



## PROGRAMME MIXTE FAO/OMS SUR LES NORMES ALIMENTAIRES COMITÉ DU CODEX SUR L'ÉTIQUETAGE DES DENRÉES ALIMENTAIRES

### Trente-neuvième session

Québec, Québec (Canada), 9 – 13 mai 2011

**Avant-projet de révision des Directives concernant la production, la transformation, l'étiquetage et la commercialisation des aliments issus de l'agriculture biologique (GL 32-1999)**

**Rapport du Groupe de travail électronique sur la révision des Directives concernant la production, la transformation, l'étiquetage et la commercialisation des aliments issus de l'agriculture biologique**

Ce document comprend le rapport du groupe de travail électronique et

- une proposition de refonte de l'approche de travail structurée (Annexes III et XI)
- un projet de modèle d'étude de l'ajout de nouvelles substances à l'Annexe 2 (Annexe IV)
- des applications du projet de grille d'étude
  - Proposition d'ajout du spinosad, du bicarbonate de potassium et de l'octanoate de cuivre à l'Annexe 2, Tableau 2 de CX/FL 10/38/17; (Annexes V – VII) et
  - Élargissement des autres usages de l'éthylène pour le déverdissement des agrumes, pour l'amorçage de la floraison de l'ananas et comme inhibiteur de germination des oignons et des pommes de terre (en remplacement du document CX/FL 11/39/8) (Annexes VIII – X)

### I. État de la question

Le Comité du Codex sur l'étiquetage des denrées alimentaires (CCFL) a tenu sa 38<sup>ème</sup> session en mai 2010 et a convenu de mettre sur pied un groupe de travail électronique chargé de :

- Réexaminer les propositions de nouvelles substances à ajouter à la liste des substances autorisées pour la production d'aliments biologiques en vertu de l'Annexe 2 des Directives concernant la production, la transformation, l'étiquetage et la commercialisation des aliments issus de l'agriculture biologique : (CAC/GL 32-1999);
- Proposer des révisions à d'autres sections de ces directives au besoin. (ALINORM 10/33/22); et;
- Examiner les propositions de nouvelles substances suivant un cycle de deux ans.

Pour le cycle de révision 2010-2012, le Comité a décidé que les États-Unis présideraient le groupe de travail électronique qui examinera les substances soumises par l'Union européenne à la 38<sup>ème</sup> session du CCFL : spinosad, bicarbonate de potassium, octanoate de cuivre et éthylène. Trois usages de l'éthylène ont été étudiés séparément : déverdissement des agrumes, amorçage de la floraison des ananas et inhibition de la germination des oignons et des pommes de terre.

Le Comité a conféré les attributions suivantes à ce groupe de travail électronique (ALINORM 10/33/22, para 126-130) :

- Examiner les substances proposées aux points 5a et 12a de l'ordre du jour de la 38<sup>ème</sup> session du CCFL (spinosad, bicarbonate de potassium, octanoate de cuivre et éthylène) qui devront figurer à l'annexe II des *Directives concernant la production, la transformation, l'étiquetage et la commercialisation des aliments biologiques* (CAC/GL 32-1999);
- Repérer le complément d'informations nécessaires pour répondre aux critères de la section 5.1 et collecter de telles données auprès des pays qui les soumettront ou des membres du groupe de travail électronique;
- Formuler des recommandations à la 39<sup>ème</sup> session du CCFL sur l'inclusion éventuelle de ces substances à l'annexe 2;

- Fournir des conseils au Comité à sa 39<sup>e</sup> session sur l'utilité d'une démarche privilégiant la création d'un groupe de travail pour faciliter un cycle de deux ans au regard des substances qui doivent être incluses à l'annexe 2.

## II. PARTICIPATION AU Groupe de travail électronique

En octobre 2010, les États-Unis, actuellement à la tête de ce groupe de travail électronique, ont invité tous les membres du CCFL à participer à ce groupe chargé de revoir les *Directives concernant la production, la transformation, l'étiquetage et la commercialisation des aliments issus de l'agriculture biologique*. Dix pays, une organisation membre et un observateur ont dit vouloir participer à ce groupe de travail électronique. La liste des participants est donnée en *Annexe I*.

En décembre 2010, les États-Unis ont transmis aux membres du groupe de travail électronique une compilation de tous les commentaires reçus et un projet de document de discussion résumant les commentaires et les constatations. Les États-Unis ont demandé que les membres du groupe de travail électronique fournissent des commentaires additionnels sur la nécessité d'un complément d'information pour répondre aux critères de la Section 5.1 et du recours à une démarche structurée privilégiant un groupe de travail pour revoir les substances de l'Annexe 2. Le groupe de travail électronique a aussi posé les questions suivantes concernant les critères en 5.1 : (1) les membres pensent-ils que l'utilisation d'une grille d'examen standard pour évaluer les critères en 5.1 est utile; et (2) les membres ont-ils des suggestions d'orientations additionnelles à fournir conformément aux critères de 5.1.

Des questions additionnelles ont été soulevées, à savoir si ce groupe de travail électronique devrait être chargé de déterminer si les substances proposées sont en dehors de la portée de l'Annexe 2 et de les étudier – par exemple, l'éthylène utilisé pour le mûrissement des bananes et d'autres fruits tropicaux, qui est traité dans l'Annexe I. Une autre question a été celle de savoir si les substances hors de la portée de l'Annexe 2 devraient être soumises aux critères de 5.1. Les États-Unis ont prié les membres de soumettre tout commentaire additionnel sur ces questions avant le 1<sup>er</sup> février 2011.

Les commentaires reçus en réponse au projet de document de discussion et à la proposition de révision du texte forment la base du rapport de ce groupe de travail soumis au Secrétariat aux fins d'étude à la 39<sup>e</sup> session du CCFL. À titre d'information, le calendrier actualisé pour le travail de ce groupe de travail électronique est donné en *Annexe II*.

## III. REVUE DES SUBSTANCES DE L'ANNEXE 2 : SPINOSAD, BICARBONATE DE POTASSIUM, OCTANOATE DE CUIVRE ET ÉTHYLÈNE

### A. Résumé des réponses

Sept réponses en tout ont été reçues à la demande de commentaires initiale d'octobre 2010.

Les réponses comprennent les commentaires de cinq pays (Australie, Brésil, Croatie, Royaume-Uni et États-Unis), de l'Union européenne et de la Fédération internationale des mouvements d'agriculture biologique (IFOAM).

