



**United Nations  
Environment Programme**

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

Distr.  
GENERAL

UNEP/FAO/PIC/ICRC.5/10/A  
dd.2  
27 November 2003

ENGLISH ONLY

**Interim Chemical Review Committee**  
Fifth session  
Geneva, 2 – 6 February 2004  
Item 5(a) of the provisional agenda\*

**INCLUSION OF CHEMICALS IN THE INTERIM PRIOR INFORMED CONSENT  
PROCEDURE - SUPPORTING DOCUMENTATION**

**Endosulfan**

**Note from the Secretariat**

1. Annexed to this note is the documentation provided by the Netherlands in support of their notification of final regulatory action on endosulfan.

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

**List of Documentation Annexed to UNEP/FAO/PIC/ICRC5/10/Add.2**

**Supporting documentation on endosulfan from the Netherlands:**

**Focused summary – endosulfan**

**The Chairman of the Board of Appeal for the Business Community report**

## FOCUSED SUMMARY – ENDOSULPHAN

### I. INTRODUCTION

(a) *The events that led to the final regulatory action*

The registration of endosulphan and all relating products were withdrawn from the market in The Netherlands. This decision was based on an evaluation of the aquatic ecotoxicological properties of endosulphan and subsequently confirmed in a civil court procedure.

(b) *Significance of regulatory action, e.g. one use or many uses, level or degree of exposure*

The decision aims at a complete reduction of the risk of endosulphan emission to surface water due to the application of the substance in the culture of fruit. It was estimated that a drift percentage of about 10% of the dosage of the substance to near surface waters would result in concentrations up to about 0.014 mg/L. If this value is compared to the lowest LC50 for fish (0.00017 mg/L) a risk quotient of 82 is calculated, which was considered unacceptable.

(c) *An overview of the regulatory system of the notifying country if relevant*

Registered plant protection products will receive a registration period of maximally 10 (ten) years in The Netherlands. Depending on whether or not there are problems with the application during this period a re-evaluation is possible on any moment. The re-evaluation takes place after the preparation of a summary and decision making document by the registration authorities. The re-evaluation is based on all relevant and available information sent to the authorities by the registrant. The registrant is informed on the decision taken and may appeal against the decision. In case of endosulphan the registrant asked the Board of Appeal for the Business Community to destroy the decision.

(d) *Scope of the regulatory action - precise description of the chemicals subject to the regulatory action*

The decision of the court took place at the 28<sup>th</sup> of February 1990 and resulting that the registration of endosulphan in The Netherlands was withdrawn.

### II. RISK EVALUATION

(a) *Key findings of the national risk evaluation*

The risk evaluation of The Netherlands focussed on the behaviour and effects of endosulphan in surface water. It took account of the estimation of the drift process after the application of the substance using conventional spraying equipment. The estimation of the amount of spray drift is 10%, based on field research carried out in The Netherlands and the calculation procedure for surface waters as established in the registration procedure using at that time the model SLOOT.BOX (Linders *et al.*, 1990). The resulting concentration estimated in surface water (PEC) was found to be 0.014 mg/L, whilst the lowest

effect concentration for fish was determined at 0.00017 mg/L. The ratio of these two data (the PEC/LC50-ratio) is 82, which is considered unacceptable.

