



## PROGRAMA CONJUNTO FAO/OMS SOBRE NORMAS ALIMENTARIAS

### COMITÉ DEL CODEX SOBRE ETIQUETADO DE ALIMENTOS

#### Trigésimo Novena Sesión

Ciudad de Quebec, Canadá del 9 al 13 de mayo del 2011

### ANTEPROYECTO DE ENMIENDA A LAS DIRECTRICES PARA LA PRODUCCIÓN, ELABORACIÓN, ETIQUETADO Y COMERCIALIZACIÓN DE ALIMENTOS PRODUCIDOS ORGÁNICAMENTE

(GL 32-1999)

#### Reporte del Grupo de Trabajo Electrónico sobre la Revisión de las Directrices para la producción, elaboración, etiquetado y comercialización de alimentos producidos orgánicamente

Este documento incluye el reporte del grupo de trabajo electrónico y

- Un Proyecto de Nueva Redacción para el Enfoque de Trabajo Estructurado (Apéndices III y XI)
- Proyecto de Modelo para revisar las inclusiones de nuevas sustancias en el Anexo 2 (Apéndice IV)
- Aplicaciones del proyecto de modelo enmendado
  - Propuesta para nuevo trabajo para incluir el espinosad, el bicarbonato potásico y el octanoato de cobre en el Anexo 2, Tabla 2 CX/FL 10/38/17; (Apéndices V – VII), y
  - Expansión de otros usos para el etileno para remover el color verde de los cítricos, para la inducción de la floración en piñas y para la inhibición de los brotes en papas y cebollas (esto reemplaza al documento CX/FL 11/39/8) (Apéndices VIII –X)

## I. ANTECEDENTES

El Comité del Codex sobre Etiquetado de Alimentos (CCFL) celebró su 38ª sesión en mayo del 2010 y acordó establecer un grupo de trabajo electrónico (GTe) para:

- Revisar las propuestas para nuevas sustancias que deberían incluirse en la lista de sustancias permitidas para producción de alimentos orgánicos en el Anexo 2 de las *Directrices para la Producción, Elaboración, Etiquetado y Comercialización de Alimentos Producidos Orgánicamente*; (CAC/GL 32-1999);
- Proponer, de ser necesario, enmiendas a otras secciones de estas Directrices. (ALINORM 10/33/22); y
- Revisar propuestas para nuevas sustancias utilizando un ciclo de dos años.

Para los ciclos de revisión 2010-12, el Comité acordó que los Estados Unidos presidirá el GTe, el cual revisará las sustancias nominadas por la Unión Europea durante la 38ª Sesión del CCFL: espinosad, bicarbonato potásico, octanoato de cobre y etileno. Se consideraron por separado tres usos para el etileno: para remover el color verde de los cítricos, para la inducción de la floración en piñas y para la inhibición de los brotes en papas y cebollas.

El Comité estableció los siguientes términos de referencia para este grupo de trabajo electrónico (ALINORM 10/33/22 párrafos 126-130):

- Revisar las sustancias propuestas durante la 38ª sesión del CCFL (Temas 5a y 12a del Programa) (espinosad, bicarbonato potásico, octanoato de cobre y etileno) para su inclusión en el Anexo 2 de las *Directrices para la Producción, Elaboración, Etiquetado y Comercialización de Alimentos Producidos Orgánicamente* (CAC/GL 32-1999);

- Identificar datos adicionales que pudieran ser necesarios para satisfacer los criterios de la Sección 5.1 y trabajar en recolectar tales datos de los países que han hecho sumisiones y/o de miembros del GTe;
- Realizar recomendaciones para la 39ª sesión del CCFL sobre si estas sustancias deberían incluirse en el Anexo 2; y,
- Proveer asesoría al Comité sobre la utilidad de un enfoque de grupo de trabajo para facilitar un ciclo de dos años respecto a las sustancias a ser incluidas en el Anexo 2.

## II. PARTICIPACIÓN EN EL GTe

En octubre del 2010, Estados Unidos, en su presente calidad de Presidente de este GTe, invitó a todos los miembros del CCFL a participar en el GTe para la revisión de las *Directrices para la Producción, Elaboración, Etiquetado y Comercialización de Alimentos Producidos Orgánicamente*. Diez países, una organización miembro y un observador expresaron interés en participar en este GTe. Se provee una lista de participantes en el *Apéndice I*.

En diciembre del 2010, los Estados Unidos distribuyeron a los miembros del GTe una compilación de todos los comentarios sometidos y un proyecto de documento de discusión resumiendo los comentarios y conclusiones. Los Estados Unidos solicitaron que los miembros del GTe proveyeran comentarios adicionales respecto a la necesidad de datos adicionales para satisfacer los criterios de la Sección 5.1 y el uso de un enfoque de grupo de trabajo estructurado para revisar las sustancias del Anexo 2. El GTe también preguntó a los miembros las siguientes preguntas respecto a los criterios de la sección 5.1: (1) Creen los miembros que sería útil el uso de un modelo estandarizado de revisión para la evaluación de los criterios de la Sección 5.1; y (2) Tienen los miembros sugerencias para orientaciones adicionales en base a los criterios de la sección 5.1.

Se levantaron preguntas adicionales sobre si este GTe debería ser responsable de determinar si las sustancias propuestas caen fuera del ámbito de aplicación del Anexo 2 y de revisar estas sustancias, como por ejemplo el etileno utilizado para madurar bananas y otras frutas tropicales, lo que está cubierto bajo el Anexo 1. Otra pregunta que se hizo fue sobre si las sustancias que caen fuera del ámbito de aplicación del Anexo 2 deberían someterse a los criterios bajo 5.1. Los Estados Unidos solicitaron que cualquier comentario adicional que los miembros tuvieran respecto a estas preguntas fuera sometido para el 1 de febrero de 2010.

