Organisation de Coopération et de Développement Economiques
Organisation for Economic Co-operation and Development

01-Jun-2001

English - Or. English

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

ENV/JM/MONO(2001)3
Unclassified

OECD SERIES ON PESTICIDES
Number 11

Survey of Best Practices in the Regulation of Pesticides in Twelve OECD Countries

English - Or. English

JT00108865

OECD Environment, Health and Safety Publications

Series on Pesticides No. 11

Survey of Best Practices in the Regulation of Pesticides in Twelve OECD Countries

Environment Directorate

Organisation for Economic Co-operation and Development

Paris 2001

Also published in the Series on Pesticides:

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

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

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

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

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

No. 6, *OECD Governments' Approaches to the Protection of Proprietary Rights and Confidential Business Information in Pesticide Registration* (1998)

No. 7, *OECD Survey on the Collection and Use of Agricultural Pesticide Sales Data: Survey Results* (1999)

No. 8, *Report of the OECD/FAO Workshop on Integrated Pest Management and Pesticide Risk Reduction* (1999)

No. 9, *Report of the Survey of OECD Member Countries' Approaches to the Regulation of Biocides* (1999)

No. 10, *Guidance Notes for Analysis and Evaluation of Repeat-Dose Toxicity Studies* (2000)

Published Separately:

OECD Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances - Monograph Guidance (1998, revised 2001)

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

Report of the Pesticide Aquatic Risk Indicators Expert Group (2000)

About the OECD

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

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

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

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

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

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

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

Summary

At the Eighth Meeting of the Pesticide Forum (November 1998), Canada presented a proposal for sharing information on best management practices among regulatory agencies. The Forum agreed that collecting and exchanging such information could be worthwhile but felt that a survey of all countries' approaches should not be initiated because of an already heavy work load. However, interested countries were encouraged to work together with Canada and to report on the activity at the next Forum meeting.

Canada with Australia, the Netherlands, Sweden and the United States of America developed a survey questionnaire and distributed it to interested countries in April 1999. Twelve countries volunteered to complete the questionnaire - Australia, Canada, Denmark, Finland, Hungary, Japan, New Zealand, Norway, Slovenia, Sweden, the U.K. and the U.S.A.

This survey, therefore, reflects the experiences and opinions only of those OECD countries, which participated and it reflects their views as reported in the first half of 1999. As such, it is acknowledged that systems for the regulation of pesticides in all OECD countries - including those which participated - have evolved since that time and are continually being refined and improved. However, within these limitations, the survey may still provide useful information and contact points to all OECD partners interested in comparisons, benchmarking and/or worksharing activities.

The survey was divided into four distinct parts:

- **Part 1. Who Does What** - countries indicated the activities they carry out in the regulatory decision process as well as any obligations under law, fees charged and time-frames established for the activities;
- **Part 2. Best Practices - Successful Approaches** - countries identified innovative, successful approaches employed in their countries to improve the efficiency of the regulatory process;
- **Part 3. Best Practices - Rating the Best Practices** - countries listed the five best practices that have led to the largest gains in efficiency in their countries; and
- **Part 4. Best Practices - Fees** - countries provided details on specific services for which fees are charged as well as the reasons for charging fees and their opinions on the value of fees.

In **Part 1. Who Does What**, all participating countries reported that they carry out health assessments (mammalian toxicity, worker exposure, residues in food) and environmental assessments (animal toxicity, environmental fate). All countries except one establish Maximum Residue Levels (MRLs) and all countries except one do efficacy assessments (although they are limited in two others). Most countries are obligated by law to carry out these assessments and charge a fee for the service.

All countries reported that they establish data requirements, screen the data prior to evaluation, have a review process and a decision making process and reevaluate registered pesticides. The majority of countries are obligated by law to carry out these assessments and charge a fee for the services. Most countries reported that they carry out compliance/enforcement activities, have public consultations and pre-submission consultations and have a process for approving research permits. Time-frames for accomplishing these activities varied considerably from country to country. For example, the time-frame for the review process ranged between 55 days and 3 years.

In **Part 2. Best Practices - Successful Approaches**, the participating countries considered the best practices for each of eleven steps in the regulatory process by first reviewing some examples of best practices to improve the efficiency of the regulatory process and then identifying additional best practices

in place in their country. A large number and wide variety of ideas were contributed. Themes that emerged included:

- international harmonization of requirements and sharing of reviews;
- the preparation, submission and tracking of information electronically;
- the establishment of performance standards;
- the use of third party accreditation and auditing of policies and practices;
- consultation with the public and with industry;
- providing ready and wide public access to data and assessments; and
- organizing scientific expertise into multi-disciplinary groups.

In **Part 3. Best Practices - Rating the Best Practices**, the participating countries provided a wide variety of responses. Appearing on more than one country's list as best of the best practices were:

- pre-submission consultation;
- clearly defining data requirements;
- data screening and preliminary review for deficiency to ensure quality; and
- sharing review reports and acceptance of data assessments from other countries.

In **Part 4. Best Practices - Fees**, the participating countries showed that money is collected for services rendered in a variety of ways. The main ways are:

- a specific fee for a specific service such as assessment of mammalian toxicity;
- a combined fee for health assessment, environmental assessment and the establishment of MRLs;
- a yearly fee based entirely or partially on the previous year's sales; and
- a yearly set fee covering all services.

The main reason for charging fees was given as cost recovery for the services provided in the registration process. A majority of the countries felt that fees encourage efficient delivery of services and good submissions although one country felt that the fees are too low to encourage the companies to give the proper information while another saw no clear relationship between fees and the efficient delivery of services and good submissions.

Table of Contents

Introduction

At the Eighth Meeting of the Pesticide Forum (November 1998), Canada presented a proposal for sharing information on best management practices among regulatory agencies. (This was outlined in document ENV/JM/PEST(98)13.) The Forum agreed that collecting and exchanging information on process improvements and management practices could be worthwhile but felt that a survey of all countries' approaches should not be initiated, in view of the already heavy work load within the Pesticide Programme. However, interested countries were encouraged to work together with Canada and to report on the activity at the next Forum meeting. Countries expressing interest at the Forum included Australia, the Netherlands, Sweden and the US. Other countries wishing to take part in the activity were asked to contact Canada directly.

Canada, as lead, in conjunction with Australia, the Netherlands, Sweden and the United States of America, drafted a survey questionnaire and fourteen OECD member countries volunteered to participate in the survey. The survey questionnaire was sent to the participants on April 8, 1999, with responses due by May 15, 1999. Twelve countries have completed the questionnaire - Australia, Canada, Denmark, Finland, Hungary, Japan, New Zealand, Norway, Slovenia, Sweden, the U.K. and the U.S.A.

This survey, therefore, reflects the experiences and opinions only of those OECD countries, which participated and it reflects their views as reported in the first half of 1999. As such, it is acknowledged that systems for the regulation of pesticides in all OECD countries - including those which participated - have evolved since that time and are continually being refined and improved. However, within these limitations, the survey may still provide useful information and contact points to all OECD partners interested in comparisons, benchmarking and/or worksharing activities.

Background

The questionnaire was divided into four distinct parts. The first part asked each respondent to review a list of activities that may be involved in the regulatory decision process and to indicate those activities that are carried out in the respondent's country, whether the activity is required by law, whether there is a fee charged for carrying out the activity and, for some activities, to indicate the time-frame established for completing the activity.

The second part of the questionnaire asked each respondent to consider the best practices for each step in the regulatory process by first reviewing some examples of best practices and then identifying additional best practices in place in their country to improve the efficiency of the regulatory process.

The third part asked each respondent to list the five "best practices" that have led to the largest gains in efficiency in their organization.

The fourth part asked each respondent to provide details on the specific services for which fees are charged, to indicate the main reasons for charging fees and to comment on whether fees encourage efficient delivery of services and good submissions.

Part 1. Who Does What

Respondents were asked to review a list of eighteen activities that may be involved in the regulatory process and to indicate those activities that are carried out in the respondent's country, whether the activity is required by law, whether there is a fee charged for carrying out the activity and, for some activities, to indicate the time-frame established for completing the activity. They were also invited to provide the same information for any additional activities that make up the regulatory process in the respondent's country.

These eighteen activities can be sub-divided into two groups. The first group are assessment activities and describe what data is being gathered in the regulatory process. Assessment activities include health assessment (mammalian toxicity, worker exposure, residues in food), environmental assessment (animal toxicity, environmental fate), the establishment of Maximum Residue Levels (MRLs) and efficacy assessment.

The second group of activities describe the workings of and the steps involved in the regulatory process. Included are the process to establish data requirements, screening/checking/sifting, the review process, the decision making process, public consultation, policy development, compliance/enforcement, reevaluation of registered pesticides, management and administration, research permits and pre-submission consultation.

Please note that a rather broad definition of "charge a fee" has been used for this report. Different countries collect money for services rendered in a variety of ways. The main ways are:

- a specific fee for a specific service such as assessment of mammalian toxicity;
- a combined fee for health assessment, environmental assessment and the establishment of MRLs;
- a yearly fee based entirely or partially on the previous year's sales; and
- a yearly set fee covering all services.

A summary of the responses to this part of the survey is provided in Annex 1 and includes comments made by the individual countries.

Assessment Activities

All countries that completed the survey questionnaire reported that they carry out the following assessment activities:

Health Assessment
- mammalian toxicity;
- worker exposure;
- residues in food;

Environmental Assessment
- animal toxicity; and
- environmental fate.

With one exception, in all countries these activities are required by law and a fee is charged. Slovenia does not charge for assessment of residues in food and did not indicate whether this assessment is required by law.

There are two remaining assessment activities, establishment of MRLs and assessment of efficacy.

- establishment of MRLs

All countries except Slovenia establish MRLs as a requirement by law and, of these countries, all except Finland charge a fee for this service. Finland does not establish national MRLs but rather follows European Union directives.

- assessment of efficacy

All countries except New Zealand carry out efficacy assessment, although it is limited in Sweden and limited in the U.S.A. to public health pesticides only. Efficacy assessment is required by law in all of these countries (limited as indicated in Sweden and the U.S.A.). All except Finland and the U.S.A. charge a fee for this service.

The survey also asked the respondents to identify other steps or approaches.

- Canada added two additional activities: *review of product chemistry and value assessment.* There is a fee charged for each. The time frame for the review of product chemistry is 60 days while value assessment is part of the efficacy review.

- New Zealand added two additional activities. The first is an *economic and related benefits/risk analysis*. The second is *consultation with the Maori in terms of culture and traditions with respect to ancestral lands, water, sites, waahi tapu (sacred sites), valued flora and fauna and other taonga (treasures)*. Both are required by law and are covered in assessment costs. These activities are included in the time frame for assessments.

Process Activities

All countries that completed the survey questionnaire reported that they carry out the following process activities:

- establish data requirements

  The establishment of data requirements is required by law in all countries except Australia, New Zealand and the U.S.A. (where it is authorized). Denmark did not respond to the question on legal requirement.

  <u>time frames</u>
  There was little information provided about the time frames set for the establishment of data requirements. Canada and the U.S.A. indicated that the time frames would vary depending on type and need while Sweden responded that it would be dealt with as quickly as possible.

- screening/checking/sifting

  Screening/checking/sifting activities are required by law in all countries except Australia, Japan, Slovenia and the U.S.A. Denmark did not respond to the question on legal requirement.

time frames
The time frames for this activity varied from 5 days to 18 months. The U.S.A. allocates 5 days for this activity, New Zealand - 10days, Australia, Denmark and Japan - 1 month, the U.K. - 6 weeks, Canada - 45 days, Hungary - 18 months and Sweden - as quickly as possible. The other countries did not respond with information on time frames for this question.

- review process / decision making

  A review process is required by law in all countries except Japan and Slovenia while a decision making process is required by law in all countries.

  time frames
  Time frames for these activities varied from 70 days to 3 years. New Zealand allocates 55 days for the review process and 15 days for decision making, Slovenia - 90 days, Canada - 12-18 months, U.S.A. - 12-18 months (reduced risk pesticides) but up to 3 years for others, U.K. - up to 53 weeks, Australia - 13 months, Japan - within 18 months, Hungary - included in 18 month period identified in *Screening* question above, Finland - 1-3 years, Norway - up to 2 years, Denmark - 2 years and Sweden - as quickly as possible.

- reevaluation of registered pesticides

  Reevaluation of registered pesticides is required by law in all countries except Japan and New Zealand. Slovenia did not respond to the question on legal requirement.

  time frames
  This activity takes place within 1 year in Denmark, every 5^{th} year in Norway and every 10^{th} year in Finland. The other countries did not respond with definitive information for this question.

In addition, all countries (with the exception of Hungary and Slovenia which did not respond to the questions on policy and on compliance/enforcement and with the exception of Denmark that did not respond to the question on management and administration) reported that they carry out the following process activities:

- policy work (includes regulatory affairs and communication)

- compliance / enforcement

  The countries that responded to this question indicated that compliance / enforcement is part of the regulatory process.

  time frames
  There was little information provided about the time frames set for compliance / enforcement.

- management and administration

The remaining process activities are carried out by most, although not all, of the countries participating in the survey.

- public consultation

  Eight of the twelve responding countries have a public consultation process. The exceptions are Denmark, Hungary, Norway and Slovenia. It is required by law in Australia, New Zealand, the U.K. and the U.S.A.

  time frames
  Time frames for this activity varied from 1 month to 90 days. Australia and New Zealand allocate 30 days, Canada - 45 to 60 days, U.S.A. - 60 or 90 days for published proposals and Sweden - as quickly as possible. The other countries did not respond with information on time frames for this question.

- research permits

  Nine of the twelve responding countries include research permits in their regulatory process. The exceptions are Japan and Norway while Hungary did not respond to this question. It is required by law in all these countries except Sweden. All countries charge a fee for this service except Japan and Norway while Finland, Hungary and the U.S.A. did not respond to this question on fees.

  time frames
  Time frames for this activity varied from 40 days to 180 days. New Zealand allocates 40 days, Denmark - 2 months, Canada - 90-180 days and Finland 3 months. The other countries did not respond with information on time frames for this question.

- pre-submission consultation

  Ten of the twelve responding countries include pre-submission consultation in their regulatory process. The exceptions are Norway and Sweden.

  time frames
  There was little information provided about the time frames set for pre-submission consultation.

Part 2. Best Practices - Successful Approaches

Respondents were asked to consider the best practices for each of eleven steps in the regulatory process by first reviewing some examples of best practices to improve the efficiency of the regulatory process and then identifying additional best practices in place in their country. The survey also asked the respondents to identify other steps or approaches used in member countries and the best practices that apply to those steps.

A summary of the each country's response to this part of the survey is provided in Annex 2.

