



UNITED NATIONS ENVIRONMENT PROGRAMME

Programme des Nations Unies pour l'environnement Programa de las Naciones Unidas para el Medio Ambiente
Программа Организации Объединенных Наций по окружающей среде برنامج الأمم المتحدة للبيئة

联合国环境规划署



Existing sources and approaches to risk assessment and management of pesticides, particular needs of developing countries and countries with economies in transition

Concise information on existing instruments, tools and approaches

UNEP Chemicals Branch, DTIE
November, 2009

Table of Contents

1.	Introduction.....	4
2.	Pesticide legislation, registration	5
2.1	Guidance Available from International Organizations	5
2.1.1	FAO.....	5
2.1.2	OECD.....	6
2.2	Regional Organizations.....	7
2.2.1	European Union	7
2.2.2	Sahel (CILSS) PERMANENT INTERSTATES COMMITTEE FOR DROUGHT CONTROL IN THE SAHEL	8
2.3	National Systems	9
2.3.1	Australia.....	9
2.3.2	Sri Lanka.....	9
2.3.3	Tanzania.....	10
2.3.4	USA.....	11
3	Risk assessment and risk management	11
3.1	Guidance from International Organizations.....	11
3.1.1	FAO.....	11
3.1.2	FAO/WHO (JMPR).....	12
3.1.3	ILO.....	12
3.1.4	OECD.....	12
3.1.5	WHO	13
3.2	Regional Organizations.....	13
3.2.1	European Union	13
3.3	National Systems	14
3.3.1	Australia.....	14
	Assessing and managing the risks.....	15
3.3.2	US EPA.....	15
4	Socio-economic analysis.....	16
4.1	Guidance from International Organizations.....	16
4.1.1	OECD.....	16
4.2	Regional Organizations.....	17
4.2.1	European Union	17
4.3	National Information.....	17
4.3.1	Tanzania.....	17
4.3.2	USA EPA.....	17
Annex I	Detailed information on the existing instruments and tools and additional references	19
1.	Guidance from International Organizations.....	19
1.1	FAO.....	19
1.2	FAO/WHO.....	22
1.3	ILO.....	24
1.4	OECD.....	24
1.5	UNEP/WHO	34
1.6	WHO	35
2.	Guidance from Regional Organizations.....	39

2.1	European Union	39
2.2	Sahel (CILSS)PERMANENT INTERSTATES COMMITTEE FOR DROUGHT CONTROL IN THE SAHEL	43
3	National Information.....	44
3.1	Australia.....	44
	Assessing and managing the risks.....	45
3.2	Sri Lanka.....	46
3.3	Tanzania.....	47
3.4	USEPA.....	47
4.	List of other relevant pesticide(chemicals) documents.....	50
5.	Databases on pesticides and chemicals	61
6.	International networks on pesticides	63
Annex II	Websites of national pesticides registration authorities, links to national pesticide legislation and pesticide related documents	64

Existing sources and approaches to risk assessment and management of pesticides, particular needs of developing countries and countries with economies in transition

Concise information on existing instruments, tools and approaches

1. Introduction

Pesticides are chemicals, most of which are intrinsically hazardous to man and the environment. They are designed to cause harm to living organisms and deliberately released to the environment. For these reasons at national level they are regulated in most of the countries and there are also instruments at international and regional levels. Although pesticides are regulated there are still problems with enforcement, monitoring and unwanted amounts of some pesticides exist in the environment particularly in water and soil and high levels of pesticide residues occur in crops.

This document targets developing countries and countries with economies in transition in relation to risk assessment and management, focusing on sound management of pesticides, taking into account environmental, ecological and socio-economic factors.

Risk assessment and management are addressed at international chemicals meetings, conferences such as UNCED in 1992 and it is in the work areas of the SAICM global plan of action which is the recent policy development in chemicals management.

This document is made up of two parts. The first part provides information on existing instruments on pesticide legislation, risk assessment and risk management at international level and examples from regional and national level. It does not cover all regulatory aspects but focus on registration and risk assessment and management. Although other regulatory instruments related with pesticides, e.g. Rotterdam, Stockholm are not addressed specifically, this document would assist countries to fulfill the requirements of these conventions such as preparing notification proposals.

Annex I gives detailed information on the instruments referred to at the first part, as well as some additional references.

The document is intended to assist developing countries and countries with economies in transition to identify international, regional and other systems that can be built on and provide useful information for national assessments and management decisions regarding chemical risks, main factors that need to be taken into consideration when assessing and managing risks from pesticides, identify gaps in knowledge and capacities for adequately addressing the above factors at national level.

2. Pesticide legislation, registration

2.1 Guidance Available from International Organizations

2.1.1 FAO

Legislation

At the international level the main tool on pesticide legislation is the voluntary code on the “International Code of Conduct on the Distribution and Use of Pesticides” After its adoption in 1985, the code has been revised in the light of new developments in 2002. It establishes the voluntary standards of conduct for all public and private entities involved with pesticides management including distribution, use of pesticides especially to assist countries that with inadequate or no legislation.

Pesticide management is carried out within the overall framework of the Plant Production and Protection Division of FAO. The division works together with member countries and other International Organizations as a partner to introduce sustainable and environmentally sound agricultural practices that reduce health and environmental risks associated with the use of pesticides.

See Annex I Resource document: 1.1.1 FAO Code of Conduct

The International Code of Conduct on the Distribution and Use of Pesticides also cover the pesticides used in public health. Within WHO, WHOPES (WHO Pesticides Evaluation Scheme) is the unit that promotes and coordinates the testing and evaluation of pesticides for public health. It’s recommendations facilitate registration of public health pesticides by Member States. WHOPES also produces specifications on public health pesticides and guidelines on judicious use, quality control and testing.

Registration

FAO published “Guidelines for the registration and control of pesticides” in 1985 and its update in 1988. They were developed particularly to assist developing countries in setting-up or strengthening registration and control of pesticides. Since then and especially after the adoption of the Code of Conduct, and awareness raised on the importance of pesticide registration, many developing countries developed their pesticide registration and control schemes. Taking into account experience and developments that took place during the last two decades on pesticide registration in developed world, and that basic systems exist in most developing countries FAO is currently further developing its guidelines on pesticide registration.

FAO also published a legislative study on “Designing national pesticide registration” in 2007 <ftp://ftp.fao.org/docrep/fao/010/a1467e/a1467e.pdf>

The purpose of this document is to provide governments wishing to review, update or design national pesticide legislation with up-to-date advice on legislating for pesticide management. It encourages countries to design and approve a parliamentary law on pesticides to provide a firm legal basis for all further regulation on pesticides, through subsidiary instruments such as regulations and decrees. It also elaborates design of a national pesticide law.

2.1.2 OECD

The OECD Pesticides Programme aims at assessing and reducing risks of the use of agricultural pesticides while non-agricultural pesticides are dealt under Biocides Programme. OECD Guidance documents for pesticide registration establish 2 formats, one for the government, one for the industry.

The main guidance document for government is the “OECD Guidance for Country Data Review Reports on Plant Protection Products and Their Active Substances (Monograph Guidance) <http://www.oecd.org/dataoecd/42/57/38588738.pdf>”

The document provides guidance to regulatory authorities and sets the criteria for the evaluation of dossiers, the preparation of reports relating to evaluation of active substances, registration of plant protection products, establishment of maximum residue limits (MRLs) and import tolerances. It aims to facilitate the exchange of monographs between OECD countries to share the work necessary to evaluate plant protection products.

OECD Guidance format for the industry is the (<http://www.oecd.org/dataoecd/43/26/34870180.pdf>) . Guidance provided applies to preparation of dossiers submitted in support of applications for approval of active ingredients, registration of plant protection products, for the establishment of a maximum residue limit (MRL), or for the establishment of import tolerance or tolerances. The guidance was developed with the aim of facilitating the compilation of data submissions to OECD countries by providing a common format and structure for their preparation, that would reduce redundancies in the preparation of submissions by industry. A common format would also facilitate the use of electronic data submissions, and enable governments to use each others review reports easily, saving time and resources.

The guidance document is based on and is consistent with Guidelines and criteria for the preparation and presentation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), issued by the European Commission (Commission Document 1663/VI/94, rev 8 of 22 April 1998)

Detailed information on these guidance documents is provided in Annex I Resource Guide, 1.4.

2.2 Regional Organizations

2.2.1 European Union

A new legislative framework on pesticides based on the Commission proposal has recently been adopted by the European Parliament and the Council. It consists of:

1. A Regulation on placing on the market of plant protection products, specifying strict criteria for approval of substances, to ensure a high level of protection for human and animal health and the environment. In particular this Regulation provides that carcinogens, mutagens, endocrine disruptors, substances toxic for reproduction or which are very persistent will not be approved, unless exposure to humans is negligible. It also establishes a mechanism for the substitution of more toxic pesticides by safer (including non-chemical) alternatives.
2. A Directive on the sustainable use of pesticides, which aims at reducing the risk linked to the use of pesticides, improving the quality and efficacy of pesticide application equipment, ensuring better training and education of users and developing integrated pest management schemes.

An EU list of approved active substances created by the European Commission (Annex I to Directive 91/414/EEC) is established, and Member States may authorize only plant protection products containing active substances included in this list.

In March 2009 EU completed the review of existing pesticides that were on the market before 1993. The programme concerned about 1,000 substances, of which about 250 have passed the harmonised EU safety assessment. All reviewed pesticides have undergone a detailed risk evaluation with respect to their effects on humans and on the environment. This list is available from: http://ec.europa.eu/sanco_pesticides/public/index.cfm

and the EU Pesticides Database which was launched by 16 March 2009 is available from :

http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=activesubstance.selection&a=1

COUNCIL DIRECTIVE of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC)

<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1991L0414:20090101:EN:PDF>

The evaluation, marketing and use of pesticides (herbicides, insecticides, fungicides etc.) in plant protection in the Community are regulated under Council Directive 91/414/EEC. This Directive lays out a comprehensive risk assessment and authorisation procedure for active substances and products containing these substances. Each active substance has to be proven safe in terms of human health, including residues in the food chain, animal health and the environment, in order to be allowed to be marketed.

Directive 98/8/ec of the European Parliament and of the council
of 16 February 1998 concerning the placing of biocidal products on the market
<http://ecb.jrc.ec.europa.eu/legislation/1998L0008EC.pdf>

Pesticides have been regulated for a long time in most EU Member States and the Community. The Biocidal Product Directive (Directive 98/8/EC) aims to harmonise the European market for biocidal products and their active substances. It also aims to provide a high level of protection for humans, animals and the environment.

Technical Guidance Document in Support of Directive 98/8 Concerning the Placing of Biocidal Products on the Market and other documents See Annex I, 2.1.

2.2.2 Sahel (CILSS) PERMANENT INTERSTATES COMMITTEE FOR DROUGHT CONTROL IN THE SAHEL

Under the umbrella of the Committee on Drought Control in the Sahel, the Member States (Burkina Faso, Cape Verde, Chad, Guinea Bissau, The Gambia, Mali, Mauritania, Niger, and Senegal) established a Common Regulation for Pesticide Registration.

The main objective of this Common Regulation was to combine the expertise on pesticide evaluation and management of all CILSS Member States for pesticides registration. The Sahelian Pesticide Committee (CSP), the common pesticide registration body, became operational in 1994. It assesses registration dossiers submitted by the agro-chemical industry and grants sales permits valid for all its Member States. Harmonised tests and field trials have been established, and regional laboratories for conducting various analyses relating to pesticides are being identified. The mandate of the Committee includes a review of notifications under the PIC Procedure and to advise Member States.

Common regulation for the registration of pesticides in CILSS member states
<http://www.insah.org/protectiondesvegetaux/csp/RCenglish.pdf>

The CSP is composed of at least 2 experts representing each State. Main task of the CSP is to assess the registration dossiers submitted by the pesticide industry. The CSP assess if the pesticide can be accepted to be used in the CILSS area by granting full or provisional registration. See Annex I 2.2.

The CSP maintains an inventory of pesticides used or commercialized in the CILSS Member States. The list of pesticides authorized in CILSS by January 2009 is available at: <http://www.insah.org/protectiondesvegetaux/csp/CSP-Liste-globale-Pesticides-autorises-CSP-Janvier2009.pdf>

Requirements for composition of dossier for authorization of pesticides in Sahel is specified by the CSP in December 2008 and is available at:

<http://www.insah.org/protectiondesvegetaux/csp/synthesepesticide.pdf> (In French)

2.3 National Systems

2.3.1 Australia

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian government authority responsible for the assessment and registration of pesticides and veterinary medicines and for their regulation up to and including the point of retail sale.

The APVMA administers the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS) in partnership with the States and Territories and with the active involvement of other Australian government agencies (Department of Health and Aging-the Office of Chemical Safety, the Department of the Environment and Heritage, State/Territory primary industry or agriculture departments, environment protection authorities and independent reviewers) <http://www.apvma.gov.au/index.asp>

They independently evaluate the safety and performance of chemical products intended for sale, making sure that the health and safety of people, animals and the environment are protected. The APVMA notifies the public of the results of the evaluation and invites public comment on the registration proposal before making its decision. It also invites members of the public to participate in its programs such as reporting adverse chemical experiences through the Adverse Experience Reporting Program (AERP) (<http://www.apvma.gov.au/qa/agaerp.shtml>) and contributing to chemical reviews.

Legal background to the National Registration Scheme (Agricultural and Veterinary products) See Annex I, 3.1

2.3.2 Sri Lanka

Registration of Pesticides in Sri Lanka http://www.agridept.gov.lk/SCPP/opr_indx.htm

Enforcement of the Control of Pesticides Act No. 33 of 1980, its amendments and regulations are the responsibility of the Office of the Registrar of Pesticides. The Act provides provisions to control, import, packing, labeling, storage, formulation, transport, sale and use of pesticides through registration of individual products. All pesticide products, such as those used in agriculture, public health, domestic, industrial and veterinary etc. are coming under the purview of the Act. The office of the Registrar of Pesticide is the national authority to ensure that only the high quality pesticides those are least hazardous to human health and environment enter the market in Sri Lanka.

Application for registration of pesticides and list of pesticides registered in Sri Lanka See Annex I, 3.2.

2.3.3 Tanzania

Distribution and sale of pesticides in Tanzania is regulated under the Plant Protection Act (1997) and the Plant Protection Regulations (1998). The Minister of Agriculture may delegate some functions to any specified individual or institution, assigns duties, appoint officers. The Act stipulates establishment of the National Plant Protection Advisory Committee and its functions and acts as a scientific advisory agent to the Minister.

The Plant Protection Act, 1997

<http://www.agriculture.go.tz/Regulations/Plant%20Protection%20Act,%201997.pdf>

This Act makes provision for the protection of plants against pests and diseases by introducing a variety of measures aiming at control of production of and trade in plants. The Act is in six parts and part III is on plant protection substances and plant resistance improvers. Provisions in this part regulate the production, sale, import, packing, labelling, analysis, handling and use, plant protection equipment of plant protection substances and plant resistance improvers. Section 17 provides requirements for application for the registration of a plant protection substance. Section 18 stipulate that the Minister shall publish in the Gazette, a list of any plant protection substance registered and, time to time amend the list.

List of pesticides registered in Tanzania are available at:

<http://www.agriculture.go.tz/MAFSServices/list%20of%20pesticides%20registered%20in%20Tanzania%20by%20Nov%202007.htm>

The Plant Protection Regulations 1998

<http://www.agriculture.go.tz/Regulations/The%20Plant%20Protection%20Act%20No%2013%20of%201997-Regulations.pdf>

Part II of this regulation is on pesticides control. It specifies the composition of the pesticides approval and technical sub-committee (PARTS), its functions, procedure for importation of pesticides, registration of pesticides, application for registration, submission and analysis of samples, testing of pesticides, restricted use which includes pesticides subject to PIC procedure, highly toxic, persistent and biologically cumulative and causes poisoning effects to human and animals of which no effective antidote is available. It also has provisions on manufacturers obligations for safety guidelines and to maintain quality control, clearance and licensing and of pesticide handlers, pesticide records that should be kept, labeling, protective gear, packing, handling and storage areas of pesticides, information on pesticides and empty containers, disposal of unwanted pesticides and empty pesticide containers, users obligation on pesticide procurement, and pesticides advertisements.

Pesticide Control Regulations 1984

<http://www.kilimo.go.tz/Regulations/The%20Tropical%20Pesticides%20Research%20Institute%20%20Regulations,%201979.pdf>

2.3.4 USA

EPA and the states (usually that state's agriculture office) register or license pesticides for use in the United States. EPA receives its authority to register pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). States are authorized to regulate pesticides under FIFRA and under state pesticide laws. States may place more restrictive requirements on pesticides than EPA. Pesticides must be registered both by EPA and the state before distribution.

Federal law requires that before selling or distributing a pesticide in the United States, a person or company must obtain [registration](#), or license, from EPA. Before registering a new pesticide or *new use* for a registered pesticide, EPA must first ensure that the pesticide, when used according to label directions, can be used with a reasonable certainty of no harm to human health and without posing unreasonable risks to the environment. Where pesticides may be used on food or feed crops, EPA also sets tolerances (maximum pesticide residue levels) for the amount of the pesticide that can legally remain in or on foods.

Federal Insecticide, Fungicide, and Rodenticide Act

<http://agriculture.senate.gov/Legislation/Compilations/Fifra/FIFRA.pdf>

This is an Act to regulate the marketing of economic poisons and devices, and for other purposes. It describes procedure for registration, re-registration of registered pesticides, experimental use permits, administrative review, suspension, registration of establishments, records, inspection of establishments, protection of trade secrets and other information, use of restricted use pesticides, unlawful acts, stop sale, use, removal and seizure, penalties, indemnities.

Pesticides, data requirements for conventional chemicals See Annex I, 3.4.

As part of a cooperative NAFTA project, EPA's Office of Pesticide Programs (OPP) and the Canadian Pest Management Regulatory Agency (PMRA) developed standard data evaluation formats, or templates. The templates have been in use by these agencies since 2002 for writing their data evaluation records (DERs) of studies submitted under the U.S. data requirements for pesticide registration (40 CFR, Part 158) and the Canadian data codes (DACOs). The DER that the agencies prepare contains a study profile documenting basic study information such as materials, methods, results, applicant's conclusions and the evaluator's conclusions.

3 Risk assessment and risk management

3.1 Guidance from International Organizations

3.1.1 FAO

Assessing soil contamination: a reference manual (2000)

This manual aims to help the user to determine if pesticide spills have caused soil or groundwater contamination and, if so, whether or not that contamination implies risks for human health. <http://www.fao.org/docrep/003/x2570e/x2570e00.htm>

3.1.2 FAO/WHO (JMPR)

The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) is an international scientific-expert group that is administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). It serves as a scientific body to FAO, WHO, their member governments, and to the Codex Alimentarius Commission. Advice to the Codex Alimentarius Commission on pesticides is provided via the Codex Committee on Pesticide Residues.

JMPR consists of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. During the meetings the FAO Panel of Experts is responsible for reviewing residue and analytical aspects of the pesticides under consideration, including data on their metabolism, fate in the environment, and use patterns, and for estimating the maximum residue levels that might occur as a result of the use of the pesticides according to good agricultural practices. The WHO Core Assessment Group is responsible for reviewing toxicological and related data and for estimating, where possible, acceptable daily intakes (ADIs) for humans of the pesticides under consideration.

The conclusions of Joint Meetings are summarized in reports published in the FAO Plant Production and Protection Paper series. Toxicological monographs are published after the meetings by WHO. These summarize the data used in the Meeting's evaluations and provide full references to the relevant literature. See Annex I, 1.2.

3.1.3 ILO

ILO activities for sound chemicals management are integrated within its overall activities for occupational safety and health and are undertaken in the context of the ILO Programme on Safety and Health at Work and the Environment (Safework).

ILO and WHO developed an international chemical toolkit based on the UK Control of Substances Hazardous to Health (COSHH) scheme to assist SME's in complying with the national chemical safety regulations. The International Chemical Control Toolkit outlines a scheme for protection against harmful and dangerous chemicals in the workplace. It is designed for small and medium sized enterprises (SMEs) in developing countries. See Annex I, 1.3.

3.1.4 OECD

The OECD risk assessment programme focuses on developing and harmonizing methods for environmental exposures, specifically on four main areas: release estimation; exposure models, use of monitoring data and reporting of exposure estimation. OECD develops Emission Scenario Documents that describes the sources, production processes, pathways and use patterns with the aim of quantifying the emissions (or releases) of a chemical into water, air, soil and/or solid waste. Detailed information on how to conduct release estimates in environmental exposure assessment is available in the document

“OECD Environmental Exposure Assessment Strategies for Existing Industrial Chemicals in OECD Member Countries

[http://www.oilis.oecd.org/oilis/1999doc.nsf/LinkTo/NT00000A7E/\\$FILE/04E94750.PDF](http://www.oilis.oecd.org/oilis/1999doc.nsf/LinkTo/NT00000A7E/$FILE/04E94750.PDF)

See Annex I, 1.4 for detailed OECD risk assessment documents.

3.1.5 WHO

The objective of the WHO IPCS chemicals assessment programme is to provide a consensus scientific description of the risks of chemical exposures. These descriptions are published in assessment reports and other related documents so that governments and international and national organizations can use them as the basis for taking preventive actions against adverse health and environmental impacts. These documents include:

- Environmental Health Criteria Series
- Concise International Chemical assessment Documents(CICADs)
- International Chemical Safety Cards(ICSC)
- The WHO Recommended classification of pesticides by hazard

UNEP/IPCS also developed training modules on chemical safety and risk assessment.

See Annex I, 1.6 for detailed WHO risk assessment documents.

The International Agency for Research on Cancer (IARC) is part of the World Health Organization. The objective of this programme is to elaborate and publish in the form of monographs critical reviews of data on carcinogenicity for agents to which humans are known to be exposed and on specific exposure situations; to evaluate these data in terms of human risk with the help of international working groups of experts in chemical carcinogenesis and related fields; and to indicate where additional research efforts are needed. Summaries and evaluations are available at:

<http://www.inchem.org/pages/iarc.html>

WHO Pesticides Evaluation Scheme(WHOPES) collects, consolidates, evaluates and disseminates information on the use of pesticides for public health. Its recommendations facilitate the registration of pesticides by Member States <http://www.who.int/whopes/en/>.