- (b) *Reference to national studies, e.g. toxicological and ecotoxicity studies*
- National Institute for Public Health and the Environment – March 1984. Environmental evaluation on endosulphan. Doc/Tox 300/484. English Summary.
  - Environmental Support Group – April 1984. Besluit onderbouwend document Steungroep M over endosulfan (in Dutch)
  - National Institute for Public Health and the Environment – May 1984. Endosulfan Field Studies, addendum to the March report. English Summary.
  - Commissie Toelating Bestrijdingsmiddelen – 28 januari 1985. Advies ten aanzien van het gebruik in waterwingebieden aangaande endosulfan (in Dutch).
  - Environmental Support Group – 1989. Milieusamenvatting en –evaluatie endosulfan (in Dutch).
  - Commission of the European Communities, Scientific Advisory Committee to Examine the Toxicity and Ecotoxicity of Chemical Compounds – 29 November 1989. Opinion on endosulphan in the aquatic environment.
  - Advisory Centre Toxicology – 12 February 1990. Risico van endosulfan voor waterorganismen. Bilthoven, The Netherlands (in Dutch).
  - College van Beroep voor het Bedrijfsleven – 28 March 1990. Uitspraak van het College aangaande de stof endosulfan (in Dutch, English translation available).

- (c) *Summary of actual (or potential) human exposure and/or environmental fate*
- Environmental exposure assessment
- The risks of endosulphan focus on the risk to aquatic organisms, especially fish. In ecotoxicological studies an LC50 for fish is established of 0.00017 mg/L. Using the calculation methodology used at the date of evaluation (SLOOT.BOX, reference Linders et al., 1990) a concentration in surface water, a typical Dutch ditch), of 0.014 mg/L can be calculated. The ratio of these two figures reveals 82, indicating that the expected concentration in surface water is 82 times higher than the concentration in water that would cause death to 50% of the fish population.

### III. RISK REDUCTION AND RELEVANCE TO OTHER STATES

- (a) *Estimates of the quantity of chemicals used, or imported/exported at the time of the regulatory action and, if possible information on ongoing trade*
- The use of endosulphan in Dutch agriculture reduced in about 10 (ten) years from about 50,000 kg in 1984 to zero in 1991. It may be concluded that the applicant already anticipated on a withdrawal from the Dutch market.
- (b) *Relevance to other States, i.e. those with similar conditions of use*
- After the described decision the use of endosulphan in The Netherlands reduced to zero. Therefore, no risk is to be expected any more to aquatic organisms, especially fish in surface water in The Netherlands. Current use in surrounding countries is limited to zero as well.

(c) *Comments on the typical use of the chemical within the notifying country, with comments on possible misuse (if appropriate)*

As stated the substance is typically used in the culture of fruit as an insecticide. A distinction may be made in tall fruit and small fruit. The application takes place in spring and summer with dosages of 0.75 – 1.5 kg a.i./ha for tall fruit and 0.5 – 1.0 kg a.i./ha in small fruit.

## The Chairman of the Board of Appeal for the Business Community

Verdict on basis of the stated in article 65 of the Law administrative procedure business organisation in the case of:

1. Public limited company Hoechst Holland B.V., settled in Amsterdam and
2. Private limited company with restricted liability Luxan B.V., settled in Elst, requestors,  
attorney: mr. F.B.J. Grapperhaus, lawyer in Amsterdam,

against

The Minister of Agriculture, Nature management and Fisheries, settled in The Hague, defendant,

Attorney: mr. M.J. Timman, dr. W.H. van Eck, both civil servants at the ministry.

### 1. COURSE OF THE PROCEDURE

By dispositions from the 27<sup>th</sup> November 1989, the defendant, also on behalf of the State Secretary of the department for Welfare, Public Health and Culture (WVC), the Minister of Spatial Planning, Housing and the Environment (VROM), and the State Secretary for Social Affairs and Employment (SZW), has notified the requestors about the decisions not to prolong the granted registrations of the pesticides with the active substance endosulfan and more detailed named in these dispositions, after the 1<sup>st</sup> of January 1990.

The requestors have lodged an appeal with the College against these conclusions by a petition, which reached the registry clerk on the 4<sup>th</sup> of December 1989. With a separate letter, which reached the registry clerk at the same date, they also made a request to the Chairman of the College to suspend the decisions, against which the appeal was lodged, and furthermore by means of a temporary provision to assign the defendant to behave as if, by disposition, the issued registrations were prolonged for an indefinite time with a maximum time length possible according to the Pesticide Act, at least to make such temporary provision as is considered by the Chairman to be required for good justice, costs by right.

