



**United Nations
Environment Programme**

**Food and Agriculture Organization
of the United Nations**

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Interim Chemical Review Committee

Fifth session

2–6 February 2004

Item 5 (a) (v) of the provisional agenda *

Inclusion of chemicals in the interim prior informed consent procedure:

**Review of notifications of final regulatory actions to ban
or severely restrict a chemical:**

Vinclozolin

Vinclozolin

Note by the secretariat

1. In line with article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, when the secretariat has received at least one notification from each of interim two prior informed consent (PIC) regions that contain the information required in Annex I of the Convention, it shall forward the notifications and accompanying documentation to the members of the Interim Chemical Review Committee. The Committee shall review the information provided in such notifications and, in accordance with the criteria set out in Annex II, recommend to the Intergovernmental Negotiating Committee whether the chemical in question should be made subject to the interim PIC procedure and a decision guidance document drafted.
2. In decision INC-7/6, the Intergovernmental Negotiating Committee adopted a process for drafting decision guidance documents. The process is based on that developed by the Committee at its first session, held in Geneva in February 2000. An excerpt from the decision may be found in document UNEP/FAO/PIC/ICRC.5/INF/3.
3. The secretariat has identified two verified notifications from two interim PIC regions relating to vinclozolin (Near East – Jordan and Europe – Norway). Summaries of these notifications are included in PIC circulars XIV, for December 2001, and XVIII, for December 2003.
4. The annex to the present note contains the two notifications as they were received from the notifying countries.
5. The relevant documentation, including focused summaries, provided by Jordan and Norway in conjunction with their notifications is before the Committee in the addenda to the present note (UNEP/FAO/PIC/ICRC.5/12/Add.1 and Add.2, respectively).

* UNEP/FAO/PIC/ICRC.5/1.



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

IMPORTANT: See instructions before filling in the form

COUNTRY: **JORDAN**

OK

PART I: PROPERTIES, IDENTIFICATION AND USES

1. IDENTITY OF CHEMICAL		
1.1	Common name	vinclozolin
1.2	Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists	(RS)-3-(3,5-dichlorophenyl)-5-methyl-5-vinyl-1,3-oxazolidine-2,4-dione
1.3	Trade names and names of preparations	Ronilan wp
1.4	Code numbers	
1.4.1	CAS number	50471-44-8] unstated stereochemistry Development codes BAS 352F (BASF)
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	<input type="radio"/> This is a first time notification of final regulatory action on this chemical (YES)
1.5.2	<input type="radio"/> This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ <input type="radio"/> This notification replaces all previously submitted notifications on this chemical. Date of issue of the previous notification: _____

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

CH

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Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@fao.org

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

1.8.3	Description of ecotoxicological properties of the chemical
	Birds Acute oral LD ₅₀ for quail >2510 mg/kg. LC ₅₀ for quail >5620 mg/kg. Fish LC ₅₀ (96 h) for trout 22-32, guppies 32.5, bluegill sunfish 50 mg/l. Daphnia LC ₅₀ (48 h) 4.0 mg/l. Bees Not toxic to bees. LD ₅₀ >200 mg/bee. Worms Not toxic to earthworms.

PART II: FINAL REGULATORY ACTION

2.	FINAL REGULATORY ACTION	
2.1	The chemical is: BANNED θ	
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 (VINCLOZOLIN)	
2.2.2	Reference to the regulatory document	
	INFORMATION RECEIVED FROM MANUFACTURE (BASF)	
2.2.3	Date of entry into force of the final regulatory action	
	1993	

2.3	Was the final regulatory action based on a risk or hazard evaluation?	θ Yes
	If yes, give information on such evaluation	
	Reference to the relevant documentation	

2.4	Reasons for the final regulatory action	
2.4.1	Is the reason for the final regulatory action relevant to the human health?	θ Yes
	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>it may cause harm to to the un born child</i>	

