UNITED NATIONS

Food and Agriculture Organization of the United Nations

UNEP/FAO/RC/CRC.18/13

Distr.: General
28 June 2022

English only

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

Chemical Review Committee
Eighteenth meeting
Rome, 19–23 September 2022
Item 5 (c) (ix) of the provisional agenda*

Technical work: review of notifications of final regulatory action: paraquat

Paraquat: notifications of final regulatory action

Note by the Secretariat

I. Introduction

1. In accordance with paragraph 5 of Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, the Secretariat had received, prior to the seventeenth meeting of the Chemical Review Committee, two notifications of final regulatory action for paraquat that meet the requirements of Annex I to the Convention from Parties in the following two prior informed consent regions:

(a) Africa: Mozambique (pesticide);[1]

(b) Asia: Malaysia (pesticide).[1]

2. An intersessional task group was set up and undertook an initial assessment of whether the notifications met the criteria set out in Annex II to the Convention, with a view to its full review during the seventeenth meeting of the Committee. However, taking into account the coronavirus disease (COVID-19) pandemic and the fact that the Committee could not meet in a face-to-face setting for its seventeenth meeting, as well as the challenges linked to online meetings, the Bureau agreed to prioritize certain items on the agenda of its seventeenth meeting. Consideration of the notification for paraquat was thus deferred to a future meeting of the Committee.

3. The notifications from Malaysia and Mozambique are set out in the annex to the present note. The supporting documentation provided by Mozambique and Malaysia is set out in documents UNEP/FAO/RC/CRC.18/INF/28 and UNEP/FAO/RC/CRC.18/INF/29, respectively.

II. Proposed action

4. The Committee may wish:

(a) To review the information provided in the notifications and the supporting documentation from Malaysia and Mozambique related to paraquat, in accordance with the criteria set out in Annex II to the Convention;

* UNEP/FAO/RC/CRC.18/1.

[1] See PIC Circular LII, Dec. 2020.

(b) If it concludes that both notifications mentioned in subparagraph (a) above meet the criteria set out in Annex II to the Convention, to recommend to the Conference of the Parties that the chemical in question be made subject to the prior informed consent procedure and, accordingly, be listed in Annex III to the Convention, and to agree on a workplan for the preparation of a draft decision guidance document on paraquat.

Annex

Notifications of final regulatory action for paraquat

A. Notification of final regulatory action for paraquat in the pesticide category submitted by Malaysia

B. Notification of final regulatory action for paraquat in the pesticide category submitted by Mozambique

ROTTERDAM CONVENTION

SECRETARIAT FOR THE ROTTERDAM CONVENTION
ON THE PRIOR INFORMED CONSENT PROCEDURE
FOR CERTAIN HAZARDOUS CHEMICALS AND PESTICIDES
IN INTERNATIONAL TRADE

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

Country: MALAYSIA

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	Paraquat, paraquat dichloride
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	**IUPAC**: 1,1'-dimethyl-4,4'-bipyridinium dichloride
1.3	**Trade names and names of preparations**	**Formulation types:** Soluble Concentrate (SL); Technical Concentrate (TK); Technical Material (TC) **Selected trade names:** GRAMOXONE 100; CAPAYAM; CS PARAQUAT 13; FARMCARE PARAQUAT 13; CH PARAQUAT P130; PP PARAQUAT 13; AGR PARA 13; WA PARAQUAT 130
1.4	**Code numbers**	
1.4.1	CAS number	4685-14-7 (paraquat) 1910-42-5 (paraquat dichloride) 27041-84-5 (paraquat bistribromide) 2074-50-2 (paraquat bis(methylsulfate)

1.4.2	Harmonized System customs code	293339, 38.08
1.4.3	Other numbers (specify the numbering system)	

1.5 Indication regarding previous notification on this chemical, if any

1.5.1 ☒ This is a first time notification of final regulatory action on this chemical.

1.5.2 ☐ This notification replaces all previously submitted notifications on this chemical.
Date of issue of the previous notification: _____

SECTION 2 FINAL REGULATORY ACTION

2.1 The chemical is: ☒ **banned** **OR** ☐ **severely restricted**

2.2 Information specific to the final regulatory action

2.2.1 Summary of the final regulatory action

Circular was issued on May 16, 2014 informing the termination of paraquat dichloride registration in Malaysia on 1 January 2020. The use of paraquat dichloride was banned since January 1, 2020.

