ensure that product continues to be effective and can be used safely with minimum impact on users, consumers, the environment and trade.
BELGIUM	Active substance : all information necessary to demonstrate technical equivalence Formulation : all physical-chemical analysis on relevant parameters necessary to demonstrate equivalence	Examination by experts – approval by Authorisation Committee – modification of Authorisation document where necessary
CANADA	Revised product specifications form New batch data to support the product specifications and any levels of contaminants of concern Method validation for any new enforcement analytical method	Information is used to support an applicant's request for registration
GERMANY	See question 1a including changes in the content of impurities	The information is assessed and evaluated. In case of major or unacceptable changes, a new registration must be submitted.
IRELAND	5 Batch analysis, Synthetic Pathway and Methods of analyses	The above information is compared to approved specification for equivalence.
JAPAN		
MEXICO	None of the above changes are allowed by law, except for the first one (changes in manufacturing site) that through authorization may change the site and maintain the same sanitary registration number. For the rest of the changes listed above the	

	Information required to support changes to the product chemistry / specifications?	How information used to approve continued registration/approval
	regulation mandates fro a new sanitary registration thus requiring all the information as in a new molecule/formulation submission.	
NEW ZEALAND	Dependent on the proposed changes information must be supplied to address the risk areas managed under the Agricultural Compounds and Veterinary Medicines Act (the relevant regulatory tool for the management of pesticides in NZ).	This information is assessed against a set of criteria and thresholds established under the ACVM Act.
NORWAY		
SLOVAK REPUBLIC	Phys-chem properties must be acceptable and in conformity with FAO specification	Comparison of major and minor changes, re-evaluation of biological efficacy, re-evaluation of toxicology and exotoxicology if it is relevant
SWITZERLAND	Revised product specifications	Data are assessed to determine whether the changes affect the existing risk assessment
UNITED KINGDOM	Cases based on HDSD if minor or storage stability data and possibly efficacy and tox case/data for classification if more significant changes	Data/case assessed to determine whether the changes affect the original risk assessment and to determine if the product will still be stable, biologically effective and crop safe and/or require change in CHIP classification
UNITED STATES	New or updated confidential statement of formula and supporting chemistry data.	This information is reviewed and used to make risk and regulatory decisions of whether or not to approve the changes.

(b) Do you conduct the following post-registration activities?
Periodic Renewal YES NO
Re-evaluation / re-registration YES NO

If 'YES' to either:
i) At what frequency are these post-registration activities conducted?
ii) What information do you collect regarding the product chemistry/specifications?
iii) How is this information used to approve continued registration?

	Type of Post-registration Activity Conducted & Frequency	Information Collected regarding product chemistry	How used to approve continued registration
AUSTRALIA	Periodic Renewal Product registration is undertaken annually and involves payment of a renewal fee but does not require any further product evaluation.	none	Not applicable
BELGIUM	According to Dir 91/414/EEC : Periodic Renewal: every 10 years Re-registration: after inclusion of the active substance in annex I to Dir 91/414/EEC	Annex III requirements of Dir 91/414/EEC	Examination by experts – approval by Authorisation Committee – modification of Authorisation document where necessary
CANADA	Periodic Renewal: 5 year Re-evaluation: 15 year cycle	Renewal: The submission of the Statement of Product Specification Form (SPSF) is required for every product, to support continued registration. A comparison of the SPSF submitted with the renewal application is made against the approved SPSF on file with the pesticide regulator, to determine if there are any changes. This process permits verification of product specifications to ensure compliance with registration. Approximately 9% of renewal applications include product changes on the SPSF that necessitate an amendment application. When this occurs, registrations are renewed for one year and require an application to amend the registration (with supporting data if required) within 90 days. Re-evaluation: When the active is under re-evaluation, batch data supporting current active ingredient specifications are updated if (data?) ≥ 10 years old and levels of contaminants of concern in the TGAI are validated.	The information is reviewed against data on file to verify completeness and to identify any outstanding deficiencies

	Type of Post-registration Activity Conducted & Frequency	Information Collected regarding product chemistry	How used to approve continued registration
GERMANY	Re-registration must be carried out after ten years. In view of post-registration monitoring, random PPP samples from the market are analysed at the BVL (active substance(s), formulants, physical-chemical data, impurities)	See i)	The information is used to update the registrations
IRELAND	Periodic Renewal Re-evaluation/Re-registration. 10 years in most cases, EU COM deviated from this 10 year period in a limited number of instances.	5 Batch analysis, Synthetic Pathway and Methods of analyses	The above information is compared to approved specification for equivalence
JAPAN	Re-evaluation/Re-registration: Every three years	All information required at registration application is collected.	This information is reconfirmed at the re-registration review.
MEXICO	Periodic Renewal: The registers are in force for 5 years and after that they will be renewed. Renewal process will begin in 2010	Since the process is not yet implemented the information that will be required is still not defined.	
NEW ZEALAND	Periodic Renewal: The period of registration renewal is 3 years.	Registrants are required to confirm that no changes have been made to those chemistry/specifications registered. If there are changes, a variation to registration needs to be lodged and the data reviewed for compliance with the ACVM Act requirements.	If no changes have been made, the original data assessment is considered still valid.
NORWAY	Re-evaluation / re-registration: Every fifth year		
SLOVAK REPUBLIC	Renewal: 10 years Re-evaluation, re-registration: in dependance on the state of evaluation process of particular active substance according to Council Directive 91/414/EEC	The same as it it for new registration	Comparison of new and old data, comparison of major and minor changes, re-evaluation of biological efficacy, re-evaluation of toxicology and exotoxicology if it is relevant

	Type of Post-registration Activity Conducted & Frequency	Information Collected regarding product chemistry	How used to approve continued registration
SWITZERLAND	Renewal and Re-evaluation/Re-registration. Renewal 10 years cycle	new phys-chem package	The information is used to update and, if necessary, modify the registration.
UNITED KINGDOM	Re-evaluation/Re-registration. Under national legislation, COPR, we can give provisional approval with a data submission deadline for minor data gap e.g. 2nd year of storage stability study, confirmatory efficacy data. If the data are submitted at the deadline then approval is reassessed along with the new data. If successful full approval is given. Under European based legislation, PPPR, provisional approval can be given prior to Annex I inclusion of the active substance. Once active is on Annex I then the product must be registered to Uniform Principles and Standard Approval given. All products approved under COPR will be re-registered to the Uniform Principles once all the actives within those products are on Annex I of 91/414/EEC. Once actives are on Annex I then they will be re-reviewed after 10 years of inclusion. If the Annex I inclusion is renewed then it is expected that products containing those actives would have to be re-registered again.	When an application for full approval or re-registration is submitted then the formulation details are provided and the required physical/chemistry and storage stability data.	At re-registration the information is used to ensure that the product is stable for at least 2 years and correctly classified
UNITED STATES	Re-evaluation/Re-registration: Every 15 years or sooner.	Generally, we do not plan to collect additional product chemistry information for our reassessment program.	Ensures EPA fully understands the toxicity, chemistry, environmental fate and effects and aggregate exposure of the product and can make the required finding that the product continues to meet the stringent safety standards for registration.

iv) How does this activity contribute to ensuring product integrity?

(c) Describe other post-regulatory activities that contribute to product integrity (consistency with approved/registered specifications):

	Contribution of information to product integrity	**Other activities**
AUSTRALIA		The APVMA has introduced the Quality Assurance Scheme for Agricultural Active Constituents and Agricultural Chemical Products (AgQA) which ensures the quality of active constituents used in agricultural chemical products in the Australian marketplace. The scheme is based on a set of standards for active constituents. These standards set out the purity of the active constituent and the maximum allowable impurity level. Conditions on product registrations hold product registrants responsible for ensuring the active constituents in agricultural chemical products are sourced from an APVMA listed manufacturing site. They also require that the active constituents meet the relevant APVMA standards. Under the scheme registrants must keep records demonstrating compliance with the conditions of registration. The APVMA monitors compliance with the conditions through product record call-ins (desk audits) and on-site company record inspections. The APVMA also conducts focussed testing of product available for supply to check the accuracy and validity of these records. Products are tested for toxicologically significant impurities and active constituent concentration. Full details of the AgQA Scheme are available at: http://www.apvma.gov.au/agqa/agqa.shtml.
BELGIUM	The products on the market should be complying with the authorisation dossier, which is examined by experts.	At random sampling on the market in the framework of the annual enforcement programme; Analysis for most important parameters for which an FAO specification exists (which are enforceable); Infractions are reported to the Authorisation Committee; in case of repetitive infractions, the authorisation holders is requested to take structural actions to solve the problem; in case of non compliance with information submitted for obtaining the authorisation (e.g. use of other composition): withdrawal of the authorisation.
CANADA	Modern standards of assessment are applied to the review of the re-evaluated active, ensuring that all registered products are registered under the latest regulatory infrastructure	Compliance inspection programs at manufacturing sites, sample analysis (guarantee, micro-contaminants), inspections/investigations into improper manufacture due to reported/suspected incidents of non-compliance (i.e. whistleblowers, ineffective product complaints, adverse incidents from products, active ingredient suppliers identifying lack of sales to end product producers, Information submitted to scientific

	Contribution of information to product integrity	Other activities
		evaluators pointing to potential data falsification or reports of changes to physical properties of products).
GERMANY		
IRELAND	Re-review often to higher standard.	Product samples taken at retail and wholesale level for formulation analysis.
JAPAN	This activity contributes to periodically evaluate the registered pesticide product under the current data requirement based on the latest scientific knowledge.	On-site inspection into pesticide manufacturers.
MEXICO	It allows the authority to confirm that the information provided for registration is still current and the commercialization of the product is safe for the public health.	There is routine inspection and surveillance of manufacturers and distributors to confirm consistency with the approved specification including labelling.
NEW ZEALAND	Registrant declares product is the same as when the last data assessment was made.	Periodic random inspection of manufacturers for compliance with the current approved dossier.
NORWAY		
SLOVAK REPUBLIC	The same or better biological efficacy, maintenance of safe use	Inspection program of PPPs – sample analyses, inspections on registration, distribution, market and user levels.
SWITZERLAND		Investigations after reported or suspected incidents or after market control activities
UNITED KINGDOM	This information will just determine if the product meets the data requirements for approval. It will not check what is actually out in the market place.	Rolling annual programme of formulation analysis
UNITED STATES	See answer to iii above.	Enforcement cases reviews may trigger an evaluation of a product's chemistry or toxicity; manufacturers submit amendments to their product registrations which provides opportunities to reassess the products integrity.

