

**Sub-Regional DNA Consultative Meeting on the Final Regulatory Action  
Evaluation Toolkit and Other Approaches under the Rotterdam Convention**

**MEETING REPORT**



**BANGKOK, THAILAND**

**26 to 28 November 2016**

## **1. Background**

The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade establishes an international mechanism to provide Parties with a first line of defence against hazardous chemicals. It promotes international efforts to protect human health and the environment as well as enables countries to decide if they want to import hazardous chemicals and pesticides contained in its Annex III. Chemicals are listed in Annex III based on the notifications of Final Regulatory Actions (FRAs) submitted by the Parties within the scope of the Rotterdam Convention that have been banned or severely restricted for health or environmental reasons.

The CRC adopted a working paper for the acceptability of a notification of final regulatory action with respect to the criteria in Annex II in cases where the notifying country had used a risk evaluation from another country, multilateral environmental agreement or an international body, for bridging information to establish a final regulatory action. It has been established that the number of FRAs from developing countries has been far lower in numbers, and also their scientific quality mostly does not meet Annex I and Annex II criteria of the Convention, when compared to those from developed countries. This was attested to by requests made by most developing countries during some of the previous COP meetings that they have very limited capacity to undertake risk assessments and related other evaluations for a scientifically sound decision-making on hazardous chemicals. In response to such requests, the Conference of the Parties (COP) to the Rotterdam Convention, at its sixth meeting requested the Secretariat to undertake activities as presented in the annex to document COP.6/16 to increase notifications of FRAs.

Over 200 chemicals with notifications of final regulatory actions by Parties from single PIC region are currently and have been awaiting another notification from a different PIC region to initiate a review by the Chemical Review Committee (CRC) of the Rotterdam Convention. Additionally, there are risk assessments and scientific literature available at the Secretariat on chemicals that have met Annex II criteria and those already listed in Annex III. Scientific literature is also available on chemicals reviewed by the POPs Review Committee of the Stockholm Convention. A user-friendly access to information resource and technical guidance is expected to facilitate Designated National Authorities (DNAs) to undertake a review of chemicals for regulatory actions and implement pragmatic approaches to consider scientifically sound information for risk evaluation of chemicals should facilitate increased and improved scientific quality notifications of FRA by Parties.

The Secretariat of the Basel, Rotterdam and Stockholm Conventions (BRS) in consultation with few experts of the CRC, in conjunction with selected DNAs, developed an online interactive FRA Evaluation Toolkit for user-friendly access to scientific and technical literature in sound management of chemicals. It aimed at assisting and enhancing the efforts by DNAs, especially from developing countries, to facilitate scientifically sound decision making and submission of the notifications of FRAs.

Consultative meetings of DNAs at sub-regional level are organised to promote and familiarise using the FRA Evaluation toolkit when considering information for the evaluation of risk for final regulatory actions on chemicals. Also, tools and guidance

developed by other international institutes to assist scientifically sound management of chemicals were also to be shared with the participants of the meeting. DNAs of both pesticides and industrial chemicals from Cambodia, Iran, Lao PDR, Oman, Pakistan, Philippines, South Korea and, Thailand including one scientific/technical officer closely associated with decision making on FRAs from each country, were invited to the meeting. The meeting was conducted in English.

### **1.1.Goal of the meeting**

The overall goal of the Rotterdam Convention DNA Consultative meeting was to strengthen the decision-making capacities of especially developing countries in scientifically sound lifecycle management of chemicals within the scope of Rotterdam Convention. This would, in line with the objective of the convention, to contribute to protecting human health and the environment from the adverse effects of these chemicals while meeting obligations under the Rotterdam Convention and other related multilateral environmental agreements (MEAs).

### **1.2.Objectives of the Meeting**

1. Raise awareness on the Prior Informed Consent (PIC) procedure and national decision making on the newly listed chemicals.
2. Guidance for the compilation of scientific and technical information on hazardous chemicals within the scope of Rotterdam Convention.
3. Prioritise chemicals of national concerns with respect to health and environmental risks by taking into consideration of information accessible through the FRA Evaluation Toolkit and other relevant Tools.
4. Facilitate the strengthening of existing national structures and mechanisms for cooperation and coordination for the sustainable management of chemicals in an integrated manner.
5. Assist identifying exposure and other information related to local context on priority chemicals for consideration in national decision-making.
6. Provide guidance on data collection systems necessary for surveillance and monitoring, risk assessment/management of hazardous chemicals.
7. Assist participants with compiling the information in the format of notification of FRAs for submission under the Convention.
8. Participants to subsequently submit notifications of FRAs to the Secretariat.

### **1.3. Expected outputs of the meeting**

1. A set of priority chemicals identified by the participating DNAs for further evaluation of risks under local conditions towards decision making on final regulatory actions;
2. Access to available tools and resources of scientific and technical information available for the implementation of the Convention;
3. A network of DNAs and technical experts within the sub-regional level for sharing technical information and experience related to hazardous chemicals;
4. Increased awareness on the Prior Informed Consent procedure and on the information exchange provisions of the Convention and how this might be used to strengthen chemicals management at the national level;
5. An increase in the number of Import Responses for newly listed chemicals and/or notifications of Final Regulatory Actions.

#### **1.4 Approach of the meeting**

1. Participating countries were selected based on the advances made on the capacity for scientifically sound regulatory control on chemicals with similar social, cultural and environmental backgrounds at sub-regional level.
2. A regional expert on risk evaluation on chemicals for regulatory actions within the scope of the Rotterdam Convention, preferably from a participating country with advanced capacity for sound management of chemicals was approached to be engaged as a resource person for the meeting and to facilitate any follow-up actions by the DNAs. As the expert identified for this purpose could not be present at the meeting, ad-hoc arrangement was made to engage an expert from another region who had undertaken similar task.
3. Prior to the meeting, to facilitate prioritizing the chemicals, the DNAs were provided with a list of chemicals for which final regulatory actions have already taken by Parties to the Convention. The DNAs were requested and advised to review their national chemical inventory and prioritize at least 5 industrial chemicals and/or pesticides based on national concerns of health and/or environment. The DNAs did the prioritisation of the 5 industrial chemicals and/or pesticides as advised by the Secretariat.

## **2. Meeting Progress and Presentations**

The Secretariat, welcomed all the participants and specified the objectives of the meeting.

### **2.1.The Opening Remarks**

#### **2.1.1. UN Environment Asia-Pacific regional office**

Dr. Kakuko Nagatani-Yoshida, the Regional Subprogramme Coordinator for Chemicals and Waste for the UN Environment Asia - Pacific Regional Office, on behalf of Dr. Isabelle Louis, Acting Regional Director and Representative for Asia and the Pacific of the UN Environment, made opening remarks and welcomed all participants to Bangkok. She indicated that, according to the Asian Development Bank, Asia accounted for more than half of the world's population in 2015, therefore, when it comes to delivering on two of 2015's most important sustainability milestones, i.e., the Paris Agreement and the 2030 Agenda, the scale of the challenge is huge, and so are the opportunities. She highlighted the benefits of governments, private sector, youth, civil society promoting and exploring integrated approaches to implement the sustainable developmental goals (SDGs) as the donors frame their funding criteria around the SDGs. She further applauded local business promoting clean technology, innovative solutions to waste management and capacity building for accessing financing.

Dr. Nagatani-Yoshida brought to the attention of participants the recently adopted declaration made on 8th October 2016, in Manila, Philippines, ministers and High-level officials from 36 countries and territories that met and adopted the "Manila Declaration" of the Asia-Pacific Regional Forum on Health and Environment. The governments at a high political level unanimously agreed to "Substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water, and soil

pollution and contamination (SDG 3.9), through environmentally sound management of chemicals and all wastes throughout their life-cycle (SDG 12.4) and substantial reduction of waste through prevention, reduction, recycling, and reuse (SDG 12.5)". She indicated that the Asia Pacific's sustainability challenges are as complex, vast and varied as the region itself, and need to be addressed with a simple yet robust Tool that works.

Dr. Nagatani-Yoshida confirmed that the national implementation of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade is a particular tool needed to address the region's challenges. Dr Nagatani-Yoshida underscored the fact that addressing chemicals management challenges is not about new additional resources but rather strengthening network, support, and better coordination with relevant stakeholders. She indicated that the UN Environment would like to provide assistance to the countries in this regard and also in line with achieving the objective of the Rotterdam Convention. She extending best wishes for a successful and practical meeting.

### **2.1.2. World Health Organisation (WHO)**

A regional WHO representative Dr. Liviu Vedrasco made opening remarks on behalf of WHO. Dr. Vedrasco, appreciated the invite extended to WHO as a recognition by the meeting organisers that WHO has a significant role to play in Chemicals Management, more so as chemicals introduced into the environment are linked to causing more than one quarter of all diseases globally. Emerging economies are those that often have least developed capacities to manage the risks of production and use of chemicals. He further appreciated the opportunity afforded WHO during the meeting to introduce some recently released tools/databases of WHO towards chemicals management.

Dr. Vedrasco indicated the historical role WHO has been actively working with member states to build capacities in the risk assessment of chemicals; work which continues to be a core part of the WHO including the monograph series known as Environmental Health Criteria, Concise Chemical Risk Assessment Documents, International Chemical Safety Cards, and IARC Monographs on carcinogens and joint FAO/WHO monographs on pesticide residues and food additives. Dr. Vedrasco further indicated that much work has been done to establish good practices and methods to evaluate chemical risks, including harmonization of existing risk assessment approaches. He shared with the meeting that in recent years, efforts have been made to improve accessibility using internet-based technologies. Such efforts are in line with the Rotterdam Convention, which provides a valuable international mechanism for sharing responsibility and resources to improve the sound management of chemicals. Dr Vedrasco reiterated WHO's unwavering commitment and readiness to support, collaborate and work with member states, together with UNEP and FAO in promoting the full implementation of the Convention and its objectives in all endeavours to prevent inadvertent effect of chemicals on human health.

### **2.1.3. Rotterdam Convention Secretariat**

A representative of the BRS Secretariat, Mr. Gamini Manuweera, thanked the Government of Thailand and UN Environment Asia - Pacific Regional Office for hosting the meeting, the resource persons for their contributions and the participants for attending the meeting. He indicated that holding the meeting in the various

regions was in response to a COP decision to assist countries in the area of FRA and subsequent submission of good quality notifications to the Rotterdam Secretariat. He indicated that a similar meeting had already been held in the African region. Concluding his remarks, Mr. Manuweera thanked the European Union for its generous financial support for organizing the meeting and for the development of the FRA Evaluation toolkit.

### **3. Summary of the proceedings**

To facilitate ownership of the meeting and more participation by the participants, one of the participants, Mr. Iftikhar-ul-Hassan Shah Gilani of the Pakistan delegation, chaired the meeting after the opening remarks were made by the various representatives.

The provisional agenda of the meeting was adopted without amendments. Presentations made by various speakers at the meeting are set-out as Annexes to this report.

#### **3.1. Rotterdam Convention Secretariat**

Mr. Manuweera from the BRS Secretariat made a presentation (Annex 1) on the purpose of the meeting. He highlighted that the objective was to enhance scientific soundness in decision making on FRAs, and also to subsequently increase notifications of FRAs under the Rotterdam Convention. He underscored the nature of the meeting to actively participatory throughout as it was meant to transfer knowledge and understanding; he urged participants to be free and to ask questions so that they are carried along by the various presenters and the Facilitator throughout the meeting. He outlined the meeting programme and indicated that the participants were asked to compile a list of a minimum of 5 priority chemicals in their respective countries. A preliminary assessment of priority chemicals to identify information gaps and way-forward for the collection and compilation of additional information to facilitate scientifically sound decision-making on possible regulatory actions would be done by the participants supported by the Facilitator. The meeting would include briefing sessions, group activities and discussions (within groups and plenary sessions). He indicated that the participants would undertake an initial review of scientific and technical information on the chemicals identified as being of national priority using the FRA evaluation toolkit and other resources including Industrial Chemicals Toolkit, IOMC Toolbox for Decision-Making in Chemicals Management, WHO Human Health Risk Assessment Toolkit. Mr Manuweera informed participants that towards the end of the meeting, there would be an opportunity to identify areas for collaboration and information sharing among the DNAs from participating countries and from possible other regions. He also indicated that on the last day of the meeting, participants were expected to develop road maps for follow up actions at national level, including areas for further assistance.

Mr. Aleksandar Mihajlovski from the Rotterdam Convention Secretariat at FAO, Rome made a presentation (Annex 2) on the Rotterdam Convention's history, objective, scope, key provisions and key operational elements. His presentation focused mostly on what the PIC Procedure is, how the PIC Procedure works, the chemicals subjected to the PIC Procedure, responsibilities of importing and exporting countries in applying the PIC Procedure, obligations and benefits of parties.

Mr. Alex Mangwiro from the BRS Secretariat made a presentation (Annex 3) on the new Industrial Chemicals under the Rotterdam and Stockholm Conventions, the

various previous and current applications of such chemicals, alternatives, and the status of such chemicals under the conventions.

Mr. Alex Mangwiro also made an oral presentation on how countries could benefit from the information that is being shared through the Prior Informed Procedure (PIC). He urged countries to make informed decisions about the chemicals on Annex III of the Rotterdam Convention about exports to their countries. He requested them to, subsequently, submit their Import Responses to the Secretariat of the Rotterdam Convention for those chemicals, and that the Secretariat would then inform other parties about such decisions. He highlighted the benefits of submitting Import Responses especially for developing countries that might not have all the necessary systems in place and resources to ensure that unwanted chemicals are not dumped into their respective countries.

### **3.2. Country Presentations**

Delegates representing each participating country made presentations on their national profiles of regulatory management of chemicals including how they implement the Rotterdam Convention in their countries including achievements and challenges.

#### **3.2.1. Cambodia**

The participant made a presentation (Annex 4) and indicated that they have achieved to collaborate with their Customs and that continues to yield good results in their country. He indicated that they ban chemicals based on the WHO hazard classification and not necessarily due to any adverse local effects observed. He indicated that the main challenge they have is a lack of legislation on industrial chemicals management but have a Ministerial Kampras that is like a Framework management instrument. He indicated that paraquat is a problematic chemical in their country.

#### **3.2.2. Islamic Republic of Iran**

The participant from Iran made a presentation (Annex 5) and indicated that they have a national subsidiary committee on chemicals and waste including members of environment, plant protection & health that deals with challenges facing the country on chemicals and waste. She indicated that they also have institutional arrangements in place for risk assessment and that they do have information on toxicity that is obtained from animal tests for decision making. She indicated that they have banned asbestos in Iran and only allow it to be used in materials or applications that are without alternatives. She listed their priority chemicals as being PFOA, Decabromodiphenyl, SCCP, and Dicofol.

#### **3.2.3. Lao People's Democratic Republic**

The participant from Lao People's Democratic Republic made a presentation (Annex 6) and indicated that they have a Consumer Protection law which allows the report on incidences to be made, and also appeals or report by consumers to be made. He indicated that they compile yearly a report on incidents. He also indicated that they have a Ministerial Decision that mandates entrepreneurs within the sector of the chemicals industry to report incidents to the relevant government department or ministry. The Participant indicated that the reason they are not able to notify the Secretariat of any FRA it is due to the challenge of a lack of capacity to undertake risk assessment in their country. He indicated that paraquat is the chemical that is of high priority.

#### **3.2.4. The Islamic Republic of Oman:**

The participant from Oman made a presentation (Annex 7) and indicated that they have a Chemicals section that is tasked with monitoring and data collection on chemicals and hazardous waste issues. She indicated that they also have a Permanent Committee for chemicals management that works with other relevant departments or ministries. There is a Technical Committee that submits reports and makes recommendations to the Permanent Committee. The participant indicated that they are intending to be involved in the UNEP project on Chemicals in Products and that they intend to follow up soon so as to be involved in the project. She also indicated that they have laboratories for primarily undertaking laboratory assessments on toxicity, product quality and bio-efficacy in Agriculture. Oman has managed to train technical staff at borders on basic chemicals management so as to prevent the influx of chemicals that have not been consented to be imported into the country. She indicated that the main challenges facing their country were the lack of specialised laboratories and also a lack of specialised technical personnel for undertaking the much needed research and analysis to inform the FRAs.

#### **3.2.5. Pakistan**

The representative of Pakistan made a presentation (Annex 8) and indicated that they generally conduct efficacy trials for 2 crop seasons before allowing registration of chemicals. He indicated that for their registration process they use the WHO and EPA classification rather than locally generated data. The regulatory infrastructure is in place for sound management of both pesticides and industrial chemicals. However, the lack of technical / human resources capacity, effective networking with other stakeholders for making decisions and insufficient infrastructure for monitoring and reporting of poisoning from industrial chemicals were among the gaps to be addressed.

#### **3.2.6. Philippines**

The participant from Philippines made a comprehensive presentation (Annex 9) on her country's status of implementation of the convention. She indicated that they have an Environmental Management Bureau which is responsible for deciding on permitting requirements of chemicals. She indicated that they also have institutional arrangements in place (pre-registration, priority chemicals, monitoring) which makes it possible and easier to establish a multi-stakeholder platform. Philippines also have a national incident report mechanism in the form of an inter-agency for the technical advisory council, and an inter-agency for the occupational safety and health. She indicated their challenge is to find safer affordable alternatives to highly toxic chemicals.

#### **3.2.7. Thailand**

The participant of Thailand made a presentation (Annex 10) and indicated that they have categorised as Type 1 & 2 categories, which are not subjected to applying for license for registration and use. There is a Type 3 category which is subjected to application for license for registration and use. She indicated that they have a National Strategic Plan on chemicals management whose goal is similar to the SAICM goal of 2020. She further indicated that the National Strategic Plan on



chemicals management is reviewed and updated from time to time. Thailand produces awareness raising publications yearly and distribute these to the public.

### **3.2.8. Scientific and technical information of final regulatory actions:**

The Facilitator Ms Noluzuko Gwayi used chemical examples and made a presentation (Annex 11) specifically on the Rotterdam Convention Annex I information, and also on the Annex II criteria information in terms of what is expected for an FRA to meet the set criteria. She supplied a comprehensive list of websites where participants can access freely Annex I information including from the Rotterdam Convention Toolkit that is being developed. She underscored the importance of having an FRA informed by the locally prevailing circumstances such as incidences reported, research undertaken when there's pollution or suspected pollution by a particular chemical as that is the type of information that is critical for increasing the chances of a successful notification. She indicated the importance of stakeholder collaboration at all levels in ensuring that data was collected and collated nationally. She concluded by explaining the legal meaning of misuse and intentional misuse under the Convention and that FRAs based on those reasons are considered outside the scope of the Rotterdam Convention as the chemical in question would not have been used for its intended primary use.

### **3.2.9. Tools for decision-making and notification of final regulatory actions**

#### **3.2.9.1.FRA Evaluation Toolkit**

Mr. Gamini Manuweera, made a presentation (Annex 12) on the FRA Evaluation Toolkit using some of the chemicals prioritised by the meeting participants as examples when navigating one way on the toolkit website. He indicated that the target audience for the Toolkit was DNAs of developing countries as access to scientific and technical information to undertake a risk evaluation is identified as one of the major challenges. The purpose of the Toolkit is for parties to have a user-friendly access to scientific information within the context of the Rotterdam Convention for decision making on hazardous chemicals, so as to facilitate scientific soundness of the notifications of FRAs. He showed participants how to search for, and import information from the toolkit onto the FRA form. He further indicated that the Toolkit was still under development and that it is expected that upon completion the toolkit will automatically import the selected information directly onto the FRA form. He indicated to participants that during the upcoming session on the preliminary evaluation of chemicals of national concerns, that participants will be afforded ample time to do practically experiment using the Toolkit and other available search engines to fill in FRA forms for their respectively nominated prioritised chemicals, supported by the Facilitator throughout the exercise.

#### **3.2.9.2.IOMC Toolkit**

The IOMC Toolkit as one of the tools for the environmental management of chemicals was presented (Annex 13) to the participants by Dr. Daam Settachan, of the Chulabhorn Research Institute in Thailand. The IOMC toolkit is an internet-based tool developed by the Inter-Organization Programme for the Sound Management of Chemicals (IOMC), which is comprised of FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank, OECD. It enables countries to identify most relevant & efficient tools to address specific national problems in chemicals management. Its

focuses mainly on: (i) The European Pollutant Release and Transfer Register (PRTR), (ii) management scheme for pesticides, (iii) Occupational Health and Safety, (iv) chemical accidents prevention, preparedness and response, (v) industrial chemicals management, (vi) public health management of chemicals, (vii) classification & labelling system.