Los comentarios recibidos en respuesta al proyecto de documento de discusión y el texto revisado propuesto formaron las bases para este informe del grupo de trabajo sometido al Secretariado para su consideración durante la 39ª sesión del CCFL. Para propósitos de información, los plazos actualizados para el trabajo de este GTe se proveen en el *Apéndice II*.

## III. REVISIÓN DEL ANEXO 2 SUSTANCIAS: ESPINOSAD, BICARBONATO POTÁSICO, OCTANOATO DE COBRE ETILENO

### A. Resumen de respuestas

Se recibió un total de siete respuestas a la solicitud inicial de comentarios con fecha de octubre del 2010.

Las respuestas incluyeron comentarios de cinco países (Australia, Brasil, Croacia, Reino Unido y los Estados Unidos), la Unión Europea, y la Federación Internacional de Movimientos de Agricultura Orgánica (IFOAM).

Un total de seis respuestas se recibieron de cuatro países (Suiza, Canadá, Australia, y Croacia), la Unión Europea, y la IFOAM respecto a la segunda solicitud de comentarios. Los comentarios recibidos por este GTe apoyaron en general la inclusión del espinosad, el bicarbonato potásico y el octanoato de cobre, y del etileno para el control de las moscas de la fruta en cítricos y como agente para el control de la floración en piñas en la lista de sustancias permitidas para la producción de alimentos orgánicos que se encuentra en el Anexo 2 (CAC/GL 32-1999).

En general, la mayoría de los comentarios no dieron detalles de cómo cada sustancia cumplió con los criterios de la sección 5.1. Un país sugirió que un modelo estándar, que tenga tanto la información sobre la solicitud y los comentarios de los miembros sobre cada sustancia, podría facilitar la revisión. Con ese objetivo se creó un modelo para evaluar sustancias en base a los criterios bajo el Anexo 2 de las Directrices en conjunción con los comentarios recibidos respecto a cada sustancia. El modelo también provee orientaciones adicionales respecto a las justificaciones de apoyo para sustancias y los datos requeridos. (*Ver el Apéndice IV*). Los comentarios recibidos por el GTe apoyaron el uso de un modelo estándar pues

asegura la consistencia en la información sometida por los solicitantes de nuevas propuestas de trabajo y provee una orientación clara a los miembros que buscan añadir o eliminar nuevas sustancias.

**(a) Espinosad (ver el Apéndice V)**

El GTe apoya en general la aprobación del espinosad como insecticida bajo el Anexo 2, Tabla 2. En base a los comentarios recibidos, el espinosad se usa actualmente en la producción orgánica en la Unión Europea, los Estados Unidos, Suiza y Brasil. La sumisión de la Unión Europea respecto al espinosad respondió a cada uno de los criterios bajo el punto 5.1 e incluyó datos e investigaciones apoyando sus respuestas. Algunos miembros indicaron sin embargo que deberían tomarse precauciones para minimizar el riesgo a especies de insectos, predadores y parásitos que no sean intencionadas como blanco y para minimizar el desarrollo de resistencias, con mención especial a preocupaciones para la acuicultura y las abejas. Algunos miembros indicaron que factores de tiempo, frecuencia y condiciones climáticas para su aplicación pudieran minimizar tales riesgos.

Para responder al tema de condiciones o restricciones apropiadas, los miembros del GTe ofrecieron las siguientes declaraciones para su inclusión en la Tabla 2:

- Necesidad, prescripción y tasa de aplicación reconocidas por el organismo o autoridad de certificación
- Usar solo cuando se toman medidas para minimizar el riesgo para parasitoides claves y para minimizar el riesgo de que se desarrollen resistencias.

Otro miembro sugirió que el Comité estableciera un período de dos años posteriores a la evaluación para determinar cualquier limitación que pudiera ocurrir durante la aplicación del espinosad y de otros pesticidas que se incluyan en el futuro.

**(b) Bicarbonato potásico (ver el Apéndice VI)**

El GTe apoya en general la aprobación del bicarbonato potásico como fungicida bajo el Anexo 2, Tabla 2. La sumisión de la Unión Europea respondió a cada uno de los criterios bajo el punto 5.1 e incluyó datos e investigaciones apoyando sus respuestas. En base a los comentarios recibidos, el bicarbonato potásico puede ser usado como fungicida bajo condiciones húmedas en las cuales se disuelve y solo el ion de bicarbonato causa el efecto fungicida. Algunos miembros confirmaron que el bicarbonato potásico se usa para controlar diversas enfermedades micológicas en una gama de cultivos en la producción orgánica en la Unión Europea, Brasil, Estados Unidos y también en los otros países. El bicarbonato potásico está también aprobado como aditivo alimentario en la Tabla 3 del Anexo 2. El GTe no identificó ninguna deficiencia en los datos y las investigaciones sometidas como antecedentes. No se sometieron declaraciones para su uso.

**(c) Octanoato de cobre (ver el Apéndice VII)**

El GTe apoya en general la aprobación del octanoato de cobre como fungicida bajo el Anexo 2, Tabla 2. La sumisión de la Unión Europea respondió a cada uno de los criterios bajo el punto 5.1 e incluyó datos e investigaciones apoyando sus respuestas. En base a los comentarios recibidos, las sales de cobre se usan extensamente como fungicidas en los sistemas de producción orgánica. Un miembro indicó su preocupación respecto a las acumulaciones de cobre en los suelos y tejidos de las plantas; sin embargo, el uso del octanoato de cobre debería reducir la cantidad de cobre que se necesita para obtener el mismo resultado fungicida que otras sales de cobre. Un observador indicó que el uso del octanoato de cobre está restringido a la aplicación máxima de 8 Kg/ha sobre la base de un promedio progresivo. En su sumisión, la Unión Europea indicó que la acumulación no debería ser problemática si se cumple con las tasas para su uso indicadas en la etiqueta y la dosis máxima de aplicación en la Unión Europea es de 6 Kg/ha.