	Reference to the relevant documentation	
	Expected effect of the final regulatory action	
	complet risk reduction for plant protection uses (especially pregnant woman))	

2.4.2	Is the reason for the final regulatory action relevant to the environment?	⊖ No
	If yes, give summary of the known hazards and risks to the environment	
	Reference to the relevant documentation	
	Expected effect of the final regulatory action	

2.5	Category or categories where the final regulatory action has been taken	
2.5.1	Final regulatory action has been taken for the chemical category	⊖ Industrial
	Use or uses prohibited by the final regulatory action	
	Use or uses that remain allowed	

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2.5.2	Final regulatory action has been taken for the chemical category	θ Pesticide
	Formulation(s) and use or uses prohibited by the final regulatory action	
	ALL FORMULATION.AND ALL USES FOR PLANT PROTETION	
2.5.2	Formulation(s) and use or uses that remain allowed	

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.		
	Quantity per year (MT)	Year
Produced		
Imported	962KG	1992
Exported		
Used	926KG	1992

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

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

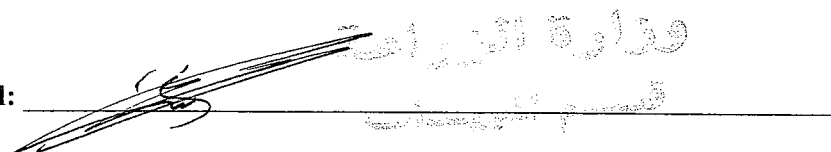
2.7.2	Information on alternatives and their relative risks	
	CARBENDAZIM	

2.7.3	Relevant additional information	

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Designated National Authority	
Institution	MINISTRY OF AGRICULTURE
Address	P.O.BOX :961044- -2099 AMMAN
Name of person in charge	MAHMOUD AL-KHTOOM
Position of person in charge	DIRECTOR OF PLANT PROTECTION DEPARTMENT
Telephone	5686151
Telefax	5686310
E-mail address	PRD@JOINNET.COM.JO.

Date, signature of DNA and official seal: _____



Date 12/11/2003

To: The Interim Secretariat of Rotterdam Convention,
Food and Agriculture Organization of the United Nations,
AGPP, Rome, Italy
Attention: Murray William
Cc: Elisabetta Tagliati

Subject: Amendments to entries in the notification submitted by the Hashemite Kingdom of Jordan regarding endosulfan, vinclozolin, endrin, dimefox and mevinphos

Dear Sir,

Reference your fax dated 28/10/2003 regarding clarification of some entries in the notification forms submitted by Jordan; please amend the forms to read as indicated below:

1-Endosulfan:

• Section 2.2.2

Amend entries to read as session 271 of Agricultural Pesticide Committee, date 25/7/1991. Application for registration of endosulfan was also rejected by the committee in session 325 date 4/5/1994.

• Section 2.2.1

Amend entries to read as stop granting any new import license for formulations containing this active ingredient. Registered products will continue to be used until the expiry of their license (max. 4 years) after which registration will be cancelled.

• Section 2.2.3

Amend date of entry into force to read as 1991

• Section 2.5.2

Amend uses remain allowed to read as no uses remain allowed.

2-Vinclozolin:

• Section 2.2.2

Waiting for translation into English

• Section 2.4 (reference to relevant documents)

Amend entry to read as information submitted by manufacturer (BASF)

• Section 2.5.2

Amend uses remain allowed to read as no uses remain allowed.

3-Endrin

• Section 2.2.2;

Amend entry to read as session 68 of the Agricultural Pesticide Committee, date 29/10/1980

• Section 2.2.3

Amend date of entry into force to read as 1/1/1981.

• Section 2.5.2

Amend uses remain allowed to read as no uses remain allowed.

