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Listing of chemicals in Annex III to the Rotterdam Convention: review of notifications of final regulatory actions to ban or severely restrict a chemical: paraquat

Paraquat

Note by the Secretariat

Addendum

Supporting documentation provided by Sweden

The Secretariat has the honour to provide, in the annex to the present note, documentation received from Sweden to support its notification of final regulatory action for paraquat as a pesticide. The documentation was originally provided to the Chemical Review Committee at its fifth meeting as document UNEP/FAO/RC/CRC.5/8/Add.1/Rev.1 and has been reproduced, without changes and formal editing by the Secretariat, in the annex to the present note.

* UNEP/FAO/RC/CRC.6/1.

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Annex

1. **Focused summary in English on the supporting documentation for the notification for paraquat**

2. **English summaries of the two Swedish dossiers upon which the regulatory action was based**

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Additional information
Swedish PIC notification
Of Paraquat

Stockholm 13 June 2006
Ref nr 320-173-06

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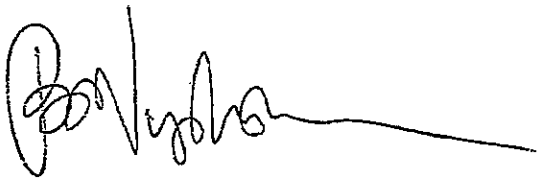
Dear Mr. van der Niek,

Referring to your letter referenced PL 36/11, Sweden would like to submit additional information in support of our notification of the Swedish final regulatory action for Paraquat. Paraquat is not produced in Sweden and has not been imported since the ban in 1983. The submitted information consists of:

- A focussed summary in English of the supporting documentation of the notification.
- The two main dossiers upon which the regulatory action was based. This material is in Swedish, but English summaries are attached.
- Copies of the articles the dossiers are referring to.

Please don't hesitate to contact us again should it be that the CRC would benefit from additional material or information from Sweden.

Yours Sincerely



Bo Nyström

Focused summary – Paraquat

I. Introduction

This section should provide a brief statement or summary of the final regulatory actions and the reasons for the action taken (e.g., occupational health concerns, environmental concerns). It may include:

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

Paraquat was banned in Sweden in 1983 by a decision of the Swedish Chemicals Inspectorate due to its acute high toxicity, risk for irreversible effects on health and for accidents during handling and use of the substance. The risk for intoxication due to accidents when handling the substance was considered unacceptably high..

(b) The significance of the regulatory action, e.g., one use or many uses, level or degree of exposure;

The substance used to be approved for weed control in agriculture, horticulture and orchards. All these uses of paraquat were banned, since it was estimated that mechanical failure of e.g. spraying equipment or protective clothing could easily lead to excessive exposure.

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

According to EC Directive 91/414/EEC, active substances in plant protection products have to be mutually assessed within the EU. Before a plant protection product can be placed on the Swedish market, it has to be approved by the Swedish Chemicals Inspectorate

(d) The scope of the regulatory action: a precise description of the chemicals subject to the regulatory action.

All uses of paraquat as a pesticide

II. Risk evaluation

This section should contain evidence, as available, that a risk evaluation was carried out under the prevailing conditions of the notifying country. It should confirm that the criteria in Annex II, subparagraph (b), have been met. It may include:

(a) Key findings of the national risk evaluation;

Death-rates after paraquat intoxication are very high even at such low doses as 1-5 g, orally. More than 500 cases worldwide of deadly intoxication had been reported at the time of the

national regulatory action. Cases of systemic mortal intoxication after dermal contamination had also been reported, including occupational dermal exposure.

On the national level it was noted that two serious intoxications were registered in Sweden since 1975, one boy acquired permanent eye damage from getting concentrated solution of paraquat in the face and one young man died 10 days after ingestion of paraquat for suicidal purpose.

Taking this information into consideration, it was concluded that the risk for intoxication when handling the substance was unacceptably high also for Swedish users. Mechanical failure of e.g. spraying equipment or protective clothing could easily lead to excessive exposure.

