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**INSTRUCTIONS –
NOTIFICATION OF FINAL REGULATORY ACTION TO
BAN OR SEVERELY RESTRICT A CHEMICAL**

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

I. INTRODUCTION

The Conference of Plenipotentiaries held in Rotterdam on 10 and 11 of September 1998, adopted the text of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (hereinafter referred to as the "Convention").

The Conference considered that interim arrangements are required to continue to operate a voluntary PIC procedure in order to protect human health and the environment from certain hazardous chemicals and pesticides pending entry into force of the Convention and to prepare for its effective operation once it enters into force. The Conference changed the original, voluntary, procedure to bring it into line with the procedure established by the Convention with effect from the date on which the Convention was opened for signature (11 September 1998). The original PIC procedure with these changes is hereinafter referred to as the "interim PIC procedure".

The Conference designated the Intergovernmental Negotiating Committee (hereinafter referred to as the "Committee") to oversee the operation of the interim PIC procedure. The Committee decides, between the date on which the Convention is opened for signature and the date of its entry into force, on the inclusion of any additional chemicals under the interim PIC procedure in accordance with the provisions of Articles 5, 6, 7 and 22 of the Convention. It will establish an interim subsidiary body to discharge the functions entrusted to the subsidiary body to be established under Article 18, paragraph 6, of the Convention.

Nominations of designated national authorities, notifications of control actions and import responses made under the original PIC procedure remain in effect under the interim PIC procedure unless and until the State or regional economic integration organization concerned notifies the interim secretariat in writing that it has decided otherwise.

States and regional economic integration organizations should submit notifications of final regulatory action in accordance with the provisions of Article 5 of the Convention. Developing countries and countries with economies in transition that are in a position to do so should submit proposals concerning severely hazardous pesticide formulations in accordance with the provisions of Article 6 of the Convention.

The interim PIC procedure shall cease to operate on a date to be specified by the Conference of the Parties at its first meeting.

This document provides instructions for the completion of the form for notification of final regulatory action to ban or severely restrict a chemical. The procedure regarding notification is described in the [Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Article 5.](#)

II. DEFINITIONS

According to Article 3 of the Convention, the Convention applies to: (a) banned or severely restricted chemicals; and (b) severely hazardous pesticide formulations.

“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.

“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 was taken in order to protect human health or the environment.

“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, for virtually all use, has been refused 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 was taken in order to protect human health or the environment.

The Convention does not apply to: (a) Narcotic drugs and psychotropic substances; (b) Radioactive materials; (c) wastes; (d) chemical weapons; (e) pharmaceuticals, including human and veterinary drugs; (f) chemicals used as food additives; (g) food; (h) chemicals in quantities not likely to affect human health or the environment provided they are imported; (i) for the purpose of research or analysis; or (ii) by an individual for his or her own personal use in quantities reasonable for such use.

III. GENERAL INSTRUCTIONS

- *These instructions seek to assist DNAs to complete the Notification of Final Regulatory Action to Ban or Severely Restrict a Chemical form. They provide detailed explanation of the information required under the various sections of the form. Please study these instructions carefully before filling out the form.*
- *The Notification form is available in English, French and Spanish. Countries may respond in any of these three languages.*
- *Please type the information into the form.*
- *If you wish to submit the Notification form electronically, please contact the Secretariat. Electronic submission will greatly facilitate the manipulation of the submitted information, and the Secretariat encourages DNAs to do so.*
- *Where “Reference to the relevant documentation” is requested in the form, you should provide the source of the information reported. This can e.g. be published or unpublished documents, internal reports, etc.*
- *Although you may attach copies of such relevant documentation, please note, however, that the form must be filled in with the relevant information, it is not sufficient to refer only to supporting documentation.*
- *If additional space is needed, please continue on a separate sheet of paper, clearly indicating which section of the form the information is related to.*
- *If you have any additional information that is not requested in the form, this may also be reported on a separate sheet of paper attached to the form.*
- *Please return the completed form to:*

