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SUMMARY NOTE ON WORKSHOPS: COMMENTS AND PROPOSALS RELATED TO THE PRACTICAL EXPERIENCE OF DESIGNATED NATIONAL AUTHORITIES IN USING THE DOCUMENTATION AVAILABLE FOR THE OPERATION OF THE INTERIM PIC PROCEDURE

Note by the Chair of the Interim Chemical Review Committee (ICRC)

1. The Interim Chemical Review Committee, at its second session in Rome, concluded that the participation of Committee members in regional workshops would provide an opportunity for them to meet designated national authorities and become more familiar with their needs and problems in implementing the interim PIC procedure.

2. The Committee recommended that the reports of sub-regional workshops, including the presentations prepared by country participants, should be reviewed by the Committee experts from the regions hosting the workshops for comments and proposals related to the practical experience of designated national authorities in using the documentation available for the operation of the interim PIC procedure. Those comments and proposals should then be consolidated and presented to the next full meeting of the Committee in order that they might be considered in the work of the Committee.

3. Annexed to this note are the summary reports for the three workshops held on the Rotterdam Convention:

Annex I: Bangkok, Thailand; report prepared by R. Arndt
Annex II: Nairobi, Kenya; report prepared by A. Abdelbaghi
Annex III: Cartagena de Indias, Colombia, report prepared by M. Bolanos

• UNEP/FAO/PIC/ICRC3/1

Annex I

Summary report on the Subregional Awareness Raising Workshop on the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

Bangkok, Thailand, 8-11 December 1998

1. Background

There were 26 participants form 15 countries attending the workshop.

The main goals of the workshop were inter alia:

- to provide detailed information on new procedural elements like proposals for severely hazardous pesticides*;*
- to strengthen the capability of DNAs to actively participate in and contribute to the PIC procedure, including bodies like Chemicals Review Committee;

2. Key issues in implementation of the Rotterdam Convention (Severely hazardous pesticide formulations, DGD)

As this was the first awareness raising workshop on the Rotterdam Convention the main emphasis was on the content of the convention and to a smaller degree on practical questions of implementation and problems relevant for the work of the ICRC.
Nevertheless some parts of the working group reports and two presentations concerning the DGD and severely hazardous pesticide formulations seem to be relevant for the work of the Committee and the respective excerpts from the workshop report are given below.

2.1 excerpt from presentation 12. Perspectives on identifying Severely Hazardous Pesticide Formulations, by Ms. Nursiah Mohamad Tajol Aros (Malaysia)

1. Introduction

1.1. Under Article 2 of the Final Text of the Convention on the PIC Procedure, a "severely hazardous pesticide formulation" means a chemical formulated for pesticide use that produces severe health or environmental effects observable within a short period of time after single or multiple exposure, under conditions of use.
1.2. The above implies that there must be a way of identifying what constitutes a severely hazardous pesticide formulation. Identifying such formulations is difficult and this is compounded by the fact that it may depend on the climatic, economic and social scenario in individual countries.

3. Recommendations

3.1. Basically it is felt that the present proposals for criteria to identify severely hazardous formulations could be followed in the interim and these include :
3.1.1. toxicity classification
3.1.1.1 In the London Guidelines on the Exchange and Information on Chemicals in International Trade, these formulations are referred to as "acutely hazardous pesticide formulations". The initial consideration was formulations which met the criteria for the WHO Class Ia. This may, however leave out certain formulations which may not be in Class Ia but still pose specific problems under conditions of use in developing countries. Provisions must be added in order to accommodate this possibility in the identification procedure.

3.1.2. Pesticide formulations in a developing country which can be regarded as severely hazardous should be identified on the basis of documented reports of adverse effects. For this reason, developing countries which have not yet established a system for the documenting and reporting of such incidents, for example establishment of a Poison Control Center, should make efforts to do so as soon as possible.

3.1.3. Review of data on poisoning incidents and adverse effects documented in industrialized countries could be carried out to supplement any such information available from the developing country concerned. Since these countries are presumably more capable of imposing and enforcing safety precautions, the presence of such data on specific pesticides in these countries would serve as a guide to identifying the severely hazardous formulations which the developing country would be likely to have even greater difficulty in controlling.

