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

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Technical work: consideration of draft decision guidance documents: paraquat

Draft decision guidance document for paraquat

Note by the Secretariat

I. Introduction

1. At its eighteenth meeting, the Chemical Review Committee reviewed notifications of final regulatory action for paraquat submitted by Malaysia and Mozambique, together with the supporting documentation referred to therein, and concluded that the notifications met all the criteria of Annex II to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.

2. In decision CRC-18/4, the Committee adopted a rationale for its conclusion related to the notifications from Malaysia and Mozambique and recommended, in accordance with paragraph 6 of Article 5 of the Convention, that the Conference of the Parties list paraquat in Annex III to the Convention as a pesticide. By paragraph 4 of that decision, the Committee decided, in accordance with paragraph 1 of Article 7 of the Convention, to prepare a draft decision guidance document for paraquat.

3. Pursuant to decision CRC-18/4 and the workplan for the preparation of draft decision guidance documents adopted by the Committee (UNEP/FAO/RC/CRC.18/15, annex III), the intersessional drafting group established at the eighteenth meeting has prepared a draft decision guidance document for paraquat, which is set out in the annex to the present note, without formal editing. A compilation of comments relating to the draft decision guidance document received from Committee members and observers, including information on how those comments were addressed, is set out in document UNEP/FAO/RC/CRC.18/INF/5.

II. Proposed action

4. The Committee may wish to finalize the draft decision guidance document and to forward it, together with its recommendation to list paraquat in Annex III to the Convention as a pesticide, for consideration by the Conference of the Parties at its twelfth meeting.

* UNEP/FAO/RC/CRC.19/1/Rev.1.

Annex

Draft Decision Guidance Document

Paraquat

Rotterdam Convention

Operation of the prior informed consent procedure
for banned or severely restricted chemicals

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

Introduction

The objective of the Rotterdam Convention is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties. The Secretariat of the Convention is provided jointly by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization of the United Nations (FAO).

Candidate chemicals[1] for inclusion in the prior informed consent (PIC) procedure under the Rotterdam Convention include those that have been banned or severely restricted by national regulatory actions in two or more Parties[2] in two different regions. Inclusion of a chemical in the PIC procedure is based on regulatory actions taken by Parties that have addressed the risks associated with the chemical by banning or severely restricting it. Other ways might be available to control or reduce such risks. Inclusion does not, however, imply that all Parties to the Convention have banned or severely restricted the chemical. For each chemical included in Annex III of the Rotterdam Convention and subject to the PIC procedure, Parties are requested to make an informed decision whether they consent or not to the future import of the chemical.

At its […] meeting, held in […] on […], the Conference of the Parties agreed to list paraquat in Annex III of the Convention and adopted the decision-guidance document with the effect that this group of chemicals became subject to the PIC procedure.

The present decision-guidance document was communicated to designated national authorities on […], in accordance with Articles 7 and 10 of the Rotterdam Convention.

Purpose of the decision guidance document

For each chemical included in Annex III to the Rotterdam Convention, a decision-guidance document has been approved by the Conference of the Parties. Decision-guidance documents are sent to all Parties with a request that they make a decision regarding future import of the chemical.

Decision-guidance documents are prepared by the Chemical Review Committee. The Committee is a group of government-designated experts established in line with Article 18 of the Convention, which evaluates candidate chemicals for possible inclusion in Annex III of the Convention. Decision-guidance documents reflect the information provided by two or more Parties in support of their national regulatory actions to ban or severely restrict the chemical. They are not intended as the only source of information on a chemical nor are they updated or revised following their adoption by the Conference of the Parties.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical and others that have not banned or severely restricted it. Risk evaluations or information on alternative risk mitigation measures submitted by such Parties may be found on the Rotterdam Convention website (www.pic.int).

Under Article 14 of the Convention, Parties can exchange scientific, technical, economic and legal information concerning the chemicals under the scope of the Convention including toxicological, ecotoxicological and safety information. This information may be provided directly to other Parties or through the Secretariat. Information provided to the Secretariat will be posted on the Rotterdam Convention website.

Information on the chemical may also be available from other sources.

Disclaimer

The use of trade names in the present document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply any approval or disapproval of any particular company. As it is

[1] According to the Convention, the term “chemical” means a substance, whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial.

[2] According to the Convention, the term “Party” means a State or regional economic integration organization that has consented to be bound by the Convention and for which the Convention is in force.

not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included in the document.

While the information provided is believed to be accurate according to data available at the time of preparation of the present decision-guidance document, FAO and UNEP disclaim any responsibility for omissions or any consequences that may arise there from. Neither FAO nor UNEP shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of this chemical.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of FAO or UNEP concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitation of its frontiers or boundaries.

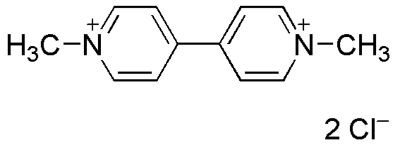
Standard core set of abbreviations

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to
μg	microgram
μm	micrometre
ARfD	acute reference dose
a.i.	active ingredient
a.s.	active substance
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
b.p.	boiling point
bw	body weight
ºC	degree Celsius (centigrade)
CAS	Chemical Abstracts Service
DT_{50}	dissipation time 50%
EC	European Community
EC_{50}	median effective concentration
EEC	European Economic Community
EHC	Environmental Health Criteria
EU	European Union
ETL	Environmental Toxic Load
FAO	Food and Agriculture Organization of the United Nations
g	gram
h	hour
ha	hectare
HHP	Highly Hazardous Pesticide
IARC	International Agency for Research on Cancer
IEDI	international estimated daily intake
IESTI	international estimated short-term dietary intake
IPCS	International Programme on Chemical Safety
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
k	kilo- (x 1000)
Kd	Soil partition coefficient
kg	kilogram
Koc	soil organic carbon-water partition coefficient.
Kow	octanol–water partition coefficient
kPa	kilopascal
L	litre
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOAEL	lowest-observed-adverse-effect level
m	metre

STANDARD CORE SET OF ABBREVIATIONS	
mg	milligram
ml	millilitre
MRL	maximum residue limit
ng	nanogram
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect concentration
NOEL	no-observed-effect level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
PPE	personal protective equipment
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/L are used).
RfD	reference dose (for chronic oral exposure; comparable to ADI)
SL	Soluble Concentrate formulation
STMR	supervised trials median residue
STMR-P	supervised trials median residue in a processed commodity
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
UV	ultraviolet
WHO	World Health Organization
wt	weight

Decision guidance document for a banned or severely restricted chemical

1. Identification and uses (see annex 1 to the decision guidance document for further details)

Common name	Paraquat
Chemical name and other names or synonyms	<u>IUPAC:</u> Paraquat ion: 1,1'-dimethyl-4,4'- bipyridinium Paraquat dichloride: 1,1'-dimethyl-4,4'- bipyridinium dichloride Synonyms: methyl viologen
Molecular formula	$C_{12}H_{14}N_2Cl_2$ (paraquat dichloride); $C_{12}H_{14}N_2$ (ion)
Chemical structure	Paraquat dichloride 
CAS-No.(s)	4685-14-7 (paraquat ion) 1910-42-5 (paraquat dichloride) 27041-84-5 (paraquat bistribromide) 2074-50-2 (paraquat bis(methylsulfate)
Harmonized System Customs Code	2933.39 (paraquat ISO), 3808.93 (preparation containing paraquat (ISO), used as herbicide)
Other numbers	EC No.(s): 225-141-7 (paraquat dication) 217-615-7 (paraquat dichloride) 218-196-3 (paraquat bis(methylsulfate) Combined nomenclature (CN) code for the European Union: 29333999 (paraquat ISO) 38089327 (preparation containing paraquat (ISO), used as herbicide) CIPAC No: 56 (dication); 56.302 (dichloride)
Category	Pesticide
Regulated category	Pesticide
Use(s) in regulated category	In Malaysia, the use of paraquat as an herbicide was restricted since May 2014 to oil palm below 2 years, rubber, pineapple stump and hill paddy crops until its total ban. In Mozambique, paraquat was registered for use as herbicide on various crops including sugar cane, various vegetables and bananas.
Trade names	Trade names listed in the notification from Malaysia are: Gramoxone® 100; Capayam; CS Paraquat 13; FarmCare Paraquat 13; CH Paraquat P130; PP Paraquat 13; AGR Para 13; WA Paraquat 130. Trade names listed in the notification and supporting information from Mozambique are: Moz Paraquat 20% SL; Paracot 20% SL; Para-Cure 20% SL; Paraxone 20% SL; Gramozat 20% SL; Agroquat 200 SL; Universal Skoffos 14,5% SL; Volquato 20% SL

Additional trade names of formulations containing paraquat (IPCS, 1991).

Paraquat only	Paraquat + Diquat	Paraquat + Urea Herbicides
Barclay Total®	Actor®	Anuron®
Crisquat ®	Dukatalon®	Dexuron®
Cyclone®	Opal®	Gramocil®
Dextrone X®	Pathclear®	Gramonol®
Dragocson®	PDQ®	Gramuron®
Esgram®	Preeglox L®	Tota-Col®
Efoxon®	Preeglone®	
Goldquat®	Seccatuto®	
Herbaxon®	Weedol®	
Herbikill®	Spray Seed®	
Gramoxone®		
Katalon®		
Osaquat®		
Parakill®		
Pilarxone®		
Plusquat®		
Priquat®		
R-Bix®		
Speeder®		
Speedway®		
Starfire®		
Sweep®		
Total®		
Weedless®		

Additional trade names: Allquit™, Boa® 250, Flash® Herbicide, Gramoxone Inteon®, Gramo, Gramosyn, Herbucsone, Milquat, Kapiq, Kataar,Parable™ 250 (discontinued product), ParaneX, Paraxzone, Horizon 250, Kuatout, Rainquat, Speedy 250, Synergy, Uniquat®, Parachlor 24, and Parable®.

This is an indicative list. It is not intended to be exhaustive.

Formulation types

The main formulation types for paraquat are soluble concentrate (SL). Other formulation types are Suspension Concentrate (SC) and Water-Soluble Granule (SG) formulations.

Uses in other categories

There is no reported use as an industrial chemical.

Basic manufacturers

AgriGuard, Clayton, Syngenta (Source: The Pesticide Product Database https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/505.htm)

This is an indicative list of current and former manufacturers. It is not intended to be exhaustive.

2. Reasons for inclusion in the PIC procedure

Paraquat is included in the PIC procedure as a pesticide. It has been listed on the basis of the final regulatory actions to ban its use, notified by Malaysia and Mozambique. Contact details of the designated national authorities of these two Parties are set out in annex 3 to the decision guidance document.

No final regulatory actions relating to industrial chemical uses have been notified.

2.1 Final regulatory action (see annex 2 to the decision guidance document for further details)

Malaysia

Malaysia prohibited all applications of paraquat as a pesticide product as well as its import and export. The ban was introduced by the official circular JP/KRP/207/12/656/2 Vol.6 (54) published on 16 May 2014, which detailed the phase-out strategies and plans. The phase-out of paraquat was implemented in stages and the effective date of the total ban entered into force on 1 January 2020. The ban of paraquat was introduced due to its highly toxic nature which has caused many poisonings and deaths of consumers.

The banning of paraquat is consistent with the principle of precautionary measures, as it has been shown that paraquat cannot be applied and used safely without complete PPE to prevent exposure under the hot and humid conditions, which is not always feasible in a country like Malaysia.

The final regulatory action has been taken for the pesticide category to protect human health.