The request for temporary provisions has been heard in court at the 4<sup>th</sup> of December 1989, where parties have expounded their point of view in more detail through their attorney. For the requestors have spoken Dr. E. Dörn and Ir. H.T.A.M. Schepers. For the defendant has spoken Dr. J.A. van Haasteren, civil servant at the ministry of VROM. By invitation of the Chairman, the defendant has, in session, considered the appeal as an objection based on prescription as laid down in article 36a of the Law for administrative business organisations. The Chairman then has adjourned the consideration of the appeal, pending further notice by the parties to appoint experts with respect to two questions formulated during the session.

On the 12<sup>th</sup> en 13<sup>th</sup> of February 1990 the further report in question has reached the petition parliament. The Chairman has continued the consideration of the appeal in court at the 14<sup>th</sup> of February 1990, where, besides the aforementioned attendants in court of the 4<sup>th</sup> of December 1989, also was spoken by the experts, Ir. J.B.H.J.

Linders, from the Institute for Public Health and the Environment (RIVM), and Dr. L. Blommers, from the Institute for Plant Research.

## 2. THE FACTS RECOGNISED AND THE BASIS OF THE DISPUTE

- The requestor under 1 is since the 2<sup>nd</sup> of March 1981 registration holder of the pesticide Thiodan Spray powder Concentrate, registration number 5756 N. To the requestor under 2 has been granted a registration on the 15<sup>th</sup> of January 1985, under registration number 6046 N, for the pesticide Luxan Endosulfan 50% Spray powder.
- The use of endosulfan containing pesticides is already discussed for years. By letter of the 21<sup>st</sup> of January 1986 the Commission for Registration of Pesticides (CTB) has notified the registration holders concerned, that the registration of pesticides, which contain endosulfan as active substance, will be terminated by a phased process.
- Since the 1<sup>st</sup> of January 1987 the greater part of the registrations concerned has only been prolonged by one year for the purpose of sale and use up. An exception was made for the application of endosulfan as insecticide and mite pesticide for the benefit of an integrated pest control in the cultivation of apples. These registrations were prolonged by disposition at the 12<sup>th</sup> of May 1989 for the last time until the 1<sup>st</sup> of January 1990 by the defendant. Further registration of this application is the subject of this dispute.
- By letter of the 4<sup>th</sup> of August 1989, the CTB has notified the requestors of its intention not to prolong the outstanding registrations any longer after the 1<sup>st</sup> of January 1990.

## 3. THE DISPUTED DECISIONS

The defendant has underlied the following considerations to the disputed decisions.

“The registration of a pesticidal product can be prolonged if, after re-evaluation concerning the further registration has been established that the product is in compliance with specifications laid down in article 3, first paragraph, of the Pesticide Act from 1962.

If a product is not in compliance with this shall amongst others be decided to prolong the registration if this is necessary to reach a reasonable transition period after termination of the registration, considering all concerned interests.

With respect to endosulfan containing pesticides may no longer be assumed with reasonable certainty, that by using the product conform its intention and for the subscribed or recommended application no harmful side effects of the formulation or its metabolites shall appear.

To substantiate this viewpoint the following remarks can be made.

Based on the investigations for this case, the complex endosulfan and its major metabolites have to be regarded as being persistent in soil and water to an unwanted extent.

As a result of the extreme toxicity of endosulfan for fish and of the established persistency, the application of endosulfan can lead to acute harmful effects (especially mortality). This circumstance applies also to the temporary regis-

tered restricted application in the cultivation of apples. The appearance of acute harmful effects for aquatic organisms is a harmful side effect as laid down in article 3, second paragraph, part e, of the Pesticide Act from 1962.

Therefore it can be established that the application of pesticides based on the active substance endosulfan can lead to harmful side effects.

