codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item No. 4 c) **CX/FL 08/36/7**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING
THIRTY-SIXTH SESSION
OTTAWA, CANADA, 28 APRIL – 2 MAY 2008

Proposal for New Work: Deletion of Rotenone from the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods*, Table 2 of Annex 2

(Project Document is attached as Annex)
(Proposal from Japan)

Japan wishes to propose to delete "preparations of Rotenone from *Derris elliptica, Lonchocarpus, Thephrosia* spp." from Table 2, Annex 2 of the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods* (CX/GL 32-1999, hereafter referred to as "GL 32") or to restrict its use to prevent flowing into waterways because of its toxicity to fish.

Background

At the 34th Session of CCFL, Japan introduced the proposal and project document concerning the deletion of "preparations of Rotenone from *Derris elliptica, Lonchocarpus, Thephrosia* spp." from Table 2, Annex 2 of GL 32, because of its toxicity to fish (para.78, ALINORM 06/29/22). The Committee did not support new work on the deletion of Rotenone but agreed that Japan should prepare a more detailed proposal with scientific justification according to the criteria in section 5 for consideration of the 35th Session (para. 80, ALINORM 06/29/22). At the 35th Session of CCFL, Japan presented its proposal again with scientific justification as CRD 10. Several delegations felt that as the document had been available only recently, more time was needed to study it. (paras. 146, ALINORM 07/30/22) The Committee agreed that Japan should submit their proposal as a working document for the next Session of the CCFL (para. 147, ALINORM 07/30/22).

Justification

Section 5.3 of GL 32 provides that the lists in Annex 2 are open and subject to the inclusion of additional substances or the removal of existing ones on an ongoing basis. The following justifications are based on the requirements under Section 5.1.

Assessment against general criteria

1. They are consistent with principles of organic production as outlined in these Guidelines

The use of Rotenone is generally in line with principles of organic production because it remains on the surface of the plant and it decomposes into carbon dioxide and water. However, it has toxic effects on fish as shown in 4

below. In this point of view, the use of Rotenone does not meet the principle of enhancing biological diversity within the whole system, which is outlined in paragraph 7 (a) in Foreword.

2. Use of the substances is necessary/essential for its intended use

Rotenone is used on fruit trees as insecticide, especially against aphids. As substitutes of Rotenone, pyrethrins, neem and mechanical control devices such as sticky bands are available and listed in Table 2 of Annex 2.

At the 35th Session, the Delegation of the European Community said that the substances was also being evaluated in the EC and requested more date concerning criteria 5 on availability of alternatives (para. 146, ALINORM 07/30/22). In the evaluation process, the company supporting the inclusion of Rotenone in the list of approved pesticides in the European Community withdrew its request in 2007. Therefore, Rotenone will not be included in the list in the European Community. A grace period is provided for essential uses in some Member States of the European Community where the use of Rotenone was authorised for specific plant protection techniques related to organic farming and where no alternatives were available.

3. Manufacture, use and disposal of the substance does not result in, or contribute to, harmful effect on the environment

The manufacturing process of Rotenone does not create any harmful effect on the environment. Use and disposal of Rotenone may negatively impact on the environment because of its toxicity to fish if Rotenone goes into waterways. Its toxicity is described in 4 below.

4. They have the lowest negative impact on human or animal health and quality of life

Rotenone does not satisfy the criterion of having the lowest negative impact on animal health and the aquatic environment as the data below show.

a. International Classification of Chemicals

The United Nations adopted "Globally Harmonized System of Classification and Labelling of Chemicals (GHS)" in order to address classification of chemicals by types of hazard and propose harmonized hazard communication elements, including labels and safety data sheets, in 2003.[1] Chemicals are classified from Category 1 to Category 5 depending on their acute toxicity to health, or from Category 1 to Category 3 depending on their acute toxicity to the aquatic environment, in a descending order of hazard.

Table 1: Acute toxicity hazard categories and approximate values defining the respective categories

Exposure Route	Category 1	Category 2	Category 3	Category 4	Category 5
Oral (mg/kg bodyweight)	5	50	300	2000	5000
Dermal (mg/kg bodyweight)	50	200	1000	2000	
Gases (ppm per volume)	100	500	2500	5000	
Vapours (mg/l)	0.5	2.0	10	20	
Dusts and Mists (mg/l)	0.05	0.5	1.0	5	

[1] United Nations, "Globally Harmonized System of Classification and Labelling of Chemicals (GHS) ," First revised edition, 2005

Source: United Nations "Globally Harmonized System of Classification and Labelling of Chemicals (GHS)," First revised edition, 2005, p. 109

Table 2: Acute hazard to the aquatic environment

Category	Category 1	Category 2	Category 3
Criteria	$LC_{50} \leq$ 1 mg/l	1 mg/l $< LC_{50} \leq$ 10 mg/l	10 mg/l $< LC_{50} \leq$ 100 mg/l

Source: United Nations "Globally Harmonized System of Classification and Labelling of Chemicals (GHS)," First revised edition, 2005, p.221

b. Effects of Rotenone on Animal Health

Effects of Rotenone on animal health have been widely studied in the past. The International Programme on Chemical Safety (IPCS), a joint programme of ILO, UNEP and WHO, published an evaluation on Rotenone as "Poisons Information Monograph 474." Among substances for plant pest and disease control listed in Table 2, Annex 2 of GL 32, Pyrethrins were also evaluated by the IPCS and reported as "Group Poisons Information Monograph G 026."