1. Establish Data Requirements

best practices identified prior to survey

- accept/adopt decisions of other countries
- harmonizing data requirements with other countries so industry need generate data only once for use in many countries
- improving the communication of data requirements to industry
- providing comprehensive training of industry on data requirements
- utilizing tiered data requirements
- requiring less data for lower risk products
- providing exemptions for certain types of products from registration, amendment or approval

additional best practices identified in survey

- working closely with industry in defining data requirements
- making data requirements available in electronic format
- allowing data requirements to be " flexible" if supported by sound scientific argument
- considering reviews from other countries as part of decision making in-house
- reregistering pesticides with similar areas of use at the same time to facilitate substitution
- establishing formal process for establishing new, deleting outdated and clarifying other data requirements
- harmonizing test methods for use by all OECD member nations through the OECD test guideline program

2. Screening / Checking / Sifting

best practices identified prior to survey

- screening submissions before they enter the review process to ensure that all the elements required for review are present
- rejection of low or poor quality submissions

additional best practices identified in survey

- "3 strikes" policy - industry given 3 attempts to get it right (with assistance), application rejected if submission then not acceptable

- providing applicants with screening criteria and encouraging them to complete screens (templates) for inclusion with their submissions
- computerising screening methods to accelerate the procedure
- ensuring that industry receives a consistent message on requirements, responsibilities and quality and format of data to be submitted
- establishing, unambiguously at the time of submission, the nature and scope of any claims of confidentiality for all submitted data

3. Review Process

best practices identified prior to survey

- sharing reviews with other countries
- harmonizing evaluation reporting formats among countries
- designing the organizational structure and relationships between organizational units to optimize work flow
- maintaining effective tracking systems to ensure efficient scheduling and work flow
- rationalizing the timing of review streams (example: review the efficacy and chemistry reviews are conducted first - if the this data is not sufficient the process stops and no further resources are expended in other science areas - it this data is sufficient reviews are then conducted in other areas)
- arresting review until company provides required/additional data
- maintaining a formal process for establishing work priorities
- contracting out tasks
- using electronic information
- using expert systems such as models, computerized decision support systems

additional best practices identified in survey

- ensuring ISO accreditation across whole organization (ISO 9002)
- having peer review of assessments
- sharing work with other countries
- using comprehensive Data Summaries prepared by applicant to streamline review process
- consulting external experts to get advice on single aspects in the evaluation
- using flexible staff deployment and training to provide a reservoir of staff expertise that can be called upon as required by changes in workloads and priorities
- encouraging secondments between specialist and generalist areas coupled with appropriate training opportunities
- formation of multi disciplinary teams mandated to work exclusively on certain application types in response to particular peaks in workload and freeing these teams from other work commitments and empowering them to devise new work practises and procedures to improve processing times while maintaining overall quality
- using a prioritization scheme that accelerates reviews for certain types of pesticides, including methyl bromide alternative, safer pesticides and for minor uses
- creating inter-disciplinary divisions that handle both risk assessment and use management for certain classes of pesticides, including biopesticides and antimicrobials
- using standing meetings between use assessors and use managers to discuss problematic issue and reach resolution early in the review process

4. Decision Making

best practices identified prior to survey

- formalizing and maintaining a process of internal peer review
- periodically subjecting regulatory decisions to external peer reviews
- establishing performance standards and measuring performance against these standards

additional best practices identified in survey

- having an annual external audit of the quality of policy advice and of scientific quality
- requiring the recommendation of an independent expert committee that a product will not present unacceptable risks to people, animals or the environment before it can be approved

5. Public Consultation

best practices identified prior to survey

- establishing stakeholder advisory mechanisms
- implementing a process for public consultation on regulatory decisions
- implementing a process for communication of regulatory decisions
- responding promptly and effectively to stakeholder/industry inquiries (information request, consumer complaints)
- measuring client satisfaction and monitoring changes in needs or expectations

additional best practices identified in survey

- providing public access to assessment reports
- providing public access to underlying data
- communicating through open letters to industry and other interested parties
- publishing newsletters and other reports with details on regulatory developments and results of decision making
- providing information through the Internet
- publishing service standards and establishing a formal complaints system
- implementing a tracking system for correspondence to allow quick response to external inquiries
- producing and distributing educational materials on topics such as worker protection and endangered species
- providing a toll free hot line staffed by experts on pest management regulatory and safety issues
- providing an ombudsman to act as a contact for parties outside the regulatory agency

6. Policy

best practices identified prior to survey

- ensuring policy development is well informed by science issues
- ensuring policy development is well informed by international direction
- developing communication plans on specific issues to ensure appropriate coverage

- providing easy, free access to information through toll free call-line and frequently updated and comprehensive website
- ensuring outreach and visibility by senior management to stakeholders
- ensuring good contact and timely sharing of information with other governments, both foreign and provincial/territorial/state/prefectural, as well as other federal departments

additional best practices identified in survey

- establishing informal and formal agreements with other federal governments
- discussing pesticide issues with Advisory Council
- ensuring scientific consultation on toxicological issue with toxicological scientific experts and on environmental issues with ecotoxicological scientific experts
- providing periodic reports and information, for example - monitoring and surveillance reports
- developing long term strategies
- establishing international principles of Good Pesticide Registration Process (GPRP)
- preparing medium term action plans for reduced risk products
- implementing new knowledge into decision making as soon as it appears

7. Compliance / Enforcement

best practices identified prior to survey

- work closely with other jurisdictions in the country to ensure no duplication / overlap in compliance activities
- work closely with other jurisdictions in the country to prevent misuse
- maintain an early response system for pesticide misuse issues
- implementation of measures that are intermediate between educational initiative and criminal prosecutions such as Administrative Monetary Penalties
- co-operate / contract with other inspection agencies to cross-utilize resources and enhance coverage of activities
- plan inspection programs but maintain a pool of resources to respond to issues as they occur
- provide regions with resources to deal with emerging issues at that level
- communicate with communicators and extension workers at provincial/territorial levels so that messages get out effectively to targeted group

additional best practices identified in survey

- priorizing compliance activities on risk-management basis
- ensuring that inspection programs re-evaluated and updated regularly
- identifying new areas / programs for inspection on an on-going basis
- establishing education programs at different levels to prevent abuse
- organizing enforcement resources at headquarters into one office developing comprehensive enforcement policies/overall strategies for environmental compliance instead of many offices doing the same
- establishing Memoranda of Understanding among regional offices to define expectations and set priorities
- establishing and providing consistent policies and procedures in a decentralized program
- providing one stop shopping for the agriculture community to all relevant laws/ regulations

8. Reevaluation

best practices identified prior to survey

- utilization of reviews from other countries in the assessment and decision making processes for older pesticides
- assess older products in related chemical groupings at the same time
- assess older products within a certain time period

additional best practices identified in survey

- priorizing reevaluations on a risk-management basis taking into consideration age of data, gaps in data, science issues relating to the chemical, any problems arising during use, etc.
- providing for public involvement in the priority selection process and provision of information/data to be considered in the reevaluation process
- allowing flexibility in the reevaluation process with either formal consideration of all aspects or focus on specific issues of concern
- involving users at an early stage so that they can encourage/cooperate with registrants to produce a timely response
- conducting media briefings about review outcomes
- conducting seminars to explain what actions are expected following a reevaluation
- approving product for five years only and the importer must send in a new submission within these 5 years to get the product reevaluated

9. Management and Administration

best practices identified prior to survey

- establishing effective ways to maintain quality staff members and expertise
- finding effective ways to keep staff motivated and trained
- establishing effective measures of performance, efficiency gains
- establishing effective ways to maintain quality while improving productivity
- establishing and maintaining effective international cooperation

additional best practices identified in survey

- ensuring ISO accreditation across whole organization (ISO 9002)
- requiring all managers to demonstrate productivity gains in their area
- having well defined corporate and operational plans
- standardizing review practices between review groups
- ensuring all staff have the possibility each year to participate in internal or external courses
- having academic staff works in groups where scientific problems are discussed
- achieving accreditation as an ‘Investor in People’ (IPP) organisation, awarded after a through examination of an organization’s training and development policies and practices
- establishing a Training and Development Group to define and develop an overall training and development strategy and ensure continual IPP accreditation
- ensuring that each member of staff has their own training and development plan which is regularly updated
- ensuring each individual’s work objectives are designed to be challenging but achievable with a clearly defined target dates for completion

- using an IT tracking system to measure the progress of all fee based registration applications, so that problems can be identified at an early stage and remedial action/resource re-deployment put in place swiftly
- ensuring that a process of continual improvement operates throughout the Agency through regular assessment of current performance
- encouraging performance of scientific regulatory assessments in interdisciplinary groups to reduce the requirement for coordination between groups, speed up decisions, and make work more rewarding to staff through a better understanding of the whole range of issues involved in a decision, and of how their individual contribution figures within the whole
- supporting work at alternate sites such as home offices to reduce stress from commuting, provide time to work independently with minimal interruptions, and help meet other needs

10. Research Permits

best practices identified prior to survey

- requiring only notification (i.e. no permit) for some research activities (related to level of risk)

additional best practices identified in survey

- research in approved facilities do not need individual permits
- certain government institutions do not require permits
- setting performance standards for approval of research permits
- research permits considered as priority submissions
- charging only administration fees for research permits
- permits needed only for placing products on market and for biological field trials outside of laboratories
- permits not needed for laboratory or green house test; small-scale tests on less than 10 terrestrial acres provided that food/feed is either destroyed or fed to experimental animals; small-scale tests on less than 1 surface water acre, provided that the food/feed is either destroyed or fed to experimental animals and treated waters cannot be used for recreational, irrigation, or drinking water purposes; animal treatments conducted only on experimental animals

11. Pre-Submission Consultation with Registrant or Applicant

best practices identified prior to survey

- ensuring that industry receives a consistent message on requirements, responsibilities and quality and format of data to be submitted
- discussion of potential regulatory questions to ensure adequate data submitted

additional best practices identified in survey

- arranging technical meetings with evaluators if science issue may be of concern
- providing single-window approach for industry enquiries
- sending newsletters to industry when amendments to requirements are made
- developing and publishing a guidebook on pesticide registration in co-operation with applicants

12. Other Steps / Other Approaches

best practices identified prior to survey

- improving processes and systems
- reengineering
- improving the management of Information Resources
- applying risk management principles

additional best practices identified in survey

- training staff in process reengineering techniques
- training staff in applying risk management to all aspects of their work
- providing immediate access to databases
- using Electronic Data Submission for evaluation
- enforcing Performance Standards through Database tracking system
- setting up regional registration authorities
- use of taxes to reduce use of pesticides and promote use of "safer" pesticides to reduce risk
- establishing a Strategic Management Group to oversee a series of work programmes designed to assess current practices and procedures and to investigate and implement improvements and change
- establishing a tracking system with the following key characteristics:
  - database resides on the Internet, so it is equally accessible both to agency staff and to outside inquirers
  - when a regulatory application is received, it is assigned a unique identifier and a unique password - the password is provided only to the submitter of the application, in the acknowledgement of receipt
  - at any time the submitter can then connect to the database over the Internet, provide the password, and find out the internal status of the pending action
  - a link is provided to e-mail so that a submitted with a question can write to the regulatory case manager, and the message is automatically captured for the case record
  - the case manager's response to e-mail inquiries is also automatically captured for the case record

Part 3. Best Practices - Rating the Best Practices

The third part asked each respondent to list the five "best practices" that have led to the largest gains in efficiency in their organization.

A summary of the each country's response to this part of the survey is provided in Annex 3.

A wide variety of responses were received. The following best practices appeared on more than one list:

- pre-submission consultation (3 countries)
- clearly defining data requirements (3 countries)
- data screening and preliminary review for deficiency to ensure quality (4 countries)
- sharing review reports and acceptance of data assessments from other countries (3 countries)

Part 4. Best Practices - Fees

The fourth part asked each respondent:

- to provide details on the specific services for which fees are charged;
- to indicate the main reasons for charging fees; and
- to comment on whether fees encourage efficient delivery of services and good submissions.

A summary of the each country's response to this part of the survey is provided in Annex 4 and additional information on fees charged for specific services can be found in Annex1.

Fees charged for specific services

Different countries collect money for services rendered in a variety of ways. The main ways are:

- a specific fee for a specific service such as assessment of mammalian toxicity;
- a combined fee for health assessment, environmental assessment and the establishment of MRLs;
- a yearly fee based entirely or partially on the previous year's sales; and
- a yearly set fee covering all services.

Main reasons for charging fees

Cost recovery for the services provided in the registration process, from the people and organizations receiving the services, is given as the main reason for charging fees. Several countries noted that the cost recovery is a government mandated function.

Some countries structure their fee schedule so as not to deter development of small volume products or products to fill niche markets. There is also a belief that fees help to discourage frivolous applications.

Do fees encourage efficient delivery of services and good submissions?

Three of the twelve responding countries did not feel that fees encourage efficient delivery of services and good submissions while eight felt that they did.

Of the countries responding in the negative, one felt that, with some exceptions, the fees are too low to encourage the companies to give the proper information while another saw no clear relationship between fees and the efficient delivery of services and good submissions.

Of the countries responding in the affirmative, several countries felt that high enough fees encourage the applicants to provide good information and the authority to deliver better services to the applicants. One country felt that fees coupled with effective business management had dramatically improved the efficient delivery of services but not always good submissions. Clear guidelines and requirements, industry education, penalties and direct liaison with company CEOs were viewed as more effective ways to encourage good submissions. Another country felt that fees require the establishment of performance standards and that performance standards enforce accountability from both parties. It was emphasized that the fee structure must be simple if the resources needed to institute a collection program are to be minimized.

Conclusions

OECD countries, as exemplified by those who participated in the survey, are focussed on improving the regulatory process for pesticides and are progressing to that goal through the implementation of an array of innovative and effective “best practices”.

This report has compiled many of these best practices and provides an indication of those best practices that have produced the largest gains in efficiency. The report also provides a tally of pesticide regulatory activities by country along with an indication of the legal obligations, the fees charged and the time frames established for their completion.

To obtain more information on the best practices activities in the countries participating in this survey, please see Annex 5 for contact names and addresses.

Annex 1
Who Does What

Activity	Carried out by:	Required by Law in:	Charge Fee in:	Comments	Countries' Comments:
Health Assessment					
Mammalian toxicity	12 / 12 countries	12 / 12 countries	12 / 12 countries	some countries have: - a specific fee for this service - combined fee for health, environmental assessment, establish MRLs - yearly fee based entirely or partly on previous year's sales - yearly set fee covering all services	A1, D1, F1, H1, J1, NZ1 & NZ2,N1, SL1, SW1, UK1, US1 & US2
Worker Exposure	12 / 12 countries	12 / 12 countries	12 / 12 countries	as above	A1, D1, F1 & F2, H1, J1, NZ1 & NZ2, N1, SW1, UK1, US1
Residues in Food	12 / 12 countries	11 / 12 countries - no response from Slovenia	11 / 12 countries - exception: Slovenia	as above	A1, D1, F1 & F3, H1, J1, NZ1 & NZ2, N1, SL2, SW1,UK1, US1
Environmental Assessment					
Animal Toxicity	12 / 12 countries	12 / 12 countries	12 / 12 countries	as above	A1, D1, F1, H1, J1, NZ1 & NZ2, N1, SL3, SW1, UK1, US1
Environmental Fate	12 / 12 countries	12 / 12 countries	12 / 12 countries	as above	A1, D1, F1, H1, J1, NZ1 & NZ2, N1, SL3, SW1, UK1, US1
Establish MRLs	11 / 12 countries - exception: Slovenia	11 / 12 countries - exception: Slovenia	10 / 12 countries - exceptions: Finland, Slovenia	as above	A1, D1, F4, H1, J1, NZ1 & NZ2, N1, SL4, SW1, UK1, US1

Activity	Carried out by:	Required by Law in:	Charge Fee in:	Comments	Countries' Comments:
Efficacy Assessment	9/12 countries - exceptions: New Zealand, Sweden (limited), US (limited)	11/12 countries - exception: New Zealand	9/12 countries - exceptions: Finland, New Zealand, US	as above	A1, D1, H2, J1, N1, SL5, SW1, IK1, US3
Establish Data Requirements	12 / 12 countries	8 / 12 countries - exceptions: Australia, New Zealand, US (but authorized) - no response: Denmark	4 / 12 countries - exceptions: Australia, Canada, New Zealand, Slovenia, UK - no response: Finland, Hungary, Japan	time frames: Australia - no response, Canada - variable, Denmark - no response, Finland - not defined, Hungary, Japan, New Zealand, Norway and Slovenia - no response, Sweden - as quickly as possible, UK - no response, US - differs by type and need	D1, J2, NZ3, N1, SL6, SW1 & SW2, US1
Screening / Checking / Sifting	12 / 12 countries	7 / 12 countries - exceptions: Australia, Japan, Slovenia, US - no response: Denmark	8 / 12 countries - exceptions: Australia, Finland, Japan, Slovenia	time frames: Australia - 1 month, Canada - 45 days, Denmark - 30 days, Finland - not defined, Hungary - 18 months, Japan - ~1 month, New Zealand - 10 days, Norway and Slovenia - no response, Sweden - as quickly as possible, UK - 22 weeks, US - 5 days	A2, D1, F5, H3, NZ1 & NZ2, N1, SW1 & SW2, UK2, US1 & US5
Review Process	12 / 12 countries	10 / 12 countries - exceptions: Japan, Slovenia	9 / 12 countries - exceptions: Australia, Slovenia - no response: Finland	time frames: Australia - 13 months, Canada - 12-18 months, Denmark - 2 years, Finland - 1-3 years, Hungary - included in 18 month period identified in *Screening* question above, Japan - within 18 months - decision making included in all processes from application to registration, New Zealand - 55 days for review process and 15 days for decision making, Norway - up to 2 years, Slovenia - 90 days, Sweden - as quickly as possible, U.K. - up to 53 weeks, U.S.A. - 12-18 months (reduced risk pesticides) but up to 3 years for others	D1, H4, J3, NZ1 & NZ2, N1, SW1 & SW2, UK1 & UK3, US1 & US6
Decision Making	12 / 12 countries	12 / 12 countries	9 / 12 countries - exception: Australia - no response: Norway, UK		C1, D1, H1, J3, NZ4, N1, SL7, SW1 & SW2, US1 & US6