Reason: Human Health

Mozambique

Mozambique banned the further import and use of paraquat in its territory by the decision Nr 001/DNSA/2014 of the National Directorate of Agrarian Services.

The ban of all formulations for all uses and also the cancellation of the registration of the products containing paraquat in the country was decided due to the toxic nature and hazardous properties of this active substance, which combined with the local conditions of use can damage human and animal health and cause potential damage to the environment.

The final regulatory action has been taken for the pesticide category to protect human health and the environment.

Reason: Human Health and the Environment

2.2 Risk evaluation (see annex 1 to the decision guidance document for further details)

Malaysia

Malaysia developed a risk evaluation where they analysed international risk assessments and applied bridging with local conditions of use of paraquat and actual exposure. Specifically, paraquat has been classified by the Pesticides Board under Class Ib - very highly hazardous to humans instead of Class II (of WHO classification) because it was taken into consideration that under local conditions paraquat cannot be used safely due to hot and humid weather, which makes wearing full protective gears not always practical. This is supported by the evaluation of the paraquat study undertaken by the Malaysian Palm Oil Board, which identified unacceptably high OEL (Operator Exposure Level) under local conditions of use. Furthermore, the Ministry of Health of Malaysia has confirmed actual exposure to the pesticide according to the cases of poisoning referred to government clinics/hospitals where the poisoning data shows that the causes of paraquat poisoning are suicide, followed by accidental drinking and occupational poisoning.

In 2018 and 2019 a total of 424 320 L and 137 740 L of paraquat, respectively, were used in Malaysia prior to the entry into force of the total ban in 2020. The use of paraquat in Malaysia was restricted since May 2014 to oil palm (below 2 years), rubber, pineapple (stump) and paddy (hill crops). No information is available in the notification and supporting information provided by Malaysia on the volumes of paraquat imported before the adoption of the final regulatory action in 2014.

Summarising the above, the final regulatory action was based on a health hazard evaluation of paraquat, the prevailing conditions of use of pesticides in Malaysia (intended uses, application doses, methods, protective measures, agricultural practices, etc.), and a risk assessment with a particular focus on occupational risks.

Mozambique

Mozambique developed a risk evaluation, referenced to Project EP/MOZ/101/UEP, with the objective of reducing the greatest risks associated with pesticide use in the country and to develop and implement a “Highly Hazardous Pesticides Risk Reduction Action Plan” for the most dangerous pesticides and use situations.

The notification states that the ban of all uses and the cancellation of the registration of the products containing paraquat in Mozambique was decided based on the toxic nature and hazardous properties, which combined with the improper use in the country due to the local specific conditions of use can damage human and animal health.

In the first step of the project, a review of all pesticides registered in Mozambique was carried out and a shortlist of highly hazardous pesticides was established. This shortlist was based on an assessment of the hazards of the pesticides, based on criteria established by the FAO/WHO Joint Meeting on Pesticide Management.

Paraquat and the products containing paraquat were considered as harmful for human health and the environment taking into consideration the local conditions of use in Mozambique and the requirements for risk mitigation measures. The notification refers to a consultancy report “Reducing Risks of Highly Hazardous Pesticides in Mozambique: Step 1 – Shortlisting highly hazardous pesticides” (Come & van der Valk, 2014), which identified the paraquat 200 g/l SL pesticide formulation as ‘coming close to highly hazardous pesticides (HHPs)’, based on its classification as WHO Class II with a note on serious delayed effects if absorbed (note 7 in the WHO classification - *Paraquat has serious delayed effects if absorbed. It is of relatively low hazard in normal use but may be fatal if the concentrated product is taken by mouth or spread on the skin*); dermal hazard close to Class Ib and very low AOEL) The occupational hazard of paraquat was confirmed by the very low AOEL defined in the EU (2003).

Field surveys with 325 subsistence farmers were carried out during the step 2 of the project in selected regions and cropping systems in Mozambique (Come et al., 2014). The main goal of the survey was to identify the conditions under which pesticides are being used in the country and their contribution to potential risks for human health and the environment.

The notification and supporting documentation provide information on the imports of paraquat formulations in Mozambique prior to and including the period when the field survey with farmers was carried out: 22700 L (2010), 35100 L (2011), 17952 L (2012) and 18440 L (2013).

The registered uses for paraquat formulations in Mozambique were forestry, fruits, vegetables, cotton, coffee, tea, flowers, banana, sugar cane, forestry and potatoes. Vegetables, cotton and tobacco cropping systems were included in the field survey and were the predominant crops in three of the regions of Mozambique surveyed. These cropping systems are generally managed by smaller subsistence farmers.

The third step of the project consisted of a stakeholder consultation to further discuss the use and risks of highly hazardous pesticides in Mozambique and fine-tune the shortlist based on the survey results and the expertise and experience of stakeholders.

In the fourth step of the project, the risk of occupational exposure was assessed, in particular when spraying the products, in seven different cropping systems and using 13 application scenarios, each with and without PPE (Come & van der Valk, 2014). The exposure assessment used the registered dose rates and other application parameters for each pesticide based on farming conditions in Mozambique. Exposure was estimated using occupational exposure models. The results of the occupational exposure risk assessment reported in the notification and supporting documentation showed that AOELs for paraquat were greatly exceeded for all crops and all pesticide application scenarios, irrespective of the application rate or use of PPE. This indicates that the application of paraquat likely poses a high risk under Mozambican conditions. Given the large risk quotient, it is unlikely that locally feasible mitigation measures would reduce the risk of paraquat to acceptable levels.

The notification and supporting documentation indicate that the use of pesticides in general (including pesticides ‘coming close to ‘HHPs’) and of HHPs in particular, was likely to result in excessive exposure of farmers given the low availability and knowledge in the use of PPE among farmers, and was evidenced by a high number of reports on adverse health effects.

The final regulatory action was taken as a result of the national objective of Mozambique of reducing the greatest risks associated with pesticide use. Thus, paraquat and the products containing paraquat were considered harmful for human health under the local conditions of use in Mozambique requiring risk mitigation measures. Therefore, the authorities decided to ban paraquat from future use in the country and to cancel the registration of all the products containing paraquat.

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

Malaysia	Paraquat was banned by the official circular JP/KRP/207/12/656/2 Vol.6 (54) on 16 May 2014 for all applications as a pesticide product as well as its import and export. The phase-out of paraquat was implemented in stages and the total ban entered into force on 1 January 2020.
Mozambique	Paraquat was banned by the National Directorate of Agrarian Services from further import and use in Mozambique by the decision Nr 001/DNSA/2014. The regulatory action entered into force on 31 December 2014.

3.2 Other measures to reduce exposure

Malaysia

None reported.

Mozambique

None reported.

3.3 Alternatives

Malaysia

Malaysia included the following chemical alternatives in its notification and supporting documentation:

2,4-d-dimethylammonium (CAS No 2008-39-1)
2,4-d-sodium monohydrate (CAS No 2702-72-9)
Ametryn (CAS No 834-12-8)
Atrazine (CAS No 1912-24-9)
Bromacil (CAS No 314-40-9)
Clethodim (CAS No 99129-21-2), diuron (CAS No 330-54-1)
Fluazifop-p-butyl (CAS No 79241-46-6)
Fluroxypyr-meptyl (CAS No 81406-37-3)
Glufosinate-ammonium (CAS No 77182-82-2)
Glyphosate (CAS No 1071-83-6)
Glyphosate-ammonium (CAS No 114370-14-8),
Glyphosate-dimethylammonium (CAS No 34494-04-7)
Glyphosate-isopropylammonium (CAS No 38641-94-0)
Glyphosate-potassium (CAS No 39600-42-5)
Glyphosate-sodium (CAS No 34494-03-6)
Imazapyr-isopropylammonium (CAS No 81510-83-0)
Imazethapyr (CAS No 81335-77-5)
Metolachlor (CAS No 51218-45-2)
Metsulfuron-methyl (CAS No 74223-64-6)
Napropamide (CAS No 15299-99-7)
Oxyfluorfen (CAS No 42874-03-3)
Pendimethalin (CAS No 40487-42-1)
Pyrazosulfuron-ethyl (CAS No 93697-74-6)
Quizalofop-ethyl (CAS No 76578-14-8)
Disodium Methylarsonate (CAS No 144-21-8) + diuron (CAS No 330-54-1) +2,4-D-sodium (CAS No 2702-72-9).

Mozambique

The Ministry of Agriculture and Food Security through the National Directorate of Agriculture and Agrarian Services (the pesticide register authority) with link to the producers' associations and private sector are engaged to assess alternative weed control options and facilitate registration of lower risk herbicides.

General

It is essential that before a country considers substituting a substance with alternatives, it ensures that the use is relevant to its national needs, and the anticipated local conditions of use. The hazards of the substitute materials and the measures needed for safe use should also be evaluated.

There are a number of alternative methods involving chemical and non-chemical strategies, including alternative technologies available, depending on the individual crop under consideration. Where necessary, priority should be given to the introduction of integrated weed management and agro-ecological approaches that reduce reliance on herbicides. This is explicitly supported by a broad range of international policy documents, including those of FAO, UNEP, WHO, World Bank and the OECD Development Assistance Committee.

SAICM's Fourth International Conference on Chemicals Management recommended that awareness should be raised to identify and share information about viable alternatives to HHPs, including cultural and environmental management measures, biological controls, biopesticides or less hazardous pesticides (FAO/WHO 2008).

Information on such agroecologically-based practices can be found at the following websites:

FAO Agroecology hub: http://www.fao.org/agroecology/en/

IPAM (International Peoples Agroecology Multiversity): http://ipam-global.org/

OISAT (Online Information Service for Non-Chemical Pest Management in the Tropics): http://www.oisat.org/

Replacing Chemicals with Biology: Phasing out Highly Hazardous Pesticides with Agroecology:

https://saicmknowledge.org/library/replacing-chemicals-biology-phasing-out-highly-hazardous-pesticides-agroecology

3.4 Socio-economic effects

Malaysia

During the review period conducted from 2002 to 2013, the Agriculture Department in collaboration with relevant government agencies conducted studies on the effectiveness of alternative pesticides to paraquat. The Agriculture Department and the Pesticides Board had also held a series of consultations with stakeholders such as the paraquat pesticide industry, producers of alternative pesticides, plantation sector, consumer unions, Non-Governmental Organizations (NGOs), academia and the general public.

In assisting the Pesticides Board to make decisions on paraquat, the Department of Agriculture of Malaysia conducted an alternative efficacy study to control weeds in the recommended crop areas. The Alternative to Paraquat Study Committee was formed and was comprised of members from Malaysia Agricultural Research and Development Institute (MARDI), Cocoa Board, Malaysian Rubber Board, Malaysian Palm Oil Board (MPOB) and the Department of Agriculture. Studies have been conducted for mango, starfruit, cocoa, rubber, oil palm and vegetables. In this study, paraquat herbicides, glufosinate and glyphosate were used for comparative purposes in terms of effectiveness, cost and phytotoxic effects.

The study was conducted from 19 May 2010 to March 2011.

The results of the above study were presented at the Pesticides Board in 2011. The findings of the study were summarized as follows:

- All three herbicides were effective in controlling weeds on all crops tested.
- All crops tested did not show phytotoxic effects to the three herbicides if used according to the instructions on the label.
- Although all pesticides can control weeds, the control period varies according to the pesticides where the longest control was with glyphosate and followed by glufosinate-ammonium.
- After taking into account all the costs involved (pesticides, equipment, manpower, transportation, water and spray frequency) it was concluded that the cost of using glyphosate was the lowest (65 USD/ha/year) and followed by paraquat (90 USD/ha/year) and glufosinate (100 USD/ha/year).