At the time of the Swedish evaluation, and the following regulatory action, it was not clear to what extent survivors had acquired a permanent damage on lung function. It was noted however, that such effects may follow severe cases of intoxication. A recent study from South Africa has however shown that working with paraquat under usual field conditions can be associated with abnormal exercise physiology due to arterial oxygen desaturation. Increased risks for Parkinson's disease has also been connected to similar long-term exposure to paraquat as well as dermatitis and nail destruction.

(b) Key data reviews consulted together with a brief description;

The regulatory action was primarily based on two Swedish dossiers where relevant literature was reviewed. The study of the fate of paraquat (Torstensson) in water and soil is describing the behaviour of the herbicide at Swedish environmental conditions. The toxicological study (Ahlborg & Skerving) is evaluating experimental data from controlled laboratory experiments which are relevant also for Swedish national conditions. The English summaries of the documents are attached to the focused summary.

(c) Reference to national studies, e.g. toxicological and ecotoxicity studies;

- *Lennart Torstensson (1982), Litteraturgenomgång rörande herbiciden paraquats uppträdande i mark och vatten. Sveriges Lantbruksuniversitet, Institutionen för mikrobiologi.*
- *U. G. Ahlborg, S. Skerving (1982) PARAQUAT - En diskussion av toxicitet och human risk. Statens Miljömedicinska Laboratorium Box 60208, 104 01 Stockholm / Yrkesmedicinska kliniken, Lasarettet, 221 85 LUND*

(d) A summary of actual or potential human exposure and/or environmental fate.

Relevant cases of intoxication from other similar countries were studied and the risks for excessive exposure during handling and use of the substance was estimated to be too high. It was also concluded that negative health effects due to long-term, low-intense exposure, could not be excluded. Recent studies have demonstrated that the use of paraquat is conditioned by the use of advanced personal protective equipment. According to the recent evaluation under the EC Directive 91/414/EEC, the AOEL is clearly exceeded unless advanced personal protection equipment is worn.

Paraquat is very persistent in the soil and strongly adsorbed to soil particles. Paraquat will therefore be accumulating in the soil after repeated exposure. This has been demonstrated in field trials with paraquat and it also contributed to the decision to ban paraquat in Sweden.

III. Risk reduction and relevance to other States

This section should contain evidence that the control action is of relevance to other States. It may include information on the following:

(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 quantity of use of paraquat as a pesticide before the ban in 1983 is unfortunately not possible to retrieve. There is no ongoing trade in Sweden.

(b) Relevance of the control action to other States, i.e., those with similar conditions of use;

The use of paraquat at the time of authorization in Sweden was only authorized for professional use and conditioned with a certificate of adequate knowledge about safe use and handling of pesticides (compulsory for pesticides in "class I and II"). The high risk for irreversible effects on human health makes paraquat especially dangerous for use in home gardening and by consumers in general.

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

Risk reduction in connection to the use of paraquat is highly dependent on adequate information and knowledge of potential adverse effects on human health. Conditions of use in many developing countries mean it is difficult to follow label instructions and recommendations for use. The use in some developing countries is therefore a matter of concern. High temperature in tropical and subtropical areas also increases the risk for the inadequate use of protective clothing and excessive exposure.

The potential misuse for suicidal purposes was also considered in the Swedish risk assessment before the regulatory action. It was noted that the intake of paraquat for suicidal purposes was not a reason for sustaining from risk reduction measures, since such actions, as a rule, are acts in despair, and not seriously intended. The fact that in case of intoxication, either deliberate or accidental, no antidote or remedial cure exists, was seen as strong reason for substitution of paraquat with other herbicides available on the market.

Litteraturgenomgång rörande herbiciden paraquats uppträdande i mark och vatten.

