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Technical work: review of proposals for the inclusion of severely hazardous pesticide formulations in Annex III to the Rotterdam Convention: cypermethrin emulsifiable concentrate 10%

# Task group report on cypermethrin emulsifiable concentrate 10%

### Note by the Secretariat

The annex to the present note contains the task group report on cypermethrin emulsifiable concentrate 10%. It is presented as submitted by the task group, without formal editing.

#### Annex

# Rotterdam Convention Twentieth meeting of the Chemical Review Committee Rome, Italy, 17-20 September 2024

### Report of the task group on cypermethrin emulsifiable concentrate 10%

#### **Task group members**

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Members

Observers

Secretariat

#### Information available to the task group

UNEP/FAO/RC/CRC.20/24: Cypermethrin emulsifiable concentrate 10%

UNEP/FAO/RC/CRC.20/INF/47: Cypermethrin emulsifiable concentrate 10%: information collected by the Secretariat

### Introduction

1. A proposal from the Lao People's Democratic Republic to list cypermethrin emulsifiable concentrate 10% in Annex III to the Convention as a severely hazardous pesticide formulation was available to the Committee together with supporting documentation from this country. The proposal has undergone an initial review by the Secretariat, who concluded that the proposal did appear to meet the information requirements of part I of Annex IV to the Convention (UNEP/FAO/RC/CRC.20/24).

2. As laid down in Article 6 of the Convention, the Secretariat forwarded a summary of the information received to all parties and collected additional information as specified in part 2 of Annex IV. This information is available in documents UNEP/FAO/RC/CRC.20/INF/47.

3. The purpose of this report is to present the task group's analysis of the proposal from the Lao People's Democratic Republic together with the supporting documentation for the Committee's consideration.

4. The report includes a summary of the background of the proposal, a summary of the documentation required according to Annex IV, part 1, a summary of the availability of information that was collected by the Secretariat according to part 2 of Annex IV (tabular format) and an analysis of compatibility with the criteria of Annex IV part 3 (tabular summary and detailed analysis).

5. The report contains an overall analysis.

# I. Analysis of the proposal from the Lao People's Democratic Republic

#### A. Background of the proposal

6. Within the Rotterdam Convention project on monitoring pesticide survey on Highly Hazardous Pesticides (HHPs) and Severely Hazardous Pesticides (SHPFs) conducted in Lao People's Democratic Republic (Lao PDR) in the period from January 2019 to May 2020, a field monitoring survey was carried out in 25 villages of 10 districts in three provinces in June-July 2019. A total of 169 farmers participated. The farmers from the survey were predominately males and most had a secondary/high school level education.

7. All pesticides produced, imported, exported, distributed and used in Lao PDR, must be registered with the Department of Agriculture, Ministry of Agriculture and Forestry, in accordance with Regulation on the Control of Pesticides in Lao PDR (No. 2860/MAF, Vientiane Capital, dated 11 Jun 2010). The survey showed, however, that the use of illegal pesticide products is widespread and that pesticides illegally imported and bought from unlicensed shops are still a common practice in the provinces. Also, the use of banned products is a problem in Lao PDR.

8. A total of 40 pesticide products were used by the farmers (active ingredients of different product names i.e. 22 insecticides, 12 herbicides and 6 fungicides), but only four of these products were registered with label in Lao language. The rest of the 36 products were illegally traded unregistered or banned pesticides with labels in foreign language i.e. Thai, Vietnamese and others.

9. Farmers reported a range of poisoning symptoms due to pesticide exposure. Some of the symptoms were very generic in nature while others were typical symptoms of pesticide poisoning. Lao PDR does not have a reporting system for incidents of pesticide poisoning. Three of these incidents were reported to be caused by using one of the unregistered products Super PHONEWDOL 10 labelled in Thai (cypermethrin 10% EC), a synthetic pyrethroid insecticide. The product was used with a hand-held battery-operated sprayer at a dose of 15 to 30 ml/20L of water. For two of the incidents, adverse effects reported were itchiness of the skin and excessive sweating after application in the field for half day period on maize and cucumber. One of these incidents was treated with medicine from a pharmacy. For the third incident, mixing/loading and spraying application for > 4 hours in watermelon caused insomnia, excessive sweating and cough. In all three incidents the operators were male, aged between 20 to 60 years, using protective clothing comprising gloves, boots/shoes, long-sleeve shirt and long pants. The symptoms occurred within 4-12 hours after using the pesticide.

