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AGENDA ITEM NO. 5(b) **CX/FL 11/39/9**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING

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PROPOSED DRAFT REVISION OF THE GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS (GL 32-1999)

Report of the Electronic Working Group on the Review of the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods

This document includes the report of the electronic working group and

- a Proposed Redraft of the Structured Work Approach (Appendices III and XI)
- a Draft Template for Review of New Substance additions to Annex 2 (Appendix IV)
- applications of the draft review template
  - Proposal for New Work to include Spinosad, Potassium Bicarbonate and Copper Octanoate in Annex 2, Table 2 CX/FL 10/38/17; (Appendices V – VII) and
  - Expansion of Other Uses of Ethylene for Degreening of Citrus Fruit, for the Induction of Flowering in Pineapples and for Sprout Inhibition in Potatoes and Onions (this replaces document CX/FL 11/39/8) (Appendices VIII –X)

I. BACKGROUND

The Codex Committee on Food Labelling (CCFL) held its 38th session on May 2010 and agreed to establish an electronic working group (eWG) to:

- Review proposals for new substances that should be included in the list of permitted substances for the production of organic foods under Annex 2 of the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods; (CAC/GL 32-1999);
- Propose revisions to other sections of these Guidelines, if needed. (ALINORM 10/33/22); and,
- Review proposals for new substances using a two year cycle.

For the 2010-12 review cycles, the Committee agreed that the United States will chair the eWG, which will review the substances nominated by the European Union at the 38th CCFL Session: spinosad, potassium bicarbonate, copper octanoate and ethylene. Three uses of ethylene were separately considered: degreening of citrus fruit, induction of flowering in pineapples, and sprout inhibition in potatoes and onions.

The Committee established the following terms of reference (TOR) for this electronic working group (ALINORM 10/33/22 paras 126-130):

- Review substances proposed at the 38th session of CCFL (Agenda Item 5a and 12a) (spinosad, potassium bicarbonate, copper octanoate, and ethylene) to be included in Annex 2 of the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods* (CAC/GL 32-1999);
- Identify additional data that may be needed to satisfy Section 5.1 criteria and undertake to collect such data from the submitting countries and/or from members of the eWG;
- Make recommendations to the 39th session of CCFL on whether these substances should be included in Annex 2; and,

- Provide advice to the Committee on the utility of a working group approach to facilitate a two-year cycle regarding substances to be included in Annex 2.

II. PARTICIPATION IN THE eWG

In October 2010, the United States as current chair of this eWG, invited all CCFL members to participate in the eWG on the review of the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods*. Ten countries, one member organization, and one observer expressed interest in participating in this eWG. A list of participants is provided in *Appendix I*.

In December 2010, the United States distributed to eWG members a compilation of all of the submitted comments and a draft discussion document summarizing the comments and findings. The United States requested that eWG members provide additional comments on the need for additional data to satisfy Section 5.1 criteria and the use of a structured working group approach to the review of Annex 2 substances. The eWG also asked members the following questions regarding the 5.1 criteria: (1) do members believe that using a standard review template for evaluation of the 5.1 criteria is helpful; and (2) do members have suggestions for additional guidance per the 5.1 criteria.

Additional questions were raised as to whether this eWG should be responsible for determining whether proposed substances fall outside the scope of Annex 2and for reviewing these substances—for example, ethylene used for ripening of bananas and other tropical fruits, which is covered under Annex I. Another question posed was whether substances outside the scope of Annex 2 should be subject to the 5.1 criteria. The United States requested that any additional comments Members have on these questions be submitted by February 1, 2010.

Comments received in response to the draft discussion paper and proposed revised text formed the basis of this working group report submitted to the Secretariat for consideration by the 39th session of CCFL. For information, the updated timeline for the work of this eWG is provided in *Appendix II*.

III. REVIEW OF ANNEX 2 SUBSTANCES: SPINOSAD, POTASSIUM BICARBONATE, COPPER OCTANOATE, AND ETHYLENE

A. Summary of Responses

A total of seven responses were received on the initial request for comments dated October 2010.

The responses included comments from five countries (Australia, Brazil, Croatia, the United Kingdom, and the United States), the European Union, and the International Federation of Organic Agriculture Movements (IFOAM).

A total of six responses were received from four countries (Switzerland, Canada, Australia, and Croatia), the European Union, and IFOAM on the second request for comments. The comments received by this eWG generally supported including spinosad, potassium bicarbonate and copper octanoate, and ethylene for fruit fly control in citrus and as an agent to control flowering in pineapples in the list of substances permitted for the production of organic foods found in Annex 2 (CAC/GL 32-1999).

In general, the majority of comments did not elaborate on how each substance met the criteria of section 5.1. One country suggested that a standard template that has both the application information and member comments on each substance might facilitate review. To that end, a template was created for evaluating substances based on the criteria under Annex 2 of the Guidelines in conjunction with the comments received on each substance. The template also provides additional guidance on supporting justifications for substances and data requirements. (*See Appendix IV).* The comments received by the eWG supported the use of a standard template as it ensures consistency in the information submitted by applicants for new work proposals and provides clear guidance to members seeking to add or remove new substances.

(a) Spinosad (see Appendix V)

The eWG generally supports the approval of spinosad as an insecticide under Annex 2, Table 2. Based on the comments received, spinosad is currently used in organic production in the European Union, the United States, Switzerland and Brazil. The European Union application on spinosad addressed each of the 5.1 criteria and included data and research that supported their responses. However, some members noted that precautions should be taken to minimize the risks to species of non-target insects, predators and parasites and the development of resistance, with specific mention of concern for aquaculture and bees. Some

members indicated that factors of time, frequency and climatic conditions for application would minimize such risks**.**

To address the issue of appropriate use conditions or restrictions, members of the eWG offered the following statements for inclusion in Table 2:

- Need, prescription and application rates recognized by certification body or authority
- Use only where measures are taken to minimize the risk to parasitoids and to minimize the risk of development of resistance

Another member suggested that the Committee establish a two-year post evaluation period for any limitations that would occur during the application of spinosad and other pesticides that are included in the future.

(b) Potassium Bicarbonate (see Appendix VI)

The eWG generally supports the approval of potassium bicarbonate as a fungicide in Annex 2, Table 2. The submission by the European Union addressed each of the 5.1 criteria and included data and research that supported their responses. Based on the comments received, potassium bicarbonate can be used as a fungicide under moist conditions where it dissolves and only the bicarbonate ion causes the fungicidal effect. Some members confirmed that potassium bicarbonate is used to control various fungal diseases in a range of crops in organic farming in the European Union, Brazil, United States, as well as other countries. Potassium bicarbonate is already approved as a food additive under Annex 2, Table 3. The eWG did not identify any deficiencies in the data and background research submitted. No statements for use were submitted.

(c) Copper Octanoate (see Appendix VII)

The eWG generally supports the approval of copper octanoate as a fungicide under Annex 2, Table 2. The submission by the European Union addressed each of the 5.1 criteria and their responses were supported by data and research. Based on the comments received, copper salts are widely used as fungicides in organic production systems. One member noted concern with the accumulations of copper in soils and plant tissues; however, the use of copper octanoate should reduce the amount of copper needed to achieve the same fungicidal outcome as other copper salts. One observer highlighted that the use of copper octanoate is restricted to the maximum application amount of 8kg/ha on a rolling average basis. In their application, the European Union stated that accumulation should not be problematic if rates for use on the label are followed, and the European Union maximum use rate is 6kg/ha.

To address the issue of appropriate use conditions, members of the eWG offered the following:

- Inclusion of a general restriction for a maximum annual amount for all copper preparations as opposed to a specific restriction on copper octanoate.
- Existing phrasing on copper in general is sufficient and that there is no need for a specific restriction on the use of copper octanoate.

(d) ***Ethylene (see Appendix VIII-X)***

-for degreening of citrus fruit,

-for the induction of flowering in pineapples,

-and for sprout inhibition in potatoes and onions.

The EU circulated the justification submitted jointly by the EU and Costa Rica for the above three uses of ethylene to eWG members on February 1, 2010. One member supported the justification for all three uses. One member supported the use of ethylene as an agent for fruit fly control in citrus and agreed only in principle to the other two uses. This same member also remarked that more information would be helpful on how ethylene as a sprout inhibitor in potatoes and onions meets the Section 5.1v requirements. One member similarly supported all the proposed uses of ethylene except for the use of ethylene as an inhibiting agent to control sprouting in potatoes and onions because alternative practices and natural materials are available for sprout inhibition.

The eWG generally supports the approval of ethylene for degreening of citrus fruit, and for flower induction in pineapple. However, it is unclear where these uses for ethylene should be listed under Annex 2. The eWG did not fully agree on approving the use of ethylene as an inhibiting agent to control sprouting in potatoes and onions.

B. Recommendation on Whether These Substances Should be Included in Annex 2.

The eWG supports including spinosad, potassium bicarbonate, copper octanoate, and ethylene for use for the degreening of citrus fruit and use as an agent to control flowering in pineapples in Annex 2, Table 2 of the Guidelines for Production, Processing, Labelling and Marketing of Organically Produced Foods as outlined in the discussion paper CX/FL 10/38/17 and recommends incorporation of the following insertions to Table 2:

TABLE 2: SUBSTANCES FOR PLANT PEST AND DISEASE CONTROL

Substance	Description; compositional requirements; conditions for use
I. Plant and Animal	
[Spinosad]	[Need recognized by the certification body or authority] [Need, prescription and application rates recognized by certification body or authority] [Use only where measures are taken to minimize the risk to parasitoids and to minimize the risk of development of resistance]
II. Mineral	
Copper in the form of copper hydroxide, copper oxychloride, (tribasic) copper sulfate,[copper octanoate], cuprous oxide, Bordeaux mixture and Burgundy mixture	Need, prescription and application rates recognized by certification body or authority. As fungicide on condition that the substance be used in such a way as to minimize copper accumulation in the soil.[1] [[1]Members should set limits for the maximum application on a national level taking into account pedo-climatic conditions type of crops and periodic disease attacks]
[Potassium Bicarbonate]	[--------]

The eWG is unable to make a final determination on the use of ethylene for sprout inhibition in potatoes and onions.