### **3.2.9.3.FAO Pesticide Registration Toolkit**

The FAO Pesticide Registration Toolkit, although still being developed, was also presented (Annex 14) to the participants by Mr. Aleksandar Mihajlovski as one of the tools they can utilise. The objectives of the Toolkit is to make existing information relevant for pesticide registrars available “at fingertips”, provide guidance about key registration procedures and methods in an interactive manner, assist registrars in informed decision making, and also to create a basis for training and capacity building of pesticide registration authorities. The Toolkit was presented to be a focused decision support system for pesticide registrars in developing countries that as a web-based registration handbook intended for day-to-day use by those involved in the registration of pesticides. It is however not an automated system for the evaluation of pesticides, but it supports and facilitates informed decision-making by registrars.

### **3.2.9.4.The WHO Human Health Risk Assessment Toolkit: Chemical Hazards**

The WHO Human Health Risk Assessment Toolkit: Chemical Hazards was presented (Annex 15) as one of the tools to the participants towards their efforts of chemicals management. It is a tool mainly for developing countries and countries with economies in transition, assisting them when they need to conduct chemical risk assessments by helping to assess the health risks from chemical exposures.

### **3.2.9.5.Electronic Distance Learning Tool on Risk Assessment & Management of Chemicals**

The Chulabhorn Research Institute (CRI) made a presentation (Annex 16) and indicated that they offer short-term and long-term training in environmental health science and toxicology. The Short-term 2-3-week courses geared mainly towards government officials from the South-East Asian region (Environmental Toxicology; Occupational & Environmental Medicine; & Risk Assessment), whereas the Long-term courses are international, graduate-level education in the fields of: (a) Chemical Biology, (b) Applied Biological Sciences– Environmental Health, and (c) Environmental Toxicology. CRI indicated that it has organized face-to-face training on risk assessment and toxicology, both at CRI and in-country, for the past 25 years.

### **3.2.10. Notification of Final Regulatory Actions under the Rotterdam Convention – Bridging Information**

The Facilitator made a presentation (Annex 17) on bridging information on the notification of final regulatory actions under the Rotterdam convention. She indicated that there was no set formula but that the CRC considers such bridging information on a case-by-case basis guided by set conditions on exposure or potential exposure, science-based knowledge, and the extent of detail of the information provided. She used examples on what type and how information can be bridged from a country within the same region or from another region having similar environmental conditions and climatic conditions or geographic conditions, including the concentration and conditions of use of the chemical in question. She emphasized how collaboration is essential with all the relevant stakeholders within the various

countries and even across borders, including academics so as to maximise the use of limited available skills, expertise, data and information.

### **3.2.11. Preliminary evaluation of chemicals of national concerns**

The Facilitator explained to the participants that the whole session was to be practical and informal. She encouraged participants to indicate to her when they need her assistance as she moves around them to facilitate their familiarity with accessing the much needed information from the FRA Evaluation Toolkit and other search engines she indicated to them earlier on. She then requested participants to fill in the FRA forms using the chemicals they have prioritised. They were encouraged to work on different chemicals as individual even if they are working as a country and sharing what they are learning to ensure participants practise on more than one chemical on their list and using the various tools presented to them through the hands on practical session whilst being supported by the Facilitator.

Participants were also engaged in filling the FRA notification forms using their respective priority chemicals with guidance from the Facilitator. The Secretariat of the Rotterdam Convention also assisted participants with accessing the FRA Evaluation Toolkit as they were filling in their FRA forms. At the end of the practical session, participants gained their confidence and familiarity in using the different search engines including the Toolkit but indicated that they needed to continue getting more practise.

### **3.2.12. National coordination and regional collaboration**

The Facilitator made a presentation (Annex 18) on national and regional coordination. The presentation emphasized the importance of a multi-stakeholder approach in generating, collecting and collating all the necessary information needed to complete a scientifically sound FRA, including towards improving efforts on better chemicals management. She emphasized the fact that chemicals respect no borders, thus making regional collaboration more critical. The Manila declaration of 2016 by Ministers of Health and Ministers of Environment at the Asia-Pacific Regional Forum on Health and Environment 6–8 October 2016, Manila, Philippines is a great opportunity that needed to be seized by the parties in getting support for the work they needed to undertake. Furthermore, she identified the environmentally sound management (ESM) of chemicals as critical for the region's health & environment priorities, specifically towards achievement of the Sustainable Development Goals (SDGs). She underscored that there is need to strengthen the science & policy interface as one of the essential initiatives towards protecting the environment and human health. She also identified that there is need for governments, researchers & industry to work together in ensuring that countries have the relevant information by providing the necessary empirical data for the country to make appropriate policy decisions (eg. FRA). There is a need for the health sector to conduct research to establish whether there are diseases relating to chemicals exposures. Linked to the success of that is the need to build capacity on how health practitioners manage poisoning incidents, including adapting and adopting the FRA form so as to capture the incidence information as and when a healthcare professional assesses a patient that has been exposed to a chemical. The Facilitator identified that the DNAs needed to collaborate more often so as to learn from each other. She also indicated how participants can develop a database for the PIC notifications process and use such data to make informed decisions on the country's Import Responses, and to prevent dumping in their countries.

The participants were advised to draft their respective roadmaps for follow-up national actions, taking into consideration what they might have learnt during the meeting. The roadmaps were presented the following day.

### **3.2.13. National Road Maps:**

The participants were requested to present to the meeting their respective Road Maps for follow-up national actions, and also for other countries could also learn from such Road Maps. After each presentation, a discussion was held among the participants for further improvement. The respective Road Maps are set out in Annex 19 of this report.

The Facilitator presented to the participants a time table for follow up actions expected from the participants and the Facilitator. The participants were urged to work further on at least 5 of the chemicals countries have prioritised towards decision making on FRAs, as follow-up actions. The Facilitator would then be able to provide input, as needed and then send them back to the respective participant.

### **3.2.14. Recommendations and evaluation of the meeting**

During the concluding session, the participants considered the substantive matters deliberated during the meeting and agreed on the following general recommendations:

- Explore the possibilities for the participants to undergo the online risk assessment module of Chulabhorn Research Institute, Thailand;
- Inflow of funds for effective implementation of the Convention (e.g. Special fund) for technical assistance to parties to strengthen the institutional capacity for NIPs/NAPs implementation;
- Participants to develop strategies to involve research institute, academia and regional centers to facilitate development of databases and related scientific reports/articles;
- Establish close coordination with Health Sector in monitoring and evaluation of health risks;
- Link to Sustainable Development Goals and Manila Declaration in relevant programmes and activities, as appropriate.

Participants also made following recommendations related to the FRA Evaluation toolkit:

- Make the toolkit more user-friendly;
- Develop a user guide;
- Include antidote information;
- Conduct training session when the toolkit is completed.

Finally, the Rotterdam Convention Secretariat requested the participants to evaluate the meeting with respect to its approach, content and expected outputs towards areas of further improvements where applicable.

Generally, the response was appreciative and positive. Participants wished that more time was allocated to the meeting since they felt that there was too much valuable information they had to assimilate within a very limited time. They requested that

similar meeting be held again as a follow up action and also to refresh their memories, including accommodating possible staff turnover in some countries to ensure continuity in the work that needs to be done nationally.

### **3.2.15. Closure of the meeting**

Mr. Mylvakanam Iyngararasan representing the UN Environment Asia-Pacific regional office made closing remarks. The meeting was closed on 28<sup>th</sup> Friday afternoon at 3:30pm.

## Annex 1. Rotterdam Convention Secretariat

**Sub-Regional DNA consultative meeting**

FRA Evaluation Toolkit and other approaches under the Rotterdam Convention

BRS Secretariat

Bangkok  
26 to 28 Nov 2016

www.brsmeas.org @brsmeas

### BACKGROUND

- Chemicals are listed in the Convention based on the notifications FRAs by the Parties that have been banned or severely restricted **for health or environmental reasons**
- Developing countries have limited capacity to undertake
  - Scientifically sound **assessments of health & Env. risks**
  - Evaluation of risks** for scientifically sound decision-making
- Number of notifications of FRAs decline in both submission and meeting the Annex I and Annex II
- COP 7 requested the Secretariat to assist parties in preparing notifications of FRA and user-friendly access to scientific and technical information

### PURPOSE OF THE WORKSHOP

### SCOPE

Prior Informed Consent (PIC) procedure for certain hazardous chemicals and pesticides in international trade

Scientific and technical information of notifications of final regulatory actions (FRAs): Annex I

Criteria for reviewing FRAs for listing under the Convention: Annex II

### SPECIFIC OBJECTIVES

- Guidance on scientific information for decision-making on hazardous chemicals within the scope of Rotterdam Convention.
- Prioritise chemicals of national concerns with respect to health and environmental risks for decision-making
- Strengthening of national structures and mechanisms for sustainable management of chemicals in an integrated manner
- Data collection for surveillance and monitoring, risk assessment/management of hazardous chemicals.
- PIC procedure and newly listed chemicals.
- Notification of FRAs under the Convention.

### DAY 1

**Wednesday 26 October**

**Session 1: Opening, Introduction and Background Information**

09:00-09:20	Registration of participants	
09:20-09:40	Opening Remarks: <ul style="list-style-type: none"> <li>UNEP Regional Office</li> <li>BRS Secretariat</li> </ul>	
09:40-09:50	Introduction of participants	All
09:50-10:00	Scope, purpose and structure of the	BRS Secretariat
10:00-10:20	<b>COFFEE BREAK</b>	
10:20-10:40	Rotterdam Convention Overview: <ul style="list-style-type: none"> <li>PIC Procedure</li> <li>National obligations</li> </ul>	BRS Secretariat
10:40-12:00	Presentation of national profiles of regulatory management of chemicals	Participants
12:00-13:00	Plenary discussion	
13:00-14:00	<b>LUNCH BREAK</b>	
14:00-14:45	Scientific and technical information in Final Regulatory Actions: <ul style="list-style-type: none"> <li>Annex I information</li> <li>Annex II criteria</li> </ul>	Facilitator
14:45-15:10	Presentation on the FRAE toolkit	BRS Secretariat
15:10-15:30	<b>COFFEE BREAK</b>	
15:30-18:00	Other related <ul style="list-style-type: none"> <li>RC industrial chemicals toolkit</li> <li>IOMC toolbox</li> <li>e-learning tool</li> </ul>	BRS Secretariat UNITAR
RECEPTION		

DAY 3 Thursday 27 October Session		
<b>2: Preliminary assessment of priority chemicals</b>		
08:30-09:15	Notification of Final Regulatory Actions under the Rotterdam Convention – Bridging Information	Facilitator
09:15-10:00	FAO pesticide registration toolkit	RC Secretariat
<b>COFFEE BREAK</b>		
10:00-10:20	WHO Human Health Risk Assessment Toolkit:	WHO
10:20-12:00	- Introduction to risk assessment - Demonstration of toolkit	
12:00-13:00	Breakout groups – Review of information on priority chemicals	Facilitator
<b>LUNCH BREAK</b>		
13:00-14:00	Breakout groups (cont.) – Information gaps	Facilitator
14:00-15:10	Breakout groups – Compilation of initial information in the format of notification of FRAs under the Convention.	Facilitator
<b>COFFEE BREAK</b>		
15:10-15:30	Breakout groups (cont.) – Compilation of initial information in the format of notification of FRAs under the Convention.	Facilitator
15:30-17:00	Breakout groups (cont.) – Compilation of initial information in the format of notification of FRAs under the Convention.	Facilitator
17:00-18:00	National coordination and regional collaboration for follow-up actions on priority chemicals	Facilitator

DAY 3 Friday 28 October		
<b>ion3: Data collection and follow-up actions</b>		
0-10:00	Country's National coordination for follow-up actions on priority chemicals	
<b>COFFEE BREAK</b>		
0-10:20	Country's National coordination for follow-up actions on priority chemicals (cont.)	
<b>LUNCH BREAK</b>		
0-14:00	Recommendations and national roadmaps	Facilitator
0-15:00	Areas for further improvements in the FRA evaluation toolkit	All
0-15:30	Workshop evaluation	
0-16:00	Closing	

## ACKNOWLEDGEMENTS



UNEP (ROAP)



**Financial support:**  
European Union



**Technical support:** World Health Organization and other partners

## THANK YOU

Annex 2. Rotterdam Convention Secretariat

OVERVIEW OF THE ROTTERDAM CONVENTION

Rotterdam Convention, key provisions, key operational elements

Aleksandar Mijajlovski

26 October 2016

RC IS BORN FROM A NEED

1998

Adoption of Text in Rotterdam

1998 – 2004

Interim PIC Procedure – voluntary FAO/UNEP as Interim Secretariat

2004

Entry into force – LEGALLY BINDING INSTRUMENT

2013

Synergy decision among Basel, Rotterdam and Stockholm Conventions

Born from a need to protect countries lacking adequate infrastructures to manage hazardous chemicals in international trade

CONSEQUENCES of a weak pesticide and in general weak chemicals management:

- Improper use
- inadequate storage and control
- environmental damage
- serious illness, sick and absent farm workers and death
- obsolete stockpiles and expensive clean-up operations

A key challenge for countries is to balance the benefits and risks when taking national decisions on chemicals

THE KEY ELEMENTS OF RC

Legally binding MEA addressing hazardous chemicals (pesticides and industrial chemicals)

Parties:155

Info exchange on nationally banned or restricted chemicals and severely hazardous pesticides formulations (PIC Circular)

Sharing responsibility among Parties to prevent unwanted trade (Prior Informed Consent procedure)

Technical Assistance Programme

National, Regional and Global outreach

Global network of DNAs and Focal points

Social Aspect  
Gender and Vulnerability of different social groups

Synergies  
among BC-SC-RC addressing life cycle of chemicals

WHAT IS THE ROTTERDAM CONVENTION?

A Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

- legally binding international instrument
- creates rights/benefits and obligations for parties
- 155 parties (May2016)
- No ban!
- → Prevents unwanted trade

THE OBJECTIVE OF RC

THE OBJECTIVE - Article 1

To promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to the environmentally sound use of such chemicals.

HOW???

- by facilitating information exchange about their characteristics
- by providing for a national decision-making process on their import and export
- by disseminating these decisions to Parties

SCOPE OF THE CONVENTION

- Chemicals banned or severely restricted to protect human health or the environment
- Severely hazardous pesticide formulations (SHPF) causing problems for human health or the environment under conditions of use in developing countries or countries with economies in transition



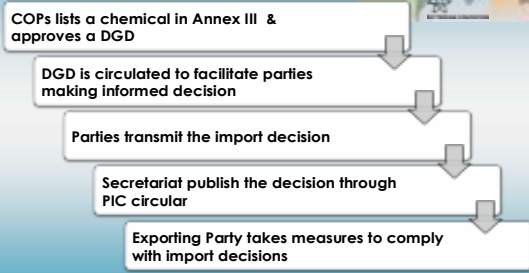
## TWO MAIN PROVISIONS: PIC PROCEDURE AND INFORMATION EXCHANGE

- prevents **unwanted trade** of hazardous chemicals (**PIC PROCEDURE** and Annex III)
- calls for the provision of **technical assistance** to help establish the infrastructure and capacity necessary to safely manage chemicals
- enables member governments to alert each other to potential dangers by **exchanging information** on **banned or severely restricted chemicals**
- makes the international trade in hazardous chemicals **more transparent and less vulnerable** to abuse through its export notification provisions and by encouraging harmonized labelling of exported chemicals

## KEY PLAYERS

- Conference of the Parties (COP)
- Designated National Authorities (DNAs)
- Official Contact Point (OCP)
- Chemical Review Committee (CRC)
- Secretariat

## KEY PROVISION: PIC PROCEDURE



```

graph TD
    A[COPs lists a chemical in Annex III & approves a DGD] --> B[DGD is circulated to facilitate parties making informed decision]
    B --> C[Parties transmit the import decision]
    C --> D[Secretariat publish the decision through PIC circular]
    D --> E[Exporting Party takes measures to comply with import decisions]
    
```

## PIC procedure

- WHAT is the PIC procedure**
- facilitates **informed decision making** by countries on the import of chemicals listed in Annex III
- ensures compliance with these import decisions by exporting Parties

## PIC procedure

- WHAT chemicals are involved**
- 47 chemicals in TOTAL listed in Annex III
- 33 pesticides (including 3 severely hazardous formulations)
- 14 industrial chemicals

<http://www.pic.int/TheConvention/Chemicals/AnnexIII/Chemicals/tabid/1132/language/en-US/Default.aspx>

## PIC procedure

### HOW it operates

#### Key elements

- Decision guidance documents (DGDs)  
<http://www.pic.int/TheConvention/Chemicals/DecisionGuidanceDocuments/tabid/2413/language/en-US/Default.aspx>
- Import responses
- PIC Circular

## PIC PROCEDURE

**WHO – Shared responsibility**

Importing and Exporting countries

**Key Players**

- Designated National Authorities
  - transmits the decisions to the Secretariat
  - informs the relevant national stakeholders
- Customs officials
- Chemical Industry – including manufacturers, formulators, traders etc.

## PIC procedure

### IMPORTING COUNTRY RESPONSIBILITIES DNA

- ensure that importers, relevant authorities and where possible users are informed of national import decisions
- ensure that import decisions apply uniformly to imports from all exporting countries and
- to any domestic manufacturing of the chemical for domestic use

## PIC procedure

### EXPORTING COUNTRY RESPONSIBILITIES DNA

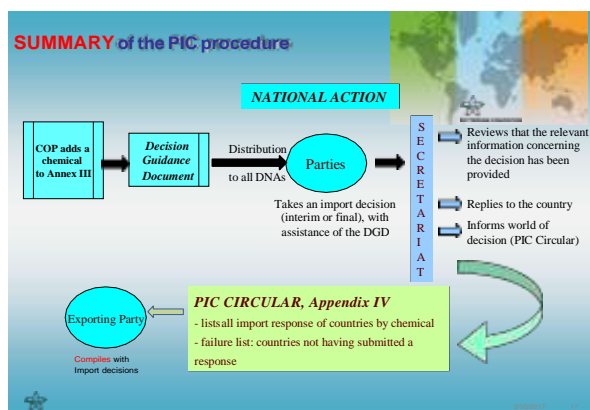
- implement legislative and administrative measures to communicate import decisions within its jurisdiction
- take appropriate measures to ensure that its exporters comply with import decisions
- ensure appropriate labeling (GHS) and information accompanies exports
- advise and assist importing Parties
  - to obtain further information to help them make import decisions
  - to strengthen their capacities and capabilities to manage chemicals safely

## PIC PROCEDURE

### WHY

- prevents unwanted trade of hazardous chemicals through a shared responsibility between importing and exporting Parties
- provides information to facilitate informed decision making on future imports – opportunity to:
  - obtain further information on a chemical or assistance in evaluating a chemical
  - the list of chemicals in Annex III will continue to grow
- helps prevent accumulation of obsolete stockpiles

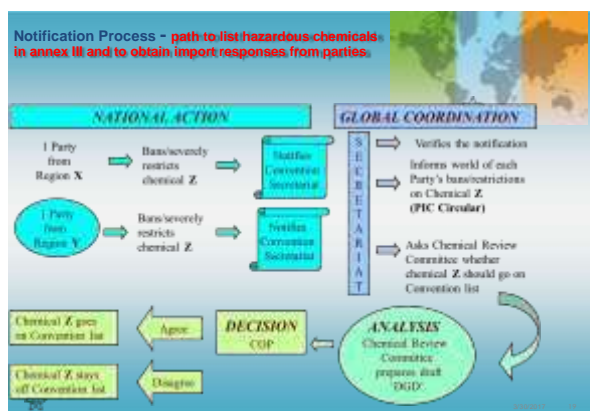
**PROTECTION OF HUMAN HEALTH AND ENVIRONMENT**



## CHEMICALS IN PIC PROCEDURE

Two main mechanisms:

- Notifications of Final Regulatory Actions (FRAs)
- Submission of proposals for Severely hazardous pesticide formulations (SHPFs)



## What is a notification of Final regulatory action?

➤ Notifications of final regulatory actions are the means by which Parties inform the Secretariat of their national actions, the purpose of which is to ban or severely restrict a chemical for human health and/or environmental reasons.