3.2 *Regional Organizations*

3.2.1 European Union

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0060:0061:EN:PDF>

On 16 December 2008 the European Parliament and the Council adopted a new Regulation on classification, labelling and packaging of substances and mixtures (CLP) which aligns existing EU legislation to the GHS (Globally Harmonized System of Classification and Labelling). The new Regulation enters into force on 20 January 2009. The deadline for substance classification according to the new rules will be 1 December 2010 and for mixtures 1 June 2015. The CLP Regulation will ultimately replace the current rules on classification, labelling and packaging of substances (Directive 67/548/EEC) and preparations (Directive 1999/45/EC) after a transitional period.

<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF>

Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market.

This set of technical guidance documents is intended for use by the competent authorities appointed by Member States under the provisions of Directive 67/548, Regulation 793/93 and Directive 98/8. It is issued by the European Commission (DG JRC) to help competent authorities to carry out the risk assessments on new notified substances, existing substances and on biocidal active substances or a substance of concern present in a biocidal product.

3.3 National Systems

3.3.1 Australia

The APVMA sets maximum residue limits (MRLs). An MRL is the highest concentration of an agricultural and veterinary chemical residue permitted in food or animal feed. MRLs are used to check whether chemical users are following the directions on the label. MRLs are normally set well below the level that would harm health. When an MRL is exceeded, it usually indicates a chemical is being misused, rather than a public health or safety concern.

The APVMA is responsible for ensuring that off-target pesticide spray drift does not harm human health, the environment or Australia's international trade.

In assessing applications for product registrations the APVMA undertakes spray drift risk assessment for agricultural chemical products (including biological control agents) labelled for use outdoors, that can be applied as sprays or dusts.

Assessing and managing the risks

- **Operating principles**
The APVMA has developed a risk assessment framework - *APVMA Operating Principles in Relation to Spray Drift Risk*. These [Operating Principles](#) describe the methods and scientific principles the APVMA uses to assess and manage spray drift issues.
- **Standard risk scenarios**
[Standard spray drift scenarios](#) provide detailed information about spray drift behaviour for a range of ground and aerial spray drift application methods. They include APVMA modelling input parameters.
- **No-spray zones**
These are the protective buffer zones that the APVMA requires between an application area and an area downwind that needs to be protected. The APVMA sets the [size of no-spray zones](#) based on the inherent hazard the pesticide presents and an assessment of the specific risk.

3.3.2 US EPA

Before a pesticide can be sold in the United States, EPA evaluates its safety to terrestrial and aquatic animals and plants based on a wide range of laboratory and field studies. The environmental studies, conducted mostly by pesticide manufacturers examine ecological effects or toxicity of a pesticide and its breakdown products (degradation products) to various terrestrial and aquatic animals and plants that the pesticide is not intended to kill (non-target species) and chemical fate and transport of a pesticide (how it degrades and where it goes) in soil, air, and water.

After EPA scientists review all the available information on toxicity, chemical fate and transport, and proposed use of a pesticide, they develop documents on environmental exposure characterization that estimates the potential exposure of plants, animals, and water resources to pesticide residues in water, food, soil and air and ecological effects characterization that describes the types of effects a pesticide can produce in an organism and how those effects change with varying pesticide exposure levels. The effects and exposure characterizations are integrated into a risk characterization that describes the ecological risk from the use of the pesticide or the likelihood of effects on aquatic and terrestrial animals and plants based on varying pesticide use scenarios.

Guidelines for Ecological Risk Assessment
Federal Register 63 (93) 26846-26924, 14 May 1998
<http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=12460>

These Guidelines describe general principles and give examples to show how ecological risk assessment can be applied to a wide range of systems, stressors, and biological, spatial, and temporal scales. They describe the strengths and limitations of alternative

approaches and emphasize processes and approaches for analyzing data rather than specifying data collection techniques, methods, or models.

Guidelines for Exposure Assessment

Federal Register 57 (104) 22888-22938, 29 May 1992

<http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=15263>

The Guidelines for Exposure Assessment describe the general concepts of exposure assessment including definitions and associated units, and by providing guidance on the planning and conducting of an exposure assessment. Guidance is also provided on presenting the results of the exposure assessment and characterizing uncertainty. The Guidelines focus on exposures of humans to chemical substances but much of the guidance also pertains to assessing wildlife exposure to chemicals, or human exposures to biological, noise, or radiological agents. The Guidelines discuss and reference a number of approaches and tools for exposure assessment, along with discussion of their appropriate use.

See Annex I, 3.4 for EPA Risk Assessment Guidelines

4 Socio-economic analysis

4.1 Guidance from International Organizations

4.1.1 OECD

The OECD Member countries identified the integration of socio-economic analysis (SEA) in chemical risk management decision-making as another technique that could improve risk management effectiveness.

Three documents were developed to promote and facilitate the integration of SEA in chemical risk management decision-making:

- a guidance document for conducting retrospective studies on completed SEAs;
- a "framework" document that will describe how to integrate socio-economic analysis into chemical risk management decision-making; and
- a technical guidance document for analyst.

Guidance for conducting retrospective studies on socio-economic analysis

[http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/NT00002CA2/\\$FILE/00071625.PDF](http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/NT00002CA2/$FILE/00071625.PDF)

(General chemicals)

Framework for integrating socio-economic analysis in chemical risk management decision making

[http://www.olis.oecd.org/olis/2000doc.nsf/LinkTo/NT00000B9E/\\$FILE/00075130.PDF](http://www.olis.oecd.org/olis/2000doc.nsf/LinkTo/NT00000B9E/$FILE/00075130.PDF)

(General chemicals)

Technical guidance document on the use of socio-economic analysis in chemical risk management decision making

[http://www.oilis.oecd.org/oilis/2002doc.nsf/LinkTo/NT00000E76/\\$FILE/JT00122669.PDF](http://www.oilis.oecd.org/oilis/2002doc.nsf/LinkTo/NT00000E76/$FILE/JT00122669.PDF) (General chemicals)

4.2 Regional Organizations

4.2.1 European Union

Guidance on socio-economic analysis-Restrictions

This document provides technical guidance on how to undertake socio-economic analysis as part of a proposal to restrict the manufacturing, placing on the market and/or use of a substance in accordance with Article 69 of REACH. In the context of REACH, SEA is an approach used to describe and analyse all relevant impacts (i.e.both positive and negative effects) of imposing a restriction compared to continued use.

http://guidance.echa.europa.eu/docs/guidance_document/sea_restrictions_en.pdf

4.3 National Information

4.3.1 Tanzania

Socio-Economic Database <http://www.tsed.org>

Tanzania established the Tanzania Socio-Economic Database (TSED) that was supported by UNDP and UNICEF within the National Bureau of Statistics in collaboration with over 20 Ministries and Government Institutions. The main purpose of TSED is to allow an overall, up-to-date view of the socio-economic situation in Tanzania and to facilitate use of data for analysis by policy makers and other users. Sectors for which indicators developed include agriculture, demography, economy, education, environment, governance and accountability, health, HIV/AIDS, infrastructure development, labour force and nutrition.

4.3.2 USA EPA

A framework for the economic assessment of ecological benefits

<http://www.epa.gov/osa/spc/pdfs/feaeb3.pdf>

This document is intended to address the need for a common approach to analyzing ecological benefits and a better understanding of both the scientific and economic techniques used in conduct of economic and other social science analyses at EPA.

Guidelines for preparing economic analysis

<http://yosemite.epa.gov/ee/epa/eed.nsf/Webpages/Guidelines.html>

The Guidelines provide guidance on analyzing the economic impacts of regulations and policies, and assessing the distribution of costs and benefits among various segments of the population, with a particular focus on disadvantaged and vulnerable groups.

Annex I Detailed information on the existing instruments and tools and additional references

1. Guidance from International Organizations

1.1 FAO

Code of Conduct on the Distribution and Use of Pesticides

The revised Code includes the life-cycle concept of pesticide management. It aims to address sound management of pesticides, focuses on risk reduction, protection of human and environmental health, and support for sustainable agricultural development by using pesticides in an effective manner and applying IPM strategies.

The 12 Articles of the Code include objectives, terms and definitions, pesticide management, testing of pesticides, reducing health and environmental risks, regulatory and technical requirements, availability and use, distribution and trade, information exchange, labeling, packaging and disposal, advertising and monitoring and observance of the code. International policy instruments in the field of chemical management, environmental and health protection, sustainable development and sustainable development and international trade that are relevant to the Code are specified in the Annex 1 of the Code.

<http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Code/Download/code.pdf>

The FAO has produced several guidelines on different aspects and details of the legislation and is in the process of updating some older ones. These guidelines are prepared to support the Code of Conduct. See other documents.

Guidelines on Monitoring and Observance of the Code of Conduct

Under the Article 12, the Code of Conduct invites all stakeholders to monitor and report on implementation of the Code. The Guidelines on Monitoring and Observance of the Code of Conduct” have been developed in order to strengthen the implementation of various provisions of the Code of Conduct and based on recommendations made by the FAO Panel of Experts on Pesticide Management. They provide governments and other stakeholders the tools to participate effectively in monitoring and observance.

The Guidelines provide a basis to monitor the observance of each provision of the Code of Conduct. They are directed primarily to governments.

The guideline envisions two types of monitoring, regular monitoring and reporting, and ad hoc monitoring. For regular monitoring and reporting, governments should, and

stakeholders are invited to, gather information on the items identified in Annex A on a regular basis, and submit to FAO, every three years.

The Regular Monitoring Report Annex A is made up of three parts.

- I. Background Information
- II. Initial Focus for Monitoring
- III. General

The topics included in initial focus for monitoring (II) are:

- A. Pest management
- B. Testing, Quality Control and Effects in the Field
- C. Health and Environmental Information
- D. Trends in Manufacture, Use and Trade
- E. Selected Standards of Conduct
- F. General Input on Observance of Code of Conduct

The section on Health and Environmental Information (II.C) requests information on occupational exposure to pesticides, and poisonings; gathering data on environmental contamination and incidents; monitoring pesticide residues in food, which correspond to Articles 5.1.3, 5.1.5, 5.1.9 and 5.1.10 of the Code of Conduct.

Information on risk reduction efforts by pesticide industry, cooperative actions for risk reduction, national legislation and enforcement, registration system, conformity with relevant FAO and WHO specifications, voluntary responsive action, provision of data on trade, manufacture and sale by pesticide industry, prohibitions on highly hazardous products, corresponding to Articles, 5.2.3, 5.3, 6.1.1, 6.1.2, 6.2.4, 6.2.4, 6.2.6 and 6.2.7 of the Code are requested from industry and governments in II.E Selected Standards of Conduct.

Annex B *Ad hoc* Monitoring Report should be used by entities recognized under the Code of Conduct that wish to provide *ad hoc* reporting information relating to observance of the Code of Conduct. The requested information should include:

1. Contact details
2. Description of the Entity submitting the report
3. Types of pesticides involved in the *Ad Hoc* report
4. *Ad Hoc* Monitoring Information

<http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Download/Monitoring06.pdf>

Registration

The new FAO guidelines on concerning pesticide registration include, but not limited to guidelines on data requirements and test methods for different types of pesticides and guidelines on evaluation of data on chemical pesticides-environment, consumer protection and occupational health.

The new guidelines on pesticide registration cover:

- Principles of pesticide registration

- Outline of the pesticide registration process
- Data requirements/the registration dossier
- Evaluation of the registration dossier(data review)
- Decision making
 - Risk benefit analysis
 - Efficacy assessment
 - Quality assessment
 - Residue assessment
 - Health and environmental hazard assessment
 - Health and environmental risk assessment
 - Pesticide classification
 - Resistance management
 - Pesticide labeling
 - Pesticide packaging
- Specific issues e.g. pesticide mixtures, lists of banned or severely restricted pesticides
- Institutional and administrative organization
- Coordination and collaboration
- The pesticide register
- Phased development of a pesticide registration scheme
- Funding of pesticide registration

Revised guidelines on environmental criteria for the registration of pesticides (*) – Old guideline (1989)

www.fao.org/ag/AGP/AGPP/Pesticid/Code/Download/ENVICRI.pdf

FAO published the “Revised guidelines on environmental criteria for the registration of pesticides” in 1989. Part I of the guideline is on the principles and Part II is the guidelines for appropriate test procedures.

A stepwise sequence that allows an efficient selection of tests essential to each individual risk analysis is specified in Part I Principles. The steps are:

Step 1: Standard laboratory tests on physical and chemical properties, primary fate of the compound and acute or short term biological effects - generally necessary for all products.

Step 2: Supplementary laboratory studies on environmental distribution and degradation and additional toxicity tests including sub-lethal and chronic effects. The choice will be determined by the individual properties and uses of a substance.

Step 3: Simulated field and field studies, in case a product's hazard cannot sufficiently be assessed from laboratory studies (Steps 1 and 2) and experience.

Step 4: Post-registration monitoring, designed programmes and/or incident investigations during commercial use.

Tests necessary for each step to assess exposure, effects and hazard are specified. This part also includes evaluations of ecological significance, importance of environmental effects caused by pesticides, risk and risk management.

Part 2- Guidelines for appropriate test procedures specifies tests for:

Fate and mobility in the environment

- physical-chemical properties (vapour pressure, water solubility, octanol/water partition coefficient),
- fate in the environment (degradation in mammals and plants, degradation in soil, degradation in the aquatic environment,
- mobility in the environment(adsorbtion/desorbtion, leaching,, volatility)

Effects on the environment

- vertebrate wildlife-mammals and birds
- non-target aquatic organisms
- soil non-target micro-organisms and earthworms
- honey bees
- predatory and parasitic arthropods
- plants

1.2 FAO/WHO

Guidance manuals on pesticide management

In order to provide practical guidance and assistance to the pesticide regulatory authorities and to other stakeholders, various guidelines are being developed or revised within the framework of the Code of Conduct. These guidelines are in support of the implementation of the Code of Conduct and provide specific guidance and information covering various areas of pesticide management.

Guidelines are developed by the FAO Expert Panel on Pesticide Management, a statutory body of the Organization in collaboration with the FAO/WHO Joint Meeting on Pesticide Management, which identifies topics that require guidance, carries out technical evaluation of the draft documents, and ensures quality control and follow-up after publication.

Decision making for the judicious use of pesticides- facilitator's guide **Decision making for the judicious use of pesticides- participant's guide**

This training course targets vector-borne disease control programme managers at national and district levels who are responsible for planning and implementing vector management

programmes. The goal of this course is to enable participants to make decisions on the safe and judicious use of insecticides in public health. The course material is prepared in two versions, for the facilitator with guidelines for course delivery and suggestions for answers to the questions posed to participants and for the solutions they should develop during group exercises and for the participants.

http://whqlibdoc.who.int/hq/2004/WHO_CDS_WHOPES_2004.9b.pdf n

http://whqlibdoc.who.int/hq/2004/WHO_CDS_WHOPES_2004.9a.pdf

Guidelines on the management of public health pesticides

http://whqlibdoc.who.int/hq/2003/WHO_CDS_WHOPES_2003.7.pdf

The objective of this guideline is to assist Member States to develop national policies and guidelines and the legislative basis for the effective management of pesticides in public health. Guidelines for the major aspects of management of public health pesticides are provided in this document, including legislative control, administrative set-ups, product registration, procurement, storage and transport, distribution, application, maintenance and disposal, monitoring and surveillance, management of insecticide resistance, and quality control. Recommendations are made to WHO and to Member States for effective use of the guidelines.

FAO/WHO (JMPR)

Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed

<http://www.fao.org/ag/agp/agpp/pesticid/JMPR/Download/FAOM2002.pdf>

The Manual provides background information on the operation of the Joint Meeting on Pesticide Residues (JMPR), its objectives, the procedures involved in selection of compounds, preparation of data dossiers for the consideration of the FAO Panel of the JMPR, estimation of residue levels for calculation of dietary intake of pesticide residues, the data requirements for estimating maximum residue levels and the principles followed in the evaluation of experimental results and information provided. The update of this document is available at:

http://www.fao.org/ag/AGP/AGPP/Pesticid/JMPR/DOWNLOAD/bilthoven_2005.pdf

and Guidelines for Predicting Dietary Intake of Pesticide Residues:

http://www.who.int/foodsafety/publications/chem/en/pesticide_en.pdf

The revised guidelines address methods for exposure assessment of long-term hazards posed by pesticide residues to be conducted at the international and national levels. The procedures described for the international level are used, in part, by the Codex Committee on Pesticide Residues (CCPR) in considering the acceptability of MRLs being developed by that committee.

The guidelines cover the exposure assessment of acute hazards which are of particular concern for certain pesticides. Worked examples of various intake calculations are also

included to illustrate the best use of data in assessing exposure and characterizing risk. The guidelines are intended to assist national authorities in their considerations on the acceptability of Codex MRLs and in making national decisions on granting of pesticide registration. The approaches described are designed to provide reasonable assurance that use of Codex MRLs will not result in a dietary intake of a pesticide that exceeds its ADI, or acute Reference Dose (acute RfD) when appropriate.

1.3 ILO

Risk assessment and risk management

International Chemical Toolkit

http://www.ilo.org/public/english/protection/safework/ctrl_banding/toolkit/icct/index.htm

The toolkit developed involves a scheme of 5 stages. First stage is finding the hazard classification and matching it to a hazard group using the table supplied. In following stages, amount to be used, amount released to the air, control approach and task-specific control guidance sheets are identified. For pesticides there are 5 task control sheets developed on concentrate dilution, application (spraying and dusting), fumigating, using poison baits and disposing of used containers. Toolkit control sheets describes key points to do follow-up to reduce exposure to an adequate level.

Pesticides(http://www.ilo.org/public/english/protection/safework/ctrl_banding/toolkit/icct/pesticides.htm) .

Guidance sheets

(http://www.ilo.org/public/english/protection/safework/ctrl_banding/toolkit/icct/sheets.htm)) Apart from pesticide guidance sheets, there are 4 series of control approach guidance sheets, as well as fact sheets on skin and eye contact, respiratory protection equipment, safety issues and environmental issues.

Environmental issues guidance sheet provides general advice on the control of chemical emissions into the air, water and disposal of solid waste. The sheets describe the key points needed to follow to ensure adequate control and that environmental exposure is reduced to acceptable levels.

1.4 OECD

OECD Guidance for Country Data Review Reports on Plant Protection Products and Their Active Substances (Monograph Guidance)

<http://www.oecd.org/dataoecd/42/57/38588738.pdf>

Checking by scientific secretariat for completeness of dossiers is required before any evaluation is taken and a checklist is prepared for this reason. Forms have been

developed for the process of checking dossiers for completeness
<http://www.oecd.org/dataoecd/1/21/1944042.pdf>).

Guidance on how to prepare a monograph is provided in the 9 appendices on:

Appendix 1 - Standard terms and abbreviations,
(<http://www.oecd.org/dataoecd/46/43/1943970.pdf>)

Technical terms (Part 1), organizations and publications(Part 2) and the format for the compilation of listings of chemical names, common names, synonyms, trade names, code names for active substances, metabolites and formulations(Part 3) are provided.

Appendix 2 - Preparation (formulation) types and codes,
(<http://www.oecd.org/dataoecd/45/61/1943914.pdf>)

Code description and definition of preparation (formulation) types and codes are provided (e.g. EC Emulsion concentrate A liquid, homogenous preparation to be applied as an emulsion after dilution in water).

Appendix 3 - Guidance with respect to pagination, lay-out, tables and references,
(<http://www.oecd.org/dataoecd/46/40/1943946.pdf>)

Guidance with respect to pagination, lay-out, tables and references is given.

Appendix 4 - Suggested order for the preparation of each of the four levels and three annexes of the monographs to be prepared by regulatory authorities,
(<http://www.oecd.org/dataoecd/39/34/40553664.pdf>)

Documentation to be provided at each level is specified:

- Level 1 Statement of subject matter and purpose for which the monograph was prepared
- Level 2 Reasoned statement of the overall conclusions drawn by the regulatory authority
- Level 3 Proposed decision with respect to the application
- Level 4 Further information to permit a decision to be made, or to support a review of the conditions and restrictions associated with any approval or registration

Appendix 5 - Form for use in reporting details of intended uses (GAP information),
(<http://www.oecd.org/dataoecd/45/62/1943922.pdf>)

Form include details on: crop and or situation, product name, use(e.g. outdoor, field, glasshouse or indoor application), pest or group of pests controlled, formulation(type, concentration), application, application rate per treatment, minimum pre-harvest interval and remarks which may include extent of use, economic importance, restrictions.

Appendix 6 - Format for the listing of end points to be included in the reasoned statement of the overall conclusions drawn by the regulatory authority (Level 2),
(<http://www.oecd.org/dataoecd/46/41/1943954.pdf>)

Provides the format for the listing endpoints to be included (for Level 2) and include

Identity, physical and chemical properties, details of uses, classification and labeling (with regard to physical/chemical data, toxicological data, fate and behaviour data, ecotoxicological data, methods of analysis, impact on human and animal health (absorption, distribution, excretion and metabolism in mammals, acute toxicity, short-term toxicity, genotoxicity, long term toxicity and carcinogenicity, reproductive toxicity, neurotoxicity / delayed neurotoxicity, other toxicological studies, medical data, summary -ADI, AOEL, drinking water limit, acute reference dose (ArfD), dermal absorption, acceptable exposure scenarios-operator, workers, by-stander) residues, summary of critical residues data, consumer risk assessment.

Fate and behaviour in the environment (route of degradation (aerobic) in soil, route of degradation in soil - supplemental studies, rate of degradation in soil, soil adsorption/desorption, mobility in soil, PEC (soil), route and rate of degradation in water, PEC (surface water, sediment, groundwater), fate and behaviour in air, PEC (air), monitoring data, if available (soil, surface water, ground water, air)

Effects on non-target species: effects on terrestrial vertebrates, toxicity/exposure ratios for terrestrial vertebrates, toxicity data for aquatic species, toxicity/exposure ratios for most sensitive aquatic organisms.

Bioconcentration

Effects on honeybees, other arthropod species, earthworms, soil micro-organisms.

Appendix 7 - Format for the listing of test and study reports and other documentation evaluated (Annex A), (<http://www.oecd.org/dataoecd/45/63/1943930.pdf>)

The listing should cover each separate chapter specified for the preparation of the evaluation and assessment to be included as Annex A of the Monograph. It should include a listing of all test and study reports, test guidelines, and published papers submitted in support of the application and other relevant information available to, or brought to the attention of, the regulatory State. Guidance is provided on how references should be listed.

Appendix 8 - Format for the listing of test and study reports and other documentation relied on (Annex B), (<http://www.oecd.org/dataoecd/46/42/1943962.pdf>)

The listing should include only those test and study reports, test guidelines, and published papers relied on by the regulatory authority in reaching its conclusions, whether submitted in support of the application or, consisting of other relevant information available to, or brought to the attention of the regulatory authority.

