



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

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Chemical Review Committee Seventh meeting

Rome, 28 March–1 April 2011

Item 4 (c) (iii) of the provisional agenda*

**Technical work: review of notifications
of final regulatory action: endosulfan**

Endosulfan

Note by the Secretariat

1. Under 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 of final regulatory action to ban or severely restrict a chemical from each of two prior informed consent (PIC) regions containing the information required in Annex I to the Convention, it shall forward the notifications and accompanying documentation to the members of the Chemical Review Committee. The Committee shall review the information provided in such notifications and, in accordance with the criteria set out in Annex II to the Convention, recommend to the Conference of the Parties whether the chemical in question should be included in Annex III to the Convention and whether a decision guidance document should be drafted.
2. At its sixth meeting, the Committee reviewed a notification of final regulatory action related to endosulfan from the Southwest Pacific region (New Zealand). The Committee agreed to defer its consideration of the notification until its seventh meeting. The notification, as provided to the Committee at its sixth meeting, has been reproduced without change in the annex to the present note.
3. The Secretariat has since received another notification relating to endosulfan as a pesticide that meets the information requirements of Annex I from another PIC region: Africa (Benin). A summary of this notification was included in PIC Circular XXXII of December 2010. The notification, as received from the notifying country, is set out in the annex to the present note.
4. The documentation provided by New Zealand in support of its final regulatory action on endosulfan was circulated for consideration at the Committee's sixth meeting and has been reproduced without change in document UNEP/FAO/RC/CRC.7/6/Add.1. The supporting documentation provided by Benin is set out in document UNEP/FAO/RC/CRC.7/6/Add.2.
5. A list of other notifications for endosulfan previously considered by the Committee is set out in document UNEP/FAO/RC/CRC.7/INF/5.

* UNEP/FAO/RC/CRC.7/1.

Annex

**Notification of final regulatory action for endosulfan by
New Zealand**

**Notification of final regulatory action for endosulfan by Benin
(original in French and English translation)**



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:

NEW ZEALAND

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1 Common name

Endosulfan

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

6,9-Methano-2,4,3-benzodioxathiepin,
6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-
hexahydro-, 3-oxide (CAS name)

1.3 Trade names and names of
preparations

Formulation types: Emulsifiable concentrate
containing 350 g/litre endosulfan.
Trade names: Thiodan, Flavylan 350EC, Thionex
350EC, Endo 350EC.

1.4 Code numbers

1.4.1 CAS number

115-29-7

1.4.2 Harmonized System
customs code

2920 9090

1.4.3 Other numbers
(specify the numbering
system)

EINECS: 204-079-4
New Zealand HSNO Act Approval numbers:
Endosulfan - HSR002846
350 g/litre EC formulations - HSR000487,
HSR000677, HSR000678, HSR000679
NZ HSNO Act Reassessment number: HRC07003

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**

On 15 December 2008, the Environmental Risk Management Authority of New Zealand, under the Hazardous Substances and New Organisms Act 1996, announced the revocation of all approvals for the import, manufacture or use of endosulfan and endosulfan products. The ban (including on use) took effect from 16 January 2009 and all existing stocks must be disposed of by 16 January 2010.

This revocation of approvals followed a reassessment carried out under the provisions of section 63 of the HSNO Act, which included a determination that the environmental and human health risks associated with the use of the products outweighed the benefits obtained from its use.

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

ERMA New Zealand Decision on an application for the reassessment of endosulfan and formulations containing endosulfan, HRC07003, 10 December 2008
<http://www.ermanz.govt.nz/appfiles/execsumm/pdf/HRC07003-005.pdf>
(Ref.1)

2.2.3 Date of entry into force of the final regulatory action

16 January 2009 (all remaining stocks must be disposed of (not by use) by 16 January 2010)

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**

Insecticide on certain vegetable, citrus and berry fruit crops, and on ornamentals. Also used for earthworm control on turf on golf courses, sports fields, airports, etc.

2.3.2 Final regulatory action has been taken for the category Industrial**Use or uses prohibited by the final regulatory action**

All uses of endosulfan and endosulfan products are now prohibited (ie. no approvals remain for any use of endosulfan products). However, there were no previous industrial uses recorded.

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 approvals for the import and manufacture of endosulfan and endosulfan containing formulations, for all uses, have been revoked. Specifically, the approvals for endosulfan (active ingredient) and for emulsifiable concentrate formulations containing 350 g/litre endosulfan (trade name products: Thiodan, Flavytan 350EC, Thlonex 350EC, Endo 350EC) have been revoked.

All uses of endosulfan and endosulfan formulations have thus been prohibited.

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

The revocation of approvals followed a reassessment carried out under the provisions of section 63 of the Hazardous Substances and New Organisms Act 1996, which included a determination that the environmental and human health risks associated with the use of the products outweighed the benefits obtained from its use.

The decision on the reassessment application is available at:

<http://www.ermanz.govt.nz/appfiles/execsumm/pdf/HRC07003-005.pdf> (Ref.1)

The reassessment application is:

Application for Reassessment of a Hazardous Substance under section 63 of the Hazardous Substances and New Organisms Act 1996: Endosulfan and formulations containing endosulfan, ERMA New Zealand, June 2008

<http://www.ermanz.govt.nz/appfiles/execsumm/pdf/HRC07003-001.pdf> (Ref.2)

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

Human health risks were determined for a number of use patterns and exposure scenarios. These included exposure of pesticide operators to spray, occupational post-application and re-entry worker exposures, bystander and residential exposures, exposure to treated sports field turf. This risk assessment is detailed in Ref.2, paras 4.3.113 – 4.3.247, pages 96 – 135. The conclusions of the risk assessment were as follows:

- Endosulfan has high acute oral and inhalation toxicity, but is less toxic via the dermal route due to relatively incomplete absorption. Neurotoxicity is the primary effect observed both acutely and chronically in both humans and animals.
- Endosulfan has not been proven to be mutagenic, carcinogenic, or a

reproductive or developmental toxicant.

- ERMA New Zealand has set an AOEL = 0.0192 mg/kg bw/day and, confirmed the ADI = 0.006 mg/kg bw/day.
- No New Zealand exposure data for endosulfan are available for mixers, loaders, applicators, re-entry workers, bystanders or residents, so estimates of exposure have been modelled where possible.
- Risks to operators involved in mixing, loading and applying endosulfan for outdoor crops (including hand-held application) in accordance with current labelled application rates (0.7kg a.i./ha) are estimated as acceptable, provided that adequate (PPE) is used. The required PPE includes gloves during mixing and loading; gloves, visor, hood, overalls and boots during application.
- Risks to operators involved in mixing and loading within glasshouses are acceptable provided adequate PPE is used. Risks to workers within glasshouses have not been separately modelled but are assumed to be unacceptable. For that reason, application should be by remote automated systems.
- Risks to operators for turf and citrus applications even if full PPE (including respiratory protection) is used are high. This is due to the application rates being higher than for the current label uses for both turf and citrus and the different application method for citrus only.
- Risks to workers re-entering areas treated in accordance with label uses, including glasshouse use, indicate that risks are acceptable provided appropriate PPE is used or REIs are applied.
- Risks to bystanders and residents are estimated as acceptable for boom application to turf and in accordance with the label uses. However, risks to bystanders and residents from air-blast applications in citrus are estimated as unacceptably high at current application rates and procedures.
- Risks to sports people from use of endosulfan on treated turf are acceptable if application is in accordance with the current standard practices involving watering in and one annual treatment and an appropriate REI is applied (in the case of "ground contact" sports such as rugby, football or hockey and for public parks where children may play).