82 03 08, Swedish Chemicals Inspectorate

English Summary

General state of knowledge	The fate of paraquat in soil is well known, especially regarding its adsorption to clay minerals and organic material.
Adsorption	Paraquat is strongly adsorbed to clay minerals, in expanding clay minerals to such an extent that it is questionable if any desorption at all occur from within the mineral layers. The adsorption to organic material is not as strong. In the soil, paraquat adsorbed to organic material is reemitted and subsequently more strongly bound to clay minerals.
Adsorptive capacity	Most soils have such a large paraquat-binding capacity (several hundreds of kg/ha in the upper soil layer) that the amount in the pore-water is below the threshold concentration where phytotoxic effects occur.
Mobility	Paraquat is not mobile in the soil
Photochemical degradation	Paraquat, attached to the surface of plants, may degrade due to the action of sunlight. Photochemical degradation does however not seem to occur to a substantial degree, when paraquat is bound onto the surface of the soil.
Microbial degradation	Paraquat may be degraded by micro-organisms in the soil. Abiotic chemical degradation is not likely. For a degradation to take place, paraquat has to be dissolved in the soil water. Desorption from organic material is occurring relatively rapidly, while desorption from clay minerals is either not occurring or slow.
Persistence in soil	The persistence of paraquat in soil is primarily dependent on the strong adsorption to first of all clay minerals, but also organic material. Disappearance through evaporation is negligible as well as loss through leakage. The reduction of the amount of paraquat takes place via microbial activity in the soil. The phytotoxic persistenc of paraquat in the soil is short (less than a week to some months) while the chemical persistence is very long (for some soils dominated by clay, paraquat will remain detectable also in the foreseeable future). At repeated application, paraquat is accumulated at least to the limit of the adsorptive capacity of the soil. If this limit is passed, desorption of paraquat may occur, and hence degradation.
Persistence in water	The persistence of paraquat in the water column is short (about a month), but substantially longer in the sediment (several years).

Bioavailability	Paraquat is available for living organisms in the soil the first time after the application, especially in soils high in organic content. Uptake through plant roots may harm plants establishing after the application of the herbicide. Paraquat is taken up by micro-organisms which in turn lead to degradation of the herbicide or occasionally inhibition of microbial activity. Earth worms may absorb paraquat via ingestion of soil particles containing adsorbed paraquat. This may lead to further transfer of the herbicide to animals consuming worms.
Effects on soil organisms	Paraquat in normal doses, gives rise to no effects or small negative effects on earth worms and other soil-living primitive organisms. The herbicide has an impact on soil micro-organisms, in some cases negative (e.g. reduced degradation of plant debris), and in some cases positive (e.g. inhibition of nitrification, inhibition of plant pathogenic fungi). Some disturbance in the function of the soil ecosystem is thus expected, but in general of limited magnitude.

PARAQUAT – En diskussion av toxicitet och human risk

82 05 13 Swedish Chemicals Inspectorate

English Summary

Paraquat is a highly toxic compound. Harmful effects may first of all appear in the kidneys, the liver and the lungs. The most interesting effect is the delayed lung-damage that may follow upon a period of no symptoms, of a duration within an interval of days to weeks.

Administration of sufficiently high doses can thus result in severe lung fibrosis. Death-rates are very high even at such low doses as 1-5 g, orally. More than 500 cases of deadly intoxication have been reported. It is not clear to what extent survivors have acquired a permanent damage on lung function. It is likely, however, that such effects may follow severe cases of intoxication.

Almost all cases of intoxication have occurred after oral intake of a single dose, accidentally, or for suicidal purposes. The potential for medical treatment is limited. Not seriously meant suicidal incidents can therefore have mortal consequences to a high extent. Several cases of systemic intoxication have been reported after dermal contamination, including occupational dermal exposure.

Studies with experimental animals have shown that lung damage with fibrosis development can arise after inhalation of high concentrations. Only a few cases of human intoxication have never the less been reported after especially high exposure through inhalation. The causal link can in these cases be questioned. The explanation to the apparent low risk may partly be that the concentration is low in the air in the normal case, partly because the generated aerosol only contains a smaller fraction of respirable particles.

However, taking into account the extensive use, it is remarkable that only a limited number of methodologically unsatisfactory studies on chronic effects on spraying workers have been published. The need for more studies on the effects on lung-function is especially apparent. Data suggesting the accumulation of paraquat in lung tissue also give reason for additional studies. It should however be kept in mind that short-term exposure giving rise to harmful effects in experimental animals has occurred at two to three orders of magnitude higher concentrations compared to normal occupational exposure.

Concentrated formulations of paraquat are highly corrosive, and may give rise to contact dermatitis as well as severe and permanent eye damage.

Teratogenic, mutagenic or carcinogenic effects of paraquat have not been reported.