3.1.4. Data on handling restrictions by industrialized countries on pesticides could be used as an additional mechanism, where inventories of handling restrictions in selected countries could be compared and formulations subject to restrictions designed to minimize occupational exposure in more than one country could be identified. These would then serve to „flag" candidates for the severely hazardous pesticide formulation category. Some examples of restrictions would include requirements for operators to wear special protective equipment, closed mixing and loading systems and that certain pesticides be handled only by trained or certified applicators. Although at present the development of such inventories appear to be making little progress; however it could still be considered for the future.

3.1.5. It may be useful to look into the possibility of using computer models, either existing ones or developing new ones, which help to predict situations that may happen and recommend the remedial or precautionary measures to resolve the anticipated problems. For example, models which help predict the use of and type of personal protective equipment during occupational application of pesticides could be modified somewhat in order to assist in identifying and „flagging" severely hazardous formulations. Studies could then be carried out on these formulations in order to verify the findings. The parameters that could be incorporated in these models could include toxicity data, usage, exposure duration and formulations

3.1.6. Data could be taken from a survey carried out among member countries where each country cite at least two pesticide formulations which have been found to be problematic under local conditions of use. A list compiling all the pesticide formulations mentioned could then be prepared from which the pesticide formulations which appear most often could then be identified. The criteria for classifying severely hazardous formulations could then be worked out from the characteristics of these formulations as well as the information (on poisoning incidents, adverse effects etc.) submitted by the countries which mentioned them.

4. Issues for consideration

4.1. Identification of a certain formulation of pesticide at a certain concentration, e.g. a 600 g a.i./l formulation of monocrotophos, as a severely hazardous formulation to be placed under PIC procedures, has its constraints as a manufacturer may then produce a similar monocrotophos product at a slightly lower concentration, e.g. a 500 g. a.i./l formulation. There is no guarantee that this slightly lower concentration will not pose severe hazards as much as the 600 g a.i./l formulation. Perhaps in addition to the active ingredient, more focus should be given to the type of formulation of the pesticide.

4.2. Developing countries generally lack the resources and infrastructure i.e. the desired capacity to achieve the required information-gathering processes in order to obtain or produce sufficient data to expedite a decision on identification and restriction or enforcement measures regarding severely hazardous formulations. Due to this, the assistance of international relevant bodies will be needed. FAO and UNEP can play a

role in this and the areas in which they could help both financially as well as in technical support include :

4.2.1. harmonizing of guidelines to help developing countries to identify severely hazardous pesticide formulations;

4.2.2. allocation of funds to carry out a study on development of criteria for identifying severely hazardous formulations in developing countries;

4.3.3. assistance to developing countries which do not as yet have a scheme to control pesticides so that they can establish such a scheme e.g. comprehensive legislation to control pesticides;

4.3.4. assistance in developing or reviewing computer models to develop criteria for identifying severely hazardous pesticide formulations and to carry out subsequent studies on verification of the findings; and

4.3.5. assistance in establishment of poisoning data collection centers.

2.2 excerpt from presentation 15. Perspectives on the Decision Guidance Documents by Ms.Yang Yong Zhen (China)

The Decision Guidance Documents (DGD) is a recommendation from the PIC Secretariat to Designated National Authorities (DNA) to review the document and take an import decision regarding this chemical or pesticide. The DGD is very useful and helpful to the countries participating in the PIC procedure, especially to the developing countries.

The following information should be in the DGD to assist the DNA to take an import decision regarding the pesticide or chemical listed in PIC in accordance with our experience in the use of DGD:

- Chemical properties
- Reasons for inclusion in PIC
- Toxicity (acute, short-term, chronic and other effects)
- International hazard classification
- Environmental characteristics
- Exposure
- Measures to reduce exposure
- List of reported control actions

All of the information given in the DGD is useful to the DNA at present. The more detailed information is needed in identification of the substance which may exist in several types of chemical combinations to clear and definite the product listed in PIC. For instance we can't make sure of the specific salt combination of Maleic hydrazide been nominated as the candidate of PIC based on the information given in the draft DGD. The information from Uniroyal company is shown that the potassium salt of Maleic hydrazid do not cause health problem, only the sodium salt causes the problem. We need additional detailed information to determine whether the registration of potassium salt of Maleic hydrazid (Royal MH -30) should be continued or discontinued.