10. The field monitoring survey reported that in cases of serious poisonings, farmers would seek medical treatment from the government hospital whereas some farmers treated the poisonings by traditional means (drinking lemon grass tea, sniffing out ants, taking a long rest etc.).

11. The use of full Personal Protective Equipment (PPE) among farmers during pesticide handling application is not common, due to hot weather and unavailability of these items at affordable cost. The pesticide products were generally applied with motorized or hand-operated knapsack sprayers in small plantation areas, but in larger farm areas or big plantation areas the farmers usually used mini tank-mounted tractors for spraying.

12. The result of the implementation of the Rotterdam Convention project on monitoring pesticide survey on HHPs and SHPFs from January 2019 to May 2020 concluded that the dissemination of the decrees and legislation related to pesticide management has not been widely distributed in Lao PDR and that the accessibility of information related to pesticide rules and regulations is still limited. There is also little awareness and technical knowledge of the selection and application of pesticides among farmers. The country still does not have legal backing for taking action against illegal pesticide smuggling.

13. As a result of the monitoring pesticide survey Super PHONEWDOL 10 was identified as a SHPF by Lao PDR and consequently, the Lao PDR submitted a proposal to list cypermethrin 10% emulsifiable concentrate in Annex III to the Rotterdam Convention as a severely hazardous pesticide formulation.

# **B.** Summary of information provided in the proposal and analysis of its compatibility with requirements of Annex IV

Information and criteria for listing severely hazardous pesticide formulations in Annex III

#### 1. Part 1. Documentation required from a proposing Party

(PIC Circular LVI (56) – December 2022)

- (a) Name of the hazardous pesticide formulation: Cypermethrin 10% EC
- (b) Name of the active ingredient or ingredients in the formulation: Cypermethrin
- (c) Relative amount of each active ingredient in the formulation: 10%
- (d) Type of formulation: Emulsifiable Concentrate
- (e) Trade names and name of producers, if available: Super PHONEWDOL 10
- (f) Common and recognized patterns of use of the formulation within the proposing Party:

14. The formulation is not registered in Lao PDR; hence no use was permitted. The monitoring field survey of 2019 collected information on the usage of cypermethrin 10% EC. In three occasions, the product was applied using hand-held sprayer at a dose of 15 to 30 ml/20L of water for mixing/loading and spraying application in watermelon and for application in the field on maize or cucumber. The farmers used gloves, boots, long-sleeve shirt, long pants and simple hat as PPE.

15. The field monitoring survey of 2019 describes the common and recognized pesticide application practices in the field in the Lao PDR, such as the use of illegally traded unregistered or banned pesticides with labels in foreign language (90% of the pesticides in the survey), as well as the use of partial PPE by the farmers during pesticide handling due to the high temperature or unavailability of PPE at affordable cost. The surveyed farmers reported a range of poisoning symptoms due to pesticide exposure, where some of the symptoms were very generic in nature while others were typical symptoms of pesticides poisonings.

(g) A clear description of incidents related to the problem, including the adverse effects and the way in which the formulation was used:

16. The survey in 2019 collected details on three incidents relating to Super PHONEWDOL 10. The incidents relating to Super PHONEWDOL 10 can be summarized as follows: The incidents occurred after spraying the pesticide in fields where watermelon, maize or cucumber was grown. The product was applied using hand-held sprayer at a dose of 15 to 30 ml/20L of water. The label of the pesticide formulation (in Thai) contains information on the use (use in households), dosage (100 ml/2.5 l water, then spray 2.5 ml per 1 m<sup>2</sup>) and use of PPE (use of gloves and mask during handling of pesticide). The frequency of application is from 2 to 5 times per crop season. Symptoms occurred in 4-12 hours after exposure as excessive sweating, itchiness of the skin, cough and insomnia. The route of exposure was through skin and/or inhalation during the use of the pesticide for more than 4 hours to half a day. Partial protective equipment such as gloves, boots, long-sleeve shirts, long pants and simple hats were used. No information is available on the date or year of the incidents.