3) Quality Assurance in Manufacturing

(a) Are Quality Assurance Practices conducted at the factory level?
YES NO UNKNOWN
If 'YES', please describe the practices:

(b) Are Quality Assurance Practices required by industry associations?
YES NO UNKNOWN
If 'YES', please describe the practices:

(c) Are Quality Assurance Practices required by pesticide regulators or another regulating authority?
YES NO UNKNOWN
If 'YES', please describe the practices

	Quality Assurance Practices conducted at the factory level	**Quality Assurance Practices required by industry associations**	**Quality Assurance Practices required by pesticide regulators or another regulating authority**
AUSTRALIA	In most instances in which the APVMA has conducted inspections of local manufacturers, however, QA in overseas manufacturing sites is unknown. Registrants and ultimately manufacturers and formulators must comply with the requirements of the AgQA Scheme.	unknown	Under the AgQA Scheme registrants must provide batch analysis records to demonstrate that each batch of an active constituent has been tested for compliance with APVMA Standards. Registrants must demonstrate through batch manufacturing records that the end-use product contains a compliant active constituent. The legislative scheme contains provisions to allow the introduction of a conditioned licensing scheme. Introduction of such a scheme would be considered further if similar schemes were introduced internationally.
BELGIUM	see below	see below	Manufacturers are required to set up a system of "auto-enforcement" concerning the safety (and quality) of their products (Arrêté royal du 14/11/2003 relatif à l'autocontrôle, à la notification obligatoire et à la traçabilité dans la chaîne alimentaire). The national PPP industry association has developed a sectorial guide for application of this auto-enforcement (http://www.phytofar.be/).

CANADA	In Canada, pesticide regulators do not have Good Manufacturing Practices (GMP) oversight of pesticide manufacturers Many of the larger manufacturers/registrants have quality assurance programs in place as they have much at stake should problems arise linked to liability. Small and medium sized manufacturers are less likely to have such measures in place. Although PMRA Regulators do not have specific quality control measures in place that must be followed, questions are asked of manufacturers/formulators and registrants through consultation/inspection programs to attempt to characterize the quality assurances in place (in Canada) and to identify those companies of greatest risk of non-compliance so that they can be given extra attention.	unknown	In Canada, studies/ data (including batch data) must be conducted according to the OECD Principles of Good Laboratory Practice to support corresponding data quality in registering or amending products. From a post-registration inspection perspective, Canada does not have required quality assurance practices to be followed, but manufacturers must adhere to product specifications and labelling requirements which include directions of use for manufacturing concentrates and active ingredients used to make end products
GERMANY	unknown	unknown	unknown
IRELAND	Good Laboratory Practice	unknown	Good Laboratory Practice or equivalent
JAPAN	At on-site inspection, inspectors confirm activities of quality control performed in each manufacturing factory.	unknown	no
MEXICO	unknown	unknown	unknown
NEW ZEALAND	Product must be tested to the currently registered release specifications.		see (a) above
NORWAY	unknown	unknown	unknown
SLOVAK REPUBLIC	unknown	unknown	unknown
SWITZERLAND	unknown	unknown	5 – batch analysis, Chemical analyses have to be conducted under GLP – conditions, field trials under OECD (GEP) conditions
UNITED KINGDOM	unknown	unknown	Good Laboratory Practice (GLP)

UNITED STATES	Good Manufacturing Practices and Good Laboratory Practices	unknown	These are required by EPA regulations and by EPA policy. OPP has a team in place that provides an annual review of QA practices in each office.

4) Product integrity issues encountered for registered products

Active Substances

(a) Do you monitor for changes to the active substance specifications or manufacturing process?
YES NO

(b) Do you monitor for unacceptable variability in levels of contaminants of concern
YES NO

If 'YES' to either 4(a) or 4(b):
i) Describe the monitoring activities and indicate the approach (e.g., targeted, random, periodical) or triggers.
ii) Identify the types of responses available when cases of non-conformity are discovered:
iii) What criteria are used to determine the appropriate response?

Active substances

	Monitoring				
	changes to the active substance specifications or manufacturing process	unacceptable variability in levels of contaminants of concern	Activities and approach	Types of Responses available	Criteria for response
AUSTRALIA	yes	yes	Undertaken as part of the AgQA Scheme and as required based on information received from the industry. In the latter case this may be as a result of testing competitor products and information from overseas about integrity of QA or non existence of manufacturing sites.	Compulsory testing order Stop supply notice Product recall notice Injunction to stop importation, supply or recall Prosecution Product suspension or cancellation	Minor non-compliance such as constituent concentration slightly out of tolerance can result in warnings, major non-compliance which poses a risk to humans, animals, the environment, trade with other countries or will be ineffective can result in stop supply, recall or suspension. Critical non-compliance which results in injury or death, crop failure,

	Monitoring				
	changes to the active substance specifications or manufacturing process	**unacceptable variability in levels of contaminants of concern**	**Activities and approach**	**Types of Responses available**	**Criteria for response**
					loss of trade or is continuing non-compliance can result in prosecution or product cancellation.
BELGIUM	yes	yes	At request/After complaint	New or unidentified impurity, or impurity at higher concentration present : In case of danger for public health : recall from the market and by the user Otherwise : only action for analysed batch of products at the market level; request for correction of formulation	Danger to public health
CANADA	yes	yes	Historical compliance programs consisted of periodic lab analysis to monitor the level of micro-contaminants in pest control products. Triggers for determining targets included selecting companies known for not testing for micro-contaminants or product guarantees and companies with previous violation history. Targets were also chosen from complaints regarding product efficacy or adverse effects. A current program on pet products includes lab analysis of contaminants, guarantees and formulants of risk as a targeted response to complaints received	Responses available include: Person – No Action; a reasonable belief by the violator that the product (active source) was packaged in accordance with the regulations and conditions of registration as per Subsection 6(4) PCPA Verbal education-informing of regulatory requirements; Educational letter; Enforcement letter; Administrative Monetary Penalties (AMPs); Compliance Orders;	Risk-based analysis for impact on human health, environment and regulatory integrity that considers: History of compliance; Knowledge, Will and Ability to comply; Evidence of corrective plan action; Degree of Harm as a result of non compliance; Level of response to achieve/maintain compliance; Impact on human health, environment and regulatory integrity;

	Monitoring				
	changes to the active substance specifications or manufacturing process	**unacceptable variability in levels of contaminants of concern**	**Activities and approach**	**Types of Responses available**	**Criteria for response**
			in the incident reporting database. The systematic review of information provided by manufacturers is effective for detecting unreported changes to product specifications. However, it relies on manufacturers being forthcoming. Regulators can request that manufacturers submit updated analytical results e.g., batch data to demonstrate that product is being produced without any unexpected or unsafe consequences/results.	Prosecution; Product – No action; Deny entry; Forfeiture by consent; Disposal / return / removal/ recall/ relabeling by Order of by voluntary request; Detention/seizure; or Note: More than one response may be required.	Potential short or long term negative consequences on the violator from the response; and Role of industry/other regulators.
GERMANY	no	no			
IRELAND	yes	yes	A mixture of targeted and random samples of products are taken. Analyses are performed to ensure compliance with specification. Where applicable, certain products are monitored for levels of particular contaminants.	Where there is an issue of concern, the scope of actions varies from prosecution to formal letter requiring actions to done including removal of product from the market.	Level of non compliance or repeat offence. Is there a safety issue or is it a commercial issue. What is the extent of the non compliance. Is it 10% or 0.1% etc
JAPAN	yes	yes	Periodical on-site inspection into pesticide manufacturers.	When the changes of the active substances get over the acceptable range of the registered product, MAFF may take measures such as: - Order of report for internal investigation result and improvement. - Limitation of sales.	-Compliance history of the related companies. -Degree of non-compliance by checking the product according to the acceptable criteria. -Analysis of cause of incidents. -Effectiveness and practicability of improvement plan by the related companies.

	Monitoring				
	changes to the active substance specifications or manufacturing process	unacceptable variability in levels of contaminants of concern	Activities and approach	Types of Responses available	Criteria for response
				- Prohibition of sales. - Invalidity of registration. -Cancellation of registration.	-Impact on human health and environment caused by its non-conformity.
MEXICO	yes	no	Targeted sampling only after a public complaint on an specific product.	Product seizure	Product seizure when the pesticide poses a threat to human health or when it does not comply with the basics requirements established by the General Health Act (Article 414)
NEW ZEALAND	no	no			
NORWAY	no	no			
SLOVAK REPUBLIC	yes		National inspection program – part of post-registration control - analyses of identity and content of active substances	Enforcement letter - Removal of concerning batch from the market, application of correctional measures and requirement of declaration of conformity of new batch .	Degree of harm as a result of non - compliance, repeated infringement
SWITZERLAND	no	yes	Yearly random market control campaigns at sale points	- Correction measures for the product - Possible prosecution by a court - Cancelling of authorisation	Case dependent
UNITED KINGDOM	yes	yes	Combination of targeted and triggers	UK has a range of enforcement options and applies appropriate proportionate sanctions	Case by case dependant on the nature of the offence

	Monitoring				
	changes to the active substance specifications or manufacturing process	unacceptable variability in levels of contaminants of concern	Activities and approach	Types of Responses available	Criteria for response
				available under EU and UK regulations (e.g. those set out under FEPA, COPR, PPPR, and PP(BC)R)	
UNITED STATES	yes	yes	Monitoring conducted by EPA and state labs on specific products when there is reason to suspect a possible problem.	May require additional information, suspend the sale of the product, take enforcement action including levying a fine against the registrant.	Enforcement regulations and procedures; see answers to questions in Part B.

iv) Describe cases of non-conformity that have occurred in the last 5 years:

	Cases of non-conformity that have occurred in the last 5 years:
AUSTRALIA	The APVMA has investigated several cases involving the sourcing of AC from non existent overseas manufacturing sites, cases of fraudulent documentation and cases of AC imported into Australia which exceeds the concentration of toxicologically significant impurities.
BELGIUM	Presence of impurities
CANADA	In the last 5 years, micro-contaminants have not been monitored. However, cases of non-conformity were seen in programs run prior to 2004. In 1997, 59 samples tested for hexachoro-dibenzo-p-dioxin with 6 samples testing positive for levels above the reporting level of 0.01 ppm (Compliance level of 89%.); In 1998, 21 samples were tested for presence of nitrosamines and all 21 samples were in compliance with their registration specifications. In 1999, micro-contaminant sampling was conducted as a program whereby Ethafluralin and trifluralin end use products were tested for nitrosamines and none were detected;

	Cases of non-conformity that have occurred in the last 5 years:
	In 2000 micro-contaminant analysis was done for emana, folpet and N-nitrosodi-n-propylamine (NDPA). Small quantities of emana (0.067ppm) and folpet (0.002% based on Captan active content) were detected in the two products sampled. Until 1995, the PMRA requested nitrosamine analysis and batch data on potentially contaminated registered products. Data suggested that less than 5–10% of tested samples contained nitrosodimethylamine (NDMA) above the review standard of 1 ppm based on the technical grade ingredient. Results from 1997 to 1999 for micro-contaminant testing showed a level of compliance ranging from 89.8% to 100% with the standards for micro-contaminants. In general it was found that micro-contamination occurs in a very small percentage of registered pest control products and that the level of compliance with respect to micro-contaminants is high. Although this monitoring was discontinued in 2001 as a result of these findings, micro-contaminant analysis is still feasible if required. High levels of compliance were also found for guarantee analyses resulting in no specific guarantee programs being run in the last 5 years. From 1998–2002, percent compliance with a product guarantee ranged from 92% to 100%.
GERMANY	
IRELAND	none
JAPAN	
MEXICO	Unlabeled, label in a language different to Spanish, unregistered, false registration number, different use to the one authorized, expired, damaged package.
NEW ZEALAND	
NORWAY	
SLOVAK REPUBLIC	In 2007 – 2 infringements - Content of the active substance In 2008 – 6 infringements - Content of the active substance
SWITZERLAND	
UNITED KINGDOM	Variation in levels of active substances in excess of FAO tolerances
UNITED STATES	See description of cases below for end-use products.