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

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

2.2.3 Date of entry into force of the final regulatory action

1 January, 2020

2.3 Category or categories where the final regulatory action has been taken

2.3.1 All use or uses of the chemical in your country prior to the final regulatory action

Restricted for only four crops as following:

I. Oil palm bellow 2 years
II. Rubber
III. Pineapple stump
IV. Hill paddy

2.3.2 Final regulatory action has been taken for the category ☐ Industrial

Use or uses prohibited by the final regulatory action

Use or uses that remain allowed (only in case of a severe restriction)

2.3.3 Final regulatory action has been taken for the category ☒ Pesticide

Formulation(s) and use or uses prohibited by the final regulatory action

All applications as pesticide products.

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

2.4 Was the final regulatory action based on a risk or hazard evaluation?

☒ **Yes**

☐ **No** (If no, you may also complete section 2.5.3.3)

2.4.1 If yes, reference to the relevant documentation, which describes the hazard or risk evaluation

- The Pesticides Board was designated to undertake the review a 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 impacts on socio- economy.

- Decision taken in Ministerial cabinet meeting to ban totally in 1 January 2020. Prior the effective enforcement date a few step were taken to restrict the use of paraquat.
- Restricted the access - Highly Toxic Pesticides Regulations 1996.
- Restricted uses – Can be applied for 4 crops only.
- Restricted packaging – 20 L and 200 L.
- Restricted Formulation – 13 %w/w and TC/TK.

2.4.2 Summary description of the risk or hazard evaluation upon which the ban or severe restriction was based.

2.4.2.1 Is the reason for the final regulatory action relevant to human health? ☒ Yes ☐ No

If yes, give summary of the hazard or risk evaluation related to human health, including the health of consumers and workers

Highly toxic via ingestion, one teaspoonful of paraquat is fatal. Following ingestion of very small amounts of the liquid concentrate, pulmonary oedema, cardiac failure, renal failure, liver failure and convulsions caused by central nervous system involvement, can occur. Under these circumstances, death from multiple organ failure may follow within hours or days. There is no antidote for paraquat.

Long-term and delayed health effects may also occur, including Parkinson's disease, lung effects and skin cancer.

Expected effect of the final regulatory action

Poisoning cases to public citizen, consumers and bystanders can be reduced dramatically.

2.4.2.2 Is the reason for the final regulatory action relevant to the environment?

☐ Yes

☒ No

If yes, give summary of the hazard or risk evaluation related to the environment

Expected effect of the final regulatory action

2.5 Other relevant information regarding the final regulatory action

2.5.1 Estimated quantity of the chemical produced, imported, exported and used

	Quantity per year (MT)	Year
produced	Not available	2020
imported	Not available	2020
exported	January – June 2019 (1st phase) = 10,938.74MT July – December 2019 (2nd phase) = 1,524,645.64MT	2019
used	424,320 L 138,740 L	2018 2019

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

Once banned no importation and exportation activities allowed.

2.5.3 Other relevant information that may cover:

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

Aggressive awareness program conducted by the Pesticides Board Malaysia in collaboration with various stakeholders to educate public to use alternatives control of weed.

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

Alternatives chemicals – 2,4-D-dimethylammonium, 2,4-D-sodium monohydrate, ametryn, atrazine, bromacil, clethodim, DSMA+diuron+2,4-D-sodium, diuron, fluazifop-P-butyl, glufosinate-ammonium, glyphosate-ammonium, glyphosate-dimetnylammonium, glyphosate-isopropylammonium, glyphosate-isopropylammonium+2,4-D-isopropylammonium, glyphosate-potassium, glyphosate-sodium, metolachlor, metsulfuron-methyl, napropamide, oxyfluorfen, pendimethalin, quizalofop-ethyl, sethoxydim, S-metolachlor, sodium chlorate, triclopyr-butotyl, glyphosate, fluroxypyr- meptyl, etc.

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

The high persistence of paraquat in soil and sediment and possible effects on sediment dwelling organisms is a matter of concern, but the regulatory action was mainly due to risks for adverse effects on human health an occupational safety.

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

Poisoning cases reported by Ministry of Health showed paraquat is highly use for suicidal purposes.