The results of the verification study conducted on the alternative herbicides were disseminated to consumers through demonstration plots. Apart from that, the Department of Agriculture organised a series of briefings to consumers to disseminate information on alternative pesticides that can be used in weed control to replace paraquat.

Based on the verification and demonstration study, the Malaysian authorities considered that there are cost effective alternative herbicides to control weeds under all crop conditions in place of paraquat, thus supporting the argument that the banning of paraquat will not result in negative implications to farms and plantations industry in Malaysia.

The following studies were also considered during the review period:

- 'The Economic And Social Impact of A Paraquat Prohibition In Malaysia: A Position Paper' conducted by Intercedent Asia (Asian Consultation & Research) sponsored by Syngenta Malaysia in 2003.
- A study on the use of pesticides in the oil palm plantation sector in Malaysia conducted by the Commonwealth Agricultural Bureau International (CABI) on behalf of The Roundtable On Sustainable Oil Palm (RSPO).
- A study on the implication of paraquat banning in Malaysia conducted by the Malaysian Palm Oil Board (MPOB) in collaboration with University of Sains Malaysia (USM), University of Putra Malaysia (UPM) and several other parties.

4. Hazards and Risks to human health and the environment	
4.1 Hazard Classification	
WHO / IPCS	Moderately hazardous (Class II) with notes 7 and 15. (WHO, 2010, 2019) Note 7. Paraquat has serious delayed effects if absorbed. It is of relatively low hazard in normal use but may be fatal if the concentrated product is taken by mouth or spread on the skin. May be used as paraquat dichloride (CAS number 1910-42-5). Notes 15. A high case fatality has been reported in poisoning cases with this substance.
IARC	Not evaluated
European Union	Classification according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (CLP-Regulation) Acute Tox. 3 * — H301 -Toxic if swallowed Acute Tox. 3 * — H311 – Toxic in contact with skin Skin Irrit. 2 — H315 – Causes skin irritation Eye Irrit. 2 — H319 – Causes serious eye irritation Acute Tox. 2 * — H330 – Fatal if inhaled STOT SE 3 — H335 – May cause respiratory irritation STOT RE 1 — H372 ** - Causes damaged to organs through prolonged or repeated exposure Aquatic Acute 1 — H400 – Very toxic to aquatic life Aquatic Chronic 1 — H410 – Very toxic to aquatic life with long lasting effects * The manufacturers or importers must apply at least the minimum classification but must classify in a more severe hazard category in the event that further information is available which shows that the hazard(s) meet the criteria for the classification in the more severe category (see Annex VI, Section 1.2.1 of the CLP Regulation.) ** The classification under 67/548/EEC indicating the route of exposure has been translated into the corresponding class and category according to this Regulation, but with a general hazard assessment not specifying the route of exposure as the necessary information is not available
US EPA	Highly toxic (Class I) by inhalation route Moderately toxic (Category II) by the oral route Slightly toxic (Category III) by the dermal route Category E (no evidence of carcinogenicity in animal studies) (US EPA, 1997)

4.2 Exposure limits

JMPR (2003a, b)

Acute reference dose (ARfD): 0.006 mg paraquat ion/kg bw based on the NOAEL of 0.55 mg of paraquat ion/kg bw per day in the 13-week study in dogs, with a safety factor of 100. Histopathological changes in the lungs were present at higher doses in both studies in dogs.

Acceptable Daily Intake (ADI): 0-0.005 mg of paraquat ion/kg bw based on a NOAEL of 0.45 mg of paraquat ion/kg bw per day in the 1-year study in dogs and using a safety factor of 100. Although a 1-year study in dogs is not considered to be a long-term study, the nature and time-course of the pathogenesis of the lung lesions were such that the application of an additional safety factor was not considered to be necessary.

European Union (2003)

ADI: 0.004 mg of paraquat ion/kg bw based on a NOAEL of 0.45 mg of paraquat ion/kg bw per day in the 1-year study in dogs and using a safety factor of 100.

AOEL systemic (long term): 0.0004 mg of paraquat ion/kg bw/d based on the 1-year dog study corrected for 10 % oral absorption and using a safety factor of 100.

AAOEL systemic (short term): 0.0005 mg of paraquat ion/kg bw/d based on the NOAEL of 0.55 mg of paraquat ion/kg bw per day in the 90-day dog study corrected for 10 % oral absorption and using a safety factor of 100.

AEOL inhalation N/A, use systemic value.

AOEL dermal: N/A, use systemic value.

ARfD: 0.005 mg of paraquat ion/kg bw/d based on the NOAEL of 0.55 mg of paraquat ion/kg bw per day in the 90-day study in dogs, with a safety factor of 100.

Maximum Residue Limits

Codex Alimentarius Maximum Residue Limits (MRLs)

Commodity	MRL (mg/kg)	Year of Adoption	Symbol
Almond hulls	0.01	2006	(*)
Assorted tropical and sub-tropical fruits - inedible peel	0.01	2006	(*)
Berries and other small fruits	0.01	2006	(*)
Citrus fruits (group)	0.02	2006	
Cotton seed	2	2006	
Edible offal (mammalian)	0.05	2006	
Eggs	0.005	2006	(*)
Fruiting vegetables, cucurbits (group)	0.02	2006	
Fruiting vegetables, other than cucurbits (group)	0.05	2006	
Hops, dry	0.1	2006	
Leafy vegetables	0.07	2006	
Maize	0.03	2006	
Maize flour	0.05	2006	
Maize fodder (dry)	10	2006	dry wt
Meat (from mammals other than marine mammals)	0.005	2006	
Milks	0.005	2006	(*)
Pome fruits (group)	0.01	2006	(*)
Poultry meat	0.005	2006	(*)
Poultry, edible offal of	0.005	2006	(*)
Pulses (group)	0.5	2006	
Rice	0.05	2010	
Rice, hay and/or straw	0.05	2010	
Root and tuber vegetables (group)	0.05	2006	
Sorghum grain	0.03	2006	
Sorghum straw and fodder, dry	0.3	2006	dry wt
Soya bean fodder	0.5	2006	dry wt
Stone fruits (group)	0.01	2006	(*)
Sunflower seed	2	2006	
Table olives	0.1	2006	
Tea, green, black (black, fermented and dried)	0.2	2006	
Tree nuts (group)	0.05	2006	

(*): At or about the limit of determination.

The definition of residues for plant and animal commodities should be: Paraquat cation (for both compliance with MRLs and estimation of dietary intake).

Source: https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticide-detail/en/?p_id=57

The Joint meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group (JMPR, 2004 a, b) recommended the update of some of the MRLs on the basis of the data from supervised trials.

European Union
Pursuant to Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin (Official Journal of the European Union L 70, 16.3.2005, p. 1), the maximum residue limit is 0.02 mg/kg, except 0.05 mg/kg for bananas. The limit values are specified in Commission Regulation (EU) No 520/2011 (OJ L 140, 27.5.2011, p. 2–47).

Products	**Pesticide residues and maximum residue levels (mg/kg)**
Fruits, fresh or frozen; tree nuts	0.02*
Vegetables, fresh or frozen	0.02*
Pulses	0.02*
Oilseeds and oil fruits	0.02*
Cereals	0.02* (except rice, where the MRL is 0.05)
Teas, coffee, herbal infusions, cocoa and carobs	0.05*
Hops	0.05*
Spices	0.05*
Sugar plants	0.02*
Products of animal origin	0.01 (default)

* Indicates lower limit of analytical determination

Source : https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/mrls/?event=details&pest_res_ids=172&product_ids=&v=1&e=search.pr

4.3 Packaging and labelling

The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:

Hazard Class and Packing Group:	UN Number 2781 UN Hazard Class: 6.1 UN Pack Group: I Source: https://inchem.org/documents/icsc/icsc/eics0005.htm
International Maritime Dangerous Goods (IMDG) Code	IMDG Transport Code is usually 6.1 -Toxic substances Source: UNEP/FAO/RC/CRC.18/INF/29
Transport Emergency Card	Not available

Further specific guidance on appropriate symbols and label statements for paraquat products may be available in the FAO Guidelines on Good Labelling Practice for Pesticides (FAO, 2015).

4.4 First aid

NOTE: The following advice is based on information available from the World Health Organisation and the notifying countries and was correct at the time of publication. This advice is provided for information only and is not intended to supersede any national first aid protocols.

Main Human Health Hazards, Prevention and Protection, First Aid

Paraquat is highly toxic and often fatal if swallowed. Contact with liquid products can cause severe damage to the skin or eyes. Utmost care must be taken to avoid exposure during handling operations and application in the field. In applications where inhalation exposure to aerosols containing paraquat is likely, proper respiratory protective equipment should be used. The human health hazards, together with preventive and protective measures and first-aid recommendations, are listed in the table below.

Hazard/Symptoms	Prevention and protection	First aid
Skin: Irritating to skin, may cause blisters, redness	Proper application technique; proper skin protection, including impervious clothing and gloves Do not take working clothes home. Remove PPE immediately after handling this product. Wash the outside of gloves before removing	Remove contaminated clothing; wash skin with soap and water; wash clothes before re-use
Eyes: Severe irritant. Symptoms: Redness. Burning sensation. Pain.	Wear face shield or eye protection in combination with breathing protection if powder.	Flush immediately with clean water for at least 15 minutes; seek medical advice and observe for delayed effects
Inhalation: Cough. Sore throat. Headache. Nosebleeds.	Use local exhaust or breathing protection.	Fresh air, rest. Refer immediately for medical attention.
Ingestion: Accidental or deliberate ingestion may cause vomiting, abdominal discomfort, and soreness of mouth and throat; signs of liver and kidney damage may appear in 1-3 days; the symptoms of lung fibrosis (shortness of breath, laboured breathing) do not become manifest until several days; paraquat can kill	Do not eat, drink, or smoke during working hours; wash hands Paraquat products must never be transferred to a food, drink, or any other container	Obtain medical attention immediately, transport to hospital urgently. If the patient is not vomiting, give a slurry of activated charcoal or Fuller's Earth in water to drink.

Advice to physicians

The most important measures are the immediate neutralization of ingested paraquat by 15% Fuller's earth, bentonite, or activated charcoal, and urgent removal of the poison by vomiting or, when possible, gastric lavage. The urgency of these measures is such that, where transfer to hospital may involve a delay of an hour or more, the emergency treatment may need to be given by a paramedical person, e.g., a nurse or a medical assistant, without any delay. Furthermore, Fuller's earth should be given together with a strong purgative, such as magnesium sulfate or mannitol.

Admission to a hospital (preferably a specialized intensive care unit), either directly, or after emergency treatment elsewhere, is essential. Where a person has swallowed a lethal dose, the most important single determinant of survival is the early commencement of treatment. Depending on local facilities, patients who reach hospital after the initial treatment will have further treatment aimed at neutralizing paraquat in the gastrointestinal tract (Fuller's earth, bentonite, activated charcoal) or its excretion in the faeces (purgatives, 10% mannitol, gut lavage). In addition, attempts to remove absorbed paraquat from the circulation (haemoperfusion, haemodialysis) or aid its excretion by the kidney (forced diuresis) can be instituted. Care must be exercised in the administration of most of these treatments, as the following serious complications may occur: perforation of the oesophagus during gastric intubation; serious blood chemistry disturbance, when severe diarrhoea is induced; fluid overload during forced diuresis.

In centres where facilities for analytical procedures are available, measurement of urinary, or, ideally, plasma levels of paraquat may give guidelines for the required intensity of treatment or likely prognosis. Determination of paraquat levels in stomach washings, serum, and urine is useful for the management of poisoning. The urinary levels decline rapidly during the 24 h following exposure and may remain low for some weeks.