<u>End-Use Product Formulations</u>

(c) Do you monitor for a new source of active substance that has not been previously assessed?
YES NO

(d) Do you monitor for changes in end-use product guarantee (i.e., active content) that has not been previously assessed?
YES NO

(e) Do you monitor for changes in the end-use product specifications (identity of formulants, proportion of formulants, formulation type) that have not been previously assessed?
YES NO

If 'YES' for 4(c), 4(d) or 4(e):

- ***i) Describe the monitoring activities and indicate the approach (e.g., targeted, random, periodical) or triggers.***
- ***ii) Identify the types of responses available when cases of non-conformity are discovered:***
- ***iii) What criteria are used to determine the appropriate response?***

End-Use Product Formulations

	Monitoring					
	New source of active substance no previously assessed	Changes in end-use product guarantee	Changes in end-use product specifications	Activities and approach	Types of Responses available	Criteria for response
AUSTRALIA	yes	yes	no	see 4(a)	see 4(a)	see 4(a)
BELGIUM	no	yes	no	At random sampling on the market in the framework of the annual enforcement programme; Analysis for most important parameters for which an FAO specification exists (which are enforceable); Infractions are reported to the Authorisation Committee; in case of repetitive infractions, the authorisation holders is requested to take structural actions to solve the problem; in case of non compliance with information submitted for obtaining the authorisation (e.g. use of other composition) : withdrawal of the authorisation.	In case of danger for public health : recall from the market and by the user Otherwise : only action for analysed batch of products at the market level; request for correction of formulation	Danger to public health
CANADA	yes	yes	yes	The National Pesticide Compliance Program (NPCP) active prevention monitoring programs included a Guarantee Verification Program from 1996-2001. In 2003 and 2004, the guarantee verification was associated with the Registrant NPCP program. This program targeted activity on registrants, including sample guarantee verification, chosen based on their size and the last date of inspection of the registrant. Inspections may be targeted, random or periodical	Responses available include: Person-No Action, Verbal education-informing of regulatory requirements, Educational letter, Enforcement letter, Administrative Monetary Penalties (AMPs), Compliance Orders, Prosecution, Product- No action, Deny Entry, Forfeiture by consent, Disposal/return/removal/reca	Risk-based analysis for impact on human health, environment and regulatory integrity that considers: History of compliance; Knowledge, Will and Ability to comply; Evidence of corrective plan action; Degree of Harm as a result of non compliance; Level of response to achieve/maintain compliance; Impact on human health,

	Monitoring					
	New source of active substance no previously assessed	**Changes in end-use product guarantee**	**Changes in end-use product specifications**	**Activities and approach**	**Types of Responses available**	**Criteria for response**
				depending on the level of knowledge of potential non-compliance. They can be used to confirm the formulants used through visual observation, speaking with the manufacturers or review of batch records. Although specific to pesticide regulator lab's ability to analyze product formulations, the potential sometimes exists to monitor formulations where specific formulants are to be replaced to confirm that this has been done. It is very difficult to confirm if one active source has been replaced by another source through lab analysis. Specification forms are checked whenever a submission comes to the PMRA including at least every 5 years for renewal to verify that the formulation or the source of the ingredients has not changed.	ll/relabelling by Order or by voluntary request, or Detention/seizure. Note: More than one response may be required	environment and regulatory integrity, Potential short or long term negative consequences on the violator from the response, and Role of industry/other regulators.
GERMANY	no	no	yes	Random PPP samples from the market are analysed at the BVL (active substance(s), formulants, physical-chemical data, and impurities).	The producers are asked to comment the result and to submit information about the changes in the formulation of the PPP's.	The producers must apply for an authorisation of changes in the formulation of the PPP's if they would cause major modifications of the properties of the PPP's, i.e. different Phys.-chem. properties, higher toxicity, phytotoxicity or ecotoxicity, lower efficiency,

	Monitoring					
	New source of active substance no previously assessed	Changes in end-use product guarantee	Changes in end-use product specifications	Activities and approach	Types of Responses available	Criteria for response
						higher toxicity to bees, or a change in the application procedures.
IRELAND	yes	yes	yes	A mixture of targeted and random samples of products are taken. Analyses are performed to ensure compliance with specification. Where applicable, certain products are monitored for levels of particular contaminants.	Where there is an issue of concern, the scope of actions varies from prosecution to formal letter requiring actions to done including removal of product from the market.	Level of non compliance or repeat offence. Is there a safety issue or is it a commercial issue. What is the extent of the non compliance. Is it 10% or 0.1% etc.
JAPAN	yes	yes	yes	Periodical on-site inspection into pesticide manufacturers.	Order of report for internal investigation result and improvement. - Limitation of sales. - Prohibition of sales. - Invalidity of registration. -Cancellation of registration.	Compliance history of the related companies. -Degree of non-compliance by checking the product according to the acceptable criteria. -Analysis of cause of incidents. -Effectiveness and practicability of improvement plan by the related companies. -Impact on human health and environment caused by its non-conformity.
MEXICO	yes			New source of active substance must be submitted as registration modification and then it is evaluated through the documents the submitter provided.		
NEW ZEALAND	no	no	no			
NORWAY	no	no	no			
SLOVAK REPUBLIC	yes	yes		National inspection program – part of post-registration control - analyses of	Enforcement letter - Removal of concerning batch from the	Degree of harm as a result of non compliance, repeated

	Monitoring					
	New source of active substance no previously assessed	Changes in end-use product guarantee	Changes in end-use product specifications	Activities and approach	Types of Responses available	Criteria for response
				identity and content of active substances	market, application of correctional measures and declaration of conformity of new batch	infringement
SWITZERLAND	yes	yes	yes	Yearly random market control campaigns at sale points	- Correction measures for the product - Possible prosecution by a court - Cancelling of authorisation	Case dependent
UNITED KINGDOM	yes	yes	x	Combination of targeted and triggers	UK has a range of enforcement options and applies appropriate proportionate sanctions available under EU and UK regulations (e.g. those set out under FEPA, COPR, PPPR, and PP(BC)R)	Case by case dependant on the nature of the offence
UNITED STATES	no	no	no	While EPA typically does not monitor (i.e., analyze) products, there are instances that can trigger evaluations of individual products, such as attempted entry into the US or tips from competitors.	Prohibition of entry into the US, enforcement action, possibility of a stop sale order, against the product.	A combination of the available information and the regulations.

iv) Describe cases of non-conformity that have occurred in the last 5 years:

Cases of non-conformity that have occurred in the last 5 years:

AUSTRALIA	see 4(a)
BELGIUM	Insufficient/excessive amount of active substance Excessive foaming Insufficient amount of repulsive in anti-slugs products
CANADA	As part of the Registrant National Pesticide Compliance Program from 2003-2005, 6/29 products were identified that did not meet the specified/ approved guarantee (compliance level of 79%). Investigations were initiated and educational letters were administered. Registrants using sources of technical grade active ingredients not specified on their specification form were asked to submit written requests to amend the product registrations and bring their products into compliance. In 2005, there was a case where a new source of active ingredient was suspected of being used. It was not possible to determine through lab analysis whether it was a registered or unregistered active. Also, because the end product was manufactured outside of Canada and no agreements were in place with the foreign country's regulator, onsite inspection was not an option. Furthermore, there is no Canadian requirement for product manufacturers to maintain records. In the end the alternate source was deemed equivalent to the previous source through a submission, but it highlighted the challenges faced by Canadian pesticide regulators in confirming foreign sources of actives. In 2006, a swimming pool product manufacturer was issued 15 Notices of Violation under AMPS totalling $60,000 for using an unregistered source of a TGAI. They paid in 15 days reducing the fine to $30K. In another case, a pet product was analyzed for potential residues of other active ingredients and residues of permethrin and phenothrin were found. The registrant was requested to identify how this happened and to take corrective action.
GERMANY	Content of the active substance, content of formulants, physical-chemical properties
IRELAND	none
JAPAN	A pesticide manufacturer produced a pesticide product in a process which is different from the registered one. After receiving alleged information, as a result of on-site inspection and report from the company, it was revealed that the company intentionally has produced the pesticide product which contains the half amount of active substances compared with the registered specification. For this reason, the registration of the pesticide became invalid. The related companies also recalled the product from the market.

Cases of non-conformity that have occurred in the last 5 years:

MEXICO	
NEW ZEALAND	
NORWAY	
SLOVAK REPUBLIC	
SWITZERLAND	
UNITED KINGDOM	Variation in levels of active substances/co-formulants in excess of FAO tolerances
UNITED STATES	Examples: 1) A manufacturer (registrant) failing to inform EPA that product had changed it's formulation and therefore did not have an approved product in marketplace. 2) Similar to example 1 and the new source of active ingredient results in contaminants of toxic concern which were not in the original product and failed to inform Agency of this source change.

(f) Do you monitor for changes in the formulating plant of the end-use product (process, location, starting material, etc.)?
YES NO

If 'YES':
- ***i) Describe the monitoring activities and indicate the approach (e.g., targeted, random, periodical) or triggers.***
- ***ii) Identify the types of responses available when cases of non-conformity are discovered:***
- ***iii) What criteria are used to determine the appropriate response?***
- ***iv) Describe cases of non-conformity that have occurred in the last 5 years.***

(g) Describe other product integrity issues that may result in unacceptable health or environmental risks:

(h) As part of your monitoring program, are chemical analysis conducted at a:
Government laboratory
Private laboratory

	Chemical analysis laboratory	Monitoring changes in the formulating plant of the end-use product	Monitoring Activities and approach	Types of Responses available	Criteria for response
AUSTRALIA	private	no			
BELGIUM	government	no			
CANADA	government	yes	Product specification forms require identification of the end-use product formulation site, and this is tracked electronically. A change in end-use product formulation site can be done through notification (i.e. does not require supporting data, review or approval by regulators). The product specification form also identifies all the ingredients and the sources of those materials, but the formulant sources and location sites are not areas of concern for compliance other than to know where products are made for inspection purposes. The formulating sites may be checked periodically through discussions with registrants, contact with the formulators or through on site inspections in Canada.	Responses available include: Person-No Action, Verbal education-informing of regulatory requirements; Educational letter.	Risk based analysis: Considers history of compliance; Ability to comply; Willingness to achieve compliance; Evidence of corrective plan action; Degree of Harm as a result of non compliance; Level of response to achieve/maintain compliance; Impact on human health, environment and regulatory integrity
GERMANY		yes			yes
IRELAND	government	no	n/a	n/a	n/a
JAPAN	government	yes	Periodical on-site inspection into pesticide manufacturers.	Order of report for internal investigation result and improvement. - Limitation of sales. - Prohibition of sales.	-Compliance history of the related companies. -Degree of non-compliance. -Analysis of cause of incidents. -Effectiveness and practicability

	Chemical analysis laboratory	Monitoring changes in the formulating plant of the end-use product	Monitoring Activities and approach	Types of Responses available	Criteria for response
				- Invalidity of registration. -Cancellation of registration.	of improvement plan by the related companies. -Extent of adverse effect on human health and environment caused by its non-conformity.
MEXICO		yes	Targeted and random through the sanitary inspection of the establishment	To stop temporally, partially or completely the function according to the situation	Case by case basis
NEW ZEALAND		no			
NORWAY		no			
SLOVAK REPUBLIC	government	no			
SWITZERLAND	government	yes	Periodical control during re-evaluation	-Correction measures for the product - Restriction of allowed applications - Possible prosecution by a court - Denying of further authorisation	Case dependent
UNITED KINGDOM	government	no			
UNITED STATES	private	no			

iv) Describe cases of non-conformity that have occurred in the last 5 years.