*Interim Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy*

or

*Interim Secretariat for the Rotterdam Convention
UNEP Chemicals
11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland*

IV. INSTRUCTIONS FOR THE SPECIFIC SECTIONS OF THE FORM

PART I: PROPERTIES, IDENTIFICATION AND USES

1. IDENTITY OF CHEMICAL	
1.1	<p>Common name</p> <ul style="list-style-type: none"> The chemical identified in Section 1.1 to 1.4 is the chemical for which the final regulatory action reported in Part II below should apply. If reporting a final regulatory action that applies to a group of chemicals, please provide specific chemical name for each chemical covered by the final regulatory action.
1.2	<p>Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists</p> <ul style="list-style-type: none"> Chemical name, using an internationally recognized nomenclature must be provided, in order to allow for a precise identification of the chemical. Please always indicate the nomenclature system used here.
1.3	<p>Trade names and names of preparations</p> <ul style="list-style-type: none"> Trade names and names of preparations of the chemical must be given.

1.4 Code numbers	
1.4.1	<p>CAS number</p> <ul style="list-style-type: none"> The CAS (Chemicals Abstract Service) number must always be provided, in order to allow for a precise identification of the chemical being notified. If reporting a final regulatory action that applies to a group of chemicals, please provide CAS-number for each chemical covered by the final regulatory action.
1.4.2	<p>Harmonized System customs code</p> <ul style="list-style-type: none"> The code number for the chemical from the Harmonized Commodity Description and Coding System, generally referred to as the Harmonized System, developed by the World Customs Organization (WCO), should be given.
1.4.3	<p>Other numbers (specify the numbering system)</p> <ul style="list-style-type: none"> Other numbers can also be given (i.e. EINECS, RTECS), please remember to specify the numbering system used.

1.5 Indication regarding previous notification on this chemical, if any

A notification can be revised with a resubmitted notification form. When revising a notification, you can either provide modifications to certain sections, or provide a new notification that replaces all previous notifications.



Please check **ONLY ONE** of the three options to indicate whether this is:

- a first time notification on this chemical from your country;
- a modification of a previous notification on this chemical from your country;
- a notification which replaces all previously submitted notifications on this chemical.

In case of a modification or a replacement of a previous notification, please indicate the date of issuing of the last notification.

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

The hazard classification given here should be **for the active ingredient**. Please enter in the first column the hazard classification system and in the second column the hazard class the chemical is assigned to. In the first part, information on hazard classification of the chemical from international systems (e.g. WHO, IARC,

etc.) must be given. In the second part, information from any other hazard classification system (e.g. EU, US EPA or other national hazard classification system) can be given.

1.7	Use or uses of the chemical
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Please check **ONE OR BOTH** of the chemical categories (pesticide or industrial) for which there is use in your country and describe the main and/or most significant uses of the chemical, within each category.

1.8	Properties
1.8.1	Description of physico-chemical properties <ul style="list-style-type: none"> Please provide relevant information only, e.g. on description of the form, solubility in water and organic solvents, melting point and vapour pressure with an indication of the temperature.
1.8.2	Description of toxicological properties <ul style="list-style-type: none"> Please provide relevant information only, e.g. on acute toxicity, short- and long-term exposure, effects on reproduction, mutagenicity and carcinogenicity. Please continue on a separate sheet of paper if needed. Please indicate whether the information is based on national studies or taken from references. A reference to the relevant documentation should be given.
1.8.3	Description of ecotoxicological properties <ul style="list-style-type: none"> Please provide relevant information only, e.g. on toxicity to fish, aquatic invertebrates, birds and bees. Please continue on a separate sheet of paper if needed. Indicate whether the information is based on national studies or taken from references. A reference to the relevant documentation should be given.

PART II: FINAL REGULATORY ACTION


2.	FINAL REGULATORY ACTION
2.1	The chemical is: <input type="checkbox"/> banned OR <input type="checkbox"/> severely restricted




Please check **ONLY ONE** of the two options to indicate whether the final regulatory action reported in the notification form is a ban or a severe restriction.