Many other therapies including corticosteroids, immunosuppressive treatment, vitamins, beta-blocking and alkylating agents, alpha-tocopherol, superoxide dismutase and/or glutathione peroxides proved to be of no significant importance in human paraquat poisoning. The administration of oxygen should be avoided, unless vital for the patient's comfort.

It should be noted that, as with the great majority of chemicals, there is no specific antidote. Despite such an array of both simple and sophisticated measures, the response to therapy in paraquat poisoning is disappointing and the mortality rate remains high.

In cases of skin and eye contamination irrigation with water (preferably running water) should be commenced urgently and must be continued uninterrupted for at least 15 minutes (timed by the clock). Eye cases should always be taken for medical treatment. In cases of skin contamination by the concentrate, or extensive and/or prolonged contamination by the diluted material (particularly where signs of skin irritation are present), the patient must be assessed at hospital for systemic poisoning.

Personal protection and hygienic measures

Avoid all contact with skin, eyes, nose, and mouth, when handling concentrated paraquat. Wear PVC-, neoprene- or butyl-rubber gloves (preferably gauntlet form), neoprene apron, rubber boots, and face shield.
* Wear a face-shield when handling and applying the diluted formulation.
* Immediately remove heavily contaminated clothing and wash underlying skin.
* Wash clothes before re-use.
* Do not eat, drink, or smoke, when using paraquat.
* Wash splashes from skin or eyes immediately.
* Do not inhale spray.
* Wash hands and exposed skin, before meals and after work.
* Keep away from food, drink, and animal feed.
* Paraquat should not be sprayed with inadequate dilution, e.g., by hand-held, ultra-low-volume application.
* It should not be used by people suffering from dermatitis or by people with wounds, notably on the hands, until these have healed.

Explosion and Fire Hazards

Paraquat products are generally not flammable. If involved in a fire, control with dry powder or alcohol-resistant foam. Advise the fire service that protective clothing and self-contained breathing apparatus should be worn, to avoid skin contamination and the breathing of toxic fumes. Confine the use of water spray to the cooling of unaffected stock, thus avoiding the accumulation of polluted run-off from the site.

Accident procedures

Avoid exposure by the use of appropriate protective clothing, gloves, and goggles or masks. Keep spectators away from leaking or spilled product and prevent smoking, and the use of naked flames, in the immediate vicinity. Extinguish fires with dry powder, carbon dioxide, alcohol-resistant foam, sand, or earth.

Prevent liquid from spreading to other cargo, vegetation, or waterways by containing it with the most readily available barrier material, e.g., earth or sand. Absorb spilled liquid and cover contaminated areas with earth, lime, sand, or other absorbent material; sweep up and place in a secure container for subsequent safe disposal.

Spillage and Disposal

Consult an expert! Avoid exposure by the use of appropriate protective clothing and face-shield. Empty any product remaining in damaged or leaking containers into a clean empty drum and label. Absorb spillage with lime, damp sawdust, sand, or earth and dispose of safely. If spillage is large, contain it by building a barrier of earth or sandbags. Decontaminate empty, damaged, or leaking containers with a 10% sodium carbonate solution, added at the rate of at least 1 litre per 20-litredrum. Puncture or crush containers to prevent re-use. Store and dispose of according to local regulations.

Sources:
IPCS (1991) International Programme on Chemical Safety, Poisons Information Monograph 399, Paraquat. Available at http://www.inchem.org/documents/pims/chemical/pim399.htm

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IPCS/WHO (1991) Paraquat: health and safety guide. http://www.inchem.org/documents/hsg/hsg/hsg051.htm

4.5 Waste management

Regulatory actions to ban a chemical should not result in creation of a stockpile requiring waste disposal. For guidance on how to avoid creating stockpiles of obsolete pesticides, the following guidelines are available: FAO Guidelines on Prevention of Accumulation of Obsolete Pesticide Stocks (FAO, 1995), The Pesticide Storage and Stock Control Manual (FAO, 1996a) and Guidelines for the management of small quantities of unwanted and obsolete pesticides (FAO, 1999).

In all cases waste should be disposed of in accordance with the provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1996), any guidelines thereunder, and any other relevant regional agreements.

It should be noted that the disposal/destruction methods recommended in the literature are often not available in, or suitable for, all countries, e.g., high temperature incinerators may not be available. Consideration should be given to the use of alternative destruction technologies. Further information on possible approaches may be found in Technical Guidelines for the Disposal of Bulk Quantities of Obsolete Pesticides in Developing Countries (FAO, 1996b).

The most recent FAO tools and resources on pesticide related waste management are available from the Pesticide Related Waste Management section of the International Code of Conduct on Pesticide Management website https://www.fao.org/pest-and-pesticide-management/pesticide-risk-reduction/code-conduct/waste-management/en/

and via the FAO's Pesticide disposal series webpage at https://www.fao.org/publications/search/en/?serialtitle=RkFPIFBlc3RpY2lkZSBEaXNwb3NhbCBTZXJpZXM

<u>Disposal Methods for paraquat</u>

Waste containing paraquat should be burnt in a proper high temperature incinerator with effluent gas scrubbing. Where no incinerator is available, contaminated absorbents or surplus products should be decomposed by hydrolysis at pH 12 or above. A 5% sodium hydroxide (caustic soda) solution or saturated (7-10%) sodium carbonate (washing soda) solution can be used. Before disposal of the resultant waste, the material must be analysed to ensure that the active ingredient has been degraded to a safe level.

Paraquat is rapidly inactivated by clay soil. If the above-mentioned methods are not possible, it can be buried in an approved landfill. Never pour untreated waste or surplus products into public sewers or where there is any danger of run-off or seepage into streams, watercourses, open waterways, ditches, fields with drainage systems, or the catchment areas of boreholes, wells, springs, or ponds.

Source: World Health Organization & International Programme on Chemical Safety. (1991). Paraquat: health and safety guide. World Health Organization. http://www.inchem.org/documents/hsg/hsg/hsg051.htm

5. References

Regulatory actions

Malaysia

Official circular JP/KRP/207/12/656/2 Vol.6 (54) published on 16 May 2014

Mozambique

Deliberação Nr. 001/DNSA/2014 by the National Directorate of Agriculture and Agrarian Services (The pesticide register Authority).

Supporting Documentation

Malaysia

European Union (EU), 2003. Review report for the active substance paraquat. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 3 October 2003 in view of the inclusion of paraquat in Annex I of Directive 91/414/EEC. SANCO/10382/2002 -final. https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/backend/api/active_substance/download/1106

Paraquat: notifications of final regulatory action. UNEP/FAO/RC/CRC.18/13

Paraquat: supporting documentation provided by Mozambique. UNEP/FAO/RC/CRC.18/INF/28

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Other Documents

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Annexes to the decision guidance document

Annex 1	**Further information on paraquat**
Annex 2	**Details on final regulatory actions reported**
Annex 3	**Addresses of designated national authorities**

Annex 1 to the decision guidance document - Further information on paraquat

The information presented in this Annex reflects the conclusions of the notifying Parties: Malaysia and Mozambique. The notifications from Malaysia and Mozambique were published in PIC Circular LII of December 2020.

Where possible, information on hazards provided by the notifying Parties has been presented together, while the evaluation of the risks, specific to the conditions prevailing in the notifying Parties are presented separately. This information has been taken from the documents referenced in the notifications in support of the final regulatory actions to ban paraquat.

Furthermore, information from the IPCS (1991), the FAO/WHO JMPR (2003, 2004) and the EU (2003) evaluations of paraquat has been taken into account.

1. Physico-Chemical properties

1.1	**Identity**	Paraquat dichloride IUPAC: 1,1'-dimethyl-4,4'-bipyridinium dichloride CAS No: 1910-42-5
1.2	**Formula**	$C_{12}H_{14}N_2Cl_2$
1.3	**Colour and Texture**	Off-white hygroscopic solid without characteristic odour
1.4	**Decomposition temperature**	~340 ºC (613ºK)
1.5	**Boiling point**	Not applicable. Decomposes before reaching boiling point
1.6	**Relative density**	1.55 at 25 ºC
1.7	**Vapour Pressure**	$<<1 \times 10^{-5}$ Pa at 25 °C
1.8	**Henry's Law Constant**	4×10^{-9} Pa m^3/mol
1.9	**Relative density**	1.11 at 20 °C
1.10	**Solubility in water**	618 g/L at pH 5.2 620 g/L at pH 7.2 620 g/L at pH 9.2
1.11	**Solubility in organic solvents**	Solubility < 0.1 g/L for each of the following solvents at 20 °C: Acetone, hexane, dichloromethane, toluene and ethyl acetate. Solubility 143 g/L for methanol (99.5% purity)
1.12	**Partition coefficient**	Log K_{ow} -4.5 at 25 ºC
1.13	**Dissociation constant**	Not applicable; compound does not dissociate
1.14	**Hydrolysis**	No hydrolysis was observed at pH 5, 7 or 9 (91 mg/L; 25 or 40 ºC for 30 days)
1.15	**Photolysis**	In aqueous solution, photochemically decomposed by UV radiation
1.17	**Resistance to acids**	Hydrolytically stable under acidic conditions
	Resistance to alkalis	Hydrolytically stable under alkaline conditions
1.18	**Storage stability**	Stable but decomposes in the presence of UV light

Purity of test substance 95%
Source: JMPR (2003)

2 Toxicological properties

2.1	**General**	
2.1.1	**Mode of Action**	**JMPR (2003a, b)** The primary target organ of paraquat is the lungs. The main molecular mechanism of paraquat toxicity in the lungs is based on redox cycling and intracellular oxidative stress generation.
2.1.2	**Symptoms of poisoning**	**IPCS (1991)** Symptoms are largely dependent on the route of exposure, concentration of paraquat in the product and the amount involved.

Paraquat is irritating to the eyes, the skin and the respiratory tract. Inhalation of this substance may cause lung oedema. The substance may cause effects on the kidneys, liver, gastrointestinal tract, cardiovascular system and lungs, resulting in impaired functions, tissue lesions including haemorrhage and lung fibrosis. Exposure to high doses (> 40 mg paraquat ion per kg body weight = 20 mL of 20 to 24% concentrate) may result in death.

Nearly all products contain an emetic and if this has been ingested vomiting may be severe and repeated.

After ingestion of low dose (<20 mg paraquat ion per kg body weight = 10ml of a 20 to 24% concentrate), patients are often asymptomatic or may develop vomiting or diarrhoea. Complete recovery occurs but there may be a transient impairment of lung function tests.

After ingestion of moderate dose (20 to 40 mg paraquat ion per kg body weight = 10 to 20 ml of 20 to 24% concentrate), initially renal and hepatic dysfunction are common. Mucosal damage may become apparent with sloughing of the mucous membranes in the mouth. Dyspnoea may develop after a few days in the more severe cases. By about 10 days crepitations and radiological signs of lung damage usually develop. Renal function often returns to normal at this stage. Massive pulmonary fibrosis manifested by progressive dyspnoea may cause death between 2-4 weeks after ingestion.

Ingestion of high dose (> 40 mg paraquat ion per kg body weight = 20 ml of 20 to 24% concentrate) result in much more severe toxicity, and death occurs early (24-48 hrs) from multiple organ failure. The initial gastrointestinal symptoms are similar but very severe with considerable fluid loss. Renal failure, cardiac arrythmias, coma, convulsions, oesophageal perforation and death soon follow.

There is no antidote as such available.

Overall mortality rate of accidental poisoning is estimated to be 33 - 50%.