Further details relating to the human health risk assessment are contained in Appendix G of Ref. 2.

Expected effect of the final regulatory action

Complete risk reduction as there will be no remaining uses of endosulfan products.

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

Environmental risks were determined in the following areas:

Aquatic risk assessment (Ref.2, paras 4.3.36 – 4.3.73, pages 77 – 88)
Tier I modelling indicated high acute and chronic risks to freshwater fish and invertebrates (paras 4.3.64 – 4.3.65)
An analysis of overseas Tier II modelling and evaluation of the results in respect to New Zealand use patterns is presented in Appendix D of Ref. 2.

Terrestrial risk assessment – plants, terrestrial invertebrates (including soil invertebrates, honey bees and other invertebrates), soil micro-organisms, and birds (paras 4.3.74 – 4.3.110, pages 88 – 96, Ref. 2)

The conclusions of the environmental risk assessment undertaken as part of the ERMA New Zealand reassessment of endosulfan were as follows (paras 4.3.111 – 4.3.112, Ref. 2):

- There is a high acute and chronic risk to aquatic species (fish and invertebrates) from all current uses of endosulfan in New Zealand. This conclusion is based on lower sensitivity environmental exposure modelling.
- Exposure of non-target areas, including the aquatic environment, can be reduced by the use of buffer zones. Such buffer zones would need to be substantial, possibly extending over 100 metres.
- There is a risk to earthworms when endosulfan is used in accordance with label uses. Runoff from use could lead to risks to earthworms and soil arthropods outside the application area. Endosulfan is used to control earthworm populations under specific circumstances including use on sports fields and grass areas at airports.
- Laboratory data suggests that endosulfan is toxic to bees and other non-target terrestrial invertebrates. There is uncertainty as to whether such effects occur in the field.
- There is no indication of risks to plants.
- There may be a risk to birds feeding in fields where crops have been recently treated. There is an acute risk to birds associated with the use of endosulfan on turf.
- The risk to water birds is low. Using a conservative model there is some risk to large water birds which feed exclusively on piscivorous fish.
- No assessment can be made of the risk to marine mammals (seals, dolphins) due to an absence of New Zealand-based data.

Further details relating to the environmental risk assessment are contained in Appendices E and F of Ref. 2.

Expected effect of the final regulatory action

Complete risk reduction as there will be no remaining uses of endosulfan products.

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	n/a	
imported	Around 15,000 – 20,000 litres of endosulfan products (350 g/litre) were imported per year, prior to the revocation of approvals. Use had been declining in NZ over the previous 10 years but no figures are available to quantify this.	1998 - 2008
exported	n/a	
used	As above	

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

Much of the data and analysis used in the NZ reassessment of endosulfan and products was taken from overseas sources. Similar concerns to those identified in the reassessment are likely to be encountered in other countries where endosulfan is used. The use of endosulfan to control earthworms in turf at airfields and sports fields appears to be a NZ specific use and the risks associated with this would, if this is correct, not be applicable to other countries.

2.5.3 Other relevant information that may cover:

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

Likely effects of endosulfan insecticides not being available in New Zealand are presented in section 6 of Ref. 2. Advantages of these products were cited as including:

- Broad spectrum insecticidal/ acaricidal efficacy on difficult to control target pests.
- Useful for resistance management as it belongs to a different class of chemicals with a unique mode of action.
- Tool for IPM due to high selectivity on pollinators and many beneficial insects.
- Relatively non-toxic to beneficial insects.
- Excellent crop tolerance – no phytotoxicity.

Problems that would arise if endosulfan was unavailable were described as:

- Combinations and mixtures of other insecticides would be necessary to control the pests.
- Depending on the alternatives chosen a significant effect on non-target invertebrates could be expected, leading to pest infestation increases or to higher use of other insecticides.
- The risk of development of resistance to other insecticides is possible.
- Increased cost to users/industry.

Horticulture New Zealand and the Citrus Industry Council reported that endosulfan is the only compound that effectively controls broad mite on lemons and is also a possible control option for Australian citrus whitefly, a new pest of citrus.

Although the reassessment process identified that there were benefits to the horticultural community and through the control of earthworms in turf from the use of endosulfan products in New Zealand, the Environmental Risk Management Authority decided that the adverse effects (risks and costs) associated with this use outweighed the positive effects (benefits).

(Further information on the benefits of the availability of endosulfan is presented in paras 4.3.259 – 4.3.290 of Ref.2).

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

A number of alternative insecticide products are currently registered in NZ for the crop/pest combinations for which endosulfan was registered. These include organophosphate, pyrethroid, carbamate and chloronicotinyl products, and carbendazim for turf use. A number of these substances are also on New Zealand's reassessment list.

The New Zealand Sports Turf Institute advised that the following non-chemical (physical) means have been used overseas for earthworm control where endosulfan is not available:

- acidification of the soil profile to reduce earthworm populations. However, this has implications for the availability of plant nutrients and the survival of some grass types;
- greater reliance on heavier sand topdressing to discourage earthworm feeding activity and dilute castings. However, use of sand in the way in New Zealand would impose substantial costs on sports users.

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

Hazard class

e.g. WHO, IARC, etc.

UN GHS system of hazard classification (New Zealand HSNO Act classifications)	Acute oral toxicity – GHS category 2 (HSNO 6.1B) Acute dermal toxicity – GHS category 2 (HSNO 6.1B) Acute inhalation toxicity – GHS category 1 (HSNO 6.1A) Eye irritant – GHS category 2 (HSNO 6.4A) Specific target organ toxicity – GHS category 1 (repeated exposure) (HSNO 6.9A) Hazardous to the aquatic environment - GHS category chronic 1 (HSNO 9.1A)

Other classification systems

Hazard class

e.g. EU, USEPA

New Zealand HSNO Act (additional to GHS based classifications)	Very ecotoxic in the soil environment (toxicity to earthworms) – HSNO category 9.2A Very ecotoxic to terrestrial vertebrates (toxicity to the rat) – HSNO category 9.3A Ecotoxic to terrestrial invertebrates (toxicity to the honey bee) – HSNO category 9.4B

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

CAS Registry Number: 115-29-7
Molecular Formula: C9H6Cl6O3S

Molecular Weight: 406.96 g/mol

Appearance (colour, odour, physical state or form):

Physical state - solid

Colour - off white powder; white crystalline solid

Technical endosulfan flakes with a tendency to agglomerate; cream to tan mainly beige, yellow crystalline solid; beige slightly yellow granules

Odour - has been described as being like sulphur dioxide or odourless

Density - 1.745 g/cm³ at 20°C; 1.87g/cm³ at 20°C (purified endosulfan)

Vapour pressure - α endosulfan = 1.05×10^{-3} Pa;

β endosulfan = 1.38×10^{-4} Pa

Melting point - α endosulfan = 109.2 °C; β endosulfan = 212-213°C; mixture of isomers = 76-124°C

Solubility in water - α endosulfan = 0.41 mg/l; β endosulfan = 0.23 mg/l

Octanol/Water partition log Kow - α endosulfan = 4.94 at pH 4, 20°C;

4.77 at pH 7, 20°C; 5.64 at pH 10, 20°C

β endosulfan = 4.87 at pH 4, 20°C; 4.55 at pH 7, 20°C; 5.65 at pH 10, 20°C

Reference

Section 3.2 (page 23) of Ref. 2

3.2.2 Description of toxicological properties of the chemical

Acute Oral Toxicity:

SPECIES: Rat

ENDPOINT: LD50

VALUE: 22.7 mg/kg b w

Acute Dermal Toxicity:

SPECIES: Rat

ENDPOINT: LD50

VALUE: 34 mg/kg b w

Acute Inhalation Toxicity:

SPECIES: Rat (F)

ENDPOINT: LC50

VALUE: 13 mg/m³ (= 0.013 mg/L)

Eye Irritation:

EU R-PHRASE: R 36 'Irritating to eyes.'

