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SECRETARIAT OF THE ROTTERDAM CONVENTION

GUIDANCE TO COMPLETE THE FORM FOR NOTIFICATION OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

INTRODUCTION

The purpose of this document is to provide guidance to designated national authorities (DNAs) in completing a "Notification of final regulatory action" form. It has been developed by the Secretariat of the Rotterdam Convention to assist Parties successfully complete the form. The Secretariat hopes that Parties will more clearly understand the sections of the form and information requested, enabling them to easily submit complete notifications.

Article 5, paragraph 1, of the Convention requests Parties who have adopted a final regulatory action to ban or severely restrict and chemical to notify the Secretariat. Article 5, paragraph 3, tasks the Secretariat with verifying whether notifications contain the information required by Annex I of the Convention. As the recipient of the notifications, the Secretariat has gained much experience and a good understanding of the problems faced by Parties in successfully submitting all the information required by Annex I. In order to assist Parties in preparing complete notifications and to standardise the format in which they are submitted, the "Form for Notification of Final Regulatory Action" was developed and is based on the information requirements set out in Annex I.

This guidance follows the structure of the notification form and has been developed based on the experience of the Secretariat as well as the lessons learned by members of the Chemical Review Committee. This guidance is considered a work-in-progress that will continue to evolve and be updated as experience is gained and more feedback from Parties is received. Parties are encouraged to send comments on the guidance to the Secretariat at pic@pic.int or pic@fao.org.

STRUCTURE OF THIS DOCUMENT

The guidance provided in this document is structured as follows:

Background: provides information on the notification process, including submission, verification and review by the Chemical Review Committee (CRC).

Chapter 1: provides highlights on the preparation of notifications of final regulatory action and on key points, such as the need to submit supporting documentation and the label of the chemical for which the notification has been prepared. It also provides information on the submission process.

Chapter 2: provides, for each of the four sections of the notification form, a brief overview of the information required.

Chapter 3: uses the notification form to illustrate an example of a completed notification and provide detailed advice on the key information elements that might be included in the specific sections of the form.

BACKGROUND

Under Article 5 of the Rotterdam Convention, Parties have an obligation to notify the Secretariat when they take a final regulatory action to ban or severely restrict a chemical. These notifications play an important role in the information exchange on hazardous chemicals and identification of candidate chemicals for the PIC procedure.

Upon receipt of a form for notification of final regulatory action, the Secretariat verifies that the form contains all of the information called for in Annex I of the Convention. Where the notification form is verified to be complete, a summary of the final regulatory action is prepared by the Secretariat and sent to the DNA for their comments and indications as to any omissions or mistakes. The summary is then published in Appendix I of the PIC Circular. The DNA is also asked to submit the supporting documentation used as the basis for the final regulatory action and further details on risk evaluation, if any.

Where the notification form is verified not to be complete, the Secretariat writes to the DNA and provides a detailed list of what information is missing and invites the DNA to provide that information.

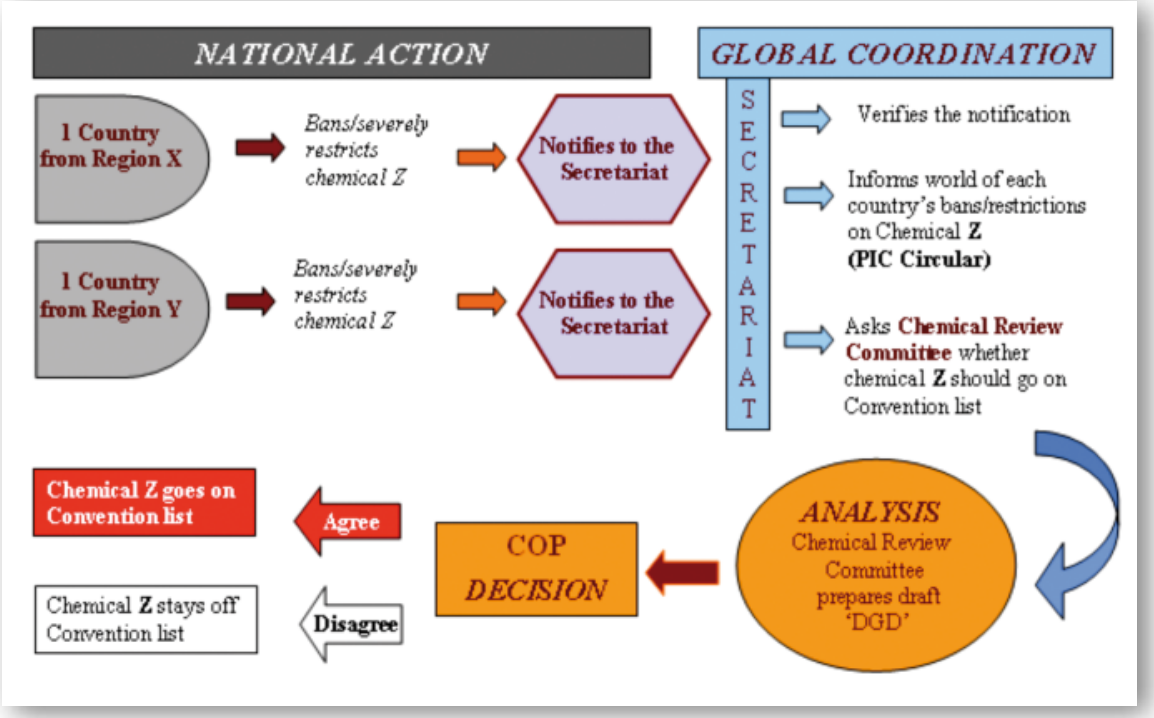
All notifications verified as complete by the Secretariat represent a

key input into the information exchange mechanism under the Convention. Summaries published in the PIC Circular provide Parties with information about hazardous chemicals that are banned or severely restricted in order to protect human health or the environment.

Where there are at least two notifications of final regulatory action for the same chemical from two different PIC regions the notifications forms and related supporting documentation are forwarded to the Chemical Review Committee (CRC) for review. The CRC reviews the notifications in the light of the information requirements and criteria set out in Annexes I and II of the Convention, respectively. In order for a notification of final regulatory action on a chemical to support the listing of that chemical in Annex III, the notification must be found by the CRC to meet the criteria in Annex II.

Where two notifications are found to meet the above-mentioned criteria, the CRC may recommend to the Conference of the Parties that the chemical be listed in Annex III of the Convention and subject to the PIC procedure. The CRC then drafts a decision guidance document (DGD) which uses as its basis the information in the notifications and supporting documentation. For these reasons, it is important that notifications are as complete as possible. The final decision to add the chemical to Annex III and adopt the DGD is made by the Conference of the Parties.

Fig. 1: From notification to inclusion of a hazardous chemical in Annex III



The progression of a notification from national decision to inclusion as a chemical in Annex III and subsequently becoming subject to the PIC procedure is illustrated in Figure 1.