(h) Any regulatory, administrative or other measure taken, or intended to be taken, by the proposing Party in response to such incidents:

17. Lao People's Democratic Republic does not have an incident reporting system for pesticide poisoning.

18. Lao PDR decided on national risk reduction measures (legislative and non-legislative measures) as a follow up from the monitoring survey:

- (a) Legislative measures:
  - (i) Disseminate related legislations to pesticide investors and users;
  - (ii) Disseminate the implementation of Rotterdam Convention to all related stakeholders; monitor the importers of pesticides by checking authorization licenses, import permits and registration certificates, records of distribution and other requirements and encourage to import tools and plant protection equipment;

- (iii) Inspect regularly retailer's shops of pesticides by checking related licenses, labelling, and record of buying and selling;
- (iv) Continue to monitor pesticide use in field by extending areas and add more type of crops especially crops for export;
- (v) Technique of pesticide disposal.
- (b) Non-legislative measures:
  - (i) Strengthen training and education system on effective and judicious use of pesticide among farmers;
  - (ii) Disseminate related pesticide legislation for improving pesticide management system;
  - (iii) Train on pesticide management for pesticide inspectors at district level, taskforce team, pesticide investors, and users including pesticide applicators services;
  - (iv) Strengthening pesticide inspectors on updating technical knowledge related to pesticide;
  - Training more on HHPs and SHPFs before carrying out to monitor pesticide survey;
  - (vi) Disseminate the implementation of RC to all related stakeholders;
  - (vii) Update knowledge and continue to set up pesticide inspectors at provincial and district level throughout the country;
  - (viii) Establish network and national database on pesticide management.
- 19. Current legal infrastructure/admin procedure:

(a) Ministerial Decision on Registration of Pesticides in Lao PDR No. 3604/MAF, dated 17 Sep 2019 (improvement registration scheme and advice pesticide investors to follow the decision of Registration Unit of DOA);

(b) Ministerial Decision on Using Uniform and Insignia of Pesticide Inspector No. 1232/MAF, dated 23 April 2019 (dissemination and preparation of model uniform and insignia for pesticide inspector);

(c) Ministerial Instruction on Establishment and responsibilities of Taskforce team to inspect and apply the measures to violation pesticide legislation 0278/MAF, dated 19 Feb 2020;

(d) Ministerial Decision on Control of Pesticide Businesses No.0238/MAF, dated 14 Feb 2019.

Part 2. Information to be collected by the Secretariat			
Type of information	Information available?	Documentation in:	
(a) The physico-chemical, toxicological and ecotoxicological properties of the formulation;	Yes	Information was provided by the following Parties: Australia, Canada, Brazil, Chile, European Union, Kuwait, New Zealand, Norway, Oman, and Switzerland (in document UNEP/FAO/RC/CRC.20/INF/47)	
(b) The existence of handling or applicator restrictions in other States;	Yes		
(c) Information on incidents related to the formulation in other States;	Yes		
(d) Information submitted by other Parties, international organizations, nongovernmental organizations or other relevant sources, whether national or international;	Yes		
(e) Risk and/or hazard evaluations, where available;	Yes		
(f) Indications, if available, of the extent of use	Yes		

#### 2. Part 2. Information to be collected by the Secretariat

of the formulation, such as the number of registrations or production or sales quantity;	
(g) Other formulations of the pesticide in question, and incidents, if any, relating to these formulations;	Yes
(h) Alternative pest-control practices;	Yes
(i) Other information which the Chemical Review Committee may identify as relevant.	Yes

#### 3. Part 3. Criteria for listing severely hazardous pesticide formulations in Annex III

Part 3. Criteria for listing severely hazardous pesticide formulations in Annex III		
Criteria	Criterion met?	
(a) The reliability of the evidence indicating that use of the formulation, in accordance with common or recognized practices within the proposing Party, resulted in the reported incidents;	Met	
(b) The relevance of such incidents to other States with similar climate, conditions and patterns of use of the formulation;	Met	
(c) The existence of handling or applicator restrictions involving technology or techniques that may not be reasonably or widely applied in States lacking the necessary infrastructure;	Met	
(d) The significance of reported effects in relation to the quantity of the formulation used;	Met	
(e) That intentional misuse is not in itself an adequate reason to list a formulation in Annex III.	Met	