2.1.3 Absorption, distribution, excretion and metabolism in mammals

JMPR (2003a, b), IPCS (1991)

Rate and extent of oral absorption: poor.

Dermal absorption: Poor; 0.25-0.29% absorbed (humans).

Distribution: Highest concentrations found in the lungs, liver and kidneys.

Potential for accumulation: No potential for passive accumulation; active uptake into type II pneumocytes.

Rate and extent of excretion: Rapid, about 64% in 24 h; 10% in urine, the remainder in the faeces; none is found in bile.

Metabolism: Some metabolism (<5%) in gut (probably microbial); paraquat is largely excreted unchanged.

Toxicologically significant compounds: parent compound.

The pharmacokinetics and metabolism of paraquat have been the subject of many studies. Paraquat is not well-absorbed when administered orally. After oral administration of radiolabelled paraquat to rats, more than half the dose (60-70%) appeared in the faeces and a small proportion (10-20%) in the urine. In studies involving single or repeated doses, excretion of the radiolabel was rapid; about 90% was excreted within 72 h.

Paraquat is largely eliminated unchanged; in rats, approximately 90-95% of radiolabelled paraquat in urine was excreted as the parent compound.

2.2	**Toxicology studies**	
2.2.1	**Acute toxicity**	**JMPR (2003a, b) EU (2003)** Rat, LD_{50}, oral: 100-300 mg paraquat ion/kg bw Guinea pig LD_{50} oral: 22-30 mg paraquat ion/kg bw Monkey LD_{50} oral: 50-70 mg paraquat ion/ kg bw Rat, LD_{50}, dermal: > 660 mg of paraquat ion/ kg bw Rat, LC_{50}, inhalation: 0.0006-0.0014 mg of paraquat ion/L (4 h exposure) Rabbit, skin irritation: Mild Rabbit, eye irritation: Moderate Not sensitizing (Magnusson and Kligman test)
2.2.2	**Short term toxicity**	**JMPR (2003a, b)** Target organ/critical effect: Lung toxicity. Alveolar damage by oral route. Upper respiratory tract damage by inhalation. Lowest relevant oral NOAEL: 0.55 mg of paraquat ion/kg bw per day (13-week study in dogs); 0.45 mg of paraquat ion/kg bw per day (1-year study in dogs) on the basis of signs of respiratory dysfunction and histopathological changes at higher doses. Lowest relevant dermal NOAEL: 1.15 mg of paraquat ion/kg bw per day (21-day study in rabbits) on the basis of erythema, erosion, ulceration, exudate, acanthosis and chronic inflammatory change. No systemic toxicity was observed in the study at the highest dose tested (6 mg paraquat ion/kg/day). Lowest relevant inhalation NOAEC: 0.00001 mg/L (21-day inhalation study in rats using, an aerosol of technical-grade paraquat) on the basis of histopathological changes in the upper respiratory.
2.2.3	**Genotoxicity (including mutagenicity)**	**JMPR (2003a, b)** Paraquat has been tested extensively in a broad range of assays for genotoxicity in vitro and in vivo, with mixed results. Studies more commonly gave positive results when DNA damage or clastogenicity were the endpoints. Paraquat is known to produce active oxygen species and the available evidence indicates that it is probably this property that is responsible for its genotoxicity. Consequently, there is a threshold below which genotoxic activity will not be evident, provided that normally functioning antioxidant defence mechanisms have not been overwhelmed. Paraquat is unlikely to pose a genotoxic risk to humans.
2.2.4	**Long term toxicity and carcinogenicity**	**JMPR (2003 a, b)** Target organ/critical effect: The predominant feature of exposure to repeated doses of paraquat was lung toxicity. Renal toxicity (proximal tubular damage) and toxicity to the liver (jaundice and elevations of enzyme activity) were also found. Lowest relevant NOAEL: 0.77 mg of paraquat ion/kg bw per day (2-year study in rats) on the basis of histopathology of the lungs. Because of the nature of the genotoxicity observed and the lack of carcinogenicity in rats and mice, it was concluded that paraquat was unlikely to pose a carcinogenic risk to humans.
2.2.5	**Effects on reproduction**	**JMPR (2003 a, b)** Reproduction target/critical effect: Lung lesions in parental animals. No specific effects on reproduction. 3-generation study in rats: Lowest relevant parental NOAEL: 1.67 mg of paraquat ion/kg bw per day Lowest relevant reproductive NOAEL: 10 mg of paraquat ion/kg bw per day (highest dietary concentration administered) Lowest relevant off-spring toxicity NOAEL: 5 mg of paraquat ion/kg bw per day

		Developmental target/critical effect: Not teratogenic; reduced fetus weight and ossification at maternally toxic dose. Lowest relevant developmental NOAEL: 1 mg of paraquat ion/kg bw per day (rats)
2.2.6	**Neurotoxicity/ delayed neurotoxicity, Special studies where available**	**JMPR (2003 a, b)** Not neurotoxic by oral route.
2.2.7	**Summary of mammalian toxicity and overall evaluation**	The primary target organ of paraquat is the lungs. Symptoms are largely dependent on the route of exposure, concentration of paraquat in the product and the amount involved. The acute LD_{50} after oral administration was 290-360 mg/kg bw in mice and 112-350 mg/kg bw in rats, while the guinea pig was more sensitive (LD_{50} of 22-30 mg/kg bw). The LD_{50} in cynomolgus monkeys was 50-70 mg/kg bw. The acute LD_{50} after inhalation was 0.0006-0.0014 mg of paraquat ion/l (4 h exposure) in rats. Effects in the respiratory tract are observed after single and repeat dose exposures regardless of the route of exposure (oral or inhalation); however, inhalation was a more sensitive route of exposure than the oral route in both acute and repeat dose studies. The minimum lethal oral dose in humans is estimated to be 40 mg paraquat ion per kg body weight (=20 ml of 20 to 24% concentrate), with doses above 20 mg leading to severe toxic effects. The predominant feature of exposure to repeated doses of paraquat in animal studies was lung toxicity. Renal toxicity (proximal tubular damage) and toxicity to the liver (jaundice and elevations of enzyme activity) were also found. Similar effects have been observed in human poisoning cases Lung abnormalities observed in mice, rats and dogs consisted of increased lung weight and gross pathological changes. Associated histopathological changes included cell necrosis, alveolar cell proliferation and hypertrophy, oedema, infiltration of macrophages and mononuclear cells and exudate. Dogs were most sensitive to paraquat-induced lung toxicity, followed by rats and mice; a NOAEL of 0.45 mg of paraquat ion/kg bw per day was found in a 1-year study in dogs, on the basis of signs of respiratory dysfunction and histopathological changes at higher doses. Paraquat is considered to be a mild skin irritant and a moderate ocular irritant and was not a skin sensitizer. Normal skin provides a good barrier against absorption and systemic toxicity at low exposure levels. However, if there is prolonged contact leading to extensive skin damage, or exposure to high doses that erode the integrity of the skin, this may allow unimpeded access of paraquat to the bloodstream, which may lead to systemic poisoning and may result in severe toxicity.

3 Human exposure/Risk evaluation

3.1	**Food**	**JMPR (2004a, b)** Residue levels of paraquat in food resulting from its normal use are unlikely to pose a health hazard for the general population. <u>Long-term intake</u> The international estimated daily intake (IEDI) values were calculated for the five Global Environment Monitoring System (GEMS)/Food regional diets from the supervised trials median residue values for fruit, vegetables, maize, sorghum, cotton seed, sunflower, hops, tea and animal commodities and the supervised trials median residue value in processed commodities (STMR-P), as estimated by JMPR. The ADI is 0–0.005 mg/kg bw, and the calculated IEDIs were 2–5% of the ADI. The Meeting concluded that the intake of residues of paraquat resulting from uses considered by the current JMPR was unlikely to present a public health concern. <u>Short-term intake</u> The international estimated short-term dietary intake (IESTI) values of paraquat by the general population and by children were calculated for commodities for which STMR

or STMR-P values had been estimated by JMPR when information on consumption was available (see section 5 of the decision guidance document). The ARfD is 0.006 mg/kg; the calculated IESTIs for children up to 6 years range from 0 to 50% and those for the general population from 0 to 20% of the ARfD. JMPR concluded that the short-term intake of residues of paraquat from uses considered at the meeting was unlikely to present a public health concern.

EU (2003)
The EU review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is 17 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Additional intake from water and products of animal origin are not expected to give rise to intake problems.

3.2 Air

JMPR (2003a, b); IPCS (1991)
Paraquat is of very high acute toxicity when administered by the inhalation route. The acute inhalation LC_{50} in rats ranged from 0.0006-0.0014 mg of paraquat ion/L (4 h exposure). The lowest relevant short term inhalation NOAEC: 0.00001 mg/L (21-day exposure).

Paraquat is not volatile; thus, inhalation of paraquat vapour is not expected to be a significant route of exposure.

Paraquat present in airborne dust in agricultural fields was found to range from 0.0004 to 0.001 mg/m^3. The paraquat was so strongly bound to the dust particles that it did not exert any toxicological effect on rats that were exposed via inhalation.

Inhalation of paraquat spray aerosol and dust particles are relatively large and are mostly deposited in the upper respiratory tract. Inhalation of paraquat is not expected to be a significant route of exposure in non-occupational settings.

There are several studies on paraquat exposure during normal agricultural use. The main route of occupational exposure of agricultural workers is via the skin. Paraquat aerosol concentrations (total airborne) ranged up to 0.55 mg/m^3 in the work situation, depending on the method of spraying. Under normal conditions of use, the amount of respirable airborne paraquat was found to be insignificant.

3.3 Water

JMPR (2004 a, b); EU (2003)
From soil studies, there is no evidence of desorption of paraquat back into the water phase (see section 4.1.1). Therefore, exposure of paraquat via water is not considered to be representative of normal paraquat use. Non-occupational exposures via water may occur as a result of spray drift from off-target applications of paraquat.

In the unlikely event of paraquat entering an aquatic body at biologically significant concentrations, it will dissipate initially in a similar way than in soil, i.e. mainly by adsorption onto sediment (see section 4.1.2).

3.4 Occupational exposure

Malaysia
In Malaysia, the Pesticides Board classified paraquat under Class Ib, instead of Class II (of WHO classification) after taking into consideration that under local conditions paraquat cannot be used safely due to hot and humid weather making wearing full protective equipment not always practical. In addition, yearly pesticide poisoning cases reported indicate that paraquat is the number one pesticide associated with poisoning incidences either due to suicide, accidental or occupational poisoning (see section 3.5).

The supporting information provided by Malaysia refers to a report published by Syngenta in 2004 in response to the request of the German authorities to review the current situation with regards to accidents, suicides and ecotoxicological impact (Syngenta, 2004). The report included that poisoning due to exposure through the skin is quite frequently reported and is mostly due to not wearing appropriate protective clothing and unsafe working methods such as poor spraying practice. Among the effects reported are skin and eye irritation, nail damage and upper respiratory tract irritation, but the symptoms are generally minor and quickly reversible in the vast majority of cases. The study also recommended that several measures be taken to prevent poisoning from occurring, such as specific preventive measures and training to users, and Malaysia notes that these may need strict implementation and enforcement.

The Malaysian Palm Oil Board (MPOB) in collaboration with University Sains Malaysia (USM), University Putra Malaysia (UPM) and several other parties conducted a study on the implication of paraquat banning in Malaysia. The Pesticides Board's secretariat comments on the study include that "In the OEL (Operator Exposure Level) study, the findings support the argument that the risk of paraquat exposure to consumers under local conditions is unacceptably high and it was recommended to use complete PPE (long sleeves, long pants, face masks, gloves, boots and hats) when handling paraquat products. However, the use of complete PPE is not always practical under hot and humid like Malaysia." The Pesticides Board's secretariat added that there are some users who experience signs of paraquat poisoning especially when not using PPE. There was detection of paraquat at low levels in urine and blood analysis studies in samples taken from several operators who frequently sprayed paraquat.