A summary of the data concerning the fate of endosulfan in the environment and an evaluation with respect to the toxicity for aquatic organisms has been sent to Hoechst Holland N.V. as an annex to the letter of the 4<sup>th</sup> of August 1989 of the Pesticide Office, under reference CTB 89/3563". (B.V. Luxan: 89/3564)

"Based on this the registration of such a formulation based on article 3, first paragraph, part b, in conjunction with article 5, first paragraph, of the Pesticide Act from 1962, will not be prolonged. However, for the run-down of the use it is decided for a phased termination.

By my disposition from the 24<sup>th</sup> of December 1986, the firm Hoechst Holland N.V. " (B.V. Luxan) " was informed about the phased termination of the above-mentioned registration. The prolonged term granted with that was only applicable for the benefit of use of the integrated pest control in the apple cultivation.

The agricultural principle for the phased termination of the registrations of endosulfan is the extent of the availability of substitute formulations for the introduction of integrated pest control in the apple cultivation. The restriction of this use for that cultivation as of the 24<sup>th</sup> of December 1986 was, by my disposition from the 9<sup>th</sup> of March 1988, followed by a more specific restriction concerning target organisms and application period. This was possible because of the usability of formulations amongst others based on carbaryl and bromofos. This concerned insects like the apple blossom beetle and the apple sawfly.

Currently there is also enough positive experience with alternative formulations for the other target organisms mentioned in my disposition of the 9<sup>th</sup> of March 1988, namely diflubenzuron, teflubenzuron and fenoxycarb for caterpillars, pirimicarb for aphids and fenbutatinoxide for rust acarids. The research on formulations, amongst which the very promising fosalone for the incidentally as harmful pest insect occurring apple leaf-curling midge, is in the terminal phase.

Taking into account the availability of alternatives sketched above for endosulfan, the necessity, from the perspective of the run-down procedure, for the registration is not longer present.

#### 4. POSITION OF THE REQUESTORS



The requestors put forward, that the use of endosulfan containing pesticides is surrounded with many guarantees by always further reduced legal and related to these use instructions in the course of years,.

During the consideration of the appeal on the 4<sup>th</sup> of December 1989, they made notice, that the defendant, in the disputed decisions, has totally ignored the reports sent by Hoechst, with reference to the notification of the intention to terminate the registrations of the CTB dated the 4<sup>th</sup> of August 1989. This concerns the research results sent to the Commission on the 15<sup>th</sup> of August 1989 about the fate of endosulfan in aquatic ecosystems and a document by Dörn dated the 2<sup>nd</sup> of October 1989, which reached the Commission on the 11<sup>th</sup> of October 1989. In that report, the findings of the CTB concerning the consequences of the use of endosulfan based on an empirical research, carried out in American tomato plantations, has been refuted by arguments.

During the continued attendance of the appeals on the 14<sup>th</sup> of February 1990, the requestors have argued, also by means of the expert reports produced in the case, that, other than intended by the defendant, the American research results are also representative for the Dutch situation. In common with America here in this country no notion has been made during the past four years of fish mortality as a consequence of the application of endosulfan. The cause for that could be situated in the fact that the Dutch research results are exclusively based on model calculations. The requestors consider further empirical research desirable, noticing the differences established with practice. Especially concerning the "bio-availability" of endosulfan there are not enough data available. This could be lower than was assumed in the model calculations. The same is valid for the so-called emission factor. The model calculations assume that all of the endosulfan reaching the water surface also will land on the ditch. In practice a part could be lost by evaporation. Furthermore, the requestors pointed out that in practice, in spite of the wider legal use instruction, sprayings with endosulfan are only carried out based on doses specified for the use of 1000 litres of water per hectare. By that, the chance of acute toxicity of the formulation will be drastically reduced.