In order to save the time of taking import decisions for the DNA, we suggest that the detailed information regarding to the reasons for listed in PIC should be provided in the DGD. It is necessary that the PIC secretariat circulate a draft DGD before the formal document provided to the DNA.

3. Practical experience of DNAs

excerpt Working Group 1 - Challenges for DNAs in operating the PIC procedure

Making Import Decisions and Response (Industrial Chemicals DNA):

What needs to be done to make Import Decisions?

1. Assessment of the effect of the use of chemical on human health/environment.
2. What are alternative chemicals?
3. Periodic updating of the list of regulated chemicals. List to be consulted at the time of import.
4. If chemical not assessed, information regarding ecotoxiological effects to be gathered from other resources.
5. Consultation with other ministries like health/agriculture etc.
6. Request PIC Sect. to immediately take up with the International Customs Organization the task of defining separate HS code for each PIC chemical.
7. Training of personnel in risk assessment and risk management.

Discussion on making import decisions and responses (Pesticide DNA)

What needs to be done to make import decisions?

- Recognize that it is an obligation to make import decision.
- Designate a proper authority to make import decision.
- Fully utilize the information given by the DGD.
- Seek assistance from secretariat or reported countries.

What format for the DGDs would be useful for DNAs?

- Content
  - * Chemical properties
  - * Reasons for inclusion in PIC
  - * List of reported control actions
  - * Toxicity (acute, short-term, chronic, other effects) International hazard classification
  - * Environmental characteristics
  - * Exposure
  - * Measures to reduce exposure
  - * Waste disposal methods
  - * List of DNA (nomination country)
- Structure
  - * Identification
  - * Reasons for inclusion in PIC
  - * Details on reported control actions
  - * Further information
- Designate high sounding responsible authority to make import decisions.

excerpt WORKING GROUP 2 - Challenges in national implementation of the PIC procedure

Decision making at national level (Industrial Chemical DNA)

- DNA receives information from agriculture, Deptt. Labour, Health Ministries/International body literature (WHO/ILO/others)
- DNA calls a meeting of concerned Deptts/NGOs/researchers/scientists to discuss and take decision

To facilitate decision-making at national level (Pesticide DNA)

- National inter agencies committees such as a joint pesticide committee should be set up;
- A mechanism is needed to identify hazardous pesticide formulation to the technical advisory committee;
- National, regional and international networks for information exchange be established;
- DNAs of exporting parties should collect of information to help importing parties to make decision;

- Poisoning treatment centers and data collection centers be established;
- Standardized content and method of reporting poisoning cases with a central regional storage facility for such data be established.
- A proactive and collective approach accommodating cultural difference should be established to enable liaison with stakeholders;

4. Possible ways of improving the implementation of the Convention

It is proposed to take note of the proposals above and consider them in the further work of the Committee.

4.1 Severely hazardous pesticide formulations (SHPF):
– Identification of a shpf and entry into Annex III (Discussion at ICRC3)
– additional information from developed countries to assess a notification of a SHPF (Discussion at ICRC3)
– guidelines to identify/document SHPF (ongoing work)
– allocation of funds for projects to identify SHPF (Recommendation to INC7)
– assistance for countries to control pesticides
– assistance to establish poison control centers

4.2 Content of the DGD
– proposals for the content of the DGD (check against the DGD format agreed at ICRC2)

Annex II

Summary Report on the Sub-Regional Awareness Raising Workshop on the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

Nairobi, Kenya, 13-16 June 2000

1. Background

The workshop was held on UNEP headquarter in Nairobi, Kenya between the 13th- 16th of June 2000 and directed towards the English speaking countries in Africa. It was attended by 17 Designated National Authorities (DNAs) from 17 countries, eight other governmental officials from related fields, three members from the ICRC, three members from the interim secretariat, one representative from UNEP-Kenya, one representative from FAO-Ghana and five observers.

Goals of the workshop:

The goals of the workshop are to:

- Raise awareness about PIC convention and interim arrangements and how they differ from the voluntary procedure.
- To clarify the obligations for parties arising from the convention.
- To provide information on the activities of the FAO/UNEP joint secretariat.
- To exchange experience in the implementation, assess progress in national implementation and identify actions necessary at national level to implement the procedure.
- To identify issues related to the implementation to be addressed by the INC7.
- To strengthen the capacities of DNAs to actively participate and contribute to the PIC procedure.
- To strengthen the co-operation among countries in the region.