Relevant data of the monographs are shown in Table 3 for comparison. Based on the data on rabbit, corresponding to the criteria for Category 1 and 2 in Table 1, Rotenone should be classified as "Fatal if swallowed (oral)" and "Fatal in contact with skin (dermal)" in accordance with GHS. Based on the oral data on rat, corresponding to the criteria for Category 3 in Table 1, Rotenone should be classified as "Toxic if swallowed (oral)." On the other hand, corresponding to the criteria for Category 3 or 4, Pyrethrin should be classified as "Toxic or harmful if swallowed (oral)," "Toxic or harmful in contact with skin (dermal)."

Table 3: Toxicity comparison between Rotenone and Pyrethrins

Animal	LD_{50} (mg/kg bodyweight)	
	Rotenone[2]	Pyrethrins[3]
Rat	Oral 60 to 132 Dermal - Intravenous 0.2 to 0.3	Oral 584 to 900 Dermal > 1500 Intravenous -
Mouse	Oral - Dermal - Intraperitoneal 5.4	Oral 273 to 796 Dermal 375 Intravenous -
Rabbit	Oral 1.5 Dermal 100 to 200 Intravenous 0.35 to 0.65	Oral - Dermal 2060 Intravenous -

Source: IPCS. Poisons Information Monographs 474 and Group Poisons Information Monograph G026

c. Effects of Rotenone on Fish

"Poisons Information Monograph 474" also mentions that *rotenone is highly toxic to fish*. Test results are widely available. The data in Table 4 below are of the United States Environment Protection Agency.[4] Based on the data, corresponding to the criteria for Category 1 in Table 2, Rotenone should be classified as "Very toxic to aquatic life" in accordance with GHS.

Table 4: Lethal concentration to 50 % of tested fish after 96 h

Fish species	Size	LC_{50} (ppm in aquatic environment)
Bluegill	0.5 (g)	0.155
Bluegill	0.6 (g)	0.117
Bluegill	0.7 (g)	0.0495
Rainbow trout	37 (mm)	0.0028
Rainbow trout	42 (mm)	0.0019

"Group Poisons Information Monograph G026" does not refer to the toxicity of Pyrethrins to fish.

d. Studies of Rotenone in Japan

Some scientists in Japan studied Rotenone mainly in the 1960s and the 1970s as shown in Table 5 below. Data on Pyrethrins, one of the substances listed in Table 2, Annex 2 of GL 32 and a substitute to rotenone, are also included as a reference.

[2] Hayes, WJ. (1982) Pesticides Studied in Man. Baltimore/London. Williams and Wilkins pp. 81-86
[3] Hayes, WJ. (1982) Pesticides Studied in Man. Baltimore/London. Williams and Wilkins pp. 77-78; and Spencer, E.Y. (1982) Guide to the chemicals used in crop protection. 7th Edition. Publication 1093. Research institute, Agriculture, Canada, Ottawa, Canada: Information Canada p. 495
[4] Office of Pesticide Programs, United States Environment Protection Agency, "Pesticide Ecotoxicity Database," 2000

Table 5: Results in studies in Japan

Substance	Specimen		Water temperature ºC	Median tolerance limit (ppm)			Reference material
	Fish species	Size (cm)		24h	48h	96h	
Rotenone	Carp	5	25		0.032		Yoshida and Nishiuchi
	Carp	5.3	15	0.01			Nishiuchi
			20	0.01			
			25	0.0084			
			30	0.0052			
			35	0.0022			
Rotenone preparation	Rainbow trout	4.2	17.3	0.0039	0.0036	0.0033	Hashimoto
Pyrethrins	Carp	5	25		1.2		Yoshida and Nishiuchi
	Carp	5.3	15	0.78			Nishiuchi
			20	0.45			
			25	0.55			
			30	0.57			
			35	0.80			
Mineral oils	Carp	4.5	23.5		> 40		Hashimoto and Nishiuchi

Early aquatic toxicity data were reported in terms of tolerance limit, which has been superseded by lethal concentration (LC) and other terms. A simple comparison cannot be made but the median tolerance limit after 96 h and the LC 50 after 96 h are comparable. The Hashimoto's data of 0.0033 ppm is in line with the EPA data (Rainbow trout 0.0019 ppm) in Table 4.

Comparison of Rotenone with Pyrethrins and Mineral oils are also shown in Table 5. Both Pyrethrins and Mineral oil are listed in Table 2 of Annex 2 of GL 32. The data in Table 5 indicate that Rotenone is more toxic to fish than Pyrethrins and Mineral oils.

5. Approved alternatives are not available in sufficient quantity and/or quality

Alternatives are in general available, e.g., Pyrethrins, Neem and mechanical control devices such as sticky bands. However, they are partly effective or even not available for certain crop pests in certain regions.