#### Compatibility with the criteria of Annex IV, part 3 - detailed argumentation

In reviewing the proposals forwarded by the Secretariat pursuant to paragraph 5 of Article 6, the Chemical Review Committee shall take into account:

(a) The reliability of the evidence indicating that use of the formulation, in accordance with common or recognized practices within the proposing Party, resulted in the reported incidents;

In Lao PDR, the field monitoring survey on pesticide practices conducted in 2019 revealed 20. that the use of unregistered pesticides is very widespread: 36 of the pesticides recorded during the survey were unregistered pesticides while only 4 products were registered with label in Lao language. All the 36 unregistered pesticides were foreign products illegally sold in the country and the majority of them originated from Thailand (27 products), Vietnam (7 products) and from other countries (2 products). This illegal placing on the market is possible because legal action cannot be taken against violators, since related rules/regulations not being implemented at the time of the survey. Cypermethrin, which is not registered in Lao PDR, was among the common insecticides used in the country. The pesticide products were generally applied with motorized or hand-operated knapsack sprayers with 20 L capacity in small plantation areas (0.2-0.3 ha), but in larger farm areas or big plantation areas the farmers usually used mini tank-mounted tractors for spraying. All of the 169 farmers interviewed used only minimum PPE (long-sleeved shirt, long pants, head cover, face cover and shoes). The use of full PPE like coverall, eye protection, mask with filter etc., among farmers during pesticide handling is not common, due to hot weather and unavailability of these items at affordable cost.

21. One of the challenges faced by the surveyed farmers were the difficulty of recalling the pesticide formulations that has caused the poisonings they suffered. This was further complicated if more than one pesticide were used at same time. Thus, 22 of the respondents reported that they had experienced some adverse effects from using certain pesticides. Still only 20 recalled the symptoms and only eight of them recalled precisely which particular pesticide product was responsible for the symptoms they suffered from. In contrast, 12 other farmers only reported that cumulative poisoning symptoms occurred and the list of the pesticide products they used at that particular time. The use of certain pesticide formulations under local conditions has caused adverse effects to the farmers.

22. The 2019 survey collected details for three incidents relating to **Super PHONEWDOL 10** (cypermethrin 10% EC), as follows: The frequency of application was 2-5 times per crop per season.

All operators (male age 20-60 years) used gloves, boots/shoes, long sleeve shirt, long pants and simple hat. The label instructed to use masks and gloves when using the product. Masks and coveralls were not used, which can result in exposure through inhalation and skin when using hand-held sprayer. The type of gloves used is not specified (e.g., chemical resistant gloves). The duration of symptoms occurrence after exposure was not specified per incident. The date/year of the incidents is not stated.

23. **Incident one:** spraying the pesticide with a hand-held sprayer in the field on maize and cucumber with a dose of 30 ml/20L water. The duration of exposure was ½ day. Adverse effects occurred after 4-12 hours of the use were itchiness of the skin and excessive sweating. The route of exposure was skin and inhalation. Treatment: bought medicine in pharmacy. The type of medical treatment was not specified.

24. **Incident two:** spraying the pesticide with a hand-held sprayer in the field on maize and cucumber with a dose of 30 ml/20L water. The duration of exposure was ½ day. Adverse effects occurred after 4-12 hours after the use were itchiness of the skin and excessive sweating. The route of exposure was skin and inhalation. No treatment was given.

25. **Incident three:** the activities were mixing/loading and spraying the pesticide with a hand-held sprayer in the field on watermelon with a dose 15 ml/20L water. The duration of exposure was > 4 hours. Adverse effects occurred after less than 4 hours were insomnia, excessive sweating and cough. Route of exposure was inhalation. No treatment was given.

26. The evidence indicating that the use of **Super PHONEWDOL 10** (cypermethrin 10% EC), in accordance with common and recognized practices within Lao PDR, resulted in the reported incidents can be considered reliable with certain limitations (e.g. date/year of incident).

27. Based on the above, this criterion appears to be met.

(b) The relevance of such incidents to other States with similar climate, conditions and patterns of use of the formulation;

28. Documentation was made available to the CRC (UNEP/FAO/RC/CRC.20/INF/47) indicating that the above listed conditions for Lao PDR are similar to the conditions prevailing in other neighbouring States.