## 5. THE POSITION OF THE EXPERTS

In the session of the court of the 4<sup>th</sup> of December 1989, the Chairman has instructed parties to appoint one or more experts in order to answer the following questions based on the research results available at present:

- I Are the legal use instructions valid at present for the use of endosulfan, like for example the 25 metre distance requirement, sufficient to prevent harmful side effects?
- II If it was found that, in spite of the legal use instructions, the use of endosulfan from an ecological point of view is undesirable, should then the use of the alternative formulations brought up by the defendant indeed be preferred above endosulfan. For answering this question both ecological and agricultural aspects of the use of the products concerned should be considered.

On request of the parties dr. H. Canton and dr. P. Leeuwangh, as well as ir. J.H.B.J. Linders, all working at the RIVM, have subsequently, answered the above sub I formulated question with a report titled "Risks of endosulfan for aquatic organisms", like this:

“During application of endosulfan according to the legal use restriction valid at present it has to be expected that harmful side effects will occur. For a considerable number of fish at least for 50% mortality will occur.”

In annex 4 of the report a risk evaluation has been given, which assumes the dose which will be used at a water volume of 1000 litre/ha instead of the 1500 litres prescribed in accordance with the legal use instruction. Also in that situation the chance on acute effects for sensitive and average sensitive fishes is still present, according to the elucidation of the experts in court.

On being asked the experts have also declared, that within the fish population of ditches, which surround orchards, in which sprayings with endosulfan take place, the whole range of sensitive, average sensitive and not sensitive fish species occurs.

The question formulated above sub II with respect to agricultural aspects has been answered by dr. L. Blommers, in his report “The significance of endosulfan in the integrated pest control in orchards”.

This report contains the following conclusion:

“In the integrated pest control on apples (GPBA) endosulfan can not be missed.

- In a single case no control at all is possible without endosulfan.
- Likewise selective formulations are missing for the control of a few pests. By these replacing formulations important natural enemies will be killed. Because of that (other) pests will be induced, and extra sprayings will be necessary.
- A spraying with endosulfan sometimes can replace the application of two or three other formulations. This simplification is especially attractive if the grower has just started with integrated pest control.
- Endosulfan makes it possible to keep the use of organophosphates and carbamates limited. By that, the growing uselessness of these formulations as a result of resistance will be slowed down.
- Without endosulfan the number of sprayings against pests in GPBA will increase up to 50%.

The ecological aspects of this question have been further elucidated as a result of a report of the Plants Diseases Service of the defendant submitted in court. This report will be under discussion below sub 6.

## 6. FURTHER POSITION OF THE DEFENDANT

In court the defendant has taken the position that, also given the expert reports brought to the attention of the court, there is no reason not to follow the legal use instruction valid at present. The defendant considers further empirical research unnecessary, already because in advance he has the opinion that this will not provide results, which will remove the existing complaints against the ongoing use of endosulfan. The defendant has underpinned this thesis as follows:

In the expert report, other than the requestors have stated, already a lower emission factor, than the normal 10%, has been assumed. With that the specific, very limited use instructions of the formulation has been considered. Furthermore, in the report a “bio-availability” of endosulfan of 80 – 90% has been assumed, so that the thesis of the requestors also on this point misses its mark. Finally, also the “1000 litres

spraying" mentioned by the requestors have been evaluated in the expert report. The acute effects feared at that application – as described by the experts – are still unacceptable, according to the defendant in court.

The alternatives policy started since 1986 was elucidated by the defendant on the basis of a memo of the Plants Diseases Service entitled: "The policy for alternatives in the perspective of the intended termination of endosulfan for the integrated pest control in apples". From the overview given in a list accompanying this memo, it appears that at present there are sufficient alternative products for the use of endosulfan available. Thus, the formulation can be missed. For the control of the red-belted clearing and the European snout beetle, indicated by Blommers as small incidental pests, for which no good alternatives are available, endosulfan is also forbidden in accordance with the legal use instruction valid at present, according to the defendant in court. Furthermore, the defendant has taken the position that the harmful side effects of the alternatives, if well applied, will be controllable and acceptable. In the education for starting farmers much attention has been paid to the right use of the alternatives available at present.