CHAPTER 1
HIGHLIGHTS

1. It is important that all parts of the form are completed. Where information is not available for a specific element this should be clearly indicated rather than leaving the section empty or blank (e.g. indicate "not available").

2. Whenever additional space is needed, separate sheets of paper may be attached to the form and should clearly indicate to which section of the form the information is related.

3. Information in the notification should be presented as clearly and unambiguously as possible. It is also particularly important that the documentation that supports the final regulatory action is clearly referenced in the relevant sections of the form.

4. Along with the completed notification form, documents and references that are mentioned in the form should be provided or the source of the information should be reported. This can include published or unpublished information and internal or national reports. Although copies of such documentation may be submitted, please note that it is not sufficient to only refer to the documentation and that the form itself must be completed with the relevant information.

5. The notification form should be submitted with the information and documentation which was used to support the national decision to ban or severely restrict the chemical. It is not intended that a Party collect information in order to complete the notification form, however, it is assumed that information is collected in order to make the regulatory decision. That is the information that should be submitted together with the notification form. In addition, a reference provided to an international risk evaluation that was completed after the national regulatory action was taken would not be accepted by the CRC as a relevant supporting document for a notification.

6. Together with the notification form, the label of the chemical, which is a mandatory part of the product packaging, should be submitted. It is essential for the CRC to have the label when reviewing a notification and the documentation supporting the national decision.

7. Where possible, copies of the text of the national decision and supporting risk evaluation should form a part of the supporting documentation that is submitted with the notification. Similarly, other information that would help to explain the use of the chemical in the country before and after the regulatory action should be provided, e.g. product labels, which are particularly important for chemicals that are severely restricted.

8. Where supporting documentation is voluminous or not available in English, a focussed summary should be prepared. Detailed guidance on the preparation of a focussed summary may be found at www.pic.int in the section dedicated to the CRC.

Information on the submission process

The form for notification of final regulatory action developed by the Secretariat is available on the Rotterdam Convention website in English, French and Spanish. The forms are available in an interactive electronic version with pop-up instructions and also in a simple printable Word version. DNAs may type the information into the forms in any of these three languages.

For the official submission to the Secretariat, the completed form must be printed, signed, dated and stamped or sealed by the DNA. The Secretariat encourages DNAs to submit electronic scanned versions of the completed forms by fax or email, but they can also be sent in hard copy by regular mail to the following addresses:

Secretariat at FAO
Food and Agriculture Organization of the United Nations
Viale delle Terme di Caracalla
00153 Rome, Italy
Tel: (+39 06) 5705 2188
Fax: (+39 06) 5705 6347
E-mail: pic@pic.int

Secretariat at UNEP
United Nations Environment Programme
11-13, Chemin des Anémones
CH – 1219 Châtelaine,
Geneva, Switzerland
Tel: (+41 22) 917 8296
Fax: (+41 22) 917 8082
E-mail: pic@pic.int

CHAPTER 2
BRIEF OVERVIEW ON THE INFORMATION REQUIRED BY EACH SECTION OF THE FORM

SECTION 1 of the FORM: Identity of the Chemical

This section serves to clearly identify the chemical that is the subject of the final regulatory action. The exact identity of the chemical is important to clearly establish as only when two notifications from two PIC regions for the same chemical are received will the chemical be referred to the Chemical Review Committee for consideration for inclusion in Annex III and subject to the PIC procedure.

In most instances, the information needed to complete this section can be found in international sources and the documentation used to support the national final regulatory action. If any of the information requested in this section is missing, the form could be considered incomplete. It is preferable to indicate "not available" in a section for which information has not been found.

Where available, copies of the label of the products containing the chemical(s) should be provided in order to better identify the chemical.

SECTION 2 of the FORM: Final Regulatory Action

This section serves to provide detailed information concerning the national regulatory action and the underlying basis for the national decision to ban or severely restrict the chemical. The form was developed to be in line with the information requirements set out in Annex I.

The information provided in this section makes up the main content of the summary of the regulatory action prepared by the Secretariat for publication in Appendix I of the PIC Circular. This information and the relevant supporting documentation are also the basis for the work of the Chemical Review Committee in reviewing candidate chemicals.

It is important that the information provided regarding the national regulatory action be as complete as possible and presented in a clear and unambiguous way. The underlying supporting documentation should be clearly referenced in the appropriate sections and where the supporting documentation is not publicly available (such as on the internet) copies should be provided to the Secretariat along with the notification form.

Copies of product labels should be provided, where available, since they might help to describe the conditions of use in a country by defining the use or uses, including the rate and frequency of application.

Section 2.1 identifies whether the chemical was banned or severely restricted in line with the definitions in Article 2 of the Convention. This distinction is important because the information required in subsequent sections regarding use(s) and risk evaluation are different depending on whether the chemical was banned or severely restricted.

Section 2.2 provides for a brief summary of the final regulatory action (section 2.2.1) and an opportunity to provide a specific reference to the relevant regulatory document (section 2.2.2) and the date of entry into force of the final regulatory action (section 2.2.3).

Section 2.3 clarifies whether the category of the chemical subject to the final regulatory action is a pesticide or an industrial chemical. In most instances chemicals are used as either pesticides or as industrial chemicals, but some chemicals can also be used as both. Where a regulatory action applies to a pesticide then only those sections relevant to pesticide use need to be completed, and the same goes also for industrial chemicals.

The specific use(s) before and after the final regulatory action need to be defined for each category of chemical. This is particularly important where a chemical is severely restricted and only certain uses remain allowed. The information on use(s) is particularly important for chemicals that are subject to a severe restriction as this will help verify if the action is in fact a severe restriction as defined by the Convention.

Section 2.4 identifies whether the final regulatory action was based on a hazard or risk evaluation. This is perhaps the most challenging part of the notification process as this section requires an explanation of the basis for the national decision. This information is critical for the CRC in reviewing the notifications in the context of the criteria in Annex II.

Where no hazard or risk evaluation has been conducted, Parties are not required to complete the following sections and may proceed directly to section 2.5.3.3. Where a hazard or risk evaluation has been conducted, further information on the hazard or risk evaluation is to be provided. Parties are requested to provide a reference to the detailed information as well as to describe the hazard or risk evaluation and, in particular, whether it is applicable to human health or the environment or both (Section 2.4.2). Where, for example, a national decision is based on human health concerns only, a Party is not obliged to provide information on the environmental effects of the chemical (e.g. complete section 2.4.2.1 only).

The Chemical Review Committee has developed a guidance paper entitled Bridging information on notifications of final regulatory actions making use of risk evaluations and/or exposure assessments completed in another country or from an international risk evaluation. These guidelines may be of particular interest for those countries whose national regulatory programmes require the use of risk evaluations but which lack the capacity and resources to perform such evaluations. A key element of these guidelines is the exposure or potential exposure to the chemical.