29. The same or similar formulations are used as pesticides or biocides (EU) in other countries with a similar climate and conditions. Information was received from Australia, Brazil, Canada, Chile, the European Union, including Germany, Spain, Lithuania, the Netherlands, Portugal and Sweden, Kuwait, New Zealand, Norway, Oman and Switzerland.

30. A summary of the available documentation regarding use of cypermethrin formulations, is presented below.

31. **Australia:** there are no registered products with 10% active concentration, and product specific handling or applicator restrictions in Australia; the number of similar registered products with the a.i. cypermethrin (**any formulation**) is 116.

32. **Brazil:** there are 24 formulated products containing cypermethrin in Brazil. A formulation based on 10% cypermethrin is not registered. Cypermethrin is a product widely used in Brazil for various crops, including: "cotton, peanuts, rice, potatoes, sweet potatoes, yacon potatoes, beets, coffee, yams, carrots, citrus fruits, peas, beans, beans, chickpeas, yams, lentils, cassava, parsley, millet, corn, soybeans, sorghum and tomatoes. The product is a pyrethroid insecticide that acts through contact and ingestion on indicated biological targets which cause considerable damage to the production of the indicated crops. Currently, approximately 5.6 million hectares are treated with products formulated with cypermethrin, acting mainly on caterpillars, bedbugs, kitties and leafhoppers".

33. **Canada**: the formulations based on 10% cypermethrin emulsifiable concentrates are not registered in Canada. The following products are registered in Canada with the same or higher concentrations, and similar formulation types to the proposed formulation: emulsifiable concentrate 407 g/L - two products (registration numbers 15738 and 30316) and 250 g/L – two products (registration numbers 15738).

34. Based on the results of the risk assessment, use restrictions were included on the label to minimize the exposure to cypermethrin. Canadian handling and applicator restrictions are detailed on labels of registered Canadian products. The re-evaluation decision for cypermethrin required amendments to those handling and applicator restrictions, which are reflected on current Canadian product labels:

35. To protect mixer/loader/applicators, the following statements are proposed to be added to all agricultural product labels:

(a) Wear long-sleeved shirt, long pants and chemical-resistant gloves during mixing, loading, application, clean up and repair. In addition, wear goggles or face shield during mixing and loading;

(b) For mechanically pressurized handgun (MPHG) application to strawberry: Wear coveralls (over single layer of clothes) and chemical-resistant gloves during mixing, loading and application.

36. To protect workers entering treated sites, modified restricted-entry intervals (REI) must be added to all agricultural labels. Products containing cypermethrin are unlikely to affect your health when used according to the proposed label directions.

37. The re-evaluation decision further includes label amendments for products containing cypermethrin: The following statement is to be added to the labels of technical grade cypermethrin under the section entitled "Toxicological Information":

*Skin exposure may cause transient sensations (tingling, burning, itching, numbness). Treat symptomatically.* 

38. No registered applications have been identified for watermelon and cucumber (detected unregistered uses in Lao's PDR).

39. **Chile:** there are two pesticide formulations based on cypermethrin with current registration, there is no information on existence of restrictions on manipulation or application in Chile.

40. **European Union:** cypermethrin is approved for use as plant protection products and is classified as candidate for substitution. There are particular conditions to be taken into account by Member States in relation to the granting of plant protections products containing cypermethrin. Accordingly, the Review Report includes a list of restrictions that "Member States shall pay particular attention to:

- (a) the protection of aquatic organisms, non-target arthropods, including bees;
- (b) the consumer risk assessment;
- (c) the technical specification of the active substance used in plant protection products.

41. As pesticides for use in biocidal products, cypermethrin has been approved in the product type 08 (wood preservatives) and products type 18 (insecticides) and has 70 authorized biocidal products in the EU in the product type 08 (wood preservatives). Information on the intrinsic properties of the substance, and the risk assessments performed on the active substances and the risk mitigation measures are also available.

42. Cypermethrin was not considered as skin irritant in the EU evaluation.

43. **Germany:** the active substance cypermethrin is approved at EU level for use in plant protection products (PPP). After approval of an active substance, national authorisations of the formulated PPP must be granted before placing PPP on the market. PPPs with cypermethrin are currently authorised in almost all EU Member States. PPP with the active substance cypermethrin have been authorised in Germany since 1978. As of October 2023, five different PPP with cypermethrin are authorised. 68 poisoning cases involving cypermethrin are recorded in the German national register on human poisonings with chemicals. No poisonings of vertebrates with cypermethrin have been recorded in the German national register. Information on risk reduction measures is available (in German).