	Cases of non-conformity that have occurred in the last 5 years
AUSTRALIA	
BELGIUM	
CANADA	There are no instances of non-conformity in the last 5 years that we are aware of. However, several problems/issues were encountered when a compliance program was run in 2002 to verify formulating site locations. Registrants often identify several formulating sites for their end-use products just in case they decide to switch sites for a variety of reasons (costs, ease of distribution, etc.). In some cases, the formulators are even unaware that are listed on the product specification form. Some companies registrants did not feel obliged to provide details on the products they formulate/manufacture stating the information is available on Product Register. Some formulators/manufacturers, which were not the registrants of the products in question, consider the details regarding who makes the product to be confidential to the registrant. Company mergers and lack of reporting site changes or incorrect listing of the registrant address instead of the formulating site on product specification forms on file lead to difficulties in confirming locations. Because there are no specific formulating/manufacturing requirements in place other then adhering to product specifications and use directions for TGAI's and manufacturing concentrates it is difficult to say switching to a new formulator is a concern although clearly some have better quality assurances in place than others.
GERMANY	
IRELAND	
JAPAN	Refer to 4) (d) iv) of Part A.
MEXICO	Lack of sanitary license Factories established on residential, school, and hospital areas Inadequate facilities Lack of safety and hygiene measures Use of forbidden substances Imminent harm to health
NEW ZEALAND	
NORWAY	
SLOVAK REPUBLIC	

	Cases of non-conformity that have occurred in the last 5 years
SWITZERLAND	
UNITED KINGDOM	
UNITED STATES	

***(g) Describe other product integrity issues that may result in unacceptable health or environmental risks*:**

	Product integrity issues that may result in unacceptable health or environmental risks
AUSTRALIA	Product and AC instability resulting in development toxicologically significant impurities. Toxicologically significant impurities introduced into the formulation through poorly tested excipients.
BELGIUM	No information
CANADA	Mistakes in packaging, labelling, storage, cleaning of tanks/product lines, of the pest control product.
GERMANY	
IRELAND	Level of contaminants, level of active substance
JAPAN	Based on alleged information, an analysis of an agricultural material revealed that the material included a pesticide active substance, rotenone. As a result of on-site inspection of the importer and distributor, MAFF concluded this material as illegal unregistered pesticide product. In addition, there was concern about adverse effect of rotenone on fish, the related companies recalled the material from market. MAFF called for the purchasers not to use the material, not to discard into river and to return to the store.
MEXICO	Storage, Expiration Emissions to the environment Deficiencies in the control process and lack of quality monitoring Risk to environmental and occupational health
NEW ZEALAND	
NORWAY	

	Product integrity issues that may result in unacceptable health or environmental risks
SLOVAK REPUBLIC	Packaging, labelling, storage, cleaning of tanks,
SWITZERLAND	
UNITED KINGDOM	
UNITED STATES	Contaminants from a new unapproved source of active ingredient, the contaminant was a known carcinogen at levels of concern.

5) Manufacturing Sites

(a) As regulator, do you have the authority to regulate the manufacture of pesticides (technical and/ or end-use)?

(b) Do you keep records of Active Substance manufacturing sites?
If 'YES':
i) Do you track: domestic sites foreign sites
ii) What information do you collect?
iii) How is this information used? (e.g., trend analysis, targeted oversight, active prevention)
iv) Are you authorized to share this information with other regulators?
YES NO
v) Describe any findings as a result of your tracking activities of the past 5 years.

	Authority to regulate the manufacture of pesticides	Active Substance manufacturing sites: tracking	Active Substance manufacturing sites: Information collected	How information is used	Authorized to share information	Findings of past 5 years
AUSTRALIA	yes	Domestic Foreign	Approval number, active constituent name, approval holder, name of manufacturer, address of manufacturing site,	Compliance activities when a need to target an AC is required, or a particular manufacturer, occasional trend analysis for country of origin.	yes	Tracking has assisted in conducting inquiries in Australia and overseas. Has provided a basis for targeted testing in the AgQA scheme.
BELGIUM	yes	Domestic Foreign	Domestic site : authorisation per site; list of equivalent production site Foreign site : list of equivalent production site	Only for registration purposes	yes	No information
CANADA	yes	Domestic Foreign	Name and location (address) of technical manufacturing site.	Verified with Product Specification forms, and may be used for inspection purposes in Canada. Not used in trend analysis, targeted oversight or active prevention.	yes, probably	Refer to 4(e)(iv).

	Authority to regulate the manufacture of pesticides	Active Substance manufacturing sites: tracking	Active Substance manufacturing sites: Information collected	How information is used	Authorized to share information	Findings of past 5 years
GERMANY	yes	Domestic Foreign	Address, contact person	No systematic use. In some cases, this information is used to assess the origin of PPP's	yes	Illegal products could be identified due to different formulation sites or production sites of the active substance
IRELAND	yes	Domestic Foreign	Location and specification	We do not track per se, for each product on the Irish market there is a formulating plant identified as well as a plant(s) from which the active substance is sourced.	yes	Tracking not carried out.
JAPAN	yes	Domestic	The name of the manufacturing facility and its location.	It is used for confirmation at the on-site inspection.	no	Any problem did not occur in particular
MEXICO	yes	Domestic	Copy of sanitary licence , copy of sanitary register, flowcharts, process and occupational health programs	Targeted surveillance	yes	Products without registration, misuse of substances, illegal entry of pesticides into Mexican territory, use of banned substances.
NEW ZEALAND	yes	Domestic Foreign	Name, postal address, physical address, telephone and fax number	This information is required as part of the registration dossier. No manipulation of this data occurs.		
NORWAY	yes	no				
SLOVAK REPUBLIC	yes	Domestic Foreign	Name and location of technical manufacturing site.	Verification with Product Specification form	yes	
SWITZERLAND	no	no				
UNITED KINGDOM	yes		We do not track them – we just hold the information on the	n/a	yes	n/a

	Authority to regulate the manufacture of pesticides	Active Substance manufacturing sites: tracking	Active Substance manufacturing sites: Information collected	How information is used	Authorized to share information	Findings of past 5 years
			approved sites of manufacture and the approved specifications. If information comes to light later to show that they might be using an unapproved site then this can be investigated and if necessary post approval enforcement action taken			
UNITED STATES	yes	Domestic Foreign	Name of producer and address on confidential statement of formula. Also collect annual production information.	Not routinely used. May be used for enforcement and compliance inspections.	no	

1: We can regulate the manufacture process but do authorize pesticides for use and thereby regulate the use (Norway)

(c) Do you keep records of <u>end-use product</u> formulation sites?
YES NO

If 'YES':

i) Do you track: domestic sites foreign sites

ii) What information do you collect?

iii) How is this information used? (e.g., trend analysis, targeted oversight, active prevention)

iv) Are you authorized to share this information with other regulators?
YES NO

v) Describe any findings as a result of your tracking activities of the past 5 years.

	End-use product formulation sites: records kept & tracking	End-use product formulation sites : Information collected	How information is used	Authorized to share	Findings
AUSTRALIA	Domestic Foreign	See 1(a)	Compliance activities when a need to target products is required, or a particular formulator, occasional trend analysis for country of origin, identifying product constituents.	no	Tracking has assisted in conducting inquiries in Australia and overseas. Has provided a basis for targeted testing in the AgQA scheme. Used to identify product for product recall.
BELGIUM	Domestic Foreign	Domestic site : authorisation per site	Only for registration purposes	yes	No information
CANADA	Domestic Foreign	Name and location of each formulating site, on a product-specific basis.	Information is collected, and could be used for periodic confirmation of formulation site. It is used to identify where the majority of manufacturing/formulating occurs in Canada, and to potentially divert resources/money for compliance activities if focusing on manufacturer/formulator issues.	yes, probably	The Government of Canada's recent commitments under the Food and Consumer Safety Action Plan included some compliance activities targeting formulators of domestic consumer products – including domestic pesticides. The information collected on formulating sites helped identify where to target activities/ resources.
GERMANY	Domestic Foreign	Address, contact person	No systematic use. In some cases, this information is used to assess the origin of PPP's		Illegal products could be identified due to different formulation sites or production sites of the active substance
IRELAND	yes	Location and specification	We do not track per se, for each product on the Irish market there is a formulating plant identified as well as a plant(s) from which the active substance is sourced.	yes	Tracking not carried out
JAPAN	Domestic	-Name of company -Representative executive name	It is used for confirmation at the on-site inspection.	no	Refer to 4) (d) iv) of Part A.

	End-use product formulation sites: records kept & tracking	End-use product formulation sites : Information collected	How information is used	Authorized to share	Findings
		-Address of company -The name of the manufacturing facility and its location -Description of the manufacturing process of active substances - Description of the formulating process of products -The name of the responsible manager of the manufacture			
MEXICO	Domestic	Copy of sanitary licence , copy of sanitary register, flowcharts, process and occupational health programs	Targeted inspection	yes	Products without registration, misuse of substances, illegal entry of pesticides into Mexican territory, use of banned substances
NEW ZEALAND	Domestic Foreign	Refer to section above on active ingredient		yes	
NORWAY	no				
SLOVAK REPUBLIC	Domestic Foreign	Name and location of technical manufacturing site	Verified with Product Specification form	yes	
SWITZERLAND	Domestic Foreign	Name and address	Oversight	no	

	End-use product formulation sites: records kept & tracking	End-use product formulation sites : Information collected	How information is used	Authorized to share	Findings
UNITED KINGDOM	yes	No tracking occurs these details remain on file as the approved site of manufacture and can be scrutinised if is evidence product is formulated elsewhere.	n/a		n/a
UNITED STATES	Domestic Foreign	Name of producer and address on confidential statement of formula. Also collect annual production information.	Production information is useful for our regulatory decision-making especially for pesticides with risks of concern. Production information and use information helps with EPA's assessment of a pesticide's potential benefits.	no	EPA routinely considers production information in its re-evaluation program for those pesticides for which EPA has a risk concern and is considers taking regulatory action to further restrict its use(s).