❑ **Rotterdam Convention does not specify:**

- how to regulate chemicals or
  - how to make a regulatory decision
- solely national decisions!

❑ **Rotterdam Convention does require:**

- Secretariat to be notified of the national decision

## Article 5 - Procedures for banned or severely restricted chemicals

### Responsibilities of Parties:

- For existing national regulatory actions

DNA is to notify the Secretariat when the Convention enters into force for that country

<excludes those submitted under the voluntary PIC procedure>

- For new regulatory actions

A Party is obliged to notify the secretariat of any Final Regulatory Action, at latest 90 days after the measure has been taken

## Article 5 - Procedures for banned or severely restricted chemicals (cont.)

### Responsibilities of Parties:

- Notifications for final regulatory actions must contain the information requirements set out in Annex I

- DNA completes a "notification of final regulatory action form"

the signed and dated form is submitted to the Secretariat

[http://www.pic.int/Procedures/NotificationsOfFinalRegulatoryActions/Form\\_andInstructions/tabid/1182/language/en-US/Default.aspx](http://www.pic.int/Procedures/NotificationsOfFinalRegulatoryActions/Form_andInstructions/tabid/1182/language/en-US/Default.aspx)

## SHPF Proposals – NOT an obligation but great opportunity

- Great opportunity for developing countries and countries with economy in transition (DC and EIT)!

### GOAL???

- To share information and to inform global community about their specific problems with pesticide formulation related to local country conditions of use.



## What is a severely hazardous pesticide formulation?

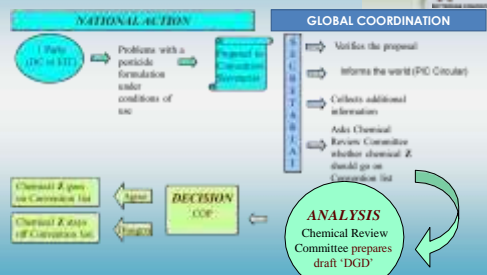
### Article 2: Definition

→ a chemical formulated for pesticidal use that produces **severe health or environmental effects** observable within a short period of time after single or multiple exposure, **under conditions of use**.

## Article 6 – Procedures for severely hazardous pesticide formulations

- Country (DC or EIT) experiences **problems** with a specific pesticide formulation **under conditions of use** in its territory
- DNA submits a proposal to the Secretariat
- Secretariat verifies that the information requirements of Annex IV, part 1 have been met
  - Summary is published in the PIC Circular (Appendix II)
- Secretariat collects additional information (Annex IV part 2)

## Submission of an SHPF proposal



## POTENTIAL ADVANTAGE FOR PARTIES

### Suggestions:

- distribute the SHPF forms to the field level as a tool to collect pesticide poisoning information
- take the opportunity to report the finding to the Secretariat
- seek cooperation with health institution and NGOs
- review summaries of proposals published in the PIC Circular on a regular basis, be aware of problems occurring in countries with similar condition

## Export notifications

➤ **Obligation** for exporting and **benefit** for the Importing Parties

- banned or severely restricted chemicals by a Party being exported from its territory
- export notification shall include the information set out in Annex V.
  - informs importing Party that a chemical that has been banned or severely restricted in the exporting Party is being shipped
  - **Articles 12 and 13**

## ARTICLE 12 – EXPORT NOTIFICATION

### Exporting Party

- must provide **export notification** including info of Annex V to importing parties
  - prior to the first export following the national regulatory decision
  - before the first export in any calendar year

### Importing Party

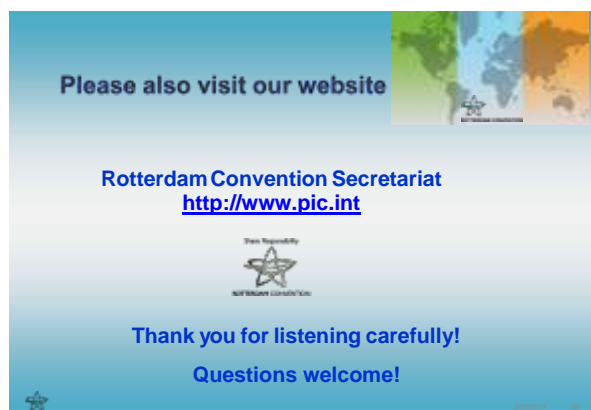
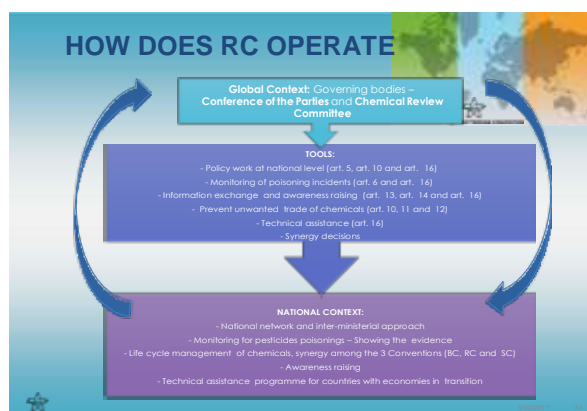
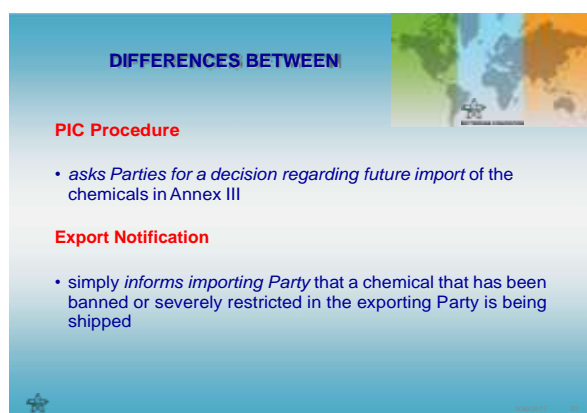
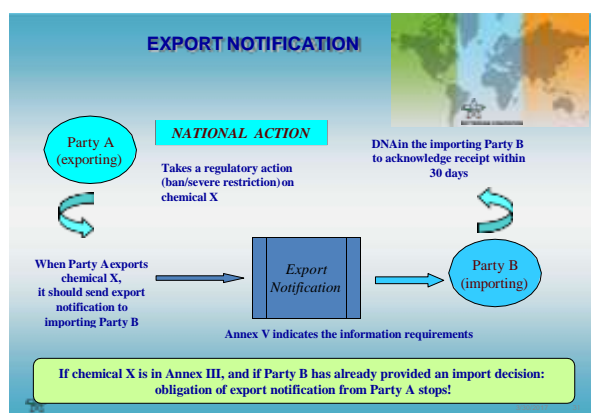
- must acknowledge receipt within 30 days

Obligation ceases when the chemical is listed in Annex III and the importing party has provided an import response

## ANNEX V – INFORMATION REQUIREMENTS

### Elements of an export notification

- name and address of the DNAs from both exporting and importing Parties
- expected date of export
- name of chemical(s) and in the case of mixture the level or concentration of the individual chemicals
- the category of the chemical and use in the importing country
- name and address of the importer
- information on precautionary measures to reduce exposure
  - further information as specified in Annex I may be requested by the importing Party



## Annex 3. Rotterdam Convention Secretariat




### The New Industrial Chemicals under the Rotterdam and Stockholm Conventions

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### PBDEs (POLYBROMINATED DIPHENYL ETHERS)

PBDEs are a group of industrial chemicals which have been widely used as additive flame retardants since 1970s.

BrC1=CC=C(C=C1)Oc2ccc(Br)cc2


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### POP-PBDEs in the Stockholm Convention

Commercial-PentaBDE and/or commercial-OctaBDE, incl.:

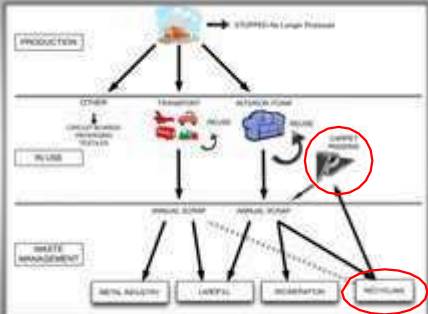
- tetrabromodiphenyl ether
- pentabromodiphenyl ether
- hexabromodiphenyl ether
- heptabromodiphenyl ether

→ Listed in: **Annex A (Elimination)**  
 → Production: **Total ban**  
 → Use: **Exemptions for recycling of articles containing POP-BDEs & Use and final disposal of articles manufactured from recycled materials containing POP-BDEs**

**PROVISIONS UNDER PART IV AND V OF ANNEX A:**  
 The recycling and final disposal are carried out in an environmentally sound way and do not lead to recovery of the POPs for the purpose of their reuse

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### Commercial Penta-BDE



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### HEXABROMOBIPHENYL

**Past use:** Flame retardants. Added to plastics used in products such as home electrical appliances, textiles, plastic foams, laptop cabinets, etc. to make them difficult to burn.

**Currently:** No production and use reported.

**Alternatives:** Available

→ Listed in: **Annex A (Elimination)**  
 → Production: **Total ban - No exemption**  
 → Use: **Total ban - No exemption**



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### HBBD

HBBD is an industrial chemical, widely used as flame retardants additive on polystyrene materials (1980s) as part of safety regulations

- Produced in China, Europe, Japan and USA
- Annual production: 28,000 tons

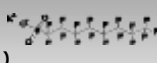
➤ 4 main products

- Expanded polystyrene foam (EPS) → Construction techniques and thermal barriers
- Extruded polystyrene foam (XPS) → Construction techniques and thermal barriers
- High polystyrene (HIPS) → Available
- Backcoating agents for textiles and furniture upholstery → Available

**ALTERNATIVES**

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## PFOS & ITS SALTS (PERFLUOROOCTANE SULFONIC ACID ) PFOS-F (PERFLUOROOCTANE SULFONYL FLUORIDE)



**Past use:** Surfactant, water and fat repellent  
PFOS is both intentionally produced and a degradation product of PFOS-related substances (PFOS precursors) in the environment.

**Currently:** PFOS is still produced and used in several countries.

**Alternatives:** Available for some types of use but no known technically feasible alternatives for some applications e.g. semi-conductor, photo imaging


→ Listed in [Annex B \(Restriction\)](#) with [Specific exemptions and Acceptable purposes](#)

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## PFOS – SPECIFIC EXEMPTIONS

**Time-limited phase-out (alternatives need phase-in)**

- Insecticides for control of red imported fire ants/termites
- Hard metal plating
- Decorative metal plating
- Photo masks in semiconductor and LCD industries
- Electric/electronic parts for some color printers/copy machines
- Chemically driven oil production
- Carpets
- Leather and apparel
- Textiles and upholstery
- Paper and packaging
- Coatings and coating additives
- Rubber and plastics




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## PFOS – ACCEPTABLE PURPOSES

**No time-bound phase-out  
(currently no alternatives available)**

- Fire-fighting foam
- Insect bait for control of leaf cutting ants
- Aviation hydraulic fluids
- Metal plating only in closed-loop systems
- Photo imaging
- Photo resist and anti-reflective coatings for semi-conductors
- Etching agent for compound semi-conductors and ceramic filters
- Certain medical devices (e.g. ETFE layers, radio-opaque ETFE, in vitro diagnostic medical devices, CCD color filters)



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## TO REMEMBER

**Stockholm Convention** is a living international treaty:

**9 new POPs listed in 2009 (at COP4):**

- 4 pesticides:
  - Main challenge is disposal of obsolete stockpiles
- 4 industrial chemicals:
  - Widespread distribution in products & articles in use
  - Contamination of recycling streams
  - Environmentally sound disposal of wastes
- 1 chemical from unintentional production:
  - Reducing releases from point and diffuse sources

**1 new pesticide POP: Endosulfan listed in 2011 (at COP5)** / e.i.f. 27 Oct 2012

**1 new industrial POP: HBCD listed in 2013 (at COP6)** / e.i.f. 26 Nov 2014

**3 new POPs listed in 2015 (at COP7)** / e.i.f. 15 Dec 2016

Guidance can be found at: <http://chem.unep.int/TheConvention/POPsReviewCommittee/Guidance/hibid/343/Default.asp>



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## 3. Exemptions under the Stockholm Convention

- **General Exemptions**
  - When no significant quantities of the chemical are expected to reach humans and the environment e.g. *Use for laboratory-scale research, unintentional trace contaminants, constituents of articles, closed-system site-limited intermediate*
- **Specific Exemptions**
  - When there are alternatives but Parties may require transitional period >> **5 years time limited exemption** Exception: *PCB, BDEs*
- **Acceptable Purposes**
  - When there are no alternatives to the use of the chemical >> **COP reviews continued need**

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## RC Toolkit on Industrial Chemicals

- <http://www.cprc.org/en/media/studies/methodological-manuals>
- <http://www.pic.int/Implementation/IndustrialChemicals/GlobalIndustrialchemicalsmanagementlandscape/tabid/1200/language/en-US/Default.aspx>

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## Annex 4. Cambodia

### ROTTERDAM CONVENTION SUB-REGIONAL DNA CONSULTATIVE MEETING: FRA EVALUATION TOOLKIT

#### CAMBODIA COUNTRY REPORT

BANGKOK, THAILAND  
26-28 OCTOBER 2016

#### Chemical Substances Management Responsible Institutions

- Ministry of Industry and Handicraft (MIH) is responsible for management and control of industrial chemicals.
- Ministry of Agriculture, Forestry and Fisheries (MAFF) is responsible for management and control of Agrochemicals.
- Ministry of Health (MOH) is responsible for poisoning cases.
- Ministry of Economic and Finance (Dept. of Customs and Excise) is responsible for border check.
- But, Coordination and cooperation among them needed to be strengthened.

#### Chemicals Management Current Rules and Regulations

There is no law on Industrial chemical management yet, but there is a Ministerial Prakas on Management and Control of Use, Importation, Exportation and Distribution of Chemical Substances in Industrial Fields was enacted, 2004.  
Law on Pesticide and Fertilizer Management was enacted, 2012

#### Pesticides Regulation

- Regulation comprises 3 main activities:
  - (1) Licensing
  - (2) Registration
  - (3) Inspection and Penalties.

#### Licensing & Certification

- License to import & export is valid for a year.
- License to formulate, repack is valid for 3 years.
- License to distribute is valid for 3 years.
- License to accredited pest control service.
- License to advertise is valid for a year.
- Certificate to storage is valid for 3 years.
- Certificate to registration is valid for 1-3 years.
- License to wholesale and resale is valid for 3 years (issued by Provincial Department of Agriculture).

#### Pesticides Registration

- All types of pesticides could be able to trade or formulate unless they have been registered in according to the law.
- There are 2 types of registration:
  - Full registration is valid for a period of 3 years
  - Provisional registration for a period of 1 year
- All pesticides subjected to registration shall be undergone the quality analysis, bio-efficacy test, and evaluation on the adverse effects by GDA.



### Lists of Pesticides

- Lists of banned and restricted pesticides have been updated and enacted by MAFF in Nov,12 based on WHO hazardous classification and technical expertise from relevant sources.
- 163 pesticides by active ingredients or common names have been banned.
- 48 pesticides by active ingredients or common names have been restricted and cannot be sold, but used in fumigation and non-commercial purpose.

### Post-registration Activities

- Inspectors of DAL & Provincial Dept of Agriculture(PDA) have the right and functions as follows:
  - conduct the primary inspection of pesticide prior to distribution.
  - monitor, investigate and inspect all trade activities.
  - collect samples of pesticides are subject to inspection and analysis for verifying the quality, seize & confiscate any suspected products.
  - issue the warning, revoke and suspend the licenses or certificates.
  - impose transactional fine for any contravention.
  - file the case of offense and send to court.

### International Conventions

Cambodia is party to multilateral Conventions:

- Rotterdam Convention: became a 151 party member in May 2013. MAFF is DNA for RC.
- Basel (March,01) and Stockholm Conventions, (May,07) and Montreal Protocol (June,01). Ministry of Environment is DNA for these conventions. National profile & National Implementing Plan on POPs were completed.

### National Incident Report Mechanism

- There are no routine procedures or mechanism in place for incident report or treatment of pesticide poisoning cases or specialized poison treatment centres. Some information relating to pesticide poisoning come from media or by NGOs (TV, newspaper, etc)
- In general, Ministry of Health is responsible for poisoning case.

### Next Step:

- 163 pesticide banned and Industrial chemicals in Annex III will be notified to the Secretariat.
- 4 Pesticides are being used and concerned of health and environment and wish to be proposed for review for regulatory action:
  - (1) Paraquat
  - (2) Carbofuran
  - (3) Aluminum Phosphat
  - (4) Methyl Bromide

### Progress and Constrain

**Progress:**

2012:- Law on Pesticide and Fertilizer Management was enacted.

- Procedure and Standard Requirement for Pesticide Registration and other relevant regulations were enacted.
- Updated Lists of Banned and Restricted Pesticide was enacted.


2013:- Procedure of management pesticide in trade was enacted.

- (May) Cambodia has acceded to the Rotterdam Convention and became a 151 party member.

2014:- Drafted National Action Plan for the implementation of RC was developed.


2015:- Focal Point for relevant ministries have been nominated.

- Import Responses for 33 pesticides currently in Annex III have been submitted to the Secretariat.



### Constraint:

- Some unregistered, substandard, and pesticide bearing labeling in foreign languages are still sold in the marketplaces.
- Both legal & technical extension activities are still limited to the public, particularly farmers.
- The current system for safe management particularly treatment of pesticide waste is not available.



### Constrains(con't)

- There are no routine procedures in place for treatment of pesticide poisoning cases or specialized poison treatment centers.
- Monitoring of pesticide residue in crops has not been carried out yet.
- The collaboration among nationally, regionally and internationally need to be strengthened.

THANK YOU FOR YOUR ATTENTION

## Annex 5. Iran

In the name of God

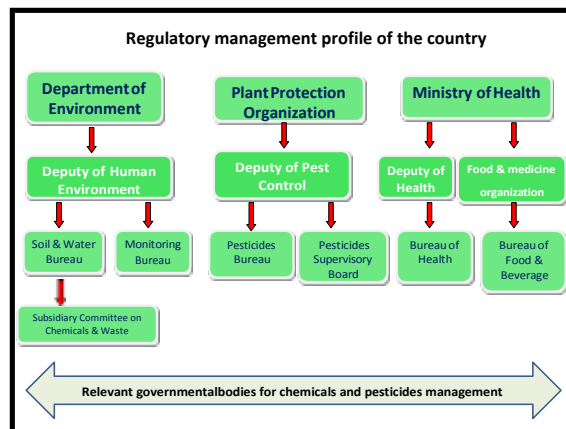



Plant Protection Organization
Department of Environment

**Sub-Regional DNA Consultative meeting on the  
FRA Evaluation Toolkit and other approaches  
under the Rotterdam Convention  
Bangkok, Thailand**

**26 to 28 October 2016**

Islamic Republic of IRAN  
Department of Environment



**Regulatory management profile of the country**

Related National & International Laws , by-laws , Regulations , ...

- The Environmental Protection and Enhancement Act- (DoE)
- The Plant Protection Act and Implementation Regulation- (PPO)
- The Executive By-Law on the Prevention of Water pollution - (DoE)
- The Waste Management law and its executive by-law- (DoE)
- The executive by-law on supervision and control of chemicals & pesticides.(Ministry of Health)
- The Rotterdam convention Acts- (DoE) & (PPO)
- The Basel and the Stockholm convention Acts- (DoE)
- The Minamata Convention on Mercury- (DoE)
- The Wastewater standards including different chemical pollutants resulting from activities of industrial, manufacturing, agricultural and urban section-(DoE)

**Regulatory management profile of the country**

- I.R. Iran has put voluntary cooperation with secretariat of the Rotterdam Convention on agenda since 1992. The convention was signed by the representative of I.R. Iran at United Nation on 17 Feb. 1994.
- Upon ratification of the convention by the Islamic Consultative Assembly on 26 Aug. 2004, the documents on adherence of I.R. Iran to the convention were submitted to the secretariat of UN on Sep. 2004 and Iran became a party to the convention on 26 Nov 2004 .