IV. ADVICE TO THE COMMITTEE ON THE UTILITY OF A WORKING GROUP APPROACH TO REVIEW SUBSTANCES TO BE INCLUDED IN ANNEX 2. (see Appendices III and XI)

A. Summary of Responses

At the 38th CCFL session, the Committee agreed to a review process using a 2-year cycle to consider proposals for the inclusion of new substances in Annex II. (ALINORM 10/33/22, para 122 and CRD 15)

EWG participants expressed no objections to the review process agreed upon at the 38th CCFL session and proposed only a few improvements to the process. This modified review process is outlined in Appendix I of this report.

Based on the comments received, the eWG generally favored the use of an electronic working group forum for reviewing new substances. One eWG member mentioned that the order in which new or existing work

proposals be reviewed should be based according to its level of priority. An observer suggested that the entire *Guidelines for the Production, Processing and Labelling and Marketing of Organically Produced Foods* should be reviewed every four years. Some comments also mentioned that the additional criteria as outlined in section 8.3 of the United States discussion paper CX/FL 10/38/11 are not needed, and the United States agreed with this assessment.

The comments received by the eWG supported the use of a standard template (*See Appendix IV*) to ensure there is consistent information submitted by applicants for new work proposals and to provide clear guidance to Members seeking to add or remove new substances. It was noted by several members that further alterations to the template may be required as the review process evolves. One member also highlighted the importance of data such as scientific reports or manufacturing statements to help determine whether substances and any associated ingredients satisfy Section 5.1 criteria.

Australia suggested that the eWG draw from the Codex Committee on Food Hygiene's model for establishing work priorities and also suggested the development of a flow chart to more clearly illustrate the process for a new work proposal, but did not submit a revised review process or flowchart reflecting these suggestions.

Comments also generally supported limiting the scope of the eWG to the review of substances within the scope of Annex 2 until the Committee determines whether substances falling outside the scope of Annex 2 should be subject to the 5.1 criteria.

B. Recommendation

Additional consideration of the Annex III Proposed Redraft of Structured Work Approach may be needed in consideration of the comments made by Australia in regards to improvement of the text.

APPENDIX I: LIST OF PARTICIPANTS

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APPENDIX II: UPDATED Timeline

Completed	Letter of invitation to join the eWG and request for comments on proposed substances and structured work approach sent to member countries and observers
Completed	Expressions of interest and comments on proposed substances and structured work approach received.
Completed	Draft discussion paper containing recommendation on proposed new substances and draft redrafted Structured Work Approach (taking into account comments received in response to CRD 15) sent to eWG members
Completed	Comments due from eWG on draft discussion paper and redrafted Structured Work Approach
March 25, 2011	Final discussion paper (incorporating comments received from eWG members) sent to Codex Secretariat for distribution and consideration at the 39th session of CCFL in May 2011

APPENDIX III

Proposed Redraft of the Structured Work Approach

Existing Difficulties with the Organic Review Process

- Specialized technical expertise may be needed for the review of new work proposals. This expertise traditionally has not been available at each session.
- Proposals for new work have not been submitted in time for adequate review by technical experts prior to the Committee meetings.
- Proposals are often not complete and have not systematically addressed the criteria established in section 5.1 of the Guidelines.
- Annex 2 lists are indicative and do not necessarily require annual updating.
- Participation by members is limited; especially by developing countries

Recommended Approach

- A timely structured review process that conserves Committee resources.
- A two year cycle for proposals.
- The use of an Organic electronic working group (eWG) to evaluate proposals and prioritization of new work for the Committee.
- Development and use of a standard template for application and collection of comments
- Chairpersonship of the eWG would rotate from country to country; where a country is proposing new work they should not be eligible to chair the eWG.
- If no proposals for new work are submitted, then the eWG would not be constituted.

Recommended Procedures for a Two Year Review Cycle For Proposals

- Year one: Proposals submitted to the Secretariat. The Committee will establish an eWG for submitting proposals.
    - Proposals for new work should be submitted 60 days prior to the plenary, so that members might have ample time for review prior to the plenary.
    - At the plenary in Year 1, the Committee would discuss basic sufficiency of the proposals. If the Committee reaches consensus that one or more proposals are sufficient, the Committee will establish a eWG and the proposals for new work under Annex 2 will go forward to the Commission for approval as a Step 1/3 document. If there is insufficient interest from members to undertake the work on a particular substance, the Member may submit the proposal for discussion again at the next cycle; this excludes any request for additional information relating to an existing new work proposal. The Committee could decide whether to have the eWG review substances that fall outside of Annex 2 at its discretion.

    - In between year one and two the eWG will undertake review of the assigned proposals and prepare a recommendation for the Committee in year two.
    - For Annex 2 revisions the eWG will review the information and provide a report as to whether the criteria in section 5.1 have been satisfied. The eWG may seek additional data as necessary for completion of proposals.

- Year two: The Committee discusses the recommendations of the eWG.

    - For Annex 2 revisions, if the Committee agrees to approve the proposals, they would advance to Step 5/8.

If no proposals for new work come forward, then the eWG would not be constituted.

APPENDIX IV: **Draft Template for Review of New Substance additions to Annex 2**

Substance: (name of substance)

Use: (Please highlight which apply: fertilization, soil conditioning purposes, plant disease or pest and weed control, additives or processing aids in the preparation or preservation of the food)

Applicable specific criteria: (a,b,c)

Submitted By: (name of submitting country(ies)

Assessment against Section 5.1 Criteria	
I. General Description of Substance	
Member/ Observer	**Description**
II. Section 5.1 General Criteria (all criteria in this section should be addressed)	
5.1.i) Is the substance consistent with the principals of organic production as outlined in the Guidelines?	
Member/ Observer	**Answer**
5.1.ii) Is use of the substance necessary/essential for its intended use?	
Member/ Observer	**Answer**
5.1.iii) Does the manufacture, use and disposal of the substance result in, or contribute to, harmful effects on the environment?	
Member/ Observer	**Answer**
5.1.iv) Does the substance have the lowest negative impact on human or animal health and quality of life?	
Member/ Observer	**Answer**
5.1.v) Are approved alternative available in sufficient quality or quantity?	
Member/ Observer	**Answer**
Has the applicant adequately addressed the general criteria in section 5.1?	
Member/	**Answer**

Observer	

III. Section 5.1 Specific Criteria: a) substance used for fertilization, soil conditioning purposes

5.1.a)1) Is the substance essential for obtaining or maintaining the fertility of the soil or to fulfill specific nutrition requirements of crops, or specific soil –conditioning and rotation purposes which cannot be satisfied by the practices included in Annex 1, or other products included in Table 2 of Annex 2?

Member/ Observer	Answer

5.1.a)2) Is the substance of plant, microbial or mineral origin? Has it undergone any of the following processes: physical (mechanical, thermal), enzymatic, microbial (composting, fermentation)? Has the substance undergone any chemical processes? Are these limited to for the extraction of carriers and binders?

Member/ Observer	Answer

5.1.a)3) Does the substance use have a harmful impact on the balance of the soil ecosystem or the physical characteristics of the soil, or water and air quality?

Member/ Observer	Answer

5.1.a) 4) Should the substance use be restricted to specific conditions , specific regions, or specific commodities?

Member/ Observer	Answer

Has the applicant adequately addressed the specific criteria in section a) for substances used for fertilization, soil conditioning purposes?

Member/ Observer	Answer

IV. Section 5.1 Specific Criteria: b) substance used for the purpose of plant disease or pest and weed control

5.1.b)1) Is the substance 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?

Member/ Observer	Answer

5.1.b)2) Does its use 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?

Member/ Observer	Answer

5.1.b)3) Is the substance of plant, microbial or mineral origin? Has it undergone any of the following processes: physical (mechanical, thermal), enzymatic, microbial (composting, fermentation)?	
Member/ Observer	**Answer**

5.1.b)4) Is the substance used in traps are as a dispenser of pheromones which are chemically synthesized? Are there alternatives products available in sufficient quantities in their natural form? Do the conditions of use directly or indirectly result in the presence of residues on edible parts of the product?	
Member/ Observer	**Answer**

5.1.b)5) Should the substance use be restricted to specific conditions , specific regions, or specific commodities?	
Member/ Observer	**Answer**

Has the applicant adequately addressed the specific criteria in section b) substances used for the purpose of plant disease or pest and weed control?	
Member/ Observer	**Answer**

V. Section 5.1 Specific Criteria: c) substance used as additives or processing aids in the preparation or preservation of the food

5.1.c)1) For additives, is it possible to produce or preserve the food without the additive? For processing aids, is it possible to produce the food without the processing aid? Is there any other available technology which would satisfy the Guidelines?	
Member/ Observer	**Answer**

5.1.c)2) Is the additive or processing aid found in nature? Has it undergone mechanical/physical processes (eg. extraction, precipitation), biological/enzymatic process or microbial processes (eg. fermentation)?	
Member/ Observer	**Answer**

5.1.c)3) Is it a chemically synthesized additive or processing aid ? Is there an absence of natural substances?	
Member/	**Answer**

Observer	

5.1.c)4) Does the use of the additive or processing aid maintain the authenticity of the product?	
Member/ Observer	**Answer**

5.1.c)5 Would the addition of the additive or processing aid cause the consumer to be deceived concerning the nature, substance and quality of the food?	
Member/ Observer	**Answer**