Target Organ Systemic Toxicity:

The proposed acceptable daily intake (ADI) is 0.006 mg/kg/day, based on the lowest NOEL estimated in animal studies of approximately 0.6 mg/kg/day, and using a 100-fold safety factor. This NOEL was derived from a range of effects (including decreased body weights and kidney pathology) observed in a variety of studies (namely a 78-week dietary study in mice, a 1-year dietary study in dogs, developmental study in rats and 2-year dietary study in rats).

Reference

Section 3.3, Ref. 2 - based on international published data.

3.2.3 Description of ecotoxicological properties of the chemical**Aquatic ecotoxicity:**

freshwater fish 96 hr LC50 = 0.2 µg/l

freshwater invertebrates 48 hr EC50 = 0.1 µg/l

Soil ecotoxicity:

Eisenia andrei (Earthworm)

14 day(s) EC50 of 0.94 mg/kg-dry-weight-soil

Terrestrial vertebrate ecotoxicity:

SPECIES: Rat

ENDPOINT: LD50

VALUE: 22.7 mg/kg b w

Terrestrial invertebrate toxicity:

SPECIES: Honey bee *Apis mellifera*

DURATION: 48 hr

ENDPOINT: LD50

VALUE: 2 µg a.i./bee (oral), 2.4 µg a.i./bee (contact)

Persistent

Bioaccumulative

Reference

Acute ecotoxicity - section 3.3, Ref. 2.

Persistence - Sections 4.3.8 – 4.3.27, Ref. 2.

Bioaccumulation - Sections 4.3.28 – 4.3.34, Ref. 2.

SECTION 4**DESIGNATED NATIONAL AUTHORITY**

Institution	Ministry for the Environment
Address	P.O. Box 10362 Wellington NEW ZEALAND
Name of person in charge	Neil Cooper
Position of person in charge	Manager, Hazardous Substances and New Organisms Team, Working with Central Government Group
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Ministry For The Environment
P.O. Box 10362
Wellington

Date, signature of DNA and official seal:

 16/4/09

PLEASE RETURN THE COMPLETED FORM TO:

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

OR

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CONVENTION DE ROTTERDAM

SECRETARIAT DE LA CONVENTION DE ROTTERDAM
SUR LA PROCEDURE DE CONSENTEMENT PREALABLE EN
CONNAISSANCE DE CAUSE APPLICABLE A CERTAINS PRODUITS
CHIMIQUES ET PESTICIDES DANGEREUX QUI FONT L'OBJET
D'UN COMMERCE INTERNATIONAL



FORMULAIRE DE NOTIFICATION

DE LA MESURE DE REGLEMENTATION FINALE VISANT A INTERDIRE
OU A STRICTEMENT REGLEMENTER UN PRODUIT CHIMIQUE

Pays:

Bénin

SECTION 1 IDENTITE DU PRODUIT CHIMIQUE SOUMIS A LA MESURE DE REGLEMENTATION FINALE

1.1	Nom commun	endosulfan
1.2	Nom chimique d'après une nomenclature internationalement reconnue (IUPAC par exemple), si une telle nomenclature existe	IUPAC et CAS: 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepine 3-oxide
1.3	Appellations commerciales et noms des préparations	Caiman, Cotofan, Endocoton, Mistral, Phaser, Plexus, Rocky, Thiofanex
1.4	Numéros de code	
1.4.1	Numéro du CAS	115-29-7
1.4.2	Code dans le Système harmonisé de code douanier	--
1.4.3	Autres numéros (préciser le système de numérotation)	EINECS: 2040794

1.5 Indication concernant une notification précédente relative au produit chimique, le cas échéant

1.5.1 Il s'agit de la première notification d'une mesure de réglementation finale concernant ce produit chimique.

1.5.2 La présente notification remplace toutes les notifications précédentes concernant ce produit chimique.

Date de la précédente notification:

SECTION 2

MESURE DE REGLEMENTATION FINALE

2.1 Le produit chimique est: interdit OU strictement réglementé

2.2 Informations sur la mesure de réglementation finale

2.2.1 Résumé de la mesure de réglementation finale

Le Comité National d'Agrément et de Contrôle (CNAC) a proposé la prise d'un texte réglementaire interdisant l'importation, la distribution et l'utilisation de tout produit phytopharmaceutique contenant de l'Endosulfan

2.2.2 Références du document de réglementation, par exemple lorsque la décision est homologuée ou publiée

Le Comité National d'Agrément et de Contrôle (CNAC) est la structure d'homologation des pesticides au Bénin.
La décision d'interdiction d'endosulfan a été prise par arrêté interministériel n447/MAEP/MEPN/MC/DC/SGM/SA du 05 novembre 2009

2.2.3 Date de prise d'effet de la mesure de réglementation finale

L'interdiction a pris effet à partir de la signature de L'arrêté interministériel n447/MAEP/MEPN/MC/DC/SGM/SA en date du 05 novembre 2009 et prend effet a cette date.

2.3 **Catégorie ou catégories à laquelle/auxquelles s'applique la mesure de réglementation finale**

2.3.1 Emploi ou emplois du produit chimique dans votre pays avant la mesure de réglementation finale

L'endosulfan a été utilisé comme insecticide et/ou acaricide dans les cultures cotonnières

2.3.2 La mesure de réglementation finale s'applique à la catégorie

Produit à usage industriel

Emploi ou emplois interdit(s) par la mesure de réglementation finale

Emploi ou emplois qui demeure(nt) autorisé(s) (seulement dans le cas d'une réglementation stricte)

2.3.3 La mesure de réglementation finale s'applique à la catégorie

Pesticide

Préparation(s) et emploi(s) interdits par la mesure de réglementation finale

Toutes les préparations contenant l'endosulfan et tout emploi, toute importation et toute distribution de ces préparations sont interdits

Préparation(s) et emploi(s) qui demeure(nt) autorisé(s) (seulement dans le cas d'une réglementation stricte)

Néant

- 2.4 La mesure de réglementation finale a-t-elle été prise après une évaluation des risques et des dangers?** **Oui**
 Non (en cas de réponse négative, compléter également la section **2.5.3.3**)

- 2.4.1 Dans l'affirmative, veuillez donner les références de la documentation pertinente décrivant l'évaluation du risque ou du danger

Voir Annexe

- 2.4.2 Description résumée de l'évaluation de risque ou de danger ayant motivé la mesure de réglementation finale.

- 2.4.2.1 La santé des personnes est-elle la raison ayant motivé la mesure de réglementation finale? **Oui**

Non

Dans l'affirmative, résumer les dangers et les risques connus pour la santé des personnes, notamment la santé des consommateurs et des travailleurs

L'endosulfan a une toxicité aigue élevée et le risque d'intoxication des utilisateurs dans les conditions de son utilisation locale au Bénin est considéré comme inacceptable.

Effets escomptés de la mesure de réglementation finale

Le risque de l'endosulfan est éliminé.