Six réponses en tout ont été reçues de quatre pays (Suisse, Canada, Australie et Croatie), de l'Union européenne et de l'IFOAM à la seconde demande de commentaires. Les commentaires reçus par le Groupe de travail électronique étaient généralement favorables à l'inclusion du spinosad, du bicarbonate de potassium et de l'octanoate de cuivre, et de l'éthylène pour la lutte contre les mouches des fruits des agrumes et comme agent de contrôle de la floraison de l'ananas dans la liste des substances autorisées pour la production d'aliments biologiques donnée dans l'Annexe 2 (CAC/GL 32-1999).

En général, la majorité des commentaires ne donnaient pas de détails sur la manière dont chaque substance répondait aux critères de 5.1. Un pays a suggéré qu'une grille standard qui comprendrait des informations concernant l'application et les commentaires des membres pour chaque substance pourrait faciliter l'examen. À cette fin, une grille a été établie pour évaluer les substances à partir des critères énoncés dans l'Annexe 2 des directives conjointement avec les commentaires reçus pour chaque substance. Cette grille offre également des orientations additionnelles concernant les raisons à l'appui des substances et les données requises. (*Voir Annexe IV*). Les commentaires reçus par le groupe de travail électronique étaient favorables à l'utilisation d'une grille standard puisqu'elle garantit l'uniformité de l'information présentée par les demandeurs de nouveaux travaux et offre des indications claires aux membres qui souhaitent ajouter de nouvelles substances ou supprimer des substances.

**(a) Spinosad (voir Annexe V)**

Le groupe de travail électronique est généralement favorable à l'approbation du spinosad comme insecticide en vertu de l'Annexe 2, Tableau 2. D'après les commentaires reçus, le spinosad est actuellement utilisé en production biologique dans l'Union européenne, aux États-Unis, en Suisse et au Brésil. Dans sa demande, l'Union européenne abordait chacun des critères de 5.1 et offrait des données et des études à l'appui de ses réponses. Toutefois, des membres ont observé que des précautions devraient être prises pour minimiser les risques pour les espèces non ciblées d'insectes, de prédateurs et de parasites et les risques de développement de résistance, en précisant que leur préoccupation concernait plus particulièrement l'aquaculture et les abeilles. Des membres ont indiqué que le moment et la fréquence de l'application et les conditions climatiques dans lesquelles elle était faite étaient des facteurs qui minimiseraient ces risques.

Pour traiter de la question des conditions et restrictions applicables à l'utilisation appropriée, les membres du groupe de travail électronique ont offert les énoncés suivants à ajouter au Tableau 2:

- Besoin, prescription et doses d'application reconnus par l'organisme ou l'autorité de certification
- Utilisation uniquement là où des mesures sont prises pour minimiser le risque aux parasitoïdes et le risque de développement de résistance.

Un autre membre a suggéré que le comité établisse une période post-évaluation de deux ans pour toute restriction qui se présenterait durant l'application du spinosad et d'autres pesticides qui seront ajoutés à l'avenir.

**(b) Bicarbonate de potassium (voir Annexe VI)**

Le groupe de travail électronique approuve généralement l'ajout du bicarbonate de potassium en tant que fongicide à l'Annexe 2, Tableau 2. Dans sa demande, l'Union européenne abordait chacun des critères de 5.1 et offrait des données et des études à l'appui de ses réponses. D'après les commentaires reçus, le bicarbonate de potassium peut être utilisé comme fongicide dans des conditions humides sous lesquelles il se dissout en ses ions et seul l'ion bicarbonate agit comme fongicide. Des membres ont confirmé que le bicarbonate de potassium est employé pour lutter contre diverses maladies fongiques d'une gamme de cultures biologiques en Union européenne, au Brésil, aux États-Unis, de même que dans d'autres pays. Le bicarbonate de potassium est déjà autorisé comme additif alimentaire dans l'Annexe 2, Tableau 3. Le groupe de travail électronique n'a trouvé aucune lacune dans les données et les études générales présentées. Aucun énoncé sur l'utilisation n'a été soumis.

**(c) Octanoate de cuivre (voir Annexe VII)**

Le groupe de travail électronique est généralement favorable à l'approbation de l'octanoate de cuivre en vertu de l'Annexe 2, Tableau 2. Dans sa demande, l'Union européenne abordait chacun des critères de 5.1 et offrait des données et des études à l'appui de ses réponses. D'après les commentaires reçus, les sels de cuivre sont largement employés comme fongicide dans les systèmes de production biologique. Un membre a fait état de la préoccupation au sujet de l'accumulation de cuivre dans les sols et les tissus végétaux; toutefois, l'utilisation d'octanoate de cuivre devrait réduire la quantité de cuivre nécessaire pour obtenir le même effet fongicide qu'avec d'autres sels de cuivre. Un observateur a fait valoir que l'utilisation de l'octanoate de cuivre est restreinte à une application maximale de 8 kg/ha sur la base d'une moyenne mobile. Dans sa demande, l'Union européenne a déclaré que l'accumulation ne devrait pas poser problème si les doses indiquées sur l'étiquette sont respectées et la dose maximale de l'Union européenne est de 6 kg/ha.

Concernant les conditions d'utilisation appropriée, les membres du groupe de travail électronique ont offert ce qui suit :

- Ajout d'une restriction générale concernant la quantité annuelle maximale applicable à toutes les préparations à base de cuivre par opposition à une restriction applicable qu'à l'octanoate de cuivre.
- Le texte actuel sur le cuivre en général est suffisant et il n'est nul besoin d'une restriction qui viserait expressément l'utilisation de l'octanoate de cuivre.

**(d) Éthylène (voir Annexe VIII-X)**

- pour le déverdissement des agrumes,
- pour l'amorçage de la floraison de l'ananas,
- pour inhiber la germination des pommes de terre et des oignons.

L'UE a présenté conjointement avec le Costa Rica les raisons à l'appui des trois usages précédents de l'éthylène aux membres du groupe de travail électronique le 1<sup>er</sup> février 2011. Un membre a appuyé les raisons avancées pour les trois usages. Un membre était favorable à l'utilisation de l'éthylène comme agent

de lutte contre les mouches des fruits chez les agrumes et n'était d'accord qu'en principe avec les deux autres usages. Ce même membre a également remarqué qu'il serait utile d'avoir un complément d'information sur la façon dont l'éthylène en tant qu'inhibiteur de la germination des pommes de terre et des oignons se conforme aux conditions exigées dans la Section 5.1v. Un membre a de la même façon appuyé tous les usages proposés de l'éthylène sauf celui comme inhibiteur de la germination des pommes de terre et des oignons parce qu'il existe d'autres pratiques et des matériaux naturels ayant le même effet.