5.1.c)6) does the addition of the additive or processing aid detract from the overall quality of the product?	
Member/ Observer	**Answer**

Has the applicant adequately addressed the specific criteria in section c) substances used as additives or processing aids in the preparation or preservation of the food	
Member/ Observer	**Answer**

VI. General questions for all proposals

Is there any information needed to complete the review of the new substance? (Please include links to supporting research here)	
Member/ Observer	**Answer**

Are any additional conditions of use needed?	
Member/ Observer	**Answer**

Would you support the addition of the new substance in Annex 2?	
Member/ Observer	**Answer**

APPENDIX V: Spinosad

Review of New Substances Proposed for Inclusion In Annex 2

A. Substance: Spinosad
B. Use: As an insecticide
C. Applicable sub-criteria: Section 5.1 Sub-Criteria: b) used for the purpose of plant disease or pest and weed control.
D. Submitted By: European Union

Assessment against Section 5.1 Criteria	
General Description of Substance	
Member/ Observer	**Description**
EU submission-CX/FL 10/38/17	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.
United States	Description is accurate.
I. Section 5.1 Main Criteria	
5.1.i) Is the substance consistent with the principals of organic production as outlined in the Guidelines?	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	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.
Australia	Australia supports the inclusion of spinosad into Annex 2, Table 2 of the Guidelines for Production, Processing, Labelling and Marketing of Organically Produced Foods as an insecticide, however due to the potential health risk to aquatic animals and bees, Australia would support risk management practices can be introduced by organic operators to effectively manage any environmental or animal health concerns.
Brazil	The insecticide spinosad is a product developed from a naturally occurring bacterium in soil, discovered in 1982 and produces compounds from fermentation metabolites. The first formulated with secondary fermentation metabolite was produced in 1988. It is considered strategic for the control of certain pests and contribute to the sustainability of organic production system. Meets the principles of organic farming, which allows the use of microorganisms derived from properly identified, as well as the requirements of Section 5.1 of the Guidelines. The product is accepted by the regulations contained in the organic and NOP / USA and EC 404/2008. For its use should be taken to minimize the risks to species of non-target insects, predators and parasites and the development of resistance, observing that for the

	time, frequency and climatic conditions for application. The spinosad is registered with the competent agency of Brazil, for use in conventional agriculture and its inclusion in Appendix II, Table 2, Standards of Production, Processing, Labelling and Marketing of Organically Produced Foods will include the resulting product to the Brazilian legislation specifies management and control of pests and diseases on plants in organic production systems.
United Kingdom	With regard to the proposals for new substances in CX/FL 10/38/17 the UK concurs with the views expressed by the European Union on these issues but would like to express particular concern that measures must be taken to ensure spinosad is not used in cases where either water courses or non-target insects could be damaged by such use. The possibility that pollinators could be harmed is of serious concern but can be dealt with by imposing stringent requirements with regard to the times of year at which spinosad may be used to ensure such insects are not present.
United States	Under the National Organic Program regulations, biological substances, such as spinosad, may be applied to prevent, suppress, or control, pests when mechanical or physical methods are insufficient, provided that the conditions for using the substances are documented in the organic system plan.
IFOAM	IFOAM supports taking up Spinosad, Potassium bicarbonate and Copper Octanoate as new work for possible inclusion into Annex 2. IFOAM's Basic Standards allow for use of all three of these substances in organic production although there are some restrictions on copper octanoate (max. amount of 8kg/ha on a rolling average basis). The assessment against the criteria, made by the European Union is considered as consistent and sufficient.

5.1.ii) Is use of the substance necessary/essential for its intended use?	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	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.
United States	May be used when other pest management practices fail in the National Organic Program Regulations.

5.1.iii) Does the manufacture, use and disposal of the substance result in, or contribute to, harmful effects on the environment?	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	No harmful effects are reported on the manufacturing and disposal of spinosad. For use: see 5.1.b)2) below.
United States	Concur with EU statement.

5.1.iv) Does the substance have the lowest negative impact on human or animal health and quality of life?	
Member/	**Answer**

Observer	
EU submission-CX/FL 10/38/17	It has the lowest negative impact on human or animal health and quality of life; See 5.1.b)2) below.
Australia	Australia supports the inclusion of spinosad into Annex 2, Table 2 of the Guidelines for Production, Processing, Labelling and Marketing of Organically Produced Foods as an insecticide, however due to the potential health risk to aquatic animals and bees, Australia would support risk management practices can be introduced by organic operators to effectively manage any environmental or animal health concerns.
United States	Concur when used as directed according to label recommendations and precautions.
5.1.v) Are approved alternative available in sufficient quality or quantity?	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	Approved alternatives are not available in sufficient quantity and/or quality. See 5.1.b)1) below.
United States	Alternatives are not as effective.
Has the applicant adequately addressed the main criteria in section 5.1?	
Member/ Observer	**Answer**
United States	Yes.
III. Section 5.1 Sub-Criteria: b) substances used for the purpose of plant disease or pest and weed control	
5.1.b)1) Is the substance essential for the control of a harmful organism or a particular disease ?	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	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 CX/FL 10/38/173. 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.
United States	Is valuable for control of pests.

5.1.b)2) Does their use 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?

Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	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 CO2. 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.
United States	Use should be consistent with label warnings for applications of product.

5.1.b) 3) Is the substance of plant, microbial or mineral origin? Has it undergone any of the following processes: physical (mechanical, thermal), enzymatic, microbial (composting, fermentation)?

Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	Spinosad is produced by a bacterium. The organism presently used is not a GMO. It is a selected strain.
United States	Concur with EU statement.

5.1.b)4) Is the substance used in traps are as a dispenser of pheromones which are chemically synthesized? Are there alternatives products available in their natural form? Do the conditions of use result in the presence of residues on edible parts of the product?

Member/ Observer	Answer
EU submission-CX/FL 10/38/17	Not applicable.
United States	N/A
5.1.b) 5) Should the substance use be restricted to specific conditions, specific regions, or specific commodities?	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	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.
United States	Use should be consistent with label warnings for applications of product.
Has the applicant adequately addressed the sub-criteria in section b) substances used for the purpose of plant disease or pest and weed control	
Member/ Observer	**Answer**
United States	Yes.
Is there any information needed to complete the review of the new substance (including supporting documents)?	
Member/ Observer	**Answer**
United States	For further information here is the link to the U.S. National Organic Standards Board, Technical Advisory Panel Report on spinosad: : http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5089350

APPENDIX VI: Potassium Bicarbonate

Review of New Substances Proposed for Inclusion In Annex 2

A. Substances: Potassium bicarbonate
B. Use: As a fungicide
C. Applicable sub-criteria: Section 5.1 Sub-Criteria: b
D. Submitted By: (See CX/FL/17 and CX/FL 10/38/17-Add.1 and CL2009/15-FL, ALINORM 09/32/22/Appendix IV))

Assessment against Section 5.1 Criteria	
General Description of Substance	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	Potassium bicarbonate is a mineral and is also known as a food additive, INS 501, listed in table 3 of Annex 2 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.
United States	Potassium bicarbonate appears in the National Organic Program regulations list for substances that can be used for plant diseases.
I. Section 5.1 Main Criteria	
5.1.i) Is the substance consistent with the principals of organic production as outlined in the Guidelines?	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	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.
Australia	Australia supports the inclusion of potassium bicarbonate into Annex 2, Table 2 of the Guidelines for Production, Processing, Labelling and Marketing of Organically Produced Foods as a fungicide.
Brazil	We agree with the inclusion of potassium bicarbonate as a fungicide, considering meets the principles of organic production and the requirements of Section 5.1 of the Guidelines, and recommended its inclusion in Appendix II, Table 2, Standards of Production, Processing, Labelling and Food Marketing Organically Produced Potassium bicarbonate is obtained by mineral and is also used as food additive (INS 501), listed in Table 3 of Annex 2 of CCS GL/32. Can be used in most conditions in which it is necessary to control phytopathogenic fungi, occurs when an ionic dissolution and bicarbonate only has fungicidal effect. It is being used in several countries in various cultures. Its use helps to reduce the total amounts of copper salts (Cu) and sulfur (S) applied to the control of fungal diseases, a fact highly desirable in organic farming. The reasons cited include the requirements of Section 5.1 of the Rules. The current legislation for management and control of pests and diseases in vegetable production in organic systems has already made a bicarbonate (baking soda) and the inclusion of potassium bicarbonate is to increase the options for the organic farmer, and his inclusion of interest in Appendix II, Table 2, Standards of Production, Processing, Labelling and Marketing of Organically Produced Foods.

United States	Its use is recognized in organic production.
IFOAM	IFOAM supports taking up Spinosad, Potassium bicarbonate and Copper Octanoate as new work for possible inclusion into Annex 2. IFOAM's Basic Standards allow for use of all three of these substances in organic production although there are some restrictions on copper octanoate (max. amount of 8kg/ha on a rolling average basis). The assessment against the criteria, made by the European Union is considered as consistent and sufficient.

5.1.ii) Is use of the substance necessary/essential for its intended use?

Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	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.
United States	Would agree with the EU's statement.

5.1.iii) Does the manufacture, use and disposal of the substance result in, or contribute to, harmful effects on the environment?

Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	No harmful effects are reported on the manufacturing and disposal of potassium bicarbonate. For use: see 5.1.b)2) below
United States	No harmful effects reported.

5.1.iv) Does the substance have the lowest negative impact on human or animal health and quality of life?

Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	Residues are no concern. Potassium bicarbonate is also a food additive (INS 501) for organic products.
United States	Yes low impact.

5.1.v) Are approved alternative available in sufficient quality or quantity?

Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	See 5.1.b)1) below

United States	Alternatives are not as effective.
Has the applicant adequately addressed the main criteria in section 5.1?	
Member/ Observer	**Answer**
United States	Yes.
III. Section 5.1 Sub-Criteria: b) substances used for the purpose of plant disease or pest and weed control	
5.1.b)1) Is the substance essential for the control of a harmful organism or a particular disease ?	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	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.
United States	It is essential for control of powdery mildew.
5.1.b)2) Does their use 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?	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	Environmental fate, hazards and risks of potassium bicarbonate are assessed in detail during pesticide registration in the EU.
United States	Label requirements would express concerns for non-target organisms.
5.1.b)3) Is the substance of plant, microbial or mineral origin? Has it undergone any of the following processes: physical (mechanical, thermal), enzymatic, microbial (composting, fermentation)?	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	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.
United States	Mineral origin with benign components.

5.1.b)4) Is the substance used in traps are as a dispenser of pheromones which are chemically synthesized? Are there alternatives products available in their natural form? Do the conditions of use result in the presence of residues on edible parts of the product?	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	Not applicable.
5.1.b)5) Should the substance use be restricted to specific conditions , specific regions, or specific commodities?	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	Not applicable.
Is there any information needed to complete the review of the new substance?	
Member/ Observer	**Answer**
United States	Yes.
Is there any information needed to complete the review of the new substance (including supporting documents)?	
Member/ Observer	**Answer**
United States	For further information here is the link to the U.S. National Organic Standards Board, Technical Advisory Panel Report on potassium bicarbonate: **http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5067008&acct=nopgeninfo**

APPENDIX VII: Copper Octanoate Template

Review of New Substances Proposed for Inclusion In Annex 2

A. Substances: Copper octanoate
B. Use: As a fungicide
C. Applicable sub-criteria: Section 5.1 Sub-Criteria: b
D. Submitted By: (See CX/FL/17 and CX/FL 10/38/17-Add.1 and CL2009/15-FL, ALINORM 09/32/22/Appendix IV))

Assessment against Section 5.1 Criteria	
General Description of Substance	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	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).
United States	Agree with EU statement and copper octanoate would be considered a fixed copper substance covered under the National Organic Program Regulations list for plant disease inputs.
I. Section 5.1 Main Criteria	
5.1.i) Is the substance consistent with the principals of organic production as outlined in the Guidelines?	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	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.
Australia	Australia supports the inclusion of copper octanoate into Annex 2, Table 2 of the Guidelines for Production, Processing, Labelling and Marketing of Organically Produced Foods as a fungicide.
Brazil	We agree with the proposal for inclusion of copper octanoate considering the principles of organic production, set forth in Section 5.1 of the Guidelines, and recommended its inclusion in Appendix II, Table 2, Standards of Production, Processing, Labelling and Organically Produced Food Marketing. Copper octanoate is a new formulation of copper that can be used for the same goal as other copper compounds already included in Part B of Annex II of Regulation (EEC No 2092/91). The total amount of copper applied per season is lower when using the copper octanoate, both in total and in each application The copper salts are still widely used as fungicides in organic production systems and there is great concern with accumulations in soils and plant tissues. Several bodies of conformity assessment, as certifiers, limit the amount of copper applied per crop and / or per hectare per year. In southern Brazil the control disease in grape production uses organic copper salts intensely for control of fungal diseases, especially during growth and flowering, usually very wet, with the accumulation of copper a constant cause of concern and measures monitoring.

	In this sense the use of copper octanoate should be considered as positive because it reduces the amount actually needed to achieve the same fungicidal effect than using other copper salts.
United States	Agree with EU statement, must be used in a manner that minimizes accumulation in the soil.
IFOAM	IFOAM supports taking up Spinosad, Potassium bicarbonate and Copper Octanoate as new work for possible inclusion into Annex 2. IFOAM's Basic Standards allow for use of all three of these substances in organic production although there are some restrictions on copper octanoate (max. amount of 8kg/ha on a rolling average basis). The assessment against the criteria, made by the European Union is considered as consistent and sufficient.

5.1.ii) Is use of the substance necessary/essential for its intended use?

Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	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.
United States	Agree with EU statement.

5.1.iii) Does the manufacture, use and disposal of the substance result in, or contribute to, harmful effects on the environment?

Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	No harmful effects are reported on the manufacturing and disposal of copper octanoate. For use: see b) 2).
United States	As effects on the environment, fixed coppers must be used in a manner that minimizes accumulation in the soil.

5.1.iv) Does the substance have the lowest negative impact on human or animal health and quality of life?

Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	See 5.1.b)2) below
United States	When used in a manner consistent with label requirements.

5.1.v) Are approved alternative available in sufficient quality or quantity?

Member/ Observer	**Answer**
EU submission-	See 5.1.b)1) below

CX/FL 10/38/17	
United States	Hard to replace fixed copper substances because other products have reduced efficacy.
Has the applicant adequately addressed the main criteria in section 5.1?	
Member/ Observer	**Answer**
United States	Yes
III. Section 5.1 Sub-Criteria: b) substances used for the purpose of plant disease or pest and weed control	
5.1.b)1) Is the substance essential for the control of a harmful organism or a particular disease ?	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	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.
United States	Agree with EU statement.
5.1.b)2) Does their use 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?	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	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.
United States	EU statement would be very beneficial to lower copper in soil.
5.1.b)3) Is the substance of plant, microbial or mineral origin? Has it undergone any of the following processes: physical (mechanical, thermal), enzymatic, microbial (composting, fermentation)?	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	Copper is of mineral origin and undergoes saponification with fatty acids. Saponification is also used in manufacture of soft soap.

United States	Agree Copper is of mineral origin.
5.1.b)4) Is the substance used in traps are as a dispenser of pheromones which are chemically synthesized? Are there alternatives products available in their natural form? Do the conditions of use result in the presence of residues on edible parts of the product?	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	Not applicable.
United States	Agree with EU statement.
5.1.b)5) Should the substance use be restricted to specific conditions , specific regions, or specific commodities?	
Member/ Observer	**Answer**
EU submission-CX/FL 10/38/17	The same restrictions as for other copper compounds should apply.
United States	Agree with EU statement.
Has the applicant adequately addressed the sub-criteria in section b) substances used for the purpose of plant disease or pest and weed control	
Member/ Observer	**Answer**
United States	Answer seems adequate.
Is there any information needed to complete the review of the new substance (including supporting documents)?	
Member/ Observer	**Answer**
United States	For further information here is the link to the U.S. National Organic Standards Board, Technical Advisory Panel Report on fixed coppers: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5089146&acct=nopgeninfo

APPENDIX VIII: Ethylene for degreening

Review of New Substances proposed for inclusion in Annex 2

A. Substance: ethylene

B. Use: Degreening of citrus for fruit fly prevention in citrus

C. Applicable specific criteria: b) substances used for the purpose of plant disease or pest and weed control

D. Submitted by: European Union (EU)

Assessment against Section 5.1 Criteria	
I. General Description of Substance	
Member/ Observer	**Description**
EU	Natural gas C_2H_4 (CH_2=CH_2) produced by all higher plants and therefore omnipresent in nature. The ethylene (identical to the naturally occurring ethylene) used for agricultural purposes is obtained through chemical processes. By harvesting citrus when they are green, fruit fly infestation can be avoided. This practice necessitates the induction of colour change of the peel in the post-harvest stage. This can be achieved by post-harvest exposure to ethylene in closed chambers for 2 days. The use of ethylene for degreening is a traditional practice in lemons. However, its use as part of a strategy for fruit fly prevention has been newly developed for organic citrus.
II. Section 5.1 General Criteria (all criteria in this section should be addressed)	
5.1.i) Is the substance consistent with the principles of organic production as outlined in the Guidelines?	
Member/ Observer	**Answer**
EU	The maintenance of plant health by preventative measures is one of the principles of organic farming.
5.1.ii) Is use of the substance necessary/essential for it's intended use?	
Member/ Observer	**Answer**
EU	Yes. It can contribute to solve problems with fruit flies in organic citrus and avoid pesticide use in the field.
5.1.iii) Does the manufacture, use and disposal of the substance result in, or contribute to, harmful effects on the environment?	
Member/ Observer	**Answer**
EU	No. Ethylene is often considered a by-product in chemical engineering process manuals, and to the extent that it is captured rather than released into the environment can be seen as reducing the ambient air pollution.
5.1.iv) Does the substance have the lowest negative impact on human or animal health and quality of life?	

Member/ Observer	Answer
EU	No adverse effect known on human or animal health. No adverse effect on intrinsic food quality (internal ripening of citrus is completed before harvest). Effect on peel colour only, which facilitates marketing.

5.1.v) Are approved alternative available in sufficient quality or quantity?

Member/ Observer	Answer
EU	Bait spraying of spinosad is an alternative. Pyrethrum and rotenone are alternatives with partial efficacy.

Has the applicant adequately addressed the general criteria in section 5.1?

Member/ Observer	Answer
United States	Yes. Under the USDA National Organic Program standards, postharvest use of ethylene is allowed for ripening of tropical fruit and degreening of citrus.

IV. Section 5.1 Specific Criteria: b) substance used for the purpose of plant disease or pest and weed control

5.1.b)1) Is the substance 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?

Member/ Observer	Answer
EU	Yes. Contribution to solve problems with fruit flies and to avoid pesticide use in he field.

5.1.b)2) Does its use 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?

Member/ Observer	Answer
EU	Environmental fate, hazards and risks are assessed in detail during pesticide registr-ation in the EU, and authorizations are accompanied by obligations for appropriate risk management. Ethylene does not raise environmental or health concerns. Theoretically, after release from the storage rooms, ethylene could affect the vegetation, but the quantities used are negligible in comparison to natural and industrial emissions.