2. Key issues in the implementation of the Rotterdam Convention

The workshop was composed of 10 sessions (7 panel sessions plus 3 working group sessions). The panel sessions include; key presentations by the secretariat followed by perspectives by invited experts and/or country perspectives and finally an in-depth panel discussion, which was formulated into recommendations. The working group sessions include; small group's discussion followed by panel presentation and discussion with final recommendations. The subjects covered were;

A\ Panel sessions:

- Opening remarks including presentations on inter-linkage to other international environmental conventions and the role of PIC procedure in the African context of chemical management.
- General overview of Rotterdam Convention on the PIC procedure and interim arrangements with In-depth explanations of various parts of the convention and an overview of the out comes from the INC6 and ICRC1. The followings are excerpts of the presentations given:

a\Perspectives regarding article5 and 6:

Speakers summarizes the major constrains as:

- Lack of resources, institutional gabs, and shortage in information and documentation.
- Difficulties in fulfilling requirements of annex 4 regarding proposal of SHPF as:

1\ Areas where incidence occurs is mostly remote, with no or limited NGO activity and no proper system of communication and documentation.

2\-Unknown active ingredient in the formulation, use of mixtures or formulations from repacked containers and lack of proper application technology.

3\ Ignorance of environmental impacts and reluctance in given information is very common.

b\ **Perspectives regarding article7, DGDs:**

- More complicated DGD require more time and expertise to deal with it.
- Confusion encountered from listing certain formulation of the same active ingredient while leaving others.

c\ **Perspectives regarding article10, import responses:**

- Type of technical assistance expected was not indicated.
- Lack of alternatives delays the responses.

d\ **Perspectives regarding article12&13 export notifications and information accompanying exported chemicals:**

- The export of a chemical from countries which does not took regulatory action will not be notified which may lead to incomplete information on the trade of the chemical. This may place those countries on a disadvantageous position. Further the notification could be starting point for assessing the risk of the chemical.
- The labeling of the chemical based on hazards, not risk gives misleading information.

B\ working group sessions:

1- Challenges for DNAs in operating the PIC procedure.

Priority issues discussed were; making import decisions and responses, capacities and capabilities of DNAs in providing notification of final regulatory action and utilization of export notifications.

Needs and processes:

- Literature and data base.
- Legal frame work.
- Meeting with stakeholders
- Communicate with secretariat and DNAs from exporting countries.

Capacities and Capabilities:

1\ at national level:

- Availability of database and information sources.
- Legal & institutional arrangement.
- Enhanced capacity building.

2\ at regional level:

- Harmonization of legislation and registration systems.
- Sharing of information, infrastructure and exchange of expertise.

2- Challenges in national implementation of the PIC procedure. Priority issues discussed were; decision making at national level and legal, technical and institutional infrastructures at national level.

Decision making at national level:

- Legal and regulatory systems must be in place. Appointment of DNA, committees, boards and inpectorates.
- Collection of information, proper documentation and information exchange system.
- Coordination between stakeholders through meetings, workshops, seminars, committees. etc.

Legal, technical and institutional infrastructures at national level:

- Existing laws, infrastructure and resources are not sufficient to implement the convention.
- Changes necessary to implement the obligations of the convention

Were as indicated above.

3- Opportunities for co-operation in implementing the PIC procedure.

Priority issues discussed were enhancing capacities and capabilities and strengthening regional co-operation.

Enhancing capacities and capabilities:

- Setting DNA offices with communication machines and documentation center.
- Strengthening the analytical facilities with human and machine resources.

Meaning of cooperate in promoting technical assistance:

- Sharing responsibilities at national and regional level.
- Establishment of regional office and regional program coordinator.

Developed parties can help developing parties by:
- Share experience, constancy, developed equipment, exchange visits.
- Training the trainers, technology transfer, proper administrative regimes for chemicals, review of legislation, access to data base and international literature, share advance analytical facilities.

How INC/COP best implement its role:
- Identify weakness in implementation.
- A coordination committee to follow up actions proposed at the meetings.
- Regional working groups to be established.