Le groupe de travail électronique est généralement favorable à l'approbation de l'éthylène pour le déverdissement des agrumes et l'amorçage de la floraison de l'ananas. Toutefois, l'endroit où faire figurer ces usages dans l'Annexe 2 n'est pas clair. Le groupe de travail électronique n'était pas pleinement d'accord pour approuver l'utilisation de l'éthylène comme agent inhibiteur de la germination des pommes de terre et des oignons.

## **B. Recommandation sur l'opportunité d'ajouter ces substances à l'Annexe 2**

Le groupe de travail électronique est favorable à l'ajout du spinosad, du bicarbonate de potassium, de l'octanoate de cuivre et de l'éthylène pour le déverdissement des agrumes et comme agent de contrôle de la floraison de l'ananas à l'Annexe 2, Tableau 2 des Directives concernant la production, la transformation, l'étiquetage et la commercialisation des aliments issus de l'agriculture biologique comme il est énoncé dans le document de discussion CX/FL 10/38/17 et recommande les ajouts suivants au Tableau 2 :

**TABLEAU 2 : SUBSTANCES POUR LA LUTTE CONTRE LES ORGANISMES NUISIBLES ET LES MALADIES DES PLANTES**

Substance	Description; composition exigée; conditions d'emploi
<b><i>I. Végétale et animale</i></b>	
[Spinosad]	[Besoin reconnu par l'organisme ou autorité de certification]  [Besoin, prescription et doses d'application reconnus par l'organisme ou autorité de certification]  [Utilisation uniquement là où des mesures sont prises pour minimiser le risque aux parasitoïdes et le risque de développement de résistance.]
<b><i>II. Minérale</i></b>	
Cuivre sous la forme d'hydroxyde de cuivre, d'oxychlorure de cuivre, de sulfate de cuivre (tribasique), d'oxyde cuivreux, bouillie bordelaise et bouillie bourguignonne	Besoin, prescription et doses reconnus par l'organisme ou autorité de certification. Comme fongicide à condition que la substance soit employée de sorte à minimiser l'accumulation du cuivre dans le sol. [1]  [ <sup>1</sup> Les membres doivent établir l'application maximale au niveau national en prenant en compte le type de conditions podoclimatiques des cultures et les attaques périodiques des maladies des plantes]
[Bicarbonate de potassium]	[-----]

Le groupe de travail électronique n'a pu décider concernant l'utilisation de l'éthylène comme inhibiteur de la germination des pommes de terre et des oignons.

#### **IV. CONSEIL AU COMITÉ SUR L'UTILITÉ D'UNE DÉMARCHE FAISANT APPEL À UN GROUPE DE TRAVAIL POUR PASSER EN REVUE LES SUBSTANCES À AJOUTER À L'ANNEXE 2. (voir Annexes III et XI)**

##### **A. Résumé des réponses**

À sa 38<sup>e</sup> session, le CCFL a convenu d'appliquer un processus de révision fondé sur un cycle de deux ans à l'examen des propositions d'ajout de nouvelles substances à l'Annexe II. (ALINORM 10/33/22, para 122 et CRD 15).

Les participants au groupe de travail électronique n'ont exprimé aucune opposition au processus de révision accepté à la 38<sup>e</sup> session et n'ont proposé que quelques améliorations à y apporter. Ce processus modifié est exposé en Annexe I de ce rapport.

Il est ressorti des commentaires reçus que le groupe de travail électronique privilégiait généralement le recours à un groupe de travail électronique pour examiner les nouvelles substances. Un membre du groupe de travail électronique a mentionné que la priorité d'un nouveau travail proposé ou d'un travail en cours serve à déterminer l'ordre suivant lequel les travaux seraient traités. Un observateur a suggéré que l'ensemble des *Directives concernant la production, la transformation, l'étiquetage et la commercialisation des aliments issus de l'agriculture biologique* soit revu tous les quatre ans. Des commentaires ont mentionné également que les critères additionnels comme ceux exposés dans la Section 8.3 du document de discussion des États-Unis CX/FL 10/38/11 n'étaient pas nécessaires et les États-Unis se sont dits d'accord avec cette évaluation.

Les commentaires reçus par le groupe de travail électronique étaient favorables à l'utilisation d'une grille standard (*Voir Annexe IV*) pour faire en sorte que l'information soumise par les demandeurs dans les propositions de nouveaux travaux soit uniforme et fournisse des orientations claires aux membres cherchant à ajouter ou à supprimer des substances. Plusieurs membres ont observé que d'autres modifications devront peut-être être apportées à la grille au fil de l'évolution du processus de révision. Un membre a également souligné l'importance de données comme les rapports scientifiques ou les déclarations de fabrication pour aider à déterminer si les substances et tout ingrédient qui y est associé répondent aux critères de la Section 5.1.

L'Australie a suggéré que le groupe de travail électronique s'inspire du modèle du Comité du Codex sur l'hygiène alimentaire pour déterminer les priorités de travail et a aussi suggéré l'établissement d'un ordiogramme pour illustrer plus clairement le processus que suivrait une proposition de nouveau travail, mais sans présenter une révision du processus de revue ou un ordiogramme illustrant ces suggestions.

Les commentaires étaient aussi généralement favorables à limiter le champ des compétences du groupe de travail électronique à la revue des substances correspondant à la portée de l'Annexe 2 jusqu'à ce que le comité détermine si les substances hors de cette portée devraient être soumises aux critères de 5.1.

##### **B. Recommandation**

Peut-être faudra-t-il examiner davantage la proposition de refonte de la démarche de travail structurée en Annexe III compte tenu des commentaires faits par l'Australie au sujet de l'amélioration du texte.

## ANNEXE I: LISTE DES PARTICIPANTS

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**Annexe II : Calendrier MIS À JOUR**

Fait	Lettre d'invitation à se joindre au groupe de travail électronique et demande de commentaires sur les substances proposées et la démarche de travail structurée envoyées aux pays membres et aux observateurs
Fait	Expression d'intérêt et commentaires sur les substances proposées et la démarche de travail structurée reçus.
Fait	Projet de document de discussion contenant la recommandation sur les nouvelles substances proposées et le projet de refonte de la démarche de travail structurée (prenant en compte les commentaires reçus en réponse à CRD 15) envoyé aux membres du groupe de travail électronique
Fait	Commentaires attendus du groupe de travail électronique sur le projet de document de discussion et la refonte de la démarche de travail structurée
25 mars 2011	Document de discussion final (comprenant les commentaires reçus du groupe de travail électronique) envoyé au Secrétariat du Codex aux fins de transmission et d'étude à la 39 <sup>e</sup> session du CCFL en mai 2011.