Activity	Carried out by:	Required by Law in:	Charge Fee in:	Comments	Countries' Comments:
Public Consultation	8 / 12 countries - exceptions: Denmark, Hungary, Norway, Slovenia	4 / 12 countries - exceptions: Canada, Denmark, Finland, Hungary, Japan, Norway, Slovenia, Sweden	3 / 12 countries - exceptions: Australia, Canada, Denmark, Hungary, Japan, Norway, Slovenia, UK - no response: Finland	time frames: Australia - 1 month, Canada - 45 days, Finland and Japan - no response, New Zealand - 30 days, Sweden - as quickly as possible, UK - no response, US - 60 or 90 day comment periods for published proposals	C2, NZ 4, SL8, SW1 & SW2, US1 & US7 & US8
Policy (includes Regulatory Affairs and Communication)	10 / 12 countries - no response: Hungary, Slovenia	6 / 12 countries - exceptions: Australia, Finland - no response: Denmark, Hungary, Japan, Slovenia	3 / 12 countries - exceptions: Australia, Canada, Japan, New Zealand, UK - no response: Finland, Hungary, Norway, Slovenia	time frames: Australia, Canada, Denmark, Finland, Hungary, Japan - no response, New Zealand - none specified, Norway, Slovenia - no response, Sweden - as quickly as possible, UK - no response, US - varies based on type and need	A3, D1, SL9, SW1 & SW2, US 1 & US9
Compliance / Enforcement	10 / 12 countries - no response: Hungary, Slovenia	9 / 12 countries - no response: Finland, Hungary, Slovenia	4 / 12 countries - exceptions: Australia, Canada, Japan, US - no response: Finland, Hungary, Norway, Slovenia	time frames: Australia, Canada, Denmark, Finland, Hungary, Japan - no response, New Zealand - as required, Norway, Slovenia - no response, Sweden - as quickly as possible, UK - no response, US - varies	D1, NZ5, SW1 & SW2, UK1, US10
Reevaluation of Registered Pesticides	12 / 12 countries	9 / 12 countries - exceptions: Japan, New Zealand - no response: Slovenia	9 / 12 countries - exceptions: Australia, Canada, Japan	time frames: Australia - no response, Canada - not yet determined, Denmark - within 1 year, Finland - every 10 years, Hungary - not defined, Japan - no response, New Zealand - sent through review process as required, Norway - every fifth year, Slovenia - no response, Sweden - each 5th year (application handled within 9 months), UK - no response, US - varies	D1, F1, H5, NZ6, SL10, SW2, UK1, US1

Activity	Carried out by:	Required by Law in:	Charge Fee in:	Comments	Countries' Comments:
Management and Administration	11 / 12 countries - no response: Denmark	6 / 12 countries - exceptions: Australia, Japan - no response: Denmark, Finland, Slovenia, UK	3 / 12 countries - exceptions: Canada, Japan, Slovenia - no response: Denmark, Finland, Hungary, Norway, Sweden, UK	time frame: Australia, Canada, Denmark, Finland, Hungary, Japan, New Zealand, Norway, Slovenia - no response, Sweden - as quickly as possible, UK - no response, US - varies	A4, H6, NZ7, SW2, US1
Other Steps / Approaches	4 / 12 countries - Canada, New Zealand, UK, US	2 / 12 countries - Canada, New Zealand	2 / 12 countries - Canada, New Zealand	Canada - renewals (by December 31 of given year) and amendments (180 days) New Zealand - economic and related risk/benefits analysis, consultation with Maori (included in assessment times)	C3 & C4, NZ8 & NZ9 & NZ10, SL11
Research Permits	9 / 12 countries - exceptions: Japan, Norway - no response: Hungary	8 / 12 countries - exceptions: Japan, Norway, Sweden - no response: Hungary	7 / 12 countries - exception: Japan, Norway - no response: Finland, Hungary, US	time frames: Australia - no response, Canada - 90-180 days, Denmark - 2 months, Finland - 3 months, Hungary - no response, New Zealand - 40 days, Slovenia, Sweden, UK, US - no response	C5, D1 & D2, H7, NZ11, SL12, UK1, US11
Pre-submission Consultation	10 / 12 countries - exceptions: Norway, Sweden	2 / 12 countries - exceptions: Australia, Denmark, Japan, New Zealand, Norway, Slovenia, Sweden, US - no response: Finland, UK	3 /12 countries - exceptions: Australia, Canada, Japan, Norway, Slovenia, Sweden, US - no response: Finland, Hungary	time frames: Australia - no response, Canada - variable, Denmark, Finland, Hungary, Japan - no response, New Zealand - as required, Norway, Slovenia - no response, Sweden - no pre-submission consultation and therefore no fee, UK - no response, US - varies	D1, NZ12, SL 13, US12

Comments

Australia (A)	A1. Assessment of new a.i. and product carries a $20620 fee. A range of fees apply to other services. A2. Included in application fee. A3. Some publication are charged for. A4. Built into overall fees.
Canada (C)	C1. Captured in review fees C2. CATA only C3. Renewals C4. Amendments C5. Administration fee
Denmark (D)	D1. No fees, but an amount of 500,-DKK annually for each approved product, plus tax ranging from 3 % to 37 % according to product-type. D2. Permits should be granted within 2 months.
Finland (F)	F1. Application fee (when applying registration and re- registration) is 5000 FMK (~ 841 euros). Application fee is paid when the application is left. The fee covers part of screening and evaluation. There is a 3.5% fee (net sale minus VAT) of previous year's sales that covers other costs, for example health and environmental costs. F2. Quantitative model assessment only recently introduced for European monographs. F3. For national registrations, res. trials were performed by the authority. For EU registrations the notifier is responsible for producing the data and only in few cases there may be reason to request trials performed in Finland for climatic reasons. F4. Today only EU directives are implemented; there are no national MRLs. F5. Only a general fee of 5000 FMK is charged when the application is accepted for evaluation.
Hungary (H)	H1. Part of the registration fee. H2. Pre-registration fee. H3. The registration fee is divided between institutes involved in the registration procedure based on an agreement. H4. Started since, 1995, has not progressed much.

	H5. No time limitation H6. Need institutional development H7. Permit is required only for efficacy trials in the pre-registration period.
Japan (J)	J1. The fee is included in the registration fee. J2. Required by administrative regulations. J3. It includes all the processes from application to registration (ie. Review, Decision making, etc.). (235,900 yen for new end use product)
New Zealand (NZ)	NZ1. Varies depending on application type. The combined initial fee for health assessment, environmental assessment and establish MRLs are: Section 28 importation/manufacture not in containment NZ$6000 for low level consideration and NZ$20000 (initial fee) for high level considerations Section 31 importation into containment NZ$2500 Section 47 emergency approval NZ$10000 Above is the cost of Health Assessment (Mammalian toxicity, Worker Exposure, Residues in Food), Environmental Assessment (Animal toxicity, Environmental Fate), Establishing MRLs/Tolerances NZ2. Also add on additional fees for any cost incurred above these levels (for example staff time at $130 /hour, Authority or Nga Kaihautu at $130/hour and for external advisors and consultants at cost plus a 45% over head charge.) NOTE : All costs are exclusive of goods and services taxes (12.5%). these fees are being revised. NZ3. Data requirements to be stated in Guidance Material designed for applicants use. NZ4. Can vary depending on how many days for hearing of public hearing/consideration (eg. One day cost could be NZ$800/day fixed charge for the hearing, plus Member costs of NZ$2600/day and any consultant time costs). NZ5. Various fees as old system changes to new Hazardous Substances and New Organisms legislation Test Certifiers NZ$200, annual renewal fee of $80 Codes of Practice approvals NZ$1000 Other activities on a cost recovery basis as per staff costs above NZ6. Depends on who instigates the review; if us then cost borne by government, if industry/lobby group then costs borne by them NZ7. Additional costs for supplying application form of NZ $5/ copy and NZ$0.20/ page of attachments; Written advice as to whether a substance is hazardous or not (above OECD threshold effect levels) NZ$1000 NZ8. Economic and related benefits/risk analysis; Consultation with Maori in terms of culture and traditions with respect to ancestral lands, water sites, waahi tapu (sacred sites), valued flora and fauna and other taonga (treasures). NA9. Included in assessment times NZ10. Cost: Covered in assessment costs (including consultant/ Nga Kaihautu staff costs).

	NZ11. NZ$ 2500 for importation/ manufacture in containment approval NZ12. If application proceeds into the system, charge at NZ$130/hour for staff time during the pre submission consultation
Norway (N)	N1. We charge total fees for ca 1.3 mill US$ / year. This fee includes efficacy assessment and the whole review process
Slovenia (SL)	SL1. We assess the data, received from the applicants like- health- medical expert opinion. SL2. Monitoring on pesticide residues is carried out out in Slovenia following a Decree on National monitoring (O.J., No. 13/99), in which responsibilities and annual programmes concerning monitoring of foodstuffs on pesticide residues are laid down. SL3. Up to now, authorized institutes have charged about 1000 DEM for the complete environmental assessment. SL4. We follow international recommendations. No national procedure for MRL-setting exists and new legislation is recently adopted or in preparation. SL5. Biological trials are required (if done in Slovenia the fee is between 1000 and 3000 DEM). SL6. Up to now, it was recommended to implement the requirements from EU Directive 91/ 414/ EEC. SL7. Two step procedure: 1. Hazard identification, classification, labelling and packaging by Commission on Ministry of Health, National Chemicals Bureau. 2. Approval from the Committee on Ministry of Agriculture. SL8. Informal consultation with NGOs, applicants. SL9. Educational activities required by the law on Plant Protection Products (O. J. No.11/01). SL10. Reevaluation in the case of new data of reclassification process. SL11. Ministry of Agriculture, Forest and Food issues licences for testing samples. SL12. Personal meetings and telephone advices during official hours.
Sweden (S)	SW1. The fee is charged for the whole assessment 10 000 SEK for application 30 000 SEK for each new active substance Annual fee 2.6% of sales value for each product Min: 2000 SEK Max: 200 000 SEK SW2. No time frame, but as quick as possible

UK	UK1. Pesticides Safety Directorate charges two types of fees - application fees and an annual sales levy: Application fees An application fee is charged for each submission processed, for a total fee revenue of £1,465,000 for PSD. PSD Fees are set by application category and range from a fee of £285 (administrative and off-label) for a simple submission to £61,200 (new active ingredient, major new uses) for the most complex. Typical application fees are shown below: New active ingredients and major new uses with full or substantial data packages £ 61,200 Applications with changes in formulation, require efficacy review and one or more other assessment (fee is an average; amount varies according to the number of additional assessments required) £ 2,350 Application requiring efficacy input or supplied with limited new data (Fast Category) £ 630 Applications (experimental) with minor changes in formulation, and require efficacy review and/or another assessment procedure (Experimental Approval Category) - fee is average, as above £ 2,350 Technical or administrative changes, including instructions for use and safety information on labels where limited technical data is supplied (Administrative and Off Label Categories) £ 285 Own use import £ 290 Research permits £ 1,650 Committee stream - sift £ 4,500 Annual Sales Levy This is based on UK sales of approved products and used to cover the balance of cost of evaluation activities (the UK re-evaluation programme for existing pesticides is funded from this levy) and monitoring. In 1996/97, the sales levy was set at 1.2% of sales and generated £6.54 million of revenue. The initial rate was set in the mid 1980s at 0.42% of sales and increased each year until it reached 1.85% in 1992/93. Since that time, the rate has been reduced on an annual basis due to: higher industry sales, increased PSD efficiency and tighter cost control. The present rate (1998-99) is equivalent to 1.11% of sales. The annual sales levy also recovers the costs of residue and usage monitoring activities, and wildlife incident investigation; this amounted to £2.8 m (1996-97). At present, industry pays 60% of the costs associated with residue monitoring, 100% of the costs of usage monitoring, and 80% of the costs of gathering and verifying information related to reported wildlife incidents - the Government pays the costs of investigation if warranted. UK2. New active substance UK3 Up to 53 weeks depending un application stream.
US	US1. The U.S. charges: (1) annual registration maintenance fees, raising about $16M annually, used for reregistration and (2) tolerance fees for individual tolerance petitions, raising about $3 M annually. The tolerance fee rule is being revised to increase fees to cover full cost. OPP briefly had registration fees in 1988, put but these were set aside by statute in 1988. OPP also raised over $30 M in the late 1980s from reregistration fees on active ingredients.

	Since fees are used for the full range of reregistration and tolerance activity, we are unable to allocate the various types of fees to the various types of scientific assessment and risk management decisions, and have responded (yes) to the activities below benefiting from fees US2. With respect to pesticides, EPA administers two statutes prescribing levels of protection: - The Federal Food, Drug and Cosmetic Act (FFDCA) **and** the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The general standards of "Reasonable certainty of no harm" and " No unreasonable adverse effects" are established by statute. These general standards are further interpreted and implemented administratively by EPA. Since the laws require risk assessment as part of reasonable interpretation, we have responded yes. US3. But only for public health pesticides US4. Differs by type and need US5. OPP checks basic formatting requirements are met. Timeframe for this completeness check is 5 days. US6. Differs by type, eg. Reduced risk pesticides may be approved in 12 - 18 months where others may take three years for decision on a new active. US7. For published proposals, normally 60 or 90 days comment periods are provided US8. There are also various consultation processes, such as Pesticide Program Dialogue Committee and Tolerance Reassessment Advisory Committee US9. Varies based on type and need
	US10. But penalties may be assessed US11. Experimental Use Permits US12. Finding these useful to work through initial questions and establish priorities

Annex 2
Successful Approaches

ESTABLISH DATA REQUIREMENTS

COUNTRY	BEST PRACTICE(S)
examples provided in the survey	-- Harmonizing data requirements with other countries so industry need generate data only once for use in many countries -- Improving the communication of data requirements to industry -- Providing comprehensive training of industry on data requirements -- Utilizing tiered data requirements -- Requiring less data for lower risk products -- Providing exemptions for certain types of products from registration, amendment or approval
AUSTRALIA	-- Work closely with industry in defining data requirements -- Conduct industry training seminars Australia - wide -- Formally gazette changes in requirements -- Requirements available in form of manuals and increasingly in electronic format -- Data requirements are " flexible" if supported by sound scientific argument
CANADA	-- Consider reviews from other countries as part of decision making in-house
DENMARK	-- Harmonizing data requirements with other countries according to Directive 91/414 with includes tiered data requirements -- Publishing "Framework for the Assessment of Plant Protection Products"
FINLAND	-- EU directive concerning plant protection products including data requirements is adopted in a form of directive of the Ministry of Agriculture -- Need for further specific data requirements for indoor use pesticides (non-PPPs) and repellents will be streamlined with the planned data requirements in the biocide directive -- Data requirements for microbials will be harmonized with EU (and OECD) countries; so far less data for such products have been requested -- Concerning minor use products there might be less data requirements (case by case under consideration)
HUNGARY	-- Harmonizing data requirements (we agree with OECD's approaches) -- Setting up minimum data requirements. -- Harmonising the data requirements for generic products concerning data protection. -- Requiring less data for lower risk products -- Utilizing information
JAPAN	-- harmonizing data requirements with other countries to avoid duplication of data generation -- utilizing tiered data requirements in some area (ie. Microbial Pesticides) -- exemption from data requirement for lower risk products (ie. Pheromones) -- At present, Japan is trying to establish and improve the following areas - taking into account other countries' decisions - further harmonizing data requirements with other countries so industry need generate data only once for use in many countries
NEW ZEALAND	-- Consider and utilize the acceptance of decisions of other countries, where appropriate -- Publish requirements stated in our Guidance Notes -- Utilizing tiered data requirements depends on type of hazardous substance approval sought by the applicant (eg. Research in containment approvals, biological pesticides) -- Provide exemptions for certain types of products from registration, amendment or approval Not under HSNO legislation but will be introduced under the new pesticides legislation (Agricultural Compounds and Veterinary Medicines Act