Appendix 9 - Guidance Notes for Analysis and Evaluation of Particular Types of Studies, (<http://www.oecd.org/dataoecd/43/27/34870089.pdf>)

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

Dossier Guidance-Main document, <http://www.oecd.org/dataoecd/43/26/34870180.pdf>

The main document specifies individual documents that are required for a proposal of an active substance, for the registration or re-registration of a plant protection product, for the establishment of a MRL, for the establishment of an import tolerance. Documents required from A to O are:

Document A	Purpose
Document B	Task Force Information.
Document C	Labels and Leaflets-
Document D-1	Supported Uses
Document D-2	Registered Uses
Document D-3	Supported Uses in Exporting Countries
Document E-1	Existing MRLs
Document E-2	MRLs in Exporting Countries -
Document F	Statements of Intention to Submit a Dossier
Documents G	Regulatory position for formulants
Document H	Safety data sheets for formulants-
Document I	Other available toxicological data on formulants -
Document J	Confidential Information
Document K	Individual Test and Study Reports-
Documents L	<i>Tier I</i> quality checks for individual tests and studies and reference lists-
Documents M	<i>Tier II</i> summaries and assessments of individual tests and studies and groups of tests and studies
Documents N	Tier III overall summary and assessment, conclusions and proposed Decision-
Document O	Completed Forms for the checking of dossiers for completeness

Appendix 1 - Standard terms and abbreviations

<http://www.oecd.org/dataoecd/1/23/1944058.pdf>

Technical terms (Part 1), organizations and publications (Part 2) and the format for the compilation of listings of chemical names, common names, synonyms, trade names, code names for active substances, metabolites and formulations (Part 3) are provided.

Appendix 2 - Preparation (formulation) types and codes

<http://www.oecd.org/dataoecd/1/14/1943986.pdf>

Code description and definition of preparation (formulation) types and codes are provided (e.g. EC Emulsion concentrate A liquid, homogenous preparation to be applied as an emulsion after dilution in water).

Appendix 3 - Forms for use in reporting:

<http://www.oecd.org/dataoecd/1/46/1944122.pdf>

1. Details of intended uses (GAP information)-
2. Registered uses and actual uses

3. Maximum residue limits (MRLs)

Appendix 4 - Format for compilation of Tier I quality checks

<http://www.oecd.org/dataoecd/1/15/1943994.pdf>

Part 1 Summary report- Information to be provided includes data requirement(s), reference point (location) in dossier, authors (year) title owner, date, testing facility, dates of work, test substance, test method, GLP(name of the accreditation authority).

Part 2 Detailed report - appropriate for studies not conducted in accordance with the test guidelines currently specified. Information to be provided includes data requirement(s), reference point (location) in dossier, authors (year) title owner, date, testing facility, lab.report no., dates of experimental work, objectives, test substance, specification, storage stability, stability in vehicle, homogeneity in vehicle, validity, physical form, vehicle/solvent, test method, justification, copy of method, choice of method, deviations, certified laboratory, certifying authority, GLP(name of the accreditation authority), justification, GEP, type of facility (official or officially recognized), justification, test system, statistics, references, unpublished data.

Appendix 5 - Forms for use in reporting:

<http://www.oecd.org/dataoecd/1/16/1944002.pdf>

1. Crop residues data from individual supervised trials in summary form-

Information required in the form are: active substance(common name), commercial product, producer of commercial product, crop/crop group, responsible body for reporting, content of active substance(g/kg or g/L), formulation, indoor/glasshouse/outdoor use, other active substances in the formulation, residues calculated as. Information on location, commodity/variety, date of sowing or planting, flowering, harvest, method of treatment, application rate per treatment, dates of treatment, number of treatment, last date, growth stage at last treatment or date, portion analyzed, residues(mg/kg), pre harvest interval, remarks are also required.

2. Individual soil dissipation studies (soil residues) in summary form-Information required are: location, cropped or bare, soil characteristics(soil texture, pH, % organic C, cation exchange capacity), method of treatment, application rate per treatment(kg as/ha), application date, soil layer, days after application, residues(mg/kg), DT50 (days), DT90 (days), remarks.

Appendix 6 - Format for the listing of test and study reports and other documentation

Parts 1. Listing by test and study type,

Part 2. Listing by author,

Part 3. Listing of test and study reports and published papers not submitted should provide information for each test and study report :

- its title, source, company and report number;
- an indication as to whether it is published or unpublished;
- whether it has been conducted in compliance with the principles of GLP or the principles of GEP, as appropriate;

In the case of unpublished reports

- an indication of the identity of the owner of the test or study concerned, where the owner is not the person or organization that submitted it; and
- an indication as to whether or not data protection is claimed in accordance with the relevant requirements of the country to which the dossier is submitted, for the purposes of the registration of formulations containing the active substance.
<http://www.oecd.org/dataoecd/2/3/1944098.pdf>

Part 4 - OECD, EU, US, Canadian, Japanese and Australian numbering systems for data and information on active substances: <http://www.oecd.org/dataoecd/43/25/34870442.pdf>

The numbering systems used in many OECD countries for the data and information relating to active substances to be submitted, are different. In this part (Part 4 of Appendix 6) OECD numbering system which applicants could use are provided. Alternatively, applicants can use the country-specific numbering system for the country to which application is being made. A compilation of the numbering systems used in some OECD countries is also provided in this section.

Part 5 - OECD, EU, US, Canadian, Japanese and Australian numbering systems for data and information on formulated product, <http://www.oecd.org/dataoecd/43/24/34870494.pdf> provides information on the numbering system from OECD, EU, US, Canada and Australia for the formulated product (see Part 4).

Appendix 7 - Format for the compilation of Tier II summaries - active substance -

Information required:

Part 1 - Identity, physical and chemical properties, further information, proposals including justification of the proposals for the classification and labelling of the active substance, <http://www.oecd.org/dataoecd/1/17/1944010.pdf> Information required:

Part 2 - Analytical methods, <http://www.oecd.org/dataoecd/1/47/1944130.pdf> Each report should include report reference, if GLP applied, principle of the method, recovery findings, linearity, specificity, limit of quantification, repeatability, reproducibility and conclusion.

Part 3 - Toxicological and metabolism studies on the active substance, <http://www.oecd.org/dataoecd/2/4/1944106.pdf>

Part 4 - Residues in or on treated products, food and feed, <http://www.oecd.org/dataoecd/2/1/1944082.pdf>

Part 5 - Fate and behaviour in the environment, <http://www.oecd.org/dataoecd/1/18/1944018.pdf> Information on fate in and behaviour in soil, water and air to be provided include:

- Route and rate of degradation in soil (laboratory studies),

- Field studies: soil dissipation studies, storage stability of chemx residues in soil, soil residue testing, soil accumulation studies
- Mobility studies with chemx and its degradation products
- Hydrolytic degradation of relevant metabolites, degradation and reaction products
- Photochemical degradation
- Ready biodegradability of chemx
- Degradation in aquatic systems: aerobic degradation in aquatic systems, water/sediment studies
- Degradation in the saturated zone
- Route and rate of degradation air
- Definition of the residue
- Monitoring data

Appendix 8 - Format for the compilation of Tier II summaries - formulated product

Part 1 - Identity, Physical, chemical and technical properties, Data on application, Further information, Proposals including justification of the proposals for the classification and labeling of the plant protection product

<http://www.oecd.org/dataoecd/1/48/1944138.pdf>

Part 2: Toxicological studies and exposure data

<http://www.oecd.org/dataoecd/1/45/1944114.pdf>

Part 3 - Ecotoxicological studies and risk assessment

<http://www.oecd.org/dataoecd/1/49/1944146.pdf>

Acute toxicity information (acute toxicity exposure ratio (TER_A) for birds that are likely to be exposed to the chemical should be provided, taking into account possible route of exposure including ingestion of insects. For calculating toxicity exposure ratios (TER values), distances and scenarios used as a basis for estimation of predicted environmental concentrations (PEC values) should reflect the results of risk assessments carried out.

Short-term toxicity exposure ratio (TER_{ST}) for birds, toxicity exposure ratios for aquatic species (acute and long term toxicity exposure ratios for birds, Daphnia, aquatic insect species, aquatic crustacean species, gastropod species, algae, aquatic plants), acute toxicity (aquatic) of the preparation, results of microcosm and mesocosm study, residues data in fish (long term), chronic toxicity to fish, accumulation in aquatic non-target organisms, effects on terrestrial vertebrates other than birds (acute, short-term, long-term toxicity exposure ratio) should be given.

Where exposure is likely, hazard quotients for bees, acute toxicity of the preparation to bees, effects on arthropods other than bees should be provided. Each report on studies should specify guidelines, report number, GLP information, materials, study design and methods used, result, discussion and conclusions. If the overall results obtained in Tier I testing of the effects of substance on arthropod species, indicated that the it's toxicity to the various non-species is very low, no further tests are carried out on non-target terrestrial arthropods. Predicted initial environmental concentrations of the chemical in

soil, based on the recommended use rate and exposure based on worst case scenarios, acute toxicity, sub-lethal effects on earthworms including field tests, residue content of earthworms, effects on other soil non-target macro-organisms, laboratory test to investigate impact on soil microbial activity, effects on non-target terrestrial plants, other/special laboratory and field studies should be given .

Part 4 - Efficacy Data and Information, <http://www.oecd.org/dataoecd/1/19/1944026.pdf>

The summary and assessment of efficacy data prepared for individual plant protection products, should be in the form of a biological dossier which should allow a comprehensive understanding of the application and facilitate evaluation and decision making having regard to the evaluative and decision making criteria which are relevant in the country to which application is made. Examples are provided to guide the preparation of the dossier.

Appendix 9 - Format for the listing of endpoints to be included in the Tier III overall summary and assessment, <http://www.oecd.org/dataoecd/2/2/1944090.pdf>

This appendix provides the listing of endpoints to be provided in the Tier III in the following order:

- Chapter 1: Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling
- Chapter 2: Methods of Analysis
- Chapter 3: Impact on Human and Animal Health
- Chapter 4: Residues
- Chapter 5: Fate and Behaviour in the Environment
- Chapter 6: Effects on Non-target Species

Appendix 10 - Format for the compilation of Tier III overall summaries and assessments, <http://www.oecd.org/dataoecd/1/20/1944034.pdf>

Chapter 1 The active substance, its properties, uses, proposed classification and labelling

Chapter 2 Methods of analysis

Chapter 3 Impact on human and animal health

Effects having relevance to human and animal health arising from exposure to the active substance or to impurities in the active substance or to their transformation products, toxicological end point for assessment of risk following long-term dietary exposure (ADI), toxicological end point for assessment of risk following acute dietary exposure - ARfD (Acute reference dose), toxicological end points for assessment of occupational and bystander risks -AOEL / MOE, drinking water limit, impact on human and animal health arising from exposure to the active substance or to impurities contained in it

Chapter 4 Residues

Chapter 5 Fate and behaviour in the environment

Definition of the residue relevant to the environment, fate and behaviour in soil, water, air

Chapter 6 Effects on non-target species

Effects on terrestrial vertebrates, aquatic species, bees and other arthropod species, earthworms and other soil macro-organisms, soil micro-organisms, other non-target organisms (flora and fauna), effects on biological methods of sewage treatment, environmental risk mitigation

Chapter 7 Efficacy data and information

Chapter 8 Overall Conclusions

Appendix 11 - Forms for use in checking dossiers for completeness,

<http://www.oecd.org/dataoecd/1/21/1944042.pdf>

Forms consist of three parts.

Part 1 Evaluation Form 1 - is for use in checking that the required supporting documentation has been provided

Part 2 Evaluation Form 2 – is for use in checking that the required active substance and formulated product dossier summaries and an overall assessment, have been provided

Part 3 Evaluation Form 5 – is for use in checking that the *Tier I* quality checks for individual tests and studies are of acceptable quality

OECD

OECD Guidance document on emission scenario documents

[http://www.olis.oecd.org/olis/2000doc.nsf/LinkTo/NT000010DA/\\$FILE/00081657.PDF](http://www.olis.oecd.org/olis/2000doc.nsf/LinkTo/NT000010DA/$FILE/00081657.PDF)

This Guidance Document intends to provide an introduction to Emission Scenario Documents (ESDs), to facilitate their development and use in OECD Member countries and at the OECD level. It is an introduction to emission scenario documents and does not include detailed guidance on how to use emission scenario documents. It specifies, what should be included in an emission scenario document, steps in production of an emission scenario document, points to be considered. A questionnaire used in obtaining emission data for a risk assessment is provided as an Annex.

Number 14 of these series is on “Insecticides for stables and manure storage systems” and one on “Insecticides used in households and for professional uses” is being prepared.

Detailed information on how to conduct release estimates in environmental exposure assessment is available in the document “**OECD Environmental Exposure Assessment Strategies for Existing Industrial Chemicals in OECD Member Countries** (OECD Environmental Health and Safety Publications, Series on Testing and Assessment No.17) [http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/NT00000A7E/\\$FILE/04E94750.PDF](http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/NT00000A7E/$FILE/04E94750.PDF)

This document reviews strategies used by OECD Member countries when assessing exposure in the context of risk assessments for existing industrial chemicals. Overall assessment strategies, fate and pathway analysis, iterative or tiered approach, bounding

and realistic point estimates (screening, typical values), realistic exposure distribution discussed. In estimation of PECs use of 'weight or multiple lines of evidence' approach, use of ambient monitoring data, use of models, spatial scales, temporal scales, environmental compartments, background exposure, connecting measured PECs to source(s) of interest, bioavailability of measured PECs, persistence and bioaccumulation, uncertainty and variability are considered.

Guidance Document on Reporting Summary Information on Environmental Occupational Exposure

[http://www.olis.oecd.org/olis/2003doc.nsf/LinkTo/NT000063FA/\\$FILE/JT00156125.PDF](http://www.olis.oecd.org/olis/2003doc.nsf/LinkTo/NT000063FA/$FILE/JT00156125.PDF)

This document contains guidance for using the summary exposure information reporting formats, which were developed by the OECD Ad Hoc Group on Reporting Summary Exposure Information. The formats developed are intended to be a flexible framework for reporting summary exposure information that are adaptable to wide range of exposure scenarios as well as to different levels of exposure information and meant not to be prescriptive.

Three basic formats are provided to facilitate reporting of summary exposure information of interest to industry, governmental organizations, other stakeholders, and the public.

- Format A: *General Information and Overview of*
- Format B: *Monitoring Evaluations* and
- Format C: *Modeling Evaluations*

Formats and in-depth guidance on how to complete them are provided in the document.

Guidance document on the use of multimedia models for estimating overall environmental persistence and long-range transport

[http://www.olis.oecd.org/olis/2004doc.nsf/LinkTo/NT00000EAE/\\$FILE/JT00160339.PDF](http://www.olis.oecd.org/olis/2004doc.nsf/LinkTo/NT00000EAE/$FILE/JT00160339.PDF)

Target audience of this Guidance Document is those who are involved in risk assessment and management of POPs (persistent organic pollutants) or PBTs (persistent and bio-accumulating toxics). It is about using multimedia models, i.e. generic evaluative models that can calculate overall environmental persistence (Pov) and potential for long-range transport (LRTP) covering multiple compartments such as air, water, sediment and soil, what models you can use to identify and characterize POPs/PBTs, what data to use, and how to use model calculations.

Pov and LRTP are not intrinsic properties of chemical pollutants, but instead derive from both chemical properties and environmental conditions. They cannot be measured directly and must be derived from models.

This document introduces the types of multimedia transport and transformation models that are currently available to estimate Pov and LRTP, the data needed for these models and their availability, and discusses how the models differ in spatial/temporal detail and

in treating various transport/transformation processes. Models are classified from Level I to IV in increasing complexity by model structure. The document defines persistence and transport potential, role of multimedia models in calculating P_{ow} and LRTP and discusses application of multimedia models in chemical assessment.

**Persistent, Bioaccumulative, and Toxic Pesticides in OECD Member Countries
Results of Survey on Data Requirements and Risk Assessment Approaches**

<http://www.oecd.org/dataoecd/23/61/2956551.pdf>

This document is the final report of the OECD survey to collect information on member countries' data requirements for persistent, bioaccumulative, and toxic (PBT) pesticides and approaches to assessing such pesticides. The purpose of the survey was to provide a clear understanding of the data and information that are used by pesticide regulators to determine the risks associated with low-dose exposure to PBT pesticides. The survey questionnaire was divided into two main parts, current data evaluation practices; data gaps and other approaches

Section on current data evaluation practices needs information on data that are received and used for evaluation of persistence, bioaccumulation, and environmental toxicity, standardized test methods used or required for generating data and models or monitoring data used in relation to persistence, bioaccumulation, and toxicity. Second section on data gaps and other approaches focuses on issues that may improve these processes.

OECD Pov and LRTP Screening Tool

http://www.oecd.org/document/17/0,3343,en_2649_34373_40754961_1_1_1_1,00.html

The tool has been developed with the aim of using multimedia models for estimating overall persistence (Pov) and long-range transport potential (LRTP) of organic chemicals at a screening level, in the context of PBTs/POPs assessments. It requires estimated degradation half-lives in soil, water and air, and partition coefficients between air and water and between octanol and water as chemical-specific input parameters. From these inputs the Tool calculates metrics of Pov and LRTP from a multimedia chemical fate model, and provides a graphical presentation of the results.

The OECD Pov and LRTP Screening Tool is available in manual and excels forms at:

http://www.oecd.org/document/17/0,3343,en_2649_34373_40754961_1_1_1_1,00.html

[Manual- http://www.oecd.org/dataoecd/54/28/40719272.pdf](http://www.oecd.org/dataoecd/54/28/40719272.pdf)

[Excel- http://www.oecd.org/dataoecd/54/29/40718984.xls](http://www.oecd.org/dataoecd/54/29/40718984.xls)

1.5 UNEP/WHO

Sound Management of Pesticides and Diagnosis and Treatment of Pesticide Poisoning - A Resource Tool, 2007

This resource tool is intended to meet the need for training in the sound management of pesticides and in the diagnosis and treatment of pesticide poisoning. It can be used to organize training courses for persons from various backgrounds, including the public, workers, healthcare professionals and registration personnel and others involved in pesticide management. The material is designed to allow flexibility in training, on the

basis of the existing infrastructure in a country or region. It addresses different needs and includes basic training materials, such as flip charts and also advanced multi-media presentations. The electronic version allows users to modify the content for local needs.

The tool contains information on different aspects of pesticide management. The Part I of the tool gives an overview of the tool and organizational aspects. Part II is made-up of modules that provide information on pesticides and their mode of action, personal protection measures as well as measures to protect the general public and the environment, its judicious and safe application within the context of Integrated Pest and Vector Management. The tool also provides information on diagnosis, first aid and treatment of pesticide poisonings. A glossary, other sources of information, images archives are covered in the Annexes. A Users Guide is prepared to facilitate the use of the resource tool.

http://www.who.int/whopes/recommendations/IPCSPesticide_ok.pdf

Users Guide to the Resource Tool

http://www.chem.unep.ch/Pesticides/PesticideResourceTool/Users%20Guide_Final.pdf

1.6 WHO

Risk assessment

Environmental Health Criteria Series provide basic scientific risk evaluation of a wide range of chemicals and groups of chemicals including pesticides. It provides comprehensive data from scientific sources for the establishment of safety standards and regulations <http://www.inchem.org/pages/about.html#ehc>

CICAD(Concise International Chemical assessment Documents) are concise documents that provide summaries of the relevant scientific information concerning the potential effects of chemicals upon human health and/or the environment. They are based on selected national or regional evaluation documents or on existing EHCs. The primary objective of CICADs is characterization of hazard and dose-response from exposure to a chemical and they include only that information considered critical for characterization of the risk posed by the chemical <http://www.inchem.org/pages/cicads.html>

International Chemical Safety Cards(ICSC) that provide information on the intrinsic hazards of specific chemicals, first aid and fire-fighting measures, and information about precautions for spillage, disposal, storage, packaging, labelling and transport. They summarize essential health and safety information on chemicals for their use at the "shop floor" level by workers and employers in factories, agriculture, construction and other work places <http://www.inchem.org/pages/icsc.html>.

And the **WHO Recommended classification of pesticides by hazard**

<http://www.inchem.org/documents/pds/pdsoter/class.pdf>

The document is arranged in 2 parts. Part I is the Classification as recommended by the World Health Assembly. It is not subject to periodic review and the classification table and text can only be changed by resolution of the World Health Assembly. Part II: Guidelines to Classification. Individual products are classified in a series of tables, according to the oral or dermal toxicity of the technical product, and its physical state. The tables are subject to review periodically.

The classification is based primarily on the acute oral and dermal toxicity to the rat. Provision is made for the classification of a particular compound to be adjusted if, for any reason, the acute hazard to man differs from that indicated by LD₅₀ assessments alone.

The main section of the guidelines consists of five tables

Table 1. Extremely hazardous (class Ia)

Table 2. highly hazardous (class Ib)

Table 3. moderately hazardous (class II)

Table 4 slightly hazardous (class III)

Table 5. Active ingredients unlikely to present acute hazard in normal use

IPCS Risk Assessment Terminology

<http://www.who.int/ipcs/methods/harmonization/areas/ipcsterminologyparts1and2.pdf>

This document is prepared in the context of a joint IPCS/OECD project to develop internationally harmonized generic and technical terms used in chemical hazard/risk assessment, that would facilitate the mutual use and acceptance of the assessment of chemicals between countries, saving resources for both governments and industry. It covers two categories of terms:

- Generic terms: general terms used in the process of determining hazard and risk.
- Technical terms: those terms used in human health and environmental hazard and risk assessment, including scientific–technical terms used in effects assessment (e.g., nomenclature of tumours and other pathological lesions and technical terms used in hazard characterization, such as teratogenicity).

Detailed definition of generic terms are also provided.

Part 2 involves IPCS glossary of key exposure assessment terminology. It is intended to help facilitate communication and consistency of language used in the exposure sciences. The document include exposure route-specific case studies illustrating the definitions in the IPCS exposure assessment terminology glossary.

A generic risk assessment model for insecticide treatment of mosquito nets and their subsequent use (WHOPES-PCS)

http://whqlibdoc.who.int/hq/2004/WHO_PCS_04.1.pdf

The document intends to develop a generic model that can be used for risk assessment of exposure to insecticides during the various stages in the production and use of insecticide-treated bednets. The model proposed covers the assessment of any risks to those treating bednets with insecticide in a domestic setting (operators) and to those sleeping under insecticide-treated bednets (users).