Based on the outcome of the above report and wide consultation, the Pesticides Board concluded that:

- The continued registration of paraquat in the country would contribute to the high incident of pesticide poisonings as paraquat has been constantly reported to be the number one pesticide associated with poisonings.
- Paraquat cannot be applied and used safely without complete PPE to prevent exposure under the hot and humid conditions, which is not always feasible in a country like Malaysia.
- Paraquat is a very highly hazardous to humans and classified by the Pesticides Board under Class Ib - very highly hazardous to humans instead of Class II (of WHO classification) and it has no antidote for treating cases of poisoning.
- Paraquat has been identified by the Roundtable on Sustainable Palm Oil (RSPO) as one of the pesticides that cannot be used in oil palm cultivation as it is not consistent with sustainable palm oil cultivation and production.
- Final analysis shows that risk of paraquat outweighs the benefit.

Mozambique
The risk of occupational exposure in Mozambique was assessed for a subset of the short-listed pesticides, including paraquat. The subset included nine pesticides in seven different cropping systems using 13 application scenarios, each with and without PPE.

For the occupational risk assessment an estimate of operator exposure was made, which was then compared to a toxicologically acceptable level.

The exposure assessment used the registered dose rates and other application parameters for each pesticide based on farming conditions in Mozambique, including application with backpack sprayers (used in vegetables, tobacco, cereals and several other crops), hand-held rotary atomisers (used in cotton), and tractor - mounted sprayers. The exposure of pesticide applicators wearing full PPE that is realistically available in Mozambique was compared to the exposure of applicators wearing shorts and a T-shirt, as is often the case for smallholder farmers. For further details of the occupational risk assessment, see annex 2 to the decision guidance document for Mozambique, Section 4.1.

The occupational risk assessments that were conducted showed that acceptable operator exposure levels were greatly exceeded for all cropping systems and all pesticide application scenarios, irrespective of the application rate or use of PPE. This indicates that the application of paraquat likely poses a high risk under Mozambican use conditions.
Given the large risk quotient, it is unlikely that locally feasible mitigation measures would reduce the risk of paraquat to acceptable levels.

3.5 Medical data contributing to regulatory decision

Malaysia
Based on the information from the Ministry of Health of Malaysia, the most common pesticide involved in poisoning cases in Malaysia for the period 1997-2009 was paraquat, which related to 1,082 cases of poisoning, involving at least 272 deaths.

Analysis of poisoning data shows that the cause of paraquat poisoning is suicide, followed by accidental drinking and occupational poisoning.

Information related to cases of poisoning caused by chemicals including pesticides in Malaysia was based on information from the Ministry of Health through cases of poisoning referred to government clinics/hospitals only. This means the actual cases of poisoning reported is far greater than this, if cases referred to private clinics/hospitals and unreported cases were also taken into account.

3.6	**Public exposure**	None reported
3.7	**Summary-overall risk evaluation**	**Malaysia** Malaysia undertook a risk evaluation where they analysed international risk assessments and did bridging with local conditions of use of paraquat and actual exposure. Specifically, Paraquat has been classified by the Pesticides Board under Class Ib - very highly hazardous to humans instead of Class II (of WHO classification) because it was taken into consideration that under local conditions paraquat cannot be used safely due to hot and humid weather, which makes wearing full protective gears not always practical. This is supported by the evaluation of the paraquat study undertaken by the Malaysian Palm Oil Board, which identified unacceptably high OEL (Operator Exposure Level) under local conditions of use. Furthermore, the Ministry of Health of Malaysia has confirmed actual exposure to the pesticide according to the cases of poisoning referred to government clinics/hospitals where the poisoning data shows that the cause of paraquat poisoning is suicide, followed by accidental drinking and occupational poisoning. **Mozambique** As part of Mozambique's national objective of reducing risks of the most dangerous pesticides including HHPs, Mozambique has conducted a risk evaluation of the human health effects of paraquat. Taking into consideration the results of the survey of pesticide use practices in selected cropping systems in Mozambique, (some of which are representative of potential paraquat use), which included the identification of inadequate availability and use of PPE, and the high acute toxicity of paraquat (WHO Class II) with a note on serious delayed effects if absorbed (note 7 - *Paraquat has serious delayed effects if absorbed. It is of relatively low hazard in normal use but may be fatal if the concentrated product is taken by mouth or spread on the skin*); dermal hazard close to WHO Class Ib and very low AOEL), along with the results of occupational risk assessments, which showed that the applications of six pesticides (among those paraquat) at registered dose rates would result in exceedance of acceptable operator exposure levels in all cropping systems that were assessed, both with and without PPE. Mozambique concluded that the use of paraquat was likely to result in excessive exposure of farmers in Mozambique and that given the large risk quotient, it was unlikely that locally feasible mitigation measures would reduce the risk of paraquat to acceptable level.

4 Environmental fate and effects

4.1	**Fate**	
4.1.1	**Soil**	**JMPR (2004a, b); EU (2003); Mozambique** Paraquat is shown to be very immobile in soil studies, from which there is no evidence of desorption of paraquat back into the water phase. Reported Koc values: 8,400 to 40,000,000 (very strong adsorption in all the soils tested). Reported Kd values were 480 to 400,000. Adsorption of paraquat increased with clay content. No measurable correlation with soil organic matter content was found. Paraquat adsorption is predominantly related to clay content, which is so strong that it masks any relationship with the soil organic matter content. Paraquat was applied to slurries of loam, loamy sand, silty clay loam or coarse sand in 0.01 mol/l aqueous calcium chloride at rates higher than normal, to give 0.01 mg/l in the equilibrium solution after a 16-h equilibration. The calculated adsorption coefficients ranged from 480 in the coarse sand to 50 000 in the loam. At normal

application rates, the concentration of paraquat in the equilibrium solution could not be determined (< 0.0075 mg/l). No significant desorption was observed.

A field survey of 242 agricultural soils in Denmark, Germany, Greece, Italy, The Netherlands and the United Kingdom showed that paraquat was strongly adsorbed to all the soil types studied. The adsorption coefficients (Kd) calculated at application rates much higher than normal ranged from 980 to 400 000, and those adjusted for the organic carbon content of soil (Koc) were 8400–40 000 000. Adsorption coefficients could not be calculated at normal application rates because the concentration in equilibrium solution was below the limit of determination (0.01 mg/l). On the McCall scale, paraquat was classified as 'immobile' in all these soils, without leaching.

In long-term field dissipation studies conducted on cropped plots in Australia, Malaysia, The Netherlands, Thailand, the United Kingdom and the USA, the location had no major effect on the field dissipation rate. Generally, paraquat residue levels had declined to about 50% 10–20 years after the start of the studies. This implies a DT50 of 10–20 years after application of single, large doses of paraquat to soil.

Adsorption is correlated to clay content. The amount of paraquat deactivated by adsorption is determined by a wheat bioassay (SAC-WB). Most soils have a large excess of adsorption capacity relative to use rate. Exceeding SAC-WB values may be possible only in soils with very low SAC-WB values following repeated application at high rates.

The notification and supporting documentation provided by Mozambique indicate that the Groundwater ubiquity score (GUS) index for paraquat is - 6.9, which indicates a very low leaching potential (Lahr et al., 2014).

The strong adsorption of paraquat to soil precludes paraquat degradation in soil being studied effectively by standard guideline methods. The strong adsorption also greatly reduces the rate of formation of degradation products to amounts that would not be detectable using standard methods. Soil microbial degradation studies fulfil the scientific intent of demonstrating the intrinsic degradability of paraquat.

Microbiological degradation studies were conducted with microorganisms isolated from soil. The most effective soil organism for decomposing paraquat was a yeast species, *Lipomyces starkeyi*. The degradation rate of paraquat in soil was determined by cultivating 10 mg/kg [U-14Cdipyridyl] paraquat with *Lipomyces* and mixed cultures derived from two soils. The degradation of paraquat was rapid, with a DT_{50} between 0.02 and 1.3 days after a lag phase of about 2 days, accompanied by rapid mineralization to CO_2 and the formation of several unidentified minor polar metabolites.

Photodegradation on the soil surface is not considered to be a major environmental degradation process for paraquat.

4.1.2 Water

JMPR (2004a, b)
[U-14C-dipyridyl] Paraquat in deionized water was applied to the water surface of two continuously aerated sediment–water systems at a rate equivalent to 1.1 kg ai/ha. Paraquat was strongly adsorbed to the sediment in both systems, even immediately after treatment. After 100 days of incubation, 0.1–0.2% of the applied radioactivity was found in the aqueous phase, 92.9–94.9% in extracts from sediment fractions and 4.2–4.5% in unextracted sediment fractions. Most of the radiolabel recovered from the aqueous phase and sediment extract was attributed to paraquat, while no degradation products were detected. The DT_{50} or the DT_{90} could not be estimated as no significant degradation of paraquat was observed during the experimental period.

Aqueous photolysis of paraquat was examined by maintaining ring-labelled paraquat in sterilized 0.01 mol/l phosphate buffer solution (28 mg/l) at 25 °C under light. After 36 days of irradiation simulating summer sunlight in Florida (USA), most of the recovered radioactivity was attributed to paraquat, with 0.13% as CO_2 and no photodegradation products. When solutions of radiolabelled paraquat were exposed to unfiltered ultraviolet light, no paraquat remained after 3 days, with formation of CO_2, methylamine and 4- carboxy-1-methylpyridinium ion; the last metabolite further degraded to CO_2 and methylamine. These results indicate that, while paraquat appears to be stable to photolysis at pH 7, it readily degrades into CO_2 and methylamine when exposed to unfiltered ultraviolet light.

4.1.3 Air

Paraquat is not expected to volatilize due to its low vapor pressure < 10^{-8} kPa at 25 °C

4.1.4 Bioconcentration

EU (2003)
Paraquat is not subject to bioconcentration and has not been found to accumulate in food chains.

4.1.5 Persistence

JMPR (2004a, b) EU (2003)
Overall, paraquat should be considered very persistent in soil, noting most field soil DT50 values are >10 years. Similarly, paraquat should be considered very persistent in aquatic systems, as it partitions rapidly to sediment where it does not degrade.

4.2 Effects on non-target organisms

4.2.1 Terrestrial vertebrates

EU (2003)
Acute toxicity to mammals: LD_{50} = 93.4 mg paraquat ion/kg bw.

Short term oral toxicity to mammals: NOEC 100 mg paraquat dichloride/kg (13-week rat study). Equal to 4.74 mg of paraquat ion/kg bw per day for males and 5.14 mg of paraquat ion/kg bw for females.

Acute toxicity to birds: LD_{50} = 35 mg paraquat ion/kg bw

Dietary toxicity to birds: LC_{50} = 698 mg paraquat ion /kg-diet (*Coturnix coturnix)*

Reproductive toxicity to birds: NOEC = 30 mg paraquat ion/kg diet (*Anas platyrhynchos*).

4.2.2 Aquatic species

EU (2003)
Acute toxicity invertebrate: EC50 = 4.4 mg a.s./L (*Daphnia magna* - 48 h study).

Chronic toxicity invertebrate: 14 – 21day NOEC = 0.12 mg a.s./L.