SECTION 3 PROPERTIES

3.1 Information on hazard classification where the chemical is subject to classification requirements

International classification systems e.g. WHO, IARC, etc.	Hazard class
WHO Classification	II
GHS	III

Other classification systems e.g. EU, USEPA	Hazard class
USEPA	Category I (Inhalation)

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Empirical Formula: C12H14Cl2N2
Molecular Weight: 257.2
CAS Registry No.: 1910-42-5
Melting point: >400°C
Boiling point: not applicable
Decomposition temperature: 340°C
Octanol/water partition coefficient: log Pow = -4.5 at 20°C
Stability: Stable in neutral and acidic media, but readily hydrolysed in alkaline media.
Photochemically decomposed by UV irradiation in aqueous solution
(75% loss in 96 h in UV light).
Hydrolysis characteristics : Paraquat dichloride is hydrolytically stable under acidic, neutral and alkaline conditions, no significant decrease in concentration having been recorded at pH 5, 7 and 9 after 30days at 25°C and 40°C
Photolysis characteristics : The environmental half-life of paraquat dichloride in water under mid-European conditions was calculated to be between 2 and 820 years, depending upon seasonal sunlight and depth of water

Reference

http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Specs/Paraquat08.pdf FAO/WHO (2003) EVALUATION REPORT ON PARAQUAT DICHLORIDE

3.2.2 Description of toxicological properties of the chemical

The acute oral toxicity of paraquat is moderate in rodents (LD50 = 100-249), and very high in guinea pigs, rabbits, dogs, monkeys and humans. The acute dermal toxicity of paraquat is low and the acute inhalational toxicity extremely high. Paraquat is a slight skin irritant, a severe eye irritant and not a skin sensitiser. Percutaneous paraquat absorption is low, however, toxicologically-significant absorption can occur via damaged skin, or sensitive skin areas such as the scrotum. • Repeat-dose toxicity studies confirmed that the target organ is the lungs while renal toxicity was also evident. Localised tissue damage was apparent following inhalational or dermal exposure. •

Long-term feeding studies conducted in mice, rats and dogs revealed no evidence that paraquat was carcinogenic. The weight-of-evidence indicates that paraquat is nongenotoxic, however it can damage genetic material at high and/or cytotoxic concentrations due to the generation of reactive oxygen species.

There was no evidence that paraquat caused reproductive toxicity despite evidence of systemic toxicity in parental animals and their offspring. There was no evidence that paraquat had any teratogenic potential. • The neurotoxicity of paraquat has not previously been addressed as it has been considered unlikely based on its known mechanism of toxicity. Based on the current data and using a weight-of-evidence approach, paraquat is not considered to pose a significant neurotoxic risk to humans. •

The current ADI for paraquat is 0.004 mg/kg bw/d established by the application of a 100-fold safety factor to the NOEL of 0.45 mg/kg bw/d in a one-year dog study, based on the occurrence of lung lesions at the next highest dose. • An ARfD of 0.004 mg/kg bw was established by applying a 100-fold safety to the same NOEL of 0.45 mg/kg bw/d in the one-year dog study. The rationale for choosing the same endpoint as for the ADI was that acute toxicity testing indicated that lung lesions could develop following a single exposure.

Reference

EC (2003) Paraquat. Review report for the active substance paraquat. SANCO/10382/2002. Health & Consumer Protection Directorate-General.

Directorate E - Food safety: plant health, animal health and welfare, international questions. E1 - Plant health. European Commission. 3 October 2003
Health and Safety Guide No. 51. Paraquat Health and Safety Guide. World Health Organization, Geneva. 1991
JMPR (2003) Paraquat. Toxicological evaluations. Pesticide residues in food-2003-Joint FAO/WHO Meeting on Pesticide Residues. WHO/PCS/04.1. Geneva, Switzerland, 15-24 September 2003.

US EPA (1997) Reregistration eligibility decision (RED). Paraquat Dichloride (EPA 738-F- 96-018). United States, Environmental protection Agency, Washington.

3.2.3 Description of ecotoxicological properties of the chemical

Paraquat dichloride is moderately toxic to aquatic invertebrates, slightly toxic to fish, moderately toxic to avian species and relatively non-toxic to bees

Reference

http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Specs/Paraquat08.pdf FAO/WHO (2003)EVALUATION REPORT ON PARAQUAT DICHLORIDE

SECTION 4 DESIGNATED NATIONAL AUTHORITY

Institution	PESTICIDES BOARD MALAYSIA
Address	PESTICIDES CONTROL DIVISION, DEPARTMENT OF AGRICULTURE, 4th-6th FLOOR, WISMA TANI, JALAN SULTAN SALAHUDDIN, 50632 KUALA LUMPUR, MALAYSIA.
Name of person in charge	MOHAMMAD NAZRUL FAHMI BIN ABDUL RAHIM
Position of person in charge	SECRETARY OF PESTICIDES BOARD
Telephone	+603-20301480
Telefax	+603-26917551
E-mail address	nazrulfahmi@doa.gov.my