## Annexe III

### Projet de refonte de la démarche de travail structurée

#### **Inconvénients du processus d'étude et de revue de la production biologique**

- Fait que l'examen de propositions de nouveaux travaux puisse exiger des compétences techniques spécialisées. Ces compétences n'ont habituellement pas été disponibles à chaque session.
- Fait que les propositions de nouveaux travaux n'ont pas toujours été soumises à temps pour permettre leur étude par des experts techniques avant les réunions du comité.
- Fait que les propositions sont souvent incomplètes et n'abordent pas systématiquement les critères établis dans la section 5.1 des directives.
- Fait que les listes de l'Annexe 2 sont indicatives et n'exigent pas forcément une mise à jour annuelle.
- Fait que la participation des membres est limitée; particulièrement celle des pays en développement.

#### **Démarche recommandée**

- Un processus d'étude et de revue structuré opportun qui économise les ressources du comité.
- Un cycle de deux ans pour les propositions
- Le recours à un groupe de travail électronique de la production biologique groupe de travail électronique pour évaluer les propositions et établir l'ordre de priorité des nouveaux travaux du comité
- Établissement et utilisation d'une grille standard applicable aux demandes et à la collecte de commentaires
- La direction du Groupe de travail électronique serait assumée à tour de rôle par les pays; le pays proposant un nouveau travail ne sera pas être admissible à la direction du Groupe de travail électronique
- En l'absence de propositions de nouveaux travaux, le Groupe de travail électronique ne sera pas constitué.

#### **Procédure recommandée pour un cycle d'étude et de revue de deux ans des propositions**

- Année un : Soumission des propositions au Secrétariat. Le comité mettra sur pied un Groupe de travail électronique pour soumettre des propositions :
  - Les propositions de nouveaux travaux seront soumises 60 jours avant la plénière de sorte que les membres aient amplement le temps de les étudier avant la plénière.
  - À la plénière de l'année un, le comité discutera de l'intérêt de base des propositions pour déterminer s'il est suffisant. Si le comité arrive à un consensus sur l'importance suffisante de l'intérêt suscité par une ou plusieurs propositions, il constituera un Groupe de travail électronique et les propositions de nouveaux travaux en vertu de l'Annexe 2 seraient transmises à la Commission aux fins d'approbation à titre de document à l'étape 1/3. Faute d'un intérêt suffisant des membres pour entreprendre un travail sur une substance, le membre demandeur pourra présenter de nouveau sa proposition au prochain cycle; cela exclut toute demande de complément d'information concernant une proposition existante de nouveau travail. Le comité pourra décider comme bon lui semblera de faire étudier par le Groupe de travail électronique des substances qui n'entrent pas dans le cadre de l'Annexe 2.
  - Entre l'année un et l'année deux, le Groupe de travail électronique entreprendra l'étude des propositions dont il a été chargé et préparera une recommandation au comité au cours de l'année deux.
  - Pour les révisions de l'Annexe 2, le Groupe de travail électronique examinera l'information et fournira un rapport qui indiquera si les critères de la Section 5.1 ont été respectés. Le Groupe de travail électronique pourra chercher à obtenir des informations additionnelles au besoin pour achever les propositions.
- Année deux : Le comité discute les recommandations du Groupe de travail électronique.
  - Pour les révisions à l'Annexe 2, si le comité accepte d'approuver les propositions, ces dernières seront avancées à l'étape 5/8.

Si aucune proposition n'est faite, alors le Groupe de travail électronique ne sera pas constitué.

**ANNEXE IV : Projet de grille pour l'étude de l'ajout d'une nouvelle substance à l'Annexe 2****Substance** : (nom de la substance)**Utilisation** : (Prière de préciser l'utilisation applicable : fertilisation, amendement des sols, lutte contre les maladies et les nuisibles des plantes et les mauvaises herbes, additifs et auxiliaires technologiques dans la préparation et la conservation d'aliments)**Critères particuliers applicables** : (a, b, c)**Demande soumise par** : (nom du (des) pays faisant la demande)**Évaluation par rapport aux critères de la section 5.1****I. Description générale de la substance**

Membre/Observateur	Description

**II. Section 5.1 Critères généraux (tous les critères de cette section doivent être abordés)****5.1.i) La substance respecte-t-elle les principes de la production biologique tels qu'ils sont énoncés dans ces directives?**

Membre/Observateur	Réponse

**5.1.ii) L'utilisation de la substance est-elle nécessaire/essentielle à la fin visée ?**

Membre/Observateur	Réponse

**5.1.iii) La fabrication, l'utilisation et l'élimination de la substance donnent-elles lieu ou contribuent-elles à des effets inacceptables sur l'environnement?**

Membre/Observateur	Réponse

**5.1.iv) La substance a-t-elle le plus faible effet néfaste sur la santé et la qualité de vie des humains ou des animaux?**

Membre/Observateur	Réponse

**5.1.v) Des substances alternatives autorisées sont-elles disponibles en quantité suffisante ou en qualité adéquate?**

Membre/Observateur	Réponse

**Le demandeur a-t-il abordé de manière adéquate les critères généraux de la Section 5.1?**

Membre/Observateur	Réponse

**III. Section 5.1 Critères spécifiques : a) substance utilisée à des fins de fertilisation,**

**d'amendement des sols**

5.1.a)1) La substance est-elle essentielle pour fertiliser le sol ou en préserver la fertilité ou combler des besoins nutritionnels spécifiques des végétaux cultivés ou répondre à des besoins particuliers en matière d'amendement du sol et de rotation des cultures qui ne peuvent être satisfaits par les pratiques mentionnées à l'Annexe 1 ou d'autres substances comprises dans le Tableau 2 de l'Annexe 2?

Membre/Observateur	Réponse

5.1.a)2) La substance est-elle d'origine végétale, microbienne ou minérale? A-t-elle subi un des traitements suivants : physique (mécanique, thermique), enzymatique, microbien (compostage, fermentation)? La substance a-t-elle été soumise à des procédés chimiques? Ces derniers ont-ils été limités à l'extraction des supports et des liants?

Membre/Observateur	Réponse

5.1.a)3) L'utilisation de la substance a-t-elle un effet inacceptable sur l'équilibre de l'écosystème des sols ou les caractéristiques physiques du sol, ou la qualité de l'eau et de l'air?

Membre/Observateur	Réponse

5.1.a)4) L'utilisation de la substance devrait-elle être restreinte à des conditions, des régions ou des denrées spécifiques?