Strengthening regional cooperation:
- Networking of DNAs
- Newsletter, regional laboratories, exchange of information and expert. - Training, regular meetings and harmonization of registration schemes.

3. Practical experience of DNAs in using documentation available

Africa is confronted by many problems including endemic and epidemic diseases, plant pests and diseases, low productivity, weak economy, poor legislative system, poor infrastructure and ever-growing population. Most of these problems, which are also common in other developing countries, may compel Africa to work at low profile in implementing the PIC or any other environmental related conventions. Looking at presentations and discussions raised by DNAs, one could summaries the following points about their experience in using documentation available;

- any of the DNAs and their national teams lack proper training on chemical management.
- Lack understanding of issues related to the PIC procedure.
- Lack or poor legislative tools for chemical management.
- Poor institutions for enforcement of existing law.
- Limited access to international literature and database on chemical management.
- Limited resources and technical facilities such as means of communications, access to Internet, poison centers…etc.
- Lack of proper documentation, reporting, information exchange system within the country.
- Poor co-ordination among stakeholders at national level.
- Sometimes authorities are exposed to powerful lobbying of interest groups and to political pressure.
- Sometimes authorities faced with urgent needs to compact vectors of epidemic diseases or to protect crops from pest outbreak, which may compel them to use environmentally unsafe chemicals or to miss, manage their environment.
- Available DGDs need to be improved to ensure that they give the appropriate level of information that is manageable by developing countries' DNA i.e. DGDs should not include all complex details that may be required by other countries which have more expertise to deal with it.
- Confusion of some DNAs by listing certain severely hazardous pesticide formulations while leaving other formulations of the same active ingredient, of course this indicate improper understanding of the PIC procedure.
- Confusion with documentation from other related conventions such as POPs. This should definitely be improved specially when considering the fact that both conventions operates under similar joint secretariat (FAO and UNEP).
- Lack of coordination at regional level.

4. Possible ways of improving the implementation of the Convention

The following means were suggested/recommended to improve the implementation of the convention in developing countries. Serious efforts are necessary to be successful on the followings:
- Proper training of DNAs and their assisting team on chemical management and how to deal with this convention through the current interim phase or the future legally binding instrument when the convention enters into force. This can be done by workshops, seminars. etc.

- Capacity building in order to assist developing countries in establishing or improving existing laws and legislation for the implementation and proper enforcement of the convention.
- Technical assistance in infrastructures, access to international database and better national information exchange system.
- Coordination at regional level.
- Improvement of available documentation (see below).

The available documentation can be improved by:

- Improvement in the PIC circular by adding indexes for easy search and including a reminding section on status of ratification of the PIC Convention.
- Translation of PIC circular in all the six languages of the United Nations.
- Improvement of the content and frame of the DGDs as proposed by ICRC.
- Pre-prepared forms should be send to DNAs specifying the issue to be addressed (as the case of incident report form and other related forms).
- Issuing regional newsletter (to avoid confusion with the secretariat circular) or magazine addressing the problems which are common to the region and those several DNAs or states are facing in implementing the PIC procedure. A regional office may assist in issuing the newsletter or the magazine as well as help in coordinating the technical assistance needed.
- Access to electronic versions of all documentation. But this may needs improvement in communication systems in the parties concerned by establishing a net working process.
- Further sessions of awareness raising workshops and seminars at continental and national levels.

Annex III

Summary Report on the Sub-Regional Awareness Raising Workshop on the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

Cartagena de Indias, Colombia, 3-6 October 2000

1. Background

The Vice-Director and Regional Representative of FAO in Chile organized the Cartagena's workshop, during the period of 3-6 October 2000 in Cartagena, Colombia. The FAO Representative Office in Colombia coordinated it. The structure of the meeting was divided in three topics. i) The representatives of the Interim Secretariat presented a summary of the articles of the Rotterdam Convention; ii) the ICRC experts from Latin American countries, various DNAs and other invited delegations spoke about the situation in implementing the Convention in their countries, presenting the status in the fulfillment of the Rotterdam Convention, and, finally; iii) three task groups were composed to discuss the priorities and define recommendations for a better application of the Rotterdam Convention in the countries of Latin America.