Para responder el asunto de condiciones apropiadas de uso, los miembros del GTe sugirieron lo siguiente:

- Incluir de una restricción general para un máximo anual para todas las preparaciones de cobre en contraste con solo una restricción específica para el octanoato de cobre.
- Las frases existentes respecto al cobre son suficientes en general y no hay necesidad para una restricción específica respecto al uso del octanoato de cobre.

**(d) Etileno (ver el Apéndice VIII-X)**

- para remover el color verde de los cítricos,
- para la inducción de la floración en piñas,
- y para inhibir los brotes en papas y cebollar.

El 1º de febrero del 2010 la UE circuló a los miembros del GTe la justificación sometida en conjunto entre la UE y Costa Rica para los tres usos antedichos del etileno. Un miembro apoyó la justificación para los tres usos. Un miembro apoyó el uso del etileno como agente de control de la mosca de la fruta en cítricos y estuvo de acuerdo solamente en principio con los otros dos usos. El mismo miembro también indicó que sería útil tener mayor información sobre cómo el etileno cumple, como inhibidor de los brotes en papas y cebollas, con los requisitos de la Sección 5.1v. Otro miembro apoyo de manera similar todos los usos propuestos del etileno excepto como inhibidor de los brotes en papas y cebollas pues hay disponibles prácticas y materiales naturales alternativos para la inhibición de los brotes.

El GTe apoya en general la aprobación del etileno para remover el color verde de los cítricos y para inducir la floración en piñas. Sin embargo, no está claro que estos usos para el etileno debieran listarse bajo el Anexo 2. El GTe no estuvo totalmente de acuerdo en aprobar el uso del etileno como agente inhibidor de los brotes en papas y cebollas.

## B. Recomendación sobre si estas sustancias deberían incluirse en el Anexo 2.

El GTe apoya la inclusión del espinosad, el bicarbonato potásico, el octanoato de cobre y el etileno para su uso en remover el color verde de los cítricos y como agente para el control de la floración en piñas, en el Anexo 2, Tabla 2 de las *Directrices para la Producción, Elaboración, Etiquetado y Comercialización de Alimentos Producidos Orgánicamente* tal como se reseña en el documento de discusión CX/FL 10/38/17 y recomienda la incorporación de las siguientes inserciones en la Tabla 2:

**TABLA 2: SUSTANCIAS PARA CONTROL DE PLAGAS Y ENFERMEDADES DE LAS PLANTAS**

Sustancia	Descripción; requisitos de composición; condiciones para su uso
<b><i>I. Planta y Animal</i></b>	
[Espinosa]	<p>[Necesidad reconocida por el organismo o autoridad de certificación]</p> <p>[Necesidad, prescripción y tasas de aplicación reconocidas por el organismo o autoridad de certificación]</p> <p>[Uso solo cuando se toman medidas para minimizar el riesgo para parasitoides y para minimizar el riesgo de que se desarrollen resistencias.]</p>
<b><i>II. Mineral</i></b>	
Cobre en la forma de hidróxido de cobre, oxocloruro de cobre, sulfato (tribásico) de cobre,[octanoato de cobre], óxido cuproso, mezcla de Burdeos y mezcla de Borgoña	<p>Necesidad, prescripción y tasas de aplicación reconocidas por el organismo o autoridad de certificación. Como fungicida con la condición que la sustancia se use de tal manera que minimice la acumulación de cobre en el suelo.[1]</p> <p>[<sup>1</sup> Los miembros deberían establecer límites para la aplicación máxima a nivel nacionales tomando en consideración las condiciones pedo-climáticas, tipos de cosechas y ataques periódicos de enfermedades]</p>
[Bicarbonato potásico]	[-----]

El GTe no es capaz de alcanzar una determinación final sobre el uso del etileno para inhibir los brotes en papas y cebollas.

#### **IV. RECOMENDACIONES AL COMITÉ SOBRE LA UTILIDAD DE UN ENFOQUE DE GRUPO DE TRABAJO PARA REVISAR SUSTANCIAS A SER INCLUIDAS EN EL ANEXO 2. (Ver el Apéndice III y XI)**

##### **A. Resumen de respuestas**

Durante la 38ª sesión del CCFL, el Comité acordó un proceso de revisión para utilizar un ciclo de dos años 2 para considerar propuestas para la inclusión de nuevas sustancias en el Anexo 2. (ALINORM 10/33/22, para 122 y CRD 15)

Los participantes en el GTe no expresaron objeciones respecto al proceso de revisión acordado durante la 38ª sesión del CCFL y propusieron solo unas cuantas mejoras al proceso. Este proceso de revisión modificado se reseña en el Apéndice I de este informe.

En base a los comentarios recibidos, el GTe favoreció en general el uso de un foro de grupo de trabajo electrónico para revisar nuevas sustancias. Un miembro del GTe mencionó que el orden en que se revisen propuestas nuevas o existentes debería basarse en su nivel de prioridad. Un observador sugirió que todas las *Directrices para la Producción, Elaboración, Etiquetado y Comercialización de Alimentos Producidos Orgánicamente* deberían ser revisadas cada cuatro años. Algunos comentarios también mencionaron que los criterios adicionales, tales como se reseñan en la sección 8.3 del documento de discusión de los Estados Unidos, CX/FL 10/38/11, no son necesarios y los Estados Unidos estuvieron de acuerdo con esta aseveración.

Los comentarios recibidos por el GTe apoyaron el uso de un modelo estándar (*Ver el Apéndice IV*) para asegurar la existencia de informaciones consistentes sometidas por los solicitantes para propuesta de nuevos trabajos y para proveer orientaciones claras a los miembros que deseen añadir o eliminar nuevas sustancias. Varios miembros indicaron que pudieran ser necesarias más alteraciones al modelo al evolucionar el proceso de revisión. Un miembro también hizo notar la importancia de datos, tales como reportes científicos o declaraciones de manufactura, para ayudar a determinar si las sustancias y cualesquiera otros ingredientes asociados satisfacen los criterios de la Sección 5.1.