Membre/Observateur	Réponse

Le demandeur a-t-il abordé de manière adéquate les critères spécifiques de la section a) pour les substances destinées à la fertilisation, à l'amendement des sols?

Membre/Observateur	Réponse

**IV. Section 5.1 Critères spécifiques : a) substance utilisée à des fins de lutte contre les maladies et les nuisibles des plantes et contre les mauvaises herbes**

5.1.b)1) La substance est-elle essentielle pour la lutte contre un ravageur ou une maladie particulière pour lesquels il n'existe pas d'autres procédés de nature biologique, physique ou faisant appel à la sélection des végétaux et/ou de pratiques de gestion efficaces?

Membre/Observateur	Réponse

5.1.b)2) L'utilisation prend-elle en compte la possibilité d'impact nocif sur l'environnement, l'écologie (particulièrement les organismes non ciblés) et la santé des consommateurs, des animaux d'élevage et des abeilles?

Membre/Observateur	Réponse

<b>5.1.b)3) La substance est-elle d'origine végétale, microbienne ou minérale? A-t-elle été soumise à un des procédés suivants : physique (mécanique, thermique), enzymatique, microbien (compostage, fermentation)?</b>	
<b>Membre/Observateur</b>	<b>Réponse</b>
<b>5.1.b)4) La substance est-elle utilisée dans des pièges et des distributeurs, comme les phéromones qui sont synthétisées par voie chimique? Existe-t-il des produits de substitution en quantité suffisante sous leur forme naturelle? Les conditions de leur utilisation entraînent-elles directement ou indirectement la présence de résidus du produit dans les parties comestibles?</b>	
<b>Membre/Observateur</b>	<b>Réponse</b>
<b>5.1.b)5) L'utilisation de la substance devrait-elle être restreinte à des conditions, des régions ou des denrées spécifiques?</b>	
<b>Membre/Observateur</b>	<b>Réponse</b>
<b>Le demandeur a-t-il abordé de manière adéquate les critères spécifiques de la Section b) substance utilisée à des fins de lutte contre les maladies et les nuisibles des plantes et contre les mauvaises herbes?</b>	
<b>Membre/Observateur</b>	<b>Réponse</b>
<b>V. Section 5.1 Critères spécifiques : c) substance utilisée comme additif ou auxiliaire technologique dans la préparation ou la conservation de l'aliment</b>	
<b>5.1.c)1) Pour les additifs, est-il possible de produire ou de conserver l'aliment sans l'additif? Pour les auxiliaires technologiques, est-il possible de produire l'aliment sans l'auxiliaire technologique? Existe-t-il d'autres technologies satisfaisant les directives?</b>	
<b>Membre/Observateur</b>	<b>Réponse</b>
<b>5.1.c)2) L'additif ou l'auxiliaire technologique se trouve-t-il dans la nature? A-t-il été soumis à des procédés mécaniques/physiques (par ex. extraction, précipitation), biologiques/enzymatiques ou microbiens (par ex. fermentation)</b>	
<b>Membre/Observateur</b>	<b>Réponse</b>
<b>5.1.c)3) S'agit-il d'un additif ou d'un auxiliaire technologique qui a été synthétisé chimiquement? Y a-t-il absence de substances naturelles?</b>	
<b>Membre/Observateur</b>	<b>Réponse</b>
<b>5.1.c)4) L'utilisation de l'additif ou de l'auxiliaire technologique préserve-t-elle</b>	

<b>l'authenticité du produit?</b>	
<b>Membre/Observateur</b>	<b>Réponse</b>
<b>5.1.c)5) L'adjonction de l'additif ou de l'auxiliaire technologique n'induirait-elle pas le consommateur en erreur quant à la nature, la substance et la qualité de l'aliment?</b>	
<b>Membre/Observateur</b>	<b>Réponse</b>
<b>5.1.c)6) L'adjonction de l'additif ou de l'auxiliaire technologique ne porte-t-elle pas atteinte à la qualité globale du produit?</b>	
<b>Membre/Observateur</b>	<b>Réponse</b>
<b>Le demandeur a-t-il abordé de façon adéquate les critères spécifiques de la section c) substance utilisée comme additif ou auxiliaire technologique dans la préparation ou la conservation de l'aliment?</b>	
<b>Membre/Observateur</b>	<b>Réponse</b>
<b>VI. Questions générales applicables à toutes les propositions</b>	
<b>Faut-il d'autres informations pour achever l'étude de la nouvelle substance? (Prière d'indiquer ici les liens aux études à l'appui)</b>	
<b>Membre/Observateur</b>	<b>Réponse</b>
<b>Faut-il ajouter d'autres conditions d'emploi?</b>	
<b>Membre/Observateur</b>	<b>Réponse</b>
<b>Seriez-vous favorable à l'ajout de la nouvelle substance à l'Annexe 2?</b>	
<b>Membre/Observateur</b>	<b>Réponse</b>

**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

<b>Assessment against Section 5.1 Criteria</b>	
<b>General Description of Substance</b>	
<b>Member/Observer</b>	<b>Description</b>
<b>EU submission-CX/FL 10/38/17</b>	<p>Spinosad is produced by the bacterium <i>Saccharopolyspora spinosa</i>. 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).</p> <p>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.</p>
<b>United States</b>	Description is accurate.
<b>I. Section 5.1 Main Criteria</b>	
<b>5.1.i) Is the substance consistent with the principals of organic production as outlined in the Guidelines?</b>	
<b>Member/Observer</b>	<b>Answer</b>
<b>EU submission-CX/FL 10/38/17</b>	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.
<b>Australia</b>	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.
<b>Brazil</b>	<p>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.</p> <p>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.</p> <p>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.</p>
<b>United Kingdom</b>	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.
<b>United States</b>	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.
<b>IFOAM</b>	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?

<b>Member/Observer</b>	<b>Answer</b>
<b>EU submission-CX/FL 10/38/17</b>	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.
<b>United States</b>	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?

<b>Member/Observer</b>	<b>Answer</b>
<b>EU submission-CX/FL 10/38/17</b>	No harmful effects are reported on the manufacturing and disposal of spinosad. For use: see 5.1.b)2) below.
<b>United States</b>	Concur with EU statement.

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

<b>Member/Observer</b>	<b>Answer</b>
<b>EU submission-CX/FL 10/38/17</b>	It has the lowest negative impact on human or animal health and quality of life; See 5.1.b)2) below.
<b>Australia</b>	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.
<b>United States</b>	Concur when used as directed according to label recommendations and precautions.

