codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda item 12 **CX/FL 10/38/17**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING
THIRTY-EIGHTH SESSION
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PROPOSAL FOR NEW WORK TO INCLUDE SPINOSAD, POTASSIUM BICARBONATE AND COPPER OCTANOATE IN ANNEX II, TABLE 2, OF THE GUIDELINES FOR PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS

Background

At the CCFL meeting in May 2009 the EU proposed to undertake new work to include three new substances in Annex II, table 2, of the Guideline. In this document the EU comes forward with further justification against the criteria in Section 5.1. of the Guidelines, as requested in section 139 of CL 2009/15-FL.

The proposal is about including three substances in Annex II, Table 2:

1. spinosad as an insecticide
2. potassium bicarbonate as a fungicide
3. copper octanoate as a fungicide.

All three substances are relatively new and have been evaluated in the EU for their use as a pesticides allowed in organic farming.

1. Inclusion of spinosad as an insecticide

Description:
Spinosad is produced by the bacterium Saccharopolyspora spinosa.
It is currently used in organic production in the EU, the US, Switzerland and other countries.

It is mainly used in the control of Lepidoptera (caterpillars), Thysanoptera (thrips) and Diptera (mainly fruit flies and stable flies).
Two basic spray formulations are currently used in different crops: formulations without baits can be used in many crops, while formulations containing baits can be used for fruit fly control (currently in citrus and olives).
A different formulation is used for the control of stable flies.

a) Assessment against general criteria in section 5.1 of the Guidelines
These criteria are intended to be evaluated as a whole in order to protect the integrity of organic production.

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

The use of spinosad is generally in line with principles of organic production. The substance is of microbial origin. It fulfils a number of so far insufficiently covered needs in plant protection. Certain precautions need to be taken when it is used.

2) Use of the substance is necessary/essential for its intended use;

The EU considers that the new substance spinosad is essential for the control of some key pests in organic crops (e.g. thrips in leek, fruit flies in citrus, olive fly).
For some other crop-pest situations, spinosad contributes to the sustainability of production systems that are particularly vulnerable to pests or diseases, as it is often more efficient than the available alternatives and it may contribute to resistance management.

3) Manufacture, use and disposal of the substance does not result in, or contribute to, harmful effects on the environment;

No harmful effects are reported on the manufacturing and disposal of spinosad.
For use: see b) 2).

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

See b)2).

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

See b)1).

b) Justification against specific criteria for substances used for plant disease or pest control in section 5.1 of the Guidelines

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

Spinosad is essential for the control of some key pests (e.g. thrips in leek, fruit flies in citrus, olive fly).
Spinosad is compatible with biological control (e.g. release of predators and parasitoids), provided that direct exposure is avoided.

For many intended uses (crop-pest situations), there are no alternative products or viable methods available. Currently available alternatives: pyrethrum, rotenone, neem, *Bacillus thuringiensis*, granulosis viruses. Some of these may not be available in the future, e.g. rotenone. Where there are alternative products, spinosad will contribute to decrease the risk of pest resistance to the few pesticides available.
Some of the available alternatives are less desirable than spinosad: for example, certain pyrethrum formulations and rotenone show more undesired side-effects.

For some other crop-pest situations, spinosad contributes to the sustainability of production systems that are particularly vulnerable to pests or diseases, as it is often more efficient than the available alternatives and it may contribute to resistance management. For example, in the control of codling moth, alternation of spinosad and granulosis virus decreases the risk of resistance development.

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; and

Environmental fate, hazards and risks of spinosad were assessed in detail during pesticide registration in the EU and authorizations are accompanied by obligations for appropriate risk management practices such as buffer zones.

No concerns were reported on environmental fate of the substance, i.e. rapid photodegradation, and also microbial breakdown. The end-product is CO_2.