- 2.4.2.2 La protection de l'environnement est-elle la raison ayant motivé la mesure de réglementation finale? Oui
 Non

Dans l'affirmative, résumer les dangers et les risques connus pour l'environnement

L'endosulfan est considéré très toxique pour les poissons et pour certains invertébrés aquatiques. Le risque d'impact environnemental dans les eaux de surface dans les zones cotonnières du Bénin est inacceptable (Voir Annexe)

Effets escomptés de la mesure de réglementation finale

Les risques sanitaires et environnementaux de l'endosulfan sont éliminés.

2.5 Informations supplémentaires pertinentes concernant la mesure de réglementation finale

- 2.5.1 Estimation des quantités du produit chimique, produites, importées, exportées et employées

	Quantité annuelle (tonne métrique)	Année
produite	Néant	
importée	312118 litres	2009
exportée	Néant	
employée		

- 2.5.2 Indiquer, dans la mesure du possible, l'intérêt de la mesure de réglementation finale pour d'autres Etats et régions

L'endosulfan pourrait être utilisé dans d'autres pays dans des domaines d'application et des conditions similaires à celles rencontrées au Bénin

- 2.5.3 Autres informations utiles dont:

- 2.5.3.1 Evaluation des impacts socio-économiques de la mesure de réglementation finale

Néant.

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2.5.3.2 Renseignements disponibles sur les solutions de remplacement et leurs risques
(Par exemple IPM, produits chimiques et non chimiques alternatifs)

Tihan

2.5.3.3 Raisons ayant motivé la mesure de réglementation finale autres que l'évaluation de risque ou de danger

Non

2.5.3.4 Informations supplémentaires concernant le produit chimique ou la mesure de réglementation finale, le cas échéant

Au Bénin, la présence des habitations des paysans à l'intérieur des champs de coton augmente davantage le risque d'exposition au pesticide de toute la famille.

SECTION 3 PROPRIETES

3.1 Informations sur la catégorie de danger du produit chimique lorsqu'il fait l'objet d'une classification

Systèmes internationaux de classification des dangers
Par exemple: OMS, CIRC, etc.

Catégorie de danger

WHO / IPCS	Matière active technique: DL50 pour le rat: 80 mg/kg p.v. (WHO, 2004) Classe II (modérément dangereux) Formulations liquides : 350 g m.a./litre : classe II
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	500 g m.a./litre : classe Ib (hautement dangereux)
CIRC	Non évalué

Autres systèmes de classification

Catégorie de danger

Par exemple: UE, USEPA

3.2 Renseignements supplémentaires sur les propriétés du produit chimique

3.2.1 Décrire les propriétés physico-chimiques du produit chimique

Voir Annexe

Référence

NRA (1998) [voir Annexe]

3.2.2 Décrire les propriétés toxicologiques du produit chimique

Voir Annexe

Référence

OMS (1998) [voir Annexe]

3.2.3 Décrire les propriétés éco-toxicologiques du produit chimique

Voir Annexe

Référence

NRA (1998) [voir Annexe]

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SECTION 4**AUTORITE NATIONALE DESIGNEE**

Institution	Ministère de l'Environnement et de la Protection de la Nature
Adresse	01 BP 3621 Cotonou
Nom de la personne responsable	SIMEON DONOUMASSOU Pulchérie
Position de la personne responsable	Conseiller Technique Juridique, Point Focal National de la Convention de Rotterdam
Téléphone	0022990031780/0022997734946
Télécopieur	00 229 21 31 50 81
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Date, signature de l'AND et cachet officiel: 27/08/10

**PRIERE DE RETOURNER LE FORMULAIRE COMPLETE AU:**

Secrétariat de la Convention de Rotterdam
Organisation des Nations Unies pour
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OU

Secrétariat de la Convention de Rotterdam
Programme des Nations Unies pour
l'environnement (PNUE)
11-13, Chemin des Anémones
CH - 1219 Châtelaine, Geneva, Suisse
Tél: (+41 22) 917 8177
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Mél: pic@pic.int

Définitions aux fins de la Convention de Rotterdam selon l'article 2:

(a) "Produit chimique" s'entend d'une substance, soit présente isolément, soit dans un mélange ou une préparation, qu'elle soit fabriquée ou tirée de la nature, à l'exclusion de

Annexe

Notification de mesure d'interdiction d'endosulfan

Réf. section 2.4.2.1

L'endosulfan a une toxicité aigue élevée et le risque d'intoxication des utilisateurs dans les conditions écologiques du Bénin est considéré inacceptable.

Raisonnement :

Toxicité

[voir aussi section 3.2.2]

L'endosulfan a une toxicité aigue par ingestion élevée. La DL₅₀ (rat) de la matière active technique citée par la classification de l'OMS (WHO, 2004) est 80 mg/kg p.v. Toutefois, sa variabilité est relativement large, et une DL₅₀ (rat) aussi bas que 9.6 mg/kg p.v. a été listée (WHO, 1998).

La DL₅₀ aigue par voie dermale de la matière active technique est également variable, et la valeur la plus basse est de 290 mg/kg p.v. (lapin) (WHO, 1998).

La toxicité par inhalation est élevée, avec une CL₅₀ (rat - 4 heures d'exposition) de 13 – 35 mg/m³ (WHO, 1998).

L'OMS classe l'endosulfan technique comme modérément toxique (WHO, 2004).

La plupart des spécialités qui ont été utilisées au **Bénin** ont une concentration de matière active de 350 ou 500 g m.a./litre. Ces formulations sont classées, selon la classification de l'OMS, respectivement comme « modérément dangereux » ou « hautement dangereux ». Toutefois, il est à noter que la classification de la concentration de 350 g/litre se rapproche également de la classe « hautement dangereux ».

Risque

L'endosulfan est appliqué dans le coton au **Bénin** à des doses entre 300 et 750 g m.a. par hectare, généralement deux fois durant la saison cotonnière. Le produit est appliqué avec des pulvérisateurs terrestres (appareils à disque rotatif ou parfois appareils pneumatiques à dos) par les paysans mêmes, généralement sans protection adéquate.

L'**Australie** autorise l'utilisation d'endosulfan sur le coton, à une dose de 735 g m.a./ha, au maximum 3 fois par saison cotonnière. Le produit est appliqué dans un volume d'eau d'au minimum 50 litres par ha, généralement utilisant des pulvérisateurs montés sur véhicule/tracteur. Le produit est strictement réglementé et son utilisation est uniquement autorisée pour des personnes autorisées ayant un certificat d'applicateur de pesticides. L'endosulfan est considéré comme « *très dangereux, en particulier le produit concentré. Produit non-dilué est toxique si absorbé par la peau, inhalé ou ingéré* ». L'endosulfan est autorisé sur le coton sous conditions que les applicateurs de pesticides portent un équipement de protection complet. Pendant le remplissage des pulvérisateurs il est exigé une combinaison en coton fermé au cou et au poignet, des gants à manche longue en PVC, et un respirateur avec masque de visage complet. Pendant la pulvérisation, il est exigé une combinaison en coton fermé au cou et au poignet (APVMA, 2005).