In the document detailed requirements of the risk assessment model are specified (hazard assessment, exposure assessment, risk characterization), range of toxicity tests normally

required for pesticide approval are listed and methods of net treatment are given. A worked example (deltamethrine) is provided for the generic method for treated bednets.

Three more generic risk assessments models for application of pesticides in public health are in preparation by WHOPES-PCS. These are:

- Generic risk assessment model for indoor and outdoor space spraying,
- Generic risk assessment model for insecticides used for mosquito larviciding,
- Generic risk assessment model for indoor residual spraying of insecticides

Health risks of persistent organic pollutants from long range transport of air pollutants

<http://www.euro.who.int/document/e78963.pdf>

The document provides a concise review of the available evidence on the characteristics of 13 groups of POPs (pentachlorophenol, DDT, hexachlorocyclohexanes, hexachlorobenzene, heptachlor, polychlorinated dibenzo-*p*-dioxins and dibenzofurans, polychlorinated biphenyls, polycyclic aromatic hydrocarbons, polychlorinated terphenyls, polybrominated diphenylethers, polybrominated dibenzo-*p*-dioxins and dibenzofurans, short-chain chlorinated paraffins and ugilec). It reviews pathways of human exposure related to the long-range transport of the POPs through the atmosphere, and the potential hazards associated with them. The review concludes with an expert assessment of the risks to health associated with exposure due to the long-range transport of each of the pollutants.

It is intended that the assessment will serve to strengthen the commitment of the parties to the Convention on Long-range Transboundary Air Pollution to improve air quality in Europe and to prevent adverse effects of air pollution on human health.

IPCS Training documents on chemical safety and risk assessment consists of four modules.

Training module 1: Fundamentals of applied toxicology

<http://www.cepis.org.pe/tutorial6/fulltext/WHOPCS-81.pdf>

Training module 2: Laboratory handling of mutagenic and carcinogenic products

http://whqlibdoc.who.int/hq/1998/WHO_PCS_98.9.pdf

Training module 3 UNEP/IPCS: Chemical risk assessment

Human risk assessment

http://whqlibdoc.who.int/hq/1999/WHO_PCS_99.2_SectionA_eng.pdf

Environmental risk assessment

http://whqlibdoc.who.int/hq/1999/WHO_PCS_99.2_SectionB_eng.pdf

Ecological risk assessment

http://whqlibdoc.who.int/hq/1999/WHO_PCS_99.2_SectionC_eng.pdf

Training module 4: General scientific principles of chemical safety
<http://www.bvsde.paho.org/bvstox/i/fulltext/training/training.htm>

Guidance documents

Uncertainty and Data Quality in Exposure assessment (Part1, Part 2)

http://www.who.int/ipcs/publications/methods/harmonization/exposure_assessment.pdf

Part 1: Guidance document on characterizing and communicating uncertainty in exposure assessment <http://www.who.int/ipcs/methods/harmonization/areas/uncertainty%20.pdf>
(General chemicals)

Part 2: Data quality in chemical exposure assessment

<http://www.who.int/ipcs/methods/harmonization/areas/exposedataquality.pdf>

(General chemicals)

The guidance has been developed as a basis for transparently characterizing uncertainty in chemical exposure assessment to enable its full consideration in regulatory and policy decision-making processes. Uncertainties in exposure assessment are grouped under three categories- parameter, model and scenario—with the guidance addressing both qualitative and quantitative descriptions.

The document recommends a tiered approach to the evaluation of uncertainties in exposure assessment using both qualitative and quantitative (both deterministic and probabilistic) methods, with the complexity of the analysis increasing as progress is made through the tiers.

The report defines and identifies different sources of uncertainty in exposure assessment, outlines considerations for selecting the appropriate approach to uncertainty analysis in line with the specific objective and identifies the information needs of decision-makers and stakeholders. It also recommends the adoption of 10 guiding principles for uncertainty analysis which are considered to be the general desirable goals or properties of good exposure assessment.

WHO also has on-going work on:

Draft Guidance on Mutagenicity Testing for Chemical Risk Assessment (Open for Comment)

http://www.who.int/ipcs/methods/harmonization/areas/mutagenicity_testing_draft.pdf

(General chemicals)

Draft Guidance on Principles of Characterizing and Applying PBPK Models in Risk Assessment

http://www.who.int/ipcs/methods/harmonization/areas/mutagenicity_testing_draft.pdf

(General chemicals)

Skin sensitization in chemical risk assessment

http://www.who.int/ipcs/methods/harmonization/areas/skin_sensitization.pdf (General chemicals)

Chemical-specific adjustment factors for interspecies differences and human variability: guidance document for use of data in dose/concentration–response assessment

http://whqlibdoc.who.int/publications/2005/9241546786_eng.pdf (General chemicals)

2. Guidance from Regional Organizations

2.1 European Union

Registration-Technical guidance documents

[Technical Guidance Document in Support of the Directive 98/8EC Concerning the Placing of Biocidal Products on the Market](http://ecb.jrc.ec.europa.eu/documents/Biocides/TECHNICAL_NOTES_FOR_GUIDANCE/TNsG_DATA_REQUIREMENTS/TNsG-Data-Requirements.pdf)
[http://ecb.jrc.ec.europa.eu/documents/Biocides/TECHNICAL NOTES FOR GUIDANCE/TNsG_DATA_REQUIREMENTS/TNsG-Data-Requirements.pdf](http://ecb.jrc.ec.europa.eu/documents/Biocides/TECHNICAL_NOTES_FOR_GUIDANCE/TNsG_DATA_REQUIREMENTS/TNsG-Data-Requirements.pdf)

[Six Technical Notes for Guidance \(TNsG\) have specifically been developed for biocides:](#)

1. TNsG on Data Requirements:

This document provides guidance on the data requirements and waiving arguments that are required for biocidal active substances and products. It specifies common

- core data set for active(chemical) substances and biocidal products,
- product specific data set for active substances and biocidal products regarding ecotoxicological profile, including environmental fate and behaviour,
- additional data and guidance for active(chemical) substances and biocidal products
- data requirements for substances of concern
- data requirements for active substances and biocidal products in regard to simplified procedures
- guidance on good laboratory practice

2. TNsG on Annex I Inclusion:

This document identifies criteria for unacceptable/acceptable effects and associated conditions for inclusion of active substances onto Annex I (or IA or IB).

[http://ecb.jrc.ec.europa.eu/documents/Biocides/TECHNICAL NOTES FOR GUIDANCE/TNsG_ANNEX_I_INCLUSION/TNsG-Annex-I-Inclusion.pdf](http://ecb.jrc.ec.europa.eu/documents/Biocides/TECHNICAL_NOTES_FOR_GUIDANCE/TNsG_ANNEX_I_INCLUSION/TNsG-Annex-I-Inclusion.pdf)

3. TNsG on Product Evaluation

This document provides guidance on how to perform the administrative and scientific evaluation of applications for authorisation and registration.

http://ecb.jrc.ec.europa.eu/documents/Biocides/TECHNICAL_NOTES_FOR_GUIDANCE/TNsG_PRODUCT_EVALUATION/TNsG-Product-Evaluation.pdf

4. TNsG on Human Exposure:

This document provides guidance on the estimation of Human Exposure to biocidal products for all Product Types.

http://ecb.jrc.ec.europa.eu/documents/Biocides/TECHNICAL_NOTES_FOR_GUIDANCE/TNsG_ON_HUMAN_EXPOSURE/TNsG%20-Human-Exposure-2007.pdf

5. TNsG on Dossier Preparation and Study Evaluation:

This guidance focuses primarily on applications for the inclusion of active substances onto Annex I (or IA or IB). It is intended to give guidance on how the documentation to be submitted by the applicant should be prepared and presented.

<http://ecb.jrc.ec.europa.eu/biocides>

6. TNsG on the assessment of technical equivalence:

This guidance is intended to establish harmonised criteria and processes for assessing the equivalence of different sources of a substance versus the reference source

http://ecb.jrc.ec.europa.eu/DOCUMENTS/Biocides/TECHNICAL_NOTES_FOR_GUIDANCE/TNsG_TECHNICAL_EQUIVALENCE/TNsG-Technical-Equivalence.pdf

REACH Regulation (EC) No 1907/2006 does not exclude biocidal active substances (active substances) from its scope and many provisions of the REACH Regulation apply to biocidal active substances. The Regulation is concerned with substances, whether on their own or in one or more preparation(s) or article(s). Active substances used in biocidal products are considered substances for the purposes of the REACH Regulation.

Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. This set of technical guidance documents is intended for use by the competent authorities appointed by Member States under the provisions of Directive 67/548, Regulation 793/93 and Directive 98/8. It is issued by the European Commission (DG JRC) to help competent authorities to carry out the risk assessments on new notified substances, existing substances and on biocidal active substances or a substance of concern present in

a biocidal product. It is also intended to be useful for notifiers of new substances as well as for applicants of a risk assessment of a biocidal active substance and for those manufacturers and importers who are obliged under the provisions of Regulation 793/93 to submit all relevant information for the risk assessments and to fulfil any request for further information or testing as a consequence of a risk assessment

This guidance document is made-up of 4 parts.

Part I includes 2 chapters, general information and risk assessment for human health.

http://ecb.jrc.ec.europa.eu/documents/TECHNICAL_GUIDANCE_DOCUMENT/EDITI ON_2/tgdpart1_2ed.pdf

Chapter 1 General Introduction

In this chapter information is provided on legislative background, general principles of risk assessment, procedures for preparing risk assessments for notified new substances, priority existing substances and biocidal active substances. In Appendix I Base set, information required for the technical dossier is given. This includes physico-chemical properties of the substance, toxicological studies and ecotoxicological studies.

Chapter 2 Risk Assessment for Human Health

This chapter includes core principles of human exposure assessments, workplace, consumer and exposure of human via the environment, effects assessment(dose-response assessment, toxicokinetics, acute toxicity, irritation and corrosivity, sensitization, repeated dose toxicity, mutagenicity, carcinogenicity, carcinogenicity, reproduction toxicity) and risk characterization.

Part II

http://ecb.jrc.ec.europa.eu/documents/TECHNICAL_GUIDANCE_DOCUMENT/EDITI ON_2/tgdpart2_2ed.pdf

The chapter 3 in Part II is on environmental risk assessment. It provides information on general principles of assessing environmental risks, model calculations, effects assessments (for aquatic compartment, microorganisms in sewage treatment plant, sediment, terrestrial compartment, air compartment, assessment of secondary poisoning), environmental risk assessment-marine(marine exposure assessment, marine effects assessment, PBT assessment), risk characterization and testing strategies.

Part III

http://ecb.jrc.ec.europa.eu/documents/TECHNICAL_GUIDANCE_DOCUMENT/EDITI ON_2/tgdpart3_2ed.pdf

This part has 3 chapters.

Chapter 4 Use of (Quantitative) Structure Activity Relationships ((Q)SARs) describes general criteria for selecting (Q)SARs for use within the risk assessment process, use of acceptable QSARs, specific guidance on use of QSRs in environmental risk assessment including aquatic effects, n-octanol-water partition coefficient, Henry's Law constant, bio-concentration factor(aquatic organisms, terrestrial organisms), biodegradation,

phytolysis(atmosphere, water), hydrolysis, use of QSR in human risk assessment. Appendix I outlines reporting on (Q)SAR models.

Chapter 5 Use Categories

This chapter lists categories to describe the exposure relevance of the use(s) of a substance. Lists of industry in which the substance is used, function category/use category are provided.

Chapter 6 Risk Assessment Report Format

Format for risk assessment report is provided as Appendix I. It includes overall conclusions of the risk assessment, summary of conclusions, general substance information, general information on exposure, environment(environmental exposure, effects assessment, risk characterization), human health(toxicity, exposure assessment, effects assessment, risk characterization), human health(physico-chemical properties) conclusions/results.

Part IV

http://ecb.jrc.ec.europa.eu/documents/TECHNICAL_GUIDANCE_DOCUMENT/EDITI ON_2/tgdpart4_2ed.pdf

Chapter 7 Emission Scenario Document

This chapter is a collection of the emission scenario documents (ESDs) that are currently available for the different industrial categories (IC's) and Biocidal Product-Types (BPTs). The Emission Scenario Documents have been developed by different competent authorities and by industry. ESDs are not available for all industrial categories and biocidal product-types. There are 9 ESDs for the industrial categories.

REACH

Guidance on registration.

http://guidance.echa.europa.eu/docs/guidance_document/registration_en.pdf?vers=26_11_08

This guidance aims to assist industry in determining which tasks and obligations have to be complied with to fulfill their registration requirements under REACH. It consists of two parts. Part I is on registration and provides information on what is covered by the legislation and the approach in chemicals assessment. Part II gives detailed guidance on how to prepare a registration dossier. A chemical safety report that includes hazard assessments (human health hazard assessment, physicochemical hazard assessment, environmental hazard assessment, persistent bioaccumulative and toxic(PBT)/very persistent and very bioaccumulative (vPvB) assessment), exposure assessment and risk characterization is required.

Guidance on inclusion of substances in Annex XIV (substances subject to Authorisation)

http://guidance.echa.europa.eu/docs/guidance_document/annex_xiv_en.pdf?vers=12_08_08

The guidance document describes the process of inclusion of substances of very high concern (SVHC) in Annex XIV (List of Substances subject to Authorisation). It relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006. It provides general information on authorization,

procedure to include substances in the authorization system, assistance in the preparation of a decision by the Commission to include a substance in Annex XIV and consultation of the Member State Committee and interested parties. It has to annexes on:

Annex I: Overview of the roles, obligations and rights of actors

Annex II: Format for a notice that an annex XV dossier for the identification of a substance as a CMR, PBT, vPvB or a substance of equivalent concern

Guidance on priority setting for evaluation

http://guidance.echa.europa.eu/docs/guidance_document/prioritisation_evaluation_en.pdf?vers=12_08_08

The guidance describes how to prioritise registration dossiers and testing proposals for evaluation under REACH. It involves priority setting in the context of REACH and availability of input data, priority setting for examination of testing proposals, priority setting compliance check of registration dossiers

Guidance on Socio-Economic Analysis – Restrictions

http://guidance.echa.europa.eu/docs/guidance_document/sea_restrictions_en.pdf

2.2 Sahel (CILSS)PERMANENT INTERSTATES COMMITTEE FOR DROUGHT CONTROL IN THE SAHEL

Registration

Common regulation for the registration of pesticides in CILSS member states

<http://www.insah.org/protectiondesvegetaux/csp/RCenglish.pdf>

Under the umbrella of the Committee on Drought Control in the Sahel a Common Regulation for Pesticide Registration in the CILSS Member States (Burkina Faso, Cape Verde, Chad, Guinea Bissau, The Gambia, Mali, Mauritania, Niger, and Senegal)was established.

The common regulation concerns authorization, placing on the market, use and control of the active ingredients and formulated products of pesticides in the Member States. It is applicable to the classification, labeling, packing and packaging of pesticide formulations. Evaluation and registration of active ingredients and formulated products falls within the competence of CILSS and it is carried out for all Member States.

The control of import, export, placing on the market, use and destruction of pesticides registered under this Common Regulation falls within the competence of the responsible authorities of the Member States. The regulations of advertising with respect to pesticides are part of this control. Member States stipulate that pesticides must be used properly, have overall responsibility of post-registration control of the distribution and use of the pesticide.

Member States have their own National Pesticide Management Committees (NPMCs) and keep the right not to authorize the placing on the national market of a pesticide that is registered or provisionally registered by the CSP if :

- area of use does not exist in the country
- it is impossible to satisfy the conditions and/or the restrictions related to the registered use
- the ecological conditions are different
- there is contradiction with national policies in agriculture, environment or in public health

The annexes to the Common regulation for registration of pesticides in CILSS Member States include:

- Annex 1: Common procedure for pesticide registration in CILSS Member States
- Annex 2: Composition of the dossier to be submitted for pesticide registration
- Annex 3: Criteria for the registration of pesticides in the Sahel (to be included at a later stage)
- Annex 4: Labeling
- Annex 5: Official languages within CILSS Member States, for labeling purpose

The CPS maintains an inventory of pesticides used or commercialized in the CILSS Member States. The list of pesticides authorized in CILSS by January 2009 is available at: <http://www.insah.org/protectiondesvegetaux/csp/CSP-Liste-globale-Pesticides-autorises-CSP-Janvier2009.pdf>

Requirements for composition of dossier for authorization of pesticides in Sahel are specified by the CSP in December 2008 and are available at:

<http://www.insah.org/protectiondesvegetaux/csp/synthesepesticide.pdf> **(In French)**

3 National Information

See Annex II for further national information

3.1 Australia

Legal background to the National Registration Scheme (Agricultural and Veterinary products)

http://www.apvma.gov.au/MORAG_ag/vol_1/legal_background.html

Regulatory controls over pesticides and veterinary medicines require:

- all active constituents for agricultural and veterinary chemical products to be approved by the Australian Pesticides and Veterinary Medicines Authority (APVMA)

- the particular source identity of the manufacturing plant used to make an active constituent for an agricultural or veterinary chemical product is an essential part of this approval;
- all agricultural and veterinary chemical products to be registered by the APVMA prior to their distribution, sale or use in Australia;
- all agricultural and veterinary chemical products being sold in Australia to have a label approved by the APVMA attached to their containers; and
- manufacturers of veterinary chemical products in Australia to be licensed by the APVMA.

Agricultural Manual of Requirements and Guidelines - Ag MORAG

http://www.apvma.gov.au/MORAG_ag/MORAG_ag_home.shtml

AgMORAG provides information on data requirements and guidelines for applications to register or approve agricultural chemical products, labels, active constituents and issue permits. It is made up of 5 volumes; Volume 1 sets out the legal background and also gives information on how to make an application, and how APVMA manages the registration process. Twenty-five different application categories that the applicant can apply are described in the Volume 2. Details of the requirements and guidelines for each of the 10 data (chemistry and manufacture, toxicology, metabolism and kinetics, residues, trade, OHS, environment, efficacy and safety, special data) parts which might apply to different types of applications are provided in Volume 3. Guidelines for applications to register specific types of products are given in Volume 4 and Volume 5 contains the Ag Labelling Code which sets out requirements and best practice for product labels and describes labeling approval process.

http://www.apvma.gov.au/MORAG_ag/vol_2/vol2_alldocs.pdf;

http://www.apvma.gov.au/MORAG_ag/vol_3/vol3_alldocs.pdf

http://www.apvma.gov.au/MORAG_ag/vol_5/vol5_alldocs.pdf

Risk Assessment

The APVMA is responsible for ensuring that off-target pesticide spray drift does not harm human health, the environment or Australia's international trade.

In assessing applications for product registrations the APVMA undertakes spray drift risk assessment for agricultural chemical products (including biological control agents) labelled for use outdoors, that can be applied as sprays or dusts (there are some exceptions that are outlined in section 3.2 of the Operating Principles).

Assessing and managing the risks

- **Operating principles**
The APVMA has developed a risk assessment framework - *APVMA Operating Principles in Relation to Spray Drift Risk*. These [Operating Principles](#) describe the

methods and scientific principles the APVMA uses to assess and manage spray drift issues.

2 Standard risk scenarios

[Standard spray drift scenarios](#) provide detailed information about spray drift behaviour for a range of ground and aerial spray drift application methods. They include APVMA modelling input parameters.

- **No-spray zones**

These are the protective buffer zones that the APVMA requires between an application area and an area downwind that needs to be protected. The APVMA sets the [size of no-spray zones \(PDF - 381KB\)](#) based on the inherent hazard the pesticide presents and an assessment of the specific risk.

3.2 Sri Lanka

Application for registration of pesticides

Guidelines are available for registration of pesticides and forms are provided for registration. Applicant should provide information on product details, source active ingredient, technical material, formulation and additional submissions. Registration Application Guide is available at http://www.agridept.gov.lk/SCPP/opr_indx.htm Different forms are available for application for re-registration of pesticides application for importation of a pesticide and application for suitability for the registration of mosquito coil/mat.

Label templates are provided for different formulations.

http://www.agridept.gov.lk/SCPP/opr_indx.htm

Pesticides Control Act (Act Nos 33 of 1980; 6 of 1994).

<http://www.customs.gov.lk/docs/25343.pdf> Pesticide Control Act (amendment)

[http://www.agridept.gov.lk/content/admin/pdf/Control%20of%20Pesticides%20\(Amendment\)%20Act%20No.%206%20of%201994.pdf](http://www.agridept.gov.lk/content/admin/pdf/Control%20of%20Pesticides%20(Amendment)%20Act%20No.%206%20of%201994.pdf)

This Act apply to active ingredients and pesticide formulations with adjuvants. The Act designates Registrar of Pesticides as the licensing authority, establishes a Pesticide Technical and Advisory Committee and specifies its members (including tea research, rubber research institute directors) and its functions, sets the rules for application, issue of license, analysis of samples, fees, penalties among other provisions.

Office of the registrar of pesticides (ROP)

http://www.agridept.gov.lk/SCPP/opr_indx.htm

Guidelines on Application for Approval of Advertisement on Pesticides

http://www.agridept.gov.lk/SCPP/opr_indx.htm

List of pesticides registered in Sri Lanka http://www.agridept.gov.lk/SCPP/opr_indx.htm restricted pesticides http://www.agridept.gov.lk/SCPP/opr_indx.htm, public health pesticides http://www.agridept.gov.lk/SCPP/opr_indx.htm and list of banned pesticides are available http://www.agridept.gov.lk/SCPP/opr_indx.htm.

3.3 Tanzania

Socio-economic considerations

Socio-Economic Database <http://www.tsed.org>

Tanzania established the Tanzania Socio-Economic Database (TSED) that was supported by UNDP and UNICEF within the National Bureau of Statistics in collaboration with over 20 Ministries and Government Institutions. The main purpose of TSED is to allow an overall, up-to-date view of the socio-economic situation in Tanzania and to facilitate use of data for analysis by policy makers and other users. Sectors for which indicators developed include agriculture, demography, economy, education, environment, governance and accountability, health, HIV/AIDS, infrastructure development, labour force and nutrition.

3.4 USEPA

Registration

Pesticides, data requirements for conventional chemicals

<http://www.epa.gov/fedrgstr/EPA-PEST/2007/October/Day-26/p20826.htm>

The EPA examines the ingredients of a pesticide; the site or crop on which it is to be used; the amount, frequency and timing of its use; and storage and disposal practices for registration purposes. It evaluates the pesticide to ensure that it will not have unreasonable adverse effects on humans, the environment and non-target species. Pesticides must be registered or exempted by EPA's Office of Pesticide Programs before they may be sold or distributed in the U.S. Once registered, a pesticide may not legally be used unless the use is consistent with the approved directions for use on the pesticide's label or labeling.