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

<b>Member/Observer</b>	<b>Answer</b>
<b>EU submission-CX/FL 10/38/17</b>	Approved alternatives are not available in sufficient quantity and/or quality. See 5.1.b)1) below.
<b>United States</b>	Alternatives are not as effective.

Has the applicant adequately addressed the main criteria in section 5.1?	
Member/ Observer	Answer
United States	Yes.
<b>III. Section 5.1 Sub-Criteria: b) substances used for the purpose of plant disease or pest and weed control</b>	
<b>5.1.b)1) Is the substance essential for the control of a harmful organism or a particular disease ?</b>	
Member/ Observer	Answer
EU submission- CX/FL 10/38/17	<p>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.</p> <p>For many intended uses (crop-pest situations), there are no alternative products or viable methods available. Currently available alternatives: pyrethrum, rotenone, neem, <i>Bacillus thuringiensis</i>, 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.</p> <p>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.</p>
United States	Is valuable for control of pests.
<b>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?</b>	
Member/ Observer	Answer
EU submission- CX/FL 10/38/17	<p>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.</p> <p>No concerns were reported on environmental fate of the substance, i.e. rapid photodegradation, and also microbial breakdown. The end-product is CO<sub>2</sub>.</p> <p>Spinosad is hazardous to aquatic organisms and to some non-target insects (pollinators, beneficials):</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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)</li> </ul> <p>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.</p>
United States	Use should be consistent with label warnings for applications of product.
<b>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)?</b>	
Member/ Observer	Answer



<b>EU submission-CX/FL 10/38/17</b>	Spinosad is produced by a bacterium. The organism presently used is not a GMO. It is a selected strain.
<b>United States</b>	Concur with EU statement.
<b>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?</b>	
<b>Member/Observer</b>	<b>Answer</b>
<b>EU submission-CX/FL 10/38/17</b>	Not applicable.
<b>United States</b>	N/A
<b>5.1.b) 5) Should the substance use be restricted to specific conditions, specific regions, or specific commodities?</b>	
<b>Member/Observer</b>	<b>Answer</b>
<b>EU submission-CX/FL 10/38/17</b>	<p>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.</p> <p>Spinosad is compatible with biological control (e.g. release of predators and parasitoids), provided that direct exposure is avoided.</p> <p>Authorizations need to be accompanied by obligations for appropriate risk management practices such as buffer zones and prohibition of spraying during flowering periods.</p>
<b>United States</b>	Use should be consistent with label warnings for applications of product.
<b>Has the applicant adequately addressed the sub-criteria in section b) substances used for the purpose of plant disease or pest and weed control</b>	
<b>Member/Observer</b>	<b>Answer</b>
<b>United States</b>	Yes.
<b>Is there any information needed to complete the review of the new substance (including supporting documents)?</b>	
<b>Member/Observer</b>	<b>Answer</b>
<b>United States</b>	For further information here is the link to the U.S. National Organic Standards Board, Technical Advisory Panel Report on spinosad: : <a href="http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5089350">http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5089350</a>

**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))

<b>Assessment against Section 5.1 Criteria</b>	
<b>General Description of Substance</b>	
<b>Member/Observer</b>	<b>Answer</b>
<b>EU submission-CX/FL 10/38/17</b>	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.
<b>United States</b>	Potassium bicarbonate appears in the National Organic Program regulations list for substances that can be used for plant diseases.
<b>I. Section 5.1 Main Criteria</b>	
<b>5.1.i) Is the substance consistent with the principals of organic production as outlined in the Guidelines?</b>	
<b>Member/Observer</b>	<b>Answer</b>
<b>EU submission-CX/FL 10/38/17</b>	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.
<b>Australia</b>	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.
<b>Brazil</b>	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.
<b>United States</b>	Its use is recognized in organic production.
<b>IFOAM</b>	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.
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#### 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	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.

10/38/17	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.
<b>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?</b>	
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.
<b>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)?</b>	
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.
<b>5.1.b)4) Is the substance used in traps as a dispenser of pheromones which are chemically synthesized? Are there alternative products available in their natural form? Do the conditions of use result in the presence of residues on edible parts of the product?</b>	
Member/Observer	Answer
EU submission-CX/FL 10/38/17	Not applicable.
<b>5.1.b)5) Should the substance use be restricted to specific conditions, specific regions, or specific commodities?</b>	
Member/Observer	Answer
EU submission-CX/FL 10/38/17	Not applicable.
<b>Is there any information needed to complete the review of the new substance?</b>	
Member/Observer	Answer
United States	Yes.
<b>Is there any information needed to complete the review of the new substance (including supporting documents)?</b>	
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: <a href="http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5067008&amp;acct=nopgeninfo">http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5067008&amp;acct=nopgeninfo</a>

**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))

<b>Assessment against Section 5.1 Criteria</b>	
<b>General Description of Substance</b>	
<b>Member/Observer</b>	<b>Answer</b>
<b>EU submission - CX/FL 10/38/17</b>	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).
<b>United States</b>	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.
<b>I. Section 5.1 Main Criteria</b>	
<b>5.1.i) Is the substance consistent with the principals of organic production as outlined in the Guidelines?</b>	
<b>Member/Observer</b>	<b>Answer</b>
<b>EU submission -CX/FL 10/38/17</b>	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.
<b>Australia</b>	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.
<b>Brazil</b>	<p>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.</p> <p>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</p> <p>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.</p>
<b>United States</b>	Agree with EU statement, must be used in a manner that minimizes accumulation in the soil.
<b>IFOAM</b>	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

	<p>octanoate (max. amount of 8kg/ha on a rolling average basis).</p> <p>The assessment against the criteria, made by the European Union is considered as consistent and sufficient.</p>
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#### 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 -CX/FL 10/38/17	See 5.1.b)1) below
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	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.