5.1.b)3) Is the substance of plant, microbial or mineral origin? Has it undergone any of the following processes: physical (mechanical, thermal), enzymatic, microbial (composting, fermentation)?

Member/ Observer	Answer
EU	Ethylene is a natural gas produced by all higher plants. The ethylene (identical to the naturally occurring ethylene) used for agricultural purposes is obtained through decomposition of petroleum gases or by dehydration of alcohol.

5.1.b)4) Is the substance chemically synthesized? Are there alternatives products available in their natural form? Do the conditions of use result in the presence of residues on edible parts of the product?	
Member/ Observer	**Answer**
EU	The ethylene used is chemically produced and is identical to the naturally occurring ethylene. Ethylene does not result in the presence of residues in any part of the plant.
5.1.b)5) Should the substance use be restricted to specific conditions , specific regions, or specific commodities?	
Member/ Observer	**Answer**
EU	It should be limited to citrus and to situations were degreening is part of a strategy for the prevention of fruit fly damage in citrus.
Has the applicant adequately addressed the specific criteria in section b) substances used for the purpose of plant disease or pest and weed control	
Member/ Observer	**Answer**
Australia	Australia agrees with the paper relating to the use of ethylene for fruit fly control in citrus.
United States	Yes. In the United States, ethylene used postharvest is considered a plant growth regulator and is regulated as a pesticide. We concur that section b is the appropriate section of Annex II for consideration of ethylene for degreening of citrus. Under the USDA National Organic Program standards, postharvest use of ethylene is allowed for ripening of tropical fruit and degreening of citrus.
VI. General questions for all proposals	
Is there any information needed to complete the review of the new substance? (Please include links to supporting research here)	
Member/ Observer	**Answer**
United States	No.
Are any additional conditions of use needed?	
Member/ Observer	**Answer**
EU	Yes: for degreening of citrus fruit only as part of a strategy for the prevention of fruit fly damage in citrus
Would you support the addition of the new substance in Annex 2?	
Member/	**Answer**

Observer	
EU	Yes
United States	Yes. Under the USDA National Organic Program standards, postharvest use of ethylene is allowed for ripening of tropical fruit and degreening of citrus.
Australia	Australia agrees in principle with the paper relating to the use of ethylene for fruit fly control in citrus.
Switzerland	Switzerland supports the inclusion of ethylene for the degreening of citrus, as a sprouting inhibitor for onions and potatoes, and for the induction of flowering in pineapple. For the extension of the use of ethylene to other fruits, justifications according to the Codex criteria will be needed.
IFOAM	IFOAM allows in their Basic Standards the use of ethylene for ripening purposes. For the extension of the use of ethylene in the Codex Guidelines for other product groups then the ones already mentioned and the application of ethylene for other purposes than ripening, IFOAM requests that more elaborated justifications against all the Codex criteria – and not just economic ones – will be provided by the applicant countries. These justifications have in particular to show that no other alternative strategies are feasible, taking also consumer concerns in the countries of consumption of the products into account.

APPENDIX IX: Ethylene – flowering agent

Review of New Substances Proposed for Inclusion In Annex 2

A. Substance: Ethylene
B. Use: As a flowering agent – Pre- harvest application
C. Applicable sub-criteria: not applicable. This substance would be listed in Annex 2, Table 2, Other.
D. Submitted By: European Union and Costa Rica

Assessment against Section 5.1 Criteria	
I. General Description and Placement of Substance	
Member/ Observer	**Description**
Costa Rica/EU Application	Ethylene is a colorless gas at room temperature with characteristic slightly sweet odor. Ethylene is a liquid at low temperatures and a gas at room temperature and soluble in water. The gas is flammable and soluble in water. Ethylene use for the ripening of kiwi and bananas is a largely accepted international practice, and has been approved by Codex. Additionally, ethylene can be used as a traditional flowering agent, purpose is uniform flowerbed development, in the organic agricultural production system as a pre-harvest treatment of pineapple plants (*Ananas comosus*). For induction of flowering in pineapple plants, ethylene gas is dissolved in water and sprayed over the plants. Pure ethylene gas (rated as 99,99% pure gas) should be used, which comes in steel cylinders and is securely mounted on the spray boom vehicle and by means of a flow measuring device the gas is injected into the boom through which abundant water flows with the activated charcoal (mixed in the tank). As the ethylene bubbles through the water it gets partially hydrolysed and partially adsorbed by the activated charcoal which subsequently releases the ethylene slowly to the plants after it is applied by means of flood nozzles. The source of commonly used ethylene gas are natural gas liquids or crude oil. Ethylene is often considered a by-product in chemical engineering process manuals, and to the extent that it is captured rather than released into the environment can be seen as reducing the ambient air pollution. Ethylene reacts with ozone in the atmosphere to form water, carbon dioxide, carbon monoxide and formaldehyde, though this reaction can reduce ozone air pollution. UV light destroys ethylene in the upper atmosphere, producing hydrogen, acetylene, n-butane, and ethane. (Abeles, 92) The amount released by agricultural use is hard to judge, but can be safely assumed to be a small fraction. Ethylene can be applied at a rate of 2.25-3.5 Kg (ethylene) per hectare with an excess of water >7000L/ha. The amount of activated charcoal is app. 0,5% of the total. Application is to (mature) plants; older than 8 months; applied 5 months before harvest. Application rates can vary depending on rainfall, once or twice (both can be applied at two times half the dosage to obtain greater uniformity) per crop cycle, which can be 12 to 18 months from planting to harvest. The red bud of the developing flowers will be visible in the part of the plant at 48 – 60 days after the application of the ethylene for the induction.

Member/ Observer	What is the appropriate placement of the substance?
Costa Rica/EU Application	Flower induction takes place months before harvest, therefore the substance for use of flower induction is most appropriately placed in Annex 2, Table 2, section IV "Other". No sub-criteria need to be addressed; only the section 5.1 main criteria.

II. Section 5.1 Main Criteria

5.1.i) Is the substance consistent with the principles of organic production as outlined in the Guidelines?

Member/ Observer	Answer
Costa Rica/EU Application	The use of ethylene is generally in line with principles of organic production: • Pineapples naturally produce flowering as a reaction to stress provoked by environmental effects, particularly temperatures, but it takes place unevenly. • For commercial production such flowering must take place all at the same time, which can only be done using ethylene. • Alternatives to ethylene are not available on a commercial scale. • Flower induction is not an artificial process but rather use of an element (ethylene) to facilitate and provide uniformity to the natural process of the plant itself. • The substance (ethylene) is found in nature and plants themselves produce it in some of their physiological stages. • There are no reports of negative effects of this product or its method of application over human or animal health or their quality of life. Ethylene is already approved by Codex for ripening of kiwi and banana, which implies that, as far as the substance as such is concerned, it has already been assessed as consistent with the organic principles. In addition, the use of ethylene for flowering induction in pineapple has been approved under US and EU organic regulations, which both contain standards and criteria that are very similar to those of Codex Guidelines.

5.1.ii) Is use of the substance necessary/essential for its intended use?

Member/ Observer	Answer
Costa Rica/EU Application	Flower inducing of the pineapple plant is necessary for the following reasons: • Flowering in pineapple occurs spontaneously when plants reach a certain size. While some research shows an enhancement in flowering from short days, low night temperatures and water stress, the flowering can happen in one field at quite different times because the plants have been growing for at least 20 months before they start to flower (Reinhardt, et al, 1986). The yields will be spread out over several years without flower induction. • A uniform synchronous flowering period results in a relative short(er) period in which attractive stages of the pineapple flower is available for insects in the same field. In this way the losses due to serious insects damage, such as from Techla fruit borer, can be reduces and the use and the time period during which (organic) pesticides are needed can be reduced as well. Well-timed cycles of a

	pesticide allowed in organic farming (based on the bacterium Bacillus thuringiensis) can then protect the whole field. An additional effect can be expected since the growers are able to control possible plague(s) better since they know in which area insects might 'flourish' and can control these plague(s) in the smaller area. This approach is in perfect line with the organic pest management principle of 'prevention before correction'. • Controlled flower induction prevents induction of immature plants triggered trough ethylene production of flowering plants within the same field. Flowering of non-mature plants, with underdeveloped root systems, which are necessary for sufficient nutrient flow for fruit filling, results in poor and small fruits, which are not marketable. • When flower induction applications (with ethylene) are timed and thus done at an optimum plant size (plant weight), all the plants in field will be able to bear a fruit the size in proportion and according to the capacity of the plant to fill the fruit. • To be able to produce for overseas markets a producer will need to supply clients and ultimately the consumer with fresh pineapples on a regular basis. Ethylene applications synchronize flower induction and thus fruit set. This reduces the harvest picking rounds from a dozen or more to 3 to 5. Without the use of ethylene the percentage of market ready fruit would be very low and erratic in the same field. It would take a dozen of harvesting rounds to pick all the fruit under a natural setting. Damage to the plants and the fruit left in field some time more, and soil compaction will be increased when the equipment for harvesting needs to go trough the fields a dozen times instead of a few times. For transport and marketing reasons certain quantities are necessary in order to make it commercially feasible to grow pineapples. • All recommendations for pineapple culture suggest using a material for flower induction to achieve even flowering and a uniform harvesting period. While the induction can result in producing a crop out of season, it is also necessary to produce a uniform crop in season. This is considered important for processing as well as for predictable marketing of the crop, as most pineapple is grown for export and a shipping container must be filled for each harvest. • For the potential organic pineapple markets it is important to be able to produce fruits of top quality all year round. Flower induction by ethylene applications allows programming harvests all year round and employing a steady labour force all year round, which contributes to the economic welfare and stability of the areas in the tropics where pineapples are grown. • Through the application of ethylene the total crop cycle will be reduced by several months if not almost a year, as there will be no endless harvest tail. The production efficiency of the organically certified land as a valuable natural resource will be increased and making it more attractive as a farming option, leaving more time for leaving fields fallow, growing green manure, grow a rotation crop, or plant the next pineapple crop.