Australia sugirió que el GTe extraiga del modelo para establecer prioridades de trabajo del Comité del Codex sobre Higiene de los Alimentos y también sugirió el desarrollo de un diagrama de flujo para ilustrar de manera más clara el proceso para propuestas de nuevos trabajos, pero no sometió un proceso revisado del proceso de revisión o un diagrama de flujos que reflejaran estas sugerencias.

Los comentarios también se apoyaron en general limitar el ámbito de aplicación del GTe a la revisión de sustancias dentro del ámbito de aplicación del Anexo 2 hasta que el Comité determine si las sustancias que caen fuera del ámbito de aplicación del Anexo 2 deberían estar sujetas a los criterios bajo 5.1.

##### **B. Recomendación**

Consideración Adicional del Anexo III Propuesta de Nueva Redacción para el Enfoque de Trabajo Estructurado pudiera ser necesaria en consideración a los comentarios realizados por Australia respecto a mejoras al texto.

## APÉNDICE I: LISTA DE PARTICIPANTES

País/ Observador	Nombre	Afiliación e información de contacto
Australia	Kate Slater	Codex Australia Department of Agriculture, Fisheries and Forestry 18 Marcus Clarke Street Canberra City ACT G PO Box 858 Canberra ACT 2601 AUSTRALIA Teléfono: +61 2 6272 3933
	Codex Australia	Correo electrónico: <a href="mailto:Codex.contact@daff.gov.au">Codex.contact@daff.gov.au</a>
Brasil	Roberto Guimarães Habib Mattar	Agronomist Federal Inspector Agroecology Coordination Ministry of Agriculture, Livestock and Food Supply Esplanada dos Ministérios Bloco D, Anexo B, Sala 152-B 70043-900 Brasilia – DF, BRASIL Teléfono: +55 61 3218 2453 Fax: +55 61 3223 5350 Correo electrónico: <a href="mailto:roberto.mattar@agricultura.gov.br">roberto.mattar@agricultura.gov.br</a>
Canadá	Elizabeth Corrigan	Regulatory Standards Officer, Organic Office, Agrifood Division Agrifood, Meat and Seafood Safety Directorate Floor 4, Room 145 1400 Merivale Road, Tower 1 Ottawa, On K1A 0Y9 Teléfono: +1 (613) 773-6221 Fax : +1 (613) 228-6633 Correo electrónico: <a href="mailto:elizabeth.corrigan@inspection.gc.ca">elizabeth.corrigan@inspection.gc.ca</a>
Costa Rica	Dr. Eric Guevara	Asesor de Tecnología de Alimentos - Codex Alimentarius Dirección de Mejora Regulatoria y Reglamentación Técnica Ministerio de Economía, Industria y Comercio Teléfono: (506) 2235-2700 ext. 248 Fax: (506) 2235-8192 Correo electrónico: <a href="mailto:eric.guevara@ucr.ac.cr">eric.guevara@ucr.ac.cr</a>
Croacia	Željko Herner	Ministry of Agriculture, Fisheries and Rural Development República de Croacia Correo electrónico: <a href="mailto:zeljko.herner@mps.hr">zeljko.herner@mps.hr</a>
Unión Europea	Herman Van Boxem	Europea Comisión Teléfono: +32 - 2 - 295 01 21 <a href="mailto:herman.vanboxem@ec.europa.eu">herman.vanboxem@ec.europa.eu</a>
	EC Codex Contact Point	Correo electrónico: <a href="mailto:codex@ec.europa.eu">codex@ec.europa.eu</a>
Irán	Roya Noorbaksh	Miembro del CCFL en Irán Teléfono/Fax: +982188654059 <a href="mailto:roybaksh@yahoo.com">roybaksh@yahoo.com</a>
India	Shri S Dave	Director Agricultural and Processed Food Products Export Development Authority Ministry of Commerce Government of India Teléfono: 00-91-11-2651 3162 Fax: 00-91-11-2651 9259 Correo electrónico: <a href="mailto:director@apeda.com">director@apeda.com</a> <a href="mailto:codex-india@nb.nic.in">codex-india@nb.nic.in</a>

Suiza	Barbara Steiner	Federal Office for Agriculture FOAG Mattenhofstrasse , 5 CH-3003 Berne SUIZA Teléfono: +41 31 325 80 08 Fax +41 31 322 26 34 Correo electrónico: <a href="mailto:barbara.steiner@blw.admin.ch">barbara.steiner@blw.admin.ch</a>
Reino Unido	Robin Fransella	Policy Advisor Organic Team Department for Environment, Food and Rural Affairs 8C Millbank c/o 17 Smith Square London SW1P 3JR REINO UNIDO Teléfono: +44 (0)207 238 6348 Correo electrónico: <a href="mailto:Robin.fransella@defra.gsi.gov.uk">Robin.fransella@defra.gsi.gov.uk</a>
Estados Unidos de América	Jeff Canavan	Food Safety and Inspection Service U.S. Department of Agriculture Teléfono: +1-301-504-0860 Correo electrónico: <a href="mailto:Jeff.Canavan@fsis.usda.gov">Jeff.Canavan@fsis.usda.gov</a>
IFOAM	Otto Schmid	Head of Delegation Senior Researcher, Standards Officer Research Institute of Organic Agriculture (FiBL), Ackerstrasse CH-5070 Frick SUIZA Teléfono: +41 62 865 72 72 Fax: +41 62 865 72 73 Correo electrónico: <a href="mailto:OTTO.SCHMID@FIBL.ORG">OTTO.SCHMID@FIBL.ORG</a>