The toxic effects for aquatic organisms of the alternatives are significantly lower than of endosulfan, according to the defendant, in addition to an estimation given in court by the expert Linders.

## 7. THE APPROPRIATE LEGAL REGULATIONS

According to the text specified in article 3, first paragraph, introduction and under b of the Pesticide Act – further also: the Act – , a pesticide will only be permitted, if, based on previous investigations with reasonable certainty may be assumed .... that by the use of the product in agreement with its intention and the prescribed or recommended application no harmful side effects by the formulation or its metabolites will occur.

Pursuant to the second paragraph of the article mentioned, introduction and sub e, to harmful side effects can amongst others counted harming of .... animals of which preservation is desired, in an extent that is not acceptable.

## 8. EVALUATION

8.1. The Chairman sees himself for the evaluation of the present appeal first of all placed for the question whether the defendant in fairness has reached the judgement that the further use of endosulfan containing pesticides harms animals, for which preservation is desirable, in an extent that is not acceptable. First of all this question has to be answered affirmatively. For that the following is considered.

8.2. According to the available research results, as evaluated in the expert report mentioned under 5., in which, with reference to the specific use instructions of endosulfan, the emission factor hypothetically has been set lower than for the evaluation of pesticides is habitual and by lack of further data already a "bio-availability" of 80 – 90% is assumed, the use of endosulfan causes an acute fish mortality of 50% in sensitive and average sensitive fish species, which are present in ditches around orchards where the application takes place. In view of the elucidation of the experts in court, it has to be assumed for the time being that the risks, also at application of endosulfan in low doses in such way as already takes place in practice at present, are not removed in an acceptable

way. The consequences of prolonged application have to be qualified as serious from an ecological point of view. Considering that, the defendant has for the time being, in fairness, decided that endosulfan, as far as possible, has to be replaced by less harmful formulations.

8.3. At present the development of these alternative products has reached a stage, in which the continuing use of the product is not longer necessary. The Chairman has thus also considered that from the expert report brought to the attention of the court for this case, it indeed appears that there are specific applications of endosulfan, for which no usable alternatives exist, but that the use of endosulfan exactly for those applications in agreement with at present legal use instruction is also forbidden. Moreover, the defendant has in court uncontradictedly declared, that the toxic effect on aquatic organisms of the available alternatives are clearly – according to the expert Linders by estimation a factor of five – lower than those of endosulfan. That the integrated control in the fruit culture by the omission of endosulfan will be somewhat hampered, was recognised by the defendant through its statement in court. He has declared to meet these agricultural objections by paying much attention in education, especially to starting farmers, to a precise integrated pest control with the use of alternatives, also to prevent a theoretically imaginable development of resistance. With this state of affairs the defendant has reached, on provisional judgement, after consideration of all upcoming interests, in fairness, a verdict that the harm, which will be inflicted to animals, for which preservation is desirable, by the use of endosulfan containing pesticides is not longer acceptable.

8.4. Once this judgement was reached, the defendant was bound, by provisional judgement in accordance with the text stated in article 3, first paragraph, introduction and under b of the Act, to a refusal of a further prolongation of the issued registrations.

8.5. At present no facts or circumstances are apparent, on the basis of which the defendant, judged in complaint, in spite of this should meet the objections of the requestors.

Therefore, there is no position for the assignment of the requested temporary provision. This leads to the following decision.

## 9. DECISION

The Chairman of the Board for Appeal for the Business Community rejects the appeal for temporary provisions.

Accordingly pronounced by mr. J.J.R. Bakker, Chairman, in the presence of mr. A. Bruining, as clerk of the Court, and pronounced in public at the 28<sup>th</sup> of February 1990.