Aux **Etats Unies**, l'endosulfan a été homologué sur le coton, à une dose maximale de 1700 g m.a. par ha, et un maximum de deux applications par saison, cumulant au maximum 2200 g m.a. par ha. Toutes formulations sont du type EC ou WP, et sont diluées à l'eau. Il a été constaté que l'endosulfan pose un risque occupationnel élevé dans beaucoup de domaines d'utilisation, y inclut le coton. Par conséquent, toute une série de mesures de réduction des risques est exigée. Pour les applications avec pulvérisateurs à dos sous pression, il est exigé de porter une combinaison en dessus d'une

chemise à manche longue et un pantalon, des chaussures/bottes imperméables aux produits chimiques, des gants imperméables, un tablier imperméable (pendant le remplissage du pulvérisateur) et un masque respiratoire contre vapeurs organiques (EPA, 2002). L'utilisation des mesures « d'ingénierie », comme les systèmes de remplissage des cuves fermés ou des tracteurs avec cabine fermée, est recommandé pour réduire l'exposition des applicateurs.

Au **Bénin** des doses d'application comparables à celles utilisées en Australie ou aux Etats-Unis sont appliquées. En règle générale, l'endosulfan est appliqué à très bas volume, à environ 10 litres de produit dilué par ha, en utilisant de préférence des pulvérisateurs à disque rotatif. Ce sont des mélanges d'application nettement plus concentrées qu'en Australie ou aux Etats-Unis. Les applicateurs n'utilisent généralement peu ou pas d'équipement de protection, par manque de moyens financiers ou parce que le climat chaud ne le permet pas. L'utilisation d'équipement de protection personnelle exigé en Australie ou aux Etats-Unis ne peut actuellement pas être garantie au Bénin. En outre, le niveau de formation des paysans béninois dans le domaine de l'utilisation judicieuse des pesticides est beaucoup plus limité que dans ces deux pays. Par conséquent, le risque occupationnel d'utilisation d'endosulfan dans le coton au Bénin est sans doute beaucoup plus élevé qu'en Australie et aux Etats-Unis.

Le Comité National d'Agrément et de Contrôle considère, pour ces raisons, le risque d'utilisation d'endosulfan au Bénin comme inacceptable.

Réf. section 2.4.2.2

L'endosulfan est hautement toxique pour les poissons et pour certains invertébrés aquatiques. Le risque d'impact environnemental dans les eaux de surface dans les zones cotonnières au Bénin est considéré comme inacceptable.

Raisonnement

Toxicité

[voir aussi section 3.2.3]

L'endosulfan est extrêmement toxique pour les poissons et certains invertébrés des eaux douces. La toxicité aiguë (96h-CL₅₀) pour les poissons varie entre 0,02 – 8 µg/litre. La toxicité aiguë (48h ou 96h CL₅₀) pour les invertébrés aquatiques varie 0,04 – 478 µg/litre ; en particulier les crustacées estuariennes sont très sensibles à ce pesticide.

L'US-EPA (Etats Unis), le NRA (Australie) et l'OMS considèrent l'endosulfan comme extrêmement toxique pour les poissons et les invertébrés des eaux douces et les eaux marines/estuariennes (EPA, 2002 ; NRA, 1998 ; IPCS, 1984).

Risque

Une étude d'analyse des risques des pesticides pour les eaux de surface a été effectuée au **Burkina Faso** (Toé *et al.* 2003), **pays limitrophe du Bénin et dont les conditions écologiques sont similaires**. Elle a appliqué un logiciel Australien, le *Pesticide Impact Rating Index* (PIRI) sur 14 insecticides foliaires utilisés dans le coton. Cinq scénarios d'exposition d'eau de surface ont été évalués, avec les distances entre la parcelle traitée et la surface d'eau variant de 10 à 1000 m ; une zone tampon avec végétation de 0 à 100 m ; et de 0 à 3 jours entre le traitement et la première pluie majeure. L'endosulfan était le seul des 14 insecticides évalués qui posait un risque élevé ou très élevé pour la faune aquatique pour tous les 5 scénarios. Même dans les conditions qui peuvent être considérées comme « protectrices » pour l'écosystème aquatique (1000 m entre parcelle traitée et la surface d'eau, dont 100 m avec végétation), le risque d'impact sur la faune aquatique était élevé.

Aux **Etats Unis**, l'endosulfan est autorisé dans le coton à une dose maximale de 1700 g m.a.par ha, et une maximum de deux application par saison, cumulant au maximum 2200 g m.a. par ha. Le pesticide peut être uniquement utilisé dans 5 états (l'Arizona, le Californie, le Texas, le Nouveau

Mexique et l'Oklahoma) où les eaux de surface sont relativement peu importantes. Dans ces états, une zone tampon générale de 33 m, et une zone tampon avec végétation de 10 m, entre la parcelle traitée et les eaux de surface sont exigées. L'endosulfan ne peut pas être utilisé dans les régions où les eaux de surface sont abondantes et potentiellement vulnérables (EPA, 2002).

Dans les zones cotonnières au **Bénin**, les eaux de surface sont abondantes, surtout durant la saison des pluies quand les traitements dans le coton ont lieu, et importantes sur le plan écologique. Elles sont souvent situées adjacentes aux parcelles de coton. Les zones tampons comme exigées aux Etats-Unis ne peuvent pas être appliqués de manière réaliste et efficace au Bénin.

L'**Australie** autorise l'utilisation d'endosulfan sur le coton, à une dose de 735 g m.a./ha, au maximum 3 fois par saison cotonnière (APVMA, 2005). Une évaluation détaillée des risques d'endosulfan pour l'environnement a été effectuée en 1998 (NRA, 1998). Suite à cette évaluation, les mesures suivantes ont été exigées et incluses sur l'étiquette du produit :

Toutes les étiquettes doivent porter un avertissement concernant la toxicité pour les organismes aquatiques :

- Hautement dangereux pour les poissons ; ne contaminez pas des mares, cours d'eau ou canaux avec ce produit ou des emballages utilisés.

Pour minimiser le risque de contamination d'eau, les mesures suivantes doivent être prises :

- Ne pas appliquer sous des conditions, ou en utilisant un équipement de pulvérisation, qui pourraient résulter dans la dérive sur des zones adjacentes, en particulier les zones marécageuses, des cours d'eau ou d'autres eaux de surface.
- Ne pas appliquer quand des pluies fortes qui pourraient causer l'écoulement du produit sont prévues dans les deux jours qui suivent l'application, sauf si l'eau d'écoulement puisse être retenue.
- Ne pas irriguer durant l'application, ou durant les deux jours qui suivent l'application.
- Ne pas appliquer dans les conditions chaudes (températures > 30°C) (pour minimiser la volatilisation de l'endosulfan).

Dans les zones cotonnières au **Bénin**, les eaux de surface sont abondantes, et les traitements se font en plein hivernage qui est caractérisée par des fortes pluies dont la localisation et le timing sont difficiles à prédire. En outre, le respect des mesures de réduction des risques exigées en Australie est quasiment impossible à garantir au Bénin.

Vu la toxicité très élevée de l'endosulfan pour la faune aquatique, et le risque d'exposition des eaux de surface dans les zones cotonnières au Bénin, et en tenant compte des mesures d'atténuation des risques exigées par d'autres structures d'homologation des pesticides, le Comité National d'Agrément et de Contrôle considère le risque d'endosulfan au Bénin comme inacceptable.