2.2	Information specific to the final regulatory action
2.2.1	Summary of the final regulatory action <ul style="list-style-type: none"> Please provide a summary description of the ban or severe restriction you are reporting on, taking into account what constitutes such an action according to the definitions given in Section II of these instructions.
2.2.2	Reference to the regulatory document <ul style="list-style-type: none"> Please provide a reference to the national regulatory document where the decision on the final regulatory action can be found.
2.2.3	Date of entry into force of the final regulatory action <ul style="list-style-type: none"> The date (day, month, year) of entry into force of the final regulatory action must be provided. Please note that this is the effective date when the regulatory action came into force for the chemical, not e.g. the date when the decision was taken or when the decision was published.

2.3	Was the final regulatory action based on a risk or hazard evaluation?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	If yes, give information on such evaluation	
	<ul style="list-style-type: none"> • <i>Please provide a summary description of the risk or hazard evaluation upon which the ban or severe restriction was based.</i> • <i>When providing such a summary, you might want to indicate whether:</i> <ul style="list-style-type: none"> (i) <i>the evaluation is based on a review of scientific data in the context of the conditions prevailing in the country;</i> (ii) <i>the documentation demonstrates that data have been generated according to scientifically recognized methods;</i> (iii) <i>data reviews have been performed and documented according to generally recognized scientific principles and procedures;</i> (iv) <i>the final regulatory action was based on a risk evaluation involving prevailing conditions within the country taking the action.</i> 	
	Reference to the relevant documentation	
	<ul style="list-style-type: none"> • <i>Please provide a reference to the relevant documentation.</i> 	

2.4	Reasons for the final regulatory action	
2.4.1	Is the reason for the final regulatory action relevant to human health?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers	
	 <i>Please check <input checked="" type="checkbox"/> ONLY ONE of the two options to indicate whether the final regulatory action was taken because of human health considerations.</i> <ul style="list-style-type: none"> • <i>If you check <input checked="" type="checkbox"/> “Yes”, please provide a summary of information on the concerns your government had, relevant to human health, including the health of consumers and workers, when the government took the final regulatory action. Add a separate sheet of paper if necessary.</i> • <i>It is extremely important to provide details regarding the reasons for the final regulatory action for each notification. The reasons for the decision should be relevant to the conditions of use in the reporting country. This information is essential for the Chemical Review Committee when reviewing the notification and making a recommendation on whether or not the chemical should be included in the PIC procedure.</i> 	
	Reference to the relevant documentation	
	<ul style="list-style-type: none"> • <i>Please provide a reference to the relevant documentation.</i> 	
	Expected effect of the final regulatory action	
	<ul style="list-style-type: none"> • <i>Please give an assessment of the expected improvement in human health due to the final regulatory action.</i> • <i>Such an assessment might include a consideration of whether the final regulatory action led, or would be expected to lead:</i> <ul style="list-style-type: none"> (i) <i>to a significant decrease in the quantity of the chemical used or the number of its uses;</i> (ii) <i>to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health, including the health of consumers and workers.</i> 	

2.4.2	Is the reason for the final regulatory action relevant to the environment?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	If yes, give summary of the known hazards and risks to the environment	
 Please check <input checked="" type="checkbox"/> <u>ONLY ONE</u> of the two options to indicate whether the final regulatory action was taken because of environmental considerations.		
<ul style="list-style-type: none"> If you check <input checked="" type="checkbox"/> “Yes”, please provide a summary of information on the concerns your government had, relevant to the environment, when the government took the final regulatory action. Add a separate sheet of paper if necessary. It is extremely important to provide details regarding the reasons for the final regulatory action for each notification. The reasons for the decision should be relevant to the conditions of use in the reporting country. This information is essential for the Chemical Review Committee when reviewing the notification and making a recommendation on whether or not the chemical should be included in the PIC procedure. 		
Reference to the relevant documentation		
<ul style="list-style-type: none"> Please provide a reference to the relevant documentation. 		
Expected effect of the final regulatory action		
<ul style="list-style-type: none"> Please give an assessment of the expected improvement in environment due to the final regulatory action. Such an assessment might include a consideration of whether the final regulatory action led, or would be expected to lead: <ol style="list-style-type: none"> to a significant decrease in the quantity of the chemical used or the number of its uses; to an actual reduction of risk or would be expected to result in a significant reduction of risk for the environment. 		