4-Dimefox:

- Section 1.6

Please refer to WHO Hazard Classification, table 6, Active Ingredients believed to be obsolete,

- Section 1.8.1

Please refer to Organophosphorus pesticides (group monograph 1989) by INCHEM,

- Section 2.2.2

Amend entry to read as session 68 of the Agricultural Pesticide Committee, date 29/10/1980

- Section 2.2.3

Amend date of entry into force to read as 1/1/1981

- Section 2.5.2

Amend uses remain allowed to read as no uses remain allowed.

5- Mevinphos:

- Section 2.2.2

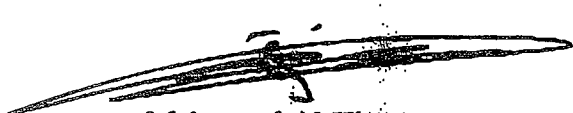
Amend entry to read as session 331 of the Agricultural Pesticide Committee, date 9/8/1994

- Section 2.5.2

Amend uses remain allowed to read as no uses remain allowed.

Please find attached all relevant documentation translated into English.

Regards



Mahmoud Al-Khtoom
Director of Plant Protection Department
(DNA for Pesticides)

مدير وقاية النبات
المهندس محمود الختوم



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

IMPORTANT: See instructions before filling in the form

COUNTRY: NORWAY

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	IDENTITY OF CHEMICAL	
1.1	Common name	Vinclozolin
1.2	Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists	(RS)-3-(3,5-dichlorophenyl)-5-methyl-5-vinyl-1,3-oxazolidine-2,4-dione
1.3	Trade names and names of preparations	Ronilan FL
1.4	Code numbers	
1.4.1	CAS number	50471-44-8
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	<input checked="" type="checkbox"/> This is a first time notification of final regulatory action on this chemical.	
1.5.2	<input type="checkbox"/> This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____	
	<input type="checkbox"/> This notification replaces all previously submitted notifications on this chemical.	
	Date of issue of the previous notification: _____	

1.6 Information on hazard classification where the chemical is subject to classification requirements	
International classification systems	Hazard class
EU	T – Toxic
	R60 May impair fertility
	R63 Possible risk of harm to the unborn child
	R43 May cause sensitisation by skin contact
	R215 Possible risk of cancer
Other classification systems	Hazard class
Norwegian	Toxic to fish and other water organisms

1.7 Use or uses of the chemical	
1.7.1	<input checked="" type="checkbox"/> Pesticide
	Describe the uses of the chemical as a pesticide in your country:
	Not relevant (not in use since 1.1.99)
1.7.2	<input type="checkbox"/> Industrial
	Describe the industrial uses of the chemical in your country:

1.8 Properties																											
1.8.1	Description of physico-chemical properties of the chemical																										
	<table> <tr> <td>Identity</td><td>White solid</td></tr> <tr> <td>Formula</td><td>C₁₂H₉Cl₂NO₃</td></tr> <tr> <td>Chemical name</td><td>(RS)-3-(3,5-dichlorophenyl)-5-methyl-5-vinyl-1,3-oxazolidine-2,4-dione</td></tr> <tr> <td>Chemical type</td><td></td></tr> <tr> <td>CAS number</td><td>50471-44-8</td></tr> <tr> <td>Molecular weight</td><td>286.1</td></tr> <tr> <td>Solubility</td><td>2.6 mg/l (water, 20 °C). Organic solvents (mg/100 ml, temperature not given): 6.3 (diethylether), 1.4 (ethylalcohol), 31.9 (chloroform), 43.5 (acetone), 25.3 (ethylacetat), 0.9 (cyclohexan), 14.6 (benzen).</td></tr> <tr> <td>logKow</td><td>3</td></tr> <tr> <td>Vapour pressure</td><td>1.3 x 10⁻⁴ Pa (20°C)</td></tr> <tr> <td>Melting point</td><td>108°C</td></tr> <tr> <td>Boiling point</td><td>-</td></tr> <tr> <td>Dissociation constant</td><td>-</td></tr> <tr> <td>Henry's law constant</td><td>-</td></tr> </table>	Identity	White solid	Formula	C ₁₂ H ₉ Cl ₂ NO ₃	Chemical name	(RS)-3-(3,5-dichlorophenyl)-5-methyl-5-vinyl-1,3-oxazolidine-2,4-dione	Chemical type		CAS number	50471-44-8	Molecular weight	286.1	Solubility	2.6 mg/l (water, 20 °C). Organic solvents (mg/100 ml, temperature not given): 6.3 (diethylether), 1.4 (ethylalcohol), 31.9 (chloroform), 43.5 (acetone), 25.3 (ethylacetat), 0.9 (cyclohexan), 14.6 (benzen).	logKow	3	Vapour pressure	1.3 x 10 ⁻⁴ Pa (20°C)	Melting point	108°C	Boiling point	-	Dissociation constant	-	Henry's law constant	-
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Boiling point	-																										
Dissociation constant	-																										
Henry's law constant	-																										