Date, signature of DNA and official seal: 2 SEP 2020

MOHAMMAD NAZRUL FAHMI BIN ABDUL RAHIM
SECRETARY
PESTICIDES BOARD OF MALAYSIA

PESTICIDES BOARD MALAYSIA

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
Food and Agriculture Organization
of the United Nations (FAO)
Viale delle Terme di Caracalla
00153 Rome, Italy
Tel: (+39 06) 5705 2188
Fax: (+39 06) 5705 3224
E-mail: pic@fao.org

OR

Secretariat for the Rotterdam Convention
United Nations Environment
Programme (UNEP)
11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland
Tel: (+41 22) 917 8296
Fax: (+41 22) 917 8082
E-mail: pic@pic.int

Definitions for the purposes of the Rotterdam Convention according to Article 2:

(a) '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;

(b) 'Banned chemical' means a chemical all uses of which within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a chemical that has been refused approval for first-time use or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(c) 'Severely restricted chemical' means a chemical virtually all use of which within one or more categories has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a chemical that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(d) 'Final regulatory action' means an action taken by a Party, that does not require subsequent regulatory action by that Party, the purpose of which is to ban or severely restrict a chemical.

ROTTERDAM CONVENTION

SECRETARIAT FOR THE ROTTERDAM CONVENTION
ON THE PRIOR INFORMED CONSENT PROCEDURE
FOR CERTAIN HAZARDOUS CHEMICALS AND PESTICIDES
IN INTERNATIONAL TRADE

FORM FOR NOTIFICATION

OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

Country: MOZAMBIQUE

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	Paraquat
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	1,1'-dimethyl-4,4'-bipyridinium
1.3	**Trade names and names of preparations**	Moz Paraquat 20% SL (Paraquat 200 g/l) Paracot 20% SL (Paraquat 200 g/l) Para-Cure 20% SL (Paraquat 200 g/l) Paraxone 20% SL (Paraquat 200 g/l) Gramozat 20% SL (Paraquat 200 g/l) Agroquat 200 SL (Paraquat 200 g/l) Universal Skoffos 14,5% SL (Paraquat 145 g/l)

1.4 Code numbers

1.4.1	CAS number	4685-14-7
1.4.2	Harmonized System customs code	2933.39..
1.4.3	Other numbers (specify the numbering system)	225-141-7(EC)

1.5 Indication regarding previous notification on this chemical, if any

1.5.1 ☐ This is a first time notification of final regulatory action on this chemical.

1.5.2 ☒ This notification replaces all previously submitted notifications on this chemical.
Date of issue of the previous notification: 14/08/2019

SECTION 2 FINAL REGULATORY ACTION

2.1 The chemical is: ☒ **banned** **OR** ☐ **severely restricted**

2.2 Information specific to the final regulatory action

2.2.1 Summary of the final regulatory action

Based on the decision N. 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 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 additionally cause potential damage to the environment The decision to cancel the registration of paraquat was taken as the last step of the project for Risk Reduction of Highly Hazardous Pesticides, which identified Highly Hazardous Pesticides 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.

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

Deliberação Nº 001/DNSA/2014 by the National Directorate of Agriculture and Agrarian Services (The Pesticide Register Authority).

2.2.3 Date of entry into force of the final regulatory action

31/12/2014

2.3 Category or categories where the final regulatory action has been taken

2.3.1 All use or uses of the chemical in your country prior to the final regulatory action

Was registered as herbicide on various crops including: sugar cane, various vegetables and bananas.

2.3.2 Final regulatory action has been taken for the category ☐ Industrial

Use or uses prohibited by the final regulatory action

N/A

Use or uses that remain allowed (only in case of a severe restriction)

N/A

2.3.3 Final regulatory action has been taken for the category ☒ Pesticide

Formulation(s) and use or uses prohibited by the final regulatory action

Ban all formulation and for all uses.

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

None.

2.4 Was the final regulatory action based on a risk or hazard evaluation?

☒ **Yes**

☐ **No** (If no, you may also complete section 2.5.3.3)

2.4.1 If yes, reference to the relevant documentation, which describes the hazard or risk evaluation

Project document EP/MOZ/101/UEP – Reducing Risks of Highly Hazardous Pesticides in Mozambique