44. The following product is registered with the same concentration SHERPA DUO 100 g/L EC (registration number 00A031-00) in Germany.

45. **Spain:** there are pesticide products authorized as biocides and also as plant protection products that contain cypermethrin. As pesticides for use in agriculture, there are 19 products authorised that contain cypermethrin. As biocides, there are still two systems, the EU registry under Regulation (EU) No 528/2012 and a national registry under transitional measures that coexist. Under Regulation (EU) No 528/2012, there are 14 products for product type 18 (insecticides) and 20 for product type 8 (wood preservatives). Under Transitional measures, there are 189 products authorized as insecticides and one product as wood preservatives that contain cypermethrin.

46. Additional information was also provided by **Lithuania**, the **Netherlands** (in Dutch), **Portugal** and **Sweden** on authorised biocidal products or plant protection products that have as an active substance cypermethrin in the composition.

47. **Kuwait:** a restricted pesticide (cypermethrin 10% EC) for baits and traps has been registered for only one company and no quantity has been imported so far.

48. **New Zealand:** cypermethrin is currently listed on the Environmental Protection Authority Priority Chemical List (PCL) and is one of 11 synthetic pyrethroids currently under reassessment after grounds for a reassessment application was decided in 2018. There are two substances containing cypermethrin 10% (approval numbers HSR001755 and HSR001771).

49. The controls imposed on cypermethrin EC 10 (HSR001755) include "Requirements for protective clothing and equipment" as follows; Protective clothing/equipment must be employed when cypermethrin EC 10% is being handled. The clothing/equipment must be designed, constructed and operated to ensure that the person does not come into contact with the substance and is not directly exposed to a concentration of the substance that is greater than the Workplace Exposure Standard (WES) for that substance. The person in charge must ensure that people using the protective clothing/equipment have access to sufficient information specifying how the clothing/equipment may be used, and the requirements for maintaining the clothing/equipment.

50. **Norway:** cypermethrin is currently not approved in any plant protection products in Norway. A previous approval of a product containing 100 g Cypermethrin /l (Ripcord), expired 31.12.1995.

51. **Oman:** Oman has registered six products containing cypermethrin 10% EC and all are restricted according to MD160/2023 for veterinary use only. The Material Safety Data Sheet for Vetarin EC10 (10% cypermethrin) has the following information on hazard identification through SKIN CONTACT:

52. Short single exposure may cause skin irritation. Prolonged or repeated exposure may cause severe skin irritation.

53. **Switzerland:** cypermethrin is included in Annex 1 of the Plant Protection Products Ordinance, which lists the active substances authorized in Switzerland. The following plant protection products (PPPs) containing cypermethrin are currently authorized: cypermethrin 47,5% EC, **cypermethrin 11% EC**, cypermethrin 0.96% ME, cypermethrin 0.0055% AL, cypermethrin 10.2% EW, cypermethrin 7.89 % and piperonyl butoxide 22.5% EC, cypermethrin 2.24% and piperonyl butoxide 6.34% UL1. Between 1 January 1995 and 31 December 2022, the Swiss poison information centre Tox Info Suisse documented 227 cases (80 children among them) of human intoxication or suspected intoxication by cypermethrin (excluding alpha-cypermethrin). Of these, 22 cases occurred in an occupational setting.

54. In Switzerland, the use of plant protection products is subject to authorization in accordance with the Ordinance of 18 May 2005 on the Reduction of Risks relating to the Use of Certain Particularly Dangerous Substances, Preparations and Articles (Chemical Risk Reduction Ordinance). The use of plant protection products and pesticides on behalf of third parties may only be carried out on a professional or commercial basis by natural persons holding a permit, or qualifications recognized as equivalent, or under their direction. The permit is issued to anyone who has passed an examination demonstrating that they have the necessary knowledge to use PPPs, particularly in the areas of ecology, toxicology, disposal of PPPs and measures to protect human health and the environment, as well as knowledge of legislation on the protection of the environment, health and workers. No registered uses have been identified in Switzerland for watermelon, cucumber and maize.