1.8.2	Description of toxicological properties of the chemical
	1. Acute toxicity to laboratory animals Oral: LD ₅₀ , rats > 10 000 mg/kg bw Dermal: LD ₅₀ rats > 2500 mg/kg bw Inhalation: LC ₅₀ rats > 29.1 mg/l Intraperitoneal: LD ₅₀ rats ca 5000 mg/kg bw

Irritant and allergenic properties: Vinclozolin is a mild irritant to skin and eyes. It has been shown to cause sensitisation in contact with skin.

2. Short-term exposure: Subacute and subchronic studies in Wistar rats and dogs caused anemia and vacuolation and lipidosis in the adrenal cortex, Leydig cell hyperplasia in the testes and atrophy of the prostate. In rats there was also seen degeneration of the liver, pancreas, ovaries and of the pituitary gland, and atrophy of the epididymis and seminal vesicles. Degeneration of the lenses was seen at 2.7 mg/kg bw/day, and cataracts were seen at 7.5 mg/kg bw/day.

3. Long-term exposure/Carcinogenicity:

Rats, study performed in 1994. There was a dose-response effect of Leydig cell benign tumors in the males and also benign tumors seen in the ovaries of the females. This was seen even at the lowest dose (2.7 mg/kg bw/day). In the females there was seen a significant increase in frequency of adrenocortical adenomas and adenocarcinomas in the uterus (only in the high dose group – 1318 mg/kg bw/day). A NOAEL was not possible to establish since some of the tumors seen in the study did not seem to have a threshold limit. The lowest dose level caused eosinophile foci with cellular changes in the liver in males, calcification of lenses in one male, adrenal hyperplasia in males, adenomas of the prostate and benign tumors of the ovaries.

Rats: another study with the same doses as above was done using only 20 animals. In this study there were no effects seen in the group receiving the lowest dose (2.7 mg/kg bw/day). This is thus seen as the NOAEL for this study. However this dose did cause a number of effects in the study described above.

Mice: Hepatocellular carcinomas were seen at the highest dose (which exceeded maximal tolerated dose) NOAEL was 150 ppm = 25 mg/kg bw/day.

4. Effects on reproduction/teratogenicity:

In multigeneration studies, vinclozolin led to infertility of males, due to feminization of the outer genital organs, at dietary levels of 1000 ppm or more. At 300 ppm, although all males were eventually proved fertile, the observed effects may have indicated sub-fertility. At 50 ppm, the only adverse effect was a reduction in epididymal weight (with no associated morphological changes) in F2 offspring. The NOAEL was 40 ppm, equivalent to approximately 4 mg/kg bw/day. Recent investigations of developmental toxicity have been conducted in rats and rabbits. In rats, the most sensitive indicator of teratogenicity was a reduction in anogenital distance; in a series of studies, the NOAEL for a change in anogenital distance was 15 mg/kg bw/day. The NOAEL for fetotoxicity was about 100 mg/kg bw/day, on the basis of signs of developmental delay, while the NOAEL for maternal toxicity was about 400 mg/kg bw/day, on the basis of clinical signs of toxicity.