Réf. Section 3.2.1

Propriétés physico-chimiques

Endosulfan est un insecticide du groupe des organochlorés. La matière active technique (MAT) de l'endosulfan consiste d'une mélange de deux stéréo-isomères : α -endosulfan (64-67% du produit technique) et β -endosulfan (29-32% du produit technique)

Formule chimique	$C_9H_6Cl_6O_3S$
Masse volumique	406,9
Etat physique	Solide cristalline
Couleur	Marron (MAT)
Odeur	Odeur terpénoïde (MAT)
Point de fusion	80°C (MAT) ; 109,2°C (α -endosulfan) ; 213,3°C (β -endosulfan)
Densité	1,8 (MAT)
K_{oc}	4,74 (α -endosulfan) ; 4.79 (β -endosulfan) [à pH 5]
Tension de vapeur	1,7 mPa (MAT) ; 1,9 mPa (α -endosulfan) ; 0,09 mPa (β -endosulfan) [à 25°C]
Solubilité dans l'eau	0,33 mg/litre (α -endosulfan) ; 0,32 mg/litre (β -endosulfan) [à 22°C et pH < 7].
Solubilité dans les solvants organiques	200 g/litre en acétate d'éthyle, toluène et dichlorométhane; 65 g/litre en éthanol ; 24 g/litre en hexane
Stabilité	Stable en températures ambiantales
Hydrolyse	Très lentement en environnement acide ; plus rapide en environnement alcaline. En solution aqueuse, les demi-vies [à 22°C] sont de : α -endosulfan : > 1 an à Ph 5 22 jours à pH 7 7 heures à Ph 9 β -endosulfan : > 1 an à pH 5 17 jours à pH 7 5,1 heures à pH 9

Source : NRA (1998)

MAT : matière active technique

Réf. Section 3.2.2

Propriétés toxicologiques

Toxicité aiguë – endosulfan			
DL ₅₀ orale	MAT :	80 mg/kg m.c. (rat) – OMS (2004) 9.6 – 2800 mg/kg m.c. (rat) 14 – 35 mg/kg m.c. (souris)	
	α-endosulfan :	71 mg/kg m.c. (rat) 11 mg/kg m.c. (souris)	
	β-endosulfan :	240 mg/kg m.c. (rat) 36 mg/kg m.c. (souris)	
DL ₅₀ dermique	MAT :	500 – >4000 mg/kg m.c. (rat) 290 – 2000 mg/kg m.c. (lapin)	
DL ₅₀ inhalation	MAT :	13 – 35 mg/m ³ (4 heures d'exposition)	
Toxicité aiguë – métabolites			
DL ₅₀ orale	Sulfate d'endosulfan	8 mg/kg p.v. (souris) 40 – 570 mg/kg m.c. (rat)	
	Endosulfan lactone	120 mg/kg m.c. (souris) 100 – 290 mg/kg m.c. (rat)	
Irritation de la peau	Endosulfan MAT n'est pas un irritant de la peau		
Sensibilisation	Endosulfan MAT n'a pas de pouvoir de sensibilisation		
Toxicité à courte terme			
NOEL alimentation	2,1 mg/kg m.c./jour (souris ; 3 mois d'exposition avec MAT) 4,1 mg/kg m.c./jour (souris ; 12 mois d'exposition avec MAT) 0,64 mg/kg m.c./jour (rat ; 3 mois d'exposition avec MAT)		
	NOAEL dermique		6 mg/kg m.c./jour (rat ; 30 jours d'exposition avec MAT) 3 mg/kg m.c./jour (rat ; 30 jours d'exposition avec MAT)
Toxicité chronique			
NOEL alimentation	0,58 mg/kg m.c./jour (souris ; 78 semaines d'exposition avec MAT) 0,84 mg/kg m.c./jour (souris ; 24 mois d'exposition avec MAT) 0,6 mg/kg m.c./jour (rat ; 104 semaines d'exposition avec MAT) 1,5 mg/kg m.c./jour (rat ; 104 semaines d'exposition avec MAT)		
	Génotoxicité	Il n'y avait pas évidence de génotoxicité d'endosulfan, dans la plupart des tests effectués	
	Cancérogénité	L'endosulfan n'est probablement pas cancérogène	
	Dose journalière acceptable (ADI)	0 – 0,006 mg/kg m.c.	
Dose aiguë de référence (AfD)	0,02 mg/kg m.c.		
<i>Source</i> : OMS (1998), sauf si indiqué autrement m.c. : masse corporelle MAT : matière active technique NOAEL : No observed adverse effect level			

Réf. Section 3.2.3

Propriétés éco-toxicologiques

Eco-toxicologie terrestre		
Oiseaux	Toxicité aigue (diverses espèces)	DL ₅₀ orale : 28 – 243 mg/kg m.c. <i>Modérément à hautement toxique</i>
	Toxicité à court terme à travers l'alimentation (diverses espèces)	DL ₅₀ diète : 805 – 1275 mg/kg diète
	Effets sur la reproduction	Effets observés à des doses à partir de 100 mg/kg diète
Abeilles	Toxicité aigue (abeille à miel)	DL ₅₀ contact : 2,4 µg/abeille DL ₅₀ orale : 2 µg/abeille <i>Modérément toxique</i>
Ver de terre	Toxicité aigue (diverses espèces)	<i>Modérément toxique</i>
Eco-toxicologie aquatique		
Poissons	Toxicité aigue (diverses espèces)	96h-CL ₅₀ : 0,02 – 8 µg/litre <i>Très hautement toxique</i>
Invertébrés aquatiques	Toxicité aigue (diverses espèces)	48h ou 96h-CL ₅₀ : 0,04 – 478 µg/litre <i>Très hautement toxique, en particulier pour les espèces estuariennes</i> <i>Note : toxicité est nettement plus grande à des températures plus élevées</i>
Source : NRA (1998) m.c. : masse corporelle		

Références bibliographiques

APVMA (2005) The reconsideration of approval of the active constituent Endosulfan, registrations of products containing Endosulfan and their associated labels. Final review report and regulatory decision. June 2005. Australian Pesticides & Veterinary Medicines Authority, Canberra.

EPA (2002) Reregistration eligibility decision for endosulfan. November 2002. United States Environmental Protection Agency, Washington D.C.

IPCS (1984) Endosulfan. Environmental Health Criteria 40. International Programme on Chemical Safety, World Health Organization, Geneva.

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Toé A, Correll R, Kookana R & Miller R (2003) Application of the Pesticide Impact Rating Index to cotton production in Burkina Faso: surface and ground waters risks assessment. Institut des Recherches en Science de la Santé, Bobo Dioulasso & Commonwealth Scientific and Industrial Research Organization CSIRO Adelaide Laboratory, Urrbrae.

Toé A (2007) Rapport de mission de consultation – Etude des dossiers pour le passage de l'autorisation provisoire de vente à l'homologation. Comité Sahélien des Pesticides, Bamako.

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WHO (2004) The WHO recommended classification of pesticides by hazard and Guidelines to classification 2004. World Health Organization, Geneva.



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:

Benin

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1 Common name

endosulfan

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

IUPAC and CAS: 6,7,8,9,10,10-hexachloro-
1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-
benzodioxathiepine 3-oxide

1.3 Trade names and names of
preparations

Caiman, Cotofan, Endocoton, Mistral, Phaser,
Plexus, Rocky, Thiofanex

1.4 Code numbers

1.4.1 CAS number

115-29-7

1.4.2 Harmonized System
customs code

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1.4.3 Other numbers
(specify the numbering
system)

EINECS: 2040794

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

The National Committee of Accreditation and Control (CNAC) has proposed a statutory instrument prohibiting the import, distribution and use of all plant products containing Endosulfan

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

The National Committee of Accreditation and Control (CNAC) is the body in charge of pesticides registration in Benin.

The decision to ban Endosulfan was taken by inter-ministerial decree n447/MAEP/MEPN/MC/DC/SGM/SA of 5th November 2009

2.2.3 Date of entry into force of the final regulatory action

The ban took effect as from the signature of the inter-ministerial decree n447/MAEP/MEPN/MC/DC/SGM/SA of 5th November 2009 and takes effect on that date.