Spinosad is hazardous to aquatic organisms and to some non-target insects (pollinators, beneficials):

- Aquatic organisms: spinosad is toxic for aquatic organisms. Authorization procedures have to deal with this risk, requiring e.g. buffer zones or prohibiting air plane spraying.
- Non-target insects: spinosad is highly toxic for Hymenoptera (bees, bumble bees, parasitoid wasps, ants) and earwigs (Dermaptera) when they are directly sprayed or exposed to fresh residues. Authorization procedures have to deal with this risk, requiring e.g. buffer zones to protect terrestrial habitats and prohibiting spraying during flowering periods (to protect pollinators)

Human health risks were assessed in detail during pesticide registration in the EU, and authorizations are accompanied by obligations for appropriate risk management practices (e.g. pre-harvest intervals).
As long as registration requirements are fulfilled (e.g. maximum field rate, maximum number of applications, pre-harvest intervals), the residues of spinosad are not of concern.

3) Substances should be of plant, animal, microbial, or mineral origin and may undergo the following processes: physical (e.g. mechanical, thermal), enzymatic, microbial (e.g. composting, digestion); 7 GL 32-1999

Spinosad is produced by a bacterium. The organism presently used is not a GMO. It is a selected strain.

4) However, if they are products used, in exceptional circumstances, in traps and dispensers such as pheromones, which are chemically synthesized they will be considered for addition to lists if the products are not available in sufficient quantities in their natural form, provided that the conditions for their use do not directly or indirectly result in the presence of residues of the product in the edible parts;

Not applicable.

5) Their use may be restricted to specific conditions, specific regions or specific commodities;

Proposed use condition: as an insecticide, only where measures are taken to minimize the risk to key parasitoids and to minimize the risk of development of resistance.

Spinosad is compatible with biological control (e.g. release of predators and parasitoids), provided that direct exposure is avoided.

Authorizations need to be accompanied by obligations for appropriate risk management practices such as buffer zones and prohibition of spraying during flowering periods.

2. Inclusion of potassium bicarbonate as a fungicide

Description

Potassium bicarbonate is a mineral and is also known as a food additive, INS 501, listed in table 3 of Annex II of CAC GL/32. It can be used as a fungicide under moist conditions, under which potassium bicarbonate dissolves into its ions and only the bicarbonate ion is responsible for the fungicidal effect.
Potassium bicarbonate is used in organic farming in the EU, in the US and other countries to control various fungal diseases in a range of crops.

a) Justification against general criteria in section 5.1
These criteria are intended to be evaluated as a whole in order to protect the integrity of organic production.

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

The use of potassium bicarbonate is generally in line with principles of organic production. The substance is of mineral origin and is also listed as a food additive. It is a useful tool in the control of fungal diseases.

2) Use of the substance is necessary/essential for its intended use;

The EU considers potassium bicarbonate essential for the control of a number of fungal diseases in various crops for which no effective alternatives are available.

3) Manufacture, use and disposal of the substance does not result in, or contribute to, harmful effects on the environment;

No harmful effects are reported on the manufacturing and disposal of potassium bicarbonate.
For use: see b) 2).

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

Residues are no concern. Potassium bicarbonate is also a food additive (INS 501) for organic products.

5) Approved alternatives are not available in sufficient quantity and/or quality.
See b) 1).
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b) Justification against specific criteria for substances used for plant disease or pest 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 alternatives and/or effective management practices are not available.

Potassium bicarbonate is effective against various diseases in a range of crops (some of which are high-value crops), e.g. scab in pome fruit, powdery mildew in various crops, grey mould. It has no systemic action.
For many intended uses (crop-pest situations), copper, sulphur and a few other substances are available. Against grey mould in strawberries, there are no effective alternatives. Varietal resistance is often not sufficient, because fungi break resistance easily.

In general, substances which may complement copper and sulphur are highly desirable in organic farming.
Potassium bicarbonate is a welcome management tool. Reduction of the use of currently available fungicides contributes to the sustainability of the production system.

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; and

Environmental fate, hazards and risks of potassium bicarbonate are assessed in detail during pesticide registration in the EU.

3) Substances should be of plant, animal, microbial, or mineral origin and may undergo the following processes: physical (e.g. mechanical, thermal), enzymatic, microbial (e.g. composting, digestion); 7 GL 32-1999

Potassium bicarbonate is of mineral origin. Both potassium and bicarbonate are ubiquitous in nature. The commercial substance is manufactured from potassium chloride and carbon dioxide.