Chronic toxicity sediment dwelling organism: *Chironomus riparius*: 21-day

NOEC in sediment = 100 mg a.s./kg; 21 day water phase only NOEC = 0.367 mg as/L.

Acute toxicity fish: 96-hr LD50 = 18 mg a.s./L (*Oncorhynchus mykiss*)

Acute toxicity algae: EC_{50} = 0.00023 mg a.s./L (*Navicula pelliculosa* 96 h study)

Acute toxicity aquatic plants: EC_{50} = 0.037 mg a.s./l for *Lemna gibba* (14-day semistatic study)

Paraquat is a broad spectrum, non-selective contact herbicide, information on the mode of action is included in section 4.2.6.

4.2.3 Honeybees and other arthropods

EU (2003)

Honeybees:
Acute oral toxicity:
LD_{50} = 9.06 µg a.s./bee - 120 h study

Acute contact toxicity:
LD_{50} = 9.26 µg a.s./bee - 120 h study

Other arthropods:
Mortality: No effect on adults (1.0 g a.s./ha, SL formulation). Species tested: *Pardosa sp., Aleochara bilineata, Pterostichus melanarius.*

4.2.4 Earthworms

EU (2003)
Acute toxicity: LC_{50} >1000 mg as/kg soil - 14 d study (*Eisenia fetida*).
Reproductive toxicity: No adverse effects were observed on earthworm populations in a field study following an application of up to 720 kg as/ha in one year.

4.2.5 Soil microorganisms

EU (2003)
No adverse effects were observed after application up to 720 kg a.s./ha in one year.

4.2.6 Terrestrial plants

Paraquat is a broad spectrum, non-selective contact herbicide. It belongs to the bipyridylium family of herbicides. Paraquat is known to act on the photosynthetic membrane system called photosystem I, which produces free electrons to drive photosynthesis because it destroys that mechanism.

5 Environmental Exposure/Risk Evaluation

5.1 Terrestrial vertebrates

None reported

5.2 Aquatic species

Mozambique

An environmental risk evaluation on the use of paraquat in Mozambique was not conducted as part of the project for "Reducing Risks of Highly Hazardous Pesticides (HHPs) in Mozambique. The study conducted by Lahr et al. (2014) in the context of this project analysed the Environmental toxic load to aquatic organisms (fish, Daphnia, and algae) and bees as environmental hazard indicators, as well as the groundwater leaching potential of paraquat.

The environmental toxic load (ETL) was used as an indicator to compare average toxic loads to the environment (1) between pesticides, (2) between years and (3) in the case of the aquatic toxicity also between different groups of aquatic species (fish, water fleas and algae).

The ETL indicator represents the average amount of toxic pressure by active ingredients of pesticides applied on one hectare of agricultural land in one year.

The ETL indicator was calculated separately for fish, Daphnia, algae. The ETL is based on the total imported volume of active ingredients per year (2002 to 2011), the toxicity (either $L(E)C_{50}$ for algae, Daphnia or fish or the LD_{50} for bees), and the total agricultural area in Mozambique.

$$ETL_{yr} = \frac{\sum_{ai} \frac{V_{ai,yr}}{T_{ai}}}{A_{yr}}$$

ETL_{yr} : Environmental Toxic Load indicator value for one year
$V_{ai,\,yr}$: volume of an active ingredient imported in a particular year (kg)
T_{ai} toxicity of the active ingredient; i.e. L(E)C50 of either fish, Daphnia or algae (mg/L), or the LD_{50} of bees (µg/bee)
A_{yr} total agricultural area in Mozambique in a particular year (ha)

The ETL cannot be used to assess the actual risk (i.e., the probability of an adverse effect on organisms) as a consequence of pesticide treatments because there is no exposure assessment involved in its calculation. For instance, there is no prediction of an environmental concentration (PEC) in water that can be compared with a 'no effect concentration' for water organisms (PEC/NEC analysis). There are no thresholds of the ETL that signifies an absolute risk.

The ETL can therefore only be used to evaluate the impact of changes in relative environmental hazards between pesticides and between years.

Pesticides were classified as of "primary concern" when the active substance constitute >50% of the total annual ETL value in 2 years or more and as "secondary concern" when the active substance constitutes > 10% of the total annual ETL value in 1 year or more.

Paraquat was identified as pesticide of "secondary concern" based on the relative hazard to algae using the ETL as a hazard indicator.

Year	kg imported	% of the annual ETL for algae
2002	1745	98.5
2003	4721	21.4
2004	7418	16.3
2005	5377	8.1
2006	6604	12.8
2007	4272	11.7
2008	4600	6.3
2009	8448	11
2010	4540	5.4
2011	7020	10.7

5.3	**Honey bees**	**Mozambique** The ETL indicator of paraquat was also calculated for bees. On the basis of the ETL, paraquat was not considered of concern for bees.
5.4	**Earthworms**	None reported
5.5	**Soil microorganisms**	None reported
5.6	**Summary – overall risk evaluation**	**Mozambique** An environmental risk evaluation on the use of paraquat in Mozambique was not conducted as part of the project for "Reducing Risks of Highly Hazardous Pesticides (HHPs) in Mozambique". Paraquat was identified as pesticide of "secondary concern" based on the relative hazard to algae using the ETL as a hazard indicator. The ETL cannot be used to assess the actual risk (i.e., the probability of an adverse effect on organisms) as a consequence of pesticide treatments because there is no exposure assessment involved in its calculation.

Annex 2 to the decision guidance document – Details on final regulatory actions reported

Country Name: Malaysia

1	**Effective date(s) of entry into force of actions**	1 January 2020
	Reference to the regulatory document	Official circular JP/KRP/207/12/656/2 Vol.6 (54) published on 16 May 2014
2	**Succinct details of the final regulatory action(s)**	The notified regulatory action relates to paraquat (CAS No. 4685-14-7), paraquat dichloride (CAS No. 1910-42-5), paraquat bistribromide (CAS No. 27041-84-5), paraquat bis(methysulfate) (CAS No. 2074-50-2) in the pesticide category. The regulatory action is notified as a ban. The ban was introduced by the official circular JP/KRP/207/12/656/2 Vol.6 (54) on 16 May 2014 and entered into force on 1 January 2020 which prohibited all applications of paraquat as a pesticide product as well as its import and export.
3	**Reasons for action**	The ban of paraquat was introduced due to its highly toxic nature which has caused many poisonings and deaths of consumers. The banning of paraquat is consistent with the principle of precautionary measures, as paraquat has been shown cannot be applied and used safely without complete PPE to prevent exposure under the hot and humid conditions, which is not always feasible in country like Malaysia.
4	**Basis for inclusion into Annex III**	The final regulatory action was based on a risk evaluation taking into account the prevailing conditions in Malaysia.
4.1	**Risk evaluation**	The notification states that the final regulatory action was based on a risk evaluation to protect human health. The evaluation has referenced the tasks allotted to the Pesticides Board to undertake the review of paraquat because of concerns over its potential risk to occupational health and safety and the environment. The scope of review considered risk assessment to human and environment and also socio-economic impacts. During the review period conducted from 2002 to 2013, the Ministry of Agriculture and Agro-based Industry through the Department of Agriculture and the Pesticides Board reviewed and scrutinized many research information documents and publications related to paraquat from within and outside the country. The following were the topics covered in the paraquat registration review: a) Facts about paraquat; b) Status of paraquat registration in Malaysia; c) International status; d) Assessment of paraquat poisoning cases in Malaysia; e) Evaluation of cases of poisoning and suicide caused by paraquat at the international level; f) Status of paraquat under the Rotterdam Convention; g) Evaluation of alternative pesticides to paraquat; h) Verification of the effectiveness of paraquat and alternative pesticides and demonstration; i) Impact assessment on the agriculture sector; j) Evaluation of the study by CABI/RSPO; k) Evaluation of paraquat study by Malaysian Palm Oil Board (MPOB); l) Evaluation of the opinions of all stakeholders on paraquat. In the supporting documentation, international risk evaluations are presented, including an FAO Specification and Evaluation for Agricultural Pesticides; the

European Commission's Review report for the active substance paraquat, which includes that knapsack and handheld use should be limited to trained/certified personnel where appropriate training and certification schemes are in operation; IPCS INCHEM which included that a face shield should be worn even when handling and using a diluted formulation; and US EPA R.E.D. Facts, which states that PPE requirements include chemical resistant apron, face shield and gloves variously for mixers, loaders and sprayers.

The Pesticides Board classified paraquat under Class Ib, instead of Class II (of WHO classification) after taking into consideration that under local conditions paraquat cannot be used safely due to hot and humid weather making wearing full protective equipment not always practical. In addition, pesticide poisoning cases reported yearly indicate that paraquat is the number one pesticide associated with poisoning incidences either due to suicide, accidental or occupational poisoning. Supporting documentation further shows information related to cases of poisoning caused by chemicals including pesticides in Malaysia. The information is based on information from the Ministry of Health through cases of poisoning referred to government clinics/hospitals only. This means the actual cases of poisoning reported are far greater than this if cases referred to private clinics/hospitals and unreported cases are taken into account. The pesticide involved in the most poisoning cases is paraquat, which is 45% (1,082 cases of poisoning) involving at least 272 deaths. Analysis of poisoning data shows that the cause of paraquat poisoning is suicide, accidental drinking and occupational poisoning.

At the international level, Syngenta published a report (Syngenta, 2004) in response to the request of the German authorities to review the situation with regards to accidents, suicides and ecotoxicological impact. The report included that poisoning due to exposure through the skin is quite frequently reported and is mostly due to not wearing appropriate protective clothing and unsafe working methods such as poor spraying practice. Among the effects reported are skin and eye irritation, nail damage and upper respiratory tract irritation, but the symptoms are generally minor and quickly reversible in the vast majority of cases. The study also recommended that several measures be taken to prevent poisoning from occurring, such as specific preventive measures and training to users, and Malaysia notes that these may need strict implementation and enforcement.

The Malaysian Palm Oil Board (MPOB) in collaboration with University Sains Malaysia (USM), University Putra Malaysia (UPM) and several other parties conducted a study on the implication of paraquat banning in Malaysia. The Pesticides Board's secretariat comments on the study include that "In the OEL (Operator Exposure Level) study, the findings support the argument that the risk of paraquat exposure to consumers under local conditions is unacceptably high and it was recommended that the use of complete Personal Protective Equipment (PPE) (long sleeves, long pants, face masks, gloves, boots and hats) when handling paraquat products. However, the use of complete PPE is not always practical under hot and humid like Malaysia." The Pesticides Board's secretariat added that there are some users who experience signs of paraquat poisoning especially when not using PPE. There was detection of paraquat at low levels in urine and blood analysis studies in samples taken from several operators who frequently sprayed paraquat.

Based on the outcome of the above report and wide consultation, the Pesticides Board concluded that continued registration of paraquat in the country would contribute to the high incident of pesticide poisonings as paraquat has been constantly reported to be the number one pesticide associated with poisonings; that paraquat cannot be applied and used safely without complete PPE to prevent exposure under the hot and humid conditions, which is not always feasible in a country like Malaysia; paraquat is a very highly hazardous to humans and is in the Class Ib (Highly hazardous) and it has no antidote for treating cases of poisoning; paraquat has been identified by the Roundtable on Sustainable Palm Oil (RSPO) as one of the pesticides that cannot be used in oil palm cultivation as it is not consistence with sustainable palm oil cultivation and production. Final analysis shows that risk of paraquat outweighs the benefit.