Three studies of developmental toxicity have been conducted in rabbits. In the first, there were no signs of maternal toxicity, fetotoxicity or teratogenicity at doses up to and including 300 mg/kg bw/day. In the second study, with doses up to and including 800 mg/kg bw/day, toxicity led to extensive mortality at the high dose, precluding any meaningful assessment at this dose level. The NOAEL for maternal toxicity was 50 mg/kg bw/day, and that for fetotoxicity was 200 mg/kg bw/day; there was no evidence of teratogenicity at this dose (the highest dose available for assessment). The third study involved only one dose, 400 mg/kg bw/day. The number of female offspring exceeded the number of males, but there was no treatment-related change in the appearance of the male fetal genital organs. An increased in separated origins of the carotid arteries indicated potential teratogenicity at this maternally toxic dose.

Studies have been conducted that confirm the anti-androgenic properties of vinclozolin, which are likely to be associated with binding to the androgen receptor. This binding could prevent the cellular effects of androgenic hormones on their target tissues. In

addition, a disruption of the hypothalamic-pituitary feedback control mechanism could be induced, resulting in pronounced hormonal imbalance. This proposed mechanism of action could account for the results seen in studies of reproductive toxicity with vinclozolin and for the results of long-term toxicity studies. The development of male external genitalia and accessory genital organs is under androgen hormone control. An androgen receptor block would lead to reduction in the anogenital distance in male rat fetuses and retarded development of accessory genital organs. As to long-term effects the proposed hormonal imbalance could also explain the Leydig cell hyperplasia, and progression to tumors, and vacuolation of pituitary cells.

5. Mutagenicity: In vitro and in vivo tests have been performed (12 tests). The overall conclusion is that vinclozolin does not seem to be a mutagen, however some positive tests have been seen. There was seen point mutations in a test on mouse lymphoma cells with S-9. WHO has also reported that there was a positive result in a test for cell transformation and in an in vivo test that shows that vinclozolin is a promoter.

6. Effects on human health:

In an epidemiological study of manufacturing plant personal it was concluded that there was no evidence that vinclozolin had induced health effects in employees with potential long-term exposure to vinclozolin.

1.8.3 Description of ecotoxicological properties of the chemical

Fish:	Bluegill sunfish LC50 (96 h): 47.3 mg/l, NOEC (96 h) < 5.6 mg/l Rainbow trout LC50 (96 h): >18 mg/l, NOEC (96 h): 1.8 mg/l The metabolite 3,5-dichlor-anilin: LC50 (14 days) for guppy (<i>Poecilia reticulata</i>): 3.9 mg/l
Crustacea:	Daphnia acute LC50 (48 h): 4.0 mg/l, NOEC: 1.0 mg/l Daphnia reproduction LC0 (21 days): 7.8 mg/l, EC0 (21 days): 1.95 mg/l
Earthworms:	<i>Eisenia fetida</i> LC50 (14 days): >1000 mg a.i./kg soil, NOEC: (14 days): 1000 mg a.i./kg soil
Microorganisms:	NOEC for soil respiration, ammonification, nitrification were <10, 50 and <10 mg a.i./kg soil respectively
Honeybees:	-
Arthropods:	-
Birds:	Quail: LD50: >2420 mg a.i./kg bw (NOED = 965 gm a.i./kg bw) LC50 (dietary) >5420 mg a.i./kg Duck: LC50 (dietary) >5420 mg a.i./kg NOEC (reproduction): 50 mg a.i./kg

References

Danish report from 1993 (VINCLOZOLIN, Ecotoxicological evaluation, H. F. Larsen, T. Madsen and L. Samsøe-Petersen).