4) However, if they are products used, in exceptional circumstances, in traps and dispensers such as pheromones, which are chemically synthesized they will be considered for addition to lists if the products are not available in sufficient quantities in their natural form, provided that the conditions for their use do not directly or indirectly result in the presence of residues of the product in the edible parts;

Not applicable.

5) Their use may be restricted to specific conditions, specific regions or specific commodities;

Not applicable.

3. Inclusion of copper octanoate as a fungicide

Description

Copper compounds have been traditionally used in organic farming. The octanoate form is new and has no historic use. Other than the inorganic copper salts used so far, it is a salt of a natural fatty acid. It now used in organic farming in the EU. Copper octanoate is listed by OMRI (Organic Materials Review Institute).

a) Justification against general criteria in section 5.1
These criteria are intended to be evaluated as a whole in order to protect the integrity of organic production.

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

The use of copper octanoate is generally in line with principles of organic production when certain precautions are taken. The substance is of mineral origin. It is a useful tool in the control of fungal diseases.

2) Use of the substance is necessary/essential for its intended use;

Copper octanoate has the same uses as other copper compounds in organic farming, while it can contribute to lower the total amount of copper used.

3) Manufacture, use and disposal of the substance does not result in, or contribute to, harmful effects on the environment;

No harmful effects are reported on the manufacturing and disposal of potassium bicarbonate.
For use: see b) 2).

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

See b) 2).

5) Approved alternatives are not available in sufficient quantity and/or quality.
See b) 1).
.

b) Justification against specific criteria for substances used for plant disease or pest 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 alternatives and/or effective management practices are not available.

In principle, copper octanoate can be used for the same purposes as the other copper compounds and has a similar effectivity. In addition, it has an effect against powdery mildew.
Label rates for copper octanoate (in terms of pure copper ion) are lower than for other copper compounds, both per application and over a season.
Alternative products to copper compounds (e.g. sulphur) and methods are not sufficiently effective.
Inclusion of copper octanoate would be consistent with the current listing of the other copper compounds in Table 1 of the Guidelines.

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; and

Environmental fate, hazards and risks are assessed in detail during pesticide registration in the EU, and authorizations are accompanied by obligations for appropriate risk management practices (e.g. buffer zones).
Environmental issues are the same as for other copper compounds: they are known to pose certain risks to the environment.
The total amount of copper applied per season is lower for copper octanoate than for other copper compounds, if both are used according to label rates. Therefore, copper octanoate may contribute to reduction of copper use.

3) Substances should be of plant, animal, microbial, or mineral origin and may undergo the following processes: physical (e.g. mechanical, thermal), enzymatic, microbial (e.g. composting, digestion); 7 GL 32-1999

Copper is of mineral origin and undergoes saponification with fatty acids. Saponification is also used in manufacture of soft soap.

4) However, if they are products used, in exceptional circumstances, in traps and dispensers such as pheromones, which are chemically synthesized they will be considered for addition to lists if the products are not available in sufficient quantities in their natural form, provided that the conditions for their use do not directly or indirectly result in the presence of residues of the product in the edible parts;

Not applicable.

5) Their use may be restricted to specific conditions, specific regions or specific commodities;

The same restrictions as for other copper compounds should apply.

References

Expert group European Commission http://ec.europa.eu/agriculture/organic/files/eu-policy/expert-recommendations/report_expert_group_en.pdf

EU pesticides database
http://ec.europa.eu/sanco_pesticides/public/index.cfm

Review report for the active substance spinosad
http://ec.europa.eu/food/plant/protection/evaluation/newactive/spinosad_in_en.pdf

Review report of the substance potassium hydrogen carbonate:
http://ec.europa.eu/food/plant/protection/evaluation/existactive/list_potassium-hydrogen-carbonate.pdf

Project Document

Proposal for New Work – Codex Committee on Food Labelling

PROPOSAL TO INCLUDE SPINOSAD, POTASSIUM BICARBONATE AND COPPER OCTANOATE IN ANNEX II, TABLE 2 OF THE GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS

Prepared by: European Union

Purposes and scope of the proposed standard:

The purpose is to include **spinosad**, **potassium bicarbonate** and **copper octanoate** in Annex II, Table 2[1] of the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods.