<b>10/38/17</b>	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.
<b>United States</b>	Agree with EU statement.
<b>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?</b>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>EU submission -CX/FL 10/38/17</b>	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.
<b>United States</b>	EU statement would be very beneficial to lower copper in soil.
<b>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)?</b>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>EU submission -CX/FL 10/38/17</b>	Copper is of mineral origin and undergoes saponification with fatty acids. Saponification is also used in manufacture of soft soap.
<b>United States</b>	Agree Copper is of mineral origin.
<b>5.1.b)4) Is the substance used in traps 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?</b>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>EU submission -CX/FL 10/38/17</b>	Not applicable.
<b>United States</b>	Agree with EU statement.
<b>5.1.b)5) Should the substance use be restricted to specific conditions , specific regions, or specific commodities?</b>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>EU submission -CX/FL 10/38/17</b>	The same restrictions as for other copper compounds should apply.
<b>United States</b>	Agree with EU statement.
<b>Has the applicant adequately addressed the sub-criteria in section b) substances used for the purpose of plant disease or pest and weed control</b>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>United States</b>	Answer seems adequate.
<b>Is there any information needed to complete the review of the new substance (including supporting documents)?</b>	

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<b>Member/ Observer</b>	<b>Answer</b>
<b>United States</b>	For further information here is the link to the U.S. National Organic Standards Board, Technical Advisory Panel Report on fixed coppers: <a href="http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5089146&amp;acct=nopgeninfo">http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5089146&amp;acct=nopgeninfo</a>

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**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)

<b>Assessment against Section 5.1 Criteria</b>	
<b>I. General Description of Substance</b>	
<b>Member/Observer</b>	<b>Description</b>
EU	<p>Natural gas C<sub>2</sub>H<sub>4</sub> (CH<sub>2</sub>=CH<sub>2</sub>) 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.</p> <p>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.</p> <p>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.</p>
<b>II. Section 5.1 General Criteria (all criteria in this section should be addressed)</b>	
<b>5.1.i) Is the substance consistent with the principles of organic production as outlined in the Guidelines?</b>	
<b>Member/Observer</b>	<b>Answer</b>
EU	The maintenance of plant health by preventative measures is one of the principles of organic farming.
<b>5.1.ii) Is use of the substance necessary/essential for it's intended use?</b>	
<b>Member/Observer</b>	<b>Answer</b>
EU	Yes. It can contribute to solve problems with fruit flies in organic citrus and avoid pesticide use in the field.
<b>5.1.iii) Does the manufacture, use and disposal of the substance result in, or contribute to, harmful effects on the environment?</b>	
<b>Member/Observer</b>	<b>Answer</b>
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.
<b>5.1.iv) Does the substance have the lowest negative impact on human or animal health and quality of life?</b>	
<b>Member/Observer</b>	<b>Answer</b>
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.
<b>5.1.v) Are approved alternative available in sufficient quality or quantity?</b>	
<b>Member/Observer</b>	<b>Answer</b>
EU	Bait spraying of spinosad is an alternative. Pyrethrum and rotenone are alternatives with partial efficacy.

<b>Has the applicant adequately addressed the general criteria in section 5.1?</b>	
<b>Member/Observer</b>	<b>Answer</b>
<b>United States</b>	Yes. Under the USDA National Organic Program standards, postharvest use of ethylene is allowed for ripening of tropical fruit and degreening of citrus.
<b>IV. Section 5.1 Specific Criteria: b) substance used for the purpose of plant disease or pest and weed control</b>	
<b>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?</b>	
<b>Member/Observer</b>	<b>Answer</b>
<b>EU</b>	Yes. Contribution to solve problems with fruit flies and to avoid pesticide use in he field.
<b>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?</b>	
<b>Member/Observer</b>	<b>Answer</b>
<b>EU</b>	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. 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.
<b>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)?</b>	
<b>Member/Observer</b>	<b>Answer</b>
<b>EU</b>	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.
<b>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?</b>	
<b>Member/Observer</b>	<b>Answer</b>
<b>EU</b>	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.
<b>5.1.b)5) Should the substance use be restricted to specific conditions , specific regions, or specific commodities?</b>	
<b>Member/Observer</b>	<b>Answer</b>
<b>EU</b>	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.
<b>Has the applicant adequately addressed the specific criteria in section b) substances used for the purpose of plant disease or pest and weed control</b>	
<b>Member/Observer</b>	<b>Answer</b>
<b>Australia</b>	Australia agrees with the paper relating to the use of ethylene for fruit fly control in citrus.
<b>United States</b>	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.
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### 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/ Observer	Answer
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 than 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

<b>Assessment against Section 5.1 Criteria</b>	
<b>I. General Description and Placement of Substance</b>	
<b>Member/ Observer</b>	<b>Description</b>
<b>Costa Rica/EU Application</b>	<p>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.</p> <p>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 (<i>Ananas comosus</i>). For induction of flowering in pineapple plants, ethylene gas is dissolved in water and sprayed over the plants.</p> <p>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.</p> <p>The source of commonly used ethylene gas are natural gas liquids or crude oil.</p> <p>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.</p> <p>Ethylene can be applied at a rate of 2.25-3.5 Kg (ethylene) per hectare with an excess of water &gt;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.</p>
<b>Member/ Observer</b>	<b>What is the appropriate placement of the substance?</b>
<b>Costa Rica/EU Application</b>	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.
<b>II. Section 5.1 Main Criteria</b>	

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

Member/ Observer	Answer
<p><b>Costa Rica/EU Application</b></p>	<p>The use of ethylene is generally in line with principles of organic production:</p> <ul style="list-style-type: none"> <li>• Pineapples naturally produce flowering as a reaction to stress provoked by environmental effects, particularly temperatures, but it takes place unevenly.</li> <li>• For commercial production such flowering must take place all at the same time, which can only be done using ethylene.</li> <li>• Alternatives to ethylene are not available on a commercial scale.</li> <li>• 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.</li> <li>• The substance (ethylene) is found in nature and plants themselves produce it in some of their physiological stages.</li> <li>• 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.</li> </ul> <p>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.</p> <p>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.</p>

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

Member/ Observer	Answer
<p><b>Costa Rica/EU Application</b></p>	<p>Flower inducing of the pineapple plant is necessary for the following reasons:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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'.</li> <li>• 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.</li> <li>• 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.</li> <li>• To be able to produce for overseas markets a producer will need to supply clients</li> </ul>

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 to 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/m<sup>3</sup> = 2x10<sup>-5</sup> (0.00002) kg/m<sup>3</sup>). Worker safety is thus a concern, as the density of the gas is listed at 1.169 kg/m<sup>3</sup>. 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	<p>Alternatives have not been found successful or acceptable:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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<sub>3</sub>) and arsenic hydride (AsH<sub>3</sub>) , and therefore was rejected as an alternative.</li> <li>• The use of already ripened fruit, which releases ethylene gas is not a realistic</li> </ul>

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 than 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	<p>EU general review on ethylene  <a href="http://ec.europa.eu/food/plant/protection/evaluation/existactive/list_ethylene_en.pdf">http://ec.europa.eu/food/plant/protection/evaluation/existactive/list_ethylene_en.pdf</a>            United States technical advisory Panel (TAP) on Ethylene for Crops:  <a href="http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5067073&amp;acct=nopgeningo">http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5067073&amp;acct=nopgeningo</a>            Supplemental Info on Ethylene for Crops:  <a href="http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5085744">http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5085744</a>            NOSB database:  <a href="http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5085176">http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5085176</a></p>
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**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)