- Come A.M. & van der Valk H., 2014. Step 1 – Shortlisting highly hazardous pesticides Consultancy report undertaken under the Project EP/MOZ/101/UEP – Reducing Risks of Highly Hazardous Pesticides in Mozambique.
- Come A.M.; Dona L.L.; Mancini F. & van der Valk H., 2014. Step 2 – Survey

of pesticide use practices in selected cropping systems

- Come A.M. & van der Valk H., 2014. Step 4 – Occupational risk assessments
- Lahr J., R. Kruijne & J. Groenwold, 2014. *Hazards of pesticides imported into Mozambique, 2002-2011.* Wageningen, Alterra Wageningen UR (University & Research centre).
- FAO/WHO (2008) Report of the 2nd Joint Meeting on Pesticide Management and the 4th Session of the FAO Panel of Experts on Pesticide Management. 6-8 October 2008, Geneva. Food and Agriculture Organization of the United Nations, Rome & World Health Organization, Geneva.

http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Report.pdf
(p. 14 – 18)

2.4.2 Summary description of the risk or hazard evaluation upon which the ban or severe restriction was based.

2.4.2.1 Is the reason for the final regulatory action relevant to human health?

☒ Yes

☐ No

If yes, give summary of the hazard or risk evaluation related to human health, including the health of consumers and workers

A project entitled Reducing Risks of Highly Hazardous Pesticides (HHPs) in Mozambique was initiated by the Government of Mozambique with the objective to reduce the risks associated with pesticide use in the country. The ultimate goal was to develop and implement an "HHP Risk Reduction Action Plan" for the most dangerous pesticides and use situations, resulting over time in the implementation of a variety of risk reduction measures based on a review of use conditions.

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 identified. 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 (JMPM) (FAO/WHO, 2008).

Based on the hazard assessment in Step 1, a short list of HHPs, including "coming close" to HHPs, which were used in the country, was established.

Paraquat 200g/l (20%) SL pesticide formulation was on the short list as a pesticide "coming close" to HHPs based on the below indicated criteria:

- For liquid formulations: pesticide products with an acute oral LD50< 200 mg/kg or an acute dermal LD50< 400 mg/kg (note that these are the Class Ib limits in the previous version of the WHO Classification (WHO, 2005).

All pesticide formulations registered in Mozambique were classified using the oral and dermal LD50 value of the formulation, as provided in the registration dossier. LD50 values for the formulation 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).

Paraquat 200g/l (20%) SL pesticide formulation in Mozambique was identified as WHO class II, but chronic toxicity alert, dermal hazard was identified as close to Class Ib and very low AOEL (Come A.M. & van der Valk H., 2014). The a.i. was registered in US and banned for use in the European Union. In the case of paraquat, the WHO Classification notes in addition that it "*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*" (WHO, 2010). The occupational hazard of paraquat is confirmed by the very low Acceptable Operator Exposure Level defined in the EU (PPDB, 2012).

During the second step of the project, a pesticide use field surveys and exposure were carried out in selected regions and cropping systems in Mozambique. 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 surveys (325 subsistence farmers interviewed) revealed that most of the farmers applied pesticides (95%), and that the conditions of use were likely to result in undue (excessive) exposure. Half of the farmers interviewed never received any training on pesticides use, and even the other half that did, often lacked understanding of the risks involved. Farmers were spraying vegetable crops at least 14 times per growing season. One out of three applications was involving one of the HHP containing formulation (Farmers using HHPs includes almost 30% of the interviewed farmers).

Also almost none of the farmers (93%) owned or wore adequate PPE having only one or no protective items at all. Only 2% of those applying HHPs wore adequate full body protection PPE. About half of the farmers had not received any training on the use of pesticides. The majority of pesticide applicators used manual sprayer (36%), followed by electric sprayer (with batteries); 33% and followed by inappropriate equipment such as watering can (13.5%) or other (unknown) means (12.5%). Approximately about half of the farmers surveyed reported that they noticed to receive pesticide on their clothes, bare skin or eyes when using pesticides. The main health symptoms associated with pesticide use by farmers noticing symptoms were headaches, skin rashes, burning eyes, vomiting, burning nose, blurred vision, dizziness and excessive sweating. Almost half of the farmers declared they did not read pesticide labels, including use instructions such as proper dosage and protective measures, the main reason being illiteracy. One out of four farmers poorly understood the hazard colour band on pesticide labels that indicates acute toxicity.

The survey results showed that the use of pesticides in general, and of HHPs in particular, was likely to result in excessive exposure of farmers in Mozambique. Therefore enforcing risk mitigation measures depending solely on wearing the appropriate PPE under the local conditions of use to be difficult and unlikely to give results.

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.

During the fourth step of the project, the risk of occupational exposure was assessed for a subset of the shortlisted pesticides, including paraquat. The subset included nine pesticides in seven different cropping systems using 13 application scenarios, each with and without personal protective equipment (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.