5.1.iii) Does the manufacture, use and disposal of the substance result in, or contribute to, harmful effects on the environment?	
Member/ Observer	**Answer**
Costa Rica/EU Application	No harmful effects are observed when used to induce flowering. Ethylene is not listed as a carcinogen and is naturally occurring. In non-organic pineapple plantations a synthetic compound called ethephon is sprayed

	on the fields. This compound is not a natural compound but ultimately also emits ethylene in order to have the same effect.
United States	Concur with Costa Rica/EU. Ethylene gas is permitted as a plant growth regulator under the USDA National Organic Program standards for regulation of pineapple flowering.

5.1.iv) Does the substance have the lowest negative impact on human or animal health and quality of life?

Member/ Observer	**Answer**
Costa Rica/EU Application	According to research: ingestion, inhalation and human health effects are considered low. The EPA (Environmental Protection Agency, based in the USA) has registered ethylene since it is naturally occurring and it has been widely used as anaesthetic since 1923 without report of significant toxicity. According to the EPA the potential risk from the use of ethylene are considered negligible because ethylene is low in toxicity and highly volatile (i.e. exposure to skin and lungs is minimal). Ethylene gas is also allowed for the ripening of organic bananas (in ripening chambers). The time between application of ethylene and the consumption of the organic bananas is less than seven days. The ethylene application for pineapples is at least 130 days before the moment of consumption. The pineapples will produce ethylene itself as they get ripe, and possible residues on the final product as a result of the ethylene gas application 5 months earlier are no different, and chemical analyses can therefore not differentiate between the two. Studies have not reported any overall influence upon yield or fruit quality as long as the pineapple plants are mature enough when treated (Mwaule, 1985; Dalldorf, 1985). The ethylene gas itself is inexpensive, especially since the amount used is limited. The requirement mechanical equipment is easy to assemble and can be used by multiple users for a number of years to limit the costs. Also, “small”-farmers will be in the position the apply ethylene. Small containers to limit the start-up costs are available. The non-profit environmental organization, Environmental Defense, ranks ethylene as less hazardous than most chemicals, using 8 different ranking systems. (Environmental Defense, 2000). Two rankings for integrated human health and environmental effects place ethylene in the lower 50% of all chemicals ranked for hazard. • The UTN (from University of Tennessee hazard evaluation system) considers toxicity and persistence consideration, as well as human health impact. Ranks ethylene as 0-25th percentile (a numerical score of 31/200) for relative hazards. • IRCH (the Indiana Relative Chemical Hazard Ranking System from Purdue University) considers toxicity and exposure, and includes ecological and occupational human health impacts. The IRCH ranks ethylene as 25-50th percentile, (numerical score of 19/200) for relative hazards. UTN uses endpoints of acute toxicity to mammals and chronic and acute toxicity to aquatic organisms as measures of environmental effects. IRCH includes a wide variety of measures relating to toxicity and physical-chemical properties such as vapor pressure, tendency to bio-accumulate, corrosivity and others. The National Toxicology Program Health and Safety Information Sheet, published by the National Institute of Environmental Health, states that neither the NTP, IARC, (The International Agency for Research on Cancer, part of the World Health Organization) nor OSHA lists ethylene as a carcinogen. (NTP, 2000). The only health hazard listed by Environmental Defense is based on Cal EPA data as a suspected neurotoxicant, at a relatively high level of ingestion by inhalation (20,000 ug/m3 = 2x10-5 (0.00002) kg/m3).

	Worker safety is thus a concern, as the density of the gas is listed at 1.169 kg/m3. EDF identified the lack of basic testing in several categories of toxicity: chronic, reproductive, and neurotoxicity for this high volume use chemical.

5.1.v) Are approved alternatives available in sufficient quality or quantity?

Member/ Observer	Answer
Costa Rica/EU Application	Alternatives have not been found successful or acceptable: • Use of smoke may be a more natural source of ethylene, but environmental consequences of this use are potentially more damaging. The use of smoke from combusted wood or other materials is only successful in a contained area (i.e. greenhouse). Greenhouses are not only too expensive in most (sub) tropical area's, but will also result in too high temperatures inside the greenhouse for these regions. Smoke, containing ethylene as the active substance as well, used outside of a greenhouse will drift and gets blown over the land too fast and therefore will not result in flower induction, since the concentrations of the active ingredient is not high enough. • The use of calcium carbide is and has been used as an alternative in some parts of the world. Dissolved in water, again ethylene is released by a reaction of carbide with water. A reported problem, as mentioned in the NOSB TAP review made for the NOP approval, with the use of calcium carbide is the formation of several toxic by-products due to the impurity of the calcium carbide, like fosfine, phosphorous hydride (PH_3) and arsenic hydride (AsH_3) , and therefore was rejected as an alternative. • The use of already ripened fruit, which releases ethylene gas is not a realistic alternative. Ripened fruit attracts large amount of insects and pineapple pests and therefore will result in a bigger need for the use of natural or biological pesticides. Furthermore it does not fit in sustainable agriculture to use large amounts of eatable fruit to produce other fruits. Secondly it is not commercially viable to harvest ethylene gas produced from ripened fruits in a concentration that can be compressed into a cylinder without purifying it first, which is expensive and a dangerous process. • The use of cold water or bovine urine was reported as being practiced for a short time but did not result in a desired uniform flowering.

II. Additional Questions/Supporting Materials

Has the applicant adequately addressed the main criteria in section 5.1?

Member/ Observer	Answer
United States	Yes. Use of substance for flower induction should be limited to pineapples. Ethylene gas is permitted as a plant growth regulator under the USDA National Organic Program standards for regulation of pineapple flowering only.
Australia	Australia agrees in principle with the paper relating to the use of ethylene as an agent to control flowering in pineapples.
Switzerland	Switzerland supports the inclusion of ethylene for the degreening of citrus, as a sprouting inhibitor for onions and potatoes, and for the induction of flowering in pineapple. For the extension of the use of ethylene to other fruits, justifications according to the Codex criteria will be needed.
IFOAM	IFOAM allows in their Basic Standards the use of ethylene for ripening purposes. For the

	extension of the use of ethylene in the Codex Guidelines for other product groups then the ones already mentioned and the application of ethylene for other purposes than ripening, IFOAM requests that more elaborated justifications against all the Codex criteria – and not just economic ones – will be provided by the applicant countries. These justifications have in particular to show that no other alternative strategies are feasible, taking also consumer concerns in the countries of consumption of the products into account.
Is there any information needed to complete the review of the new substance (including supporting documents)?	
Member/ Observer	**Answer**
Costa Rica/EU Application	No
United States	No.
References	
Costa Rica/EU Application	EU general review on ethylene http://ec.europa.eu/food/plant/protection/evaluation/existactive/list_ethylene_en.pdf United States technical advisory Panel (TAP) on Ethylene for Crops: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5067073&acct=nopgeningo Supplemental Info on Ethylene for Crops: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5085744 NOSB database: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5085176

APPENDIX X: Ethylene – sprouting inhibition

Review of New Substances proposed for inclusion in Annex 2

A. Substance: ethylene

B. Use: Sprouting inhibition in potatoes and onions

C. Applicable specific criteria: b) substances used for the purpose of plant disease or pest and weed control

D. Submitted By: European Union (EU)

Assessment against Section 5.1 Criteria	
I. General Description of Substance	
Member/ Observer	**Description**
EU	Natural gas C_2H_4 (CH_2=CH_2) produced by all higher plants and therefore omnipresent in nature. The ethylene (identical to the naturally occurring ethylene) used for agricultural purposes is obtained through chemical processes. Constant exposure of stored potatoes and onions to ethylene in low concentration inhibits sprouting.
II. Section 5.1 General Criteria (all criteria in this section should be addressed)	
5.1.i) Is the substance consistent with the principals of organic production as outlined in the Guidelines?	
Member/ Observer	**Answer**
EU	This use of ethylene is consistent with the principle of careful handling of products in order to maintain their quality during the storage and contributes to the economic and ecological sustainability of organic potato and onion production, while being consistent with the other principles of organic production.
5.1.ii) Is use of the substance necessary/essential for its intended use?	
Member/ Observer	**Answer**
EU	A longer marketing period is important for the economic sustainability of farms.
5.1.iii) Does the manufacture, use and disposal of the substance result in, or contribute to, harmful effects on the environment?	
Member/ Observer	**Answer**
EU	No. Ethylene is often considered a by-product in chemical engineering process manuals, and to the extent that it is captured rather than released into the environment can be seen as reducing the ambient air pollution.
5.1.iv) Does the substance have the lowest negative impact on human or animal health and quality of life?	
Member/ Observer	**Answer**
EU	No adverse effect known on human or animal health.

	No adverse effect on intrinsic food quality. Under conditions of prolonged storage, a higher external and internal quality can be maintained (absence of sprouts and wrinkles, composition of tubers).

5.1.v) Are approved alternative available in sufficient quality or quantity?

Member/ Observer	Answer
EU	Cold storage, use of varieties with high dormancy and/or caraway seed oil (for potatoes, where registered) may provide solutions in certain situations.

Has the applicant adequately addressed the general criteria in section 5.1?

Member/ Observer	Answer
United States	No. Applicant has not adequately addressed the criteria needed to demonstrate that the substance is necessary/essential for its intended use, given the availability of alternative practices (e.g. cold storage) and alternative materials (e.g. plant essential oils such as caraway oil or clove oil, where registered) for sprout inhibition. Ethylene is not permitted for post harvest use as a sprout inhibitor in potatoes and onions under the USDA National Organic Program standards.