NORWAY	-- We have a Nordic format on submission schemes, with established data requirements -- We now use OECD-guidelines for data requirements -- We also accept EU format -- For inerts in the formulations we have additional requirements to EU, especially on ecotoxicological effects -- For microbiological plant protection products, we also have own requirements -- We are working on an approval system with data requirements for insects, mites and nematodes (etc) used in pest management -- We are now also looking at 'pesticides' used in "ecological agriculture" and the possible need for regulation of them -- We have recently developed and introduced requirements of " internal control systems" for importers of pesticides and hope that will improve the quality of their submissions
SLOVENIA	-- Harmonizing data requirements with the EU directive 91/414/EEC.
SWEDEN	– EU harmonized data requirements have been established in Directive 91/414/EEC. Exceptions may be accepted but only if the applicant gives acceptable justifications -- We use evaluations from other countries and evaluate ourselves only in specific situations -- We use efficacy data as far as possible from other countries with similar climate -- In registrations according to (ast 8) we use the RMS's (91/414/EEG) risk assessment as far as possible -- We inform the companies to present their documentation in a way so it is easy to see if it is a problematic product/substance or not -- Less data is required for lower risk products depending on the intended use -- Exemptions for registration for products for which the potential for risk reduction within a regulation work is low -- Reregistration at the same time for pesticides with time for pesticides with similar area of use, to facilitate substitution.
UNITED KINGDOM	EC harmonized data requirements have been established in Directive 91/414/EEC. This provides for a uniform set of requirements for both active substances and plant protection products within the 15 Member States of the European Community. In this context the Directive and associated legislation also provides for harmonized decision making between Member States. The data requirements, as a result of being established on an EC wide basis, are widely known within industry. Within the requirements a tiered approach has been adopted for certain areas, this is most barded in relation to biologicals
UNITED STATES	The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires EPA to publish specific data requirements to support the registration of a pesticide [3(c)2(a)]. To do this, in 1984 EPA established extensive data requirements through the rule making process in CFR Part 158. Parallel to this rule, EPA has published guidelines explaining how to fulfill these requirements. Part 158 is organized by scientific discipline, such as product chemistry, toxicology, and environmental fate,; requirements are set out in tabular form for broad categories of use, for instance, outdoor crop uses, indoor uses, and so forth. The tables which present the requirements also contain footnotes and other guidance to explain when a study is required. For instance, in product chemistry, some requirements apply only if the pesticide to be registered is a liquid; a footnote makes this point clear. Footnotes also can indicate when the result of one study make another study or studies necessary. Although determining which requirements apply to which uses can involve very complex issues of policy and science, these determinations are generally fairly straight forward. FIFRA [3(c)2(b)] authorizes the Agency to require submission of data that are not specified elsewhere, that is, in part 158. This provision of FIFRA recognizes that the state of the science can outpace the state of the regulations. Part 158 is currently being revised to include new studies which have become generally required over the years. New data requirements do not emerge from a vacuum. EPA has complicated processes whereby review and comment are sought from the regulated community, the scientific community, and the public. In addition to formally requiring studies that have become generally required, the revised Part 158 will delete outdated requirements, clarify other requirements, and make changes to increase the clarity of the requirements. OOP has promulgated regulations at 40 CFR Part 158 which set forth data requirements for pesticide registration. These data requirements incorporate test guidelines, which describe the methods of testing pesticides, by reference. Test guidelines have been issued in the several disciplines in which pesticides are evaluated. OOP has test guidelines for human health and domestic animals, ecotoxicity (toxicity to fish and wildlife), environmental fate (behaviour of pesticides in the environment), physical chemistry (basic chemical properties, product chemistry (chemical identity, and purity/impurity profiles of pesticides), worker, applicator and bystander exposure, and residue chemistry (methods of determining the nature and magnitude of residues of agricultural pesticides on crops). OOP is an active participant in the OECD test guideline program which harmonizes test methods for use by all OECD member nations. The goal is to develop a harmonized approach to testing so that industry can provide one test for each given property in such a way as to satisfy data requirements in all OECD nations. As a participant in this OECD program, OOP may initiate activity and draft test guidelines to be harmonized, or actively comment on test guidelines drafted by other OECD member nations. OOP has much to contribute to this process since it is a world leader in test guidelines for pesticides. Under NAFTA, OOP is currently developing harmonized test guidelines for measurement of behaviour of pesticides under actual field conditions, effects of pesticides on terrestrial plants, and levels of pesticides to which humans (workers, applicators or bystanders) may be exposed under typical use conditions. Ultimately, the guidelines developed under NAFTA are expected to be submitted to OECD for wider harmonization.

	Under OECD, OOP is harmonizing test requirements for antimicrobial pesticides and for biological pesticides (microbial and biochemical pest control agents). OOP's data requirements for these classes of pesticides is tiered, allowing industry to submit only the most essential data for registration. Review of first tier data may indicate that additional tests are needed to assess the risks - in which case additional data would be submitted. The story for agricultural pesticides is a little different. Most OECD countries have already developed their own regulatory data requirements for these pesticides. Although requirements for agricultural pesticides in OECD are similar, they may differ in certain areas, especially environmental fate and risk to fish and other wildlife. OECD sponsors fora for harmonizing approaches to risk assessment which will enable OECD countries to share methods and determine if greater harmonization of test requirements and test guideline might be feasible. The OECD harmonized dossier and monograph project should provide templates for countries to share approaches to risk assessment and review of pesticides.

SCREENING / CHECKING / SIFTING

COUNTRY	BEST PRACTICE(S)
examples provided in the survey	-- Screening submissions before they enter the review process to ensure that all the elements required for review are present -- Rejection of low or poor quality submissions
AUSTRALIA	-- Collegiate approach to perceiving all areas of evaluation (toxicology, environmental, residues, etc) -- "3 strikes" policy. Industry given 3 attempts to get it right (with assistance). Application rejected if submission then not acceptable
CANADA	-- Provide applicants with screening criteria and encourage them to complete screens (templates) for inclusion with their submissions
DENMARK	-- All applications are screened to ensure that all the elements required for review are present and poor quality submissions are rejected.
FINLAND	-- The submissions are screened before the plan for detailed examination programme is made; however the screening is very technical in nature. -- At first the applicant is asked to complete his/her application. -- If substantial documents are missing the submission is rejected.
HUNGARY	-- Screening submitted data to ensure that all the elements required for review are present is working, but it is not always effective. The real quality of data, and their whole aspects could not be checked at this stage -- Using computerised proper data and -- Using computerised screening methods would accelerate the procedure
JAPAN	-- Ensuring that industry receives a consistent message on requirements, responsibilities and quality and format of data to be submitted. -- Discussion of potential regulatory questions to ensure smooth evaluation. -- Screening submissions before they enter the review process to ensure that all the elements required for review are present -- Rejection of low or poor quality submissions
NEW ZEALAND	-- Informal pre-application screening process (unlimited time) and verification process once application is received (10 days) to ensure the application is sufficient (either stop application or it proceeds to notification). -- The verification process allows for insufficient applications to be stopped -- Also t ell applicants the exact requirements and what their package deficiencies are.
NORWAY	-- We have established a routine for screening submissions before entering the review process, and have also the opportunity to administrative rejection of poor quality submissions
SLOVENIA	-- Rejection of low or poor quality submissions (rarely).
SWEDEN	A quick survey is done of the completeness of the documentation prior to starting assessment. First the applicant is asked to complete given rather short time frame. If substantial documents are missing the application is rejected.
UNITED KINGDOM	EC harmonized guidance for the implementation of processes and procedures under Directive 91/414/EEC includes quality and completeness checking of regulatory dossiers. For new active substances a rapporteur Member State's conclusions on completeness are open to formal consideration and comment by all other Member States. At national level, the UK also has more detailed sifting procedures for new active substances. Of the new substance applications accepted for sifting, one or two per year will fail to gain approval (including those applications withdrawn by industry) In addition, for the product related applications based on existing registered active substances (Technical Secretariat applications0 there is a formal internal sifting process. This checks submitted application for completeness and compliance with national requirements. The purpose of this sift is also to allocate the application, on the basis of complexity, to one of a number of evaluation streams. These streams are given below: Normal stream - applications, involving the evaluation of data Fast stream - applications which do not usually involve the evaluation of data but do require technical consideration Parallel imports Off-label - applications to allow minor use of an approved product, for which there is no appropriate label recommendation

	Mutual recognition and emergency approvals - as required under 91/414/EEC Experimental approvals Poor quality or non compliant applications are rejected and detailed reasons for the rejection are communicated back to the applicant In 1997, 20 percent of Technical Secretariat applications received were rejected as incomplete at the sifting stage. Of those applications accepted by the sift, 5 percent failed to gain approval.
UNITED STATES	In 1986 OPP issued Pesticide Registration notice 86-5. This notice established formatting requirements for all data submitted to OPP in support of regulatory actions. Studies which do not meet these requirements s are not accepted for further processing until their formatting deficience are corrected by the data submitted. One of the primary purpose of PR Notice 86-5 is to establish unambiguously at the time of submission the nature and scope of any claims of confidentiality for all submitted data. All data for which a claim of confidentiality is made must be clearly identified and separated form releasable data. Format Requirements - Transmittal document (name & address of submitting company, name and telephone number of contact person, regulatory action being supported, date of submission, list of all studies being submitted) - Three copies of each study - Title page (author, title, date, guideline requirements, performing laboratory, project ID number, total number of pages). - Pagination (no missing pages) - Legibility (black ink, white paper) - Standard sized paper (8.5 x 11 in.) - English translation of any non-English text - Explicit, specific and fully supported Confidential Business Information (CBI) claims (40 CFR 158.33) must appear on page two of each study. - Good Laboratory Practice (GLP) compliance statements (40 CFR 158.34) must appear on page four of each applicable study (chronic/subchronic feeding, oncogenicity, teratogenicity, neurotoxicity, reproduction) Benefits - Reduced in-processing costs - Errors such as missing or illegible pages, foreign language text, etc. are caught up front and do not hold up the review process - Studies are auditable by Office of Enforcement and Compliance Assurance (OECA) due to presence of GLP compliance statement - Segregation of CBI facilitates response to FOIA requests.

REVIEW PROCESS

COUNTRY	BEST PRACTICE(S)
examples provided in the survey	-- Sharing reviews with other countries -- Harmonized evaluation reporting formats among countries -- Designing the organizational structure and relationships between organizational units to optimize work flow -- Maintaining effective tracking systems to ensure efficient scheduling and work flow -- Rationalizing the timing of review streams (example: review the efficacy and chemistry data first, then the rest of the data if needed) -- Arresting review until company provides required/additional data -- Maintaining a formal process for establishing work priorities -- Contracting out tasks -- Use of electronic information -- Use of expert systems such as models, computerized decision support systems
AUSTRALIA	-- ISO accreditation across whole organization (ISO 9002) -- Peer review of assessments
CANADA	-- Use of electronic submissions (pilot) -- Established International Joint Review and Work Sharing Practices -- Use of comprehensive Data Summaries prepared by applicant to streamline review process
DENMARK	-- Reviews are shared with the Nordic countries and we use the reviews of other OECD countries -- In the framework of 91/414 are established monographs -- The organizational structure has recently been redesigned to optimize work flow -- The Agency is contracting out some evaluations of dossiers of active ingredients -- Use of standard spreadsheets to perform environmental risk assessment -- Use of "Framework for the assessment of plant protection products"
FINLAND	-- Reviews from other countries are used as a supportive material or even in lieu. -- There is a harmonized reporting format between EU- (and OECD) countries (and also an order reporting format between the Nordic countries). -- There is an annual plan for Pesticide Board. -- There are also contracts for toxicological reviews. The intention is to concentrate the evaluations among different authorities. -- The models of surface/ground water and also worker exposure are not yet in every day use but the intention is to use them more in the future.
HUNGARY	-- Uniform principles in review process -- Applying different models -- Planning and optimizing work flow -- Complex approach or review process -- Delay review until company provides additional data --Training of experts -- Increasing number of specialists -- Using electronic information
JAPAN	-- Designing the organizational structure and relationships among other ministries optimize work flow
NEW ZEALAND	None
NORWAY	-- We look for recent reviews in Nordic, EU or OECD countries and also participate in Nordic and OECD exchange of reports. We are planning a hospitant period in another country for writing OECD-reports. Until now, our reports have been written in the Nordic format. -- We use electronic information if available -- We wait with evaluation until the submission is completed and we have received an efficiency report/statement. -- The new submissions enter a queue for evaluation when the submission is accepted. The reviews are done every 5th year (if not very important new data appears), but we are now organizing our "review cycles" into themes eg.: insecticides used in greenhouses; insecticides for field crops; herbicides for cereals, etc. We prepare reviews of preparation with same sort of use to a common meeting of the Pesticide Board.

	This makes the use of our substitution principle more efficient, and saves us lots of work in comparing preparations. The submission of a new preparation may not be evaluated in accordance with this system, but will be fitted in as soon as possible. -- In the review process three people work in parallel, one on each of the areas agronomy, toxicology and ecotoxicology. We can consult external experts to get advice on single aspects in the evaluation -- We make use of computerized models to evaluate human exposure and environmental fate.
SLOVENIA	-- Rationalizing the timing of review proces.
SWEDEN	-- If there are considerable data gaps, the product is rejected. If it is minor lack of data the company has to submit missing data before we review the pesticide – We use criteria for clearly unwanted properties and particularly serious properties -- We have recently started to use expert systems such as models, computerized decision support systems.
UNITED KINGDOM	-- In the context of Directive 91/414/EEC and also the exchange of review reports within the OECD framework -- In the context of Directive 91/414/EEC and also within the OECD -- PSD has a programme of flexible staff deployment and training to provide a reservoir of staff expertise that can be called upon as required by changes in workloads and priorities Secondments between specialist and generalist areas coupled with appropriate training opportunities are actively encouraged In addition, multi disciplinary teams have been formed and mandated to work exclusively on certain application types in response to particular peaks in workload. -- These teams have been freed from other work commitments and empowered to devise new work practises and procedures to improve processing times while maintaining overall quality. -- Developed as a short term expedient in response to work peaks they have led to improvements in the processes and performance. -- Resources have been devoted to the development of IT based monitoring and tracking processes to ensure that work flows can be effectively managed. The output provides forecasts of progress against established targets that are considered at regular operational management and planning meetings -- This process is adopted for some national reviews with evaluation of the human health/consumer exposure information first, followed by environmental fate/ecotox. if needed. -- This is practised for new substances and existing product applications. -- This is a regular consideration at internal management and planning meetings. Each month a management meeting is held between all PSD Heads of Branches working on registrations, and each quarter a Planning Meeting considers medium term priorities. These meetings are supplemented by separate monthly meetings of specialist evaluators and co-ordinating Branches. The IT tracking and monitoring information feeds into these meetings. -- Scientific evaluation work is contracted out during work peaks to meet performance targets Risk assessment is not contracted out. Significant effort has been devoted to identifying a pool of competent external evaluators and set quality criteria are applied -- A range of IT tools are provided to improve performance and efficiency. As mentioned previously an IT based monitoring and tracking system is used to ensure that work flows can be effectively managed Additional IT system include : A registration database A data protection/ archiving/ study location database Computer based modelling systems for environmental fate/operator exposure/consumer exposure Development of an Intranet providing information tools for the review process
UNITED STATES	SOURCE [Jay Ellenberger and Rick Keigwin - PRIORITY SCHEME] Sharing reviews with other countries - EPA created a prioritization scheme that accelerates reviews for certain types of pesticides, including (1) methyl bromide alternative, (2) safer pesticides and (30 minor uses - PR Notice 97 - 2 (**attached and under http://www.epa.gov/opppmsd1/PR_Notices/pr97-2.html**) - in certain areas, (biopesticides and antimicrobial), created inter-disciplinary divisions that handle both risk assessment and use management for these classes of pesticides - created standing meetings between use assessors and use managers to discuss problematic issue and reach resolution early in the review process - created dedicated branches in HED only responsible for registration actions - publish an annual work plant to notify the public and other interested parties what the Agency will be reviewing in the next year.