After EPA completes its review of an application for registration of a pesticide, EPA may register the pesticide. In some cases, the registration is "conditional," and issues must be resolved or monitoring must be implemented, for example, for the registration to continue. After a pesticide is registered by EPA, states can register pesticides under specific state pesticide registration laws. A state may have more stringent requirements for registering pesticides for use in that state.

In evaluating a pesticide registration application, EPA assesses a wide variety of potential human health and environmental effects associated with use of the product. Potential registrants must generate scientific data necessary to address concerns pertaining to the identity, composition, potential adverse effects, and environmental fate of each pesticide. The data allow EPA to evaluate whether a pesticide has the potential to cause harmful effects on certain nontarget organisms and endangered species that include:

- humans
- wildlife
- plants
- surface water or ground water

The data requirements for conventional pesticides include:

Subpart A General provisions
Subpart B How to use the data tables
Subpart C Experimental use permits
Subpart D Product chemistry
Subpart E Product performance
Subpart F Toxicology
Subpart G Ecological effects [comprising aquatic, terrestrial and plant species]
Subparts H - I [Reserved]
Subpart J [Reserved] [Plant protection has been consolidated into subpart G]
Subpart K Human exposure [comprising pre-application and post-application exposure]
Subpart L Spray drift
Subpart M [Reserved]
Subpart N Environmental fate
Subpart O Residue chemistry
Subparts P - T [Reserved]
Subpart U Biochemical pesticides
Subpart V Microbial pesticides
Subpart W Antimicrobial pesticides
Subparts X - Z [Reserved]

US EPA Risk Assessment Guidelines

Guidance on cumulative risk assessment of pesticide chemicals that have a common mechanism of toxicity

http://epa.gov/pesticides/trac/science/cumulative_guidance.pdf

The document was prepared to provide guidance to for evaluating and estimating the potential human risks associated with multichemical and multipathway exposures to pesticides.

Guidelines for Carcinogen Risk Assessment
2005 guidelines and 2005 supplementary guidance,
Federal Register 70 (66) 17765-17817, 7 April 2005
<http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=116283>

Supplemental guidance for assessing susceptibility from early-life exposure to carcinogens <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=160003>

Guidelines for Chemical Mixtures Risk Assessment
2000 supplementary guidance and 1986 guidelines,
Federal Register 51 (185) 34014-34025, 24 September 1986
<http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=20533>

Guidelines for Ecological Risk Assessment
Federal Register 63 (93) 26846-26924, 14 May 1998
<http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=12460>

Guidelines for Neurotoxicity Risk Assessment
Federal Register 63 (93) 26926-26954, 14 May 1998
<http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=12479>

Guidelines for Reproductive Toxicity Risk Assessment
Federal Register 61 (212) 56274-56322, 31 October 1996
<http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=2838>

Guidelines for Exposure Assessment
Federal Register 57 (104) 22888-22938, 29 May 1992
<http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=15263>

Guidelines for Developmental Toxicity Risk Assessment
Federal Register 56 (234) 63798-63826, 5 December 1991
<http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=23162>

Guidelines for Mutagenicity Risk Assessment
Federal Register 51 (185) 34006-34012, 24 September 1986
<http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=23160>

A framework for the economic assessment of ecological benefits
<http://www.epa.gov/osa/spc/pdfs/feaeb3.pdf>

Guidelines for preparing economic analysis
<http://yosemite.epa.gov/ee/epa/eed.nsf/Webpages/Guidelines.html>

Concepts, Methods and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures and Effects: A Resource Document
<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=190187#Download>

Exposure Factors Handbook <http://www.epa.gov/ncea/pdfs/efh/front.pdf>

Child-specific exposure factors handbook

<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=199243>

Example Exposure Scenarios

<http://cfpub2.epa.gov/ncea/cfm/recordisplay.cfm?deid=85843>

4. List of other relevant pesticide (chemicals) documents

FAO

Harmonized Glossary

<http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Download/Glossary.pdf>

Guidelines for legislation on the control of pesticides (1989)

<http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Download/LEGIS.pdf>

Guidelines on efficacy evaluation of the registration of plant protection products (2006)

<http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Download/Efficacy06.pdf>

Guidelines on good labeling practice for pesticides (1995)

<http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Download/label.pdf>

The Implementation of the Globally Harmonized System of Classification and Labeling of Chemicals – FAO's past and present activities

<http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/en>

Compliance and Enforcement

Guidelines on compliance and enforcement of a pesticide regulatory programme (2006)

<http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Code/Download/Compliance06.pdf>

Guidelines on the organization of schemes for testing and certification of agricultural pesticide sprayers in use

<http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Download/Testing01.pdf>

Manual on the development and use of FAO and WHO specifications for pesticides

http://www.fao.org/ag/AGP/AGPP/Pesticid/Specs/Pdf/Manual_update%202006.pdf (March 2006 revision of the first edition)

FAO/WHO pesticide specifications (2001)

<http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/en/>

Distribution and sales

Guidelines for retail distribution of pesticides with particular reference to storage and handling at the point of supply to users in developing countries (*) (1988)

<http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Download/RETAIL.pdf>

Pesticide storage and stock control manual

http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Disposal/guides_en.htm

Provisional guidelines on tender procedures for the procurement of pesticides

(1994) <http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Download/TENDER.pdf>

Use

Guidelines on personal protection when working with pesticides in tropical

climates (1990) <http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Download/PROTECT.pdf>

Guidelines on good practice for ground application of pesticides

<http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Download/Ground01.pdf>

Guidelines on good practice for aerial application of pesticides (2001)

<http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Download/Aereal01.pdf>

Training and awareness building

Guidelines on organization and operation of training schemes and certification procedures for operators of pesticide application equipment (2001)

<http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Download/Training01.pdf>

Prevention and disposal of obsolete stocks

Prevention of accumulation of obsolete stocks

http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Disposal/common/ecg/103807_en_v7460e.pdf

Disposal of bulk quantities of obsolete pesticides in developing countries

http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Disposal/common/ecg/103811_en_w1604e.pdf

Pesticide storage and stock control manual

http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Disposal/common/ecg/103809_en_No_3_Storage.pdf

Guidelines for the management of small quantities of unwanted and obsolete pesticides (1999)

http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Disposal/common/ecg/103825_en_No_7_Small_quantities_stocks.pdf

Assessing soil contamination: a reference manual(2000)

<http://www.fao.org/docrep/003/x2570e/x2570e00.htm>

Guidelines on management options for empty pesticide containers(2008)

<http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Download/Containers08.pdf>

Baseline study on the problem of obsolete pesticide stocks

<http://www.fao.org/DOCREP/003/X8639E/X8639E00.HTM>

FAO Training Manual for inventory taking obsolete pesticides (2001)

http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Disposal/common/ecg/110449_en_No_10_Training_Manuale.pdf

Country guidelines

<ftp://ftp.fao.org/docrep/fao/005/y2566E/y2566E00.pdf>

Post Registration surveillance

Guidelines on post-registration surveillance and other activities in the field of pesticides (*) (1998)

<http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Download/POSTREG.pdf>

ILO

Health, Safety and Environment: A Series of Trade Union Education Manuals for Agricultural Workers

<http://www.ilo.org/public/english/dialogue/actrav/publ/newpubl.htm#top>

Pesticides

http://www.ilo.org/public/english/protection/safework/ctrl_banding/toolkit/icct/pesticides.htm

Safety issues

http://www.ilo.org/public/english/protection/safework/ctrl_banding/toolkit/icct/safety.htm

Environment issues

http://www.ilo.org/public/english/protection/safework/ctrl_banding/toolkit/icct/environment.htm

Draft Guidelines

http://www.ilo.org/public/english/protection/safework/ctrl_banding/toolkit/icct/guide.pdf

List of Guidance sheets

http://www.ilo.org/public/english/protection/safework/ctrl_banding/toolkit/icct/sheets.htm

OECD**The Assessment of Persistency and Bioaccumulation in the Pesticide Registration Frameworks within the OECD Region**

<http://www.oecd.org/dataoecd/58/14/34375258.pdf>

Workshop on the Application of Simple Models for Environmental Exposure Assessment (Berlin, December 1991)

([http://www.olis.oecd.org/olis/2000doc.nsf/LinkTo/NT00000A9A/\\$FILE/00073590.PDF](http://www.olis.oecd.org/olis/2000doc.nsf/LinkTo/NT00000A9A/$FILE/00073590.PDF))

OECD guidance document on risk communication for chemical risk management
[http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/NT00002D5A/\\$FILE/JT00129938.PDF](http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/NT00002D5A/$FILE/JT00129938.PDF)

UNIDO**POPs portal**

POPs e-learning modules: <http://www.unido.org/index.php?id=5631>

Module 1 Overview of POPs

http://www.unido.org/fileadmin/user_media/Services/Environmental_Management/GUDDIS/e-learning/e-learning_module01.pdf

Module 2 Risk Assessment

http://www.unido.org/fileadmin/user_media/Services/Environmental_Management/GUDDIS/e-learning/e-learning_module02.pdf

Module 3 Rehabilitation and remediation of POPs

http://www.unido.org/fileadmin/user_media/Services/Environmental_Management/GUDDIS/e-learning/e-learning_module03.pdf

Checklists for site investigation <http://www.unido.org/index.php?id=5544>

Checklist I: Preliminary site investigation:

http://www.unido.org/fileadmin/user_media/Services/Environmental_Management/GUDDIS/ARETECH/chapter4/Chapter_IV_CHECKLIST_I_PRELIMINARY_SITE_INVESTIGATION.pdf

Checklist II: Detailed site investigation

http://www.unido.org/fileadmin/user_media/Services/Environmental_Management/GUDDIS/ARETECH/chapter4/Chapter_IV_CHECKLIST_II_DETAILED_SITE_INVESTIGATIONcopy.pdf

Visiting contaminated sites: <http://www.unido.org/index.php?id=5542>

UNEP

Childhood Pesticide Poisoning- Information for Advocacy and Action

<http://portalserver.unepchemicals.ch/Publications/pestpoisoning.pdf>

Reducing and Eliminating Use of Persistent Organic Pollutants- Guidance on Alternative Strategies for Sustainable Pest and Vector management

http://portalserver.unepchemicals.ch/Publications/POPred_E.pdf

Finding alternatives to persistent organic pollutants(POPs) for termite management

<http://portalserver.unepchemicals.ch/Publications/Alternatives-termite-fulldocument.pdf>

UNITAR

Developing a Risk Management Plan for Priority Chemicals. Guidance Document - Working Draft (2001)

http://www2.unitar.org/cwm/publications/cw/other/risk_gd.pdf

Development of Risk Reduction Strategies for Priority Chemicals: A Guidance Document, Pilot Version (1999)

http://www2.unitar.org/cwm/publications/cw/other/risk_pilot_gd.pdf

WHO

Training and guidance documents

IPCS Fundamental of Applied Toxicology-The Nature of Chemical Hazards

http://whqlibdoc.who.int/hq/1997/WHO_PCS_97.14_pp1-81.pdf

General Scientific Principles of Chemical Safety

http://whqlibdoc.who.int/hq/2000/WHO_PCS_00.8_pp1-104.pdf

Hazardous Chemicals in Human and Environmental Health: a Resource Book for School, College and University Students

http://whqlibdoc.who.int/hq/2000/WHO_PCS_00.1.pdf

International Chemical Safety Cards

<http://www.ilo.org/public/english/protection/safework/cis/products/icsc/>

Exposure assessment

Aggregate/cumulative risk assessment

In March 2007, IPCS convened an international workshop on current issues in aggregate/cumulative risk assessment. The workshop discussed methods for assessing the combined risk from exposure to one or more agents (with or without a common mechanism-of-action) via all relevant routes and pathways, and initiated the development of a framework for such assessments. The report of the workshop will be published along with release of a draft framework for aggregate/cumulative risk assessment for peer and public review

Insecticide treatment of mosquito nets

http://whqlibdoc.who.int/hq/2002/WHO_CDS_RBM_2002.41.pdf

Insecticides for indoor residual spraying

http://whqlibdoc.who.int/hq/2001/WHO_CDS_WHOPES_2001.3.pdf

Manual on development and use of FAO and WHO specifications for pesticides

http://whqlibdoc.who.int/publications/2006/9251048576_eng_update2.pdf

Quality control of pesticides products. Guidelines for national laboratories

http://whqlibdoc.who.int/hq/2005/WHO_CDS_WHOPES_GCDPP_2005.15.pdf

Guidelines for laboratory and field testing of long-lasting insecticidal mosquito nets

http://whqlibdoc.who.int/hq/2005/WHO_CDS_WHOPES_GCDPP_2005.11.pdf

Protocols for laboratory and field evaluation of insecticides and repellents

http://whqlibdoc.who.int/hq/1996/CTD_WHOPES_IC_96.1.pdf

Preventing health risks from the use of pesticides in agriculture: Protecting workers' health series No. 1

http://www.who.int/occupational_health/publications/en/oehpesticides.pdf

WHOPES

Pesticides and their application-for the control of vectors and pests of public health importance(six edition)

http://whqlibdoc.who.int/hq/2006/WHO_CDS_NTD_WHOPE_S_GCDPP_2006.1_eng.pdf

Guidelines for Laboratory and Field Testing of Long-lasting Insecticidal Mosquito Nets

http://whqlibdoc.who.int/hq/2005/WHO_CDS_WHOPE_S_GCDPP_2005.11.pdf

Manual on development and use of FAO and WHO Specifications for Pesticides, March

2006 revision of the First Edition

http://whqlibdoc.who.int/publications/2006/9251048576_eng_update2.pdf

European Union

Formats for Industry

Templates for a Chemical Safety Report (CSR).

http://guidance.echa.europa.eu/docs/formats/Chemical_Safety_Report_Format.dot

Part F Chemical Safety Report

http://reach.jrc.it/docs/guidance_document/information_requirements_part_f_en.pdf?vers=20_08_08

Part G Extention of SDS

http://reach.jrc.it/docs/guidance_document/information_requirements_part_g_en.pdf?vers=20_08_08

Information requirements

http://reach.jrc.it/docs/guidance_document/information_requirements_r2_en.pdf?vers=20_08_08

Guidance on Information Requirements and Chemical Safety Assessment

Structure of the Guidance on Information Requirements and Chemical Safety Assessment

Part A - Introduction to the Guidance Document

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_a_en.pdf?vers=20_08_08

Part B - Hazard Assessment

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_b_en.pdf?vers=20_10_08

Part C - PBT Assessment

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_c_en.pdf?vers=20_08_08

Part D - Exposure Scenario Building

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_d_en.pdf?vers=20_08_08

Part E - Risk Characterisation

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_e_en.pdf?vers=20_08_08

Part F - Chemicals Safety Report

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_f_en.pdf?vers=20_08_08

Appendix to part F CSR template with explanation

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_appendix_part_f_en.pdf?vers=20_08_08

Part G - Extension of SDS

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_g_en.pdf?vers=20_08_08

Information requirements

Chapter R.2: Framework for generation of information on intrinsic properties

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r2_en.pdf?vers=20_08_08

Chapter R.3: Information gathering

Information gathering

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r3_en.pdf?vers=20_08_08

Chapter R.4: Evaluation of available information

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r4_en.pdf?vers=20_08_08

Chapter R.5: Adaptation of Information requirements

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r5_en.pdf?vers=20_08_08

Chapter R.6: QSARs and grouping of chemicals

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r6_en.pdf?vers=20_08_08

Chapter R.7a: Endpoint specific guidance

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r7a_en.pdf?vers=20_08_08

Chapter R.7b: Endpoint specific guidance

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r7a_en.pdf?vers=20_08_08

Chapter R.7c: Endpoint specific guidance

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r7c_en.pdf?vers=20_08_08

Chapter R.7-13: Environmental risk assessment for metals and metal compounds

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r7_13_2_en.pdf?vers=20_08_08

Chapter R.8: Characterisation of dose [concentration] - response for human health

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r8_en.pdf?vers=20_08_08

Chapter R.9: Physico-chemical hazards

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r9_en.pdf?vers=20_08_08

Chapter R.10: Characterisation of dose [concentration] - response for environment

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r10_en.pdf?vers=20_08_08

Chapter R.11: PBT Assessment

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r11_en.pdf?vers=20_08_08

Chapter R.12: Use descriptor system

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf?vers=20_08_08

Chapter R.13: Risk management measures and operational conditions

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r13_en.pdf?vers=20_08_08

Chapter R.14: Occupational exposure estimation

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r14_en.pdf?vers=20_08_08

Chapter R.15: Consumer exposure estimation

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r15_en.pdf?vers=20_08_08

Chapter R.16: Environmental exposure estimation

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r16_en.pdf?vers=20_08_08

Chapter R.17: Estimation of exposure from articles

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r17_en.pdf?vers=20_08_08

Chapter R.18: Estimation of exposure from waste life

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r18_en.pdf?vers=20_08_08

Chapter R.19: Uncertainty analysis

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r19_en.pdf?vers=20_08_08

Chapter R.20: Table of terms

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r20_en.pdf?vers=20_08_08

Guidance mainly for Authorities Use

Guidance on Dossier and Substance Evaluation

http://guidance.echa.europa.eu/docs/guidance_document/evaluation_en.pdf

Guidance for the preparation of an Annex XV Dossier on Harmonised Classification and Labelling

http://guidance.echa.europa.eu/docs/guidance_document/harmonised_classification_en.pdf

Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern

http://guidance.echa.europa.eu/docs/guidance_document/svhc_en.pdf

Guidance on inclusion of substances in Annex XIV (substances subject to Authorisation).
http://guidance.echa.europa.eu/docs/guidance_document/annex_xiv_en.pdf?vers=12_08_08 (Updated 12/08/08)

Guidance for the preparation of an Annex XV dossier for restrictions

http://guidance.echa.europa.eu/docs/guidance_document/restriction_en.pdf?vers=19_09_08

Guidance on the different methods under REACH

Guidance for identification and naming of substances in REACH

http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf

Guidance on how to comply with the provisions of the new Regulation on Classification, Packaging and Labelling of substances and mixtures

(see <http://ecb.jrc.it/reach/rip/> for more information). It is expected that a final version will be available in 2009.

http://guidance.echa.europa.eu/03_rdds_web_content/ghs_en/ghs_en.pdf?time=1232461797

Guidance on IUCLID

[Harmonised Templates]

http://www.oecd.org/document/13/0,3343,en_2649_34365_36206733_1_1_1_1,00.html

Australia

APVMA(Australian Pesticides and Veterinary Medicines Authority)

User manual (for electronic registration)

<http://www.apvma.gov.au/registration/downloads/EARSmanual.pdf>

US EPA

Risk tools-Human health

Models

Benchmark Dose Software (BMDS) <http://www.epa.gov/NCEA/bmds/progreg.html> (for registration)

EMSOFT: Exposure Model for Soil-Organic Fate and Transport

<http://permanent.access.gpo.gov/lps38234/cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=2862.htm>

5. Databases-

Pesticides

PAHO Virtual Library of Sustainable Development and Environmental Health-Pesticides

<http://www.bvsde.ops-oms.org/sde/ops-sde/ingles/bv-plaguicidas.shtml>

International Phytosanitary Portal (IPP) <https://www.ippc.int/IPP/En/default.jsp>

U.S National Ag Safety Database <http://www.nasdonline.org/index.html>

Chemicals (pesticides)

Chemical Information Exchange Network CIEN <http://jp1.estis.net/communities/cien/>

IPCS INCHEM <http://www.inchem.org> (Chemicals, pesticides)

IARC Monographs <http://monographs.iarc.fr/ENG/Monographs/PDFs/index.php>

e-Chem portal <http://webnet3.oecd.org/echemportal>

- [CESAR](http://www.ec.gc.ca/CEPARRegistry/subs_list/Priority.cfm) Canada's Existing Substances Repository CEPA Environmental Registry http://www.ec.gc.ca/CEPARRegistry/subs_list/Priority.cfm
- [CHRIP](http://www.safe.nite.go.jp/english/kizon/KIZON_start_hazkizon.html) Information on biodegradation and bioconcentration of the existing chemical substances in the chemical risk information platform-National Institute of Technology and Evaluation-Japan http://www.safe.nite.go.jp/english/kizon/KIZON_start_hazkizon.html
- [EnviChem](http://www.ymparisto.fi/default.asp?contentid=141944&lan=en) Data bank of Environmental Properties of Chemicals-Ministry of Environment-Finland <http://www.ymparisto.fi/default.asp?contentid=141944&lan=en>
- [ESIS](http://ecb.jrc.ec.europa.eu/esis) : European Chemical Substances Information System <http://ecb.jrc.ec.europa.eu/esis>
- [HPVIS](http://www.epa.gov/hpvis/) High Production Volume Information System <http://www.epa.gov/hpvis/>
- [HSDB](http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB) Hazardous Substances Data Bank <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB>
- [HSNO CCID](http://www.ermanz.govt.nz/hs/compliance/chemicals.html) New Zealand Environmental Risk Management Authority-ERMA-Chemical Classification Information Database <http://www.ermanz.govt.nz/hs/compliance/chemicals.html>

- [INCHEM](http://www.inchem.org/) Chemical Safety Information from Intergovernmental Organizations
- [JECDB](http://dra4.nihs.go.jp/mhlw_data/jsp/SearchPageENG.jsp) Japan Existing Chemicals Database
- [NICNAS PEC](http://www.nicnas.gov.au/Publications/CAR/PEC.asp) Australian National Chemicals Notification and Assessment Scheme
- [OECD HPV](http://cs3-hq.oecd.org/scripts/hpv) High Production Volume Database
- [SIDS IUCLID](http://www.oecd.org/document/55/0,2340,en_2649_34379_31743223_1_1_1_1,0_0.html) Screening Information DataSets (SIDS) for High Production Volume Chemicals in IUCLID format
- [SIDS UNEP](http://www.chem.unep.ch/irptc/sids/OECDSEIDS/sidspub.html) Screening Information DataSets
- [US EPA IRIS](http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?IRIS) Integrated Risk Information System
- [US EPA SRS](http://iaspub.epa.gov/sor_internet/registry/substreg/home/overview/home.do) Substance Registry Services

ESIS : European Chemical Substances Information System
<http://ecb.jrc.ec.europa.eu/esis>