IV. Section 5.1 Specific Criteria: b) substance used for the purpose of plant disease or pest and weed control

5.1.b)1) Is the substance 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?

Member/ Observer	Answer
EU	This use of ethylene is not directly linked to the control of a pest or disease, but this use of ethylene can nevertheless be considered to be plant protection and therefore the same criteria should apply. Cold storage, use of varieties with high dormancy and/or caraway seed oil (for potatoes, where registered) may provide solutions in certain situations.

5.1.b)2) Does its use 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?

Member/ Observer	Answer
EU	Environmental fate, hazards and risks are assessed in detail during pesticide registr-ation in the EU, and authorizations are accompanied by obligations for appropriate risk management. Ethylene does not raise environmental or health concerns. Theoretically, after release from the storage rooms, ethylene could affect the vegetation, but the quantities used are negligible in comparison to natural and industrial emissions.

5.1.b)3) Is the substance of plant, microbial or mineral origin? Has it undergone any of the following processes: physical (mechanical, thermal), enzymatic, microbial (composting, fermentation)?

Member/ Observer	Answer
EU	Ethylene is a natural gas produced by all higher plants. The ethylene (identical to the

	naturally occurring ethylene) used for agricultural purposes is obtained through decomposition of petroleum gases or by dehydration of alcohol.

5.1.b)4) Is the substance chemically synthesized? Are there alternatives products available in their natural form? Do the conditions of use result in the presence of residues on edible parts of the product?	
Member/ Observer	**Answer**
EU	The ethylene used is chemically produced and is identical to the naturally occurring ethylene. Ethylene does not result in the presence of residues in any part of the plant.

5.1.b)5) Should the substance use be restricted to specific conditions , specific regions, or specific commodities?	
Member/ Observer	**Answer**
EU	It should be limited to sprouting inhibition in potatoes and onions.

Has the applicant adequately addressed the specific criteria in section b) substances used for the purpose of plant disease or pest and weed control	
Member/ Observer	**Answer**
United States	No. The applicant has not addressed why alternatives practices (e.g. cold storage) or alternative materials (e.g. plant essential oils such as caraway oil or clove oil, where registered) for sprout inhibition cannot be used. Ethylene is not permitted for post harvest use as a sprout inhibitor in potatoes and onions under the USDA National Organic Program standards. The applicant has not adequately addressed the criteria that the substance is 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 the United States, ethylene used for sprout inhibition is considered a plant growth regulator and is regulated as a pesticide. We concur that section b is the appropriate section of Annex II for consideration of ethylene for sprout inhibition.

VI. General questions for all proposals

Is there any information needed to complete the review of the new substance? (Please include links to supporting research here)	
Member/ Observer	**Answer**
United States	The applicant has not addressed why alternative practices (e.g. cold storage) or alternative materials (e.g. plant essential oils such as caraway oil or clove oil, where registered) for sprout inhibition cannot be used. Ethylene is not permitted for post harvest use as a sprout inhibitor in potatoes and onions under the USDA National Organic Program standards.

Are any additional conditions of use needed?

Member/ Observer	Answer
EU	Yes: for sprouting inhibition in potatoes and onions.
Would you support the addition of the new substance in Annex 2?	
Member/ Observer	**Answer**
EU	Yes
Australia	Australia agrees in principle with the paper relating to the use of ethylene as an inhibiting agent to control sprouting in potatoes and onions, however Australia considers if there is further information to support the response under Section 5.1 v), this would strengthen the new work proposal.
Switzerland	Switzerland supports the inclusion of ethylene for the degreening of citrus, as a sprouting inhibitor for onions and potatoes, and for the induction of flowering in pineapple. For the extension of the use of ethylene to other fruits, justifications according to the Codex criteria will be needed.
IFOAM	IFOAM allows in their Basic Standards the use of ethylene for ripening purposes. For the extension of the use of ethylene in the Codex Guidelines for other product groups then the ones already mentioned and the application of ethylene for other purposes than ripening, IFOAM requests that more elaborated justifications against all the Codex criteria – and not just economic ones – will be provided by the applicant countries. These justifications have in particular to show that no other alternative strategies are feasible, taking also consumer concerns in the countries of consumption of the products into account.
United States	No, the applicant has not adequately addressed why alternatives practices (e.g. cold storage) or natural materials (e.g. plant oils) for sprout inhibition cannot be used as an alternative to ethylene as required by criteria 5.1 ii

APPENDIX XI: **Complete Comments Received on the Structured Work Approach**

Country/ Observer	Comments
Australia	Australia supports the concepts relating to a structured review approach for the Guidelines for Production, Processing, Labelling and Marketing of Organically Produced Foods. Australia agrees that: • a more structured process would improve the efficiency of the review process; • proposals for additions to the list need to be provided with sufficient time for appropriate review by countries in advance of any Committee meeting; • amendments to Section 1-8 of the Guidelines can be accomplished through the normal process of a new work proposal; • the proposed cycle would allow a more structured review of the proposed additions to the list; and • the establishment of an electronic organic working group (eOWG) is a useful process to advance new or review existing work. Whilst Australia supports the concept of establishing an eOWG, Australia would not want any new or existing work proposals to be indefinitely delayed because they are considered as "low priority".
Croatia	**1. Do countries agree that a more structured process would improve the efficiency of the Review process?** Answer: Yes, we agree. **2. Do countries agree that proposals for additions to the list need to be provided with sufficient time for appropriate review by countries in advance of the Committee meeting?** Answer: Yes, we agree. **3. Do countries agree that amendments to Sections 1-8 of the Guidelines can be accomplished through the normal process of a new work proposal?** Answer: Yes, we agree. **4. Do countries agree that the proposed cycle would allow for a more structured review of proposed additions to the list?** Answer: Yes, we agree. **5. Do countries have suggestions for other cycles that would accomplish a more structured review and allow countries sufficient time to review proposals for additions to the list well in advance of the meeting and allow feedback to countries if their proposal does not contain sufficient information?** Answer: We don't have a suggestion. **6. Do countries agree that establishment of the EOWG is a helpful support mechanism?** Answer: Yes, we agree. **7. Do countries agree that additional criteria are needed for prioritization of the worked to be undertaken by the EOWG?** Answer: Yes, we agree.
EU	The structured work approach as discussed at the CCFL38 (CX/FL 10/38/11 and CRD 15) This proposal was jointly prepared by the Unites States and the European Union. We maintain our support for the proposal and have no further comments at the moment.
IFOAM	**General comments of IFOAM** • IFOAM agrees with the analysis and general aims of revising the process.

	• IFOAM agrees that the requirement for periodic review of the main text of the Codex Guideline can be replaced by requests for new work items in the general Codex procedure. • IFOAM agrees to the concept of a multi-year cycle for new work for the Annexes. • IFOAM agrees that an Electronic Working Group (EWG) can be useful for managing revisions. The work of this EWG should be very transparent. Membership in the group should be open to both Members and Observers, and it should include significant participation from developing countries. • IFOAM recommends that in addition to an Electronic Working Group, the EWG provide recommendations to an Organic Working Group (OWG) which should meet prior to the CCFL in the "Decision Year" of this cycle. The OWG will review the work of the EWG and make the final recommendations to the CCFL for decision. **IFOAM Comment to the revision of the Annexes of the Guidelines in a two year cycle** • IFOAM supports a structured review process with the two year cycle as proposed by US and EU but with more clear timelines. • IFOAM agrees that an Electronic Working Group (EWG) is useful for managing the process. • IFOAM recommends that for more substantial changes of the guidelines physical face to face meeting of an "Organic Working Group", meeting prior to the CCFL meeting, have shown in the past very useful and should be foreseen when necessary by the EWG. • With regard to the request for the uptake of new substances it might be useful to take them in on an on-going basis through the EWG-process. • IFOAM thinks that a regularly updated indicative list is very important to show to governments a broad international agreement on substances. **A last comment relates to the proposed additional criteria for the uptake of new substances by the original US paper.** • IFOAM is not comfortable with these proposed additional criteria for the uptake of new substances, as they would practically exclude third world countries to ask for new interesting substances for organic farming. (see detailed comment below). • IFOAM has a comment to the terminology used in the US Paper CX/FL 10/38/11 regarding the permitted substances, where the term "illustrative listing" is used. This term has not been used until now in all the Codex discussion. IFOAM believes that the term "indicative list" should be kept as it is much more appropriate. The word "illustrative" does not express sufficiently that for these substances a world-wide consensus has been reached ("safe harbour list" for governments). **IFOAM Comment to the revision of the whole text of the Guidelines** • IFOAM agrees that it is unrealistic to undertake reviews of the whole text of the Organic Guidelines systematically and periodically according to the current Section 8. • IFOAM thinks that reviews of sections of the Guidelines can be initiated through the main process for new work. • IFOAM thinks that it would make sense to aim for a 4 year cycle of the revision of the whole guidelines, when decided as necessary by the plenary of CCFL. • However, there should still be a system for Members and Observers to submit written comments on proposals to the full Committee. IFOAM would also support a process for the EWG to call for and accept comments from Members and Observers. • Regarding the revision of the main guidelines text, IFOAM believes that this work should include a general review of how the content of the Guidelines accord with the functional aims of the Guidelines that are presented in the Foreword, particularly with respect to the situation of organic agriculture and trade from in developing countries. **IFOAM Answers to questions in Document CX/FL 10/38/11** **Do countries and observers agree that a more structured process would improve the efficiency of the review process?**