55. Data specifically for the cypermethrin 10% EC are not available, but cases involving products containing the active substance cypermethrin were reported. Between 1 January 1995 and 31 December 2022, Tox Info Suisse documented 227 cases (80 children among them) of human intoxication or suspected intoxication to cypermethrin (excluding alpha-cypermethrin). The product was ingested orally in 62 cases, inhaled in 83 cases, dermally in 39 cases, ocularly in 29 cases and by other or combined means in 14 cases. While 210 cases were accidental, 16 cases were intentional (suicidal, abusive, other intentional exposures) and one case was in an unknown context. Of the accidental cases, 22 occurred in an occupational setting, while 168 cases occurred in a domestic setting. Three cases were classified as environmental, and a further 17 cases could not be assigned to any of these categories. Of the 24 cases for which Tox Info Suisse received medical feedback, two cases had no symptoms, 19 cases had mild symptoms and three cases had moderate symptoms. Of these, three mild cases were occupational. For two of these occupational cases the products contained cypermethrin and one other active substance (piperonyl butoxide or chlorpyrifos). The third case was relevant for cypermethrin only.

56. In summary and based on the above, it can be concluded that a safe use of pesticide formulations containing cypermethrin, including cypermethrin 10% EC, is only possible when a number of protective measures are applied.

57. Therefore, the incidents reported from Lao PDR are considered relevant to other States or regions, and this criterion is considered to be met.

(c) The existence of handling or applicator restrictions involving technology or techniques that may not be reasonably or widely applied in States lacking the necessary infrastructure;

58. The survey of 2019 indicates that cypermethrin is not registered in the country for pesticide use, including on this particular applications and crops (watermelon, cucumber and maize). Accordingly, Part A submission of the Party indicates that no handling or applicator restriction exist as a condition of a national registration of the pesticide formulation in question. In the incident reported with **Super PHONEWDOL 10**, the farmers used a hand-held battery-operated sprayer at a dose of 15 or 30ml/20 L water and PPE comprising of gloves, boots/shoes, long sleeve shirt, long pants and simple hat. The label (in Thai) recommended use of gloves and mask during handling of pesticide.

59. As regards the pesticide application technology used in Lao PDR, farmers who have small plantation area (0.2- 0.3 ha) used either motorized or hand-operated knapsack sprayers or hand-held battery-operated sprayer with 20 L capacity. Farmers who have larger farm areas or big plantation areas usually used mini tank-mounted tractors (banana, maize) for spraying.

60. The use of proper PPE among farmers during pesticide handling is not common. All of the 169 farmers interviewed, used only minimum PPE (long-sleeved shirt, long pants, head cover, face cover and shoes). The reasons why farmers do not wear full PPE such as coveralls, eye glasses or goggles, rubber mask with filter etc., were the hot weather conditions and unavailability of PPE at an affordable cost.

61. On the other hand, a number of parties have provided information on the existence of handling or applicator restrictions for registered uses of cypermethrin-containing pesticides, namely from Canada, Switzerland, Germany and New Zealand (see para (b) above). These restrictions are communicated via the products label and may include instructions for the use of baseline personal protective equipment (long pants, long-sleeved shirt and chemical-resistant gloves) for all uses except for mechanically pressurized handgun application to specific crop when additional personal protective equipment (cotton coveralls) was considered, etc.

62. Information provided by the Parties above shows that products containing cypermethrin are unlikely to affect human health if used according to the directions on the label. Accordingly, the information provided on the common use of minimum PPE and application technology in Lao PDR, and the practices carried out with the use of cypermethrin 10% EC are also relevant for the three reported incidents in this proposal.

63. Based on the above, this criterion appears to be met.

(d) The significance of reported effects in relation to the quantity of the formulation used;

64. The 2019 survey in Lao PDR found that pesticides with the active ingredient cypermethrin are among the most widely used in agricultural crops. Cypermethrin was among the common insecticides used (maize, cucumber and watermelon). The use of certain pesticide formulations under the local conditions had caused adverse effects to the farmers. Cypermethrin 10% EC was among the pesticides that has been reported by farmers to cause poisonings.