Two designated National Authorities follow and are responsible to implement the context of the convention in I.R. Iran which are as below:

**The Plant Protection Organization (PPO) on pesticides and the Department of Environment on the industrial chemicals.**

#### **Process for final regulatory actions**

All decisions on production, import and use of industrial chemicals and pesticides are made by :

- 1) the subsidiary Committee of Hazardous Wastes and Chemicals based in the Department of Environment. (for industrial chemicals)
- 2) the Pesticides Supervisory Board based in the Plant Protection Organization, ( for pesticides)
- 3) The National Committee on chemical safety set up in MoF

(Ministry of foreign Affairs) ( for the final national decisions regarding the Rotterdam Convention suggested pesticides and industrial chemicals )

#### **Process for final regulatory actions**

- The mentioned national committees membered by the representatives from :

- ✓ Department of Environment
- ✓ Plant Protection Organization
- ✓ Ministry of Industries, Mines & trade
- ✓ Ministry of petrochemicals and Oil
- ✓ Iranian Customs
- ✓ Ministry of Health
- ✓ Ministry of Power
- ✓ Ministry of Defense
- ✓ Ministry of Foreign Affairs

Decisions are made by **consensus** and if the consensus is not reached after times , vote is taken and votes of half of the members present plus one will adopt the decision.

**Main responsibility of Pesticides Supervision Board**

- National pesticide registration, removal, labeling and production (synthesis and formulation) licensing and preparing the National List of authorized Pesticides ,
- Pesticide registration applications are required to be accompanied by the latest investigations carried out by international organizations such as WHO, IRPTC , IARC and similar authorities.

**National incident report mechanism**

- The National Disaster Management Organization has been established in Iran in 2009 with the various Committees .
- One of those committees is “ Environmental Risk Committee ” with responsibility of the Department of Environment.
- This committee is responsible for developing guidance, national plans and programs in order to prevent, control and response to any activity and incident which can damage the environment and be harmful for the health of the public.

**National incident report mechanism**

- Under the provisions of the Labour Code , responsibility for planning, evaluation, monitoring and control in the field of occupational health and workers' health is the responsibility of the Ministry of Health.
- According to the Iran's national Law the all relevant units and organizations are responsible to the prevention, preparedness, immediate response to an incident as well as recovery under National Disaster Management Organization, during the crisis,
- In order to manage the chemical accidents in the workplace, the national chemicals incidents program has developed by Ministry of Health.

**National incident report mechanism**

- an official reporting is made by the Administration of Environment and submitted to the relevant provincial governor,
- a provincial emergency meeting will be held in the governor and determined some immediate necessary actions and measures to control and prevent more pollutants emissions and releases to the environment,
- an immediate announcement to the headquarters by the head of the provincial committee for the supplementary measures (the HSE offices in the central governmental bodies and in major factories and industrial units will be ready for immediate response to emergency cases,

**Capacity and institutional arrangements for risk assessment**

- At present, risk Assessment of hazardous chemicals is not taken into account in Iran however it has been considered as a one of the most important priorities of national chemical plan with cooperation of the Ministry of Health, the Ministry of Agriculture and the Department of Environment ,
- Iran is a member of (REACH) ,the EU regulation for the chemicals risk assessment which promotes alternative methods for the hazard assessment of substances ,

**Capacity and institutional arrangements for risk assessment**

- Monitoring and Forecasting Networks for Agricultural products and IPM Set up in Islamic Republic of Iran – Plant Protection Organization
- Toxicological data such as acute toxicity ,gastrointestinal ,skin and other toxicological effects obtained from testes on animals.
- Information on chronic and sub chronic toxicity, ecological toxicity data ,data on metabolism in the environment and environmental persistence and ...received from some international references and documents such as FAO –UNEP joint programs in relation to PIC procedure.
- the risk of some harmful chemical agents for population in the work areas is being determined and monitored by Ministry of Health.
- Developing of the standards and environmental risk assessment for biological and environmental nano -materials is under processing.

Proposed list of chemicals for review (high priority chemicals for possible regulatory actions) -1 slide

- Industrial chemicals:

1. Chrysotile (white asbestos)
2. Pentadecafluorooctanoic acid and its salts and esters(PFOA)
3. Decabromodiphenyl ether
4. Short-Chain Chlorinated Paraffin (SCCP)

- Pesticides :

Dicofol , fention , Amitraz and some other pesticides such as : azinphos-ethyl, carbaryl , carbofuran, Chlorfenvinphos, cyhexatin, dirotophos , endrin,,lead arsenate, methyl parathion , nitrofen , phosphomidon , trazophos

Thank you very much for  
your attention!

## Annex 6. Lao People's Democratic Republic

### Regulatory management profile of the Lao People's Democratic Republic

#### Contact Information

Ministerial Decision No 3192/MONRE Dated 17/06/2016

##### 1 Official Contact point

Department: Department of Pollution Control  
Institution: Ministry of Natural Resources and Environment

##### 2 Designated National Authority (DNA) - Pesticides

Department: Department of Agriculture  
Institution: Ministry of Agriculture and Forestry

##### 3 Designated National Authority (DNA) - Industrial Chemicals

Department: Department of Industry and Handicraft  
Institution: Ministry of Industry and Commerce

#### International Treaties

Laos became the parties of International Treaties

**Stockholm Convention**  
On Persistent Organic Pollutants (POPs)

- Signature: March 2002
- Ratify: June 2006

**Basel Convention**  
on the Control of Transboundary  
movements of Hazardous Waste and their  
Disposal

- Ratify: September 2010

**Rotterdam Convention**  
on the Prior Informed Consent Procedure  
for Certain Hazardous Chemicals

- Ratify: September 2010

#### National Legislation

- Environment Protection Law No 29/Na dated 18/12/2012
- Agriculture Law No 01/98/NA dated 10/10/1998
- Food Law No 33/NA, dated 24 July 2013
- Consumer protection Law 02 /NA 30/6/2010
- Ministerial Decision (regulation) on Pesticide Management No 2860/MAF dated 11/06/2016
- Ministerial Decision (regulation) on Industrial Chemical Management No 1041/MOIC dated 28/05/2012

#### Pesticide on the control of pesticide, No.2860/MAF, 21 June 2010

- Regulation on the Control of Pesticides in Lao PDR, was issued by the Ministry of Agriculture and Forestry as an instrument to control the importation, distribution and use of pesticides.
- The Regulation establishes the requirements and procedure for registration of pesticides. It regulates: licensing; production, import, export, distribution, sale; transport and storage; packaging, labeling and advertising; use and disposal; management and inspection.

#### Structure of Department of Agriculture



### Overview of the current system of the control of pesticides

National level (DOA)	Provincial level (PAFO)	District level (DAFO)
<ul style="list-style-type: none"> <li>- Responsible for pesticide policy development, regulation, pesticide registration,</li> <li>- Register pesticide</li> <li>- Monitoring and technical back stopping.</li> <li>- provides guidance and issues written instructions to the provincial level.</li> </ul>	<ul style="list-style-type: none"> <li>- Responsible for issuance of import permits and licenses for the retail of pesticides.</li> <li>- inspections of pesticide shops and monitoring pesticide use in the field.</li> </ul>	<ul style="list-style-type: none"> <li>- Responsible for conducting inspections of pesticide shops and monitoring pesticide use in the field.</li> </ul>

### Overview of the current system of the control of Industrial chemical

National level (DOIH)	Provincial level (PIC)	District level (DIC)
<ul style="list-style-type: none"> <li>- Responsible for Study and draft policies, strategic plan, law programs, projects and regulations in relation industrial Chemicals activities.</li> <li>- Register industrial Chemicals</li> <li>- Monitor business activities and utilization of industrial Chemicals.</li> <li>- Disseminate the laws, regulations relating to industrial Chemicals activities to provincial level and public.</li> </ul>	<ul style="list-style-type: none"> <li>- Manage, monitor the import and export including issuing of license for import and export of industrial Chemical</li> <li>- Monitor business activities and utilization of industrial Chemicals</li> </ul>	<ul style="list-style-type: none"> <li>- Responsible for Monitor business activities and utilization of industrial Chemicals</li> </ul>

### National incident report mechanism

#### Environment Protection Law

- Article 21. impact surveillance
- Article 22. Impact assessment
- Article 28. report

#### Consumer Protection Law

- Appeal or report by consumer

#### Ministerial Decision on Pesticide management

- Obligation of pesticide entrepreneur to report

### Process for final regulatory actions

A pesticide will be banned for import and use in Lao PDR based on following cases:

- The pesticide is no longer effective for its intended used
- The pesticide classified as extremely hazardous and highly hazardous substance under WHO recommended classification
- The pesticide is in the annex III of Rotterdam Convention or Listing of POPs in the Stockholm Convention

DOA in consultation with MONRE propose MAF to officially ban a pesticide.

### Process for final regulatory actions (continued)

- The prohibited of industrial chemicals base on international treaty and convention to which Lao PDR is a party, lessons of neighbors, characteristics of hazardous and capacity to manage.

### Capacity and institutional arrangements for risk assessment


- Risk Assessment of pesticide is conducted by Registration Unit, DOA, based on International Code of Conduct of FAO : Guidelines for the Registration of Pesticides.
- The industrial Chemicals shall be registered with the Department of Industry and Handicraft (DOIH) and the documents required copy of Enterprise Registration Certificate, chemical risk assessment report and safety data sheet after received all documents DOIH shall together with provincial department of industry and commerce for field monitoring at factory than consider to issue chemical registration certificate.



### Proposed list of chemicals for review

- Pesticide
  - Calcium arsenic
  - Endrin
  - Paraquat
  - Methomyl
- recently we do not have priority Industrial Chemicals for possible regulatory action. But industrial chemicals already be divided into 3 classifications according to its hazard level as chemical type I is prohibited chemical, chemical type II strictly managed chemical and chemical type III slightly managed chemical.

## Annex 7. The Islamic Republic of Oman




**The National Authority for Management of Chemicals In the Sultanate**

1. **Ministry of Environment and Climate Affairs:**  
for Industrial Chemicals represented in the Department of Chemicals
2. **Ministry of Agriculture & Fisheries:**  
for Pesticides and Fertilizers represented in Department of Plant Protection




**Rotterdam Convention for Sound Management of Chemicals In Sultanate of Oman**

Introduced by:  
Buthayna Al-Shekaili  
Azhar Juma Al-Hinai  
( Ministry of Environment & Climate Affairs (MECA))




- According to the Royal Degree No. 46/95 : Issuing the Law of Handling and Use of Chemicals. A Permanent Committee for Chemicals set up with other ministries in the sultanate.
- Technical Committee under the Permanent Committee to submit reports and proposals in the management of chemicals.



**National Legislations on the Management of Chemical Substances (MECA)**

- Royal Degree No. 46/95 : Issuing the Law of Handling and Use of Chemicals.
- Ministerial Decision No. 248/97, Dated 6 July 1997, Issuing the Regulations on Registration of Hazardous Chemical Substances and Relevant Permits.
- Ministerial Decision No. 317/2001, Issuing the Regulations for Packing, Packaging, and Labeling of Hazardous Chemicals.
- Ministerial Decision No. 25/2009, Issuing the Regulations for Organization of Handling and Use of Chemicals.




**Legislations of Ministry of Agriculture in Pesticides Managements**

- Pesticides Law by Royal Degree No. 64/2006 and Ministerial Decision No. 41/2012
- List of Prohibited & Restricted Pesticides
- Quarantine Law by 47/2004 and Ministerial Decision No. 32/2006




**MECA Activities in the management of Chemicals**

- Researches:
  1. Detection of Heavy Metals in Fruits & Vegetables
  2. Detection of Heavy Metals In Cosmetics & Children Creams
  3. Detection of heavy metals in Children Toys. (in process)
  4. Research on mercury, it's products and it's sources in the environment. (in process)




### Rotterdam Convention Implementation in Oman

- Oman Joined Rotterdam Convention on 25<sup>th</sup> Oct 1999, according to the Royal Degree no. 81/99.
- By the Data Base of all Chemicals in Data & Licensing Section in MECA, National of hazardous chemicals accomplished showing all data of hazardous chemicals and their users.
- All Infrastructures and Legislations mentioned above.
- Environmental awareness about safe methods in the use of hazardous chemicals and pesticides.




### Infrastructure for the management of Pesticides in the Ministry of Agriculture and Fisheries


- Laboratories of Toxics, quality control and bio-evaluation of pesticides and residues.
- The creation of a national data base for pesticides.
- A special section for pesticide management in the ministry.




- 39 notifications have been sent about chemicals listed in Annex III in coordination with the Ministry of Agriculture and Fisheries.
- we don't send any export notification because we are not manufacture these chemicals. If happened, the Designated National Authorities (DNAs) will send export notifications.
- 54 notifications of the final legal action were sent.



- Controls imported and exported materials by designating technical staffs at borders, trained on how to deal with these materials and the mechanism of control over the port ( Risk assessment courses)
- Replay for notifications sent by the exporting countries about chemicals listed by the Convention and follow-up the imported companies.



## Thank you



### Difficulties and Challenges

- No specialized Laboratory
- No specialized people
- Supporting Agents
- Financial deficit

## Annex 8. Pakistan

**PESTICIDES AND INDUSTRIAL CHEMICALS  
MANAGEMENT SYSTEM IN PAKISTAN**

1. DNA for Pesticides, Department of Plant Protection, Ministry of National Food Security and Research, Government of Pakistan.
2. DNA for Industrial Chemicals, International Cooperation Wing, Ministry of Climate Change, Government of Pakistan.

**REGULATORY FRAME WORK OF  
AGRO PESTICIDES**

- Agricultural Pesticides Ordinance 1971 & (Amended) Act 1992 & 1997.
- Agricultural Pesticides Rules 1973.
- Agricultural Pesticides Technical Advisory Committee (APTAC) & Sub Committee.
- Pesticide Policies

**REGISTRATION OF PESTICIDES**

No person shall import, manufacture, formulate, sell, offer for sale, hold any stock for sale or in any manner advertise any pesticide which has not been registered in the manner provided by this Act or the rules framed thereunder.

**FORM-1:**

- Efficacy trials at different Federal / Provincial research institutes for two crop seasons by at least two research institutes.
- Standardized the product by the Provincial Standardized Committee.
- Examine by the Agricultural Pesticides Technical Advisory Sub Committee & Agricultural Pesticides Technical Advisory Committee.
- Grant certificate of registration for the period of three years.

**FORM-16:** Since 01.03.1993, Generic Scheme introduced and 139 pesticides notified by the federal govt. under the generic scheme, already test & trialed.

**FORM-17:** Registration Abroad Scheme. Grant of Import permission certificate on the basis of registration documents in the country of origin / manufacturer i.e., in OECD countries, China or India.

**REGULATORY FRAMEWORK OF  
INDUSTRIAL CHEMICALS**

- National Environment Policy, 2005
- Pakistan Environmental Protection Act, 1997
- National Environmental Quality Standards
- National Technical Advisory Committee on Chemicals (NTACC)
- Import Policy Order, 2016

Continue...

**Section 14 of PEPA, 1997. Handling of hazardous substances.**

Subject to the provisions of this Act, no person shall generate, collect, consign, transport, treat, dispose of, store, handle or import any hazardous substance except—

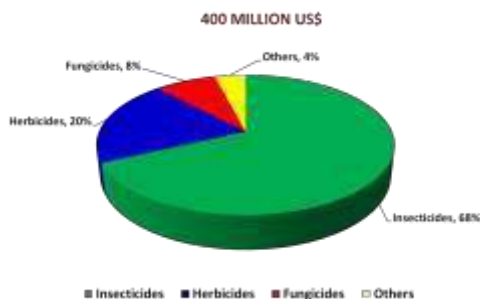
- (a) under a licence issued by the Federal Agency and in such manner as may be prescribed; or
- (b) in accordance with the provisions of any other law for the time being in force, or of any international treaty, convention, protocol, code, standard, agreement or other instrument to which Pakistan is a party.

**REGISTRATION STATUS OF THE PRODUCT IN PAKISTAN**

Toxicity Class	UNDER WHO/EPA TOXICITY				Total
	Insecticide	Herbicide	Fungicide	Others	
Ia	1 (Diazinon)	-	-	1 (Bromadiolone)	2
Ib	9 (Methidathion, Methomyl, Cadusafos)	1 (Fenitrothion)	1	-	11
II	36	10	10 (Triazolanol, Tridemorph, Benzenesulfonate)	5 (Azoxylostin, Fenazoxystin, Fenazoxystin, Methyl Bromide)	61
III	24	57	29	7 (Dicofol, Fenbutatin Oxide, Fenprophate, Tetradifon, Benomyl, etc.)	117
IV	8	14	18	1 (Hexachlorocyclopentadiene)	41

\*Others: -Acaricide, Biological, Fumigants, IGR

### Pakistan Agro Chemicals Market



Source: Pakistan Crop Protection Association presented in CAE, Lahore.

### PROCEDURE FOR IMPLEMENTATION OF INTERNATIONAL OBLIGATION

Pakistan signed the Rotterdam Convention since 1992 and ratified on 14.07.2005. All pesticides product included / to be included in PIC programme were reviewed time to time by:

- 1) The Agricultural Pesticides Technical Advisory Sub-committee headed by the Advisor & Director General, Department of Plant Protection (DNA for pesticide)
- 2) The Agricultural Pesticides Technical Advisory Committee (APTAC) headed by the Secretary, Ministry of National Food Security & Research.
- 3) The APTAC committee decided to ban PIC products in Pakistan and issue Statutory Notification (S.R.O).
- 4) All PIC pesticides registered under the provisions of the Agricultural Pesticide Ordinance 1971 and (Amendment) Act 1992 & 1997 are deregistered and officially notified.

- The Federal Government prohibit the import, marketing and use of following pesticides either in technical grade material or formulation:

#### i) PIC Products (Annexure-III) banned in Pakistan = 29

(2,4,5 - T & its salts and esters; Aldrin; Binapacryl; Captafol; Chlordane; Chlordimeform; Chlorobenzilate; DDT; Dieldrin; Dinoseb and Dinoseb Salts; DNOC and its salts; EDB (1,2 - dibromoethane); Ethylenedichloride; Ethylene oxide; Fluoroacetamide; HCH (mixed isomers); Heptachlor; Hexachlorobenzene; Lindane (gamma - HCH); Mercury compounds; Monocrotophos; Pentachlorophenol; Toxaphene; Methamidophos; Methyl parathion; Monocrotophos (Soluble liquid formulations of the substance that exceed 600 g active ingredient /l); Parathion (all formulations - aerosols, dustable powder (DP), emulsifiable concentrate (EC), granules (GR) and wettable powders (WP) - of this substance are included, except capsule suspensions (CS)); Phosphamidon; Endosulfan)

#### ii) Pesticide Formulation banned = 9 (Chlorpyrifos + Dimethoate 602 EC; Cypermethrin + Medhamidophos 550 EC; Cypermethrin + Monocrotophos 450 EC; Cypermethrin + Mephosulfan 50/300 EC; Flucythrinate + Dimethoate 50/300 EC; Flucythrinate + Mephosulfan 25/200 EC; Fluralinate + Thiometon 72+200 EC; Prothoate + Dimethoate 235/200 EC; Quinalphos + Thiometon 32 EC)

### Process for Final Regulatory Actions For Industrial Chemicals

- Seeking information on the import, export and production of industrial chemicals from relevant Ministries/stakeholders
- Sharing of information with Federal / Provincial EPAs and research institutes.
- Examining and evaluating by the National Technical Advisory Committee on Chemicals.

### National incident report mechanism

- At present, National Disaster Management Authority (NDMA) is focal point for Emergency Coordination in case of chemical disaster in the country.
- NDMA is being assisted by Ministry of Industries & Production, Ministry of Foreign Affairs, Federal Board of Revenue (FBR), Ministry of Climate Change and Ministry of Commerce.

### Capacity and Institutional Arrangements for Risk Assessment


- ✓ Pakistan Council for Scientific and Industrial Research (PCSIR) at Federal and Provincial level
  - ✓ Environmental laboratories at Federal and Provincial level
  - ✓ Advanced laboratories in Universities
- However, the following gaps exists;
- Lack of technical / human resources capacity
  - Lack of networking with other stakeholders for making decisions on industrial chemicals.
  - Lack of opportunities for individual and institutional capacity to implement obligations of RC.
  - Lack of sufficient / effective infrastructure for monitoring and reporting of poisoning from industrial chemicals.