DECISION MAKING

COUNTRY	BEST PRACTICE(S)
examples provided in the survey	-- Ensuring the consistent application of data requirements and policies -- Formalizing and maintaining a process of internal peer review -- Periodically subjecting regulatory decisions to external peer reviews -- Establishing performance standards and measuring performance against these standards
AUSTRALIA	None
CANADA	-- External expert consultation when necessary
DENMARK	-- An internal peer - review is carried out for all approvals of new active substances and reevaluations
FINLAND	-- Decision making in Pesticide Board involves many different authorities to ensure that all related views are taken into consideration. -- Quality performance standards are under discussion and under development.
HUNGARY	-- Applying uniform methods in decision making -- Establishing standards -- Collaborate with international organisations and establish international practice -- Harmonizing decision making in regional level -- Recognise each other practice and authorisation
JAPAN	-- Formalizing and maintaining a process of internal peer review -- Periodically subjecting regulatory decisions to external peer reviews
NEW ZEALAND	-- The decision is publicly notified and the reasoning for the decision (and controls) is required to be stated.
NORWAY	-- After the agronomist, toxicologist and ecotoxicologist have made their draft reports, each part is quality checked by their respective "subject groups" and by a coordinating person, before an internal peer review meeting. -- We also have an additional peer review meeting with the head of the Pesticide Board when the joint review report is completed, and shortly before the meeting of the Pesticide Board. They advise us in our decision which we (Norwegian Agricultural Inspection service) then make shortly after the meeting. We inform the registrant by letter.
SLOVENIA	-- Two step procedure.
SWEDEN	– We take the need into consideration -- We use comparative assessment to avoid pesticides with higher risk than necessary -- We refer to other relevant authorities for consultation

UNITED KINGDOM	-- Using the UK Committee system and internal checks and balances on both quality and decision making. See also the role of PSD's Ownership Board as detailed in Policy, etc) -- Annual scientific quality audit conducted externally by the Chairman of the independent ACP. See also the role of PSD's Ownership Board as detailed in Policy, etc. --Annual performance targets are set by ministers for PSD. Targets for the approval processes are set in terms of number of applications to be handled and standards for processing times. PSD's performance against these targets is published in its Annual Report. See also the role of PSD's Ownership Board as detailed in (Policy, etc. **Decision making within the UK:** The processes detailed below are also designed to ensure consistency of decision making. The independent Advisory Committee on Pesticides (ACP) is often asked to consider guidance and policy documents when new policies and practices are to be implemented and the Committee system itself acts as a check on quality and consistency of decision making (see below). PSD's scientific quality and the quality of its Policy advice are also subject to an annual audit. The scientific quality audit is conducted externally by the Chairman of the independent ACP. PSD deals with applications via four procedures, each of which is associated with a distinct level of decision making: - the Committee procedure - the Departmental procedure - the PSD Technical Secretariat procedure, and - the PSD Administrative procedure The Committee procedure -- Inter-Departmental Secretariat (IDA) and Advisory Committee on Pesticides (ACP) -- is used for new active substances seeking first commercial level of approval in the UK, or for those active substances seeking Annex I listing or provisional authorization under 91/414/EEC. It is also used for reviews of existing active substances. In this process, five government Departments (Agriculture, Health, Environment, Scotland and Wales) and the ACP are involved in the decision making. The ACP is an independent committee consisting of experts from a wide range of medical, environmental and scientific specialists. It advises all the regulatory ministries on possible legislation, on the granting amendment, or revocation of individual pesticide approvals, an on the scientific aspects of pesticides regulation more generally. Members are independent of both Government and the agrochemical industry. Lay members have also been appointed to the ACP. Ministers cannot approve a pesticide for use in the UK unless they are satisfied, based on the ACP's recommendation with respect to effectiveness and safety, that the product will not present unacceptable risks to people, farm and domestic animals, or the environment. The Committee also advises Ministers on which approved products should be reviewed. The Departmental procedure is used for the first experimental approval to be assessed for a new active substance, or for major changes in the composition or usage of a previously approved product. In this case, all five Departments (as above) are again involved in the decision making. Evaluation documents drafted by specialists are subject to internal peer review. For larger submissions this involves an additional formal 'authors meeting'. These steps are planned into the timetable and established procedures for the Committee system described above. The PSD Technical Secretariat procedure is used for most additional uses of products with active substances previously considered by the Committee or Departmental procedures, eg. Changes in composition, new sources of active substances, changes in packing, approval of identical products, etc. In these cases, decisions are made by PSD Secretariat and sent to the Health and Safety Executive (HSE part of the Department of the Environment, Transport and the Regions) for agreement. The PSD Administrative Secretariat procedure is used for minor amendments to products, eg. changes to company or product name, minor packaging changes, etc. which do not require scientific scrutiny. In these cases, decisions making power is allocated to lower levels in PSD.
	Decision making within Europe: This concerns new active substances and reviews of existing active substances conducted under directive 91/414/EEC. Where the UK acts as 'rapporteur' and is responsible for the production of a monograph - the above committee procedures are applied before submission of UK monographs into Europe. The Committee system is also used, as appropriate, for the consideration of work from other Member States to allow a UK position to be formulated. Within European system there is an additional process for decision making. EC monographs are peer reviewed by specialists drawn from across the EC at the European community Co-ordination meetings (ECCO meetings). The results of the peer review, and developing decisions, are then considered by the Working Group (Evaluation) and Working Group (Legislation) - all member States are represented at these Working groups. Final decisions are considered at the Standing committee on Plant Health prior to their finalization. Provision for independent scientific scrutiny is also built into this system in the form of the Scientific Committee on Plants which provides scientific advice to the European commission. The UK actively participates in this decision making process.
UNITED STATES	SOURCE: [Amy Rispin] OPP has always ensured consistent application of data requirements and policies by striving for a transparent process and implementing quality control and consistency provisions within the program. Part 158 is the regulation containing our data requirements. This was subjected to peer review and extensive public comment prior to its publication in 1984. Both part 158 and data review policies are public. The program also has published, after peer review, Standard Evaluation Procedures (SEPs) addressing key test requirements. In the course of reregistration, additional policies about acceptance criteria for studies were also published. The science divisions use a

	system of technical and review teams to ensure consistency of reviews from one reviewer to another. Major policy initiatives are also often written up as Standard Operating Procedures, available to the public Agency policies on risk assessment are also used by OPP scientists in their decision making. Pesticide scientists participate in Agency - wide groups developing these policies. Internal peer review is a way of ensuring highest quality of science decision making for major risk endpoints such as carcinogenicity. Internal peer review teams also provide fora for critiquing typical decisions such as assignment of Reference Doses (RfD) to agricultural chemicals. Peer review team decisions are documented. Teams are standing teams with scientists assigned to keep them running properly. OPP will also invite specialists from the Agency to join pesticide specialists in certain team decisions. FIFRA requires that the scientific component of all major science decisions and regulations be peer reviewed. In addition, the program subjects generic science policies affecting its decision making in determining risk to external peer review. The FIFRA SAP (Scientific Advisory Panel) is a standing panel which provides per review for the program. Both OPP and te Agency have well documented peer review procedures.

PUBLIC CONSULTATION

COUNTRY	BEST PRACTICE(S)
examples provided in the survey	-- Establishing stakeholder advisory mechanisms -- Implementing a process for public consultation on regulatory decisions -- Implementing a process for communication of regulatory decisions -- Responding promptly and effectively to stakeholder/industry inquiries (information request, consumer complaints) -- Measuring client satisfaction and monitoring changes in needs or expectations
AUSTRALIA	-- Have in place a range of consultative committees -- Public comment sought on decisions -- Public can have input to re-registration program -- Organization must meet client service standards as outlined in "Customer Service Charter" -- Public can have access to assessment reports -- Surveys of client satisfaction undertaken
CANADA	None
DENMARK	-- The public has access to regulatory decisions upon request (response within 10 days). -- A council of experts (including representative for all stakeholders and NGO's) has been set up by the minister to act as advisors to the Agency regarding pesticides. The council gives their opinion before new laws or statutory orders are decided.
FINLAND	-- Does not exist very much; mostly answering to requests and questions of concerned consumers.
HUNGARY	-- Huge backlog in this area Making first steps in building up links with non governmental organizations Opening to public spheres Improving public relations Monitoring changes in needs and measuring client satisfaction
JAPAN	-- As appropriate, each personnel gives advice to consultation case by case basis. There is no specific mechanism or process on public consultation.
NEW ZEALAND	None
NORWAY	-- The importer may object to our decision by letter within 3 weeks after receiving our letter We then see if they can provide any new relevant information than can alter our decision or if we have done a mistake in our decision-making and make a new decision, or keep the first. If they still do not accept our decision they may appeal to the ministry of Agriculture who make the final decision -- We have regularly meetings with "Pesticide Importer's Association" to inform them of our work and of new politics to come -- We have public hearings for new regulatory restrictions/laws. -- Written inquiries from the public 9 importers, users, consumers, general public) shall be responded within 3 weeks. We also answer on the telephone. -- We measure client/public satisfaction with our work.
SLOVENIA	-- Informal consultation with NGO's.
SWEDEN	– The public has access to decisions – The public has access to most of the documentation on request – The applicant is informed by letter before the decision if the decision will be negative for the applicant - The applicant can object to the decision within a stated time
UNITED KINGDOM	-- PSD has recently completed a 'stakeholder identification survey'. This was established to ensure that the Agency could correctly identify customers/stakeholders and their needs. It was aimed at determining a strategy to ensure that PSD works to meet identified needs. In particular the objectives were to: -- improve understanding of consumer/environmental interest groups and their concerns -- improve understanding and needs of other parts of Government with an interest in pesticide matters -- improve knowledge of agriculture, horticulture, and agrochemical industries -- Open letters to industry and interested parties and formal consultation procedures

	-- Newsletters, 'The Pesticides Monitor', and other reports; PSD website; enquiries dealt with by External Relations Branch; access to underlying data. -- PSD has published a Customer Service Statement which is available free of charge (this is regularly updated and revised 'Charter Standard' under the Government's Citizens Charter initiative is in preparation). This Statement/Standard sets out what stakeholders can expect of PSD: standards for staff; and for response times to correspondence and enquiries. A formal complaints system is also provided. -- PSD has a commitment to conduct regular 'Customer Satisfaction Surveys' (two have been conducted to date, in 1995 and 1997, and a further survey is planned for 1999). PSD is committed to respond positively to the results of these studies. PSD has an established range of measures for consultation and is committed to ensuring the maximum possible access to information on pesticides. Open letters are used to communicate information to both industry and 'interested parties' (a database of mail out addresses is maintained). Interested parties comprise several hundred organizations and individuals with an interest in pesticides, these include: pressure groups; environmental /consumer organizations; food retailing /marketing organizations; Trades unions/worker organizations; trade press; advisory /extension workers; and local councils/local government. Specific formal consultation letters are also used to invite comments on particular policy /regulatory developments. Information and announcements are also disseminated by newsletters and Press Releases 9 sent to national news organisations, newspapers, etc.). Information is also posted on the PSD website. An official publication 'The Pesticides Monitor' 9 formally the 'Pesticides Register') is published monthly and contains details of regulatory developments and results of decision making as well as a comprehensive listing of approvals issues, withdrawn/revoked (& reason for actions) and details of conditions of approval amended. Information on regulatory science and specific decisions may be communicated by the above processes but other mechanisms are available for consultation/providing information for those interested in the basis of specific decisions. PSD maintains an External Relations Branch dealing with responses to specific requests for information. The ACP publishes an Annual Report of its activities and recommendations. Evaluation documents giving the ACP's safety assessment of active ingredients are also available as priced publications. Viewing of data underlying evaluations is possible by special appointment.
UNITED STATES	SOURCE: [Lindsay Moose] The pesticide regulatory process in the United States is heavily dependent on public participation and consultation. In many cases, this is done formally through publishing proposed rules and regulations for public comment. In addition, the Environmental Protection Agency (EPA) occasionally uses opportunities such as workshops or public meetings to solicit input. <u>Best Practices</u> -- Under the Administrative Procedures Act (APA) EPA publishes proposed rules and regulations in the <u>Federal Register</u> for public comment; -- The APA requires a 30 day comment period, but the Agency typically allows for 60 days; -- For major rules or regulations, EPA will grant a longer period and may extend the comment period if there is a heavy volume of comments' -- Once a rule or regulation is made final, it is once again published in the <u>Federal Register</u> ; -- For communication with the regulated community, the Agency publishes Pesticide Registration Notices (PR Notices); -- PR Notices are occasionally published for public comment before being made final; -- For stakeholder participation, EPA may establish an advisory committee under various authorities, including the national Advisory Council for Environmental -- Policy and Technology or the Federal Insecticide Fungicide and Rodenticide Act (FIFRA); -- The Pesticide Program Dialogue Committee - a varied group of stakeholders that provide ongoing advise about issues facing the Office of Pesticide Programs; -- The Tolerance Reassessment Advisory Committee - established to assist the Agency in implementation of the Food Quality Protection Act; -- The Scientific Advisory Panel - established under FIFRA to provide EPA with independent advise on issues of a scientific nature -- EPA has implemented a tracking system for correspondence which allows for quick response to inquiries from outside sources; -- This system assigns firm due dates to incoming correspondence, tracks the correspondence according to the source (eg. The U.S. Congress), and fosters the maintenance of archives for completed correspondence; -- The Divisions of the Pesticide Program who have the most public interaction (eg. The Registration division and Antimicrobial division) have established an ombudsman who acts as a contact for non-Agency parties; -- EPA's Office of Pesticide Programs has worked hard to develop its Internet home page and the large number of visits to the site indicates that it is being utilized by people seeking general information about the program and its activities; -- The Program maintains an active communications effort, centered in its Field and External Affairs Division, which produces fact sheets, brochures, and general information documents for the public; -- There is also an extensive collection of educational materials on topics such as worker protection and endangered species produced and distributed by the Program;

	-- The Office of Pesticide Programs also prepares an Annual Report which lays out the accomplishments of the previous year and provides contacts for the pesticide program -- In preparation for the release of new regulations or decisions, EPA Communication Staff prepare and implements detail communication plans addressing target groups, key messages, necessary communication materials, press tools, and notification time frames. -- To provide consumers and stakeholders with easy access to information on pesticide safety and accurate labelling in use. EPA fund a toll free hot line staff by experts on regulatory pest management and safety issues.