TOXNET-Toxicological Data Network <http://toxnet.nlm.nih.gov/>

- Chem ID plus <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?CHEM>
- HSDB(Hazardous Substances Data Bank) <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB>
- Toxline <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?TOXLINE>
- Chemical Carcinogenesis Research Information System (CCRIS) <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?CCRIS>
- Developmental and Reproductive Toxicology Database (DART) <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?DARTETIC>
- Genetic Toxicology Data Bank (GENE-TOX) <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?GENETOX>
- Integrated Risk Information System (IRIS) <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?IRIS>
- International Toxicity Estimates for Risk (ITER) <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?iter>
- Toxics Release Inventory (TRI) <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?TRI>
- HazMap (Occupational Exposure to Hazardous Agents) <http://hazmap.nlm.nih.gov/>
- Household Products database(including pesticides)<http://hpd.nlm.nih.gov/>

Additional resource

- CPDB Carcinogenic Potency Databank <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?CPDB.htm>

Agency for Toxic Substances and Disease Registry (ATSDR) Toxic substances portal
<http://www.atsdr.cdc.gov/substances/index.asp>

6. International networks on pesticides

Regional Network on Safe Pesticide Production and Information for Asia and the Pacific (RENAP) <http://www.unido.org/index.php?id=6249>

North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides <http://www.epa.gov/oppfead1/international/naftatwg/#partners>

Pesticides-1 -- Southern African Pesticides List Server-
<https://lists.uct.ac.za/mailman/listinfo/pesticides-1>

AGORA - Access to Global Online Research in Agriculture
<http://www.aginternetwork.org/en/>

Collaborative International Pesticides Analytical Council (CIPAC) <http://www.cipac.org>

European Plant Protection Organization <http://www.eppo.org/>
EPPPO standards <http://www.eppo.org/STANDARDS/standards.htm>

International network on Environmental Compliance and Enforcement (INECE) – Pesticides Forum <http://www.inece.org/forumspesticides.html>

Asia and Pacific Plant Protection Commission (APPPC)
<https://www.ippc.int/servlet/CDSServlet?status=ND0xMzQ5NyZjdG5faW5mb192aWV3X3NpemU9Y3RuX2luZm9fdmld19mdWxsJjY9ZW4mMzM9KiYzNz1rb3M~>

INECE Pesticide Forum for Central America Region
<http://www.inece.org/centralamerica/index.html>

PAN International <http://www.pan-international.org/panint/?q=node/33>

Crop Life <http://www.croplife.org>

Other networks, programmes

Integrated Pest Management Collaborative Research Support Programme IPM CRSP
http://www.oired.vt.edu/ipmcrsp/IPM_2008/draft_home.htm (funded by USAID)

Annex II Websites of national pesticide registration authorities, links to national legislation and other pesticide related national documents

Albania

Ministry of Agriculture, Food and Consumer Protection:

<http://www.mbumk.gov.al/lajm.asp?idLajm=206&metoda=publiku&l=2>

Regulation No. 1555 laying down rules on registration and criteria for assessing plant protection products (Albanian)

<http://www.qpz.gov.al/doc.jsp?doc=docs/Vendim%20Nr%201555%20Dat%C3%AB%2012-11-2008.htm>

Argentina

Pesticide registration authority (domestic): National Administration of Medicines, Food and Medical Technology, <http://www.anmat.gov.ar>

List of pesticides and rodenticides

http://www.anmat.gov.ar/domisanitarios/Listado_de_Insecticidas_Junio_2009.pdf

Servicio Nacional de Sanidad y Calidad Agroalimentaria

<http://www.senasa.gov.ar/indexhtml.php>

Resolución N° 350/99 - Aprueba el nuevo Manual de Procedimientos, Criterios y Alcances para el Registro de Productos Fitosanitarios en la República Argentina

<http://www.infoleg.gov.ar/infolegInternet/anexos/55000-59999/59812/norma.htm>

Resolución N° 371/03 - Modifica el Manual de Procedimientos, Criterios y Alcances para el

<http://www.infoleg.gov.ar/infolegInternet/anexos/85000-89999/87438/norma.htm>

Registro de Productos Fitosanitarios en la República Argentina

<http://www.redproteger.com.ar/fitosanitarios.htm>

Ley N° 320-2004: Regulación de uso de agroquímicos

http://www.medioambiente.sanluis.gov.ar/legislacion/3_contaminacion/Ley%20IX-0320%20Agroquimicos.pdf

Resolución N° 816/06 - Normas para el Etiquetado de los Productos Fitosanitarios Formulados de Uso Agrícola

<http://www.infoleg.gov.ar/infolegInternet/anexos/120000-124999/122453/norma.htm>

Australia

Pesticides registration authority: Australian Pesticides and Veterinary Medicines Authority (APVMA)- <http://www.apvma.gov.au>

MORAG is the APVMA's Manual of Requirements and Guidelines.
http://www.apvma.gov.au/MORAG_ag/MORAG_ag_home.shtml#agMORAGvol1

The Adverse Experience Reporting Program for agricultural chemicals (AERP Ag)
http://www.apvma.gov.au/qa/aerp2004_pesticides.pdf

Austria (EU)

Pesticide registration (evaluation, authorization) authority: Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management <http://www.lebensministerium.at>

Austrian Agency for Health and Food Safety (AGES) <http://www.ages.at/ages/ueber-uns/english-what-is-ages>

Armenia

Ministry of Nature Protection http://www.mnp.am/index_eng.htm

Law on plant protection and plant quarantine (2000)
<http://faolex.fao.org/docs/texts/arm47123.doc> (Russian)

List of chemical and biological control for plants permitted to use in the Republic of Armenia
(The resolution #198-N of the Minister of Agriculture, updated 24/10/2008)
http://wtm.am/acdivoca/environmental/list_of_pesticides_permitted_in_roa.pdf

Azerbaijan

Pesticide registration authority: Ministry of Agriculture
http://www.azerbaijan.az/_StatePower/_MinistersCabinet/ministersCabinet_08_e.html

Bangladesh

Registration authority: Director of Plant Protection Wing of the Department of Agricultural Extension, Ministry of Agriculture: http://www.moa.gov.bd/about_MoA.htm

Pesticide Ordinance 1971 http://www.bdlaws.gov.bd/print_sections_all.php?id=364

Pesticides Rules 1985
<http://www.dae.gov.bd/Pdf%20forms/Policy/PESTICIDE%20RULES,%201985.pdf>

Barbados

Registration authority: Ministry of Agriculture and Rural Development
http://www.agriculture.gov.bb/default.asp?V_DOC_ID=1656

Pesticides Act <http://www.caricomlaw.org/docs/Pesticides%20Control.pdf>

Pesticides Control (Labeling of Pesticides) Regulations 1976
http://www.agriculture.gov.bb/default.asp?V_DOC_ID=1472

Pesticide Control Board: http://www.agriculture.gov.bb/default.asp?V_DOC_ID=1195

Belgium (EU)

Pesticide usage in agriculture-Belgium legislation Fytoweb
<http://www.fytoweb.fgov.be/indexfr.htm>

Pesticides A Usage Agricole: Legislation Belge

Loi du 21 décembre 1998 relative aux normes de produits ayant pour but la promotion de modes de production et de consommation durables et la protection de l'environnement et de la santé (loi de base, **(M.B. 11-02-99)**)

<http://www.fytoweb.fgov.be/FR/doc/bestrijdingsmiddel11februari1999.pdf>

modifié par les lois du: - 28 mars 2003 **(M.B. 29-04-03)**

<http://www.fytoweb.fgov.be/FR/doc/bestrijdingsmiddel29april2003.pdf>

Belize

Pesticide registration authority: Belize Pesticide Control Board
<http://www.pcbbelize.com>. This website provides information on all aspects of pesticides control in Belize, as well as links to pesticide related [legislation](#) and application forms.

Register of pesticides

http://www.pcbbelize.com/forms/pesticides_register.pdf

Pesticides Control Act

<http://www.pcbbelize.com/cap216.pdf>

Benin

Ministère de l'Agriculture de l'Élevage et de la Pêche (MAEP)

[http://www.gouv.bj/ministere.php?id_rub=25&lib_rub=Minist%20de%20l'Agriculture%20de%20l'Elevage%20et%20de%20la%20P%20Eche%20\(MAEP\)](http://www.gouv.bj/ministere.php?id_rub=25&lib_rub=Minist%20de%20l'Agriculture%20de%20l'Elevage%20et%20de%20la%20P%20Eche%20(MAEP))

Guide des usage

[http://www.gouv.bj/ministere.php?id_rub=120&id_rub=25&lib_rub=Ministère%20de%20l'Agriculture%20de%20l'Elevage%20et%20de%20la%20Pêche%20\(MAEP\)](http://www.gouv.bj/ministere.php?id_rub=120&id_rub=25&lib_rub=Ministère%20de%20l'Agriculture%20de%20l'Elevage%20et%20de%20la%20Pêche%20(MAEP))

Bolivia

Ministry of Agriculture Rural Development and Environment
<http://www.agrobolivia.gov.bo>

DECISION 436

Norma Andina para el Registro y Control de Plaguicidas Químicos de Uso Agrícola
<http://www.comunidadandina.org/normativa/dec/D436.htm>

Bosnia Herzegovina

Federal Ministry of Agriculture, Water Management and Forestry
<http://www.fmpvs.gov.ba/>

Federal Ministry of Health
<http://www.fbihvlada.gov.ba/english/ministarstva/zdravstvo.php>

Botswana

Ministry of Agriculture <http://www.moa.gov.bw/>

Agrochemical regulations <http://faolex.fao.org/docs/texts/bot65794.doc>

Brazil

Pesticide registration authority: Ministerio da Agricultura, pecuaria e Abastecimento
<http://www.agricultura.gov.br/> (Portugese)

Legislation: The legal requirements for the granting of authorization permits are, within the scope of the SUS (Unified Health System), laid down by Federal Legislation covering pesticides and similar items, under Law 7.802/89, Decree 98.816/90, Administrative Rule 03/92, of the former Sanitary Surveillance Secretariat, Ministry of Health, presently ANVISA

<http://e-legis.anvisa.gov.br/leisref/public/showAct.php?id=306>

SIA – Sistema de Informações sobre Agrotóxicos
<http://www4.anvisa.gov.br/agrosia/asp/default.asp>

AGROFIT: Sistema de Agrotóxicos Fitossanitários
http://extranet.agricultura.gov.br/agrofit_cons/principal_agrofit_cons

Cambodia

Registration authority: Ministry of Agriculture, Forestry and Fisheries
<http://www.fadinap.org/cambodia/>

Current status of pesticide registration and regulation system (2002)
<http://www.fadinap.org/cambodia/agstandard.htm>

Canada

Pesticide and pest management
<http://www.pmra-arla.gc.ca/>

Pest management regulatory agency
<http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/pmra-arla/index-eng.php>

Pest Control Act, Pest control products regulation.
<http://laws.justice.gc.ca/PDF/Statute/P/P-9.pdf>
<http://laws.justice.gc.ca/PDF/Statute/P/P-9.01.pdf>

List of pesticide formulants and contaminants of health and environmental concern
<http://laws.justice.gc.ca/PDF/Regulation/S/SI-2005-114.pdf>

Order Amending the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern
<http://gazette.gc.ca/rp-pr/p2/2008/2008-06-25/html/si-tr67-eng.html>

Pest Control Products Incident Reporting Regulations
<http://gazette.gc.ca/archives/p2/2006/2006-11-15/html/sor-dors260-eng.html>

Canadian Environmental Protection Act, 1999: Export of Substances under the Rotterdam Convention Regulations. SOR/2002-317. Dated 16 August 2002.
<http://canadagazette.gc.ca/archives/p1/2002/2002-06-01/html/reg-eng.html>

Cape Verde

Ministry of Agriculture, Food and Environment: No website available

Decree-Law No. 26/97 regulating use, trade and inspection of pesticides
<http://faolex.fao.org/docs/pdf/cvi38669.pdf> (French)

Decree No. 22/83 creating an Interministerial Consultance Committee for the Agricultural Use of Pesticides <http://faolex.fao.org/docs/pdf/cvi8298.pdf> (Portuguese)

Chile

Pesticide registration authority: Ministerio de Agricultura Servicio Agricultura y Ganadero

Resolución N° 3.670 - Normas para la evaluación y autorización de Plaguicidas
23.12.1999

<http://www.sag.gob.cl/OpenDocs/asp/pagVerRegistro.asp?argRegistroId=733&argInstanciaId=56>

amended by Resolución N° 752 - Modifica Resolución N° 3.670 de 1999, Normas para la evaluación y autorización de plaguicidas

[http://www.sag.gob.cl/opendocs/asp/pagVerRegistro.asp?boton=Doc56&argInstanciaId=56&argCarpetaId=1837&argTreeNodosAbiertos=\(1837\)\(-56\)&argTreeNodoSel=849&argTreeNodoActual=1837&argRegistroId=4285](http://www.sag.gob.cl/opendocs/asp/pagVerRegistro.asp?boton=Doc56&argInstanciaId=56&argCarpetaId=1837&argTreeNodosAbiertos=(1837)(-56)&argTreeNodoSel=849&argTreeNodoActual=1837&argRegistroId=4285)

Labeling:

<http://www.sag.gob.cl/OpenDocs/asp/pagVerRegistro.asp?argRegistroId=731&argInstanciaId=56>

Toxicological classification:

<http://www.sag.gob.cl/OpenDocs/asp/pagVerRegistro.asp?argRegistroId=730&argInstanciaId=56>

List of registered pesticides by 31 July 2009

[http://www.sag.gob.cl/OpenDocs/asp/pagVerRegistro.asp?argRegistroId=1106&argInstanciaId=56&argCarpetaId=860&argTreeNodosAbiertos=\(860\)\(-56\)&argTreeNodoActual=860&argTreeNodoSel=-56](http://www.sag.gob.cl/OpenDocs/asp/pagVerRegistro.asp?argRegistroId=1106&argInstanciaId=56&argCarpetaId=860&argTreeNodosAbiertos=(860)(-56)&argTreeNodoActual=860&argTreeNodoSel=-56)

List of restricted pesticides

[http://www.sag.gob.cl/OpenDocs/asp/pagVerRegistro.asp?argRegistroId=1104&argInstanciaId=56&argCarpetaId=860&argTreeNodosAbiertos=\(860\)\(-56\)&argTreeNodoActual=860&argTreeNodoSel=-56](http://www.sag.gob.cl/OpenDocs/asp/pagVerRegistro.asp?argRegistroId=1104&argInstanciaId=56&argCarpetaId=860&argTreeNodosAbiertos=(860)(-56)&argTreeNodoActual=860&argTreeNodoSel=-56)

Reglamento de pesticidas de uso sanitario y domestico- Decreto No 157 de 2005

http://www.minsal.cl/juridico/DECRETO_157_05.doc

Registration authority Ministry of Health

<http://www.minsal.cl/>

Aprueba Reglamento De Notificación Obligatoria De Las Intoxicaciones Agudas Con Pesticidas http://www.minsal.cl/juridico/88_de_2004.doc

China

Pesticides registration authority: Institute for the Control of Agrochemicals, Ministry of Agriculture. <http://www.chinapesticide.gov.cn/en/en.asp>

Requirements of the Pesticide Registration Document:

<http://www.chinapesticide.gov.cn/en/2.pdf>

Regulations on Pesticides Administration (1997)

<http://www.chinapesticide.gov.cn/en/1.pdf>

Colombia

DECISION 436

Norma Andina para el Registro y Control de Plaguicidas Químicos de Uso Agrícola
<http://www.comunidadandina.org/normativa/dec/D436.htm>

Resolución Número (1442) 14 de agosto de 2008 REPUBLICA DE COLOMBIA
“Por la cual se establece el procedimiento para la expedición del dictamen técnico-ambiental al que alude la Norma Andina para el Registro y Control de Plaguicidas Químicos de Uso Agrícola, Decisión 436, de la Comisión de la Comunidad Andina, y se toman otras determinaciones”
<http://www.ica.gov.co/getattachment/41221aae-24e4-4f54-9d64-1214d9e55b11/2008R1442.aspx>

Ministry of Social Protection Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA) <http://web.invima.gov.co/Invima/index.jsp>

Plaguicidas Uso Domestico

http://web.invima.gov.co/Invima///normatividad/plaguicidas_decretos.jsp?codigo=220
Decreto numero 1843 de 1991 (julio 22)
http://web.invima.gov.co/Invima///normatividad/docs_plaguicidas/decreto_1843_1991.htm

Costa Rica

Ministerio de Agricultura y Ganaderia <http://www.mag.go.cr>

Phytosanitary protection law No. 7664
http://www.protecnet.go.cr/centro_informacion/normativa/leyes/MAGLaw7664.pdf

Czech Republic (EU)

Pesticides and other plant protection products registration authority: State Phytosanitary Administration: http://www.srs.cz/portal/page/portal/SRS_Internet_EN/ho

Denmark (EU)

Pesticide regulatory authority: Danish Environment Protection Agency-
<http://www.mst.dk/English>

Framework for the environmental assessment of plant protection products
<http://www.mst.dk/NR/rdonlyres/56469ADC-337F-450E-ADB2-54578D4D6D53/0/Frameworkenvironmental.pdf>

Statutory order from the Ministry of Environment and Energy
No. 241 of April 27, 1998 on pesticides <http://www.mst.dk/NR/rdonlyres/7A3C0C59-DD18-4514-97AB-45F88AC9C962/0/02031000.pdf>

Statutory Order no. 313 of 5 May 2000 amending Statutory Order on Pesticides (only available in Danish).

Dominican Republic

State Secretary of Agriculture <http://www.agricultura.gob.do>

Ley No 311 que regula la fabricación, elaboración, envase, almacenamiento, importación, expendio y comercio de insecticidas, zoocidas, fitocidas, pesticidas, herbicidas, y productos similares <http://www.idard.org.do/legislacion/Leyes/LEY-311-67.PDF>

Decreto No. 58-03 (23.01.2003) Decreto que crea el comité nacional para la aplicación de las medidas sanitarias y fitosanitarias

http://members.wto.org/crnattachments/2009/sps/DOM/09_1350_00_s.pdf

Ecuador

Ministerio de Agricultura, Ganadería, Acuicultura y Pesca <http://www.mag.gov.ec/>

DECISION 436

Norma Andina para el Registro y Control de Plaguicidas Químicos de Uso Agrícola

<http://www.comunidadandina.org/normativa/dec/D436.htm>

El Salvador

Ministerio de Medio Ambiente y Recursos Naturales <http://www.marn.gob.sv>

Ley Sobre Control De Pesticidas, Fertilizantes Y Productos Para Uso Agropecuario

Decreto No 315 <http://www.marn.gob.sv/uploaded/content/category/1610399744.pdf>

Estonia (EU)

Pesticide registration authority: Plant Protection Inspectorate Plant Protection Department

<http://www.plant.agri.ee/?op=body&id=218>

Requirements for use of plant protection products Regulation No. 50 of the Minister of Agriculture of 20 April 2006

http://www.plant.agri.ee/failid/ENG/plant%20protection/legislation/Requirements_for_use.doc

Plant Protection Act

http://www.plant.agri.ee/failid/ENG/plant%20protection/legislation/Plant_Protection_Act.doc

Plant protection products used in Estonia in 2009

<http://www.plant.agri.ee/?op=body&id=241>

List of active substances the use of which is permitted in plant protection products

Regulation No. 177 of the Minister of Agriculture of 15 November 2004

http://www.plant.agri.ee/failid/ENG/plant%20protection/legislation/Taimekaitsevahendites_lubatud_toimeainete_loetelu.rtf

EU legislation Directive 91/414/EEC

<http://eur-lex.europa.eu/LexUriServ/site/en/consleg/1991/L/01991L0414-20051201-en.pdf>

Ethopia

Ethopian Agricultural portal

<http://www.eap.gov.et/Health-and-quality-regulatory/Plant/Pesticide.asp>

Pesticide registration form

<http://www.eap.gov.et/content/files/Documents/EAP%20Documents/Regulatory/Plant/Pesticide/Application%20Pest%20Registration.pdf>

Renewal of pesticide registration

<http://www.eap.gov.et/content/files/Documents/EAP%20Documents/Regulatory/Plant/Pesticide/APPLICATION%20FOR%20RENEWAL%20OF%20PESTICIDE%20REGISTRATION%20PRC%204.pdf>

Application for import/export certificate for pesticides

<http://www.eap.gov.et/content/files/Documents/EAP%20Documents/Regulatory/Plant/Pesticide/Application%20For%20Pesticide%20Exp.Imp%20Certificate%20of%20Pesticide%20PRC%20-2.pdf>

Inspector's format for inspecting pesticides at customs

<http://www.eap.gov.et/content/files/Documents/EAP%20Documents/Regulatory/Plant/Pesticide/Pesticides%20at%20customs.pdf>

Requirements For Obtaining Services Given By Animal And Plant Health Regulatory Department Of The Ministry Of Agriculture And Rural Development

<http://www.eap.gov.et/content/files/Documents/EAP%20Documents/Regulatory/Plant/Requirement%20Obtaining%20Quarantine%20Services%202.pdf>

France (EU)

Ministry of Food, Agriculture and Fisheries <http://agriculture.gouv.fr/>

EU legislation

Gambia

Registration authority: Chemicals and Pesticides Control and Management Board;
registrar

<http://www.nea.gm/hazardous.htm> National Environment Agency: <http://www.nea.gm/>

Hazardous Chemicals and Pesticides Control and Management Act, 1994
<http://www.gipfza.gm/Portals/1/downloads/HPCPM%20Act%201994.pdf>

Georgia

Registration body: Ministry of Agriculture, National Service of Food Safety, Veterinary and Plant Protection, Pesticide Registration and Permission Department

<http://www.fvp.ge/eng/registracia.htm>

Law No. 1696-Is on pesticides and agrochemicals

<http://faolex.fao.org/docs/texts/geo79452E.doc>

Germany (EU)

The competent authority in Germany is the BVL (Federal Office of Consumer Protection and Food Safety

http://www.bvl.bund.de/cln_007/nn_496812/EN/04_PlantProtectionProducts/PlantProtectionProducts.html__nnn=true) which collaborates with three evaluation authorities: the Federal Institute for Risk Assessment (http://www.bfr.bund.de/cd/template/index_en) , the Julius Kühn Institute (http://www.jki.bund.de/nn_813794/EN/Home/homepage_node.html__nnn=true) and the Federal Environmental Agency (<http://www.umweltbundesamt.de/index-e.htm>)