The main aims of this meeting were the following:

To create the conditions for the South and Central America countries to be able to discuss the obligations, difficulties and responsibilities of all parties integrating the Rotterdam Convention;

To exchange information and experiences in the status of application of the interim Prior Informed Consent (PIC) for certain hazardous chemicals and pesticides in the international trade;

For each country, to evaluate the progresses in the fulfillment of the Prior Informed Consent (PIC);

To identify the actions needed, at a national level, for the application of the Rotterdam Convention;

To strengthen the DNA actions and the cooperation between the countries.

2. Key issues for the application of the Rotterdam Convention

In South and Central America, many environmental and health institutions holding the responsibility for monitoring and analyzing are not efficient because of budgetary problems, and suffer from limited personnel with technical and environmental monitoring ability or capacity to carry out environmental and health risk assessments.

In order to provide a reasonable notification program at the national level, financial resources are necessary, as well as technically capable personnel and a regulatory infrastructure. Among the South and Central America countries, few are able to develop this program.

The main difficulty in completing the Annex IV - Part 1, is associated with the item (g) "a clear description of incidents related to the problem, including the adverse effects and the way in which the formulation was used".

It is necessary to conjugate the efforts of the structures of notification and to integrate activities and institutions in order to provide the national mechanisms with the means of reaching an improvement in the attendance of patients and in the notification of the cases.

To strengthen the national capacity to manage the industrial hazardous chemicals and pesticides.

To provide every country with a responsible decision process in regard to a future import and/or export of hazardous chemical products.

To exchange information between the parties, taking into account the control measures adopted for banned and severely restricted chemicals, and to allow the countries to make such an important decision on the chemical concerned;

3. Practical experience of DNAs

Even knowing that the objective of the Convention is to promote shared responsibility and cooperative efforts among the parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm, the great majority of the DNAs have not yet reached this aim. To reach this objective, each DNA must establish its operating procedures for the application of the Rotterdam Convention program for the next three (3) to five (5) years.

The Latin-American countries are at different stages in the application of the Rotterdam Convention. This was clearly noticed during the workshop in regard to some issues such as the mechanisms for pesticide registration, how to carry out a risk assessment study and how to attend the criteria for listing severely hazardous pesticide formulations.

The DNAs from Latin-American countries have different kinds of difficulties and challenges in the application of the Rotterdam Convention, but there is a consensus that the identification of the chemical products for inclusion in the PIC list is directly related with the socioeconomic needs and the technical capacity of the countries to have a system of risk assessment for pesticides. The risk assessment provides a tool to know the local problem with the use of pesticides, to formulate the environmental and human problems in the area, to estimate the environmental and occupational exposure and to define the endpoints.

Few DNAs in Latin-America are able to have a practical experience of notifying one new chemical for the PIC list, because it is difficult for some DNAs to prove that they are experiencing problems caused by a severely hazardous pesticide formulation. There is a lack of good laboratories able to analyze this formulation on time and to give a trustful result on which this action can be based.

Other difficulties to include hazardous chemicals as a result of the application of the interim Prior Informed Consent (PIC) for certain hazardous chemicals and pesticides in the international trade are due to economic reasons and the lack of regulatory infrastructure.

There is a consensus from the DNAs that the collection and flux of information in the South and Central America countries need a great improvement to provide the basic information for the notification of the banned and severely restricted chemicals. Not all the data required in the notification are available.

Some countries have difficulties in clearly understanding the scope of the Rotterdam Convention and have difficulties to satisfy the information requirements to meet the criteria in Annex II.

4. Recommendations

There is a need to strengthen the national capabilities and capacities for the management of hazardous chemicals, by promoting cooperation among the parties and providing technical and financial assistance;

In South and Central American countries, it will be necessary to strengthen the existing infrastructure to monitor the import and use of hazardous chemicals;

In order to protect human health and the environment, the information provided on the label of the chemicals must be written in the language of the importing country; to avoid misunderstanding in relation the precautionary measures necessary to protect human health;

To create an information network for hazardous chemicals in order to facilitate the provision of data required for notifications of final regulatory action, including information such as the toxicological and ecotoxicological properties, and basic information on the active ingredient or ingredients, etc.

To define the minimum scope for the risk assessment methodology.