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

 Please check **ONE OR BOTH** of the chemical categories (industrial or pesticide) for which the final regulatory action has been taken.

2.5.1	Final regulatory action has been taken for the chemical category	<input type="checkbox"/> Industrial
	Use or uses prohibited by the final regulatory action	
	<ul style="list-style-type: none"> Please list specifically the use or uses prohibited by the final regulatory action. 	
2.5.1	Use or uses that remain allowed	
	<ul style="list-style-type: none"> Please list specifically the use or uses that remain allowed. 	
2.5.2	Final regulatory action has been taken for the chemical category	<input type="checkbox"/> Pesticide
	Formulation(s) and use or uses prohibited by the final regulatory action	
	<ul style="list-style-type: none"> Please list specifically the use or uses prohibited by the final regulatory action. When reporting on pesticides please indicate whether the final regulatory action bans or severely restricts all formulations of the chemical or bans or severely restricts only certain types of formulations or certain concentrations of active ingredient of a chemical. 	
2.5.2	Formulation(s) and use or uses that remain allowed	
	<ul style="list-style-type: none"> Please list specifically the use or uses that remain allowed. If the final regulatory action bans or severely restricts only some types of formulations and concentrations of active ingredient, while other types of formulations and concentrations of active ingredient remain allowed, please list these in this section. 	

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.

State specifically, where available, the quantity in metric tons (MT) of the chemical produced, imported, exported and used annually, with the most recent data, specifying period and year(s).

For pesticides, estimate the quantity of active ingredients. For formulated products, calculate the volume of active ingredients in individual products and include this in the total quantity.

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

Please provide, to the extent possible, an indication on the likely relevance of the final regulatory action to other countries and regions. The information provided might include an assessment of whether the considerations that lead to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances.

The information you provide may be useful for the governments of other countries with the same problem as you have already recognised and regulated. Also, this information is relevant to the Chemical Review Committee when reviewing the notification and making a recommendation on whether or not the chemical should be included in the PIC procedure.

2.7 Other relevant information that may cover:**2.7.1 Assessment of socio-economic effects of the final regulatory action**

- An assessment of potential socio-economic effects at the national level, once the final regulatory action comes into force, can be provided.

2.7.2 Information on alternatives and their relative risks

- Views on availability of alternative substances or alternative strategies can be given, with their relative risks. Attach a detailed description where possible. If investigations or recommendations on possible alternative strategies to the regulated chemical have been discussed in connection with the final regulatory action, such as IPM strategies or industrial practices and processes (including cleaner technology), please provide detailed information.

2.7.3 Relevant additional information

- The DNA may include any information being of relevance to the final regulatory action, such as labelling requirements, transport regulations, etc.

PART III : GOVERNMENT AUTHORITIES**Ministry/Department and authority responsible for issuing/enforcing the final regulatory action**

The complete name of the institution, address, telephone, telefax or telex numbers, e-mail for the authority responsible for issuing/enforcing the final regulatory action should be given here.

Designated National Authority

The complete name of the institution of the DNA, address, name and position of the person in charge, telephone, telefax or telex and e-mail must be provided for each notification form.

Date, signature of DNA and official seal

The date of issuance of the form, signature of the DNA and official seal must be provided for each individual form to ensure that each document obtains its legal status. If all or part of the information regarding this point is missing, the form will be considered incomplete and can not be accepted as an official notification.