EU legislation

Ghana

Pesticide registration authority: Environmental Protection Agency, Ghana

<http://www.epa.gov.gh/>

Legislation: Act (No. 528 of 1996) to provide for the control, management and regulation of pesticides in Ghana and to provide for related matters. Date of assent: 23 December 1996. <http://www.lexadin.nl/wlg/legis/nofr/oeur/arch/gha/528.pdf>

Guatemala

Ministerio de Agricultura, Ganaderia y Alimentacion

<http://portal.maga.gob.gt/portal/page/portal/maga2009/main>

Plaguicidas y sustancias afines- Clasificación toxicológica
<http://www.agrequima.com.gt/LeyesyReglamentos/NORMASCOGUANOR/NGO44046.pdf>

Plaguicidas-Etiqueta
<http://www.agrequima.com.gt/LeyesyReglamentos/NORMASCOGUANOR/NGO44052.pdf>

Plaguicidas Ingrediente Activo
<http://www.agrequima.com.gt/LeyesyReglamentos/NORMASCOGUANOR/NGO44087.pdf>

Guyana

Pesticides and Toxic Chemicals Control Board <http://www.ptccb.org.gy/>

Pesticides and Toxic Chemicals Control Act 2000
http://www.ptccb.org.gy/documents/Pesticide_Act_2000.pdf

Regulations under Pesticides and Toxic Chemicals Control Act 2000
http://www.ptccb.org.gy/documents/Pesticides_and_Toxic_ChemicalsRegulations.pdf

Amendments to Regulations under Pesticides and Toxic Chemicals Control Act 2000 (2007)
http://www.ptccb.org.gy/documents/Regs_Pesticides_and_Toxic_Chemicals_Amendme nt_Regulations_2007.pdf

Hungary (EU)

Ministry of Agriculture and Rural Development
<http://www.fvm.hu/main.php?folderID=945>

Plant protection-pesticides <http://www.fvm.hu/main.php?folderID=1982>

India

Pesticide registration authority: Central Government in consultation with the Registration Committee of Ministry of Agriculture, Government of India, Agricultural and Processed Food Products Export Development Authority <http://www.apeda.com>;

Central Insecticides Board and Registration Committee <http://cibrc.nic.in/>

Insecticide Act 1968, Insecticide rules, 1971. http://cibrc.nic.in/insecticides_act.htm

Indonesia

Pesticide registration authority: Republic of Indonesia Ministry of Agriculture
<http://www.deptan.go.id/english/index.html>

Pesticide Committee website
http://www.deptan.go.id/pesantren/data/English%20WebSite/tentang_kompes/menu_kompes.htm

Regulation of Pesticides Registration in the Republic of Indonesia
<http://www.deptan.go.id/pengumuman/berita/regulasi-pestisida.htm>

Ministry of Agriculture Decree No 434.1/Kpts/TP.270/7/2001
http://www.deptan.go.id/pesantren/data/English%20Web-Site/pendaftaran/tata_cara.htm
Concerning Requirement and Procedure of Pesticide Registration

Ireland (EU)

Department of Agriculture and Food, Pesticide Control Service (PCS)
<http://www.pcs.agriculture.gov.ie/>

Control of marketing and use of plant protection and biocide products. The main provisions of the legislation (S.I No. 320 of 1981 as amended, S.I. No. 83 of 2003 and S.I. No. 624 of 2001), and application forms for plant protection and biocidal products are available at: <http://www.pcs.agriculture.gov.ie/control.htm>

EU legislation

Israel

Pesticide registration authority(agricultural): Ministry of Agriculture General Director of the Plant Protection and Inspection Services:
<http://www.ppiseng.moag.gov.il/PPISENG/default.htm>

Pesticide registration information:
<http://www.ppiseng.moag.gov.il/PPISENG/Pesticides/PesticidesRegistration/>

Dangerous Substances Regulations (Registration of Pesticides)-1994 (Hebrew)
<http://faolex.fao.org/docs/pdf/isr49138.pdf>

Pesticide registration list 2007
<http://www.ppiseng.moag.gov.il/NR/rdonlyres/3BEC7814-0F2C-4A22-B024-6119ACD3DE21/1297/PesticidesBook2007.doc>

Ministry of Agriculture General Director of the Plant Protection and Inspection Services
Pesticides Databank
<http://www.hadbaraeng.moag.gov.il/hadbara/english>

Italy (EU)

Consultative commission for biocides

<http://www.ministerosalute.it/ministero/sezMinisteroDettaglio.jsp?label=com&id=594>

Consultative commission for phytosanitary products

<http://www.ministerosalute.it/ministero/sezMinisteroDettaglio.jsp?label=com&id=603>

Normativa Sui Prodotti Fitosanitari

<http://www.cra-pav.it/elenco%20norme%20prodotti%20fitosanitari.html>

Consolidated list of active substances

http://www.ministerosalute.it/imgs/C_17_pagineBiocidi_5_listaFile_itemName_6_file.xls

Pesticide registration authority: Ministry of Health

<http://www.ministerosalute.it>

Il Regolamento n° 440/2008 (CE) Methodi

http://www.iss.it/binary/spps/cont/Indice_Metodi.1227522466.pdf

Institutes and Centers working on behalf of the Ministry of Health in the registration process at national and European level:

Istituto Superiore di Sanità su Sostanze e Preparati Pericolosi

<http://www.spp.iss.it> National Centre for Chemical Substances <http://www.iss.it/cnsc>

Istituto Sperimentale per la Patologia Vegetale di Roma (Plant Pathology Research Centre)

<http://www.ispave.it>

Centro Internazionale per gli Antiparassitari e la Prevenzione Sanitaria (International Centre for Pesticides and Health Risk Prevention)

<http://www.icps.it>

Jamaica

Pesticide registration authority: [The Pesticides Control Authority](http://www.caribpesticides.net/)

<http://www.caribpesticides.net/>

Legislation: Pesticide Act, 1975

http://www.caribpesticides.net/countries/jm/pest_act_1975.pdf

Pesticide regulations, 1996, amendment of regulations, 1999 and Jamaican standard specification for labelling of retail packages of pesticides are also available at:

http://www.caribpesticides.net/countries/jm/reg_1996.pdf

http://www.caribpesticides.net/countries/jm/reg_1999.pdf

http://www.caribpesticides.net/countries/jm/labelling_standards.pdf

Register of pesticides

http://www.caribpesticides.net/country.dti?country_code=jm&tab=name

Register of pesticide control operators

<http://www.caribpesticides.net/countries/jm/PestControlOperatorsApr2009.pdf>

List of managed and restricted pesticides

<http://www.caribpesticides.net/countries/jm/RestrictedPesticidesJun06.pdf>

Japan

Pesticide registration authority: Ministry of Agriculture, Forestry and Fisheries

<http://www.maff.go.jp/e/index.html>

Agricultural Chemicals Regulation Law (Law No. 82 of July 1, 1948) last amended 30 March 2007

http://www.acis.famic.go.jp/eng/hourei/regulation_law.htm

Data requirements for supporting registration of pesticides and guidelines for preparation of study results submitted when applying for registration of agricultural chemicals are available at: <http://www.acis.famic.go.jp/eng/shinsei/8147main.pdf> ;

The guidelines related to the study reports for the registration application of pesticide

<http://www.acis.famic.go.jp/eng/shinsei/8147appendix.pdf>;

Annex (Guidelines for Preparation of Study Results Submitted When Applying for Registration of Agricultural Chemicals

<http://www.acis.famic.go.jp/eng/shinsei/annex.htm>

http://www.acis.famic.go.jp/eng/shinsei/All_Documents.pdf

Regarding data to be appended to applications for Registration of Agricultural Chemicals

<http://www.acis.famic.go.jp/eng/shinsei/13-3987.pdf>

Notification on the Good Laboratory Practice (GLP) Standards for Agricultural Chemicals (No.11-6283)

<http://www.acis.famic.go.jp/eng/glp/GLPmain.pdf>

(Annex) The Standards of Good Laboratory Practice (GLP) for Agricultural Chemicals

<http://www.acis.famic.go.jp/eng/glp/GLPannex.pdf>

Guidance for Preparation of Documents Concerning the Confirmation of GLP Compliance of Agricultural Chemicals <http://www.acis.famic.go.jp/eng/glp/15-7396.pdf>

Kazakhstan

Ministry of Agriculture <http://www.minagri.kz/en/agr.php>

Ministerial Decree No. 515 validating Technical Regulation on safety of pesticides
<http://faolex.fao.org/docs/texts/kaz82134.doc> (Russian)

Ministerial Decree No. 613 validating qualification requirements for natural and legal persons carrying out manufacturing, trade and application of pesticides
<http://faolex.fao.org/docs/texts/kaz80632.doc> (Russian)

Ministerial Decree No. 310 regarding the Ministry of Agriculture
<http://faolex.fao.org/docs/texts/kaz80384.doc> (Russian)

Order No. 373 validating the Regulation on storage, transportation and application of pesticides
<http://faolex.fao.org/docs/texts/kaz80484.doc> (Russian)

Law No. 331-2 on plant protection <http://faolex.fao.org/docs/texts/kaz69148.doc>
(Russian)

Ministerial Decree No. 439 on prohibition of use and burial ecologically hazardous pesticides
<http://faolex.fao.org/docs/texts/kaz69585.doc> (Russian)

Kyrgyzstan

The Law Of The Kyrgyz Republic About chemicalization and plant protection
<http://www.libertas-institut.com/de/Mittel-Osteuropa/Law%20about%20Chemicalization%20and%20Plant%20Protection.pdf>
(English)

Resolution on Licensing of Activities for Manufacturing and Sale of Chemicals (in agrochemistry) (No. 467 of 1997) <http://faolex.fao.org/docs/texts/kyr16699.doc>
(English)

Decree implementing Government Decree No. 467 on licensing of activity on production and sale of chemicals (in agrochemical part) (No. 173 of 1997)
<http://faolex.fao.org/docs/texts/kyr16578.doc> (English)

Regulations regarding registration tests and registration of pesticides in the Kyrgyz Republic
<http://faolex.fao.org/docs/texts/kyr16668.doc>;
<http://faolex.fao.org/docs/pdf/kyr16668anx.pdf>

Lebanon

Ministry of Agriculture http://www.agriculture.gov.lb/english_file/index_e.htm

Decree 392/1 dated 24/12/2003 concerning the modification of decree 291/1
Related to entry, registration and use of pesticides in Lebanon
<http://www.agriculture.gov.lb/pesticides/REGISTRA.doc> (Arabic)

Pesticide registration form (Arabic, English)
http://www.agriculture.gov.lb/pesticides/ANNEX%20Regist_files/annexe1.doc

Pesticide re-registration form (Arabic, English)
http://www.agriculture.gov.lb/pesticides/ANNEX%20Regist_files/annexe2.doc

List of banned pesticides
http://www.agriculture.gov.lb/pesticides/Decision94_mai1998.htm

List of Maximum Levels of Tolerated Impurities for Active Ingredients Issued by the
Ministry (Arabic, English)
http://www.agriculture.gov.lb/pesticides/ANNEX%20Regist_files/annexe3.html

Inerts of toxicologic concern
http://www.agriculture.gov.lb/pesticides/ANNEX%20Regist_files/annexe4.doc

EPA List 2: Potentially Toxic Inerts/ High Priority for Testing
http://www.agriculture.gov.lb/pesticides/ANNEX%20Regist_files/annexe5.doc

Decree 392/1
http://www.agriculture.gov.lb/pesticides/ANNEX%20Regist_files/annexe6.doc

Madagascar

Ministry of Agriculture, Livestock and Fisheries <http://www.maep.gov.mg/>;
<http://www.maep.gov.mg/eg/index.htm> (English)

D E C R E T No 92-473 portant règlementation des produits agropharmaceutiques ,
http://www.ipfsaph.org/servlet/BinaryDownloaderServlet?filename=/kopool_data/FAOLEX_0/fr_mad7461.pdf

Arrêté n° 7450-92 portant modalités de contrôle et d'échantillonnage des produits
agropharmaceutiques.
http://www.ipfsaph.org/servlet/BinaryDownloaderServlet/FAOLEX005328_http_faol_ex.fao.or.pdf?filename=/kopool_data/FAOLEX_0/fr_mad7463.pdf&refID=FAOLEX005328

Arrêté n° 7451-92 portant normalisation de l'étiquetage des emballages des produits
agropharmaceutiques.
http://www.ipfsaph.org/servlet/BinaryDownloaderServlet/FAOLEX005329_http_faol_ex.fao.or.pdf?filename=/kopool_data/FAOLEX_0/fr_mad7464.pdf&refID=FAOLEX005329

Arrêté n° 7452-92 règlementant le stockage et le reconditionnement des produits agropharmaceutiques

http://www.ipfsaph.org/servlet/BinaryDownloaderServlet/FAOLEX005329_http_faolex_fao.or.pdf?filename=\kopool_data\FAOLEX_0\fr_mad7464.pdf&refID=FAOLEX005329

Malawi

Ministry of Agriculture and Food Security

<http://www.malawi.gov.mw/Agriculture/Home%20%20Agriculture.htm>

Plant Protection Act, 1969

http://www.ipfsaph.org/servlet/BinaryDownloaderServlet/FAOLEX063795_http_faolex_fao.or.pdf?filename=\kopool_data\FAOLEX_0\unknown_mlw63795.pdf&refID=FAOLEX063795

Pesticide Act 2000- Not available on-line

Malaysia

Pesticide registration authority: Pesticides Board which has its secretariat in the Department of Agriculture,

<http://www.doa.gov.my/main.php?Content=sections&SubSectionID=153&SectionID=8&CurLocation=8&IID=>

Pesticides Act, 1974 (Amended 2004). Guidelines on Registration and Labelling of Pesticides.

<http://www.doa.gov.my/main.php?Content=sections&SubSectionID=167&SectionID=8&CurLocation=8&IID=>

Mali

Ministry of Agriculture <http://www.maliagriculture.org/>

Décret n°313/p-rm du 19 juin 2009 fixant les modalités d'application de la loi instituant l'homologation et le contrôle des pesticides en République du Mali

http://www.sante.gov.ml/msante/index.php?option=com_content&task=view&id=974&Itemid=87

Malta

Food Safety Commission <http://www.health.gov.mt/fsc/fschome.htm>

Act No XI of 2001 Pesticide Control Act to provide for the control of pesticides and for other purposes connected therewith or incidental thereto. Dated 1 August 2001.

http://docs.justice.gov.mt/lom/legislation/english/leg/vol_13/chapt430.pdf

Plant Protection Products Regulations 2004

<http://www.doi.gov.mt/EN/legalnotices/2004/03/LN115e.pdf>

Mexico

Pesticide registration authority: The Federal Commission for the Protection against Sanitary Risk (COFEPRIS) .It is a decentralized organ of the Ministry of Health with technical, administrative and operational autonomy. <http://www.cofepris.gob.mx/>

Legislation: Regulation of registration, authorization for importation and exportation, exportation certification of pesticides, vegetable nutrient and dangerously toxic substances.

<http://www.cofepris.gob.mx/work/sites/cfp/resources/LocalContent/482/25/matoxicos281204.pdf>

NORMA Oficial Mexicana NOM-045-SSA1-1993, Plaguicidas. Productos para uso agrícola,

forestal, pecuario, de jardinería, urbano e industrial. Etiquetado

<http://201.147.97.103/work/sites/cfp/resources/LocalContent/339/4/045ssa1.pdf>

NORMA Oficial Mexicana NOM-046-SSA1-1993, Plaguicidas-Productos para uso doméstico-Etiquetado.

<http://201.147.97.103/work/sites/cfp/resources/LocalContent/339/4/046ssa1.pdf>

Acuerdos para el registro de plaguicidas con las principales asociaciones de agroquímicos de México

http://201.147.97.103/work/sites/cfp/resources/LocalContent/340/3/18Acuerdos_registro_plag_PLAGNV_150109.doc

Moldova

Ministry of Agriculture and Food Industry: <http://www.maia.gov.md/index.php?l=en>

Morocco

Dahir No. 1-97-01 of 21 January 1997 promulgating Law No. 42-95 on the control and organization of the market in pesticides for agricultural use. (*Bulletin officiel*, 15 May 1997, No. 4482, pp. 533-536)

<http://apps.who.int/ihlrls/results.cfm?language=english&type=ByVolume&intDigestVolume=49&strTopicCode=XVI> (WHO International Digest of Health Regulation)

Dahir n° 1-01-350 du 15 kaada 1422 (29 janvier 2002) portant promulgation de la loi n° 32-00 modifiant et complétant la loi n° 42-95 relative au contrôle et à l'organisation du commerce des produits pesticides à usage agricole

http://jp1.estis.net/sites/cien%2Dmaroc/default.asp?site=cien-maroc&page_id=CCBD67EB-FC47-4E5A-B9E0-74CA638868F2

Myanmar

The Pesticide Law. State Law and Order Restoration Council Law No. 10/90. Dated 11 May 1990. <http://sunsite.nus.edu.sg/apcel/dbase/myanmar/primary/myapst.html>

Nepal

Ministry of Agriculture and Cooperatives <http://www.moac.gov.np/home/index.php>

The Pesticide Regulation, 2050(1994)
<http://www.moacwto.gov.np/documents/ThepesticideRules.pdf>

Netherlands (EU)

Authority for the registration of pesticides: Board for the Authorisation of Plant Protection Products and Biocides (College voor de Toelating van Gewasbeschermingsmiddelen en biociden-ctgb).
<http://www.ctb-wageningen.nl/>

Authorisation Manual Plant Protection Products, Manual Biocides <http://www.ctb-wageningen.nl>

Dossier Build-Up for Applications for Authorisation of Notified Biocides
http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTBI/OCIDENZONDERTOELATING/01AANMELDINGSFORMULIER/DOSSIER%20OPBOUW%201.0B-EN.DOC

Decree Tariff Regulation Ctgb 2009
http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTBLANGUAGE_ENGELS/2009%20TARIEVENBESLUIT%20-%20UK.PDF

Manual for the Authorisation of Pesticides-Plant Protection Products

Chapter 2 Physical and chemical properties
http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTBIAPPLICATIONFORMS/02AUTHORISATIONMANUAL/01AUTHORISATIONMANUALPPP/02HTBPPP1.0/G%202%20FCE%20-EN-CHECK2.PDF

Chapter 3 Analytical Methods
http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTBIAPPLICATIONFORMS/02AUTHORISATIONMANUAL/01AUTHORISATIONMANUALPPP/02HTBPPP1.0/G%203%20ANAL%20METH%20-EN-CHECK2.PDF

Chapter 4 Human toxicology; toxicological dossier version 1.0; 14 April 2006

[http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION
FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP
P/02HTBPPP1.0/G%204%20TOX%20DOS%20-EN-CHECK2.PDF](http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION_FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP/P/02HTBPPP1.0/G%204%20TOX%20DOS%20-EN-CHECK2.PDF)

Chapter 4 Human toxicology; risk operator, worker and bystander

[http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION
FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP
P/02HTBPPP1.0/G%204%20RIS%20TOEPASSER%20-EN-CHECK2.PDF](http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION_FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP/P/02HTBPPP1.0/G%204%20RIS%20TOEPASSER%20-EN-CHECK2.PDF)

Chapter 5 Residues, residue dossier

[http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION
FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP
P/02HTBPPP1.0/G%205%20RESIDU%20DOS%20EN-CHECK2.PDF](http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION_FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP/P/02HTBPPP1.0/G%205%20RESIDU%20DOS%20EN-CHECK2.PDF)

Chapter 5 Residues; risk to consumers

[http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION
FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP
P/02HTBPPP1.0/G%205%20RIS%20VOLKSGEZH_UK_DEF.PDF](http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION_FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP/P/02HTBPPP1.0/G%205%20RIS%20VOLKSGEZH_UK_DEF.PDF)

Chapter 6 Fate and behaviour in the environment; behaviour in soil; persistence

[http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION
FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP
P/02HTBPPP1.0/G%206%20PERSISTENTIE%20EN-CHECK2.PDF](http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION_FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP/P/02HTBPPP1.0/G%206%20PERSISTENTIE%20EN-CHECK2.PDF)

Chapter 6 Fate and behaviour in the environment; behaviour in soil; leaching

[http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION
FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP
P/02HTBPPP1.0/G%206%20GEDRAG%20UITSPOELING%20EN-
CHECK2.PDF](http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION_FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP/P/02HTBPPP1.0/G%206%20GEDRAG%20UITSPOELING%20EN-CHECK2.PDF)

Chapter 6 Fate and behaviour in the environment; behaviour in surface water, sediment and sewage treatment plants (STP)

[http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION
FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP
P/02HTBPPP1.0/G%206%20WATER%20EN%20-CHECK2.PDF](http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION_FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP/P/02HTBPPP1.0/G%206%20WATER%20EN%20-CHECK2.PDF)

Chapter 6 Fate and behaviour in the environment; behaviour in air

[http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION
FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP
P/02HTBPPP1.0/G%206%20LUCHT%20EN-CHECK2.PDF](http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION_FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP/P/02HTBPPP1.0/G%206%20LUCHT%20EN-CHECK2.PDF)

Chapter 7 Ecotoxicology; aquatic

[http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION
FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP
P/02HTBPPP1.0/G%207%20ECO_AQUAT%20EN-CHECK2.PDF](http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION_FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP/P/02HTBPPP1.0/G%207%20ECO_AQUAT%20EN-CHECK2.PDF)

Chapter 7 Ecotoxicology; terrestrial

http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION_FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP/P/02HTBPPP1.0/G%207%20ECO_TERRES%20ALLE%20EN-CHECK2.PDF

Appendix B Endpoints list ecotoxicology

http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION_FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP/P/02HTBPPP1.0/G%207%20ECO_BIJLAGE%20B%20-%20LOEPECO.PDF

Appendix C: Combination toxicity

http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION_FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP/P/02HTBPPP1.0/G%207%20BIJLAGE%20C%20-%20COMBITOX%20HTB1.0_DEF-EN.PDF

Chapter 8 Efficacy

http://www.ctb.agro.nl/pls/portal/docs/PAGE/WEBSITE_CTB/APPLICATION_FORMS/02AUTHORISATION_MANUAL/01AUTHORISATIONMANUALPP/P/02HTBPPP1.0/G%208%20WERKZAAMHEID%20EN-CHECK2.PDF

New Zealand

New Zealand Food Safety Authority

<http://www.nzfsa.govt.nz/acvm/legislation/index.htm>

ACVM (*Agricultural Compounds and Veterinary Medicines Act*) registration information requirements for plant compounds in New Zealand