**APÉNDICE II: PLAZOS DE TIEMPO ACTUALIZADOS**

Completado	Carta de invitación a participar en el GTe, solicitud de comentarios sobre sustancias propuestas y enfoque de trabajo estructurado enviados a los países miembros y a los observadores
Completado	Recibidas las expresiones de interés y los comentarios sobre las sustancias propuestas y sobre el enfoque estructurado de trabajo.
Completado	Borrador de documento de discusión conteniendo recomendaciones sobre las nuevas sustancias propuestas y redactar la nueva redacción del Enfoque Estructurado de Trabajo (tomando en consideración los comentarios recibidos en respuesta a la CRD 15) que se envió a los miembros del GTe.
Completado	Los comentarios del GTe sobre el borrador del documento de discusión y sobre la nueva redacción del Enfoque Estructurado de Trabajo.
25 de marzo del 2011	Documento de discusión (incorporando los comentarios recibidos de los miembros por el GTe) enviado a la Secretaría del Codex para distribución y consideración por la 39ª sesión del CCFL en mayo del 2011



## APÉNDICE III

### Propuesta de una nueva redacción del Enfoque de Trabajo Estructurado

#### Dificultades existentes con el Proceso de Revisión Orgánico

- Pudiera necesitarse experiencia técnica para la revisión de las propuestas de nuevos trabajos. Esta experiencia no ha estado tradicionalmente disponible en cada sesión.
- Las propuestas para nuevos trabajos no han sido sometidas con suficiente tiempo para permitir su revisión por expertos técnicos antes de las reuniones del Comité.
- A menudo las propuestas no están completas y no han respondido de manera sistemática a los criterios establecidos en la sección 5.1 de las Directrices.
- Las listas del Anexo 2 son indicativas y no requieren necesariamente ser actualizadas todos los años.
- La participación de los miembros es limitada, particularmente de países en vías de desarrollo.

#### Enfoque recomendado

- Un proceso de revisión estructurado y oportuno que conserve los recursos del Comité.
- Un ciclo de dos años para las propuestas.
- El uso de un grupo de trabajo electrónico (GTe) orgánico para evaluar las propuestas y priorizar nuevos trabajos para el Comité.
- Desarrollo y uso de un modelo estándar para su aplicación y recolección de comentarios
- La Presidencia del GTe rotaría de país a país; cuando un país está proponiendo un nuevo trabajo dicho país no sería elegible para presidir el GTe.
- Si no se sometieran propuestas para nuevos trabajos, entonces el GTe no sería constituido.

#### Procedimientos recomendados para un ciclo de revisión de dos años para las propuestas

- Primer Año: Las propuestas sometidas al Secretariado. El Comité establecerá un GTe para someter las propuestas.
  - Las propuestas para nuevos trabajos deben ser sometidas 60 días antes de la reunión plenaria para que los miembros puedan tener amplio tiempo para su revisión antes de la plenaria.
  - Durante la plenaria del Primer Año, el Comité discutiría si las propuestas son básicamente suficientes. Si el Comité llega a alcanzar consenso de que una o más de las propuestas son suficientes, el Comité establecerá un GTe y las propuestas para nuevos trabajos bajo el Anexo 2 avanzarán a la Comisión para su aprobación como documento en el Trámite 1/3. De no haber suficiente interés por parte de los miembros para emprender el trabajo sobre una sustancia en particular, el Miembro puede someter la propuesta para que sea nuevamente discutida durante el siguiente ciclo; esto excluye cualquier solicitud de informaciones adicionales relacionadas a una propuesta ya existente para un nuevo trabajo. El Comité podría decidir, a su discreción, si el GTe deberá revisar las sustancias que caen fuera del ámbito del Anexo 2.
  - Entre el primer y el segundo años el GTe emprenderá la revisión de las propuestas asignadas y preparará una recomendación para el Comité en el segundo año.
  - Para las revisiones del Anexo 2, el GTe revisará la información y proveerá un reporte sobre si los criterios de la sección 5.1 han sido cumplidos. El GTe pudiera buscar datos adicionales, si fueran necesarios para completar las propuestas.
- Segundo Año: El Comité discute las recomendaciones del GTe.
  - Para las revisiones del Anexo 2, si el Comité está de acuerdo en aprobar las propuestas, estas avanzarían al Trámite 5/8.

Si no se sometieran propuestas para nuevos trabajos, entonces el GTe no sería constituido.

**APÉNDICE IV: Proyecto de Modelo para la revisión de la inclusión de nuevas sustancias al Anexo 2****Sustancia:** (Nombre de la sustancia)**Uso:** (Por favor indicar qué se aplica: fertilización o acondicionamiento del suelo; control de enfermedades o plagas de las plantas o de malas hierbas; o aditivos o coadyuvantes en la preparación o conservación de los alimentos.)**Criterios específicos aplicables:** (a,b,c)**Sometido por:** (Nombre del país o países)

<b>Evaluación utilizando los Criterios de la Sección 5.1</b>	
<b>I. Descripción General de la Sustancia</b>	
<b>Miembro/ Observador</b>	<b>Descripción</b>
<b>II. Sección 5.1 Criterios General (debe responderse a todos los criterios en esta sección)</b>	
<b>5.1.i) ¿Es la sustancia consistente con los principios de la producción orgánica expuestos en estas Directrices?</b>	
<b>Miembro/ Observador</b>	<b>Respuesta</b>
<b>5.1.ii) ¿Es el uso de la sustancia necesario/esencial para la utilización prevista?</b>	
<b>Miembro/ Observador</b>	<b>Respuesta</b>
<b>5.1.iii) ¿La fabricación, el uso y la eliminación de la sustancia tiene o contribuye a producir, efectos perjudiciales para el medio ambiente?</b>	
<b>Miembro/ Observador</b>	<b>Respuesta</b>
<b>5.1.iv) ¿Tiene la sustancia el menor efecto negativo sobre la salud humana o de los animales y sobre la calidad de vida?</b>	
<b>Miembro/ Observador</b>	<b>Respuesta</b>
<b>5.1.v) ¿Hay disponibles alternativas autorizadas en cantidad y/o de calidad suficiente?</b>	
<b>Miembro/ Observador</b>	<b>Respuesta</b>
<b>¿Ha el solicitante respondido adecuadamente a los criterios generales de la sección 5.1?</b>	
<b>Miembro/ Observador</b>	<b>Respuesta</b>

<b>Observador</b>	

**III. Sección 5.1 Criterios específicos: a) sustancias que se usan con fines de fertilización o acondicionamiento de los suelos**

5.1. a) 1) ¿Es la sustancia esencial para obtener o mantener la fertilidad del suelo o para cumplir con requisitos específicos de nutrición de cultivos, o propósitos específicos de acondicionamiento de suelos y de rotación que no pueden ser satisfechos por las prácticas incluidas en el Anexo 1, o por otros productos incluidos en el Cuadro 2 del Anexo 2?