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

Endosulfan was used as insecticide and/or acaricide in cotton production.

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 formulations containing Endosulfan and all uses, import and distribution of those formulations are prohibited

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

None

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

See Annex

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

Endosulfan has a high acute toxicity and the poisoning risk of users under the local conditions of use is considered to be unacceptable.

Expected effect of the final regulatory action

The risk of endosulfan is eliminated.

- 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

Endosulfan is highly toxic to fish and certain aquatic invertebrates. The risk of environmental impact in surface water in cotton growing areas of Benin is unacceptable (See Annex)

Expected effect of the final regulatory action

The health and environmental risks of endosulfan are eliminated.

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	None	
imported	312118 litres	2009
exported	None	
used		

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

Endosulfan may be used in other countries under use patterns and conditions similar to those encountered in Benin.

2.5.3 Other relevant information that may cover:

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

None.

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

Tihan

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

No

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

In Benin, the presence of habitations within the cotton fields increases the risk of exposure to the pesticide of the entire family.

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	Technical active ingredient: LD50 for rats: 80 mg/kg b.w. (WHO, 2004) Class II (Moderately hazardous) Liquid formulations: 350 g a.i./litre : Class II 500 g a.i./litre : Class Ib (highly hazardous)
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IARC	Not evaluated
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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

See Annex

Reference

NRA (1998) [see Annex]

3.2.2 Description of toxicological properties of the chemical

See Annex

Reference

WHO (1998) [see Annex]

3.2.3 Description of ecotoxicological properties of the chemical

See Annex

Reference

NRA (1998) [see Annex]

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SECTION 4**DESIGNATED NATIONAL AUTHORITY**

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Date, signature of DNA and official seal: ___[original signed]___27/08/2010___

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
Plant Protection Service,
Plant Production and Protection Division, FAO
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Annex

Notification of final regulatory action for endosulfan

Ref. section 2.4.2.1

Endosulfan has a high acute toxicity and the poisoning risk of users under the ecological conditions of **Benin** is considered to be unacceptable.

Reasoning:

Toxicity

[also see section 3.2.2]

Endosulfan has a high acute oral toxicity. The LD₅₀ (rat) of the active ingredient given in the WHO classification by hazard (WHO, 2004) is 80 mg/kg b.w. However, the variability is relatively high and an LD₅₀ (rat) as low as 9.6 mg/kg b.w. has been listed (WHO, 1998).

The dermal LD₅₀ of the active ingredient is also variable, and the lowest value is 290 mg/kg b.w. (rabbit) (WHO, 1998).

Inhalation toxicity is high, with an LC₅₀ (rat - 4 hours exposure) of 13 - 35 mg/m³ (WHO, 1998).

The WHO classifies the endosulfan technical product as "moderately hazardous" (WHO, 2004).

The majority of the commercial formulations used in **Benin** have a concentration of the active ingredient between 350 and 500 g a.i./litre. These formulations are classified, according to the WHO classification, as "moderately hazardous" or "highly hazardous", respectively. However, it should be noted that the classification of the 350 g/litre concentration also approaches the "highly hazardous" class.

Risk

Endosulfan is applied to cotton in **Benin** at dose rates between 300 and 750 g a.i./ha, generally twice during the cotton growing season. The product is applied with handheld sprayers (rotary disk sprayers or sometimes pneumatic backpack sprayers) by farmers themselves, generally without adequate protection.

Australia authorises endosulfan in cotton, at a dose rate of 735 g a.i./ha and at a maximum frequency of 3 times per cotton growing season. The product is applied in a volume of water of at least 50 litres per ha, generally using vehicle- or tractor-mounted sprayers. The product is strictly regulated and its use is only allowed by authorised persons having a pesticide applicator licence. Endosulfan is considered as *"Very dangerous particularly the concentrate product. Undiluted product poisonous if absorbed by skin contact, inhaled or swallowed."* Endosulfan is authorized on cotton under the condition that pesticide applicators wear full personal protective equipment. During filling of the sprayer, cotton overalls closed at the neck and the wrists, long PVC gloves and a respirator with a complete face mask are required. During spraying, cotton overalls closed at the neck and the wrists are required (APVMA, 2005).

In the **United States**, endosulfan is registered on cotton at a maximum dose rate of 1700 g a.i./ha, and a maximum of two applications per growing season, but not surpassing an overall maximum dose rate of 2200 g a.i./ha. All formulations are of the EC or WP types and are diluted in water. It has been found that endosulfan poses a high occupational health risk for many areas of use, including cotton production. As a consequence, a whole series of risk reduction measures is required. For applications with pressurised backpack sprayers, overalls worn over a long-sleeved shirt and trousers are required, chemical resistant shoes or boots, chemical resistant gloves, a chemical resistant apron (during mixing and loading of the sprayer), and a respirator protecting against organic vapours (EPA, 2002).

Engineering measures, such as closed mixing and loading systems or tractors/vehicles with closed cabins, are recommended to reduce exposure of applicators.

In **Benin**, comparable dose rates as those used in Australia and the USA are applied. As a rule, endosulfan is sprayed in very low volumes, at about 10 litres of diluted product per ha, using preferably rotary disk sprayers. These spray volumes are considerably more concentrated than those used in Australia or the USA. Applicators generally use little if any personal protective equipment, because of limited financial resources or because the climate is too hot to wear it. The use of personal protective equipment as required in Australia or the USA can at present not be guaranteed in Benin. Furthermore, the level of training of farmers in Benin in judicious pesticide use is much more limited than in the other two countries. As a result, the occupational risk of using endosulfan in cotton in Benin is undoubtedly much higher than in Australia or the USA.

The National Committee for Certification and Testing (Le Comité National d'Agrément et de Contrôle) therefore considers the risk of using endosulfan in Benin as unacceptable. .

Ref. section 2.4.2.2

Endosulfan is highly toxic to fish and certain aquatic invertebrates. The risk of environmental impact in surface water in cotton growing areas of Benin is considered to be unacceptable

Reasoning

Toxicity

[also see section 3.2.3]

Endosulfan is extremely toxic to fish and certain freshwater invertebrates. The acute toxicity (96h-LC₅₀) for fish ranges from 0.02 - 8 µg/litre. The acute toxicity (48h or 96h LC₅₀) for aquatic invertebrates ranges from 0.04 - 478 µg/litre; in particular estuarine crustaceans are very susceptible to this pesticide.

The US-EPA (United States of America) and the WHO consider endosulfan as extremely toxic to fish and to freshwater and marine/estuarine invertebrates (EPA, 2002; NRA, 1998; IPCS, 1984).

Risk

A pesticide risk assessment for surface waters was carried out in **Burkina Faso** (Toe *et al.* 2003), **a neighbouring country of Benin and whose environmental conditions are similar**. It applied an Australian computer model, the *Pesticide Impact Rating Index* (PIRI) to 14 insecticides which are applied to cotton foliage. Five exposure scenarios of surface water were evaluated, with distances between the sprayed plots and surface water ranging from 10 to 1000 m; vegetated buffer zones ranging from 0 to 100 m; and lag times between spraying and the first major rains ranging from 0 to 3 days. Endosulfan was the only one of the 14 evaluated insecticides which posed a high or very high risk to aquatic fauna under all 5 scenarios. Even in conditions that can be considered "protective" for aquatic ecosystems (1000 m between the sprayed plot and the water body, of which 100 m vegetated), the risk for adverse effects in aquatic fauna were high.