When notifying of a national decision based all or in part on a risk evaluation conducted elsewhere, every effort should be made to demonstrate the relationship of the conditions of use in the notifying country to that of the country that undertook the risk evaluation. This may take the form of actual or measured exposure, or reflect the results of modelling of expected or anticipated exposure. Any information that might be provided to facilitate this comparison should be provided, such as product labels which describe the composition of products used, rate and frequency of application, availability and practicality of personal protective equipment or other risk mitigation measures that may have been put in place as a result of the original risk evaluation yet that may be impractical in the notifying country.

A notification is still complete against Annex I if no risk evaluation is undertaken, as long as the Party clearly indicates this in the notification form (section 2.4). There is no requirement under the Convention for a Party to undertake a risk or hazard evaluation and Parties may take national decisions on whatever basis they feel appropriate. In many countries, national regulatory decisions make use of risk assessments undertaken at the international level (e.g. World Health Organization (WHO)) or under the auspices of other Conventions (e.g. Stockholm Convention or Montreal Protocol) or by other governments (e.g. European Community).

However, in order for the notification to meet the criteria of Annex II and for the CRC to consider the chemical as a candidate for inclusion in the Convention, the CRC must establish that the final regulatory action has been taken as a consequence of a risk evaluation. A risk evaluation under the Rotterdam Convention considers information on hazard and exposure. Information on hazard assessment may be taken from a range of sources however information on exposure must be related to the prevailing conditions of use in the notifying country. Therefore, if a notification is not based on a risk evaluation, it is complete but will not be considered as a notification in support of the inclusion of a chemical in Annex III of the Convention.

Section 2.5, refers to Annex I and the likely relevance that the regulatory action may have for other States and regions. It also allows putting the final regulatory action in a broader context. It includes information on quantities of the chemical traded, socio-economic effects of the regulatory action and alternatives and any other information that the notifying country would like to provide. The information in this section of the form is not mandatory.

SECTION 3 of the FORM: Properties of the chemical

This section provides detailed information on the physico-chemical, toxicological and eco-toxicological properties of the chemical subject to the national regulatory action in line with the information requirements set out in Annex I. This information is not commonly generated at the national level but may be available from a range of international sources including the Pesticide Manual, evaluations of WHO or other international agreements, such as the Stockholm Convention or Montreal Protocol, or by other governments (e.g. European Community). Although much of this information is widely available, it is part of the information required to be included in a notification by Annex I and therefore must be provided. The relevant references and supporting documentation for the information should be clearly referenced in the appropriate sections. Where the supporting documentation is not publicly available (such as on the internet) copies should be provided to the Secretariat.

This information and the relevant supporting documentation are considered by the Chemical Review Committee.

SECTION 4 of the FORM: Designated National Authority

This section is important to verify that the notification is coming from the designated national authority that has been officially nominated by the government of the Party. The form must be dated (with the date of completion of the form or its submission to the Secretariat), signed by the officially nominated DNA and stamped with the official seal. If any of this information is not provided or does not coincide with the records of the Secretariat, the notification will be considered incomplete.

CHAPTER 3
SPECIFIC GUIDANCE ON THE SECTIONS OF THE FORM FOR NOTIFICATION OF FINAL REGULATORY ACTION

The following pages contain an example of a completed notification form submitted to the Secretariat and found to be complete against Annexes I and II of the Convention. It is provided as guidance only.

EXAMPLE OF A FORM

ROTTERDAM CONVENTION

SECRETARIAT FOR THE ROTTERDAM CONVENTION
ON THE PRIOR INFORMED CONSENT PROCEDURE
FOR CERTAIN HAZARDOUS CHEMICALS AND PESTICIDES
IN INTERNATIONAL TRADE

UNEP

FORM FOR NOTIFICATION
OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

Country:

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	Parathion-methyl (BSI, E-ISO, (m) F-ISO); Synonyms: methyl parathion (ESA, JMAF); metaphos (USSR)
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	IUPAC: O,O-dimethyl O-4-nitrophenyl phosphorothioate CA: Phosphorothioic acid, O,O-dimethyl O-(4-nitrophenyl) ester
1.3	**Trade names and names of preparations**	- Formulation types: capsule suspension (CS); dustable powder (DP); emulsifiable concentrate (EC); ultra low volume liquid (UL); (wettable powder (WP). - Selected trade names: Folidol-M; Metacide; Cekumethion; Dhanuman; Faast; Fostox metil; Jiajiduiliulin; Morfos Methyl; Parataf; 'Paratox; Penncap-M; Sweeper; Thionyl; Bladan M; Declare; Dhanudol; Dipathio; Foley; Metpar; Metron; Paracrop; Prompt; R M Doll; R Methyl; Sabidol - Mixtures: Verecar T (+ tetradifon); Afidan M 40 (+ endosulfan); Seis-Tres (+ parathion); Sulfanex-Methyl (+ endosulfan); Veto (+ EPN) - Discontinued names: Methyl Bladan; Mefos

GUIDANCE

1.1 Common name
Although there may be many common names used for a chemical in a country, the name(s) provided should as far as possible represent those that are in use in the country in order to allow for the precise identification of the chemical(s) subject to the regulatory action.
If the final regulatory action applies to a group of chemicals, the common name for each of the chemicals should be provided.

1.2 Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists
Needed to precisely identify the chemical.
The nomenclature used must also be indicated so that the information can be verified.

The Pesticide Manual contains information on internationally recognized nomenclature

1.3 Trade names and names of preparations
Although trade names and names of preparations vary widely across countries, the name(s) provided should as far as possible represent those that are in use in the country in order to provide a precise identification of the chemical(s) subject to the regulatory action.
A source for this information could be the label of the product.

EXAMPLE OF A FORM

1.4 Code numbers

1.4.1	CAS number	298-00-0
1.4.2	Harmonized System customs code	3808 10 40
1.4.3	Other numbers (specify the numbering system)	RTECS: TG0175 EINECS: 206-050-1 UN: 2783 CIPAC: 487

1.5 Indication regarding previous notification on this chemical, if any

1.5.1 ☒ This is a first time notification of final regulatory action on this chemical.

1.5.2 ☐ This notification replaces all previously submitted notifications on this chemical.
Date of issue of the previous notification: _____

GUIDANCE

1.4 Code Numbers

1.4.1 The Chemical Abstracts Service (CAS) number provides for a precise identification of the chemical(s) subject to the regulatory action.
If the regulatory action applies to a group of chemicals, please provide the CAS number for the group (if available) as well as for the individual chemicals.
CAS numbers can be found in the Pesticide Manual

1.4.2 Harmonized System (HS) Customs Codes have been developed for a wide range of chemicals by the World Customs Organization (WCO) and should be included where available.

1.4.3 Identification numbers from other systems may be given where available (i.e. EINECS, RTECS) The numbering system used must also be indicated so that the information can be verified.