(d) Are active substance manufacturing sites and/or end-use product formulation sites subject to federal licensing or approval?
YES NO

If 'YES':
- ***i) What information do you collect?***
- ***ii) Are site inspections conducted?***
  YES NO
- ***iii) Are foreign sites included?***
  YES NO
- ***iv) Are you authorized to share this information with other regulators?***
  YES NO

v) Please describe any findings as a result of your licensing activities of the past 5 years

	Federal licensing or approval	**Information collected**	**Site inspections--- any foreign?**	**Authorized to share**	**Findings due to licensing**
AUSTRALIA	no				
BELGIUM	yes	All operators active in the food chain have to be registered by AFSCA. Manufacturers, importers, exporters and repackagers of PPP have to be authorised for this matter by AFSCA.	yes no foreign sites	yes	No information
CANADA	no				
GERMANY	no				
IRELAND	no				
JAPAN	yes	-Name of company -Representative executive name -Address of company -The name of the manufacturing facility and	yes no foreign sites	no	Any problem did not occur in particular

	Federal licensing or approval	Information collected	Site inspections---any foreign?	Authorized to share	Findings due to licensing
		its location -Description of the manufacturing process of active substances -Description of the formulating process of products -The name of the responsible manager of the manufacture			
MEXICO	yes	Facilities' blueprints, training program, safety data sheets, program for health monitoring, equipment for emissions control, description of the manufacturing process, products, etc. Complete list of required information is posted on the website www.cofepris.gob.mx	yes no foreign sites	yes	Unregistered products, misuse of substances, illegal entry of pesticides, use of banned substances.
NEW ZEALAND	no				
NORWAY					
SLOVAK REPUBLIC	yes	The same as for registration of pesticides.	no	yes	
SWITZERLAND	no				
UNITED KINGDOM	no1		no	n/a	
UNITED STATES	yes	Producer's name and address and annual production.	yes, no foreign sites	no	Site inspections can identify inconsistencies with GMP requirements, product integrity.

1 UK does not have "federal licensing"

PART B. IMPORTATION, SALE AND DISTRIBUTION

6) Importation of pesticides manufactured in other countries

(a) Is registration required for all pesticide active substances imported into your country?
YES NO
If "NO", describe cases where registration is not required:

(b) Have you identified issues associated with the quality of imported active substances or end-use products?
YES NO
If 'YES':
i) Describe the issues related to the quality of imported products:
ii) Describe any mechanisms that are in place to actively prevent issues, or to track incidents. Mechanisms may include government or industry initiatives.

	Registration for active	Case where registration not required	Issues with quality	Mechanisms to prevent/track
AUSTRALIA	no	Importation for formulation of pesticides for export, use under permit (e.g. research) and chemical and physical to generate data for registration.	Manufacture at fictitious sites and impurities above allowable standards	AgQA Scheme, MOU with Australian Customs Service and liaison with foreign regulatory authorities.
BELGIUM	no	Only authorisation necessary for products that are placed on the market, which is not the case for technical active substances	Most of the products placed on the market are imported, and are subject to the same enforcement programme as mentioned above. Hence, it would make no sense to list issues separately for imported products.	Most of the products placed on the market are imported, and are subject to the same enforcement programme as mentioned above.

	Registration for active	Case where registration not required	Issues with quality	Mechanisms to prevent/track
CANADA	no	For active substances: All actives imported into the country must be registered. Technical or formulated products imported into Canada for manufacture/export only, must be registered under the "Import for Manufacture and Export Program". The product must be approved for sale or registered in another OECD country, but can not be sold/used in Canada. Although the question (6a) does not specifically ask about formulated products, we will address: For end-use products, there are specific cases where registration is not required: Own Use Import Program (OUI) / Growers Own Use Import Program (GROU), Small quantities of pesticides imported for personal use under $100.00. Canada's Pest Control Products Act (PCPA) specifies exemptions when a pest control product it is regulated under another Act, even though the product is a pest control product (Section 3 PCPA). E.g., material preservative in cosmetics are regulated under the Food and Drugs Act – to avoid regulatory duplication. Also, exemptions from registration for scheduled products (fertilizers, water conditioners, pool/spa products, etc. as per Schedule 2 of the Pest Control Products Regulations) and products imported for research purposes. These products are still regulated by PMRA, but do not require registration.	Guarantee Incorrect sources of active substances Potential contaminants of health and environmental concern (e.g., nitrosamines, dioxins).	Import declaration forms, border lookouts, import certificates (OUI and GROU), Tracking via pesticide regulator's Investigation Tracking Form (ITF) database and the Incident reporting database, reports from registrants / growers.

	Registration for active	Case where registration not required	Issues with quality	Mechanisms to prevent/track
GERMANY	yes		The composition of some parallel imported products are not identical with the German reference product	If there are suspicions about a defined product, samples are collected on the market and analysed at the BVL. The industry also monitors imported products that are related to their own product portfolio.
IRELAND	no	Registration is not required for active substance being imported into Ireland, where the active substance is being formulated into products registered outside Ireland.	no	
JAPAN	no	In Japan, pesticides shall be subject to registration based on end-use products, not active substances. There is exception where non-registered end-use products are permitted to be imported for the purpose of test research.	no	
MEXICO	yes		no	
NEW ZEALAND	no	Active ingredients imported for manufacturing into end-use formulations do not require approval. Instead registration is required for the end-use formulation.	no	
NORWAY	yes		no	
SLOVAK REPUBLIC	yes		The same as in Part A., 1)	Reports from registrants and users (evidence of sale, consumption), National inspection program at all levels – import, sale, distribution and users
SWITZERLAND	no	Not for AS and products that are exported or re-exported without treatment process	Incorrect sources of As and products	Information from customs or third parties

	Registration for active	Case where registration not required	Issues with quality	Mechanisms to prevent/track
UNITED KINGDOM	no	Approval is not required for active substance to be imported	no	
UNITED STATES	yes		Some products intended for import list an unapproved source, other products had contaminants or ingredients outside of the certified limits.	EPA has requirements for imports (see EPA's website) and requires a US based representative for foreign-based registrants. US gov't also has and requires importers to complete and file forms declaring information about the product before it arrives. US Customs and EPA officials check that information against information on file with the product registration.

(c) Are there mechanisms to oversee the importation of pesticide products into your country?
YES NO

If 'YES':

i) Identify what information is required to import pesticides into your country:

Name of Product
Registration number
Active substance(s) / active ingredient(s)
Quantity of imported product / substance
Purpose for importation
Destination
Date of import
Point of entry
Country of origin
Other:

All respondents except Belgium answered "yes" to 6(c): had mechanisms to oversee the importation of pesticide products into their country.

	Information required to import pesticides into the country									
	Product Name	Registration number	Active substance(s) / active ingredient(s)	Quantity of imported product / substance	Purpose for importation	Destination	Date of import	Point of entry	Country of origin	Other:
AUSTRALIA	x	x	x	x	x	x	x	x	x	
BELGIUM										
CANADA	x	x	x	x	x		x	x		See below
GERMANY										See below
IRELAND	x	x	x	x	x	x	x	x	x	
JAPAN	x1	x2	x1		x3	x3			X3	See below
MEXICO	x	x	x		x	x	x	x		
NEW ZEALAND	x	x		x	x	x	x		x	
NORWAY	x	x	x	x						
SLOVAK REPUBLIC	x	x	x	x	x	x	x	x	x	See below
SWITZERLAND	x	x		x		x	x	x	x	
UNITED KINGDOM	x	x	x						x	See below
UNITED STATES	x	x	x	x	x	x	x	x	x	

1: Note: In both cases of registered end-use products and non-registered end-use products
2: Note: In the case of registered end-use products
3: Note: in the case of non-registered end-use products

OTHER:

CANADA: Name and postal address of the shipper, quantity of the active in the end-use product and name and address of the importer are additional declarations required by the pesticide regulations. This information is to be reported on an import declaration form (see (ii) below). The Canada Border Services Agency (CBSA) does not collect import declarations on behalf of the pesticide regulator. However, a pesticide inspector can request copies of these documents/records. CBSA collects data on the destination of the import and the country of origin as well as a variety of other data points linked to the collection of duties. *Outside of targeted requests, there is currently no regulatory/ border monitoring activities to oversee the importation of pesticides. Generally, importation of products is a task administered by CBSA.

GERMANY These duties are carried out by the customs services. Detailed informations are not available at the BVL

JAPAN : In the case of non-registered end-use products: -the amount of import -the test research period.

SLOVAK REPUBLIC: Name and postal address of the shipper and importer, quantity of active substance

UNITED KINGDOM: Note these mechanisms only apply where product is to be placed on the UK market and not for product (or active substance) which is imported for export. Approvals are given either for commercial or own use importation and for commercial importation we also need to know if the product will be re-packaged and the container details if it is to be repackaged.

ii) Describe how this information is verified:
iii) Is data analysis conducted? If yes, please describe any trends or issues related to importation of pesticides.
iv) Describe any findings as a result of border monitoring activities in the last five years.

	Verification of information	**Data analysis conducted**	**Border Monitoring findings**
AUSTRALIA	Examination of Customs Service data, importer records, AgQA scheme records and records from foreign regulatory authorities.	No	See findings in previous questions
BELGIUM			No border monitoring activities, only for products on the market.
CANADA	The vendor of the product is required to complete a Canada Customs Invoice (CCI) form. The Pest Control Products Act requires the Importer to complete the Declaration by Importer of Control Products Form for all regulated pesticides, in addition to any other certificates/forms that are	Some analysis of the CBSA data has been attempted, to try and characterize imports. However, trend analysis is limited due to generality of the data collected (i.e. the coding does not clearly identify if it is a PCP, or the	No regular border monitoring activities are conducted.