The toxicologically acceptable level of exposure applied in this study was the Acceptable Operator Exposure Level (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 pesticide were registered. In some cases, crops were grouped together when the exposure to the pesticide were likely to be similar, based on 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 (e.g. during harvesting) or bystander exposure was not evaluated. For the occupational risk assessment an estimate of operator exposure was made, which was then compared to a toxicologically acceptable level.

Exposure of pesticide applicators 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) (Hamey et al. 2008;

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. Exposure scenarios and application parameters for the models were based on Mozambican pesticides application conditions.

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

Pesticide	**Concentration & type of formulation** [1]	**Cropping systems**	**Volume application rate** (L mixture/ha)	**Dose rate** (L or kg formulation/ ha	**AOEL** [2, 3] (mg a.i./kg bw/day)
Paraquat	200 g.a.i./L SL	Sugar cane	200	3	0.0004 [A]
		Bananas	200	5	
		Vegetables	200	2.5	

[1] a.i. = active ingredient; WP = wettable powder; SL = soluble concentrate; WG -= wettable granules

[2] bw = bodyweight

[3] Sources of AOELs: [A] = FootPrint – Pesticide Properties Database (undated); [B] = Rotterdam Convention (2011); [C] = ERMA (2010)

- Expression of risk

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.i./kg bw/day) and the AOEL (in mg a.i./kg bw/day). A risk quotient > 1 implies that the risk is not acceptable; a risk quotient ≤ 1 implies an acceptable risk. For instance, a risk quotient of 100 means that the estimated exposure level of the operator, for the given pesticide application scenario, is a 100 times higher than the acceptable exposure level.

- Outcome of the risk assessments

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 a HHP".

Pesticide formulation	**Cropping system**	**Application rate**	**Exposure model**	**Use of PPE**	**Risk quotient**
200 g/L SL	Sugar cane	600 g a.i./ha	UK – hand-held sprayer; low level target	Mixing no; spraying no	1408
				Mixing yes; spraying yes	255
			UK – tractor-mounted boom sprayer; hydraulic nozzles	Mixing no; spraying no	653
				Mixing yes; spraying yes	95
	Bananas	1000 g a.i./ha	UK – hand-held sprayer; low level target	Mixing no; spraying no	2268

			Mixing yes; spraying yes	423
		UK – tractor-mounted boom sprayer; hydraulic nozzles	Mixing no; spraying no	1045
			Mixing yes; spraying yes	155
Vegetables	500 g a.i./ha	UK – hand-held sprayer; low level target	Mixing no; spraying no	1193
			Mixing yes; spraying yes	213
		UK – home/ garden; low level target	Mixing no; spraying no	203

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 use conditions.

- **Occupational risks**

The occupational risk assessments 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 (Table 3).

Given the large risk quotient, it is unlikely that locally feasible mitigation measures would reduce the risk of paraquat to acceptable levels.

The occupational risk assessments reported in this study largely confirm that the majority of pesticide products identified as highly hazardous pesticides on the basis of hazard criteria would also lead to unacceptable occupational exposure on the basis of risk assessment.

Table 3. Summary of the results of the operator risk assessments.

Pesticide	**Formulation [type]** (g a.i./L)	**Evaluated crops**	**Evaluated application rates** (g a.i./ha)	**Exceedance of AOEL**	
				With PPE	Without PPE
Paraquat	200 [SL]	Sugar cane, bananas, vegetables	≥ 500	All cases	All cases

Expected effect of the final regulatory action

Reducing the risks posed by the use of HHPs in Mozambique in the context of human health. All registration of the Paraquat were cancelled.

2.4.2.2 Is the reason for the final regulatory action relevant to the environment?

☒ Yes

☐ No

If yes, give summary of the hazard or risk evaluation related to the environment

The Alterra study carried out by Wageningen University (WUR) analysed the

following environmental hazard indicators: Environmental toxic load to aquatic organisms (fish, *Daphnia,* and algae), hazard to bees and groundwater leaching potential. The hazard assessment took into account the trends of registered pesticide imports in the country from 2002 to 2011 explored in terms of numbers (type) of pesticides and volume (amount) of pesticides. Paraquat was identified as pesticide of secondary concern based on the relative hazard to algae using the environmental toxic load (ETL) as a hazard indicator (details in Table 6, Table 1.3, Table 3.3, of Alterra report).

Environmental Toxic Loads (fish, aquatic invertebrates, algae, bees)

Secondary concern: Active ingredients of which the imported quantity of a.i. constitutes >10% of the total annual ETL value in 1 year or more.