1.5 Indication regarding previous notification on this chemical, if any

1.5.1 Choose **ONLY ONE** of the two options.

1.5.2 Notifications may be resubmitted at any time in response to changes in the regulatory status of a chemical in a country (e.g. all uses banned where previously use was severely restricted). For replacement notifications, please indicate the date of submission of the previous notification.

EXAMPLE OF A FORM

SECTION 2 **FINAL REGULATORY ACTION**

2.1 **The chemical is:** ☐ **banned** **OR** ☐ **severely restricted**

2.2 **Information specific to the final regulatory action**

2.2.1 Summary of the final regulatory action

It is prohibited to place on the market or use plant protection products containing parathion-methyl.
Parathion-methyl is not included as an authorised active ingredient in Annex I to Directive 91/414/EEC.
The authorisations for plant protection products containing parathion-methyl had to be withdrawn within a period of 6 months from the date of adoption of the Commission Decision 2003/166/EC. From that date, no authorisations for plant protection products containing parathion-methyl could be granted or renewed.

2.2.2 Reference to the regulatory document, e.g. where decision is recorded or published

Commission Decision 2003/166/EC of 10/03/2003 concerning the non-inclusion of parathion-methyl in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance (Official Journal of the European Union L67 of 12/03/2003, pp. 18-19) (copy attached, available at http://europa.eu.int/eur-lex/en/archive/2003/l_06720030312en.html).

2.2.3 Date of entry into force of the final regulatory action

9 September 2003. Authorisations for plant protection products containing parathion-methyl had to be withdrawn within a period of six months from the date of the final regulatory action.

GUIDANCE

2.1 Choose **ONLY ONE** of the two options.

The terms "banned" and "severely restricted" are defined in Article 2 of the Convention. A **ban** is when all uses of a chemical are prohibited while a **severe restriction** applies to a situation where virtually all use has been prohibited.

2.2 Information specific to the final regulatory action

2.2.1 Summary of the final regulatory action
This summary should highlight the key elements of the regulatory action that will allow others to understand the basis for the national decision to ban or severely restrict the chemical. It should include the category of chemical (pesticide or industrial chemical), the legal or administrative basis for the action, the date it entered into force, the scope of the action (ban or severe restriction) as well as the underlying reasons for the action, e.g. human health or environmental concerns or both.

The information in this summary should be consistent with the information to be provided in the sub-sections of 2.2, sections 2.3 and 2.4 and with the information on the risk or hazard evaluation underlying the national decision in section 2.4 (where applicable).

This description may be taken in part from the text of the decision of the regulatory authority as well as the relevant supporting documentation. The explanation or description of the basis for the decision should reflect the concerns identified in the risk or hazard evaluation, set out in more detail in the supporting documentation.

2.2.2 Reference to the regulatory document, e.g. where decision is recorded or published
A precise reference to the national regulatory document (e.g. national decree, national gazette or bulletin, etc.) where the decision regarding the national regulatory action is officially recorded or published should be provided.

A copy of the document should also be included with the notification.

2.2.3 Date of entry into force of the final regulatory action
The date (day, month, year) when the regulatory action came into force for the chemical in the country as specified in the national decision.

EXAMPLE OF A FORM

2.3 Category or categories where the final regulatory action has been taken

2.3.1 All use or uses of the chemical in your country prior to the final regulatory action

Parathion-methyl is a non-systemic insecticide and acaricide used worldwide to control chewing and sucking insects in a very wide range of crops, such as cereals, fruits (including citrus), vines, vegetables, ornamentals, cotton, and field crops.

Intended uses within the European Community were to control Clysia ambiguella (common names: Grape bud moth, Vine moth, Grape cochylis) on vines (grape vine and table grape) Good Agricultural Practices were considered for 1 to 3 spray applications at application rates of 0.3 kg parathion-methyl/ha.

2.3.2 Final regulatory action has been taken for the category ☐ Industrial

Use or uses prohibited by the final regulatory action

Use or uses that remain allowed (only in case of a severe restriction)

2.3.3 Final regulatory action has been taken for the category ☐ Pesticide

Formulation(s) and use or uses prohibited by the final regulatory action

All applications as plant protection product.

Formulation(s) and use or uses that remain allowed

(only in case of a severe restriction)

EC Member States may have granted a period of grace for disposal, storage, placing on the market and use of existing stocks, no longer than 18months from the date of adoption of Commission Decision 2003/166/EC (i.e. until 9 September 2004).

GUIDANCE

2.3 Category or categories where the final regulatory action has been taken

In the context of the Rotterdam Convention, chemicals are grouped into two categories: **pesticides** and **industrial chemicals**. Most chemicals fall into one or the other category, but regulatory actions can cover both.

Depending on the scope of the national regulatory action the information in sections 2.3.2 and 2.3.3 should be completed accordingly (e.g. industrial or pesticide or in some cases both).

2.3.1 All use(s) of the chemical in your country prior to the final regulatory action

List the use(s) of the chemical in the country before the final regulatory action was taken.
This information is essential where a chemical has been severely restricted to verify that the remaining uses constitute a severe restriction.
The CRC needs this information to understand the extent to which the regulatory action is expected to lead to a significant decrease in the quantity of chemical used or the number of its uses, or a reduction of risk in line with the criteria in Annex II, paragraph (c).

2.3.2 Final regulatory action has been taken for the category

Choose this option if the regulatory action addresses the category industrial chemical.

Use(s) prohibited by the final regulatory action
List the specific industrial chemical use(s) prohibited by the final regulatory action.

Use(s) that remain allowed (only in case of a severe restriction)
If the regulatory action is a severe restriction, list the specific industrial chemical use(s) that remain allowed.

2.3.3 Final regulatory action has been taken for the category

Choose this option if the regulatory action addresses the category pesticide.

Formulation(s) and use(s) prohibited by the final regulatory action
List the specific pesticide use(s) prohibited by the final regulatory action.
Indicate whether the final regulatory action bans or severely restricts all formulations or only certain formulations.

Formulation(s) and use(s) that remain allowed (only in case of a severe restriction)
If the regulatory action is a severe restriction, list the specific pesticide use(s) that remain allowed.
Where the final regulatory action is identified as a severe restriction, list the specific pesticide formulation(s) and use(s) that remain allowed.

EXAMPLE OF A FORM

2.4 **Was the final regulatory action based on a risk or hazard evaluation?**

☐ **Yes**

☐ **No** (If no, you may also complete section 2.5.3.3)

2.4.1 If yes, reference to the relevant documentation, which describes the hazard or risk evaluation

Review report for the active substance parathion-methyl 2665/01-final: 18 October 2002 (copy attached) and supporting background documents (dossier, monograph, and the peer review report under the Peer review Programme (ECCO, October 2002)
Directive 91/414/EEC provides for the European Commission to carry out a programme of work for the examination of existing active substances used in plant protection products which were already on the market on 25 July 1993, with a view to their possible inclusion in Annex I to the Directive.
Within this context, a number of companies notified their wish to secure the inclusion of parathion-methyl as an authorised active ingredient. A Member State was designated to undertake a hazard and risk assessment based on the dossier submitted by the notifiers. The assessment report was subjected to peer review, during which the Commission undertook extensive consultations with experts of the Member States as well as with the main notifier. The results were then reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health (SCFCAH) before a final decision was taken.