	Verification of information	Data analysis conducted	Border Monitoring findings
	necessary (i.e. Import certificate). Canada Border Services Agency (CBSA) customs officers may verify forms with product labels at point of entry. The Import Declaration form should be presented to the CBSA Border Services Officer when the shipment arrives at the port of entry, to aid in detection and interception of imported pesticides that are not in compliance with the Act and Regulations. This form is no longer routinely collected or reviewed by CBSA. As a result of the regulatory requirement to declare imports of pesticides, pesticide regulators can receive certain pieces of import data (e.g., Description of Goods) that CBSA collects from traders under the Customs Act.	type of PCP. Disinfectants (not pesticide) or a sanitizer (pesticide) are both called household cleaners). Import trends are identified through analysis of post-import contraventions, tracked in the pesticide regulator's Investigation Tracking Form (ITF) database. Also, imports under Canada's Own Use Import / Grower Requested Own Use Programs are tracked through the applications submitted to the pesticide regulator (assuming that most of what is requested through these programs will in fact be imported).	
GERMANY	In some cases, the customs services ask the plant protection authorities (BVL and the enforcement authorities) for information about imported PPP's.	Not known	The cooperation of customs services and plant protection services led to the revelation of illegal importations of PPP's.
IRELAND	Spot checks	Data analysis is not conducted.	No activities of this nature.
JAPAN	Registered pesticide products: Importers should demonstrate that products being imported are registered in Japan by submitting the copy of registration card which authenticity was certificated by the Ministry of Agriculture, Forestry, and Fisheries (MAFF) beforehand to the custom office where they will import shipments. Non-registered pesticide products: Importers should submit the import declaration that states this import is for the purpose of test research which was approved by MAFF beforehand to the custom office where they will import shipments. At the time of approval of MAFF, MAFF request importers to attach a test research plan with the import declaration.		Any problem did not occur in particular.

	Verification of information	Data analysis conducted	Border Monitoring findings
MEXICO	This information is reviewed at the port of entry by the customs officer		
NEW ZEALAND	MAF Biosecurity on behalf of NZFSA verify this information from the MAF Application to Import which is submitted by the registrants importing agent prior to product landing at the NZ port.		As part of the NZFSA random 'Slice of Life' audits conducted at the border by MAF Biosecurity on our behalf, findings have been that in general registrants are complying with the requirements laid out in the ACVM Act and they are meeting the conditions of registration for their pesticide products.
NORWAY			
SLOVAK REPUBLIC	Comparison of submitted data with registration data (customers with cooperation with phytoinspection)	As in ii)	There are no findings in the last five years
SWITZERLAND	Randomly after incidents	no	
UNITED KINGDOM	The country of export is contacted to obtain the details on the approved formulation, manufacturing site of the active substance and its purity. These details are compared to those for the UK product to which identicality is claimed. If the formulations are not materially different then approval is given	no	n/a
UNITED STATES	US Customs and EPA officials can compare this information listed above electronically with information on file with the product's registration.	No data analysis	Attempted importation of unregistered products, unapproved (illegal) sources, counterfeit pesticides.

(d) Is information shared among different points of entry (e.g., shipments denied entry at one point may attempt entry at another)?
YES NO
(e) Is information shared with other regulators in your country?
YES NO
(f) Is information shared with other countries?
YES NO
If 'YES' for 6(d), 6(e) or 6(f):
i) What type of information is shared, and at what frequency?
ii) How is this information shared?

	Sharing Information				
	Among points of entry	**With other regulators**	**With other countries**	**Type of information**	**How shared**
AUSTRALIA	yes	yes	no	AC name, product name, importer, quantity, port of origin and exporter at origin	Electronically under Memorandum of Understanding with Australian Customs Service
BELGIUM	no	no	no		
CANADA	unknown	yes	yes: Limited to date but could be shared if necessary upon request, or if we are seeking assistance from foreign regulators.	If the Pesticide Regulator requests CBSA (Border Services) to deny entry for a specific pesticide of concern, this information is shared with all targeted border points. The Pesticide Regulator is not aware of all denied shipments and does not know if this information is shared between border points. In the past, CBSA has provided the pesticide regulatory with import records when requested. These records can be used as evidence of an illegal importation. If the pesticide regulator had any information regarding illegal trade (or the prevention, detection and control of illegal trade), we could share this information with other Canadian government departments, including CBSA.	Data on imported pesticides may be reported/collected at the border, however they are not routinely provided to the Pesticide Regulator.

	Sharing Information				
	Among points of entry	**With other regulators**	**With other countries**	**Type of information**	**How shared**
GERMANY	unknown (customs are responsible)	yes	yes	Quantities and product names and information and suspicions about illegal PPP's	By e-mail
IRELAND	no	no	yes	Import export statistics are shared with the EU Commission (Eurostat)	Information is shared via an annual publication which hides commercially sensitive information.
JAPAN	yes	yes	yes	Type of information varies case by case. For example, manufacturer name and the contents of cargo etc. Frequency is each time an incident occurs.	Network of e-mail correspondence.
MEXICO	yes	yes	no	Name of the product Registration number Date of import Point of entry Country of origin The exchange with another regulators is not systematic	By official communications or electronically
NEW ZEALAND	yes	no	no		
NORWAY					
SLOVAK REPUBLIC	yes	yes	yes	Only in the case of illegal import – type of product, product name	Pesticide regulation - through notification to EU
SWITZERLAND	unknown	no	no		
UNITED KINGDOM		yes	yes	Ad hoc dependent on situation no fixed frequency	Ad hoc
UNITED STATES	yes	yes	yes	Information in 6.c.i. and other relevant information.	Electronically

7) Monitoring Registered Products

(a) Identify activities that are in place to ensure product integrity of registered products at importation, sale or distribution. Activities may include:

Monitoring at point of importation, sale or distribution
Product tracking
Inspection at point of importation, sale or distribution
Enforcement legislation
Compliance promotion

	Monitoring	Product Tracking	Inspection	Enforcement legislation	Compliance Promotion	Other
AUSTRALIA	x		x	x	x	
BELGIUM	x		x	x		
CANADA	x		x	x	x	Investigation and Enforcement Action
GERMANY			x	x	x	
IRELAND	x		x	x	x	
JAPAN	x		x	x	x	
MEXICO	x	x	x	x		
NEW ZEALAND	x		x	x		
NORWAY	x		x	x		
SLOVAK REPUBLIC	x		x	x	x	
SWITZERLAND				x		Yearly random market control campaigns at sale points. see below
UNITED KINGDOM				x		
UNITED STATES	x	x	x	x	x	US Customs and Border Protection (CBP) and EPA's Regional Offices evaluate requests for pesticide imports to ensure each is indeed EPA-registered, it has proper labelling and ingredients (this does not normally include a chemical analysis), and it is arriving from a EPA registered production establishment.

Switzerland: Effectively, Switzerland has an enforcement legislation, the Ordinance of 18 May 2005 on Protection against Dangerous Substances and Preparations (Chemicals Ordinance, ChemO) (http://www.admin.ch/ch/e/rs/c813_11.html) for chemicals which in the domain of market control is covered by our cantons. The ordinance on Plant protection products (http://www.admin.ch/ch/f/rs/9/916.161.fr.pdf , available only in French) refers for the domain of market control mainly on this ordinance.

(b) Describe the range of regulatory/ compliance responses available in your jurisdiction, and when they may be applied.

	Range of regulatory/ compliance responses
AUSTRALIA	Testing Notice Stop Supply Notice Product Recall Notice Warnings Export to Country of Origin Prosecution Injunction
BELGIUM	The federal Agency for the Safety of the Food Chain (FASFC) samples each year about 80 PPP on the Belgian market and analyses them for the content of active substance(s) and their physical-chemical properties. Approach : targeted with rolling program; Objectives : control all the authorised products on the market in a period of 10 years. Administrative consequences (Warning of Pro-Justicia) & penalties
CANADA	A risk-based assessment could result in: Person-No Action, Verbal education-informing of regulatory requirements; Educational letter, Enforcement letter, Administrative Monetary Penalties (AMPs), Compliance Orders, Prosecution. Product- No action, Deny Entry, Forfeiture by consent, Disposal / return/ removal/ recall/ re-labelling by Order or by voluntary request, Detention/seizure. Note: More than one response may be required.

	Range of regulatory/ compliance responses
GERMANY	The enforcement authorities are independent from the regulation authority (BVL). The BVL provides information about registered products and carries out the analysis of PPP's.
IRELAND	Where the transgression is minor in nature the investigating officer has discretion to take no further action, except to remedy the situation. If the issue is more serious and it is a first offence then it is possible to address the issue with a formal warning letter. If this is a second offence or more, then prosecution will ensue which attracts a monetary penalty as well as the possibility of a custodial sentence.
JAPAN	Timing of measures: receiving information alleged to be illegal Legislative measures: On-site inspection Timing of measures: violation of the law Legislative measures: -Order of report. -On-site inspection. -Limitation of sale. -Prohibition of sale. - Invalidity of registration. -Cancellation of registration. -Order of recall. -Application of penal regulations (accusation).
MEXICO	
NEW ZEALAND	
NORWAY	
SLOVAK REPUBLIC	Verbal education- informing of regulatory reqirements Educational letter Enforcement letter Administrative Monetary Penalties Prosecution Forfeiture by consent Detention

	Range of regulatory/ compliance responses
SWITZERLAND	-For minor findings, the cantons can order the company to modify the package, the label, the instruction or ask for other correction measures. If an imminent severe danger is detected, even the immediate withdrawal from the market can be decreed. - In a case of fraudulent action, the cantons may also initiate a prosecution by a court. - If during a regulatory/compliance control action there is a finding that a product does not comply with the corresponding authorization, the canton will signal this to our office and we will then take actions which can lead even to the withdrawal of the authorization.
UNITED KINGDOM	UK has a range of enforcement options and applies appropriate proportionate sanctions available under EU and UK regulations (e.g. those set out under FEPA, COPR, PPPR, and PP(BC)R
UNITED STATES	Once EPA finds that a violation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) has occurred, EPA determines the appropriate level of enforcement response for the violation. FIFRA provides EPA with a range of enforcement options. These options include: Notices of Warning under sections 9(c)(3), 14(a)(2), and 14(a)(4); Notices of Detention (Instruct CBP to Refuse Entry) under section 17(c); Stop Sale, Use, or Removal Orders under section 13(a); Seizures under section 13(b); Injunctions under section 16(c); Civil administrative penalties under section 14(a); Referral for criminal proceedings under section 14(b); and Recalls.

(c) Describe the criteria for selecting the appropriate regulatory/compliance response.

	Criteria for selecting the appropriate regulatory/compliance response
AUSTRALIA	Previous non-compliance Harm posed by imported chemical Prospects for limited use in Australia
BELGIUM	Risk evaluation
CANADA	A Risk based analysis considers: History of compliance; Evidence of corrective plan action; Degree of Harm as a result of non compliance; Knowledge, Will and Ability to comply; Level of response to achieve/maintain compliance; Impact to health, environment and regulatory integrity if non-compliance occurs, Reasonable belief of the violator that the product was packaged in accordance with the regulations and conditions of registration, Potential short or long term negative consequences on the violator from the response, Role of industry/other regulators
GERMANY	This is the duty of the enforcement authorities.
IRELAND	see above [b]
JAPAN	-Compliance history of the related companies. -Degree of non-compliance by checking the product according to the acceptable criteria. -Analysis of cause of incidents. -Effectiveness and practicability of improvement plan by the related companies. -Impact on human health and environment caused by its non-conformity.
MEXICO	
NEW ZEALAND	
NORWAY	

	Criteria for selecting the appropriate regulatory/compliance response
SLOVAK REPUBLIC	Evidence of infringements Degree of Harm Level of response to achieve compliance Impact to health, environment Negative consequences
SWITZERLAND	case by case
UNITED KINGDOM	Case by case dependant on the nature of the offence
UNITED STATES	Potential or actual harm to human health and/or the environment, toxicity of the pesticide, the violation history of the importer (repeat offender?), and the culpability of the importer.