### **Proposed List of Chemicals for Review**

1. Commercial octabromodiphenyl ether (including hexabromodiphenyl ether and heptabromodiphenyl ether)
2. Commercial Pentabromodiphenyl ether (including tetrabromodiphenyl ether and pentabromodiphenyl ether)
3. Perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls


*Thank  
you*

## Annex 9. Philippines




### INDUSTRIAL CHEMICAL AND PESTICIDE REGULATIONS IN THE PHILIPPINES

BY:  
**EMMANUELITA D. MENDOZA**  
OIC, Chief – Chemical Management Section  
Supervising Science Research Specialist  
Environmental Quality Management Division  
DENR - EMB  
October 26-28, 2016




### REGULATORY MANAGEMENT PROFILE (Industrial Chemical)

- **Environmental Management Bureau (EMB)**
- **Mandate:**  
"to implement various national environmental laws (PD 1586, RA 8749, RA 9003, RA 9275, RA 9512 and RA 6969 or the Toxic Substances and Hazardous and Nuclear Waste Control Act of 1990)"
- **Functions:**
  - Advise the DENR Secretary on matters relating to Environmental Management
  - Formulate plans and policies and set appropriate environmental quality standards (Water, Air, chemicals & hazardous waste) for the prevention, control of pollution and protection of the environment
  - Oversee 17 regional offices in the implementation and enforcement of environmental plans and programs
  - Issue permits and clearances under PD 1586, RA 8749, RA 9275, RA 9003, and RA 6969 and monitor compliance to said laws
  - Develop and implement a research and development program in support of the following:
    - Environmental and Compliance Monitoring
    - Study of existing and potential environmental problems and issues
    - Act as Focal Point and Secretariat to International Convention





### Four (4) Major Services in Chemical Management

CHEMICAL POLICY FORMULATION & AMENDMENT	PERMITTING AND CLEARANCE PROCESSING & ISSUANCE (ON-LINE)	MONITORING, ASSESSMENT & CAPACITY BUILDING	TECHNICAL ASSISTANCE/ STRATEGIC PARTNERSHIPS
Review and Evaluation, Public Consultation	PreManufacture and Preimportation Notification for New Chemicals *	Regional Assessment and Monitoring	LOCAL (NGO/CDO, Interagencies)
Formulation of DAOs and MCS	Priority Chemical List Compliance Certificate**	Self-Monitoring Report (SMR) from Industry Sector	International Commitments/ Conventions (MEAs)
Amendment & phase-out of existing DAOs in relation to int'l R & R	Chemical Control Orders (CCOs)***2017	Training and capacity building of Regulators and Regulated community	APEC CD/SAICM


**MULTI-STAKEHOLDERS INVOLVEMENT & PARTNERSHIPS IN EVERY PROCESS**

Note: \*/\*\* The PMPIN notification has provided for the updating of the inventory of all existing unregulated chemicals and chemical substances (PICCS)  
\*\* An Interagency Chemical Review Committee (IRC) is delegated to assist EMB in the review of new chemicals and toxic substances proposed for regulatory actions  
The framework of chemical management in the Philippines is based on the Strategic Approach to International Chemical Management (SAICM). Influence of various national, regional and international organizations




### REGULATORY MANAGEMENT PROFILE (Pesticide)



- **Fertilizer and Pesticide Authority (FPA)**
- **Mandate:**  
"to assure adequate, safe and affordable supply of fertilizers and pesticides, rationalize the manufacture and marketing of fertilizers, protect the public from risks inherent to pesticides, and educate the agricultural sector on the proper use of these inputs"
- **Functions:**
  - Regulation and control
    - Registration of pesticide products
    - Licensing of all handlers of pesticides
    - Regulatory and enforcement action
  - Information
    - Training and accreditation programs
    - Dissemination of info materials
    - Media liaisons
  - Development
    - Industry support
    - Cooperation and coordination initiatives

### Four (4) Major Services in Pesticide Management

Policy Formulation	Registration	Issuance	Monitoring
Coordinate and compile the information on existing pesticides	Review the compliance of pesticide requirements	Review the compliance of requirements	Monitor compliance the service provided in the field
Conduct stakeholder consultation	Provide submitted data requirements to tech. evaluation	Issue labeling of pesticide, deliver its marketing info.	Coordinate, investigate or conduct a case of violation
Coordinate and facilitate the review of PMPAC and PPA report	Approval (recommendation) registration	Approval (endorsement) the release of license	Generate and maintain national data for policy formulation and decision making

PPTAC – Pesticide Policy and Technical Advisory Committee (pool of scientists and technical consultants)

### NATIONAL INCIDENT REPORT MECHANISM

**Government Coordination Mechanisms**


Creation of an Inter-Agency Task Force	Formation/ Organizational Structure	Coordination Meetings and Tasking in accordance with Mandates
Review of the Environmental Technology Verification (ETV) for the MPE	Sampling and Analysis	Deliberation, Agreements & National Report

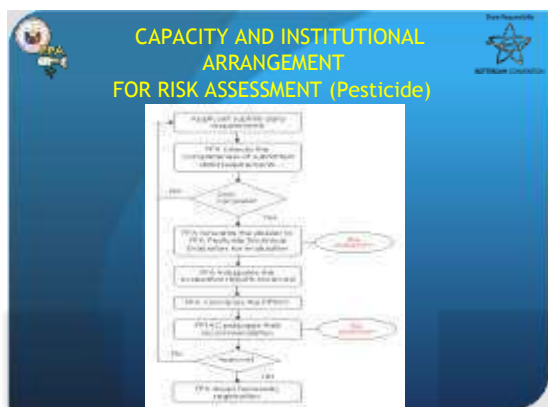
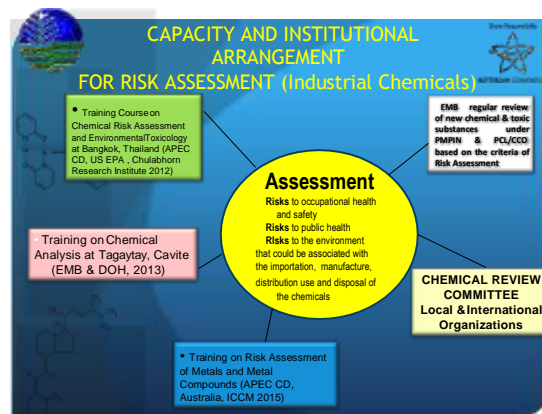
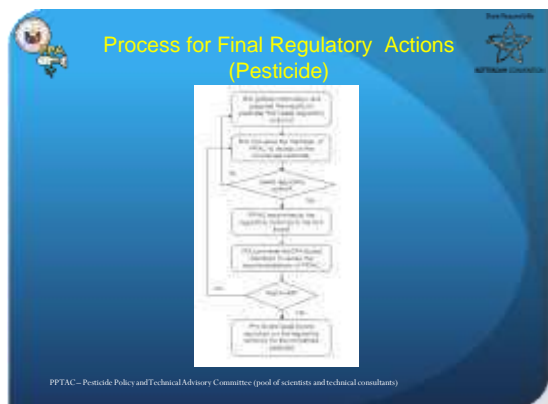
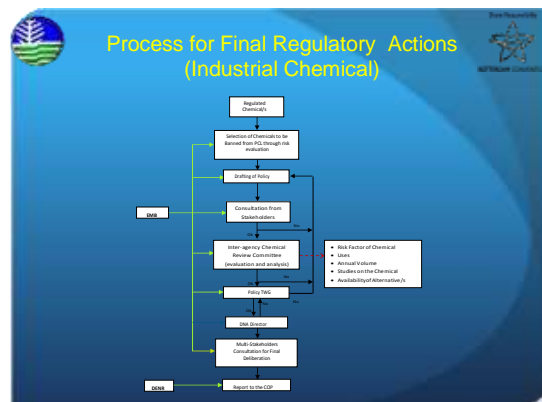
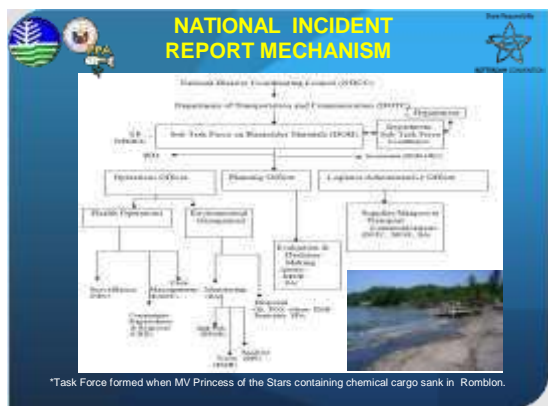
IATAC

IAC

PPTAC

- **Inter-Agency Technical Advisory Council of RA6969**  
DENR, DOH, DTI, DOST, DND, DFA, DOLE, DOP, DA, Director of PNRI, Representative from the non-governmental organization on health and safety
- **Inter-Agency Committee on Occupational Safety and Health**  
DOH-NCOS, UP-NPOIS, ECOP, LACC, FFW, TUCP, TUPAS, PCOM, IIRR, QCISCI, IOHSAD
- **Pesticide Policy and Technical Advisory Committee**  
DENR, DOH, DOLE

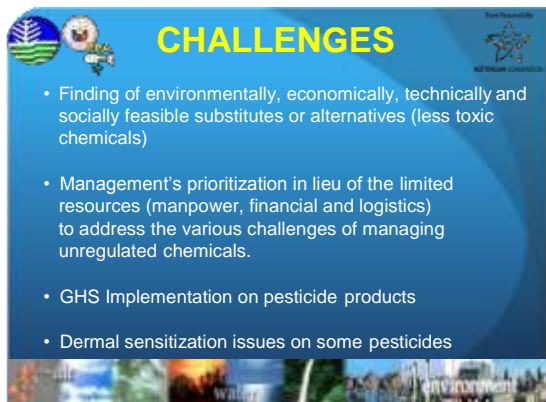




### PROPOSED LIST OF CHEMICALS FOR REVIEW

Industrial Chemicals	Pesticides
Arsenic (As)	Endrin
Cadmium (Cd)	Azinphos ethyl
Lead carbonate (PbCO <sub>3</sub> )	1,2-dibromo-3-chloropropane
Mercury (Hg)	Nitrofen
Chrysotile Asbestos (White fibers)	Thallium Sulfate





## CHALLENGES

- Finding of environmentally, economically, technically and socially feasible substitutes or alternatives (less toxic chemicals)
- Management's prioritization in lieu of the limited resources (manpower, financial and logistics) to address the various challenges of managing unregulated chemicals.
- GHS Implementation on pesticide products
- Dermal sensitization issues on some pesticides



## Thank You Very Much for Listening!

[www.emb.gov.ph](http://www.emb.gov.ph)  
[www.chemicals.gov.ph](http://www.chemicals.gov.ph)  
[fpa.lsd@gmail.com](mailto:fpa.lsd@gmail.com)

## Annex 10. Thailand

### Hazardous Substances Management in Thailand

Rotterdam Convention Sub-regional DNA Consultative Meeting  
26-28 October 2016, Bangkok



### Contents

#### • Rotterdam Convention in Thailand

- Regulatory management in Thailand
- National incident report mechanism
- Process for final regulatory actions
- Capacity and institutional arrangements for risk assessment
- Proposed list of chemicals for review

### Rotterdam Convention in Thailand

- Thailand Ratified the Rotterdam Convention on 19 February 2002 by accession
- Entered into force 24 February 2005
- Designated National Authorities (DNAs)
  - Department of Agriculture as a DNA for pesticides
  - Department of industrial works as a DNA for industrial chemicals
  - Pollution Control Department as a DNA for other chemicals & the official contact point.

### Regulatory management in Thailand

- All chemicals listed in the Annex III of the Convention are controlled under the Hazardous Substances Act B.E. 2535 (1992) and import responses have been submitted for those chemicals.
- The Hazardous Substance Committee is the main committee to set up policies and collaborate implementation of the Hazardous Substance Act among responsible agencies (Agriculture, Industry, Public Health, etc.).

- 1) an explosive
- 2) an inflammable substance
- 3) an oxidizing agent and a peroxide substance
- 4) a toxic substance
- 5) an infectious substance
- 6) a radioactive substance
- 7) a mutagen
- 8) a corrosive substance
- 9) an irritating substance
- 10) other substances, whether chemical or else, which may be harmful to person, animal, plant, property or environment.

### The Hazardous substances Act B.E. 2535 (1992)

Type 1	the production, import, export or possession must be complied with the specified criteria and procedures; no need to apply for a registration or license
Type 2	production, import, export or possession must be notified to authorities; production and import must be registered; no need to apply for license
Type 3	production, import, export or possession must be applied for license; production and import must be registered.
Type 4	production, import, export or having in possession are prohibited (banned pesticides)

## Chemicals and responsible agencies

### Industrial chemicals

- Department of Industrial Works

(DIW). Pesticides and agricultural

chemicals

- Department of Agriculture (DOA).

Household, healthcare and consumer chemicals

- Food and Drug Administration

• Office of Atomic Energy for Peace

## National incident report mechanism

Thailand has never submitted a proposal for severely hazardous pesticide formulations (SHPPFs) due to a lack of required data on pesticide poisoning.

## Process for final regulatory actions

- Notification of Final Regulatory Action to ban or severely restrict a chemical (Article 5).
- Chemicals banned or severely restricted due to health and environment reasons.

### ♦Exporting parties

- Comply with import conditions (National, PIC) for banned or severely restricted chemicals.

### ♦Importing parties

- Import restrictions for banned/severely restricted/hazardous chemicals.

## Capacity and institutional arrangements for risk assessment

Thailand's National Strategic Plan National Strategic Plan on Chemical Management

1st National Strategic Plan on CM (1997-2001)

2nd National Strategic Plan on CM (2002-2006)

3rd National Strategic Plan on CM (2007-2011)

4th National Strategic Plan on CM (2012-2021)

### Goal

"Within 2021 social and environments safe by effective Safe by effective management of chemicals in accordance with national development and participation from all sectors."

## Capacity and institutional arrangements for risk assessment

### Objectives

1. To develop systematic management of chemicals to cover their entire life cycle and to be in line with national and international development
2. To promote coordination of all sectors on national chemical management
3. To minimize impact of chemicals on health and environment

## Strategies

Strategy 1 Develop chemical database, mechanisms and tools for fully integrated system of chemical management

Strategy 2 Develop capacity and role of all sectors on chemical management Strategy

3 Reduce risk of chemical dangers

### Capacity and institutional arrangements for risk assessment

Thailand has actively involved through out the development of RC.

•Capacity-building and technical assistance – Capacity Building and Awareness Raising Programmes on the Implementation of the Rotterdam Convention in Thailand under framework of the QSP Trust Fund

- Awareness Raising Workshop:

1. Customs and Border Control Officials Training (2010-2012)
2. Awareness Raising workshops and Capacity building on SHPFs reporting (2012-2016)
3. Evaluation, Consultation, and visiting success organic rice farms (2015)

•Information Dissemination: Publications

- Monograph= 4-6 chem/year, Newsletter= 3 issues /year

### Proposed list of chemicals for review

1. Azinphos ethyl (Insecticide)-high acute toxicity, high risk to users, Toxicity class WHO (a.i)Ib
2. DDD (Insecticide)-Persistent in environment and fatty tissues of human and animals, Nervous system poisoning, Affects reproductive process of birds and fishes
3. Mevinphos (Insecticide)-very high acute toxicity, high risk to users
4. Phosphamidon (Insecticide)-very high acute toxicity, high risk to users

### For more information, please contact:

Rotterdam Convention Official Contact Point Waste & Hazardous Substance Management  
Bureau Pollution Control Department,  
Ministry of Natural Resources and Environment

Tel: + 66 2298 2426

Fax: + 66 2298 5393

email: [chem@pcd.go.th](mailto:chem@pcd.go.th) <http://pops.pcd.go.th> <http://www.pcd.go.th>

## Annex 11. Facilitator

Sub-Regional DNA consultative meeting on the FRA Evaluation Toolkit and other approaches under the Rotterdam Convention Bangkok, Thailand; 26 to 28 October 2016

**Scientific and Technical Information on Final Regulatory Actions (FRAs):**

- RC Annex I information
- RC Annex II criteria

CONFIDENTIAL

Sub-Regional DNA consultative meeting on the FRA Evaluation Toolkit and other approaches under the Rotterdam Convention Bangkok, Thailand; 26 to 28 October May 2016

**RC Annex I information:**

1. PROPERTIES, IDENTIFICATION AND USES

- (a) Common name; (*Chloroform*)
- (b) Chemical name according to an internationally recognized nomenclature (for example, International Union of Pure and Applied Chemistry (IUPAC)), where such nomenclature exists; (*Trichloromethane*)
- (c) Trade names and names of preparations; (*Freon 20, NCI-C02686, R20, R20 (refrigerant)*)
- (d) Code numbers: Chemicals Abstract Service (CAS) number, Harmonized System customs code and other numbers; A CAS Registry Number or CASRN or CAS Number, is a unique numerical identifier assigned by Chemical Abstracts Service (CAS) which is a division of the American Chemical Society (ACS), to every chemical substance described in the open scientific literature:  
CAS Registry Number search engines:  
CHEMINDEX Search via Canadian Centre for Occupational Health and Safety.  
ChemIDplus Advanced via United States National Library of Medicine.  
Common Chemistry TM, via Australian Inventory of Chemical Substances.  
European chemical Substances Information System, via the website of Royal Society of Chemistry.  
HSNO Chemical Classification Information Database, via Environmental Risk Management Authority.  
Search Tool of Australian Inventory of Chemical Substances.  
List of CAS numbers by chemical compound; International Union of Pure and Applied Chemistry (IUPAC); Academic publishing; Beilstein Registry Number; Chemical database; Chemical file format; Dictionary of chemical formulas; EC number (Enzyme Commission); ECH (EINECS and ELINCS, European Community Identifier; International Chemical Identifier (InChI); MDL number; PubChem; UN number, etc.

Sub-Regional DNA consultative meeting on the FRA Evaluation Toolkit and other approaches under the Rotterdam Convention Bangkok, Thailand; 26-28 October 2016

**RC Annex I information:**

- (e) Information on hazard classification, where the chemical is subject to classification requirements; WHO: Class Ia (extremely hazardous). Classification based on oral or dermal toxicity in rats LD50; WHO reference; IARC (Group 3: the agent is not classified as to its carcinogenicity to humans; IARC reference); EU (Classification of the active substance is (Commission Directive reference): T (toxic), Xi (Irritant), N (dangerous for the environment), R 24/25 (Toxic in contact with skin/ if swallowed), R 36 (Irritating to eyes), R 50/53 (Very toxic to aquatic organisms / may cause long-term adverse effects in the aquatic environment); USEPA (Toxicity Class I (formulation); EPA reference).
- (f) Use or uses of the chemical: Research and analysis, Laboratory use & Industrial chemical for public use banned.
- (g) Physico-chemical : Molecular weight, boiling point, etc.
- (h) Toxicological: Mode of action; Symptoms of poisoning; Absorption, distribution, excretion and metabolism in mammals: (Rate and extent of absorption, Distribution, Potential for accumulation, Rate and extent of excretion, Metabolism in animals).
- (i) Ecotoxicological properties: Environmental source, fate and effects (Soil- Field dissipation, Aerobic and anaerobic degradation, Rate of degradation, Adsorption/desorption, Mobility); (Water- Route and rate of degradation); (Air-Fate and behaviour); (Bioconcentration and bioaccumulation); (Persistence); Effects on non-target organisms; (Terrestrial vertebrates: Acute/chronic toxicity mammals, Acute/chronic toxicity birds, Dietary toxicity birds, Reproductive toxicity birds); (Aquatic species- Fish, Invertebrates, Algal species, Aquatic plants); (Honey bees and other arthropods); (Earthworms); (Soil microorganisms); (Terrestrial plants); (Environmental exposure/risk evaluation Specific reference as appropriate to the following: Terrestrial vertebrates: Mammals/birds, Aquatic species- Fish/invertebrates/algal species/aquatic plants, Honey bees, Other arthropods, Earthworms, Soil microorganisms), summary – overall risk evaluation).