POLICY (including regulatory affairs) and Communication

COUNTRY	BEST PRACTICE(S)
examples provided in the survey	-- Ensure policy development is well informed by science issues -- Ensure policy development is well informed by international direction -- Development of communication plans on specific issues to ensure appropriate coverage -- Provide easy, free access to information through toll free call-line and frequently updated and comprehensive website -- Ensure outreach and visibility by senior management to stakeholders -- Ensure good contact and timely sharing of information with other governments, both foreign and provincial/territorial, as well as other federal departments
AUSTRALIA	*1. Informal agreements with US EPA , and Canadian PMRA (For timely sharing of information with other governments)
CANADA	-- Ensure policy development is well informed by international direction - harmonization where applicable -- Preparation of Q &As on "hot"issues -- Ensure good contact and timely sharing of information with other governments, both foreign and provincial/territorial, as well as other federal departments: International - eg. Joint Review Policy FQPA involvement Federal - Interdepartmental committees - MOUs => information sharing
DENMARK	-- The Agency has an information strategy -- It provides access to information eg. Through websites and the publishing of extensive reports from a research programme. -- Newsletters to stakeholders -- Policy - discussions in the "Advisory council" for pesticides
FINLAND	-- We take into account the actual need and use. -- Scientific consultation in toxicological issue with toxicological scientific experts and in environmental issue s with ecotoxicologic scientific experts. -- There will be pesticide website on Internet hopefully during this year. -- Different reports and information for example: monitoring control or surveillance report to EU quarterly or once a year, depending on which report is concerned.
HUNGARY	-- Developing long term strategies Pointing out the role of plant protection policy -- Ensure good contact with the European Union and other governments, foreign departments, international organisations -- Development of comprehensive website -- Establish international principles of GPR (Good Pesticide Registration Practice)
JAPAN	-- Ensure good contact and timely sharing of information with prefectural governments
NEW ZEALAND	-- Access to information through website and through a register (of all decisions made)..
NORWAY	-- We take part in the preparation of action plan (199-2002) for reduced risk of plant protection products in Norway, in Committee under the Ministry of agriculture. -- We seek to be well informed about policies in EU and OECD, but cooperation with the Nordic countries is the most important to us when making a policy. We try to implement new knowledge in our decision-making as soon as it appears. -- For new accomplishments, we arrange press meetings or send a press statement as part of the process. -- We establish communication plans to ensure that registrants and users of pesticides are well informed when working on regulatory issue. -- We have regular meetings with out ministry ans some other departments, and with regulators int eh other Nordic countries. Less frequent we meet representatives from some EU countries and the Baltic states. -- We have defined press contacts within the section, and established routines for press contact. We also have a "Section for

	information" -- We have established a continuously upgraded website: (http://www.landbrukstilsynet.no) -- There is established a 24h telephone service where agriculture workers can get advice on when and how to apply pesticides in the different crops through out season. It is continuously updated.
SLOVENIA	-- Ensure good contact and timely sharing of information within ministries for agriculture and health.
SWEDEN	– We take the need and comparative assessment into consideration – We have the information on decisions and risk reduction activities through website – We have newsletters – We have long term strategies for risk reduction *i.e.* semi risk index since 1986
UNITED KINGDOM	-- PSD is serviced by the Ministry of Agriculture's Press Office -- See details in Section public consultation -- Informal consultation with all stakeholders, including regular or ad hoc meetings, as circumstances demand -- High profile in Europe and formal contacts with other EC Member States in the context of Directive 91/414/EEC. Good contacts/information exchange with OECD countries and others. PSD was established as an Executive Agency in 1993 as part of a Government-wide "Next Steps" initiative and , as such, is able to deliver specified services without the day to day involvement of the Ministry. Unlike most Agencies which work within a policy and resources framework set by the Minister, PSK - as a national centre of excellence on pesticide knowledge and advice - is also responsible for advising ministers on the development, implementation and enforcement of pesticide-related policy and associated national and European community legislation. (the costs of this activity are met by MAFF through an appropriation paid to the PSD.) As PSD is based on a single site there is direct day to day contact between those working in the various scientific disciplines an those engaged in policy work. Close consultation is maintained to ensure that policy development is under pinned & informed by science issues. The MAFF Ownership Board oversees the work of the directorate,. It meets on a quarterly basis to review PSD's activities and assess its performance against targets, and is the formal link between the PSD concerned Ministers and the Ministry. In 1998 - 99, the Board consisted of: the Deputy Secretary (MAFF); the Head of the Environment Group (MAFF); the Head of the Financial Policy Division (MAFF); Head of Food Contaminants Division (MAFF); the Chair of the Advisory Committee on Pesticides; an independent advisor in the area of health care; the Chief Executive Officer of PSD; and the head of the Agency Ownership Unit (MAFF).
UNITED STATES	SOURCE: [William Jordan and Charles Franklin] Process - Public participation on policy -- notice and comments -- scientific peer review -- coordination with other agencies (state, federal, international0 -- general stakeholders outreach -- directed stakeholders outreach (eg. working with medical community) -- standard publications (eg. annual reports and Rainbow Book) Science Policy - Guidance on 152/Public 158 -- testing guidelines -- SEPs -- risk assessment guidelines -- PR notices / labelling manual Regulatory Decision - respond in a timely fashion to inquiries from the public on status of policy decisions and our resources for more information. General Education: Target key stakeholders and affected groups with information on Agency policies and developments

COMPLIANCE /ENFORCEMENT

COUNTRY	BEST PRACTICE(S)
examples provided in the survey	-- Work closely with other jurisdictions in the country to ensure no duplication / overlap in compliance activities -- Work closely with other jurisdictions in the country to prevent misuse -- Maintain an early response system for pesticide misuse issues -- Implementation of measures that are intermediate between educational initiative and criminal prosecutions such as Administrative monetary Penalties -- Co-operate / contract with other inspection agencies to cross-utilize resources and enhance coverage of activities -- Plan inspection programs but maintain a pool of resources to respond to issues as they occur -- Provide regions with resources to deal with emerging issue at that level -- Communicate with communicators and extension workers at provincial/territorial levels so that messages get out effectively to targeted group
AUSTRALIA	-- Work with Customs, State Agencies -- Compliance activity prioritized on risk-management basis Engage trained investigators -- A State Responsibility
CANADA	-- Maintain an early response system for pesticide misuse issues - Inspection Programs in place -- Re-evaluate and update inspection programs regularly -- Identify new areas/ programs for inspection - ongoing
DENMARK	-- Inspection programs are carried out for different groups of pesticides each year. Banned products are especially surveyed. -- Close cooperation with the Food Administration is carried out in connection with the control of pesticide residues in food. -- Cooperation takes place with the customs authorities. -- Cooperation with extension officers.
FINLAND	-- EU co-ordinates medicines and biocides. -- Poisoning Info Centre maintains all the important information of pesticides (early response system). -- Agricultural Centres provide provincial/territorial help/assistance.
HUNGARY	-- Co-operation with other inspection agencies. -- Monitor the proper use of plant protection products. Penalties in case of misuse. Education programs at different levels to prevent misuse. Improving the control of pesticides use. -- Surveying quality and environmental fate of plant protection products after registration.
JAPAN	-- Work closely with other jurisdictions (ie. prefectures) in the country to ensure no duplication (overlap) in compliance activities -- Work closely with other jurisdictions in the country to prevent misuse -- Implementation of measure both educational initiatives and criminal prosecution such as Administrative Monetary Penalties -- Communicate with communicators and extension workers at provincial/territorial levels so that messages get out effectively to targeted group. -- Inspection for retailer and manufacturer of pesticide.
NEW ZEALAND	-- Respond to complaints from public users and proprietors of pesticides.
NORWAY	-- We approve importers and shops for pesticides -- Professional users of pesticides must be certified. To be certified., the use of pesticides must be relevant to their profession. Only certified persons are allowed to buy pesticides for professional use -- We have a program for control of pesticide-residues over MRL - can be withdrawn Imported foodstuffs can also be withdrawn, and if repeated exceeds, the import of that crop form the producer/state can be stopped permanently. -- We also have the possibility to withdraw the certificate from farmers who shows repeated indefensible use of pesticides -- Users of pesticides must write an application journal of pesticide use. -- We have a program for control of pesticides in drinking-water and in the environment (rivers, ground water etc) -- We inspect rooms for storage of pesticides

	-- We communicate with local agricultural administrations and with local agricultural associations -- We have contact with the Labour-Inspectorate and the Custom Service.
SLOVENIA	-- Cooperation with inspectorates.
SWEDEN	– The main responsibility for compliance lies with local and regional authorities. Their activity varies with importance of agriculture activity in the region. – Education of the farmers
UNITED KINGDOM	-- Early response to reported cases that may result form the misuse or abuse of pesticides. Prosecution can follow. Incidents arising from approved use can inform the approvals process. Wildlife Incident Investigation Scheme looks into cases where wildlife may have been put at risk through the use of pesticides. -- PSD liaises regularly with enforcement bodies. The enforcement bodies liaise locally on a case by case basis to ensure no duplication of effort Enforcement is generally the responsibility of Local Authorities and the Health and Safety Executive. Prosecutions for pesticide infringements can lead to fines. Enforcement officers can serve legal notices requiring remedial action to be taken. Breach of notice can lead to prosecution. -- Ensures consistent approach between pesticide formulations. Queries resolved with manufacturers: enforcement action can follow if queries not resolved. Residues may indicate evidence of misuse and prosecution can follow. PSD annual programme of monitoring pesticide formulations placed on the market. Analysis programme of residues in crops and produce. -- Aim to communicate legal requirements and best practices to users and others PSD and Government Departments produce Codes or Practice and other guidance documents for users and others eg. 'Code of Practice for the safe use of pesticides on farms and holdings'
UNITED STATES	SOURCE: [Phyllis Flaherty - OECA/OC] -- Achieving and maintaining a high level of compliance with environmental laws and compliance with environmental laws and regulations is one of the most important goals of federal an state environmental agencies and is an essential prerequisite to realizing the benefits of the regulatory programs. -- To do this in the most efficient way, EPA has combined it enforcement resources at headquarters into one office so that comprehensive enforcement policies/overall strategies for environmental compliance can be developed rather than 5 or 7 separate offices developing strategies/policies. This allows resources to be shifted more readily as problems arise -- For pesticides, the agency runs a very decentralized program with States having primary inspection / enforcement role and EPA Regional Offices being responsible for the day to day work of negotiating state specific agreements and overseeing them. In most cases, there are separate agreements for each status. Headquarters provides guidance/policies/strategies. Cooperative enforcement agreement guidance sets for the requirements for a core program and identifies 1 or 2 federal priorities for States and allows states to also set their priorities based on what their pesticide priorities are. More recently the Agency has moved to performance based partnerships/grants with the States to allow them more flexibility to deal with emerging issues. There is a base program for each statute that they are required to meet and then flexibility to develop a state program focussed on their environmental issues with tradeoffs allowed between programs -- To ensure the 10 Regional offices are operating effectively, specific offices, including the Office of Enforcement and Compliance Assurance, has formal Memorandum of Agreements with each office to define expectations and set priorities on a 2 year basis. This system allows for Regions to identify their own pressing environmental priorities without abandoning core work that needs to continue. -- As part of an effective partnership with States, we have clear oversight criteria, specified in advance, for EPA to assess good compliance and enforcement program performance; clear criteria for direct Federal enforcement ; and adequate State reporting. -- There are some inspection functions that remain Federal functions such as laboratory audits and Good laboratory Practice regulations. These involve oversight of laboratories that develop data submitted to EPA as part of its risk based decision making. -- Important components to a decentralized program is to establish and provide consistent policy and procedures. Ways of doing this have included National Compliance Strategies, Inspector Training Modules/ Courses, Question and Answer Documents, and Program Manager Training. Quality Management Plans are also required for all grant/ EPA activities -- Re: arising issues, the pesticide law provides for significant misuse incidents to be referred in writing to the states with Regions tracking time lines for inspection and enforcement, as well as the adequacy of the action

	-- In addition to inspections and enforcement work, EPA recognizes the important role of compliance assistance in ensuring a high compliance rate. Therefore, EPA also provides information to the regulated community and public to ensure a greater understanding of what is required. Part of this effort includes the National Agriculture Compliance Assistance Center. The Center provides one stop shopping for the agriculture community where they can access information on all of EPA's laws/regulations impacting the agriculture community. Part of their Best Practices include a fax back system, toll free number, and Internet access through their home page. The Center coordinates with the US Dept of Agriculture with much of the material for dissemination being developed by Universities.

REEVALUATION

COUNTRY	BEST PRACTICE(S)
examples provided in the survey	-- Utilization of reviews from other countries in the assessment and decision making processes for older pesticides -- Assess older products in related chemical groupings at the same time -- Assess older products within a certain time period
AUSTRALIA	-- Reevaluations prioritized on a risk-management basis taking into consideration age of data, gaps in data, science issues relating to the chemical, any problems arising during use, etc. -- Public can have input to priority selection process -- Public can provide information/data to be considered in reevaluation process -- Reevaluation can be very formal ie. All aspects are considered or focussed on specific issues of concern -- Attempt to align services with work of other countries or international organizations -- Involve users at an early stage so that they can encourage/cooperate with registrants to produce a timely response -- Conduct media briefings about review outcomes -- Conduct seminars to explain what actions are expected following a reevaluation
CANADA	None
DENMARK	-- Older products are assessed when the approvals expire. Reviews from Nordic countries and OECD countries are used in the assessment procedure -- All products with the same active ingredient expires a the same time. -- A reevaluation process is also carried out in the EU in the framework of 91/414
FINLAND	-- Same as review process. -- Time period is 10 years -- Sometimes during the evaluation similar uses are grouped; for example products meant for potatoes or growth regulators etc.
HUNGARY	-- Our reevaluation program is far behind our expectation. Need international co-operation. Sharing work load. Dividing different fields of examinations . Institutional background should be developed.
JAPAN	We don't reevaluate older pesticides so far except the case that major concern occurs, and we do reevaluate on a case by case basis. Now we are planning to: Assess older products periodically Assess older products within a certain time period
NEW ZEALAND	-- Existing substances must be transferred to the new HSNO control system within 5 years of the commencement of the Act. This transfer process can signal substances that need to undergo a reassessment process.
NORWAY	-- Products get approval for five years and the importer must send in a new submission within these 5 years to get the product reevaluated. -- We use reviews from other countries as part of our reviewing process. We also have our own documentation from the producers. We also look to national policy, and our control programs for food and water. We hold old evaluations up against new data requirements -- We assess older (and new) preparations with related chemical groups or similar use at the same time for better comparison for the substitution principle.
SLOVENIA	None
SWEDEN	– Sweden participates in the EU harmonized evaluation scheme for pesticides. By Swedish law an approval can only last 5-10 years and the product has then to be reregistered. Reregistration work depends on how problematic a substance is and if alternatives have appeared on the market – We assess products with mainly the same area of use at the same time

UNITED KINGDOM	-- In the context of Directive 91/414/EEC the UK participates in the harmonized EC programme for re-evaluation of older pesticides. -- This has been a consideration within the re-evaluation programme. Under the UK programme the recent decision to review those compounds with anticholinesterase activity exemplifies this approach, allowing consideration of aggregate and cumulative exposures to a group with common end points -- Both the UK and EC time frames for the re-evaluation of older pesticides. Progress towards achieving the originally anticipated time frames has been slower than anticipated. However, as stated in Section 3 9review process), annual performance targets are set by ministers for PSD. These targets include re-evaluation work, defining the number of re-evaluation tasks and projects to be completed within the given year. PSD's performance against these targets is published annually. **UK review programme:** the UK routine programme for the re-evaluation of older pesticides was announced by Ministers in March 1989. Before that time the ACP had conducted some reviews on an ad-hoc basis following a particular concern that needed to be addressed. The UK re-evaluation programme initially dealt with active ingredients originally cleared for agricultural use before 31 December 1965 and which had not been reviewed since, and those originally cleared for non-agricultural uses in 1976. The first candidates for reevaluation were, in broad terms, those active ingredients which had been approved the longest and were the most widely used. In November 1990 it was announced that the programme was to be extended to the 269 active ingredients approved before 1981. Five priority lists were published for review. Measures were taken to integrate the routine UK re-evaluation programme with the EC programme (see below0 from 1994 onwards. However in May 1998 Ministers announced that the UK re-evaluation programme was to be reinvigorated starting with comprehensive reviews of anticholinesterase compounds. In addition to the routine programme, special reviews have continued in the UK as a result of specific concerns being raised about an active ingredient or product. An obligation is placed on all approval holders to submit potentially adverse data and several 'special' reviews have been initiated following such submissions.
	EC review programme: The UK participates in the ongoing programme of re-evaluation of existing active substances conducted under Directive 91/414/EEC.
UNITED STATES	SOURCE: [Jay Ellenberger] The US has not used to any significant extent the reviews from other countries to reassess older pesticides. Because of legislative changes in 1988 USEPA required industry to submit a significant number of new studies for older pesticides, necessitating USEPA's review and reliance on these studies for its reassessments. Additionally, the enactment in 1996 of FQPA required the USEPA to reassess older pesticides according to new scientific standards which further limited its reliance on other countries' reviews. For its reassessment of tolerances of older pesticides, the USEPA is grouping pesticides by common modes of toxicity as required by FQPA. Organophosphates are the first group under reassessment which are to be followed by carbamates, organochlorines and probable carcinogens. The USEPA is reassessing older pesticides and their tolerances under time frames as specified by FIFRA and FQPA. While FIFRA (1988) required the reassessment of all older pesticides (those initially registered prior to 1984) by 1998, FQPA imposed two new reassessment time periods 1) all tolerances by 2006, with interim due dates of 1999 and 2002, and 2) a new 15 year cycle reassessment period of all pesticides 9 beginning date to be determined)