Table 3.3: Active ingredients with the major contribution to the annual ETL for algae (i.e. > 0.5 %).

Year	Rank Nr.	Compound Nr.	Compound name	(kg)	(%)
2002	1	128	Paraquat	1745	98.5
2003	2	128	Paraquat	4721	21.4
2004	2	128	Paraquat	7418	16.3
2005	2	128	Paraquat	5377	8.1
2006	2	128	Paraquat	6604	12.8
2007	2	128	Paraquat	4272	11.7
2008	2	128	Paraquat	4600	6.3
2009	2	128	Paraquat	8448	11.0
2010	2	128	Paraquat	4540	5.4
2011	2	128	Paraquat	7020	10.7

Expected effect of the final regulatory action

Significantly reduce the risk to aquatic organisms (algae) in Mozambique water basins.

2.5 Other relevant information regarding the final regulatory action

2.5.1 Estimated quantity of the chemical produced, imported, exported and used

	Quantity per year (MT)	Year
produced	NA	NA
imported	<table><tr><th>Qtd (L)</th><th>Year</th></tr><tr><td>23880</td><td>2003</td></tr><tr><td>37500</td><td>2004</td></tr><tr><td>27210</td><td>2005</td></tr><tr><td>33320</td><td>2006</td></tr><tr><td>26140</td><td>2007</td></tr><tr><td>23000</td><td>2008</td></tr><tr><td>42240</td><td>2009</td></tr><tr><td>22700</td><td>2010</td></tr><tr><td>32000</td><td>2011</td></tr><tr><td>16920</td><td>2012</td></tr><tr><td>18540</td><td>2013</td></tr></table>	
exported	NA	NA

used	All quantity are used	NA

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

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.

2.5.3 Other relevant information that may cover:

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

NA

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

The Ministry of Agriculture and Food Security through 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. In parallel the Ministry of Agriculture and Food Security is also promoting the use of bio-pesticides on vegetables as pest control measures.

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

NA

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

None

SECTION 3 PROPERTIES

3.1 Information on hazard classification where the chemical is subject to classification requirements

International classification systems e.g. WHO, IARC, etc.	**Hazard class**

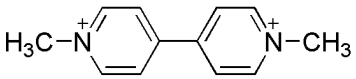
WHO	Moderately hazardous (Class II) but chronic toxicity alert; dermal hazard close to Class Ib; very low AOEL

Other classification systems e.g. EU, USEPA	**Hazard class**
USEPA	Highly toxic (Class I) - Acute Inhalation (rat) Category E (no evidence of carcinogenicity in animal studies)

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Structural formula:



2 Cl^-

Molecular formula: C12H14N2Cl2

Molecular weight: 257.2

(Molecular weight of paraquat ion is 186.3)

Physical and chemical properties

Pure active ingredient (Husband, 2001)
Purity: 99.5%
Appearance: Off-white hygroscopic solid without characteristic odour
Vapour pressure: << $1x10^{-5}$ Pa at 25ºC
Melting point: No melting below 400ºC; decomposition at around 340ºC (613ºK)
Boiling point: Boiling point of pure paraquat dichloride not measurable; decomposition at
~340ºC (613ºK)
Relative density: 1.55 at 25ºC
Surface tension: 73.4 mN/m at 20ºC (at concentration of 0.02 M)
Henry's law constant: 4x10-9 Pa m3/mol
Octanol-water
partition coefficient:
Log Pow -4.5 at 25ºC
Solubility at 20ºC: Water: 618 g/l at pH 5.2
620 g/l at pH 7.2
620 g/l at pH 9.2
Methanol: 143 g/l
Acetone: <0.1 g/l
Hexane: <0.1 g/l
Dichloromethane: <0.1 g/l

Toluene: <0.1 g/l
Ethyl acetate: <0.01 g/l
pH at 20ºC 6.4
Stability: ≥14 days at 54ºC
Hydrolysis: No hydrolysis was observed at pH 5, 7 or 9 (91 mg/l; 25 or 40ºC for 30 days)
Photolysis: In aqueous solution, photochemically decomposed by UV radiation
Technical material (Wollerton. 1987)
Purity: Minimum 362 g/l (tested material: 529 g/l)
Appearance: Dark red-brown clear liquid
Odour: Earthy odour
Density: 1.13 g/cm3 at 25ºC
pH: 3.95 at approximately 20 ºC
Flash point: > 90 ºC
Surface tension: 58.6 mN/m at 20 ºC
Storage stability: ≥2 years at 25 ºC in polythene
Formulations: SL (in various concentrations alone or in combination with diquat)