Sub-Regional DNA consultative meeting on the FRA Evaluation Toolkit and other approaches under the Rotterdam Convention Bangkok, Thailand; 26-28 October 2016

**RC Annex I information:**

2. FINAL REGULATORY ACTION

- (a) Information specific to the final regulatory action:
  - (i) Summary of the final regulatory action; Regulations for the Prohibition of the use, Manufacturing, import and export of asbestos and asbestos containing materials, 2008.
  - (ii) Reference to the regulatory document; Published under Government Notice R 341 in Government Gazette 30904 of 28 March 2008.
  - (iii) Date of entry into force of the final regulatory action; 2008
  - (iv) Indication of whether the final regulatory action was taken on the basis of a risk or hazard evaluation and, if so, information on such evaluation, covering a reference to the relevant documentation; Risk to human health in exposed individuals (mine workers, school children & communities in close proximity to the mines); too many silicosis cases were reported in exposed miners, and subsequently a research study was undertaken involving asbestos mine workers. Ref to the various local research articles; SANS 10228- The identification and classification of dangerous goods for transport, SANS 10228, published by the SABS.
  - (v) Reasons for the final regulatory action relevant to human health, including the health of consumers and workers, or the environment; Yes; too many silicosis cases were reported and a research study was done in asbestos mine workers.
  - (vi) Summary of the hazards and risks presented by the chemical to human health, including the health of consumers and workers, or the environment and the expected effect of the final regulatory action; Research outcomes (high occurrence of silicosis in asbestos mine workers than controlled groups; high conc. of asbestos fibres present in the mine dumps from the mining activities thus contaminated the soil & exposed communities in close proximity to the mines). Effect of the Final Regulatory Action will cease mining and prohibit the use, manufacturing, import and export of asbestos and asbestos containing materials but allow transit of asbestos containing trucks from SADC countries ensuring there is no repackaging or handling thereof within the RSA.

Sub-Regional DNA consultative meeting on the FRA Evaluation Toolkit and other approaches under the Rotterdam Convention Bangkok, Thailand; 26-28 October 2016

**RC Annex I information:**

2. FINAL REGULATORY ACTION

- (b) Category or categories where the final regulatory action has been taken, and for each category:
  - (i) Use or uses prohibited by the final regulatory action;
  - (ii) Use or uses that remain allowed; No
  - (iii) Estimation, where available, of quantities of the chemical produced, imported, exported and used; Data requested from SARS.
- (c) An indication, to the extent possible, of the likely relevance of the final regulatory action to other States and regions; Allows transit of asbestos containing trucks from SADC countries ensuring there is no repackaging or handling thereof within the RSA.
- (d) Other relevant information that may cover:
  - (i) Assessment of socio-economic effects of the final regulatory action; This was undertaken as jobs in the asbestos mining sector were to come to an end;
  - (ii) Information on alternatives and their relative risks, where available, such as: Integrated pest management strategies; Other available and as durable forms building material available; no alternatives on some type of break pads
  - (iii) Industrial practices and processes, including cleaner technology. Detailed inventory and a subsequent extensive remediation programme initiated by the government, including relocation of affected communities. Dept of Labour tasked with ensuring that workers involved in the closing up of operation in the relevant mines wore appropriate protective clothing.

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**RC Annex II CRITERIA:**

**CRITERIA FOR LISTING BANNED OR SEVERELY RESTRICTED CHEMICALS IN ANNEX III:**

In reviewing the notifications forwarded by the Secretariat pursuant to paragraph 5 of Article 5, the Chemical Review Committee shall:

- (a) Confirm that the final regulatory action has been taken in order to protect human health or the environment; Section 2 (a) iv, v & vi above critical.
- (b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:
  - (i) Data have been generated according to scientifically recognized methods; (Scientifically sound methodology; eg. Cohort study ( type of a medical study to investigate the causes of diseases, establishing links between risk factors and health outcomes. with an acceptable sample size to enable statistical analysis.
  - (ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures; Section 2 (a) iv, An acceptable sample size to enable statistical analysis is critical; so is the stats programme utilised in the analysis.
  - (iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action; Party notifying should have been directly affected.

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ROTTERDAM CONVENTION

**RC Annex II CRITERIA:**

**CRITERIA FOR LISTING BANNED OR SEVERELY RESTRICTED CHEMICALS IN ANNEX III:**

In reviewing the notifications forwarded by the Secretariat pursuant to paragraph 5 of Article 5, the Chemical Review Committee shall:

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses; **Section 2 (a) iv above -the expected effect of the final regulatory action- critical.**

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification; **Section 2 (a) iv above -the expected effect of the final regulatory action- critical.**

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances; **National or Sub-regional negative impact(s) of the chemical being notified through the FRA.**

(iv) Whether there is evidence of ongoing international trade in the chemical; **National or sub-regional or regional Ports officials. RC usually has this information-don't stress on this one.**

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III. **Eg., using the chemical in question for unprescribed uses and not following directives on the label for use and handling; eg., suicide cases.**

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ROTTERDAM CONVENTION

**RC Annex II CRITERIA:**

**CRITERIA FOR LISTING BANNED OR SEVERELY RESTRICTED CHEMICALS IN ANNEX III:**

In reviewing the notifications forwarded by the Secretariat pursuant to paragraph 5 of Article 5, the Chemical Review Committee shall:

**d) Legal interpretation: Meaning of "misuse":**

(a) Where a law or regulation governing the use of the chemical exists in a country, the chemical is used for the purposes not permitted under the law or regulation; or

(b) The chemical is used in a manner not intended or reasonably foreseeable by the manufacturer of the chemical, irrespective of whether there is a law or regulation governing the use of the chemical in the country.

**Meaning of "intentional":**

A person who uses the chemical is in the state of mind in which he/she seeks to accomplish certain results (i.e. the act is to be done or omitted) through a course of action. In other words, he/she desires to cause consequences of his/her act or he/she believes consequences are substantially certain to result by using the chemical.

**With regard to "intentional misuse": For a person to commit "intentional misuse" of the chemical, the following conditions should be met:**

(a) The person knows the legitimate use of the chemical, as permitted under the relevant law or regulation, or otherwise as specified in the label or other means of communication accompanying the chemical; and

(b) The person purposefully uses the chemical in contravention of the legitimate use of the chemical, with the knowledge or belief that such illegitimate use of the chemical will cause the result that he/she so desires.

**Even when the chemical is "misused" in a strict sense, it may not constitute the act of "intentional misuse" of the chemical by a person, given the prevailing circumstances, if:**

(a) The person believes that he/she is using the chemical in a manner as designed for its use (e.g. as many people use the chemical in his/her community and no one has been punished for using it); or

(b) The person does not have specific knowledge concerning the law or regulation governing the chemical or the use for which the chemical is designed, and therefore he/she is not able to ascertain its legitimate use (e.g. illiteracy, lack of understandable means for communicating the legitimate use).

Sub-Regional DNA consultative meeting on the FRA Evaluation Toolkit and other approaches under the Rotterdam Convention Bangkok, Thailand 26-28 October 2016

ROTTERDAM CONVENTION

**THANK YOU FOR YOUR ATTENTION**

Ms NOLUZUKO (Zukie) GWAYI  
SENIOR POLICY ADVISOR (DIRECTOR): INTERNATIONAL CHEMICALS AND WASTE COOPERATION  
DNA & FOCAL POINT: Basel, Rotterdam, Stockholm, SAICM, Vienna & Montreal & Minamata  
CHEMICALS MANAGEMENT  
DEPARTMENT OF ENVIRONMENTAL  
AFFAIRS REPUBLIC OF SOUTH AFRICA

## Annex 12. Rotterdam Convention Secretariat

### FRA EVALUATION TOOLKIT



BRS Secretariat



www.brsmeeas.org

@brsmeeas

BRSMEEAS

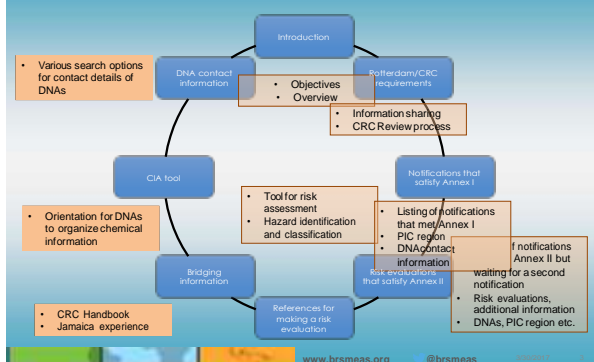
### OVERVIEW

Target audience	DNAs of developing countries
Purpose	User-friendly access to scientific information within the context of the Rotterdam Convention for decision making on hazardous chemical
Focus	Scientific soundness of the notifications of FRAs
Basis	Obligation for Parties to submit notifications of FRAs with preference that such notifications satisfy Annex I and Annex II requirements

*Not a tool for Risk Assessment of chemicals*

BRSMEEAS

### FRA EVALUATION TOOLKIT



www.brsmeeas.org

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### CIA TOOL

Guidance to collect and compile scientific information within the framework of Annex II (b) criteria

- Internationally recognized chemical property data
- Local risk related information e.g. use pattern, incidents

Guidance for prioritizing chemicals for action

- Chemicals in Annex III and SC POPs, Listings of FRAs,
- Access to risk evaluations that have met Annex II, especially those chemicals are not yet listed in Annex III

Facilitate decision making

- Reference to CRC Handbook (application of criteria (b) of Annex II)
- Use of "bridging information"

www.brsmeeas.org

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### APPROACH FOR DEVELOPMENT OF TOOLKIT



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THANK YOU

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## Annex 13. IOMC Toolkit

### IOMC Toolbox for Decision-making in Chemicals Management

SUB-REGIONAL DNA CONSULTATIVE MEETING ON THE FRA EVALUATION TOOLKIT AND OTHER APPROACHES UNDER THE ROTTERDAM CONVENTION  
26 OCTOBER 2016

DAAM SETTACHAN, PH.D.  
CHULABHORN RESEARCH INSTITUTE, THAILAND  
DAAM@CRI.OR.TH

### What is the IOMC Toolbox?

- Internet-based tool developed by IOMC
- Inter-Organization Programme for the Sound Management of Chemicals: FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank, OECD
- Enables countries to identify most relevant & efficient tools to address specific national problems in chemicals management
- Focus: (i) PRTR, (ii) management scheme for pesticides, (iii) OHS, (iv) chemical accidents prevention, preparedness and response, (v) industrial chemicals management, (vi) public health management of chemicals, (vii) classification & labeling system



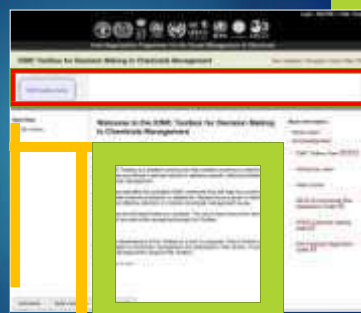
<http://www.who.int/iomc/toolbox/en/>

### Start Page

Navigation bar

Options

Info window



### Gap Analysis



### Objective selection





### Why PRTR?

- ▶ to strengthen the capabilities of countries to track the amount of certain chemicals released to air, water and land and transferred off site that may pose a threat to human health and the environment

### Why Management Scheme for Pesticides?

- ▶ to control which pesticides can be used and how thereby avoiding adverse effects to man and the environment

### Why OHS?

- to prevent or reduce the incidence of chemically induced illnesses and injuries at work and consequently to enhance the protection of the general public and environment by:
  - ensuring that all chemicals are evaluated to determine their hazards;
  - providing employers with a mechanism to obtain from suppliers information about the chemicals used at work so that they can implement effective programmes to protect workers from chemical hazards;
  - providing workers with information about the chemicals at their workplaces, and about appropriate preventive measures so that they can effectively participate in protective programmes;
  - establishing principles for such programmes to ensure that chemicals are used safely.

### Why Chemical Accidents Prevention, Preparedness & Response?

- ▶ a systematic approach to the control of hazardous substances to protect workers, the public and the environment by:
  - ▶ preventing major accidents from occurring;
  - ▶ minimizing the consequences of a major accident on site and off site

### Why Industrial Chemicals Management?

- ▶ to strengthen the capabilities of countries in assessing risks associated with industrial chemicals throughout their lifecycle and managing them safely for the protection of human health and the environment from harmful effects of industrial chemicals, protecting biodiversity and contributing to a sustainable national development

### Why Public Health Management of Chemicals?

- ▶ identify tools concerning the public health, environmental health and the medical aspects of assessing and managing chemical risks and impacts of chemicals

## Why Classification and Labeling System?

- ▶ implementing the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), which is an internationally agreed system that provides:
  - ▶ harmonized criteria for classifying substances and mixtures according to health, environmental and physical hazards; and
  - ▶ harmonized hazard communication elements, including requirements for labeling and safety data sheets

## Demonstration

<http://www.who.int/iomc/toolbox/en/>


## Annex 14. FAO Pesticide Registration Toolkit

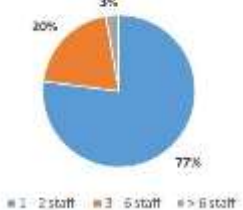

**FAO**  
**Pesticide Registration Toolkit**



**Sub-Regional DNA consultative meeting on the FRA Evaluation Toolkit and other approaches under the Rotterdam Convention**  
 Bangkok, Thailand 26 – 28 October 2016

Harold van der Valk Joost Vlaming


**Starting point**




**Perspective !?**  
 USEPA-OPP: ~ 700 staff  
 UK-CRD: ~ 150 staff  
 China ICAMA: ~ 80 staff  
 Netherlands Ctgb: ~ 120 staff


**Starting point**

Pesticide registration authorities in most developing countries tend to have **very limited resources**:


- Personnel (time)
- Specific expertise
- Finances
- Access to external information/specialists



**→ Full, or even partial, evaluations of a pesticide similar to those being conducted in resource-rich countries, are rarely possible.**

and

**→ Reinventing the wheel** (in particular if it has been well invented) is a **waste of resources**.


**IGO support for pesticide registration**


- Capacity building
- Legal & policy support
- Regional collaboration
- Technical guidance

FAO, WHO, UNEP, OECD, Conventions, ... but not well used




**→ how to provide better guidance ?!**

- Registers not aware
- Not sufficiently user friendly
- Not sufficiently interactive


**History of the Toolkit**

- FAO/WHO Joint Meeting on Pesticide Management (JMPPM) endorsed development of a **Toolkit**
- "Mock-up version" of a web-based Toolkit developed in 2011/2012
- Funding obtained by FAO for the development of a full-fledged Toolkit in late 2013
  - European Union (EU) ACP Programme
  - Organization for Economic Co-operation and Development (OECD)
  - FAO


**History of the Toolkit**


Development of the Toolkit started in early 2014

- FAO HQ coordinating unit
- Working groups of topic experts
  - Advice on contents of specific modules
  - So far: Residues, Occupational risk assessment, Registration by analogy, Pollinators & beneficials, Efficacy, Surface- & groundwater risk assessment
- Toolkit developers
  - FalConsult, Envista Consultancy, FAO IT Division
- Peer review (*ad hoc*) by registrars and experts

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## Objective of the Toolkit

- Make **existing information** relevant for pesticide registrars available “at fingertips”
- Provide **guidance** about key registration procedures and methods in an interactive manner
- Assist registrars in **informed decision making**
- Create a basis for **training and capacity building** of pesticide registration authorities




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## Pesticide Registration Toolkit

**What is the Toolkit (and what not)**

- **Decision support system** for pesticide registrars in developing countries
- Web-based registration **handbook intended for day-to-day use** by those involved in the registration of pesticides
- **Not an automated system** for the evaluation of pesticides. But it supports and facilitates informed decision-making by registrars
- **Focused**



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## Registration Tools [not pesticide-specific]

→ Processes and procedures

- Get advice on what **registration strategy** to follow
- Get advice on **steps in the registration process**
- Assess **data requirements and testing guidelines** for the evaluation of a specific type of pesticide for a particular **IIOP**
- Access **evaluation methods** for the various aspects of the pesticide registration dossier
- Get advice on **risk mitigation** measures
- Get advice on **decision making** principles and procedures

Hazardous Pesticides

Food and Agriculture Organization of the United Nations

## Links to Information Sources [pesticide-specific]


- **Existing registrations** through national databases/lists
- **Restrictions and bans** by international conventions
- **Scientific reviews** by reputable international and national bodies
- **Hazard classifications and labels**
- **Pesticide properties databases with** information on individual pesticides
- **Maximum residue limits (MRLs)**
- **Pesticide specifications**

Hazardous Pesticides

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## Pesticide registration toolkit

- Work in progress!
- Many elements of the Toolkit have not yet been (completely) filled in
- Need feedback on structure and contents by pesticide registration staff ♦ This workshop!



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## Toolkit home page

<http://www.fao.org/pesticide-registration-toolkit>



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[illegible]



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## Assessment methods

### Use of the Tool

- Assessment methods for **specific aspects** of the pesticide registration dossier
- Existing methods, whenever available
- Assessment methods at **different levels of complexity**:
  - relatively simple ➤ more complex
  - less precise ➤ more locally specific
  - less resources ➤ more resources needed
- Clarify **assumptions** underlying each method → assessment uncertainties (possibility to "have it wrong")

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[illegible]

**Finding an assessment method**

**Output of a search**

The following assessment methods are available

Severity level	Assessment
Low	[A06-21-01] Worker hazard assessment
Medium	[A06-21-03] Worker exposure models and local risk assessment [A06-21-02] Bridging of existing worker risk assessment
High	[A06-21-04] Worker exposure measurements*

**Assessment methods**

**Environmental and health risks**  
typical scheme

**Hazard assessment**

↓

**Bridging existing risk assessment**

↓

**Local risk assessment**


↓

**Local studies/monitoring**

**RESOURCES**

Personnel  
Expertise  
Finances

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## Assessment methods

For each assessment method, is provided:

- **Summary**
  - Principle
  - Data required
  - Procedures
  - Interpretation of the outcomes
- **More detailed explanatory pages** (if needed)
- **Assessment Summary Table** to capture the results of the assessment for a given pesticide and use.
- **External links** to guidelines, spreadsheet calculators, simulation models, etc.

Note: the Toolkit **does not** calculate itself the accuracy risks !!