The evaluation was based on the review of scientific data generated for parathion-methyl and for the use of a representative formulation in the context of the conditions prevailing in the European Community (intended uses, recommended application rates, good agricultural practices).Only data that had been generated according to scientifically recognized methods were validated and used for the evaluation. Moreover data reviews were performed and documented according to generally recognized scientific principles and procedures.

It was concluded tat parathion-methyl was not demonstrated to fulfil the safety requirements laid down in Article 5 (1) (a) and (b) of Directive 91/414/EEC. The following areas of concern were identified: the safety of operators potentially exposed to parathion-methyl; and the possible impact of the substance on non-target insects, birds and mammals.
In addition available data were insufficient concerning the following: identity, physical and chemical properties and methods of analysis, the environmental fate and ecotoxicology of the substance; certain aspects concerning mammalian toxicology; plant metabolism and residues in treated crops

2.4.2 Summary description of the risk or hazard evaluation upon which the ban or severe restriction was based.

2.4.2.1 Is the reason for the final regulatory action relevant to human health? ☐ Yes ☐ No

If yes, give summary of the hazard or risk evaluation related to human health, including the health of consumers and workers

Final regulatory action was taken to protect operators applying plant protection products containing parathion-methyl.

The principal issues which lead to these overall conclusions relate mainly to concerns about operator exposure. Exposure scenarios using UK Predictive Operator Exposure Model demonstrated that operator exposure was unacceptable for the proposed uses within the

GUIDANCE

2.4 Choose **ONLY ONE** of the two options.

If the response is **YES**, proceed to section 2.4.1.

If the response is **NO**, proceed directly to section 2.5.3.3.

Parties do not have an obligation to base their final regulatory actions on risk or hazard evaluation. If no risk or hazard evaluation was undertaken, the notification still meets the requirements of Annex I and will be published in the PIC Circular.

2.4.1 If yes, reference to the relevant documentation, which describes the hazard or risk evaluation

List the reference to the risk or hazard evaluation or references to the specific documents which describe the risk or hazard evaluation that supports the national regulatory action.

The risk or hazard evaluation should be submitted to the Secretariat in order for the CRC to consider if the notification meets the criteria in Annex II.

2.4.2 Summary description of the risk or hazard evaluation upon which the ban or severe restriction was based.

2.4.2.1 Chose **ONLY ONE** of the two options.

If the response is **YES**, complete the following sections.

If the response is **NO**, proceed directly to section 2.4.2.2.

If yes, give summary of the hazard or risk evaluation related to human health, including the health of consumers and workers
Provide a summary of the hazard or risk evaluation on which the ban or severe restriction was based as it relates to human health, including the health of consumers and workers.
The summary should clearly identify the conditions that led to the concern regarding human health.
Where an international risk evaluation or a risk evaluation from another country is used as a basis for a national decision, the notification must demonstrate how this risk evaluation reflects the conditions prevailing in the notifying country.
A separate sheet of paper may be added to provided more information if necessary.

EXAMPLE OF A FORM

European Com munity (grapevines and table grapes). The es timated exposure exceeded the acceptable operator expos ure level (AOEL) during the m ixing/loading and the application operations, even when personal prot ective eq uipment (PPE) was worn. Usi ng t he German Model, scenarios for high crops/tractor mounted applications were accept able using PPE, but not for high crops/hand held scenarios.

A safe use for consumers exposed to potential residues resulting from the use of these plant protection products was not demonstrated. No metabolism data relevant to grapes (and processed products) were available. The notifier provided data on several crop residues, from which no extrapolation was possible, thus preventing an adequate risk assessment. Moreover this was not considered necessary as it was already demonstrated that the use of parathion - methyl was not safe for operators, which was sufficient grounds to take the final regulatory action.

Review report for the active substance parathion-methyl 2665/01-final: 18 October 2002 (copy attached) and supporting background documents (dossier, monograph, and the peer review report under the Peer review Programme (ECCO, October 2002)

Expected effect of the final regulatory action

Complete reduction of risk from plant protection uses.

2.4.2.2 Is the reason for the final regulatory action relevant to the environment? ☐ Yes ☐ No

If yes, give summary of the hazard or risk evaluation related to the environment

Final regulatory action was taken to protect non-target organisms.

Concerns were identified with regard to:

- Insectivorous birds: the acute and long-term risk was found unacceptable following the use of parathion-methyl on vines at the application rate of 0.3 kg a.s./ha, based on technical material data.
- Herbivorous mammals: the acute risk was found unacceptable following the use of parathion-methyl on vines at the application rate of 0.3 kg a.s./ha, based on technical material data.

The risk associated with the use of microencapsulated formulation was acceptable.

- Aquatic vertebrates: The risk evaluation based on data from both technical material and formulations found an unacceptable risk at the application rate of 0.3 kg a.s./ha on vines. The risk could be acceptable when mitigation measures (buffer zone) were used.
- Aquatic invertebrates: The acute and chronic risk associated with the use of both technical material and microencapsulated formulations was unacceptable at the application rate of 0.3 kg a.s./ha on vines, even when a buffer zone of 50 m was considered.
- High toxicity was recorded for non-target arthropods, and the long-term risk to earthworms was unacceptable.

Review report for the active substance parathion-methyl 2665/01-final: 18 October 2002(copy attached) and supporting background documents (dossier, monograph, and the peer review report under the Peer review Programme (ECCO, October 2002).

Expected effect of the final regulatory action

Complete reduction of risk from plant protection uses

GUIDANCE

Expected effect of the final regulatory action
Provide a summary of the expected effects to human health as a result of the final regulatory action (e.g. a ban would be expected to reduce risk to human health by eliminating exposure).
More detailed expected effects should be contained in the supporting documentation.
In the case of a severe restriction, the summary will need to clearly outline how the severe restriction led, or would be expected to lead, to significant reduction of risk for human health, including the health of consumers and workers.
The information provided here should be linked to the criteria in Annex II on reduced use and/or risk.

2.4.2.2 Is the reason for the final regulatory action relevant to the environment?

Chose **ONLY ONE** of the two options.

If the response is **YES**, complete the following sections.

If the response is **NO**, proceed directly to section 2.5.

If yes, give summary of the hazard or risk evaluation related to the environment
Provide a summary of the hazard or risk evaluation on which the ban or severe restriction was based as it relates to the environment.
The summary should clearly identify the conditions that led to the concern regarding the environment.
Where an international risk evaluation or a risk evaluation from another country is used as a basis for a national decision, the notification must demonstrate how this risk evaluation reflects the conditions prevailing in the notifying country.
A separate sheet of paper may be added to provided more information if necessary.