<http://www.nzfsa.govt.nz/acvm/publications/information-requirements/regpc.pdf>

Hazard and risk assessment under ACVM

<http://www.nzfsa.govt.nz/acvm/publications/standards-guidelines/risk-hazard-guideline.pdf>

ACVM registration information requirements for vertebrate toxic agents including vertebrate pest control products

<http://www.nzfsa.govt.nz/acvm/publications/information-requirements/vtaregistrationinfo0305.pdf>

Fees for regulatory assessment of plant compounds

<http://www.nzfsa.govt.nz/acvm/publications/fees/fees-pc.htm>

New Zealand (Maximum Residue Limits of Agricultural Compounds)
Food Standards 2008

<http://www.nzfsa.govt.nz/policy-law/legislation/food-standards/nz-mrl-fs-2008-consolidation.pdf>

Nicaragua

Pesticide registration authority: Ministry of Agriculture and Forestry.
<http://www.magfor.gob.ni/> (Spanish)

Legislation: Law No 274. Basic law on the regulation and control of pesticides and toxic, dangerous and similar substances (Spanish)

<http://legislacion.asamblea.gob.ni/Normaweb.nsf/fb812bd5a06244ba062568a30051ce81/93e77f83f0402d1c062570a1005777d4?OpenDocument>

Decree No 49-98 Regulation of the Law No 274

<http://www.ccad.ws/documentos/legislacion/NC/D-49-98.pdf>

Plaguicidas de uso restringido (reevaluados) resolución ministerial 019-2008

<http://www.inta.gob.ni/Afiche%20Plaguicidas%20Uso%20Restringido.pdf>

Plaguicidas prohibidos a través del acuerdo Ministerial no. 23-2001

Y Resolucion Ministerial 019-2008

<http://www.inta.gob.ni/Afiche%20Plaguicidas%20Prohibidos.pdf>

Nigeria

Drugs and related products (registration, etc.) Act 1996 (as amended)

Pesticide registration regulations 2005 <http://www.nafdacnigeria.org/newregs.html>

Norway

Norwegian Food Safety Authority

http://www.mattilsynet.no/portal/page?_pageid=54,40103&_dad=portal&_schema=PORTAL&language=english

Norwegian Agricultural Inspection Service

http://landbrukstilsynet.mattilsynet.no/dokument_eng.cfm?m_id=201&d_id=1219

Regulations relating to pesticides (14 December 2000)

http://landbrukstilsynet.mattilsynet.no/vedlegg/Pesticides_Regulations_14_12_2000_%20Updated.doc

List of exceedings of MRLs for pesticide residues in foods (16.07.2009)

http://www.mattilsynet.no/mattilsynet/multimedia/archive/00050/List_of_exceedings_o_50377a.pdf

Guidelines for classification of plant protection products in tax classes differentiated according to health and environmental factors
http://landbrukstilsynet.mattilsynet.no/vedlegg/Plant_protection_product_taxes_guidance.doc

Oman

Ministry of Health <http://www.moh.gov.om/>

Royal Decree No. 46/95 Issuing the Law of Handling and Use of Chemicals
[http://www.pdo.co.om/hseforcontractors/blocks/documentation/docs/laws/decrees_46_95.pdf](http://www.pdo.co.om/hseforcontractors/blocks/documentation/docs/laws/decrees/46_95.pdf)

Ministerial Decision No. (248/97) Issuing the Regulation for the Registration of Chemical Substances and the Relevant Permits
http://www.pdo.co.om/hseforcontractors/blocks/documentation/docs/laws/decision_248_97.pdf

Pakistan

Pesticide registration authority: Department of Plant Protection, Ministry of Food, agriculture and Livestock: <http://www.plantprotection.gov.pk>

Pesticide registration department
<http://www.plantprotection.gov.pk/reg.htm>

Legislation: Ordinance No: II of 1971 to regulate the import, manufacture, formulation, sale, distribution and use of pesticides
http://www.plantprotection.gov.pk/pdf%20stuff/Ordi-1_reg.pdf

Panama

Ministry of Agricultural Development
<http://www.mida.gob.pa/>

Decree No. 116 of 18 September 1991 regulating the Inter-institutional Technical Commission on Pesticides
http://190.34.208.115/Legis-Agro/Resueltos/Resuelto_Administrativo/Le37_01_656.PDF

Resuelto N° 23/ALP - Normas para el registro y manejo seguro de aditivos, fertilizantes y plaguicidas
http://190.34.208.115/Legis-Agro/Registros_y_Controles_Sanitarios/Le35_01_016.html

Establishment of coordination between the Ministry of Agricultural Development and Ministry of Health in complimenting article 70 of the Law no 47 of 1996 (Regulation of use of pesticides)

http://190.34.208.115/Legis-Agro/Registros_y_Controles_Sanitarios/Le35_01_013.html

Ministry of Health <http://www.minsa.gob.pa>

Paraguay

Ministry of Agriculture and Livestock <http://www.mag.gov.py/>

Ley N° 123/91 Que Adoptan Nuevas Formas De Proteccion Fitosanitarias
<http://www.salvemoslos.com.py/LEY%20%20N%20123.doc>

Decreto 13.861/96. Por el cual se reglamenta el uso y manejo de productos. Fitosanitarios establecidos en la ley 123/91
<http://www.ministeriopublico.gov.py/menu/varios/delitosecologicos/archivos/delitosecologicos/anexos/anexo12.pdf>

Ministry of Public Health and Social Welfare <http://www.mspbs.gov.py>

Decreto N° 1.397/09 - Por el cual se establecen medidas sanitarias para el uso adecuado de plaguicidas en la producción agropecuaria, con vistas a la protección de la salud de las personas, así como de los alimentos y del ambiente
<http://faolex.fao.org/docs/texts/par87166.doc>

Peru

Ministry of Agriculture <http://www.minag.gob.pe/>

Decision 436 Norma Andina para el Registro y Control de Plaguicidas Químicos de Uso Agrícola La Comision De La Comunidad Andina
<http://www.senasa.gob.pe/RepositorioAPS/0/3/JER/NORMASPLAGUICIDAS/Decisión%20436,%20Norma%20Andina%20para%20el%20Registro%20y%20Control%20de%20PQUA.pdf>

Resolución 630.- Manual Técnico Andino para el Registro y Control de Plaguicidas Químicos de Uso Agrícola
<http://www.senasa.gob.pe/RepositorioAPS/0/3/JER/NORMASPLAGUICIDAS/Resolución%20630%20CAN,%20Manual%20Técnico%20Andino%20.pdf>

DECISION 684 Modificación de la Decisión 436. (Norma Andina para el Registro y Control de Plaguicidas Químicos de Uso Agrícola
<http://www.senasa.gob.pe/RepositorioAPS/0/3/JER/NORMASPLAGUICIDAS/Decisión%20684,%20modificación%20de%20la%20Decisión%20436.doc>

List of pesticides restricted and prohibited in Peru
http://www.senasa.gob.pe/0/modulos/JER/JER_Interna.aspx?ARE=0&PFL=3&JER=193

Philippines

Pesticide registration authority: fertilizer and pesticide authority of the Republic of the Philippines: <http://fpa.da.gov.ph>

Pesticide regulatory services and requirements for pesticide handlers , product registration activities, licensing requirements, product registration requirements
http://fpa.da.gov.ph/Licens_Pest.htm

Product registration activities
http://www.fadinap.org/philippines/Licens_Pest.htm#Product%20Registration

Licensing requirements
http://www.fadinap.org/philippines/Licens_Pest.htm#Licensing

Product registration requirements
http://www.fadinap.org/philippines/Licens_Pest.htm#Product%20Registration

Banned and restricted pesticides in the Philippines
<http://fpa.da.gov.ph/BANNED%20AND%20RESTRICTED%20PESTICIDES%20IN%20THE%20PHILIPPINES.doc>

List of registered agricultural products
<http://fpa.da.gov.ph/List%20of%20Registered%20Agricultural%20Pesticide%20Products.pdf>

Poland (EU)

Pesticide registration authority: Ministry of Agriculture and Rural Development, Department of Plant Breeding and Protection
<http://www.minrol.gov.pl/DesktopDefault.aspx?TabOrgId=981&LangId=1>

Legislation: EU legislation

Portugal (EU)

Ministry of Agriculture and Fisheries http://portal.min-agricultura.pt/portal/page/portal/MADRP/EN/en/agriculture_fisheries

Legislation: EU legislation

Qatar

Ministry of Municipal Affairs and Agriculture
http://www.gov.qa/wps/portal?New_WCM_Context=/wps/wcm/connect/cnt/en/1_Home/14_Ministries_and_Authorities/MMAA_EN

Russian Federation

State registration: Federal Service for Veterinary and Phytosanitary Surveillance (Rosselkhozadzor) http://www.fsvps.ru/fsvps/main.html?_language=en

Ministry of Agriculture <http://www.mcx.ru/>

Order No. 357 of the Ministry of Agriculture validating the Regulation on state registration on pesticides and agro-chemicals <http://faolex.fao.org/docs/texts/rus79872.doc> (Russian)

Federal Law № 109 FL dated July, 19, 1997 "On safe application of pesticides and agrochemicals" <http://faolex.fao.org/docs/texts/rus25302.doc> (Russian)

Order № Well-225 dated August,1, 2006 of Federal Service on Inspection in the Sphere of Consumers Rights and Men Well Being "sanitary-agrochemicals" On sanitary epidemiological expertise of pesticides and agrochemicals <http://faolex.fao.org/docs/texts/rus77578.doc> (Russian)

Order of Ministry of Agriculture of Russian Federation № 357 dated July,10, 2007 "On ratification of procedure of pesticides and agrochemicals state registration registration" <http://faolex.fao.org/docs/texts/rus77577.doc> (Russian)

Serbia

Plant Protection Law, 1999 <http://faolex.fao.org/docs/texts/yug28865.doc> (Serbian)

Singapore

Act (No. 24 of 1998) Date of commencement: 1 September 1998. (The Control of Vectors and Pesticides Act). As last amended by Act No. 2 of 2002 (Chapter 59 of the 2003 Revised Edition). <http://agevldb4.agc.gov.sg> or

Slovenia (EU)

Ministry of Agriculture, Forestry and Food Phytosanitary Administration of the Republic of Slovenia (PARS) <http://www.furs.si/en/Index.asp>

National legislation: Act On Plant Protection Products <http://www.furs.si/law/slo/ffs/ENG/angzffsPreciscen.doc>

EU Legislation

South Africa

Department of Agriculture, Forestry and Fisheries
<http://www.daff.gov.za/>

Fertilizers, farm feeds, agricultural remedies and stock remedies act 36 of 1947
<http://www.nda.agric.za/docs/NPPOZA/Fertilizers%20Act.pdf>

Registration As A Pest Control Operator In Terms Of Section 10 Of Act 36 Of 1947
http://www.nda.agric.za/doaDev/sideMenu/ActNo36_1947/PCOs/General.htm

Banned and Restricted Substances in the republic of South Africa
<http://www.daff.gov.za/#>

Spain (EU)

Ministerio de Medio Ambiente y Medio Rural Y Marino
<http://www.mapa.es/en/agricultura/agricultura.htm>

Sri Lanka

Pesticide registration authority: Office of the Registrar of Pesticides
http://www.agridept.gov.lk/SCPP/opr_indx.htm

Legislation: Control of Pesticides Act No. 33 of 1980, Registration Application Guide
<http://www.agridept.gov.lk/SCPP/Guide.pdf>

List of pesticides, fungicides, herbicides registered in Sri Lanka and recommendations for use on crops <http://www.agridept.gov.lk/Techinformations/Pesindex.htm>

Sweden (EU)

Swedish Chemicals Agency-KEMI <http://www.kemi.se/>

Pesticides register <http://apps.kemi.se/bkmregoff/default.cfm>

Description of the SPIDER pesticides database
http://www.kemi.se/upload/Statistik/Kemistat/Kvalitetsdeklaration_bkmregister_eng.pdf

Swedish Environmental Code <http://www.regeringen.se/content/1/c4/13/48/385ef12a.pdf>

KIFS Regulations http://www.kemi.se/templates/Page_3022.aspx

Switzerland

Swiss Federal Office of Agriculture
<http://www.blw.admin.ch/index.html?lang=en>

Swiss Federal Office of Agriculture Plant Protection
<http://www.blw.admin.ch/themen/00012/index.html?lang=en>

Anhang 2.5 (Art. 3)Pflanzenschutzmittel
http://www.admin.ch/ch/d/sr/814_81/app20.html

Tajikistan

Law No.1 of 2003 on manufacturing and safe management of pesticides and agro-chemicals
<http://faolex.fao.org/docs/texts/taj43152.doc> (Russian)

Tanzania

Ministry of Agriculture, Food and Cooperatives <http://www.kilimo.go.tz>

Pesticides Control Regulation <http://www.kilimo.go.tz/Regulations.htm>

The Plant Protection Act, 1997
<http://www.agriculture.go.tz/Regulations/Plant%20Protection%20Act,%201997.pdf>

List of pesticides registered in Tanzania are available at:
<http://www.agriculture.go.tz/MAFSServices/list%20of%20pesticides%20registered%20in%20Tanzania%20by%20Nov%202007.htm>

The Plant Protection Regulations 1998
<http://www.agriculture.go.tz/Regulations/The%20Plant%20Protection%20Act%20No%2013%20of%201997-Regulations.pdf>

Pesticide Control Regulations 1984
<http://www.kilimo.go.tz/Regulations/The%20Tropical%20Pesticides%20Research%20Institute%20%20Regulations,%201979.pdf>

Thailand

Pesticide registration authority (pesticides used in crop production): Ministry of Agriculture and Cooperatives, Department of Agriculture <http://www.doa.hgo.th>

Pesticide registration authority (pesticides used as household chemicals): Food and Drug Administration, Ministry of Public Health:
<http://www.fda.moph.go.th/eng/hazardous/index.stm>

Legislation: Hazardous Substance Control Act B.E. 2535 (1992)to regulate pesticides in Thailand
http://www2.fda.moph.go.th/law/Law_Book_1.asp?productcd=6&lawid=600003_1&lawname=HAZARDOUS%20SUBSTANCE%20ACT%20B.E.2535&language=e&Contents=1&v_call=lawlink&historylink=/law&arg_language=e

Hazardous Substances Act 1992(summary)
<http://www.fda.moph.go.th/eng/hazardous/laws.stm>

Togo

Ministère de l'Agriculture, de l'Elevage et de la Pêche <http://maeptogo.tg>

Décret n° 2006-023/PR portant création d'un office des fertilisants, engrais et pesticides
<http://faolex.fao.org/docs/pdf/tog65918.pdf>

Tonga

Act (No. 7 of 2002) to regulate the registration, manufacture, import, sale, storage, distribution, use and disposal of pesticides in Tonga. Date of assent: 29 October 2002. (The Pesticides Act 2002). http://www.paclii.org/to/legis/num_act/pa2002120

Trinidad and Tobago

Registration authority: Ministry of Health, Chemistry, Food and Drug Division, Pesticides and Toxic Chemicals Inspectorate
<http://www.health.gov.tt/sitepages/default.aspx?id=148>

Pesticides and toxic chemicals Act no. 42 of 1979
<http://rgd.legalaffairs.gov.tt/Laws/Chs.%2028-31/30.03/30.03%20aos.htm>

Pesticides (registration and import licensing) Regulations
[http://rgd.legalaffairs.gov.tt/Laws/Chs.%2028-31/30.03/Pesticides%20\(Registration%20and%20Import%20Licensing\)%20Regulations.pdf](http://rgd.legalaffairs.gov.tt/Laws/Chs.%2028-31/30.03/Pesticides%20(Registration%20and%20Import%20Licensing)%20Regulations.pdf)

Requirements for pesticide registration
<http://www.health.gov.tt/sitepages/default.aspx?id=148>

Turkey

Pesticide registration authority: Ministry of Agriculture and Rural affairs General Directorate of Protection and Control: <http://www.kkgm.gov.tr/indeks.html>

Act No 6869 on Agricultural Abatement and Agricultural Quarantine (Turkish)
<http://www.kkgm.gov.tr/kanun/6968.html>

Regulation on registration of plant protection products (Turkish)
http://www.kkgm.gov.tr/yonetmelik/zir_muc_kull_pestisit_benz_mad_ruhsat_.html

Requirements and registration form for pesticides and pesticide related substances (Turkish)

<http://www.saglik.gov.tr/TR/Genel/BelgeGoster.aspx?F6E10F8892433CFF404F9755767D76FFB971E71BA2225309>

Registration authority for pesticides used in public health: Ministry of Health General Directorate of Primary Health Care Services:

<http://www.tusp.saglik.gov.tr/TR/Genel/BelgeGoster.aspx?F6E10F8892433CFFA79D6F5E6C1B43FF8DF920F956B90357>

Uganda

Plant protection act

http://www.ulii.org/ug/legis/consol_act/ppa204/

Ministry of Health <http://www.health.go.ug/mcp/index2.html>

United Kingdom (EU)

Pesticide regulation authority (agricultural):

Pesticide Safety Directorate <http://www.pesticides.gov.uk/>

Health and Safety Executive (non.agricultural) <http://www.hse.gov.uk/> .

The Control of Pesticides Regulations (COPR) 1986 (SI 1986/1510)

Plant Protection Products Regulations (PPPR) Council Directive 91/414/EEC (see EU)

Pesticides Register of UK Approved Products <https://secure.pesticides.gov.uk/pestreg/>

Maximum Residue Level (MRL) Database: <https://secure.pesticides.gov.uk/MRLs/>

Toxicological Endpoint Database: <https://secure.pesticides.gov.uk/TEAWeb/intro.asp>

View Toxicological Endpoint information for active substances i.e. Acceptable Daily Intake (ADI); Acute Reference Dose (ARfD); and Acceptable Operator Exposure Level (AOEL).

Health and Safety Executive (HSE) (for non agricultural pesticides and biocides)

<http://www.hse.gov.uk/pesticides/index.htm>

Food and Environment Protection Act 1985 Part III - Schedules to the Control of Pesticides Regulations (as amended) 1986 given by ministers

<http://www.hse.gov.uk/biocides/copr/approvals/annexa.htm>

The use of pesticides is also regulated by COSHH (the Control of Substances Hazardous to Health) <http://www.hse.gov.uk/coshh/> .

Advisory Committee on Pesticides http://www.pesticides.gov.uk/acp_home.asp

Uruguay

Registration authority: Ministry of Husbandry, Agriculture and Fisheries (Ministerio de Ganaderia, Agricultura y Pesca) <http://www.mgap.gub.uy>

Decreto 149 / 977 Reglamentación para el registro, contralor y venta de plaguicidas de uso agrícola

<http://www.chasque.apc.org/dgsa/Decretosyres/decreto149profit.htm>

Reglamentación Para El Registro, Contralor Y Venta De Plaguicidas De Uso Agrícola

http://www.mgap.gub.uy/DGSSAA/Normativa/Archivos/PROD_FIT_DECRETOS/Decreto_149-977_1977-3-15_Registro_pf.pdf

Resolucion ministerial---14 mayo 2004 Aplicación de productos fitosanitarios

<http://www.chasque.apc.org/dgsa/Decretosyres/Zonaexclusion.htm>

Legal base for restrictions of use, registration, authorization of phytosanitary products

<http://www.chasque.apc.org/dgsa/>

Uzbekistan

Registration : State Commission on Chemicalization and Plant Protection

Ministry of Agriculture and Water Resources <http://www.agro.uz/> (Russian-Uzbek)

Ministry of Public Health <http://www.minzdr.uz/> (Russian-Uzbek)

State Committee on Nature Protection <http://www.uznature.uz/eng/link3.html>

Ministerial Decree No. 33 setting up the State Commission on Chemicalization and Plant Protection <http://faolex.fao.org/docs/texts/uzb80653.doc> (Russian)

Ministerial Decree No. 56 on expertise and registration of plant protection means:

<http://faolex.fao.org/docs/html/uzb75188.htm> (Russian)

United States

Pesticide regulation authority: U.S Environmental Protection Agency (EPA)

The [Federal Insecticide, Fungicide, and Rodenticide Act \(FIFRA\)](#)

<http://www.epa.gov/opp00001/regulating/fifra.pdf>

EPA Office of Pesticide Programs <http://www.epa.gov/pesticides/>

Vanuatu

Act (No. 11 of 1993) to make provisions for the regulation and control of the importation, manufacture, sale, distribution and use of pesticides, and for matters connected therewith.

Date of assent: 21 June 1993. (The Pesticides (Control) Act 1993).

http://www.paclii.org/vu/legis/num_act/pa1993210

Vietnam

Pesticide registration authority: Ministry of Agriculture and Rural Development:
<http://xttmnew.agroviet.gov.vn/TestE/>

Plant Protection Department: <http://www.ppd.gov.vn/?lang=english>

Legislation: Decree no. 58/2002/nd-cp of June 3, 2002 promulgating the Regulation on plant protection, the regulation on plant quarantine and the regulation on management of plant protection drugs
http://www.ippc.int/cds_upload/1106098140331_DECREE_1.DOC

Order no. 11/2001/l-ctn of August 8, 2001 on the Promulgation of the Ordinance on the Plant Protection and Quarantine
https://www.ippc.int/servlet/BinaryDownloaderServlet/40179_Ordinance_on_Plant_P.DOC?filename=1106097578001_ORDERN_1.DOC&refID=40179

Yemen

Ministry of Agriculture and Irrigation http://www.mai-yemen.org/laws_en.php?id=3

Resolution No. 73 of 2001 establishing the Committee of Plant Pesticide Registration

Law No. 25 of 1999 regulating the circulation and trade of plant pesticides (Arabic)
<http://faolex.fao.org/docs/pdf/yem46543.pdf>

Resolution No. 10 of 2002 issuing the Implementing Regulation of Law No. 25 of 1999 regulating the trade, circulation and handling of plant pesticides
<http://www.ecolex.org/ecolex/ledge/view/RecordDetails;jsessionid=6B692375E3B1DFA6AD0B8DE743FC5072?id=LEX-FAOC087980&index=documents>

Zambia

Pesticides and toxic substances regulation
<http://www.necz.org.zm/cap204/Regulations/PTS%20Regulations2.pdf>

Pollution Control (Pesticides And Toxic Substances) Regulations, 1994 Prescribed forms(registration) http://www.necz.org.zm/cap204/Applications/PTS_appli_form.pdf

Zimbabwe

Ministry of Agriculture <http://www.moa.gov.zw/>