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## Toolkit and the Rotterdam Convention

- **Toolkit**
  - Registration of pesticides:
  - Sale and use approval of pesticides based on evaluation of its effectiveness, targeted mode of action and safety (no risk for human health and environment)
  - Regular or unscheduled review of previously registered pesticides
  - Re-evaluation
- **Rotterdam Convention**
  - Article 1 (Objective of the Convention) – *to promote shared responsibility and cooperative efforts among Parties in the international trade of certain **hazardous chemicals** in order to **protect human health and the environment from potential harm** and to contribute to the **refused approval for free-time use** or **has been withdrawn** by industry either from the domestic market or from further consideration in the domestic approval process and where there is clear evidence that such action has been taken **in order to protect human health or the environment**;*
  - Article 2 (Definitions for Banned or Severely restricted chemical) - *all uses of which within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a chemical that has been **refused approval for free-time use** or **has been withdrawn** by industry either from the domestic market or from further consideration in the domestic approval process and where there is clear evidence that such action has been taken **in order to protect human health or the environment**;*
  - Article 5 (Procedures for banned or severely restricted chemicals):
  - **Annex I** (Information requirements for notifications made pursuant to Article 5)
  - **Annex II** (Criteria for listing banned or severely restricted chemicals in Annex III)

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## Toolkit and the Rotterdam Convention

- **Toolkit uses Rotterdam**
  - Annex III
  - Notifications of bans and severe restrictions
  - DGDs
  - Bridging approach to risk assessment
- **Rotterdam could make use of Toolkit**
  - Strengthened pesticide registration authorities
  - Access to methods for pesticide risk assessment




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## Using the Pesticide Registration Toolkit to facilitate identification of Hazardous Pesticides (HPs)



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## Criteria to identify HPs

- WHO class Ia & Ib
- GHS Categories 1A & 1B for carcinogenicity, mutagenicity & reproductive toxicity
- Rotterdam Convention Annex III
- Stockholm Convention Annex A & B, and meeting criteria Annex D
- Montreal Protocol
- High incidence of severe and irreversible adverse effects

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## Identification of HPs

Main tools to facilitate with the identification of HPs:




### Information Sources

- **Restrictions and bans** by international conventions
- **Hazard classifications and labels**
- **Pesticide properties databases with** information on individual pesticides

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Decision areas	Consequences
<p><b>Scope</b></p> <p>Worldwide agriculture-oriented            Organization for the purpose to influence the socio-economic and other conditions, an attempt will be to foster an optimal health of the environment under the conditions of some free market of export.</p> <p>Healthly agriculture is shaped by</p> <ul style="list-style-type: none"> <li>• International legislation</li> <li>• Other national legislation (climate environment, health and phytochemical development)</li> <li>• Agricultural health and other conditions in the country</li> </ul>	
<p><b>Assessment of risks, values and distribution</b></p>	<p><b>Ways to foster health</b></p> <ul style="list-style-type: none"> <li>• 2000 assessment</li> <li>• Future assessment</li> <li>• The probability of entry</li> <li>• Risk assessment</li> </ul> <p><b>Ways to the environment</b></p> <p><b>Values</b></p> <ul style="list-style-type: none"> <li>• Efficiency</li> <li>• Sustainability</li> <li>• Autonomy</li> </ul> <p><b>Alternatives</b></p> <ul style="list-style-type: none"> <li>• Technology</li> <li>• Not possible alternative</li> </ul>
<p><b>Risk management</b></p>	<p>Introduce of risk mitigation measures</p> <p>Identification and analysis of options</p> <p>e.g. migration point or another risk mitigation measures, national agriculture health mitigation measures, national agriculture food safety, agricultural participation of agricultural development, the agricultural health, farming of the agricultural, conditions of the agricultural</p> <p>Implementation of the risk mitigation measures</p>
<p><b>Monitoring and evaluation</b></p>	<p><b>Impacts &amp; Consequences</b></p> <p><b>Scarcity</b></p> <p><b>Foodstuffs</b>            (e.g. food, oil, distribution, and supply)</p>

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Pesticide Registration Toolkit

Welcome to the FAO Pesticide Registration Toolkit

Information resources

- Add new book
- Pesticide regulations
- Other contacts
- Registration procedures
- Registration guidelines
- Guidelines for use
- Guidelines for safety
- Guidelines for classification
- Guidelines for labeling
- Guidelines for pesticide safety
- Guidelines for pesticide management
- Guidelines for pesticide application

Let's check it out!



Annex 15: The WHO Human Health Risk Assessment Toolkit: Chemical Hazards

### The WHO Human Health Risk Assessment Toolkit: Chemical Hazards



**For whom + purpose**

- For developing countries and countries with economies in transition
- For people who need to conduct chemical risk assessments
- Helps to assess the health risks from chemical exposures
- Designed for all chemical exposure scenarios
- Promotes information developed by international organizations

**Content**

- Road maps for conducting human health risk assessment
- More than 90 references and web links to international resources
- Case studies that illustrate the chemical risk assessment process



2 | WHO Toolkit | April 7, 2017



**Detailed**




sk

**More than 90 web links to resources from international organizations**



3 | WHO Toolkit | April 7, 2017



**Case studies for illustration**

Water pollution



Air pollution



Pesticide use



5 | WHO Toolkit | April 7, 2017




**WHO Toolkit available soon as a web-application!**





eToolkit design



A – Stages in the process


B – Template for each stage

C – Login/logout

D – Links to key references


E – Save and proceed

7 | WHO Toolkit | April 7, 2017




eToolkit


Templates to document information



Automated reporting




8 | WHO Toolkit | April 7, 2017



- The WHO Toolkit is available at:  
[http://www.who.int/ipcs/methods/harmonization/areas/ra\\_toolkit/en/](http://www.who.int/ipcs/methods/harmonization/areas/ra_toolkit/en/)
- The WHO eToolkit will be released later in 2015.
- Further information is available from [gutschmidt@who.int](mailto:gutschmidt@who.int)

9 | WHO Toolkit | April 7, 2017



## Annex 16. Electronic Distance Learning Tool on Risk Assessment & Management of Chemicals

### Electronic Distance Learning Tool on Risk Assessment & Management of Chemicals

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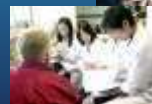
### CRI's Capacity Building Programme

Short-term and long-term training in environmental health science and toxicology



- **Short-term:**  
2-3-week courses geared mainly towards government officials from the South-East Asian region (Environmental Toxicology; Occupational & Environmental Medicine; & Risk Assessment)

- **Long-term:**  
international, graduate-level education in  
(a) Chemical Biology,  
(b) Applied Biological Sciences  
– Environmental Health,  
(c) Environmental Toxicology



### Training on risk assessment

- CRI has organized face-to-face training on risk assessment and toxicology, both at CRI and in-country, for the past 25 years
- Annual international training course on risk assessment and risk management of chemicals - three weeks, face-to-face - includes case studies and WHO HHRA Toolkit
- Despite this and other similar efforts, there is a lack of a critical mass of personnel in the region qualified to conduct risk assessments

### Need for distance learning tool

- On site, hands-on training, with interactions with experts is ideal; however, 3 weeks can be disruptive to everyday work
- Distance learning tool allows users to learn at their own pace with minimal disruption to their jobs/responsibilities
- Allows for exposure of training material to wider audience

### SAICM QSP eDLT Project

- SAICM Quick Start Programme (QSP) project: "Development of course materials & a DLT for the assessment of risk from the use of chemicals to support SAICM's capacity building efforts in developing countries"
- Collaborating partners: CRI (executing agency), WHO/IPCS, University of Ottawa, Utrecht University

### SAICM QSP eDLT Project

- Aim: build up critical mass of qualified personnel in Risk Assessment
- By:
  - make available globally-relevant material in the area of RA, RM & toxicology
  - develop DLT/courseware & make available
  - expand & strengthen network of scientists in RA in developing countries

## eDLT modules

Module	Title
1	Introduction
2	Problem Formulation
3	Hazard Assessment
4	Exposure Assessment
5	Risk Characterization - human
6	Risk Characterization - ecological
7	Risk Management
8	Risk Communication

## SAICM QSP eDLT Project

- Outcomes:
  - peer-reviewed distance learning material
  - globally applicable eDLT/courseware
  - successful training of participants from AP
  - strengthening capacity to manage chemicals in developing countries

## Launch of eDLT



## Using the eDLT

- eDLT is administered through a Learning Management System (LMS), used to manage registration, access, user progress monitoring, etc.
- A nominal fee is charged to cover expenses involved with the upkeep and maintenance of the eDLT
- Interested persons should contact CRI to request access; a username and password will then be issued, along with the time limit for completing the course
- IT experts available to troubleshoot problems with access and use, while questions on the content can be sent to CRI
- Each module has a quiz to evaluate understanding

## eDLT demonstration

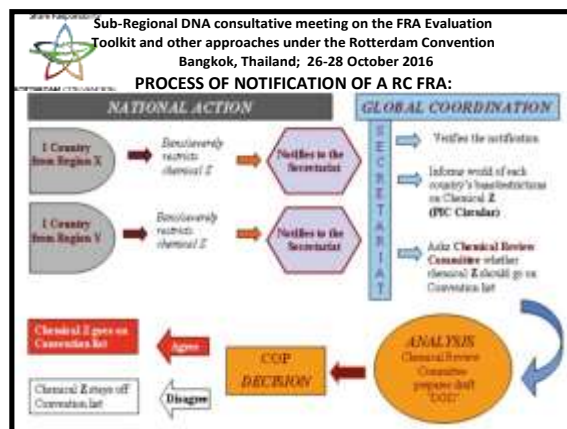
- <http://www.chemDLT.com>

## Annex 17. Facilitator

Sub-Regional DNA consultative meeting on the FRA Evaluation Toolkit and other approaches under the Rotterdam Convention  
Bangkok, Thailand; 26-28 October 2016

## Notification of Final Regulatory Actions under the Rotterdam Convention – Bridging Information

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When a Party submits a notification of final regulatory action, the risk evaluation and the “bridging” information must be sufficient to fulfil the criteria in Annex II (b) (iii) for this notification to be a trigger for further consideration under the Convention.

- The CRC will consider such bridging information on a case-by-case basis. In reviewing the information, the Committee will apply the following principles:
  - Exposure or potential exposure is a key element;
  - The information should be science-based, on the best available knowledge;
  - The information should also be sufficiently detailed to enable the CRC to make an assessment.

The following elements, if relevant for the final regulatory decision, should be considered in comparing the exposure scenario in the country that completed the original risk evaluation or the relevance of the exposure scenarios considered in the international risk evaluation to the conditions prevailing in the notifying country that has used that risk evaluation in support of its notification of final regulatory action. They address both human health and environmental exposure.

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#### A. Pesticides

Information to facilitate a comparison of human exposure between countries or to demonstrate relevance of an international risk evaluation could include:

- The form in which the chemical was used in both countries or a comparison of the form in which the chemical is used in the notifying country to those which were considered in the international evaluation;
- Formulation type:
  - Liquid, powdered, granular and so on;
  - Concentration of active ingredient(s);
- Contaminants:
- How the chemical is used in both countries or a comparison of the use conditions in the notifying country to those which were considered in the international evaluation;
- Use pattern:
  - Type of use (agricultural pesticide, non-agricultural pesticide, use as disinfectants, vector control, wood preservatives)
  - Rate, frequency and period of application
  - Method of application (spray, drip, dip)
  - Application equipment (back pack sprayer, air blast sprayer, etc.)
  - Greenhouse, field application, post-harvest, other
  - Storage conditions
- If applied in the field: climatic or geographic conditions, comparability between the countries or relevance of the conditions and assumptions of the international evaluation (e.g. ozone depletion is most relevant in polar regions but might still pose problems at lower latitudes and higher altitudes or chemicals with persistent, bioaccumulating and toxic properties such as POPs, or chemicals derived from certain heavy metals such as mercury might pose problems for human health in the notifying country, e.g. via the food chain).

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#### A. Pesticides...2

(c) Risk mitigation measures in both countries - relevance of restrictions/precautions on use in the country that undertook the risk evaluation or relevance of recommended risk mitigation measures from international evaluations, such as:

- Human health effects:**
  - Requirement for protective clothing, whether it is typically available and/or feasible in the country reporting the regulatory action
  - Special application equipment, whether it is typically available and/or feasible in the country reporting the regulatory action
  - Occupational exposure limit.

Information to facilitate a comparison of environmental exposure:

- The form in which the chemical was used in both countries or a comparison of the use conditions in the notifying country to those which were considered in the international evaluation:
  - Formulation type:
    - Liquid, powdered, granular, etc.
    - Concentration of active ingredient(s)
  - Contaminants
- How the chemical is used in both countries or a comparison of the use conditions in the notifying country to those which were considered in the international evaluation:
  - Use pattern:
    - Rate and frequency of application
    - Method of application (spray, drip, dip, etc.)
    - Application equipment (back pack sprayer, air blast sprayer, etc.)
    - Greenhouse, field application, post-harvest, etc.

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#### Pesticides...3

(ii) If applied in the field, environmental conditions such as climatic conditions, soil type and non-target organisms; comparability between the two countries or relevance of the conditions and assumptions of the international evaluation (e.g. ozone depletion is most relevant in polar regions but might still pose problems at lower latitudes and higher altitudes or chemicals with persistent, bioaccumulating and toxic properties such as POPs, or chemicals derived from certain heavy metals such as mercury might pose problems in the environment of the notifying country)

(c) Risk mitigation measures - relevance of restrictions/precautions on use in the country that undertook the risk evaluation or relevance of recommended risk mitigation measures from international evaluations, such as:

- Effects on non-target organisms:
  - Buffer zones to protect sensitive areas such as water bodies or species habitats; whether such zones are enforceable in the notifying country
- Other environmental effects.

The description of indirect exposure via the environment should address the following:

- How the presence of a chemical in the environment, results in (actual or potential) exposure of humans or organisms in the environment. Actual exposure can be directly measured. Potential exposure can be estimated.
- An explanation of how the exposure relates to the problem which was the reason for the regulatory action, taking into account the hazards of the chemical.

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Pesticides...4

(c) Risk mitigation measures - relevance of restrictions/precautionson use in the country that undertook the risk evaluation or relevance of recommended risk mitigation measures from international evaluations, such as:

(i) Effects on non-target organisms:

a. Buffer zones to protect sensitive areas such as water bodies or species habitats; whether such zones are enforceable in the notifying country

(ii) Other environmental effects.

The description of indirect exposure via the environment should address the following:

(a) How the presence of a chemical in the environment, results in (actual or potential) exposure of humans or organisms in the environment. Actual exposure can be directly measured. Potential exposure can be estimated.

(b) An explanation of how the exposure relates to the problem which was the reason for the regulatory action, taking into account the hazards of the chemical.

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B. Industrial chemicals

Information to facilitate a comparison of human exposure between countries or to demonstrate relevance of conditions considered in an international risk evaluation could include information on:

(a) Workers

(b) General population

(c) End users

(d) Others (for example specific subgroups of the population such as children, pregnant women or the elderly)

Information to facilitate a comparison of environmental exposure between countries or to demonstrate relevance of conditions considered in an international risk evaluation:

(a) Soil, air, water

(b) Habitat

(c) Wildlife.

Description of events leading to exposure either as described in the notification of another country or in the international evaluation such as one or several of the following examples:

(a) Production process: e.g., where releases to air during production or processing of the chemical leads to general population exposure;

(b) Patterns of storage and distribution;

(c) Patterns of use: e.g., where the product is used on fabric, consumers are subjected to dermal exposure from clothing made from the treated fabric;

(d) Patterns of disposal: e.g., disposal of chemical on land leads to ground water contamination.

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Industrial chemical...2

Description of the key factors, such as one or several of the following examples, affecting the chain of events leading to exposure:

(a) The form in which the chemical was used in both countries or a comparison of the use conditions in the notifying country to those which were considered in the international evaluation:

(i) Formulation type (where appropriate)

(ii) Concentration of the chemical

(iii) Contaminants.

(b) If release is associated with the production process, description of the production process:

(i) What are the key factors affecting release?

a. Open or closed

b. Waste water treatment (if relevant)

(ii) What options exist for controlling release or exposure?

a. Exposure limits

b. Protective equipment.

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Industrial Chemical..2

(c) If release is associated with storage and distribution, description of the storage and distribution process:

(i) What are the key factors affecting release?

(ii) What options exist for controlling release or exposure?

(d) If release is associated with use, description of use:

(i) What are the key factors affecting release?

(ii) What options exist for controlling release or exposure?

(iii) Hazard communication

(e) If release is associated with disposal, description of the disposal process:

(i) What are the key factors affecting release?

(ii) What options exist for controlling release or exposure?

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Industrial ..3

Any other relevant information demonstrating similarity in conditions as described by another notifying country, e.g. incident reports, monitoring data, or relevance of the conditions and assumptions of the international evaluation (e.g. ozone depletion is most relevant in polar regions but might still pose problems at lower latitudes and higher altitudes or chemicals with persistent, bioaccumulating and toxic properties such as POPs, or certain heavy metals such as mercury or their compounds might pose problems to human health (e.g. via the food chain) or in the environment of the notifying country).

The description of indirect exposure via the environment should address the following:

(a) How the presence of a chemical in the environment results in (actual or potential) exposure of humans or organisms in the environment. Actual exposure can be directly measured. Potential exposure can be estimated, e.g. by using models.

(b) An explanation of how the exposure relates to the problem which was the reason for the regulatory action, taking into account the hazards of the chemical.

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## THANK YOU FOR YOUR ATTENTION

NOLUZUKO (ZUKIE) GWAYI  
SENIOR POLICY ADVISOR (DIRECTOR): INTERNATIONAL CHEMICALS AND WASTE COOPERATION  
DNA & FOCAL POINT: Basel, Rotterdam, Stockholm, SAICM, Vienna & Montreal, Minamata  
CHEMICALS MANAGEMENT  
DEPARTMENT OF ENVIRONMENTAL  
AFFAIRS REPUBLIC OF SOUTH AFRICA

## Annex 18. Facilitator

Sub-Regional DNA consultative meeting on the FRA Evaluation Toolkit and other approaches under the Rotterdam Convention  
Bangkok, Thailand; 26- 28 October 2016

**NATIONAL COORDINATION  
AND  
REGIONAL COLLABORATION**

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Bangkok, Thailand; 26- 28 October 2016

**NATIONAL COORDINATION :**

**CHALLENGES WITH CHEMICALS MANAGEMENT & RESEARCH**

- ❖ Lack of awareness and knowledge amongst the general public.
- ❖ Illiteracy and lack of knowledge.
- ❖ Some awareness programmes developed (e.g. at the workplace), but not extended to end-users.
- ❖ Lack of easily accessible, user-friendly information on chemical hazards, production, and use.
- ❖ Limited information on chemicals in products, lack or inadequate tracking or audit system to track chemicals from production or import to secondary use and final disposal.
- ❖ Information on chemical risks to human health and the environment is often with Industry.
- ❖ Few chemicals have been thoroughly assessed for risk before they are introduced into the market, and impacts are largely undetermined.

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Bangkok, Thailand; 26-28 October 2016

**CHALLENGES OF A FRAGMENTED APPROACH:**

- ❖ Fragmentation and duplication of legislative responsibilities amongst Government Departments/Ministries.
- ❖ Certain overlaps in mandates exist (stepping on people's toes).
- ❖ Generally there's no specific Act aimed at domesticating Chemicals and Waste MEA's.
- ❖ A general lack of monitoring and enforcement throughout the life cycle of chemicals.
- ❖ Most research on chemicals is on an ad hoc basis, not coordinated to address country needs and priorities and mainly based on academic interests or funding specifications. The research-policy interface is poor.

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Bangkok, Thailand; 26- 28 to 30 October 2016

**EASY TARGETS/LOW HANGING FRUITS FOR RC FRA NOTIFICATIONS:**

- **Rotterdam Convention:** A priority list of chemicals exists.
- **Stockholm Convention:** listed chemicals and candidate POPs not in Annex III of RC.
- **UNEA:** Lead & Cadmium
- **Minamata:** Mercury
- **National problematic chemicals** –stakeholders (especially researchers & Civil Society Organisations) key in identifying these.
- **SAICM Emerging issues (nominated; in the process of nomination and those of concern):**
  - ❑ Endocrine Disrupting Chemicals & substitute alternatives.
  - ❑ Hazardous substances within the life cycle of electrical & electrical products
  - ❑ Lead in Paint
  - ❑ Chemicals in products
  - ❑ Nanotechnology and manufactured nanomaterials
  - ❑ Environmentally persistent pharmaceutical pollutants (EPPPs)
  - ❑ Highly hazardous pesticides (HHPs)
  - ❑ Perfluorinated chemicals.