In the **United States**, endosulfan is registered on cotton at a maximum dose rate of 1700 g a.i./ha, and a maximum of two applications per growing season, but not surpassing an overall maximum dose rate of 2200 g a.i./ha. The pesticide is only allowed for use in 5 states (Arizona, California, Texas, New Mexico and Oklahoma) where surface waters are relatively limited. In these states, a general buffer zone of 33 m is required, and a vegetated buffer zone of 10 m, between the treated plots and surface water. Endosulfan cannot be used in regions where surface waters are abundant and potentially vulnerable (EPA, 2002).

In the cotton growing areas of **Benin**, surface waters are abundant, particularly during the rainy season when cotton spraying takes place, and are important ecologically. They are often situated

adjacent to cotton fields. Buffer zones as required in the USA can realistically not be applied in an effective manner in Benin.

Australia authorises endosulfan in cotton, at a dose rate of 735 g a.i./ha and at a maximum frequency of 3 times per cotton growing season (APVMA, 2005). A detailed environmental risk assessment of endosulfan was carried out in 1998 (NRA, 1998). Based on this evaluation, the following measures were required on the product label:

All labels should contain warnings of toxicity to aquatic organisms

- Extremely dangerous to fish. Do not contaminate ponds, waterways and drains with this chemical or used container.

To minimize the risk of water contamination, the following measures should be taken:

- Do not apply under meteorological conditions or from spraying equipment which could be expected to cause spray to drift onto adjacent areas, particularly wetlands, water bodies or watercourses.
- Do not apply if heavy rains or storms that are likely to cause surface runoff are forecast within two days of application unless storm water can be captured.
- Do not irrigate while spraying, or for at least two days after application.
- Avoid application during hot conditions (temperatures > 30°C) (to minimize volatilization of endosulfan)

In the cotton growing areas of **Benin**, surface waters are abundant and treatments are carried out in the rainy season, which is characterized by heavy rainstorms of which the locality and timing are difficult to predict. Furthermore, it is virtually impossible in Benin to guarantee that risk reduction measures such as required in Australia are followed.

Therefore, given the very high toxicity of endosulfan for aquatic fauna, the exposure risk of surface waters in the cotton growing areas of Benin, and taking into account the risk mitigation measures required by other pesticide registration authorities, the National Committee for Certification and Testing considers the risk of using endosulfan in Benin as unacceptable.

Ref. Section 3.2.1

Physico-chemical properties

Endosulfan is an organochlorine insecticide. The technical product (TP) of endosulfan consists of a mixture of two stereo-isomers: α -endosulfan (64-67% of the technical product) and β -endosulfan (29-32% of the technical product)	
Chemical formula	$C_9H_5Cl_6O_3S$
Volumetric mass	406,9
Physical state	Crystalline solid
Colour	Brown (TP)
Odour	Terpenoid smell (TP)
Melting point	80°C (TP); 109.2°C (α -endosulfan); 213.3°C (β -endosulfan)
Density	1.8 (TP)
K_{oc}	4.74 (α -endosulfan); 4.79 (β -endosulfan) [at pH 5]
Vapour pressure	1.7 mPa (TP); 1.9 mPa (α -endosulfan); 0.09 mPa (β -endosulfan) [at 25°C]
Solubility in water	0.33 mg/litre (α -endosulfan); 0.32 mg/litre (β -endosulfan) [at 22°C and pH < 7]
Solubility in organic solvents	200 g/litre in ethyl acetate, toluene and dichloromethane; 65 g/litre in ethanol; 24 g/litre in hexane
Stability	Stable at ambient temperatures
Hydrolysis	Very slow in an acidic environment; more rapid in an alkaline environment. In an aqueous solution, half-lives [at 22°C] are: α -endosulfan : > 1 year at pH 5 22 days at pH 7 7 hours at pH 9 β -endosulfan : > 1 year at pH 5 17 days at pH 7 5.1 hours at pH 9
<i>Source:</i> NRA (1998) TP : technical product	

Ref. Section 3.2.2

Toxicological properties

Acute toxicity - endosulfan	
LD ₅₀ oral	TP: 80 mg/kg b.w. (rat) - WHO (2004) 9.6 - 2800 mg/kg b.w. (rat) 14 - 35 mg/kg b.w. (mouse) α-endosulfan: 71 mg/kg b.w. (rat) 11 mg/kg b.w. (mouse) β-endosulfan: 240 mg/kg b.w. (rat) 36 mg/kg b.w. (mouse)
LD ₅₀ dermal	TP: 500 - >4000 mg/kg b.w. (rat) 290 - 2000 mg/kg b.w. (rabbit)
LC ₅₀ inhalation	TP: 13 - 35 mg/m ³ (4 hours exposure)
Acute toxicity - metabolites	
LD ₅₀ oral	Endosulfan sulphate Endosulfan lactone
Skin irritation	Endosulfan TP is not a skin irritant
Sensitization	Endosulfan TP is not a sensitizer
Short-term toxicity	
NOEAL dietary	2.1 mg/kg b.w./day (mouse; 3 months exposure with the TP) 4.1 mg/kg b.w./day (mouse; 12 months exposure with the TP) 0.64 mg/kg b.w./day (rat; 3 months exposure with the TP)
NOAEL dermal	6 mg/kg b.w./day (rat; 30 days exposure with the TP) 3 mg/kg b.w./day (rat; 30 days exposure with the TP)
Chronic toxicity	
NOEAL dietary	0.58 mg/kg b.w./day (mouse; 78 weeks exposure with the TP) 0.84 mg/kg b.w./day (mouse; 24 months exposure with the TP) 0.6 mg/kg b.w./day (rat; 104 weeks exposure with the TP) 1.5 mg/kg b.w./day (rat; 104 weeks exposure with the TP)
Genotoxicity	There was no evidence of genotoxicity of endosulfan, in the majority of the executed tests.
Carcinogenicity	Endosulfan is probably not carcinogenic
Acceptable Daily Intake (ADI)	0 - 0.006 mg/kg b.w.
Acute Reference Dose (AfD)	0.02 mg/kg b.w.
<p>Source: WHO (1998), unless indicated otherwise b.w.: body weight TP: technical product NOAEL: No observed adverse effect level</p>	

Réf. Section 3.2.3

Eco-toxicological properties

Terrestrial ecotoxicology		
Birds	Acute toxicity (various species)	LD ₅₀ oral: 28 - 243 mg/kg b.w. <i>Moderately to highly toxic</i>
	Short-term dietary toxicity (various species)	LD ₅₀ dietary : 805 -1275 mg/kg diet
	Reproduction effects	Effects observed at doses starting from 100 mg/kg diet
Bees	Acute toxicity (honey bee)	LD ₅₀ contact: 2.4 µg/bee LD ₅₀ oral: 2 µg/bee <i>Moderately toxic</i>
Earthworm	Acute toxicity (various species)	<i>Moderately toxic</i>
Aquatic ecotoxicology		
Fish	Acute toxicity (various species)	96h-LC ₅₀ : 0.02 - 8 µg/litre <i>Very highly toxic</i>
Aquatic invertebrates	Acute toxicity (various species)	48h or 96h-LC ₅₀ : 0.04 - 478 µg/litre <i>Very highly toxic, particularly for estuarine species</i> <i>Note: Toxicity is considerably greater at higher temperatures</i>
Source: NRA (1998) b.w.: body weight		

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