65. While the report from the survey suggests that "in cases of serious poisonings, farmers would seek medical treatment from the government hospital (p7, section 4.2.9), the incident reports (Part B form) indicate that no medical treatment/hospitalization have been given in two of three cases for the recovery of the patient. In the third incident report, medicine was bought from pharmacy.

66. For cypermethrin 10% EC, the three incident reports relate to non-registered applications of the pesticide to maize, cucumber or watermelon at an average rate of 15-30ml/20 L of water (lower dose than label recommendation) using a hand-held sprayer in the field for half day period/ > 4 hours.

67. As for the types of symptoms recorded, farmers reported a range of poisoning symptoms due to pesticide exposure, and some of the symptoms are very generic in nature while others are typical symptoms of pesticide poisonings. The symptoms that occurred in 4-12 hours after exposure with cypermethrin 10% EC were *excessive sweating, itchiness of the skin, cough, and insomnia.* The reversibility of the symptoms is not reported (e.g., duration in hours or days).

68. Cypermethrin is considered to be slight eye and skin irritant by Canada. According to the Label Amendments for products containing cypermethrin in Canada the statement "Skin exposure may cause transient sensations (tingling, burning, itching, numbness). Treat symptomatically" is to be added to the label. The evaluation by Canada supports that dermal symptoms like itchiness of the skin may occur if skin is exposed, and that this symptom is transient. Information provided from Oman on

a product containing 10% cypermethrin also reports that short single exposure may cause skin irritation and that prolonged or repeated exposure may cause severe skin irritation.

69. All incidents with cypermethrin reported to the Swiss Poison centre were assigned as "mild". For the occupational incident relevant for cypermethrin only, cough was reported as a symptom after exposure through inhalation: "A 45-year-old farmer was sprayed in the face with a product containing cypermethrin and inhaled the fumes. He immediately felt a burning sensation on his lips. He later developed a chesty cough and dyspnea on exertion. The man was symptom-free after 3 days. Severity: mild."

70. In Germany, 68 poisoning cases involving cypermethrin are recorded, and most were assigned as "minor or moderate" in the German national register on human poisonings with chemicals at BfR in the period 1990-2023. Two poisoning cases were "severe", but they were not considered relevant for cypermethrin 10% EC (one of the incidents in Germany was with intravenously exposure which ended-up with death and the other was a suicidal attempt through oral exposure; document 4183-attachment 2\_cypermethrin\_DE). However, there is no information on the active concentration of cypermethrin in these formulations.

71. In Canada and the USA (incidents are not expressed by formulation type): as of 17 September 2015, there were seven human and 22 domestic animal incident reports in the PMRA database involving the active ingredient cypermethrin. There was a low degree of association between the reported effects and exposure to the pesticide in the human incidents, and some degree of association in the domestic animal incidents. In one human incident report, symptoms were consistent with effects reported in the literature. This incident occurred in Canada, and the subject experienced minor dermal symptoms following accidental contact with a contaminated glove. All but one of the domestic animal incidents occurred in the US; the Canadian incident was of minor severity.

72. In summary, it can be assumed that the symptoms reported in the three incidents are caused by exposure to cypermethrin 10% EC. Considering the information provided from other countries, health effects observed within a short period of time after exposure reveal that skin irritation and cough were some of the symptoms of exposure to cypermethrin.

73. Based on the incidents reported in Lao PDR from the use of the proposed SHPF **cypermethrin 10% EC** concerning the lower quantity of the formulation used for a long time period (half a day/ > 4 hours) and the recommended dosage in the label this criterion appears to be met.

(e) That intentional misuse is not in itself an adequate reason to list a formulation in Annex III.

74. The reason for the proposal by Lao PDR to list cypermethrin 10% EC as a SHPF in Annex III is due to acute pesticide poisoning incidents caused by occupational exposure of operators during the application in the field and/or mixing/loading under common conditions of use for pest control. Intoxication from intentional misuse was not reported as a reason for the proposal.

75. Therefore, this criterion is considered to be met.

#### II. Conclusion

76. The Task Group concluded that the proposal from Lao PDR to list cypermethrin 10% EC in Annex III to the Convention as a severely hazardous pesticide formulation met the documentation requirements of Part 1 of Annex IV, meets criteria set out in Part 3 of Annex IV of the Convention, taking into account the information collected by the Secretariat according to Part 2 of Annex IV.