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Bangkok, Thailand; 26-28 October 2016

**22 priority restriction/disabling pesticides for phase-out**

Thailand may have 22 pesticides, but only 10 are in the PIC database (2011)

Chemical	ICM	Rotterdam Convention	Stockholm Convention	Minamata Convention
Alachlor	Yes	Yes	Yes	Yes
Carbofenthrin	Yes	Yes	Yes	Yes
Chlorpyrifos	Yes	Yes	Yes	Yes
Cyfluthrin	Yes	Yes	Yes	Yes
Deltamethrin	Yes	Yes	Yes	Yes
Endosulfan	Yes	Yes	Yes	Yes
Fenitrothion	Yes	Yes	Yes	Yes
Imidacloprid	Yes	Yes	Yes	Yes
Malathion	Yes	Yes	Yes	Yes
Permethrin	Yes	Yes	Yes	Yes
Phosalone	Yes	Yes	Yes	Yes
Quinalphos	Yes	Yes	Yes	Yes
Terbufos	Yes	Yes	Yes	Yes
Thiodan	Yes	Yes	Yes	Yes
Triphenylethylene	Yes	Yes	Yes	Yes
Triphenylethylene	Yes	Yes	Yes	Yes
Triphenylethylene	Yes	Yes	Yes	Yes
Triphenylethylene	Yes	Yes	Yes	Yes
Triphenylethylene	Yes	Yes	Yes	Yes
Triphenylethylene	Yes	Yes	Yes	Yes
Triphenylethylene	Yes	Yes	Yes	Yes
Triphenylethylene	Yes	Yes	Yes	Yes
Triphenylethylene	Yes	Yes	Yes	Yes
Triphenylethylene	Yes	Yes	Yes	Yes

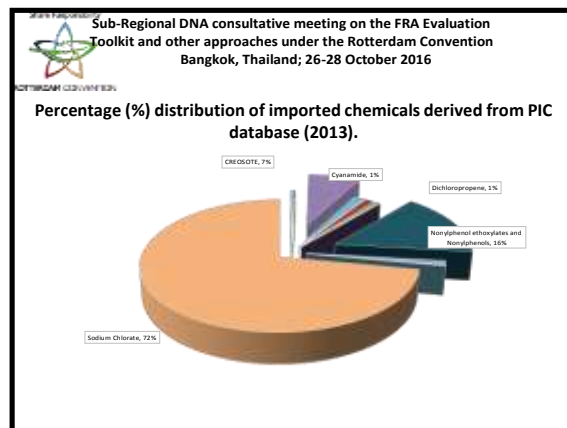
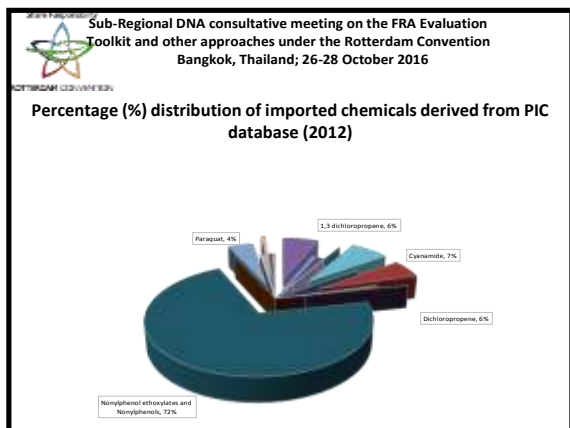
IPEN

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Bangkok, Thailand; 26-28 October 2016

**USE OF PIC DATABASE FOR IMPORT RESPONSES:**

**Percentage (%) distribution of imported chemicals derived from PIC database (2011)**

Chemical	Percentage (%)
Paraquat	26%
1,3-dichloropropene	26%
Carbamide	23%
Nonylphenol ethoxylates	16%
Nonylphenols	16%
Azine	3%



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Lusaka, Zambia; 28 to 30 May 2016

**SHARING IMMEDIATELY CRC INFORMATION TO**

**STAKEHOLDERS: CRC 12 & POPRC 12 ASSESSED CHEMICALS**

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**KEY RELEVANT STAKEHOLDER (not exhaustive) & VARIES NATIONALLY:**

- **Dept. Science & Technology**-(Mandate of leading research & innovation)
- **Dept. Environmental Affairs**-(Focal Point of MEAs & mandate protecting the environment)
- **Dept. of Health** - Health SAICM Focal Point, Environmental Health Directorate (Inspectors), Poison centres, Research Directorate, pharmaceuticals, Malaria Control Directorate (DDT), water purification chemicals; etc.
- **Dept of Agriculture, Forest & Fisheries** - (pesticides management)
- **Dept. of Water Affairs**- (water as a medium of transport & a crucial resource for life)
- **Dept of Trade & Industry** - (Trade; employment); **Revenue Services**- Revenue and border monitoring
- **Dept of Labour**- (Workplace safety, and exposure)
- **Chemicals Industry**- AVCASA, CROPLIFE, CAIA, DOW Chemicals, Syngenta, Bayer CropSciences, BASF Germany, Vestegaard, Sumitomo, etc.,
- **Civil society**- Groundwork, etc., (engagement of civil society & action at ground level).
- **Academia & academic institutions** (Universities & Technicons; CSIR, WRC, MRC, ARC, Rand Water, etc.)
- **Multi-stakeholder Committee for Chemicals Management(MCCM)/Technical Committees**-(for effective functioning-needs to be in law) (close cooperative governance and input from other relevant major stakeholders).
- **Politicians**:Use language that politicians can understand.
- **Africa Institute** (Regional Perspective & possible funding)

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**CHEMICALS OBSERVATORY (ChemObs): A UNEP TOOL FOR ESM**

- ❖ **National Emerging Issues / Chemicals Research Priorities** ??????
- ❖ **WHO: Situation Analysis and Need Assessment**???
- ❖ **National Chemicals Profile**; updated????

**WHAT IS A ChemObs ?**


- ❖ An advanced knowledge/information management system and decision making tool to be established in a national body linked to chemicals and waste mgt.
- ❖ **Aims:** Collate and collect information from stakeholders including end-users, vulnerable groups, etc., to allow policy advisors & decision makers to make recommendations on use, restriction and bans on chemicals based on evidence collected on impacts at local & national levels.
- ❖ To facilitate the link between diverse sources of information & coordination.
- ❖ To raise priority given to the ESM of chemicals through their integration into national plans and processes.

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**JUSTIFICATION AND RATIONALE FOR CHEMOBS:**


- ❖ **People have a right to know.**
- ❖ **People have a right to comprehend or understand the information made available to them.**
- ❖ **Situation Analysis and Need Assessment exercise (SANA) for countries??**
- ❖ **The SANA revealed that quantitative up-to-date data for immediate use in decision making and action is crucially missing:**
  - ❑ Incomplete information systems, fragmentation of surveillance activities, and insufficient coordination, obsolete surveillance tools and lack of standardized indicators.
  - ❑ Where data is available, its analysis to adequately inform decision-making processes remains poor.
  - ❑ Where policy recommendations exist, implementation is poor.



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**JUSTIFICATION AND RATIONALE CONT ..1:**

- ❖ The expected improvements on timely decision-making to predict and prevent environmental degradation and to minimize its impact on disease and associated risk factors are still unsatisfactory.
- ❖ It intends to provide a comprehensive and coherent health and environment inter-sectoral response to the essential capacity building and technical assistance needs.
- ❖ It aims at supporting the actions to reduce health and environment risks caused by unsound management of chemicals.
- ❖ It addresses necessary improvements in the fields of knowledge and information on chemicals, institutional coordination and regulatory frameworks and public policy to support and provide an enabling framework for the actions to be taken.
- ❖ Once established, it will facilitate the mainstreaming of chemicals into the national development agenda as it requires close cooperative governance and a multi-stakeholder engagement approach.
- ❖ The observatory will focus on chemicals controlled under MEAs and **any other priority chemicals in the country.**

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**REGIONAL/SUB-REGIONAL COLLABORATION & WAY FORWARD:**

- ❖ Chemicals respect no borders- regional collaboration is critical.
- ❖ Manila declaration of 2016 by Ministers of Health and Ministers of Environment at the Asia-Pacific Regional Forum on Health and Environment 6-8 October 2016, Manila, Philippines
  - ❖ Identified ESM of chemicals as critical for the region's health & environment priorities, specifically towards achievement of the Sustainable Development Goals (SDGs).
- ❖ There is need to strengthen the science & policy interface as one of the essential initiatives towards protecting the environment and human health.
- ❖ There is need for government, researchers & industry to work together in ensuring that countries have the relevant information by providing the necessary empirical data for the country to make appropriate policy decisions (eg.,FRA).
- ❖ Research should inform policy; policy advisors & developers should influence research.
- ❖ Facilitate shared research evidence on the chemicals and hazardous waste sector to provide a coherent platform for academics working on chemicals and hazardous waste and how this links and contributes towards the National Development Plan & International Fora (eg., CRC).

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**NATIONAL, REGIONAL COLLABORATION & WAY FORWARD CONT'D:**

- ❖ There's need for the health sector to conduct research to establish whether there are diseases relating to chemicals exposure.
- ❖ There's need to build capacity on how health practitioners manage poisoning incidents (adapt and adopt the FRA form).
- ❖ There's need to establish and strengthen research-policy:
  - ☐ Academics come together to share information;
  - ☐ Government can influence research undertaken to address country needs & priorities- conduct research on prioritised chemicals
  - ☐ Research results can assist in making informed policy decisions-FRAs
- ❖ There's need to have a platform for networking among DNAs and the BRS
- ☐ The early warning system is needed in order to provide timely and evidence based information to predict, prevent and reduce chemicals risks to the environment and human health.
- ❖ There's need for awareness raising & a platform on the possible appropriate policy interventions that could be undertaken to mitigate against risks.
- ☐ Maximize resource mobilization, and coordination amongst all key stakeholders.

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**THANK YOU FOR YOUR ATTENTION**

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DNA & FOCAL POINT: Basel, Rotterdam, Stockholm, SAICM, Vienna & Montreal, Minamata  
CHEMICALS MANAGEMENT  
DEPARTMENT OF ENVIRONMENTAL  
AFFAIRS REPUBLIC OF SOUTH AFRICA



## Annex 19: National Roadmaps

### Cambodia

#### CAMBODIA

- 1- Five Chemical to be notified
- 2- Action plan

#### 1- Five Chemical to be notified

- Amitraz
- Chlordecone
- Dichlorophen
- Methyl parathion
- Mirex

#### 2- Action plan

##### A-Import response

MIH will review the status of use and import of industrial chemical in Annex III and will inform the DNA the decisions on future import of all industrial chemical in Annex III.

##### B-Notification of final regulatory action

DNA will prepare and submit an initial set of notification on banned pesticides (5 top priority)

## Islamic Republic of Iran



### Developing the national incident report mechanism

Request the " Environmental Risk Committee  
" (The National Disaster Management Organization) to :

1. Develop a regulated structure and relevant guidance for incident reporting ,
2. Establish the online incident registration at provincial level with access of relevant headquarters
3. Planning and developing a program for immediate response to incident with cooperation and responsibilities of each national authorities

### "national criteria "

- ▶ Definition and specification the "national criteria " for listing the chemicals for FRAs
  - ▶ Providing a national list of chemicals according the mentioned criteria and with consideration of environmental and health priorities.
- 1) the subsidiary Committee of Hazardous Wastes and Chemicals based in the Department of Environment. (for industrial chemicals)
- 2) the Pesticides Supervisory Board based in the Plant Protection Organization. ( for pesticides)

- ▶ emphasis on the importance of full implementation of Article 5 -RC and with taking into account the contents of Annex 1
- ▶ Transfer the findings and results of this meeting to relevant authorities and introduce of all toolkits and databases which we learned during this consultative meeting to relevant technical staff,
- ▶ Complete the FRA forms for the chemicals below by Iran's DNAs with the help of researchers and experts (chemists , toxicologist ,...)
- ▶ Submit the completed forms in the national committees for finalizing and approving the forms before sending to the Secretary)

### high priority chemicals for possible regulatory actions)

- ▶ Industrial chemicals:
  1. Chrysotile (white asbestos)
  2. Pentadecafluorooctanoic acid and its salts and esters(PFOA)
  3. Decabromodiphenyl ether
  4. Short-Chain Chlorinated Paraffin (SCCP)
- ▶ Pesticides :
 

Dicofol , fention and Amitraz some other pesticides such as : azinphos-ethyl, carbaryl , carbofuran, Chlorfenvinphos, cyhexatin, dirotophos , endrin,,lead arsenate, methyl parathion , nitrofen , phosphomidon , trazophos

- ▶ For the next list of the chemicals we should convince the national decision-makers to agree to the costs necessary to carry out risk assessment based on studies and investigations, laboratory tests as well as environmental and health monitoring (Through correspondence and meetings(
- ▶ Planning and implementation so that the final regulatory action has been taken in order to protect human health or the environment (Transparent and based on scientific results and the rules & regulations)
- ▶ National planning not to import the chemicals from countries that the use of those chemicals have been banned in their countries.

## Lao Peoples Democratic Republic

Country's National Coordination for Follow up action on priority chemical

### Current status

Country Profile	
Lao People's Democratic Republic	
Administrative State	10/10/2010
Official contact person: G.P.P.	0
Designated national authority: G.P.P.	0
Current legislation	17
Notification of List of Regulated Substances (Annex III of Convention)	0
Progress of Domestic Regulation Programme	0
Technical assistance: Address	10
Contact information	Address: Vientiane, Lao PDR Phone: +856 21 234 567 Email: info@lao-pdr.gov.la
Rotterdam Convention - Lao People's Democratic Republic	

### Priority pesticide

- Industrial Chemical
  - Crocidolite
  - Polybrominated biphenyls (PBB)
- Pesticide
  - Calcium arsenic
  - Endrin
  - Paraquat


### Country's National Coordination

- Ministry of Natural Resource and Environment
- Ministry of Agriculture and Forestry
- Ministry of Industry and Commerce
- Ministry of Health
- Ministry of Energy and Mining
- Ministry of Education/National University of Lao
- Ministry of National security
- Custom Department

### Action plan

- Complete FRA Notification form for 5 priority chemicals (within 2 weeks)
- Review list of banned pesticide and industrial chemical
- Establish Chemical committee for registration and review of banned pesticide
- Notify Custom and trade sector on the import control of Chemical listed in Annex III of Rotterdam convention
- Coordinate with Chemical committee to monitoring/survey on the impact of priority chemical on health and environment
- Data collection on priority current situation of pesticide and industrial chemical use


## Philippine



### INDUSTRIAL CHEMICAL AND PESTICIDE REGULATIONS IN THE PHILIPPINES


BY:

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 Supervising Science Research Specialist  
 Environmental Quality Management Division  
 DENR - EMB  
 October 26-28, 2016



### REGULATORY MANAGEMENT PROFILE (Industrial Chemical)

- **Environmental Management Bureau (EMB)**
- **Mandate:**  
 "To implement various national environmental laws (PD 1586, RA 8749, RA 9003, RA 9275, RA 9512 and RA 6969 or the Toxic Substances and Hazardous and Nuclear Waste Control Act of 1990)"
- **Functions:**
  - Advise the DENR Secretary on matters relating to Environmental Management
  - Formulate plans and policies and set appropriate environmental quality standards (Water, Air, chemicals & hazardous waste) for the prevention, control of pollution and protection of the environment
  - Oversee 17 regional offices in the implementation and enforcement of environmental plans and programs
  - Issue permits and clearances under PD 1586, RA 8749, RA 9275, RA 9003, and RA 6969 and monitor compliance to said laws
  - Develop and implement a research and development program in support of the following:
    - Environmental and Compliance Monitoring
    - Study of existing and potential environmental problems and issues
    - Act as Focal Point and Secretariat to International Conventions



### Four (4) Major Services in Chemical Management

CHEMICAL POLICY FORMULATION & AMENDMENT	PERMITTING AND CLEARANCE PROCESSING & ISSUANCE (ON-LINE)	MONITORING, ASSESSMENT & CAPACITY BUILDING	TECHNICAL ASSISTANCE/ STRATEGIC PARTNERSHIPS
Review and Evaluation, Public Consultation	PreManufacture and Preimportation Notification for New Chemicals *	Regional Assessment and Monitoring	LOCAL (NGO/CSO, Interagencies)
Formulation of DAOs and MOS	Priority Chemical List Compliance Certificate**	Self-Monitoring Report (SMR) from Industry Sector	International Commitments/ Conventions (MEAs)
Amendment & phase-out of existing DAOs in relation to int'l R & R	Chemical Control Orders (CCOs)**2017	Training and capacity building of Regulators and Regulated community	APEC CD/SAICM

**MULTI-STAKEHOLDERS INVOLVEMENT & PARTNERSHIPS IN EVERY PROCESS**


Note: \*/\*\* The PMPIN notification has provided for the updating of the inventory of all existing unregulated chemicals and chemical substances (PCCS)  
 \*\* An Interagency Chemical Review Committee (IRC) is delegated to assist EMB in the review of new chemicals and toxic substances proposed for regulatory actions

The framework of chemical management in the Philippines is based on the Strategic Approach to International Chemical Management (SAICM) influence of various national, regional and international conventions.



### REGULATORY MANAGEMENT PROFILE (Pesticide)


- **Fertilizer and Pesticide Authority (FPA)**
- **Mandate:**  
 "To assure adequate, safe and affordable supply of fertilizers and pesticides, rationalize the manufacture and marketing of fertilizers, protect the public from risks inherent to pesticides, and educate the agricultural sector on the proper use of these inputs."
- **Functions:**
  - **Regulation and control**
    - Registration of pesticide products
    - Licensing of all handlers of pesticides
    - Regulatory and enforcement action
  - **Information**
    - Training and accreditation programs
    - Dissemination of info materials
    - Media liaisons
  - **Development**
    - Industry support
    - Cooperation and coordination initiatives



### Four (4) Major Services in Pesticide Management

Policy Formulation	Registration	Issuance	Monitoring
Coordinate and formulate the framework for pesticide management	Review the completeness of data requirements	Review the completeness of requirements	Monitor compliance the service provided in the field
Conduct stakeholder consultation	Provide submitted data requirements to tech. consultation	Provide testing of formulation, residue (s), identification info.	Coordinate investigations of compliance to case of violation
Coordinate and formulate the policies of PPTAC and FPA 2003	Approval/Disapprove pesticide registration	Approval/Disapprove the release of buffer	Generate and submit national data for policy formulation and decision-making

PPTAC – Pesticide Policy and Technical Advisory Committee (pool of scientists and technical consultants)



### NATIONAL INCIDENT REPORT MECHANISM

Government Coordination Mechanisms

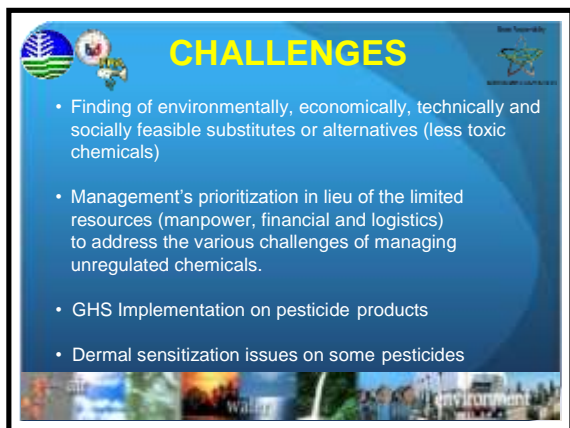
Creation of an Inter-Agency Task Force	Formation/ Organizational Structure	Coordination Meetings and Tasking in accordance with Mandates
Review of the Environmental Technology Verification (ETV) for the MPE	Sampling and Analysis	Deliberation, Agreements & National Report

**IATAC**  
 • Inter-Agency Technical Advisory Council of RA6969  
 • DENR, DOH, DTI, DOST, DND, DFA, DOLE, DOF, DA, Director of PNRI, Representative from the non-governmental organization on health and safety

**IAC**  
 • Inter-Agency Committee on Occupational Safety and Health  
 • DOH-NCDCS, UP-NPCIS, ECOP, LACC, FFW, TUOP, TUPAS, POOM, IRR, ICISCI, ICHSAD

**PPTAC**  
 • Pesticide Policy and Technical Advisory Committee  
 • DENR, DOH, DOLE





## CHALLENGES

- Finding of environmentally, economically, technically and socially feasible substitutes or alternatives (less toxic chemicals)
- Management's prioritization in lieu of the limited resources (manpower, financial and logistics) to address the various challenges of managing unregulated chemicals.
- GHS Implementation on pesticide products
- Dermal sensitization issues on some pesticides



## Thank You Very Much for Listening!

[www.emb.gov.ph](http://www.emb.gov.ph)  
[www.chemicals.gov.ph](http://www.chemicals.gov.ph)  
[fpa.lsd@gmail.com](mailto:fpa.lsd@gmail.com)

## Thailand

### Hazardous Substances Management in Thailand: Proposed list of chemicals for review



n Convention Sub-regional C  
26-28 October 2016,



### Process for final regulatory actions

- Notification of Final Regulatory Action to ban or severely restrict a chemical (Article 5).
- Chemicals banned due to health and environment reasons.

#### ◆Exporting parties

- Comply with import conditions (National, PIC) for banned chemicals.

#### ◆Importing parties

- Import restrictions for banned/severely restricted/hazardous chemicals.

### Priority chemicals for review and consideration of final regulatory actions

1. Azinphos ethyl (Insecticide)-high acute toxicity, high risk to users, Toxicity class WHO (a.i) Ib
2. DDD (Insecticide)-Persistent in environment and fatty tissues of human and animals, Nervous system poisoning, Affects reproductive process of birds and fishes
3. Mevinphos (Insecticide)-very high acute toxicity, high risk to users
4. Phosphamidon (Insecticide)-very high acute toxicity, high risk to users
5. Alachlor (Herbicide)-very high acute toxicity, high risk to users, Toxicity class WHO (a.i) II