Expected effect of the final regulatory action
Provide a summary of the expected effects to the environment as a result of the final regulatory action (e.g. a ban would be expected to reduce risk to the environment by eliminating exposure).
More detailed expected effects should be contained in the supporting documentation.
In the case of a severe restriction, the summary will need to clearly outline how the severe restriction led, or would be expected to lead, to significant reduction of risk for the environment.
The information provided here should be linked to the criteria in Annex II on reduced use and/or risk.

EXAMPLE OF A FORM

2.5 Other relevant information regarding the final regulatory action

2.5.1 Estimated quantity of the chemical produced, imported, exported and used

	Quantity per year (MT)	Year
produced	Not available	
imported	Not available	
exported	Not available	
used	Not available	

2.5.2 Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions

The final regulatory action was taken in light of the conclusions of the risk evaluation performed for uses as proposed in Northern and Southern European Member States, which covered a large and diverse geographic area.

Similar health and environmental problems are likely to be encountered in other countries where substance is used, particularly in developing countries

2.5.3 Other relevant information that may cover:

2.5.3.1 Assessment of socio-economic effects of the final regulatory action

2.5.3.2 Information on alternatives and their relative risks, e.g. IPM, chemical and non-chemical alternatives

Intended uses within the European Community were to control Clysia ambiguella (common names: Grape bud moth, Vine moth, Grape cochylis) on vines (grape vine and table grape).

Biological agents, such as Trichogrammatidae, genre Trichogramma may be used to combat Clysia ambiguella

2.5.3.3 Basis for the final regulatory action if other than hazard or risk evaluation

2.5.3.4 Additional information related to the chemical or the final regulatory action, if any

GUIDANCE

2.5 Other relevant information regarding the final regulatory action

Information in section 2.5 should be provided where it is available. Where not available, it should be indicated as such (e.g. "Not available" rather than leaving the section blank).
Information given in this section is very useful for other countries, especially developing countries and countries with economies in transition.

2.5.1 Provide the most recent data, specifying quantity and year(s).
For pesticides, estimate the quantity of active ingredient.
For formulated products, calculate the volume of active ingredients in individual products and include this in the total quantity.

2.5.2 Example – human health:
Human health concerns with respect to occupational exposure that may be relevant to countries where personal protective equipment (PPE) is not readily available or not practicable.

Example – environment:
Environmental concerns – e.g. toxicity to aquatic environment – if not possible to ensure set backs and buffer zones under conditions of use etc.

2.5.3 Other relevant information that may cover

2.5.3.1 Socio-economic effects may include a consideration of economic impacts on farmers or producers when a pesticide is no longer available, or, in the case of an industrial chemical, the ability of industry to adapt or find a less hazardous chemical for their processes.

2.5.3.2 Where the national decision making process includes a consideration of possible alternative strategies to the chemical, e.g. integrated pest management (IPM) or industrial practices and processes (including cleaner technology).

2.5.3.3 There may be national policies regarding specific types of chemicals or chemicals with certain characteristics, e.g. persistent and bio-accumulative chemicals or chemicals that are human carcinogens.
If possible please link this information to that given in section 2.4.

2.5.3.4 Information that could be provided here includes text that might help others understand the basis for the national regulatory action or any other information that the notifying country would like to highlight.

EXAMPLE OF A FORM

SECTION 3 PROPERTIES

3.1 Information on hazard classification where the chemical is subject to classification requirements

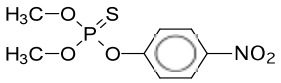
International classification systems e.g. WHO, IARC, etc.	**Hazard class**
WHO (IPCS 2000-2002)	Ia (Extremely hazardous)
IARC (1991, vol 53)	Not classifiable as to its carcinogenicity to humans (Group 3).
UN Classification	UN Hazard Class: 6.1

Other classification systems e.g. EU, USEPA	**Hazard class**
Classification in the EU in accordance with Council Directive 67/548/EEC	T+ (Very toxic), R28 (Very toxic if swallowed) T (Toxic), R24 (Toxic in contact with skin)

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Minimum purity
≥ 800 g/kg
FAO specification
≥ 950 g/Kg (FAO Specification 487/TK (2001))
Molecular Formula
C8H10NO5PS
Molecular Mass
263.23
Structural Formula



....

Reference

Full Report on parathion-methyl (ECCO, October 2002)

GUIDANCE

3.1 Information on hazard classification where the chemical is subject to classification requirements

The hazard classification relates to the active ingredient.

Enter the hazard classification from an international system in the first column and the hazard class the chemical is assigned to in the second column.

Enter the hazard classification from other systems (e.g. EU, US EPA or a national hazard classification system) in the first column and the hazard class in the second column.

3.2 Further information on the properties of the chemical

Chemical properties are usually found through international sources.

3.2.1 Provide a summary of key information only, such as description of the form of the chemical, solubility in water and organic solvents, melting point and vapour pressure with an indication of the temperature, etc.

A specific reference to the relevant documentation should be given.
The policy guidance developed for the CRC provides examples of the type of references to international sources that have been previously provided (available at www.pic.int).

Possible sources:
- Pesticide Manual
- Inchem datasheet (http://www.inchem.org/documents/pds.htm)

EXAMPLE OF A FORM

3.2.2 Description of toxicological properties of the chemical

Absorption, distribution, excretion and metabolism in mammals
Parathion-methyl is highly absorbed (>90%) and excreted within 48 hours (>99%), mainly via urine (76-92%). Parathion-methyl is extensively metabolised (desulfurization, dealkylation, sulfate conjugation, oxidation) and has no potential for accumulation.

Acute toxicity

LD50 (oral, rat)	3-20 mg/kg, (T+, very toxic)
LD50 (dermal, rat)	46-491 mg/kg (T, toxic)
LD50 (dermal, rabbit)	> 2000 mg/kg
LC50 (inhalation, nose only, 4 h, rat)	0.135 mg/l, (T+, very toxic)
Skin and eye irritation	non irritant
Sensitisation	non sensitiser (M & K)

Reference

Full Report on parathion-methyl (ECCO, October 2002)

3.2.3 Description of ecotoxicological properties of the chemical

Fate and behaviour
Soil: Parathion-methyl is not persistent in soil. Mineralisation after 120 days is about 60 % of the initial parathion-methyl treatment. Parathion-methyl degraded with half-lives of 12 to 22 days in laboratory studies. The main metabolite observed is p-nitrophenol.
Water:
- Ground water: Parathion-methyl is adsorbed and is not expected to leach in soil with water. Koc adsorption = 230 to 670.
- Surface water: hydrolysis half lives of parathion-methyl range from 33 to 68 days, depending of pH. Parathion-methyl is assumed to be biodegradable.

Air: volatilisation: 74% of the applied dose was lost from plant surfaces after 24 hours, whereas its volatilisation from soil was markedly lower.