According to the supporting documentation Malaysia developed a risk evaluation where they analysed international risk assessment and bridging with local conditions

		of use of paraquat and actual exposure. Specifically, Paraquat has been classified by the Pesticides Board under Class Ib very highly hazardous to humans instead of Class II (of WHO classification) because after taken into consideration that under local conditions paraquat cannot be used safely due to hot and humid weather making wearing full protective gears not always practical. The findings on the Operator Exposure Level (OEL) study included in the evaluation by Malaysian Palm Oil Board (MPOB) supports the argument that the risk of paraquat exposure to consumers under local conditions is unacceptably high and it was recommended that the use of complete Personal Protective Equipment (PPE) (long sleeves, long pants, face masks, gloves, boots and hats) when handling paraquat products. However, the use of complete PPE is not always practical under hot and humid like Malaysia. Furthermore, the Ministry of Health of Malaysia has confirmed actual exposure of the pesticide according to the cases of poisoning referred to government clinics/hospitals where the poisoning data shows that the cause of paraquat poisoning is suicide (suicidal) and followed by accidental drinking and occupational poisoning. Summarising the above, the final regulatory action was based on a health hazard evaluation of paraquat, the prevailing conditions of use of pesticides in Malaysia (intended uses, application doses, methods, protective measures, agricultural practices, etc.), and a risk assessment with a particular focus on occupational risks.
4.2	**Criteria used**	Risks to human health
	Relevance to other States and Region	Once banned, no importation and exportation activities allowed
5	**Alternatives**	See section 3.3.
6	**Waste management**	None reported
7	**Other**	None reported

Country Name: Mozambique

1	**Effective date(s) of entry into force of actions**	31 December 2014
	Reference to the regulatory document	Deliberação Nº 001/DNSA/2014 by the National Directorate of Agriculture and Agrarian Services (The Pesticide Register Authority).
2	**Succinct details of the final regulatory action(s)**	Based on the decision Nr 001/DNSA/2014 paraquat was banned by the National Directorate of Agrarian Services from further import and use in Mozambique. The ban of all uses and the cancellation of the registration of the products containing paraquat in the country was decided due to the toxic nature and hazardous properties of this active substance which combined with the improper use in the country due to the local specific conditions of use can damage human and animal health. The decision to cancel the registration of paraquat was taken as the last step of the project for Risk Reduction of HHPs, which identified HHPs and pesticides 'coming close' to HHPs that are registered in Mozambique. After consultations with different actors (public sector, private sector, civil society and others), cancelation of registrations and consequent non-approval for their use in Mozambique was approved.
3	**Reasons for action**	Reducing the risks for human health and the environment posed by paraquat in Mozambique.
4	**Basis for inclusion into Annex III**	The final regulatory action was based on a risk evaluation taking into account the prevailing conditions in Mozambique.
4.1	**Risk evaluation**	The notification states that the final regulatory action was based on a risk evaluation to protect human health and the environment. The risk evaluation is referenced to Project EP/MOZ/101/UEP, entitled "Reducing Risks of Highly Hazardous Pesticides (HHPs) in Mozambique" initiated by the Government of Mozambique with the objective of reducing the greatest risks associated with pesticide use in the country. The ultimate goal was to develop and implement a "Highly Hazardous Pesticides Risk Reduction Action Plan" for the most dangerous pesticides and use situations. The first phase of the project reviewed all pesticides registered in Mozambique. As a result, a shortlist of HHPs and 'coming close' to HHPs was established based. The criteria that were used in this study to identify HHPs were those established by FAO/WHO (2008). All pesticide formulations registered in Mozambique, including paraquat formulations, were classified using the formulations' oral and dermal LD_{50} values, as provided in the registration dossier. LD50 values for the formulations were available or could be estimated for all registered pesticide products except for three microbial pesticides and one citronella oil (i.e. > 99% of the total). The notification states that according to the WHO classification, paraquat 200 g/l SL pesticide formulation was classified as Class II with a note on serious delayed effects if absorbed (note 7 - *Paraquat has serious delayed effects if absorbed. It is of relatively low hazard in normal use but may be fatal if the concentrated product is taken by mouth or spread on the skin*) and dermal hazard was identified as "coming close to" Class Ib (Come & van der Valk, 2014). And specifically, the occupational hazard of paraquat is demonstrated by the very low Acceptable Operator Exposure Level (AOEL) defined in the EU (2003). Consequently, the paraquat 200 g/l SL pesticide formulation was placed on the list as 'coming close to HHP', based on the following criteria: For liquid formulations: pesticide products with an acute oral LD50< 200 mg/kg or an acute dermal LD_{50}< 400 mg/kg (note that these are the Class Ib limits in the previous version of the WHO Classification (WHO, 2005). In the second phase of the project, field surveys with farmers were carried out to assess actual use and exposure to pesticides under local conditions in Mozambique. The survey showed that the use of pesticides including HHPs and pesticides 'coming close to HHPs' was likely to result in excessive exposure of farmers in Mozambique. Half of the farmers interviewed in the survey had not received any training in using agrochemicals, and those who had often lacked a good understanding of the risks involved. Almost half of the farmers declared that they do not read pesticides labels, including instructions such as proper dosage and protective measures", the main reason being illiteracy. A third of the farmers are storing pesticides inside their

houses. Approximately half of the farmers surveyed reported that they noticed to receive pesticides on their clothes, bare skin or eyes when using pesticides, and a range of acute poising symptoms were reported but not linked to a particular pesticide. Almost none of the farmers (93%) owned or wore adequate personal protection equipment (PPE). The notification concludes that enforcing risk mitigation measures depending solely on wearing the appropriate PPE under the local conditions of use would be difficult and unlikely to give results.

In the third step of the project, stakeholders were consulted to further discuss the use and risks of HHPs and pesticides ‘coming close to HHPs’ in Mozambique and fine-tune the shortlist based on the survey results and the expertise of the stakeholders.

In the fourth step of the project, the risk of occupational exposure was assessed in further detail for a subset of the shortlisted pesticides. The subset included nine pesticides, including paraquat, in seven different cropping systems and using 13 application scenarios, each with and without PPE. Exposure of operators was estimated and then compared to a toxicologically acceptable level.

The exposure assessment used the registered dose rates and other application parameters for each pesticide based on farming conditions in Mozambique, including application with backpack sprayers (used in vegetables, tobacco, cereals and several other crops), hand-held rotary atomisers (used in cotton), and tractor-mounted sprayers. In addition, the exposure of pesticide applicators wearing full PPE realistically available in Mozambique was compared to the exposure of applicators wearing shorts and a T-shirt, as is often the case for smallholder farmers.

The toxicologically acceptable level of exposure applied in this study was the AOEL, which is defined as the maximum amount of active substance to which the operator may be exposed without any adverse health effects (EC, 2006). The cropping systems that were evaluated are those for which the pesticides were registered. In some cases, crops were grouped when the exposure to the pesticide was likely to be similar, based on the height of the crop and the application method.

The volume application rates used in the model were generally those recommended on the label of the registered pesticide in Mozambique. If a volume application rate was not indicated on the label, 200 litres of pesticide mixture per ha was used as a default for EC or SC formulations applied with hydraulic nozzles or by air-assisted sprayers (high volume application). In the case of cotton applications, a scenario where 10 litres of mixture per ha was applied using rotary atomisers (low volume application) was also evaluated. The dose rates used in the models were the highest rates recommended on the labels of the registered pesticide. In some cases where a wide range of dose rates was recommended, the lowest dose rate was also evaluated.

The risk of occupational exposure to pesticides was assessed, in particular when spraying the products. The risk of worker exposure in situations other than the application of the pesticide (e.g. during harvesting) or by a bystander was not evaluated. For the occupational risk assessment, an estimate of operator exposure was made, which was then compared to a toxicologically acceptable level, where workers’ exposure to pesticides was estimated using occupational exposure models that are often applied in the European Union: the so-called “German model” and the “UK Predictive Operator Exposure Model” (UK-POEM) (EFSA 2010).

The models are different in their exposure calculations and also include different exposure scenarios. Therefore, both models are often used in parallel in the EU when assessing occupational exposure. The models' exposure scenarios and application parameters were based on Mozambican pesticides application conditions.

The risk for the pesticide operator has been expressed as a risk quotient, which is the ratio between the estimated exposure of the operator to the pesticide (in mg a.s./kg bw/day) and the AOEL (in mg a.s./kg bw/day). A risk quotient > 1 implies that the risk is not acceptable; a risk quotient <1 implies an acceptable risk.

Table 1**.** Details on the pesticides and cropping systems used in the operator risk assessments.

Pesticide	Concentration and type of formulation	Cropping system	Volume application rate (L mixture/ha)	Dose rate (L or kg formulation/ ha)	AOEL (mg a.i/kg bw/day)
Paraquat	200 g a.s./L SL	Sugar cane	200	3	0.0004
		Bananas	200	5	
		Vegetables	200	2.5	

The results of the pesticide operator risk assessments for paraquat are summarized in the table below. Risk quotients are given for the scenario when no PPE is worn during both mixing and spraying (worst case situation) and for the scenario with full PPE during both mixing and spraying (best practice situation). Crops were grouped together as crop structure and the application scenarios were considered similar.

Table 2. Outcome of the operator risk assessments for formulations containing Paraquat, a pesticide "coming close to an HHP".

Pesticide formulation	Cropping system	Application rate	Exposure model	Use of PPE	Risk quotient
200 g/L SL	Sugar cane	600 g a.s./ha	UK- hand held sprayer; low level target	No	1408
				Yes	255
			UK -tractor mounted boom sprayer; hydraulic nozzles	No	653
				Yes	95
	Bananas	1000 g a.s./ha	UK- hand held sprayer; low level target	No	2268
				Yes	423
			UK -tractor mounted boom sprayer; hydraulic nozzles	No	1045
				Yes	155
	Vegetables	500 g a.s./ha	UK- hand held sprayer; low level target	No	1193
				Yes	213
			UK -tractor mounted boom sprayer; hydraulic nozzles	No	203

The use of personal protective equipment was taken into account in the risk assessments, both during mixing of the spray solution and loading of the sprayer. The no-PPE option in the German model represents an operator with shoes and socks, and half of the upper arms, forearms, thighs and lower legs unprotected. In the UK model, the no-PPE option represents a single layer of work clothing for professional use, or a T-shirt and shorts for home garden use.

In Mozambique, pesticide application without PPE generally means that the operator wears shorts, a short-sleeved T-shirt or a tank top, and open sandals. Therefore, the no-PPE option in both models likely underestimates actual exposure under Mozambican conditions.

The occupational risk assessments that were conducted showed that acceptable operator exposure levels were greatly exceeded for all crops and all pesticide application scenarios, irrespective of the application rate or use of PPE. This indicates that the application of paraquat likely poses a high risk under Mozambican conditions. Given the large risk quotient, it is unlikely that locally feasible mitigation measures would reduce the risk of paraquat to acceptable levels.

		Summarising the above, the final regulatory action was based on a health hazard evaluation of paraquat, the prevailing conditions of use of pesticides in Mozambique (intended uses, application doses, methods, protective measures, agricultural practices, etc.), and a risk evaluation with a particular focus on occupational risks. Paraquat and the products containing paraquat were considered harmful for the human health under the local conditions of use in Mozambique requiring risk mitigation measures. Therefore, the authorities decided to ban all formulations for all uses and also the cancellation of the products containing paraquat in the country.
4.2	**Criteria used**	Risks to human health and the environment
	Relevance to other States and Region	Countries with similar conditions as well as where the farmers use pesticides without protective equipment could make similar decision in order to protect the human health.
5	**Alternatives**	See section 3.3.
6	**Waste management**	None reported. See section 4.5.
7	**Other**	None reported

Annex 3 to the decision guidance document – Addresses of designated national authorities

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Mozambique

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