Reference

http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Evaluation04/paraquat.pdf

3.2.2 Description of toxicological properties of the chemical

- Alterra report
  - LD_{50} rat (mg/kg) 150 –HHP
- **PPDB**

Mammals - Acute oral LD_{50} (mg kg^{-1})	110	G4 Rat
Mammals - Dermal LD_{50} (mg kg^{-1} body weight)	200	A4 Rat
Mammals - Inhalation LC_{50} (mg l^{-1})	0.6	A5 Rat
ADI - Acceptable Daily Intake (mg kg^{-1} bw day^{-1})	0.004	A5 Dog SF=100
ARfD - Acute Reference Dose (mg kg^{-1} bw day^{-1})	0.005	A5 Dog SF=100
AAOEL - Acute Acceptable Operator Exposure Level (mg kg^{-1} bw day^{-1})	-	-
AOEL - Acceptable Operator Exposure Level - Systemic (mg kg^{-1} bw day^{-1})	0.0004	A5 Dog 90 day SF=100
Dermal penetration studies (%)	0.5	A5

Dangerous Substances Directive 76/464	[No unacceptable risks to bystanders identified]	-

Reference

- Lahr J., R. Kruijne & J. Groenwold, 2014. *Hazards of pesticides imported into Mozambique, 2002-2011.* Wageningen, Alterra Wageningen UR (University & Research centre).
- https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/505.htm (PPDB: Pesticide Properties Data Base)

3.2.3 Description of ecotoxicological properties of the chemical

- Alterra report

The Gus and Ground water potential class of a.i. GUS - 6.9 and Class 1 (Table 4.1. Lahr J., R. Kruijne & J. Groenwold, 2014.)

- Annual ETL for algae (i.e. > 0.5 %). – See Table 3.3

Table 3.3: Active ingredients with the major contribution to the annual ETL for algae (i.e. > 0.5 %).

Year	Rank. Nr	Compound Nr.	Compound name	(kg)	(%)
2002	1	128	Paraquat	1745	98.5
2003	2	128	Paraquat	4721	21.4
2004	2	128	Paraquat	7418	16.3
2005	2	128	Paraquat	5377	8.1
2006	2	128	Paraquat	6604	12.8
2007	2	128	Paraquat	4272	11.7
2008	2	128	Paraquat	4600	6.3
2009	2	128	Paraquat	8448	11.0
2010	2	128	Paraquat	4540	5.4
2011	2	128	Paraquat	7020	10.7

- Eco-toxicity:

LC50 Fish (mg/L) – 19 (FP)
EC50 Daphnia (mg/L) – 4,4 (FP)
EC50 Algae (mg/L) – 0,00023 (FP)
LD50 bee (ug/bee) – 9.06 (FP)

- Table 1.2 Fate proprieties

DegT50 – 2800 (HHP)
Koc (L/kg) – 1000000 (FP)

Reference

Lahr J., R. Kruijne & J. Groenwold, 2014. *Hazards of pesticides imported into Mozambique, 2002-2011.* Wageningen, Alterra Wageningen UR (University & Research centre).

SECTION 4 DESIGNATED NATIONAL AUTHORITY

Institution	Ministry of Agriculture and Rural Development
Address	c/o INIA P.O. Box 3658 Maputo Mozambique
Name of person in charge	Khalid Cassam
Position of person in charge	Technician
Telephone	+258 1 46 05 91(phone)
Telefax	+258 1 46 01 95 (fax)
E-mail address	khalidcassam@yahoo.com.br

Date, signature of DNA and official seal: _____29/10/2020_____

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
Food and Agriculture Organization
of the United Nations (FAO)
Viale delle Terme di Caracalla
00153 Rome, Italy
Tel: (+39 06) 5705 2188
Fax: (+39 06) 5705 3224
E-mail: pic@fao.org

OR

Secretariat for the Rotterdam Convention
United Nations Environment
Programme (UNEP)
11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland
Tel: (+41 22) 917 8296
Fax: (+41 22) 917 8082
E-mail: pic@pic.int

Definitions for the purposes of the Rotterdam Convention according to Article 2:

(a) '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;

(b) 'Banned chemical' means a chemical all uses of which within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a chemical that has been refused approval for first-time use or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(c) 'Severely restricted chemical' means a chemical virtually all use of which within one or more categories has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a chemical that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(d) 'Final regulatory action' means an action taken by a Party, that does not require subsequent regulatory action by that Party, the purpose of which is to ban or severely restrict a chemical.