Reference

Full Report on parathion-methyl (ECCO, October 2002)

GUIDANCE

3.2.2 Provide a summary of key information only, such as acute toxicity, short and long-term exposure, effects on reproduction, mutagenicity, carcinogenicity, etc.

A specific reference to the relevant documentation should be given. Please ensure to indicate whether the information given above is based on national studies or taken from references.

The policy guidance developed for the CRC provides examples of the type of references to international sources that have been previously provided (available at www.pic.int).

3.2.3 Provide a summary of key information only, such as toxicity to fish, aquatic invertebrates, birds, bees, etc.

A specific reference to the relevant documentation should be given. Please ensure to indicate whether the information given above is based on national studies or taken from references.

The policy guidance developed for the CRC provides examples of the type of references to international sources that have been previously provided (available at www.pic.int).

EXAMPLE OF A FORM

SECTION 4 **DESIGNATED NATIONAL AUTHORITY**

Institution	
Address	
Name of person in charge	
Position of person in charge	
Telephone	
Telefax	
E-mail address	

Date, signature of DNA and official seal: _____

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
Food and Agriculture Organization
of the United Nations (FAO)
Viale delle Terme di Caracalla
00100 Rome, Italy
Tel: (+39 06) 5705 2188
Fax: (+39 06) 5705 6347
E-mail: pic@pic.int

OR

Secretariat for the Rotterdam Convention
United Nations Environment
Programme (UNEP)
11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland
Tel: (+41 22) 917 8177
Fax: (+41 22) 917 8082
E-mail: pic@pic.int

GUIDANCE

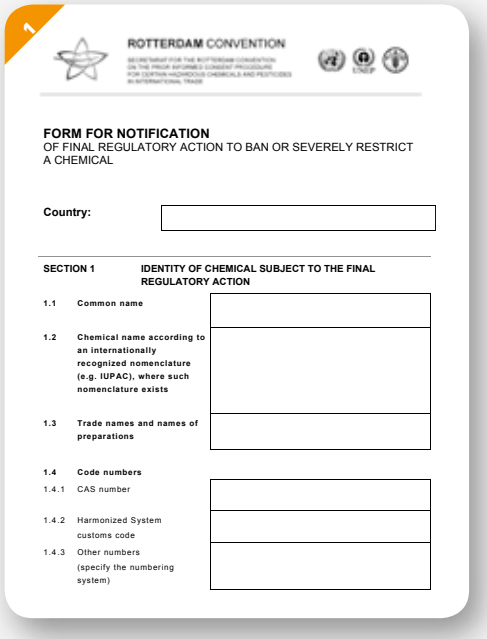
The name of the institution, complete address, name and position of the person in charge (if applicable), telephone, fax and/or e-mail for the DNA should be given here.

This information must be provided for each notification form submitted to the Secretariat.

Date, signature of DNA and official seal:
The date of completion of the form, signature of the DNA and official seal must be provided for each notification form submitted.
Please note that the date given here refers to the form itself and not the date of the regulatory action, which is given in section 1.5.

The form for notification of final regulatory action to ban or severely restrict a chemical

is available in English, French and Spanish on the website at www.pic.int



ROTTERDAM CONVENTION

SECRETARIAT FOR THE ROTTERDAM CONVENTION ON THE PRIOR INFORMED CONSENT PROCEDURE FOR CERTAIN HAZARDOUS CHEMICALS AND PESTICIDES IN INTERNATIONAL TRADE

FORM FOR NOTIFICATION
OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

Country:

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1 Common name

1.2 Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists

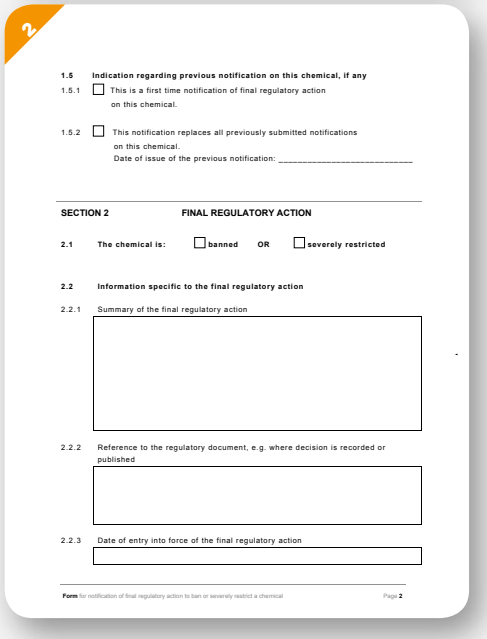
1.3 Trade names and names of preparations

1.4 Code numbers

1.4.1 CAS number

1.4.2 Harmonized System customs code

1.4.3 Other numbers (specify the numbering system)



1.5 Indication regarding previous notification on this chemical, if any

1.5.1 ☐ This is a first time notification of final regulatory action on this chemical.

1.5.2 ☐ This notification replaces all previously submitted notifications on this chemical.
Date of issue of the previous notification: _____

SECTION 2 FINAL REGULATORY ACTION

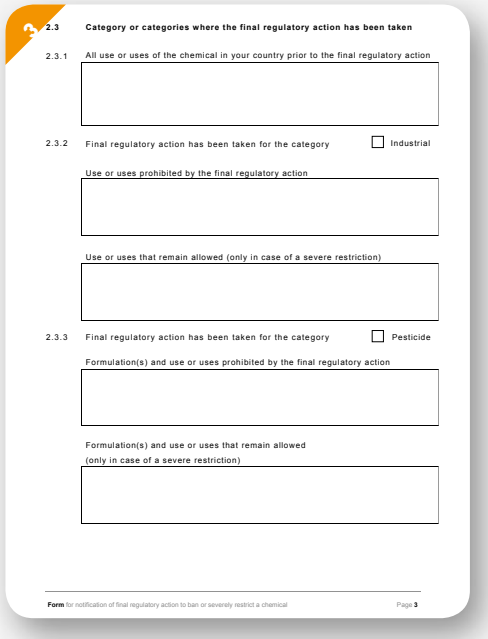
2.1 The chemical is: ☐ **banned** **OR** ☐ **severely restricted**

2.2 Information specific to the final regulatory action

2.2.1 Summary of the final regulatory action

2.2.2 Reference to the regulatory document, e.g. where decision is recorded or published

2.2.3 Date of entry into force of the final regulatory action



2.3 Category or categories where the final regulatory action has been taken

2.3.1 All use or uses of the chemical in your country prior to the final regulatory action

2.3.2 Final regulatory action has been taken for the category ☐ Industrial

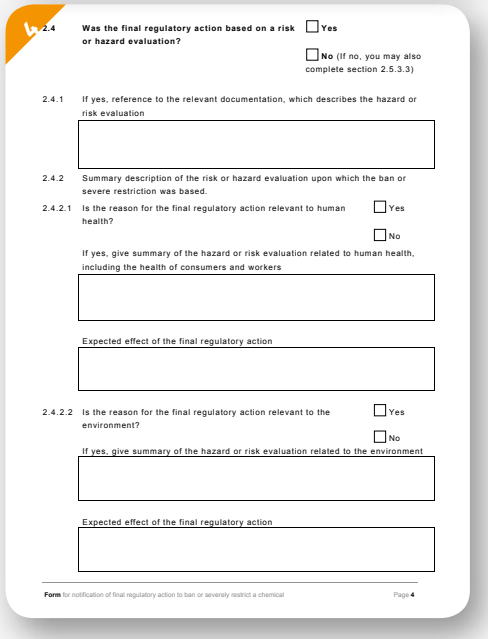
Use or uses prohibited by the final regulatory action