(d) How are the monitoring results used? (e.g.: contribute to operational planning, program development).

	Use of Monitoring Results
AUSTRALIA	Define the operational planning of AgQA program activities and permits audits.
BELGIUM	Contribute to operational planning, program development
CANADA	Operational planning, program development, and provides compliance history for future enforcement responses
GERMANY	The results are used for the planning of future controls (duty of the enforcement authorities).
IRELAND	Results are used to build a picture of the industry and individual trading units within the industry. A profile is built which aids in decision making regarding a regulatory response.
JAPAN	
MEXICO	To approve or deny the importation. To develop programs and decision making

	Use of Monitoring Results
NEW ZEALAND	
NORWAY	
SLOVAK REPUBLIC	Operational planning, program development
SWITZERLAND	Planning for further monitoring activities
UNITED KINGDOM	Both [Operational planning and program development]
UNITED STATES	Monitoring results are used to improve enforcement targeting and assess inspection needs at specific ports of entry.

(e) Describe any incident related to the importation, distribution or sale of registered products within the last 5 years. How was each incident detected? What was the regulatory/compliance response? How was the appropriate response determined*?*

	Incidents and responses
AUSTRALIA	See answer to similar questions above. Most cases are still under active investigation.
BELGIUM	Repellent in anti-slugs Active substances amount Excessive foaming Impurities In case of danger for public health : recall from the market and by the user Otherwise : only action for analysed batch of products at the market level
CANADA	Historically, Canada has few examples of non-conformity of registered products with respect to product integrity. Past programs that were completed, verifying the technical guarantee and the level of micro-contaminants in various pest control products, resulted in high levels of compliance and minor issues concerning product integrity. As a result of these findings, the targeted programs were discontinued, but the pesticide regulator still maintains the ability to perform analysis concerning product integrity as required. In recent years, numerous complaints on the quality of pet products, as a result of increasing adverse effects, were filed through the incident reporting database. These complaints led to the development of a compliance program currently being conducted on pet products available for sale in the marketplace. This program includes lab analysis of contaminants, guarantees and formulants of risk as a targeted response to the complaints received.

	Incidents and responses
GERMANY	Permissions for the importation of PPP's have been withdrawn due to the findings of the monitoring programme.
IRELAND	In 2008, a consignment of unregistered PPPs was seized by the PCS and as it was the companies first offence, the company was afforded the opportunity to return the product to the supplier in the UK, at companies own expense. Any subsequent issues with this company will result in legal proceedings.
JAPAN	Pesticide manufacturers voluntarily reported the information of complaints drawn by pesticide users to MAFF. For example, Misprint of expiry date on a pesticide label. Leak from a pesticide container. Different description on a pesticide label from registered contents. In response to these cases, MAFF requested manufacturers to conduct internal investigation and develop improvement.
MEXICO	
NEW ZEALAND	
NORWAY	
SLOVAK REPUBLIC	According to national inspection program there were several infringements during last years: Unauthorised product Unauthorised sale Labelling Content of active substances Each infringement is connected with appropriate action of phytosanitary inspection according to the National phytosanitary law.
SWITZERLAND	
UNITED KINGDOM	Sale and Supply of registered product after date of revocation (following Annex 1 inclusion) by 2 major companies. Alleged breach reported by competitor, affected product subject to enforcement notice and was product was eventually recalled and exported outside the EU. Response determined in consultation with legal advisors and reflected lack of a safety concern.

	Incidents and responses
UNITED STATES	The Southeast office of the U. S. Environmental Protection Agency (EPA Region 4) has settled an administrative penalty case against "Company A" and "Company B" for violations of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). According to the terms of the settlement, Companies A and B collectively will pay a total civil penalty of more than $800,000, and will undertake corrective actions to ensure that the violations do not recur. A and B manufacture, market, and sell a variety of pesticide products. These products are sold to farmers in the United States for use on cotton and tobacco. Based on a review of pesticide importation records and inspections conducted by EPA and the state department of agriculture at Company A's pesticide production facility, EPA determined that Companies A and B had been importing a registered pesticide active ingredient from a non-approved manufacturing facility in China, and that the composition of the ingredient differed from the composition specified in the statement of formula set out in the registration. As a result, the composition of two end-use products manufactured by the companies, "Product X" and "Product Y", differed from the compositions specified in EPA's approved registrations for those products. The original registrant, Company B, began importing the active ingredient from the unapproved facility in 1994. In 1997, Company A and Company B formed "Company C" and in 2003, Company A acquired 100% interest in Company C. Both Company C and Company A continued the practice of importing the ingredient from the unapproved source in China. EPA also determined that the containers of pesticide ingredient imported from China were misbranded in that they stated the incorrect percentage of the active ingredient contained in the product. Additionally, analytical results from samples of the two end-use products showed that they contained the pesticide ingredient in concentrations exceeding the allowable certified limits specified in their registrations. After EPA notification in April 2005 that it was in violation of FIFRA, Company A filed a registration amendment for the active ingredient to indicate the new source and to revise the formulation. Company A recently sold the registrations for these products to another company. Under FIFRA, all pesticides must be submitted to EPA for review, evaluation and registration to ensure that they do not pose an unreasonable risk to human health or the environment. Proper identification of a pesticide's active ingredients is an essential component of the regulatory scheme that helps to ensure a product's integrity and safety. Pesticide manufacturers are required to clearly state the amount of active ingredients contained in each product and must manufacture the product within a specific range of the stated composition percentages. Pesticide products that contain too little or too much active ingredient may pose unreasonable risks to human health or the environment and may not perform effectively.

8) Monitoring of illegal pesticides available for sale on the market

(a) Identify activities that are in place to actively prevent and monitor the presence of illegal pesticides on the market at the:

i) Regulatory Level
Monitoring at point of importation, sale or distribution
Product tracking
Inspection at point of importation, sale or distribution
Enforcement legislation
Compliance promotion
ii Industry Level
iii Other levels of government/state

	Regulatory Level						Industry Level	Other levels of government/state
	Monitoring	Product Tracking	Inspection	Enforcement legislation	Compliance Promotion	Other		
AUSTRALIA	x		x	x	x	AgQA scheme		
BELGIUM	x		x	x			No information	Nothing
CANADA	x		x	x	x		unknown	Provincial and municipal limitations imposed on sale of products and inspections carried out in this regard.
GERMANY			x	x	x		Compliance promotion and monitoring imported products that are related to their own products	The enforcement authorities are independent from the regulation authority (BVL). The BVL provides information about registered products and carries out the analysis of PPP's.
IRELAND	x		x	x	x		End user, retail and wholesale inspection programme	n/a

	Regulatory Level						Industry Level	Other levels of government/state
	Monitoring	Product Tracking	Inspection	Enforcement legislation	Compliance Promotion	Other		
JAPAN	x		x	x	x	MAFF requests the public to provide information on illegal pesticides for strengthening the management of them.		When the products alleged to be illegal are discovered by inspection of local governments, they promptly share the information with MAFF and MAFF determines the appropriate responses to the case.
MEXICO	x	x	x	x	x	complaint		Complaint and communication between the regulatory agencies
NEW ZEALAND	x		x	x				
NORWAY	x		x	x				
SLOVAK REPUBLIC	x		x	x	x		Cooperation with industry – identification of counterfeits	Cooperation of customers and pesticide regulators

	Regulatory Level						Industry Level	Other levels of government/state
	Monitoring	Product Tracking	Inspection	Enforcement legislation	Compliance Promotion	Other		
SWITZERLAND			x			Yearly random market control campaigns at sale points	Market monitoring by several companies	-Random control of importations by customs. −Our cantons are free in the design of their control and enforcement actions, however, FOAG designs each year a campaign in which a selected choice of products is controlled and if necessary enforced by the enforcing organs of the cantons. Coordination and necessary laboratory analysis is done mostly by a government laboratory.
UNITED KINGDOM				x				
UNITED STATES	x	x	x	x	x		EPA's Final Policy Statement, Incentives for Self- Policing: Discovery, Disclosure, Correction and Prevention of Violations, (Audit Policy), 65 Fed. Reg. 19,618 (April 11, 2000)	State

(b) Describe the range of regulatory/ compliance responses available in your jurisdiction, and when they may be applied.

AUSTRALIA	Testing Notice Stop Supply Notice Product Recall Notice Warnings Export to Country of Origin Prosecution Injunction
BELGIUM	In case of danger for public health : recall from the market and by the user
CANADA	A risk-based assessment could result in: Person-No Action, Verbal education-informing of regulatory requirements; Educational letter, Enforcement letter, Administrative Monetary Penalties (AMPs), Compliance Orders, Prosecution, Product- No action, Deny Entry, Forfeiture by consent, Disposal/return/removal/recall/re-labelling by Order or by voluntary request, Detention/seizure. Note: Any of these enforcement tools may be used as long as they are fair, supportable by law and consistent with previous enforcement responses taking into consideration any mitigating factors that could require a different approach to restore and maintain compliance. More than one response may be required
GERMANY	Permissions for the importation of PPP's can be withdrawn due to the findings of the monitoring programme.
IRELAND	Where the transgression is minor in nature the investigating officer has discretion to take no further action, except to remedy the situation. If the issue is more serious and it is a first offence then it is possible to address the issue with a formal warning letter. If this is a second offence or more, then prosecution will ensue which attracts a monetary penalty as well as the possibility of a custodial sentence.

JAPAN	Timing of measures: receiving information alleged to be illegal Legislative measures: On-site inspection Timing of measures: violation of the law Legislative measures: -Order of report. -On-site inspection. -Limitation of sale. -Prohibition of sale. - Invalidity of registration. -Cancellation of registration. -Order of recall. -Application of penal regulations (accusation).
MEXICO	
NEW ZEALAND	
NORWAY	
SLOVAK REPUBLIC	Administrative Monetary Penalties Prosecution Detention
SWITZERLAND	Correction measures for the product Possible prosecution by a court Cancelling of authorisation
UNITED KINGDOM	UK has a range of enforcement options and applies appropriate proportionate sanctions available under EU and UK regulations (e.g. those set out under FEPA, COPR, PPPR, and PP(BC)R)
UNITED STATES	Once EPA finds that a violation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) has occurred, EPA determines the appropriate level of enforcement response for the violation. FIFRA provides EPA with a range of enforcement options. These options include: -Notices of Warning under sections 9(c)(3), 14(a)(2), and 14(a)(4); -Notices of Detention (Instruct CBP to Refuse Entry) under section 17(c); -Stop Sale, Use, or Removal Orders under section 13(a); -Seizures under section 13(b); -Injunctions under section 16(c); -Civil administrative penalties under section 14(a); -Referral for criminal proceedings under section 14(b); and -Recalls.