<b>Assessment against Section 5.1 Criteria</b>	
<b>I. General Description of Substance</b>	
<b>Member/Observer</b>	<b>Description</b>
EU	Natural gas C <sub>2</sub> H <sub>4</sub> (CH <sub>2</sub> =CH <sub>2</sub> ) 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.
<b>II. Section 5.1 General Criteria (all criteria in this section should be addressed)</b>	
<b>5.1.i) Is the substance consistent with the principals of organic production as outlined in the Guidelines?</b>	
<b>Member/Observer</b>	<b>Answer</b>
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.
<b>5.1.ii) Is use of the substance necessary/essential for its intended use?</b>	
<b>Member/Observer</b>	<b>Answer</b>
EU	A longer marketing period is important for the economic sustainability of farms.
<b>5.1.iii) Does the manufacture, use and disposal of the substance result in, or contribute to, harmful effects on the environment?</b>	
<b>Member/Observer</b>	<b>Answer</b>
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.
<b>5.1.iv) Does the substance have the lowest negative impact on human or animal health and quality of life?</b>	
<b>Member/Observer</b>	<b>Answer</b>
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).
<b>5.1.v) Are approved alternative available in sufficient quality or quantity?</b>	
<b>Member/Observer</b>	<b>Answer</b>
EU	Cold storage, use of varieties with high dormancy and/or caraway seed oil (for potatoes, where registered) may provide solutions in certain situations.
<b>Has the applicant adequately addressed the general criteria in section 5.1?</b>	

<b>Member/ Observer</b>	<b>Answer</b>
<b>United States</b>	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.
<b>IV. Section 5.1 Specific Criteria: b) substance used for the purpose of plant disease or pest and weed control</b>	
<b>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?</b>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>EU</b>	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.
<b>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?</b>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>EU</b>	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. 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.
<b>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)?</b>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>EU</b>	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.
<b>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?</b>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>EU</b>	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.
<b>5.1.b)5) Should the substance use be restricted to specific conditions , specific regions, or specific commodities?</b>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>EU</b>	It should be limited to sprouting inhibition in potatoes and onions.
<b>Has the applicant adequately addressed the specific criteria in section b) substances used for the purpose of plant disease or pest and weed control</b>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>United States</b>	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

	<p>Organic Program standards.</p> <p>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.</p> <p>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.</p>
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#### 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
<b>United States</b>	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
<b>EU</b>	Yes: for sprouting inhibition in potatoes and onions.

#### Would you support the addition of the new substance in Annex 2?

Member/ Observer	Answer
<b>EU</b>	Yes
<b>Australia</b>	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.
<b>Switzerland</b>	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.
<b>IFOAM</b>	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 than 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.
<b>United States</b>	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	<p>Australia supports the concepts relating to a structured review approach for the Guidelines for Production, Processing, Labelling and Marketing of Organically Produced Foods.</p> <p>Australia agrees that:</p> <ul style="list-style-type: none"> <li>• a more structured process would improve the efficiency of the review process;</li> <li>• proposals for additions to the list need to be provided with sufficient time for appropriate review by countries in advance of any Committee meeting;</li> <li>• amendments to Section 1-8 of the Guidelines can be accomplished through the normal process of a new work proposal;</li> <li>• the proposed cycle would allow a more structured review of the proposed additions to the list; and</li> <li>• the establishment of an electronic organic working group (eOWG) is a useful process to advance new or review existing work.</li> </ul> <p>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”.</p>
Croatia	<p><b>1. Do countries agree that a more structured process would improve the efficiency of the Review process?</b> Answer: Yes, we agree.</p> <p><b>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?</b> Answer: Yes, we agree.</p> <p><b>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?</b> Answer: Yes, we agree.</p> <p><b>4. Do countries agree that the proposed cycle would allow for a more structured review of proposed additions to the list?</b> Answer: Yes, we agree.</p> <p><b>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?</b> Answer: We don't have a suggestion.</p> <p><b>6. Do countries agree that establishment of the EOWG is a helpful support mechanism?</b> Answer: Yes, we agree.</p> <p><b>7. Do countries agree that additional criteria are needed for prioritization of the worked to be undertaken by the EOWG?</b> Answer: Yes, we agree.</p>
EU	<p>The structured work approach as discussed at the CCFL38 (CX/FL 10/38/11 and CRD 15)</p> <p>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.</p>
IFOAM	<p><b>General comments of IFOAM</b></p> <ul style="list-style-type: none"> <li>• IFOAM agrees with the analysis and general aims of revising the process.</li> <li>• IFOAM agrees that the requirement for periodic review of the main text of the</li> </ul>

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.

	<p><b>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?</b></p> <ul style="list-style-type: none"> <li>• IFOAM agrees that sufficient time is needed.</li> </ul> <p><b>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?</b></p> <ul style="list-style-type: none"> <li>• Generally IFOAM does support a four year review cycle</li> <li>• 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.</li> </ul> <p><b>Do countries and observers agree that the proposed cycle would allow for a more structured review of proposed additions to the list?</b></p> <ul style="list-style-type: none"> <li>• Generally yes, but Codex should keep a certain flexibility if urgent issues are coming up.</li> <li>• 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?</li> <li>• 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.</li> </ul> <p><b>Do countries and observers agree that establishment of the EOWG is a helpful support mechanism?</b></p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p><b>Do countries and observers agree that additional criteria are needed for prioritization of the worked to be undertaken by the EOWG?</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> </ul>
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 38<sup>th</sup> 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.
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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:

	<ul style="list-style-type: none"> <li>• Is the substance registered for use in the Member Country;</li> <li>• Volume of use of the substances by individual country and volume of usage and relevance to the international community;</li> <li>• Availability of regional/national reviews and risk assessments ,and coordination with other regional/national lists;</li> <li>• Commitment by the sponsor of the substance to providing supporting data for review based on Section 5.1 criteria.</li> </ul> <p>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.</p>
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#### Additional Information/Questions Posed to the eWG

Country	Response
<b>Do members believe that using a standard review template for evaluation of the 5.1 criteria is helpful?</b>	
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.
<b>Do members have suggestions for additional guidance per the 5.1 criteria? If so, please elaborate.</b>	
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.
<b>Please submit any comments regarding the proposed changes to text found in <i>Appendix I</i> of this Report.</b>	
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.
<b>How should the eWG deal with substances that might fall outside the eWG?</b>	
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	<p>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.</p> <p>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</p>
United States	<p>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.</p> <p>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.</p>