MANAGEMENT AND ADMINISTRATION

COUNTRY	BEST PRACTICE(S)
examples provided in the survey	-- Effective ways to measure performance, efficiency gains -- Effective ways to maintain quality while improving productivity -- Effective international cooperation
AUSTRALIA	-- Organisation is accredited to ISO 9002 -- All managers report performance monthly -- All managers required to demonstrate productivity gains in their area -- Productivity widely publicised -- All staff have access to training; development awards; study leave; opportunities for farm and industry visits -- Formal Human Resource Development Plan -- Attempting to expose more product evaluators to international cooperation work -- Organisation managed by CEO reporting to Board of Management (6 weekly meetings) -- Well defined Corporate and Operational Plan -- Individual performance assessment for all staff linked to salary advancement
CANADA	-- Commitment to staff training -- Effective ways to measure performance, efficiency gains - Set Performance Standards -- Effective ways to maintain quality while improving productivity - Standardize review practices between review groups -- Effective international cooperation - Joint Review / Workshare experiences
DENMARK	-- All staff have the possibility each year to participate 2 weeks in internal or external courses -- Academic staff works in groups where scientific problems are discussed -- Each year the division makes a “Budget” on how much time has been used. -- For a long time nordic cooperation has taken place and assessments from OECD countries are also used.
FINLAND	-- We are trying to utilize the international cooperation -- The problem in certain sectors for staff are the contracts of definite duration. These contracts are not very motivating in your work. -- There is possibility for additional education but because there is deficiency of staff and everybody is busy at work there is actually no time for education. -- One other problem is that the management and administration of pesticides in Finland is scattered between different administration offices.
HUNGARY	-- Increasing the number of expertise in the registration area. Maintain quality staff -- Set up independent registration institute in the long run. -- Improving the communication between institutes participating in registration procedure Improving productivity -- Effective international cooperation
JAPAN	-- We have short-term training program (from 1 week to 6 months) in the area of toxicology analysis and so on at other institute in order to maintain: quality staff members and expertise and to keep staff motivated, trained.
NEW ZEALAND	-- Utilise expert external assessors on contract. -- Have contingency planning for when experts may leave.
NORWAY	-- Keep high competence by regular updating with seminars courses, international meetings, good availability of books and international journals. Have defined 4 weeks a year to updating. --Opportunity to take corses at universities etc. while in job (with compensation requirements). Broad training program for leaders -- Make the staff aware of each one’s importance and responsibility in the organization through a training program -- Follow up of the personal action plan that comes of this. -- Possibility of staff to participate in interdisciplinary working groups and other projects to give varied work and new challenges -- Organize reviews into projects with a bonus if the effectiveness as been as required. -- Good routines for training of new staff members -- Maintain a good social environment.
SLOVENIA	-- Education of staff and experts.

SWEDEN	-- Our staff members are kept motivated through for example, risk reduction programmes which started 1986, e.g. Reductions of used amounts of active substances by half, risk reduction exceeding reduction of amounts, cooperation with other Swedish authorities and the farmers association -- To reach the goals within the time frame we have been forced to work more effective than earlier -- We have a discussion going on with other Nordic countries and share work as far as possible -- We have the cooperation in EU and also OECD – We are developing the competence that the individuals and the organization need
UNITED KINGDOM	-- PSD has achieved accreditation as an 'Investor in People' (IPP) organisation - this is an externally assessed accreditation which is awarded after a through examination of an organization's training and development policies and practices. The award is subject to regular independent external re-assessment to ensure standards are maintained. Internally -- PSD has established a Training and Development Group to define and develop an overall training and development strategy - this Group also ensures that PSD's standards are maintained to ensure continual IPP accreditation. -- The requirements for IPP accreditation provide a framework for staff training and development. Each member of staff has their own training and development plan which is regularly appraised and updated. A large range of training and development opportunities are available - secondments, development programmes, courses, an internal seminar programme and a training & development newsletter. There is an overall training officer with contact points in each branch of PSD. In 1999 a formal staff attitudes survey is also planned to ensure that the Agency remains responsive and informed about staff motivation. -- Each year overall targets are established for the agency. Staff have a normal annual appraisal (Annual Staff Report) to assess their overall performance. Within this Annual Report te overall aims and targets of the Agency are 'cascaded down; into an individual's work objectives. Work objectives are designed to be challenging but achievable and are clearly defined with target dates for completion. Work objectives are regularly updated throughout the year to take account of new tasks and jobs to be done and changes in priority. Annual performance is assessed against theses objectives. PSD also operates a system of performance related pay with more rapid pay progression for good performers. (The overall system is operated with a high degree of scrutiny to ensure objective, impartial and consistent assessment of an individual's performance and formal appeals procedures are built into the process.) -- An application tracking IT system is used to measure the progress of all fee based registration applications 9 mentioned in Section 3). This allows management to identify /monitor progress towards performance targets. Based on this information problems can be identified at an early stage and remedial action/resource re-deployment put in place swiftly. The system generates regular reports 9 usually monthly of progress. -- Higher level efficiency gains are considered as part of the annual financial reporting process and further consideration is being given to determining efficacy indicators for the organisation as a whole. -- See Strategic Management Group work (Section 10) and work on Benchmarking (in the Extra Section) - the participation in the Benchmarking exercise is seen as a key activity for PSD and an example of best practice to identify and develop the effectiveness and efficacy of the Agency as a whole. -- See POLICY Section PSD management is conscious of the importance of ensuring that a process of continual improvement operates throughout the Agency. Under the Strategic Management Group (see Section 10) work programmes are being led on: - training and development (see above) - communications (internal and external) - operational efficiency/ Benchmarking (see below) PSD is participating in the Public Sector Benchmarking Project. The Benchmarking Project is designed to permit a structured assessment of current performance. It is anticipated that the results of this process will form the basis for further consideration of PSD's work practices and organisational structure to ensure that resources and output are optimized. As background to this process - the Efficiency & Effectiveness Group of the Government Cabinet Office has been running the UK Public Sector Benchmarking Project since April 1996. The project is designed to help public sector bodies improve their performance through conducting self-assessments against the European Foundation for Quality Management's Business Excellence Model (BEM). There are nine elements within the BEM. These are split into Enabler criteria - that is, how an organisation achieve things and Results criteria - that is, what an organization achieves. The BEM is a framework for self-assessment, for an organisation to look honestly at its own achievements. It is a way of co-ordinating an organization's activities and focussing them on improving performance. It is based on the idea that an organization can achieve better performance by involving all of their people in continuous improvement of their processes.

	Self-assessment is the process s of systematically reviewing: what has been achieved; opportunities for further improvement; and the links between what is done and performance targets. The concept of self-assessment against a model of excellence was developed over time and adopted in Europe in 1988 by the European Foundation for Quality Management (EFQM), which with the help of many organizations, developed the UK/European model for total Quality Management 9 now the BEM). PSD is participating in Benchmarking ans using the process to provide a coherent framework to assess the Agency's operations, to help identify strengths and areas for improvement, and to highlight where further effort is required. It is anticipated that involvement will also provide an opportunity to share best practice more systematically with participating organisations with both public an private sectors.
UNITED STATES	SOURCE:[John Carley] -- Perform scientific regulatory assessments in interdisciplinary groups. OPP's recent reorganization was characterized by a broad shift from the previous structure of discrete organizations defined by the disciplinary specialities of their members toward a general pattern of multi disciplinary groups, capable of resolving most issues within a single organization. This has significantly reduced the requirement for coordination between groups, sped decisions, and made work more rewarding to staff, who get a much better understanding of the whole range of issues involved in a decision, and of how their individual contribution figures within the whole. -- Support work at alternate sites Many members of OPP now perform their duties as home offices at least some of the time. For the employees this reduces stress from commuting, provides time to work independently with minimal interruptions, and helps them meet other needs. The Agency typically provides computer and necessary software, and supports the cost of communication, so that the employ can be as productive and effective from the alternate workplace as they are in the office. When thoughtfully administered, this program benefits the Agency, the employees, and all their customers.

OTHER STEPS / OTHER APPROACHES

COUNTRY	BEST PRACTICE(S)
examples provided in the survey	-- Improving processes and systems -- Reengineering -- Improving the management of Information Resources -- Application of risk management principles
AUSTRALIA	-- Regular reviews of internal processes -- Train staff in process reengineering techniques -- rain staff in applying risk management to all aspects of their work -- ISO 9002 has provision for external audits, corrective actions and complaints handling -- Immediate access to databases
CANADA	-- Piloting Electronic Data Submission in usable format for evaluation -- Enforcing Performance Standards through Database tracking system -- Standardizing review processes between science groups involved in decision-making -- Enhancement of infrastructure to support management of material ongoing
DENMARK	None
FINLAND	None
HUNGARY	-- Setting up regional registration authorities. -- Using computerized models to help effective evaluation and decision making. -- Improving a registration database of registration authorities.
JAPAN	None
NEW ZEALAND	-- Regular upgrading of the databases and registrations; -- Establishment of protocols, guidance notes and codes of practice for data requirements, complying with regulatory controls and assessment principles.
NORWAY	-- Differentiated the tax from standard dose/ square area, weighted for health and environmental effects, to reduce use of pesticides and promote use of “safer” pesticides to reduce risk.
SLOVENIA	-- On April 1999 a new Act on Chemicals was adopted and on February 2001 the new Act on Plant Protection Products was adopted. -- A whole system of registration of PPP is under reconstruction.
SWEDEN	– We have on-going development of our work to get more effective – The staff can be educated in important areas
UNITED KINGDOM	-- See MANAGEMENT AND ADMINISTRATION for details of programmes also relevant to process/system improvement and reengineering. PSD established a Strategic Management Group (SMG) in 1998 to oversee a series of work programmes designed to assess current practices and procedures; to investigate and implement improvements and change. Under the SMG staff from across the Agency have shown a willingness and commitment to work actively on programmes to improve effectiveness in four main areas: - improving communication - staff development - operational efficiency - identification of stakeholders and their needs The activities of the Strategic management Group are given in more detail in Section 10 on management and administration In addition to the IT tools identified in Section 4 9 the review process0 PSD operates a work recording database. Each employee inputs, on a weekly basis, a record of their time spend against a range of activity codes (to the nearest 0.5 hr period). This allows time spent on tasks to be identified (down the level of individual registration applications) .. This information is used in calculating fees and charges and as an information tool for refining processes and resource planning / identification o resource requirements.

UNITED STATES	SOURCE:[John Carley] -- Tracking regulatory actions / responding to status inquiries. Although it has not been fully implemented, the California Department of Pesticide Regulation has designed a new tracking system with the following key characteristics: -- The database resides on the Internet, so it is equally accessible both to agency staff and to outside inquirers. -- When a regulatory application is received, it is assigned a unique identifier and a unique password. The password is provided only to the submitter of the application, in the acknowledgement of receipt. -- At any time the submitted can then connect to the database over the Internet, provide the password, and find out the internal status of the pending action -- A link is provided to e-mail so that a submitted with a question can write to the regulatory case manager, and the message is automatically captured for the case record. -- The case manager's response to e-mail inquiries is also automatically captured for the case record. This scheme is expected to greatly reduce the number of telephone inquiries and other interruptions of the case managers, improve timeliness and accuracy of responses to status inquiries, and improve completeness and accuracy of the record of correspondence between applicants and the agency. This approach was so appealing to the regulated community that they offered to fund and develop the system jointly.

RESEARCH PERMITS

COUNTRY	BEST PRACTICE(S)
examples provided in the survey	-- Requiring only notification (i.e. no permit) for some research activities (related to level of risk)
AUSTRALIA	-- Research in approved facilities do not need individual permits -- Looking at accrediting certain research organisations, companies, etc, so that they do not need a permit
CANADA	-- Set Performance Standards New TGAI (180 days) New Use for Registered TGAI (90 days) -- Considered - Priority submissions -- Charged administration fees only -- Research Permit Guidelines Established
DENMARK	-- Certain Government institutions do not require permits -- Other require permits but permits are given only for 20 ha and on a very limited amount of information and with nearly no evaluation.
FINLAND	-- There is application for trials/tests with pesticides -- The applicant sends the application to Plant Production Inspection Centre which decides to give or not to give the permit to conduct the trials. PPIC informs Pesticide Board of these applications
HUNGARY	-- Permits needed only for placing plant protection products on the market. -- Permits needed for biological field trials outside of laboratories (GMO's need special regulation).
JAPAN	None
NEW ZEALAND	-- Have Approvals for Research in Containment (40 days) with minimal data requirements.
NORWAY	-- We evaluate the use (consumes) of crops used in research with pesticides.
SLOVENIA	-- Ministry of Agrucilture issues licenses for testing samples for progress or research.
SWEDEN	-- We intend to leave out research activities from our regulation system and only notify them.
UNITED KINGDOM	Directive 91/414/EEC requires that research and development involving the release into the environment of a plant protection product which is not approved for the use in question, may only be carried out after an experimental permit or approval has been granted. In the UK there are 4 levels of experimental approval: - Administrative (where certain conditions eg. disposal of crops can be met) - Extrapolated (from UK or other EC Member State approvals - Consumer-assessed 9 certain conditions apply eg. maximum area to be treated0 - Fully assessed
UNITED STATES	SOURCE: [Rick Keigwin, RD] Currently we receive very few request for research purposes under Section of FIFRA, the Agency is required to issue and experimental use permit (EUP) within 120 days of receiving the application. The regulations identify four scenarios that do not require the submission and approval of EUPs: 1. Laboratory or green house test 2. Small-scale tests on less than 10 terrestrial acres provided that food/feed is either destroyed or fed to experimental animals 3. Small-scale tests on less than 1 surface water acre, provided that the food/feed is either destroyed or fed to experimental animals. Treated waters cannot be used for recreational, irrigation, or drinking water purposes. 4. Animal treatments conducted only on experimental animals Recently, most of the permits we've been issuing have been larger scale tests with the provision that crop be destroyed.

PRE-SUBMISSION CONSULTATION WITH REGISTRANT OR APPLICANT

COUNTRY	BEST PRACTICE(S)
examples provided in the survey	-- Ensuring that industry receives a consistent message on requirements, responsibilities and quality and format of data to be submitted -- Discussion of potential regulatory questions to ensure smooth evaluation
AUSTRALIA	-- Will advise registrants of requirements and explain how they are to be met. -- Detailed guidelines available -- Customer Service Section established to assist -- Will arrange technical meetings with evaluators if science issue may be of concern
CANADA	-- Ensuring that industry receives a consistent message on requirements, responsibilities and quality and format of data to be submitted: - SOP to be distributed internally/externally easily in 2000 - Single - window approach for industry inquiries - Streamline internal process with set performance standards for both Agency and Industry
DENMARK	-- Data requirements etc. are give in the Statutory Order on Pesticides -- Newsletters are sent to industry when amendments to requirement are made. -- Meetings with registrants upon request.
FINLAND	-- If the applicant needs consulting help the different authorities (mostly Plant Production inspection Centre) will give that help. Particularly small companies have problems because they do not know the registration procedure.
HUNGARY	-- Continuous discussion possibilities. Ensure during the consultation that industry receives clear information for submitting quality data.
JAPAN	-- Develop and publish a guidebook on pesticide registration in co-operation with applicants. The guidebook includes information about registration procedure such as whole process of evaluation, required documents for registration, format of these documents and so on. -- In case applicants ask advice, each personnel in charge of the issues gives advise to them, if necessary.
NEW ZEALAND	-- Pre-screen applications so those unlikely to succeed are not accepted to “clog up” the system..
NORWAY	-- We send our data requirements to (new) importers of pesticides and to producers in Norway when they contact us. -- Our website gives information of our approval system.
SLOVENIA	-- Personal meetings and telephone advices during official hours.
SWEDEN	– Discussion with the applicant on request or if it is obvious that the applicant has not understood the registration procedure – Information is sent to the industry if there are new regulations
UNITED KINGDOM	See details in PUBLIC CONSULTATION AND POLICY AND COMMUNICATION -- In addition consultations and meetings with stakeholders, PSD has organized Workshops to give clients an idea of upcoming changes. Topics have included: developments in the EC pesticides regime; and a revision of the PSD application form and procedures.
UNITED STATES	SOURCE: [Peter Caulkins, RD] Pre-submission consultation with registrant or applicant: RD has taken several measures to help ensure that submissions are complete and the studies are done right the first time The Agency has conducted the rejection rate project in collaboration with the registrants to reduce the number of rejected studies and te associated rework involve. As a result industry-wide rejection rates have fallen significantly. In 1991 industry-wide average rejection rates were 32.2% for studies submitted. In 1998 that rate had fallen to 3.7% The amount of rework has also fallen. In FY91 the number of cycles (a measure of back and forth traffic between registrants and Agency) per new active ingredient decision was 60. By 1995 the number of cycles per new active ingredient decision had fallen to 10, and in 1997 the number of cycles was 8. Increasingly registrant submissions are being done right the first time Secondly, the agency has encouraged pre-registration meetings (a) to ensure that the data package to be submitted will be complete, (b) to facilitate discussion of potential problem areas, (c) for early identification of tox endpoints to coordinate scheduling of appropriate peer review committees and (d) early identification of opportunities for work sharing with other countries.