Its relevance and timeliness:
There is increasing demand for organic products and the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods should be updated on certain technical aspects to keep in line with the development of science and technology in order to remain the global benchmark for organic standards. Availability of appropriate substances for plant pest and disease control is necessary in order to be able to present products of appropriate quality. The proposed substances are authorised in a number of national and international organic standards (e.g. Spinosad: USA, EU, Switzerland; Potassium bicarbonate: USA, EU; Copper octanoate: USA, EU OMRI) and are consistent with the principles of organic production. Acceptance in the Codex Guidelines would contribute to the Codex objective of ensuring fair practices in the food trade.

Spinosad, produced by the bacterium *Saccharopolyspora spinosa*, is essential for the control of some key pests in organic crops (e.g. thrips in leek, fruit flies in citrus, olive fly). For some other crop-pest situations, spinosad contributes to the sustainability of production systems that are particularly vulnerable to pests or diseases, as it is often more efficient than the available alternatives and it may contribute to resistance management. Proposed use condition: as an insecticide, only where measures are taken to minimize the risk to key parasitoids and to minimize the risk of development of resistance. Spinosad is compatible with biological control (e.g. release of predators and parasitoids), provided that direct exposure is avoided. For many intended uses (crop-pest situations), there are no alternative products or viable methods available. Where there are alternative products, spinosad will contribute to decrease the risk of pest resistance to the few pesticides available.

Potassium bicarbonate is effective against various diseases in a range of crops (some of which are high-value crops), e.g. scab in pome fruit, powdery mildew in various crops, grey mould. Both potassium and bicarbonate are ubiquitous in nature. The commercial substance is manufactured from potassium chloride and carbon dioxide. Potassium bicarbonate is also a food additive (INS 501) listed in Table 3 of Annex II of GL 32. It does not pose environmental or human health concerns. For many intended uses (crop-pest situations), copper, sulphur and a few other substances are available. Against grey mould in strawberries, there are no effective alternatives. Varietal resistance is often not sufficient, because fungi break resistance easily.
In general, substances which may complement and/or reduce copper and sulphur use are highly desirable in organic farming as they contribute to the sustainability of the production system.

[1]Table 2: Substances for plant pest and disease control

The new substance copper octanoate (mineral copper that has undergone saponification with fatty acids) can be used for the same purposes as the other copper compounds already included in table 2 and has a similar effectivity. In addition, it has an effect against powdery mildew. Moreover, label rates for copper octanoate (in terms of pure copper ion) are lower than for other copper compounds, both per application and over a season. Inclusion of copper octanoate would be consistent with the current listing of the other copper compounds in table 2. Environmental issues are the same as for other copper compounds: they are known to pose certain risks to the environment. The total amount of copper applied per season is lower for copper octanoate than for other copper compounds, if both are used according to label rates.

The main aspects to be covered:
It is proposed to add three new entries in Table 2 of Annex II for Spinosad, Potassium Bicarbonate and Copper Octanoate.

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

The proposal is consistent with the criteria as follows:

Volume of production and consumption in individual countries and volume and pattern of trade between countries. There is substantial and growing trade in organic products.

Diversification of national legislations and apparent resultant or potential impediments to international trade. Some national standards allow for the use of the proposed substances, but some do not. This may lead to impediments in trade.

International or regional market potential. There is significant potential to develop trade in organic products.

Coverage of the main consumer protection and trade issues by existing or proposed general standards. The use of the proposed substances is not covered at present.

Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental bodies). The use of the 3 proposed substances is supported by Organic Materials Review Institute and the International Federation of Organic Agriculture Movements.

Relevance to Codex Strategic Objectives.

The proposal is consistent with:
a. Promoting sound regulatory framework
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 other existing Codex documents.

Identification of any requirement for and availability of expert scientific advice.
None identified.

Identification of any need for technical input to the standard from external bodies so that this can be planned for.
None identified.

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.

Proposed to start by CCFL in 2011. As this is a straightforward amendment it is expected that it should be completed and adopted by the Commission in 2012 or 2013.