Assessment against criteria for plant disease or pest and weed control

1. They should be essential for the control of a harmful organism or a particular disease for which other biological, physical, or plant breeding alternative and/or effective management practices are not available

For controlling aphids, Pyrethrins, Neem and mechanical control devices such as sticky bands which are all listed in Table 2 of Annex 2 can be used as substitutes for Rotenone. Those substitutes are not always effective.

2. Their use should take into account the potential harmful impact on the environment, the ecology (in particular non-target organisms) and the health of consumers, livestock and bees

If Rotenone enters waterways, it will negatively impact on the environment by killing fish.

The possibility of harmful impact on non-target organisms in organic fields cannot be precluded because Rotenone is fatal if swallowed, in contact with skin, or inhaled as shown in 4b above.

3. Substances should be plant, animal, microbial, or mineral origin and may undergo the following processed: physical (e.g. mechanical, thermal), enzymatic, microbial (e.g. composting, digestion)

Rotenone is derived from plants mainly through physical processes.

4. Their use may be restricted to specific conditions, specific regions or specific commodities

Flowing of Rotenone into waterways should be restricted.

References

Hashimoto, “Toxicity of Agricultural Chemicals to Aquatic Organisms,” Agri Chemical Production Technology, 1967

Hashimoto and Nishiuchi, “Toxicity of Agricultural Chemicals to Freshwater Organisms – I,” Fishery Stock Enhancement, 1967

International Programme on Chemical Safety, “Group Poisons Information Monograph G 026.”

http://www.inchem.org/documents/pims/chemical/pimg026.htm

Accessed: April 12th, 2007

International Programme on Chemical Safety, “Poisons Information Monograph 474.”

http://www.inchem.org/documents/pims/chemical/pim474.htm

Accessed: April 12th, 2007

Ling, N. “Rotenone – a review of its toxicity and use for fisheries management,” Science for Conservation 211, January 2003, New Zealand Department of Conservation

Nishiuchi, “Toxicity of Agricultural Chemicals to Freshwater Organisms XXXIV - X,” Fishery Stock Enhancement, 1976

Nishiuchi “Toxicity of Agricultural Chemicals to Freshwater Organisms XXXXIV – VII,” Fishery Stock Enhancement, 1977

Office of Pesticide Programs, United States Environment Protection Agency, “Pesticide Ecotoxicity Database,” 2000

United Nations, “Globally Harmonized System of Classification and Labelling of Chemicals (GHS) ,” First revised edition, 2005

http://www.unece.org/trans/danger/publi/ghs/ghs_rev01/01files_e.html

Accessed: April 12th, 2007

Yoshida and Nishiuchi, “Aids for Pesticide Workers,” Bull. Agr. Chem. Inspect. Stn., No. 12, 122, 1972

Project Document

Proposal for New Work – Codex Committee on Food Labelling

PROPOSAL TO AMEND THE GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS

Prepared by: Japan

Purposes and scope of the proposed standard.

The purpose is to delete "preparations of Rotenone from *Derris elliptica, Lonchocarpus, Thephrosia* spp." from Table 2 of Annex 2 or include "the substance should be used in such a way as to prevent its flowing into waterways" in conditions for use.

Its relevance and timeliness.

Rotenone is obtained from the roots of several tropical and subtropical plant species belonging to the genus *Lochancarpus* or *Derris*. The substance is very toxic to aquatic organisms.

Removing Rotenone from Table 2 of Annex 2 or regulating the condition for use is in line with the primary objective of an organic production system to enhance biological diversity within the whole system.

The main aspects to be covered.

Japan proposes to delete "preparations of Rotenone from *Derris elliptica, Lonchocarpus, Thephrosia* spp." from Table 2 of Annex 2 or to restrict its use to prevent its flowing into waterways.

An assessment against the *Criteria for the Establishment of Work Priorities.*

The proposal is consistent with the general criterion as follows:

Ensuring fair practices in the food trade: Some national standards for organically produced foods allow the use of Rotenone, but some do not. There are different regulations on the use of Rotenone, which may cause international disputes.

Relevance to Codex Strategic Objectives.

The proposal is consistent with:

a. Promoting sound regulatory framework; and

b. Promoting maximum application of Codex standards.

Information on the relation between the proposal and other existing Codex documents.

The proposal is an amendment to the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Food*. It does not affect existing Codex documents.

Identification of any requirement for and availability of expert scientific advice.

New Zealand Department of Conservation published a report on the toxicity and use of Rotenone in 2003.[5] The International Programme on Chemical Safety published an evaluation on Rotenone as "the Poisons Information Monograph 474."

Identification of any need for technical input to the standard from external bodies so that this can be planned for.

none

[5] Ling, N. "Rotenone – a review of its toxicity and use for fisheries management," Science for Conservation 211, January 2003, New Zealand Department of Conservation

The proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

If accepted by the 36th CCFL and agreed to undertake through Accelerated Procedure by the 31st CAC, it is expected that a proposed draft will be discussed at Step 4 at the 37th CCFL and adopted at Step 5 of the Accelerated Procedure by the 32nd CAC in 2009.