PART II: FINAL REGULATORY ACTION

2.	FINAL REGULATORY ACTION	
2.1	The chemical is: <input checked="" type="checkbox"/> banned OR <input type="checkbox"/> severely restricted	
2.2	Information specific to the final regulatory action	
2.2.1	Summary of the final regulatory action The approved use was restricted from vegetables, ornamental plants out of doors and in greenhouses, in fruits and some berries and grasslands to only oil plants and ornamental plants in nurseries. After the product was withdrawn it is now prohibited to import, sell or use vinclozolin as a pesticide.	
2.2.2	Reference to the regulatory document Decree of the Norwegian Agricultural Inspection Service of 1996. Thereafter, the product Ronilan FL was withdrawn by the Norwegian importer.	
2.2.3	Date of entry into force of the final regulatory action 01.01.99.	

2.3	Was the final regulatory action based on a risk or hazard evaluation?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	If yes, give information on such evaluation Vinclozolin has anti-androgenic properties, probably caused by binding to the androgen receptor. It is thus a likely reproductive toxin and teratogen.	
	Reference to the relevant documentation Mainly data submitted by the producer.	

2.4	Reasons for the final regulatory action	
2.4.1	Is the reason for the final regulatory action relevant to the human health?	<input checked="" 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 Vinclozolin is a reproductive toxin. It causes infertility in rats due to feminization of the outer genital organs. Studies have confirmed the anti-androgenic properties of vinclozolin, which are likely to be associated with binding to the androgen receptor. In long-term studies there have also been seen a number of effects such as hepatotoxicity, Leydig-cell hyperplasia (and progression to tumors), atrophy of accessory sex glands, atrophic uteri and lipidosis of the adrenal.	
	Reference to the relevant documentation Data submitted by the manufacturer, and reports by WHO (1995), UK-PSD (1994), National Product Control Agency for Welfare and Health (Finland, 1995), Karolinska Institut (Sweden, 1990).	
	Expected effect of the final regulatory action Reduction of risk to human health	

2.4.2	Is the reason for the final regulatory action relevant to the environment?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
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	If yes, give summary of the known hazards and risks to the environment	
	Reference to the relevant documentation	
	Expected effect of the final regulatory action	

2.5	Category or categories where 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	
	Use or uses that remain allowed	

2.5.2	Final regulatory action has been taken for the chemical category	<input checked="" type="checkbox"/> Pesticide
	Formulation(s) and use or uses prohibited by the final regulatory action	
	The approved use was restricted from vegetables, ornamental plants out of doors and in greenhouses, in fruits and some berries and grasslands to only oil plants and ornamental plants in nurseries. After the product was withdrawn it is now prohibited to import, sell or use vinclozolin as a pesticide.	
	Formulation(s) and use or uses that remain allowed	
	None.	

2.5.3	Estimated quantity of the chemical produced, imported, exported and used, where available.	
	Quantity per year (MT)	Year
Produced		
Imported		
Exported		
Used	2897 kg	1995

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

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


2.7.2	Information on alternatives and their relative risks
2.7.3	Relevant additional information

PART III : GOVERNMENT AUTHORITIES
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Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	Norwegian Agricultural Inspection Service Pesticide Section
Address	PO Box 3 1431 Ås Norway
Telephone	+ 47 64 94 44 00
Telefax	+ 47 64 94 44 10
E-mail address	Postmottak@slt.dep.no
Designated National Authority	
Institution	Norwegian Agricultural Inspection Service Pesticide Section
Address	PO Box 3 1431 Ås Norway
Name of person in charge	Reidunn Stokke / Cécile Blom
Position of person in charge	Ecotoxicologist / toxicologist
Telephone	+ 47 64 94 44 00
Telefax	+ 47 64 94 44 10
E-mail address	Reidunn.stokke@slt.dep.no Cecile.blom@slt.dep.no

20. Sept. 2000

ceah TB


Landbrukstilsynet
 Postboks 3
 1431 ÅS