<b>Miembro/ Observador</b>	<b>Respuesta</b>

5.1.a)2) ¿Es la sustancia de origen vegetal, animal, microbiano o mineral? ¿Ha sido sometida a cualquiera de los siguientes procesos: físicos (mecánicos o térmicos), enzimáticos, microbianos (compostado o fermentación)? ¿Ha sido la sustancia sometida a cualesquiera procesos químicos? ¿Están estos procesos limitados a la extracción de sustancias inertes y aglutinantes?

<b>Miembro/ Observador</b>	<b>Respuesta</b>

5.1.a)3) ¿Tiene el uso de la sustancia un efecto perjudicial para el equilibrio del ecosistema del suelo, o las características físicas del suelo, o la calidad del agua y el aire?

<b>Miembro/ Observador</b>	<b>Respuesta</b>

5.1.a) 4) ¿Debería el uso de la sustancia restringirse a condiciones específicas, regiones específicas o productos específicos?

<b>Miembro/ Observador</b>	<b>Respuesta</b>

¿Ha el solicitante respondido adecuadamente a los criterios específicos en la sección a) para sustancias que se usan con fines de fertilización o acondicionamiento de suelos?

<b>Miembro/ Observador</b>	<b>Respuesta</b>

**IV. Sección 5.1 Criterios específicos: b) sustancias que se usan con fines de control de enfermedades o plagas de las plantas o de malas hierbas**

5.1.b)1) ¿Es la sustancia esencial para el control de un organismo dañino o una enfermedad concreta para los que no hay disponibles otras alternativas biológicas, físicas, o de fitomejoramiento y/o prácticas efectivas de gestión?

<b>Miembro/ Observador</b>	<b>Respuesta</b>

5.1.b)2) ¿Toma su uso en cuenta los efectos perjudiciales para el medio ambiente, la ecología (en particular los organismos que no son determinados como objetivos) y la salud de los

consumidores, el ganado y las abejas?

Miembro/ Observador	Respuesta

5.1.b)3) ¿Es la sustancia de origen vegetal, animal, microbiano o mineral? ¿Ha sido sometidas a los siguientes procesos; físicos (mecánicos o térmicos), enzimáticos, microbianos (compostado o fermentación)?

Miembro/ Observador	Respuesta

5.1.b) 4) ¿Es la sustancia utilizada en trampas como dispensadora, tales como las feromonas, que son químicamente sintetizadas? ¿Existen productos alternativos disponibles en cantidades suficientes en su forma natural? ¿Resultan las condiciones para su uso, directa o indirectamente, en la presencia de residuos del producto en las partes comestibles?

Miembro/ Observador	Respuesta

5.1.b) 5) ¿Debería su uso restringirse a condiciones específicas, regiones específicas o productos específicos?

Miembro/ Observador	Respuesta

¿Ha el solicitante respondido adecuadamente a los criterios específicos en la sección b) sustancias con fines de control de enfermedades o plagas de las plantas o de malas hierbas?

Miembro/ Observador	Respuesta

**V. Sección 5.1 Criterios específicos: c) sustancias que usan como aditivos o coadyuvantes de elaboración en la preparación o conservación de alimentos**

5.1.c)1) En el caso de los aditivos ¿Es posible producir o conservar los alimentos sin el aditivo? Para los coadyuvantes de elaboración. ¿Es posible producir o conservar los alimentos sin el coadyuvante de elaboración? ¿Existen otras tecnologías disponibles que satisfagan estas Directrices?

Miembro/ Observador	Respuesta

5.1.c)2) ¿Se encuentra el aditivo o coadyuvante de elaboración en la naturaleza? ¿Ha sido sometido a procesos mecánicos/físicos (por ejemplo, extracción o precipitación), biológicos / enzimáticos, y microbianos (por ejemplo, fermentación) ?

Miembro/ Observador	Respuesta

5.1.c)3) ¿Es un aditivo o coadyuvante de elaboración sintetizado químicamente? ¿Hay una carencia de sustancias naturales?

<b>Miembro/ Observador</b>	<b>Respuesta</b>

**5.1.c) 4) ¿Mantiene el uso del aditivo o coadyuvante de elaboración la autenticidad del producto?**

<b>Miembro/ Observador</b>	<b>Respuesta</b>

**5.1.c) 5) ¿Podría la adición del aditivo o coadyuvante de elaboración causar que los consumidores sean engañados respecto a la naturaleza, sustancia y calidad del alimento?**

<b>Miembro/ Observador</b>	<b>Respuesta</b>

**5.1.c) 6) ¿Menoscaba la adición del aditivo o del coadyuvante de elaboración la calidad general del producto?**

<b>Miembro/ Observador</b>	<b>Respuesta</b>

**¿Ha el solicitante respondido adecuadamente a los criterios específicos en la sección c) sustancias del aditivo o coadyuvante de elaboración en la preparación o conservación de los alimentos?**

<b>Miembro/ Observador</b>	<b>Respuesta</b>

## **VI. Preguntas generales para todas las propuestas**

**¿Hay alguna información que sea necesaria para completar la revisión de la nueva sustancia? (Por favor incluir aquí vínculos a las investigaciones de apoyo)**