(c) Describe the criteria for selecting the appropriate regulatory/compliance response.

AUSTRALIA	Previous non-compliance Harm posed by imported chemical Prospects for limited use in Australia
BELGIUM	Non compliant with registration / No registration
CANADA	A risk-based analysis considers: History of compliance; Knowledge, Will and Ability to comply; Evidence of corrective plan action; Degree of Harm as a result of non compliance; Level of response to achieve/maintain compliance; Impact to health, environment and regulatory integrity if non-compliance occurs, Reasonable belief of the violator that the product was packaged in accordance with the regulations and conditions of registration, Potential short or long term negative consequences on the violator from the response, Role of industry/other regulators.
GERMANY	Under development and depending on the jurisdiction.
IRELAND	See above [b]
JAPAN	Compliance history of the related companies. Degree of non-compliance by checking the product according to the acceptable criteria. Analysis of cause of incidents. Effectiveness and practicability of improvement plan by the related companies. Impact on human health and environment caused by its non-conformity.
MEXICO	
NEW ZEALAND	
NORWAY	
SLOVAK REPUBLIC	Evidence of infringements Degree of harm Level of response to achieve compliance Impact to health, environment Negative consequences

SWITZERLAND	Case by case
UNITED KINGDOM	Case by case dependant on the nature of the offence
UNITED STATES	Potential or actual harm to human health and/or the environment, toxicity of the pesticide, the violation history of the importer (repeat offender?), and the culpability of the importer.

(d) How are the monitoring results used? (e.g.: contribute to operational planning, program development).

AUSTRALIA	Define the operational planning of AgQA program activities and permits audits.
BELGIUM	
CANADA	Operational planning, program development, and provides compliance history for future enforcement responses.
GERMANY	The results are used for the future planning of the monitoring programme.
IRELAND	Used to formulate next years inspection programme
JAPAN	
MEXICO	
NEW ZEALAND	
NORWAY	
SLOVAK REPUBLIC	Operational planning, program development
SWITZERLAND	Planning for further monitoring activities
UNITED KINGDOM	n/a
UNITED STATES	Monitoring results are used to improve enforcement targeting and assess inspection needs at specific ports of entry.

(e) Describe any incident related to the importation, distribution or sale of illegal pesticides within the last 5 years. How was each incident detected? What was the regulatory/compliance response? How was the appropriate response determined?

AUSTRALIA	See answer to similar questions above. Most cases are still under active investigation.
BELGIUM	Presence of products authorized in other EU countries (NL, FR) but not authorized in Belgium. No danger for public health. Products seized and destroyed.
CANADA	Unregistered or illegal pesticides may be available for sale at vendors across Canada. Marketplace inspection programs inspect vendors and determine the status of product. Any unregistered product or products otherwise in violation of the PCPA are noted. Investigations are initiated and after a risk based assessment to determine the correct enforcement response, the illegal product is most often disposed of, removed from sale and/or returned to the distributor outside of Canada. Verbal and written education concerning the legal requirements and the Pesticide Regulators role are distributed to vendors. One recent case involving the importation, distribution and sale of illegal pesticides occurred in 2006 when unregistered Glyphosate from China was imported and resold for personal profit. The Pesticide Regulator became aware of this illegal activity from industry complaints. The suspected candidate was identified and approached by an inspector and admitted to the import and resale, including to a retailer, of illegal glyphosate. The product was detained. Following an internal Agency consultation, regarding the course of action, a Compliance Order was issued ordering the return of this product to the original distributor in China. 3 Notices of Violation with Penalty for the import and sale of an unregistered product were issued. Although the importer paid the monetary fines, they did not take the required steps to dispose of the illegal product as defined in the compliance order. Following a lengthy correspondence with the importer in which little progress for disposal occurred, preparations were made to confiscate the product and arrange for its disposal. Unfortunately, before the Pesticide Regulator could confiscate the product, the importer reported it as stolen from the storage facility and the investigation was turned over to the police, ending the Pesticide Regulators involvement in the case. International counterparts were notified.
GERMANY	Illegal importations were discovered due to hints from customs offices, industry or consumers. Some permissions for the importation of PPP's were withdrawn due to the findings of the monitoring programme. The enforcement authorities imposed fines. In the case of outright illegal importations, criminal investigations are carried out.

IRELAND	In 2008, a consignment of unregistered PPPs was seized by the PCS and as it was the companies first offence, the company was afforded the opportunity to return the product to the supplier in the UK, at companies own expense. The consignment was seized as a result of complaints from industry. There were no negative health implications associated with the issue. Any subsequent issues with this company will result in legal proceedings.
JAPAN	Illegal unregistered pesticide products were detected in 2007 and 2008: For one example, refer to 4) (g) of Part A. A registered pesticide product became invalid in 2008: Refer to 4) (d) iv) of Part A.
MEXICO	
NEW ZEALAND	
NORWAY	
SLOVAK REPUBLIC	In 7e)
SWITZERLAND	
UNITED KINGDOM	Sale of unapproved product reported by industry, follow up investigation identified counterfeit product, which was seized and has been disposed of. Response was determined by nature of breach including origin of counterfeit, active and scale of operation.
UNITED STATES	Company C paid a $1.4 million civil administrative penalty to EPA for importing, selling and distributing seed that contained an unregistered genetically engineered pesticide. EPA also issued a Stop Sale, Use, or Removal Order specific to all quantities of violative seed within the company's control. Late in 2004, the company disclosed to EPA that it may have distributed the seed to the United States, Europe, and South America. Immediately following the disclosure, U.S. Department of Agriculture (USDA), the U.S. Food and Drug Administration (FDA) and EPA began an investigation and evaluation that confirmed the distribution of unregistered seed on over 1000 occasions. A penalty was also assessed by USDA and the company destroyed all the affected seed under USDA supervision.

9) Sharing information when incidents of non-compliance are found

(a) When incidents of non-compliance are found, do you share information with other countries or regulators?
YES NO

If 'YES',
(i) Describe what information is shared:

	Type of information shared
AUSTRALIA	Non-compliance with standards, Impurity and concentration, Supplier, importer, manufacturer name and address Quantity involved Product name
BELGIUM	Information would be shared with other countries if an incident could have consequences in these countries or if a same incident could occur in these countries.
CANADA	Results of inspection programs are currently shared with provincial regulators. Future plans include the availability of inspection reports publically via the Pesticide Regulators (PMRA's) website. Confidential Business Information cannot be released
GERMANY	Quantities and product names and information and suspicions about illegal PPP's
IRELAND	Any information required by another authority will be shared.
JAPAN	The summary of the cases e.g. the name of violators, contents of violation and applied types of regulatory measures etc.
MEXICO	Pesticides unregistered manufactured in another country Inherent properties of unregistered pesticides
NEW ZEALAND	[not shared]
NORWAY	[not shared]
SLOVAK REPUBLIC	Type of product, product name, type of infringement, importer

	Type of information shared
SWITZERLAND	[not shared]
UNITED KINGDOM	Depends on circumstance of case, typically product details
UNITED STATES	Share all relevant information except confidential business information.

(ii) Describe how information is shared (if applicable):

- ***Among different levels of government (e.g. federal and provincial/state)***
- ***Among different parts of the federal government (e.g. border control and pesticide regulators)***
- ***Between industry and government***
- ***Between countries***

	How information is shared			
	among levels of government	***among parts of federal government***	***between industry and government***	***between countries***
AUSTRALIA	Shared between relevant control of use authorities, border protection authorities, environment protection and health authorities	As above	Only with relevant industry (supplier, importer, approval holder, registrant)	Only for investigations and product cancellation
BELGIUM				
CANADA	Through Canada's Federal/Provincial/Territorial Committee on Pest Management and Pesticides; At the operational level, meetings are held to discuss concerns and areas of collaboration.	Canada Border Services Agency (CBSA) concerning Border Lookouts, PMRA can request import records for specific imports; Informally with federal bodies such as Environment Canada, Agriculture and Agri-Food Canada and Fisheries Canada as	Discussion at stakeholder meetings, Through the pesticide regulator's Incident reporting database, website postings and local media coverage of compliance actions.	Organisation for Economic Co-operation and Development (OECD), Informally with US EPA as required/requested.

	How information is shared			
	among levels of government	***among parts of federal government***	***between industry and government***	***between countries***
		required/requested to address mutual areas of concern in relation to pesticides.		
GERMANY				
IRELAND	Shared if requested	Shared if requested	Information that is not commercially sensitive may be shared with industry representative bodies.	Shared if requested
JAPAN	By using e-mail network, phone call, facsimile etc.	Information sharing with the relevant Ministries and Agencies in charge of the risk management of pesticides by using phone call, e-mail, facsimile etc.	Information sharing with the relevant industries by using phone call, e-mail, facsimile etc. Information exchange of related issues at technical committee comprising relevant parties.	
MEXICO				
NEW ZEALAND				
NORWAY				
SLOVAK REPUBLIC		Cooperation and information sharing of border control and pesticide regulators	Cooperation and information sharing of government and industry in the case of counterfeits	At the international level
SWITZERLAND				
UNITED KINGDOM		Regulatory or Information updates on Website or otherwise as necessary	Regulatory or Information updates on Website or otherwise as necessary	Direct between regulatory authorities unless other mechanism exists, e.g. RASSIF
UNITED STATES	Federal and state	EPA, Customs and Border Patrol, others as appropriate	Yes	

(b) In the future, what additional mechanisms could help collaboration and intelligence sharing with regards to non-compliance?

	Mechanisms to help collaboration and intelligence sharing
AUSTRALIA	Improved and formal cooperation arrangements with foreign regulatory authorities. Mandatory QA and record keeping for product formulation Conditional licensing of manufacturers, formulators and importers.
BELGIUM	
CANADA	Bilateral working agreements with other agencies. Publication of program results and notification of where to find these documents through regulatory forums. Increased international border control. Increased communication internationally when incidents of non-compliance occur.
GERMANY	Rapid alert system, contact persons, databases about the findings from the monitoring (illegal pesticides identified in the different countries, results of the analysis of PPP's).
IRELAND	Better communications between authorities in different jurisdictions.
JAPAN	It is important to strengthen the existing mechanism and ensure the effectiveness
MEXICO	International coordination Web site to share information Data bases
NEW ZEALAND	
NORWAY	
SLOVAK REPUBLIC	
SWITZERLAND	Switzerland is actually discussing the possibility of a free trade treaty on agricultural products with EU, which would greatly influence the exchange of data with EU
UNITED KINGDOM	EU wide database of approved products and formulations
UNITED STATES	Integration of the Notice of Arrival (EPA Form 3540-1) into Automated Commercial Environment/Import Tracking Data System (CBP's automated data exchange). This computer database tracking system integrates databases about a wide range of products (chemicals and non-chemicals) from US regulatory agencies into one system. For pesticide products, this enables US authorities for imports to easily and quickly determine whether a product should be imported and more quickly enter into US commerce or not.