Annex 3
Rating the Best Practices

COUNTRY		
AUSTRALIA	1	NRA is established as Statutory Authority with more independence than Government Department
	2	Fully cost recovered organization, charging for services
	3	Introduction of ISO9002
	4	Cooperation with industry to clearly define all requirements
	5	Networks with industry, user groups, other agencies, etc.
CANADA	1	Setting and adhering to Performance Standards for both Industry and Agency
	2	Streamlining review activities (teams/templates/communication SOPs)
	3	Data Screening and preliminary review for deficiency to ensure quality submissions for review
		Future gains well be realized with Industry completing their own data screens as well as with submission of electronic data. For review - ongoing pilots
DENMARK		Not Answered
FINLAND	1	Sharing of review reports
	2	Screening
	3	Pre-submission consultation
HUNGARY	1	Clear and consistent data requirements
	2	Well prepared documentation
	3	Strong expertises background for the evaluation (with international cooperation)
	4	Put into practice an unambiguous evaluation method
	5	Uniform conditions for decision making
JAPAN	1	Screening /Checking
	2	Pre-submission consultation with registrant or applicant
NEW ZEALAND	1	Prescreening / Verification process.
	2	Publication of protocols, guidance notes and codes of practice
	3	Database management
	4	Acceptance of OECD Country Data Assessments
	5	Use of external experts (consultants) in process
NORWAY	1	Substitution principle
	2	Reevaluation every 5th year
	3	Nordic co-operation extended to OECD
	4	Advisory Board of Pesticides with high competence

SLOVENIA	1	Use of evaluations from other countries.
	2	Risk reduction programmes.
	3	Efficient evaluation process and decision making.
SWEDEN	1	Risk reduction programmes
	2	Use of evaluations made by other countries
	3	Reregistrations are only administrative since a.i. are reviewed in EU
	4	Rejection of applications with severe data gaps
	5	National review of products with similar area of use at the same time to facilitate substitution
UNITED KINGDOM	1	Clearly defined annual performance targets set for the Agency as a whole and reflected in individuals' work objectives. These provide a clear focus of the activities of the Agency and have been a catalyst for many other improvements to ensure that they can be achieved.
	2	Continued improvement and investment in IT leading to efficiency gains throughout the Agency
	3	Commitment to improvement in internal processes and efficiency exemplified by initiatives in key areas such as Investors in People accreditation (and overall commitment to staff) and participation in Benchmarking as a basis for improvement.
	4	Commitment to the identification of stakeholders, and maintaining a focus on their requirements.
	5	The harmonization and work sharing under Directive 91/414/EEC has the greatest potential to provide efficiency gains. The process of harmonizing procedures and achieving efficient and effective processes, especially in relation to decision making, is still ongoing. However it is considered that in principle this programme should produce large efficiency gains.
UNITED STATES Source: Jim Jones and Janet Andersen	1	Rejection rates: By working with the registrants we have been able to identify those factors that most frequently caused studies to be rejected and took action to ensure that these rejection factors would not be repeated in the future. Rejection rates by discipline dropped – Toxicology from 7% in 1991 to 4% in 1998; -- Residue chemistry from 12% in 1991 to 4% in 1998; – Ecological effects from 21% in 1991 to 7% in 1998; -- Environmental fate from 27% in 1991 to 4% in 1998. Industry rejection rates by company have also fallen. The industry average rejection rate in 1991 was 32%, and in 1998 has fallen to 3.7%. Lower rejection rates have reduced significantly the amount of rework (as measured by cycles) required to register new chemicals. In 1991 the cycle to decision ratio was 60 /1 for new chemicals; in 1996 the cycle to decision ration was 9/1. The reduction in rework has resulted in shorter time frames to make decisions – in FY91 62 months on average to make new chemical decisions and in FY95 38 months.

UNITED STATES, cont. Source: Jim Jones and Janet Andersen	2	Reduced risk program– encourage the development, registration and use of lower-risk pesticide products which will result in reduced risks to human health and the environment when compared to existing alternatives. Reduced risk chemicals get expedited review priority. For new chemicals average registration time is 38 months; for reduced- risk new chemicals the average registration time is 18 months; for new uses the average registration time is 18 months and for reduced-risk new uses - 4 months. 47 candidates accepted into reduced risk (out of 73 submissions) and 23 registered. Reduced risk program has provided alternatives to OPs and carcinogens.
	3	Self certification for product chemistry has resulted in resource savings and faster review times.
	4	The development of self contained divisions - AD and BPPD - has resulted in greater efficiencies.
	5	Priority system - customers identify their highest priorities which are done first.
	6	Having a regulatory and scientific staff in the same organization and located together with the mission to expedite registration of biological pesticides.
	7	Having a regular group of regulatory staff and scientists meet to provide rapid decisions on small regulatory issues and move these minor action rapidly so they did not linger.
	8	Regulatory staff designed and implemented a working group to provide consistency on regulatory actions, answer basic question for new staff, and develop questions needing upper management attention.
	9	The web having all the materials for registration
	10	The Label Review Manual

Annex 4
Fees

(Details on the specific services for which fees are charged for the activities described above - Additional information on fees may be found in Annex 1.)

COUNTRY	
AUSTRALIA	Information in Annex 1.
CANADA	10% Application Fee 25% Screening 65% Review
DENMARK	Information in Annex 1.
FINLAND	Application fee (when applying registration and re-registration) is 5000 FMK (~841 euros) Application fee is paid when the application is left. The fee covers part of screening and evaluation. Then there is 3.5% fee (net sale minus VAT) of previous year's sales that covers other costs for example health and environmental evaluations.
HUNGARY	We charge a general fee for the different activities during the registration procedure. The registration fee is divided between institutes involved in registration procedure based on an agreement.
JAPAN	Information in Annex 1.
NEW ZEALAND	Information in Annex 1.
NORWAY	We charge US $650 for submission and additional tax base on the sold volume of the pesticide. The tax is based on dose per square area, weighted for health and environmental effects
SLOVENIA	1. Fee for the application (it includes hazard identification and in risk assessment prepared by experts) is now about 2000 and 4000 DEM. 2. Fee for health medical expert opinion (about 1000 DEM). 3. Fee for biological trials (for herbicides is the price around 1000 DEM, for other preparations it depends from the number of doses (around 2000 DEM)).
SWEDEN	Application for approval Application for extension of approval (reregistration) Application for change of condition Application for exemption from registration Application for research permits Application for Annex 1(91/414/EEC) entry for an active substance new to EU Annual fee of 2.6% of the value of the sale of each product in the year before.
UNITED KINGDOM	PSD's approval costs are financed through the payment of fees for the evaluation of approval applications and an annual levy, based on annual turnover of approved pesticide products, charged to the agrochemical industry. The levy covers mainly monitoring activities and reviews of national approvals. PSD charges two types of fees: Application fees Annual sales levy The cost of policy-related work is met by the Ministry of Agriculture. The full economic costs are included in charges made, including salaries, accommodation, overheads (IT systems, etc) , travel, training, personnel, interest on capital, depreciation, etc. against registrations and approvals.

UNITED STATES Source: Carol Peterson	EPA's Office of Pesticide Programs (OPP) has several fee authorities to help its program activities. Two fees, the annual product registration maintenance fee and the tolerance fee are active. Fees for new registration application were in place briefly in 1988, but were suspended by FIFRA '88 and again in 1996 by the Food Quality Protection Act (FQPA) until after fiscal year 2001. The product maintenance fee is expected to expire when the reregistration program is completed, however, some derivation of this fee may be retained to cover costs of registration renewals (FQPA) requires that te Agency renew each registration every 15 years). Presently, revenues generated from fees account for about 20% of OPP's total budget; 80% is appropriated by Congress. Annex 1 provides more detail on our fee authorities. Since our fee systems account for such a small portion of OPP's overall budget, they are not targeted for any specific service or activity. Revenues received via product maintenance fees go to support the reregistration program and monies from tolerance fees go into the registration program's budget are used to support the processing of tolerance petitions. Neither of these two programs is self-supporting. Currently, EPA is in the process of restructuring its fee systems. The tolerance fee system is being revised so that setting or reassessing tolerances or tolerance exemptions is completely paid for through the collection of fees. In addition, the Agency is working on a new fee structure. This "fee-for-service" will be designed to cover the costs of obtaining a registration. Both of these activities will have a complete accounting of what activities and services will be covered by the fee. This is to ensure that the two fee systems do not overlap and to assure registrants that they are not paying twice for the same service.

MAIN REASONS FOR CHARGING FEES

COUNTRY	
AUSTRALIA	Fees are charged to finance the total cost of operating the registration process. The fee structure has been constructed so as not to deter the development of small volume products or products that fill niche markets. Fees also help to exclude from the system, frivolous applications
CANADA	Government mandate - cost recovery
DENMARK	Not Answered
FINLAND	Reasons listed beside fees (FEES Section (above)).
HUNGARY	It is a service that the authority deliver. It also takes up very much time of expertise. Furthermore this fee is not enough to cover all the expenses of the registration procedure. Hence, the state finance the cost of inspections after the registration.
JAPAN	Actual expense for inspection and evaluation exclude personnel expenses.
NEW ZEALAND	Government requirement for full cost recovery.
NORWAY	The fees cover the cost related to efficiency trials, residues, and the review process.
SLOVENIA	1. + 2. Payment for experts. 3. Payment for biological trials.
SWEDEN	The government requires us to recover the cost for the registration process and all other costs from charges on industry. However the parliament sets the limits for our recovery
UNITED KINGDOM	To recover the costs of registration / evaluation activities undertaken by PSD
UNITED STATES	Generally, OPP imposes fees because it is required by law to do so. Both congress and the administration assert that certain government programs should be supported by those people receiving the service and not by the general taxpayer. Licencing pesticides is an example of such a service. The Agency is required to impose product maintenance fees under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and tolerance fees under the Federal Food, Drug , and Cosmetic Act (FFDCA).

DO FEES ENCOURAGE EFFICIENT DELIVERY OF SERVICES AND GOOD SUBMISSION AND HAVE OTHER BENEFITS?

COUNTRY		
AUSTRALIA	YES	Fees coupled with effective management of the business overall has dramatically improved the efficient delivery of services. Fees have not always brought about good submissions. It appears to clear guideline/requirements, industry education, penalties (loss of fees; rejection of application) are more effective. Direct liaison with company CEOs rather than regulatory affairs officers can also raise the level of submission quality.
CANADA	Yes	Fees require performance standards to be put in place. Performance Standards enforce accountability from both parties.
DENMARK		Not answered
FINLAND	NO	The registration fee is so low that it does not encourage the companies to provide good applications (of course there are some exceptions).
HUNGARY	YES	If the fee is high enough it will encourage the applicant to give proper information in advance. On the other hand fees inspire the authority co-operating with other institutions to deliver better services for applicants in return.
JAPAN	NO	
NEW ZEALAND	YES	The high cost for an application ensures that applicants provide good quality information for consideration by the Authority. If a substance (pesticide) is not approved, then it can not be imported into or manufactured in New Zealand.
NORWAY	NO	No clear relationship
SLOVENIA	YES	More seriously approach.
SWEDEN	YES	The companies are charged and at the same time they get our service - it is easy to see the connection between the fee and what they get back from us. Companies avoid to apply for approval if the chance to get an approval is small due to lack of or a bad documentation
UNITED KINGDOM	YES	
UNITED STATES	YES	In general yes, if the fee is high enough and is targeted to a specific service and the agency is held accountable for providing that service in a timely manner. Right now, the fees are so low that registrants routinely pay them. However, if they were to increase dramatically (as will be proposed when OPP restructures its tolerance fees of introduces a user fee) registrants will be more demanding that they get something tangible for their money. If the fee is structured such that both the registrant and the Agency are held responsible for a particular action , the revenues generated by the fee will produce increased efficiencies. Fees can also be detrimental to a program. Unless the law stipulates that the fee revenue will be above the program's regular appropriations, these revenues are offset from the program's overall annual budget – resulting in no net gain for the program and therefore no increased service for the registrant. Since fee are based on submissions, there is the potential for significant annual fluctuations in collected revenue. A particularly "bad" year could affect OPP's ability to pay base salaries. Finally., there are instances where the administrative burden outweighs the benefits of the incoming revenues. If there are numerous fee categories, based on several criteria, that require detailed tracking, several rounds of billing, results in many special circumstances, and requires the creation of a new department within the program then the collection of the fee is probably not worth the program's effort. If the fee structure is made simple the resources needed to institute a collection program are minimized.

Annex 5
Country Contacts

Australia Greg Hooper
National Registration Authority
P.O. Box E240, Kingston, ACT 2604, Australia
tel.: 61-2-62716319 fax: 61-2-62723195 em: ghooper@nra.gov.au

Canada Connie Moase
Pest Management Regulatory Agency, Health Canada
Sir Charles Tupper Building, 2250 Riverside Drive
Ottawa ON Canada K1A 0K9
tel.: 613-736-3517 fax: 613-736-3666 em: connie_moase@hc-sc.gc.ca

Denmark Eva Bartels Petersen
Miljøstyrelsen
Strandgade 29
1401 København K., Denmark
tel.: 45 32 66 01 00 fax: 45 32 66 05 35 em: EBP@mst.dk

Finland Hans Blomqvist
Plant Production Inspection Centre
Pesticide Division
P.O. Box 42
00501 Helsinki, Finland
tel.: 358-9-5765 2770 fax: 358-9-5765 2780 em: hans.blomqvist@kttk.fi

Hungary Zoltán Ocskó
1055 Budapest
Kossuth tér 11.
Hungary
tel.: (36-1) 301 4248 fax: (36-1) 301 4644 em: zoltan.ocsko@f-m.x400gw.itb.hu

Japan Fumihiko Ichinohe
2-772 Kodaira-Shi, Suzuki-cho
180-0011 Toyko, Japan
tel.: 81-423-83-2151 fax: 81-423-85-3361

New Zealand Donald Hannah
Manager, Science and Research
ERMA New Zealand
PO Box 131
Wellington, New Zealand
tel.: 64 4 496 4856 fax: 64 4 496 8433 em: sue.thomas@ermanz.govt.nz

Norway Anna Mehl
Norwegian Agricultural Inspection Service
Pesticide Section
P.O. Box 3, N-1432 Ås
Norway
tel.: 47 64944400 fax: 47 64944410 em: anna.mehl@landbrukstilsynet.dep.no

Slovenia Vesna Ternifi
Ministry of Health, National Chemicals Bureau
Breg 14, 1000 Ljubljana
Slovenia
tel.: 386 01 478 6051, 478 6251, fax: 386 01 478 6266, e-mail: vesna.ternifi@gov.si

Sweden Ulla Falk
Kemikalie inspektionen
Box 1384
S-171 27 Solna
Sweden
tel.: 468-783 11 68 fax: 468-735 76 98 em: ullaf@kemi.se

U.K. Deborah Hussey
Pesticides Safety Directorate
Mallard House
3 Peasholme Green
York YO1 7PX
United Kingdom
tel.: 44 1904 455769 fax: 44 1904 455733 em: d.j.hussey@psd.maff.gov.uk

U.S.A. Jane Hopkins
Government & International Services Branch
Field & External Affairs Division
EPA Office of Pesticide Programs (7506C)
Ariel Rios Building, 1200 Pennsylvania Avenue, N. W
Washington, DC 20460
tel.: (703) 305-7195 fax: (703) 308-1850 em: hopkins.jane@epa.gov