<b>Miembro/ Observador</b>	<b>Respuesta</b>

**¿Se requiere cualquier otra condición adicional para su uso?**

<b>Miembro/ Observador</b>	<b>Respuesta</b>

**¿Apoyarían ustedes la inclusión de la nueva sustancia en el Anexo 2?**

<b>Miembro/ Observador</b>	<b>Respuesta</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>.</p> <p>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>	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

	<p>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>	<p>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.</p>
<b>United States</b>	<p>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.</p>
<b>IFOAM</b>	<p>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).</p> <p>The assessment against the criteria, made by the European Union is considered as consistent and sufficient.</p>

#### 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>	<p>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.</p>
<b>United States</b>	<p>May be used when other pest management practices fail in the National Organic Program Regulations.</p>

#### 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>	<p>No harmful effects are reported on the manufacturing and disposal of spinosad. For use: see 5.1.b)2) below.</p>
<b>United</b>	<p>Concur with EU statement.</p>

<b>States</b>	
<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>
<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.
<b>5.1.v) Are approved alternative available in sufficient quality or quantity?</b>	
<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.
<b>Has the applicant adequately addressed the main criteria in section 5.1?</b>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>United States</b>	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>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>EU submission- CX/FL 10/38/17</b>	<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>



	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.
<b>United States</b>	Is valuable for control of pests.

**5.1.b)2) Does their use take into account the potential harmful impact on the environment, the ecology (in particular non-target organisms) and the health of consumers, livestock and bees?**

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

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

<b>Member/ Observer</b>	<b>Answer</b>
<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.

**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>Member/ Observer</b>	<b>Answer</b>
<b>EU submission- CX/FL 10/38/17</b>	Not applicable.
<b>United States</b>	N/A

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

<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.

**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>Member/ Observer</b>	<b>Answer</b>
<b>United States</b>	Yes.

**Is there any information needed to complete the review of the new substance (including supporting documents)?**

<b>Member/ Observer</b>	<b>Answer</b>
<b>United States</b>	<p>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></p>

**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>	<p>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.</p> <p>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.</p>
<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>	<p>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</p> <p>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.</p> <p>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.</p>

<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.

#### 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 potassium bicarbonate essential for the control of a number of fungal diseases in various crops for which no effective alternatives are available.
<b>United States</b>	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?

<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 potassium bicarbonate. For use: see 5.1.b)2) below
<b>United States</b>	No harmful effects reported.

#### 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>	Residues are no concern. Potassium bicarbonate is also a food additive (INS 501) for organic products.
<b>United States</b>	Yes low impact.

#### 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>	See 5.1.b)1) below

<b>United States</b>	Alternatives are not as effective.
<b>Has the applicant adequately addressed the main criteria in section 5.1?</b>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>United States</b>	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>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>EU submission- CX/FL 10/38/17</b>	<p>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.</p> <p>For many intended uses (crop-pest situations), copper, sulphur and a few other substances are available.</p> <p>Against grey mould in strawberries, there are no effective alternatives. Varietal resistance is often not sufficient, because fungi break resistance easily.</p> <p>In general, substances which may complement copper and sulphur are highly desirable in organic farming.</p> <p>Potassium bicarbonate is a welcome management tool. Reduction of the use of currently available fungicides contributes to the sustainability of the production system.</p>
<b>United States</b>	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>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>EU submission- CX/FL 10/38/17</b>	Environmental fate, hazards and risks of potassium bicarbonate are assessed in detail during pesticide registration in the EU.
<b>United States</b>	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>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>EU submission- CX/FL 10/38/17</b>	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.
<b>United States</b>	Mineral origin with benign components.

<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>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>	Not applicable.
<b>Is there any information needed to complete the review of the new substance?</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 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.</p>

	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.
<b>United States</b>	Agree with EU statement, must be used in a manner that minimizes accumulation in the soil.
<b>IFOAM</b>	<p>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).</p> <p>The assessment against the criteria, made by the European Union is considered as consistent and sufficient.</p>

#### 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>	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.
<b>United States</b>	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?

<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 copper octanoate. For use: see b) 2).
<b>United States</b>	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?

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

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

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



<b>CX/FL 10/38/17</b>	
<b>United States</b>	Hard to replace fixed copper substances because other products have reduced efficacy.
<b>Has the applicant adequately addressed the main criteria in section 5.1?</b>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>United States</b>	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>	
<b>Member/ Observer</b>	<b>Answer</b>
<b>EU submission- CX/FL 10/38/17</b>	<p>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.</p> <p>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.</p> <p>Alternative products to copper compounds (e.g. sulphur) and methods are not sufficiently effective.</p> <p>Inclusion of copper octanoate would be consistent with the current listing of the other copper compounds in Table 1 of the Guidelines.</p>
<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>	<p>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).</p> <p>Environmental issues are the same as for other copper compounds: they are known to pose certain risks to the environment.</p> <p>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.</p>
<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 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>	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>	
<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>

**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>	

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

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

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

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

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

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

**5.1.b)1) Is the substance essential for the control of a harmful organism or a particular disease for which other biological, physical or plant breeding alternatives and/or effective management practices are not available?**

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

**5.1.b)2) Does its use take into account the potential harmful impact on the environment, the ecology (in particular non-target organisms) and the health of consumers, livestock and bees?**

Member/ Observer	Answer
EU	Environmental fate, hazards and risks are assessed in detail during pesticide 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.

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

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

**5.1.b)4) Is the substance chemically synthesized? Are there alternatives products available in their natural form? Do the conditions of use result in the presence of residues on edible parts of the product?**

Member/ Observer	Answer
EU	The ethylene used is chemically produced and is identical to the naturally occurring ethylene. Ethylene does not result in the presence of residues in any part of the plant.

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

Member/ Observer	Answer
EU	It should be limited to citrus and to situations where degreening is part of a strategy for the prevention of fruit fly damage in citrus.