	• IFOAM does agree with a structured process. **Do countries and observers agree that proposals for additions to the list need to be provided with sufficient time for appropriate review by countries in advance of the Committee meeting?** • IFOAM agrees that sufficient time is needed. **Do countries and observers agree that amendments to Sections 1-8 of the Guidelines can be accomplished through the normal process of a new work proposal?** • Generally IFOAM does support a four year review cycle • Regarding the proposed criteria, IFOAM does not agree (see comment above). IFOAM proposes that the first criteria will be changed and would read: "if the substance registered by a country (and not the country sending the request). The second sentence and criteria should be deleted as the volume of use is irrelevant for new innovative substances, which recently have passed the registration process. IFOAM recommends that these criteria will be discussed in the EWG as one of their first tasks. **Do countries and observers agree that the proposed cycle would allow for a more structured review of proposed additions to the list?** • Generally yes, but Codex should keep a certain flexibility if urgent issues are coming up. • Do countries and observers have suggestions for other cycles that would accomplish a more structured review and allow countries sufficient time to review proposals for additions to the list well in advance of the meeting and allow feedback to countries if their proposal does not contain sufficient information? • Generally IFOAM can agree with the 2 year cycle but in some cases the time needed for a sound evaluation might need more time, if not sufficient information is available. **Do countries and observers agree that establishment of the EOWG is a helpful support mechanism?** • IFOAM thinks that the EOWG is helpful, but not sufficient, as it does not allow a real exchange in depth exchange of views. Therefore IFOAM proposed that in the "decision year", to foresee a physical meeting of an "Organic Working Group", which has shown in the past in addition to several EOWC to be very useful (see decision procedure about additives and processing aids). IFOAM thinks that Codex members and Observers can more easily involve specific experts in their delegations, if such physical meeting happens not every year. **Do countries and observers agree that additional criteria are needed for prioritization of the worked to be undertaken by the EOWG?** • As IFOAM has already mentioned the proposed criteria are not satisfactory and should be changed. (see above) in order to exclude countries with a less developed organic farming sector. • Furthermore it must be mentioned that existing criteria for new substances already existing in the Codex Guidelines, and which are equivalent to the criteria in IFOAM Basic Standards are generally sufficient. IFOAM does not expect many request for new substances, therefore IFOAM would rather prefer not to introduce new criteria.
United Kingdom	With regard to the proposals for a structured work approach in CX/FL 10/38/11 and CRD 15 the UK concurs with the views expressed by the European Union on the issues raised.
United States	The United States continues to support a more structured approach to the review of the Guidelines For The Production, Processing, Labelling And Marketing Of Organically Produced Foods (hereafter referred to as the Guidelines). The United States believes that

the Guidelines need regular improvement and updating to take into account technical advances, growth in the organic market and experience with their implementation. The inclusion or removal of substances from the Codex organic permitted substance list (Annex 2) must occur through a fair, scientifically-based, and transparent approval process by individual countries based on the criteria established in Section 5.1 – Requirements for Inclusion of Substances to Annex 2 and Criteria for the Development of Lists of Substances by Countries.

Any proposal for amendment of the lists should be accompanied by a complete data package addressing the criteria in Section 5.1. However, proposals for new work often are not accompanied by necessary and complete data and have resulted in ongoing yearly review of proposals. Moreover, review of amendments to the Guidelines requires significant and specialized technical expertise, and many Members are unable to provide such expertise on a yearly basis. In addition, proposals are not always submitted in sufficient time prior to the Committee's plenary session and, in some cases, the proposals are made available as Conference Room documents just after delegates arrive at the meeting. In such instances, full and thorough review by the Committee is not possible during the plenary, as only a few countries may have their organic experts on hand to advise them on such proposals.

In line with CRD 15 the United States continues to endorse the following actions:

- A timely structured review process that conserves Committee resources.
- A two year cycle for proposals. (Annex 2 lists are indicative or illustrative lists and do not necessarily require annual updating.)
- Structured Work Process as outlined applies only to Annex 2 revisions.
- The establishment of a permanent Organic electronic working group (eWG) to evaluate the completeness of proposals and prioritization of suggested new work for the Committee.
- Chairmanship of the eWG would rotate from country to country.

Upon further reflection of some of the comments offered at the 38th Session, the United States would like to offer the following clarifications about the proposed procedures for the establishment of the structured process:

    - The review process might benefit from a more structured application process which focuses clearly on the section 5.1 criteria. The eWG could develop a template for a proposal for new work which could be used by future eWGs when evaluating substances. Use of such a template would aid in the determination of basic sufficiency of proposals.
    - The United States also noted that several countries seemed confused as to which data or justification is expected as part of the application. Is there a role for the eWG to provide additional guidance (maybe as part of the template) on specific data needed to fulfill each criterion?
    - The eWG supports an accelerated review process.
    - As proposed in CRD 15, all proposals for new substances should be submitted to the Secretariat in Year 1. We recommend that all applications should be submitted 60 days prior to the plenary so that members can have ample time for review prior to the plenary.
- At the plenary in Year 1, the Committee would discuss the basic sufficiency of the proposals. In between year one and two the eWG will undertake review of the assigned proposals and prepare a recommendation for presentation to the Committee in Year 2.
-

Currently, the criteria as outlined in Section 5.1 apply only to those substances as contained in Annex 2- Permitted Substances for the Production of Organic Foods. In the event that a substance is more appropriately captured under Annex I – Principles of Organic Production, (such as the case of use of ethylene for the ripening of bananas or other tropical fruits), the Committee should decide if the full application of the 5.1 criteria would also apply in these instances, or if new criteria need to be developed. The United States would recommend that such additions to Annex I be subject to the same level of review found under Annex II.

	The additional four criteria as suggested by the United States in section 8.3 of its original discussion paper CX/FL 0/38 11 can be used to help prioritize its work: • Is the substance registered for use in the Member Country; • Volume of use of the substances by individual country and volume of usage and relevance to the international community; • Availability of regional/national reviews and risk assessments ,and coordination with other regional/national lists; • Commitment by the sponsor of the substance to providing supporting data for review based on Section 5.1 criteria. If the Committee decides to undertake additional guidance in the development of an application, perhaps such elements could be included in the general description part of the application.

Additional Information/Questions Posed to the eWG

Country	Response
Do members believe that using a standard review template for evaluation of the 5.1 criteria is helpful?	
Australia	Australia considers that a structured approach using a standardized template will provide consistency when evaluating new work proposals using the criteria, and provide clear guidance to members seeking to add or remove substances, under Section 5.1 of the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999).
Canada	Canada supports a standard review template for evaluation of the 5.1 criteria.
Croatia	We believe that the proposed standard review template is useful.
European Union	The EU considers the proposed draft template as a useful tool and has been using it for the reviews it has sent to the eWG
IFOAM	IFOAM is in favour to continue using this format, as it has been proven to be very useful. It would be helpful to request explicitly in the first box of the template the following two basic information: a) Short information on the origin b) Short information on the usage (for which crops or food, with which function). To have for all requests this information would facilitate the evaluation of the acceptability (e.g. if chemically synthesised or not) and the eventual need to restrict their (functional) use only to some crops or in the case of additives to some food-(sub) categories.
Switzerland	Switzerland considers the electronic working group approach as very appropriate for a process including participants from different regions all over the world and estimates the proposed standard review template as helpful. Using the template and gaining some experience with it will show to what extent the template meets a need or needs adaptations.
United States.	The United States supports the use of a template as a tool for the review process.
Do members have suggestions for additional guidance per the 5.1 criteria? If so, please elaborate.	
Australia	Australia's response: a flow chart may provide further useful guidance for members (proponents) when submitting a new work proposal. An example of the type of flow chart used by Australia to amend its National Standard for Organic and Biodynamic Produce for

	export is attached
Canada	Canada finds the guidance for 5.1 criteria is adequate.
European Union	The EU supports the working group approach and supports the use of the proposed template. When members have will have gained some more experience with the template, revisions of the template can be considered.
IFOAM	For the time being no additional guidance is needed for the 5.1 Criteria for the evaluation of substances, except that more explicitly in the application form the origin and the areas of usage should be mentioned.
United States	The United States notes that the current template does not specifically address suggestions for conditions of use in the table. A question could be added.
Please submit any comments regarding the proposed changes to text found in *Appendix I* of this Report.	
Australia	As a general comment Australia supports the approach but considers that the document attached could be a little clearer in terms of process and we would suggest that the eWG consider the document used by the Codex Committee on Food Hygiene as a good model for outlining how it will conduct this work. While the CCFH process is more complex due to the volume of new work we consider that it articulates a similar process. Suggested amendments are shown in the attached using bold/underline for insertions and strikethrough for deletion.
Canada	No comments.
European Union	EU has no further comments at the moment
United States	The United States has no further comment at this time.
How should the eWG deal with substances that might fall outside the eWG?	
Canada	Canada suggests that the scope of responsibility of the eWG be limited to the review of substances within the scope of Annex 2 until it is determined whether substances outside the scope of Annex 2 should be subject to the 5.1 criteria or a different set of criterion.
IFOAM	IFOAM thinks, that the eWG should be responsible for determining whether proposed substances fall outside the scope of Annex 2 but are covered generally by Annex I. In this case the eWG should be tasked to review these substances. Regarding the question whether substances outside the scope of Annex 2 should be subject to the 5.1 criteria or should different criterion be developed for these substances, IFOAM would propose to take the existing criteria as a basis but for certain categories of substances to include later additional criteria, in case needed. These could be later included in the Annex I text
United States	The scope of the eWG should be limited to review of substances contained in Annex 2. The United States understands that in limited circumstances the eWG might determine that such a substance under review by the eWG might fall outside of Annex 2. In this case the eWG could offer a recommendation on the substance and its appropriate placement to the Committee. As for the determination of whether criteria similar to those detailed in 5.1 are needed for other Annexes, the United States would note that the criteria in 5.1 were developed to facilitate the development of national lists. Procedures for new work as already outlined in the Codex should adequately address additions to other annexes.