Use or uses that remain allowed (only in case of a severe restriction)

2.3.3 Final regulatory action has been taken for the category ☐ Pesticide

Formulation(s) and use or uses prohibited by the final regulatory action

Formulation(s) and use or uses that remain allowed (only in case of a severe restriction)



2.4 Was the final regulatory action based on a risk or hazard evaluation? ☐ **Yes** ☐ **No** (If no, you may also complete section 2.5.3.3)

2.4.1 If yes, reference to the relevant documentation, which describes the hazard or risk evaluation

2.4.2 Summary description of the risk or hazard evaluation upon which the ban or severe restriction was based.

2.4.2.1 Is the reason for the final regulatory action relevant to human health? ☐ Yes ☐ No

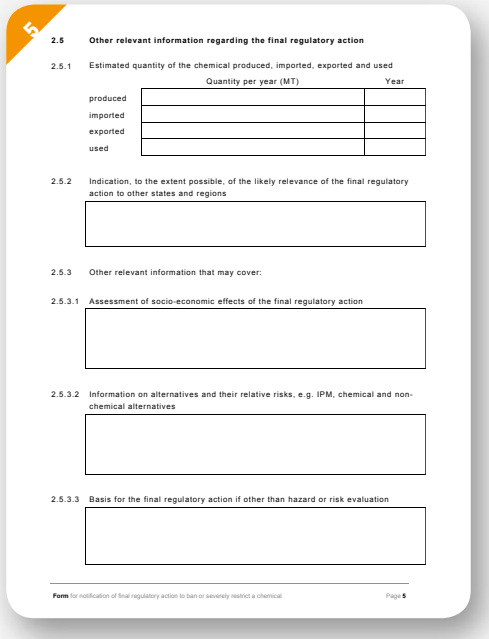
If yes, give summary of the hazard or risk evaluation related to human health, including the health of consumers and workers

Expected effect of the final regulatory action

2.4.2.2 Is the reason for the final regulatory action relevant to the environment? ☐ Yes ☐ No

If yes, give summary of the hazard or risk evaluation related to the environment

Expected effect of the final regulatory action



2.5 Other relevant information regarding the final regulatory action

2.5.1 Estimated quantity of the chemical produced, imported, exported and used

	Quantity per year (MT)	Year
produced		
imported		
exported		
used		

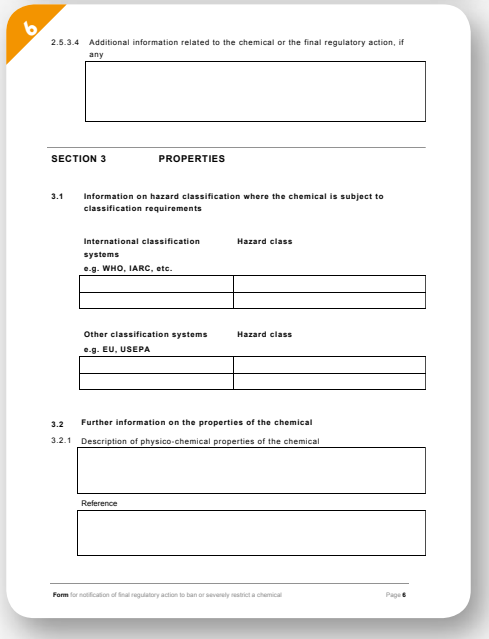
2.5.2 Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions

2.5.3 Other relevant information that may cover:

2.5.3.1 Assessment of socio-economic effects of the final regulatory action

2.5.3.2 Information on alternatives and their relative risks, e.g. IPM, chemical and non-chemical alternatives

2.5.3.3 Basis for the final regulatory action if other than hazard or risk evaluation



2.5.3.4 Additional information related to the chemical or the final regulatory action, if any

SECTION 3 PROPERTIES

3.1 Information on hazard classification where the chemical is subject to classification requirements

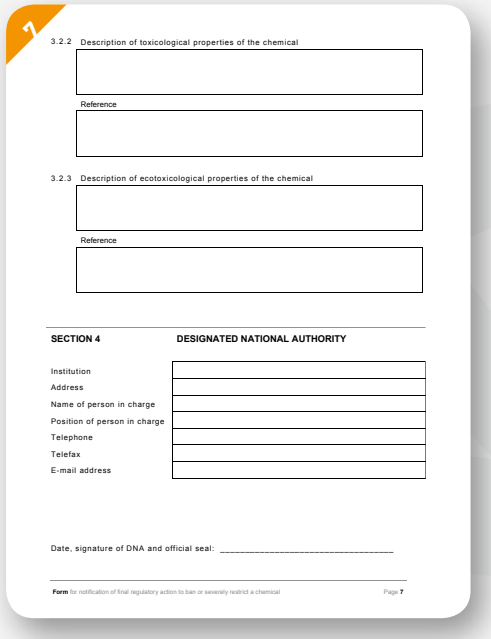
International classification systems e.g. WHO, IARC, etc.	**Hazard class**

Other classification systems e.g. EU, USEPA	**Hazard class**

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Reference



3.2.2 Description of toxicological properties of the chemical

Reference

3.2.3 Description of ecotoxicological properties of the chemical

Reference

SECTION 4 DESIGNATED NATIONAL AUTHORITY

Institution	
Address	
Name of person in charge	
Position of person in charge	
Telephone	
Telefax	
E-mail address	

Date, signature of DNA and official seal: _____

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
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of the United Nations (FAO)
Viale delle Terme di Caracalla
00100 Rome, Italy
Tel: (+39 06) 5705 2188
Fax: (+39 06) 5705 6347
E-mail: pic@pic.int

OR

Secretariat for the Rotterdam Convention
United Nations Environment
Programme (UNEP)
11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland
Tel: (+41 22) 917 8177
Fax: (+41 22) 917 8082
E-mail: pic@pic.int

Definitions for the purposes of the Rotterdam Convention according to Article 2:

(a) 'Chemical' means a substance whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial;

(b) 'Banned chemical' means a 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 first-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;

(c) 'Severely restricted chemical' means a chemical virtually all use of which within one or more categories has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a chemical that has, for virtually all use, been refused for approval or 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;

(d) 'Final regulatory action' means an action taken by a Party, that does not require subsequent regulatory action by that Party, the purpose of which is to ban or severely restrict a chemical.