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

Member/ Observer	Answer
Australia	Australia agrees with the paper relating to the use of ethylene for fruit fly control in citrus.
United States	Yes.  In the United States, ethylene used postharvest is considered a plant growth regulator and is regulated as a pesticide. We concur that section b is the appropriate section of Annex II for consideration of ethylene for degreening of citrus.  Under the USDA National Organic Program standards, postharvest use of ethylene is allowed for ripening of tropical fruit and degreening of citrus.

## **VI. General questions for all proposals**

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

Member/ Observer	Answer
United States	No.

**Are any additional conditions of use needed?**

Member/ Observer	Answer
EU	Yes: for degreening of citrus fruit only as part of a strategy for the prevention of fruit fly damage in citrus

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

Member/ Observer	Answer
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<b>Observer</b>	
<b>EU</b>	Yes
<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>Australia</b>	Australia agrees in principle with the paper relating to the use of ethylene for fruit fly control in citrus.
<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.

**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.</p> <p>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>

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

## II. Section 5.1 Main Criteria

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

Member/ Observer	Answer
Costa Rica/EU Application	<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
Costa Rica/EU Application	<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 reduced and the use and the time period during which (organic) pesticides are needed can be reduced as well. Well-timed cycles of a</li> </ul>



pesticide allowed in organic farming (based on the bacterium *Bacillus thuringiensis*) can then protect the whole field. An additional effect can be expected since the growers are able to control possible plague(s) better since they know in which area insects might 'flourish' and can control these plague(s) in the smaller area. This approach is in perfect line with the organic pest management principle of 'prevention before correction'.

- Controlled flower induction prevents induction of immature plants triggered through ethylene production of flowering plants within the same field. Flowering of non-mature plants, with underdeveloped root systems, which are necessary for sufficient nutrient flow for fruit filling, results in poor and small fruits, which are not marketable.
- When flower induction applications (with ethylene) are timed and thus done at an optimum plant size (plant weight), all the plants in field will be able to bear a fruit the size in proportion and according to the capacity of the plant to fill the fruit.
- To be able to produce for overseas markets a producer will need to supply clients and ultimately the consumer with fresh pineapples on a regular basis. Ethylene applications synchronize flower induction and thus fruit set. This reduces the harvest picking rounds from a dozen or more to 3 to 5. Without the use of ethylene the percentage of market ready fruit would be very low and erratic in the same field. It would take a dozen of harvesting rounds to pick all the fruit under a natural setting. Damage to the plants and the fruit left in field some time more, and soil compaction will be increased when the equipment for harvesting needs to go through 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	<p>No harmful effects are observed when used to induce flowering. Ethylene is not listed as a carcinogen and is naturally occurring.</p> <p>In non-organic pineapple plantations a synthetic compound called ethephon is sprayed</p>

	on the fields. This compound is not a natural compound but ultimately also emits ethylene in order to have the same effect.
<b>United States</b>	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?**

<b>Member/ Observer</b>	<b>Answer</b>
<b>Costa Rica/EU Application</b>	<p>According to research: ingestion, inhalation and human health effects are considered low.</p> <p>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).</p> <p>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.</p> <p>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).</p> <p>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.</p> <p>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.</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> </ul> <p>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.</p> <p>The National Toxicology Program Health and Safety Information Sheet, published by the National Institute of Environmental Health, states that neither the NTP, IARC, (The International Agency for Research on Cancer, part of the World Health Organization) nor OSHA lists ethylene as a carcinogen. (NTP, 2000). The only health hazard listed by Environmental Defense is based on Cal EPA data as a suspected neurotoxicant, at a relatively high level of ingestion by inhalation (20,000 ug/m3 = 2x10-5 (0.00002) kg/m3).</p>

	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
<b>Costa Rica/EU Application</b>	<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 areas, 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 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.</li> <li>• 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.</li> </ul>

## II. Additional Questions/Supporting Materials

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

Member/ Observer	Answer
<b>United States</b>	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.
<b>Australia</b>	Australia agrees in principle with the paper relating to the use of ethylene as an agent to control flowering in pineapples.
<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>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>Costa Rica/EU Application</b>	No
<b>United States</b>	No.
<b>References</b>	
<b>Costa Rica/EU Application</b>	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=nopg">http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5067073&amp;acct=nopg</a> <a href="http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5085176">eningo</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>

**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>
<b>EU</b>	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>
<b>EU</b>	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>
<b>EU</b>	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>
<b>EU</b>	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>
<b>EU</b>	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).
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**5.1.v) Are approved alternative available in sufficient quality or quantity?**

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

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

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

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

**5.1.b)1) Is the substance essential for the control of a harmful organism or a particular disease for which other biological, physical or plant breeding alternatives and/or effective management practices are not available?**

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

**5.1.b)2) Does its use take into account the potential harmful impact on the environment, the ecology (in particular non-target organisms) and the health of consumers, livestock and bees?**

Member/ Observer	Answer
EU	Environmental fate, hazards and risks are assessed in detail during pesticide 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.

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

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

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

**5.1.b)4) Is the substance chemically synthesized? Are there alternatives products available in their natural form? Do the conditions of use result in the presence of residues on edible parts of the product?**

Member/ Observer	Answer
EU	The ethylene used is chemically produced and is identical to the naturally occurring ethylene. Ethylene does not result in the presence of residues in any part of the plant.

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

Member/ Observer	Answer
EU	It should be limited to sprouting inhibition in potatoes and onions.

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

Member/ Observer	Answer
United States	<p>No. The applicant has not addressed why alternatives practices (e.g. cold storage) or alternative materials (e.g. plant essential oils such as caraway oil or clove oil, where registered) for sprout inhibition cannot be used. Ethylene is not permitted for post harvest use as a sprout inhibitor in potatoes and onions under the USDA National Organic Program standards.</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>

## **VI. General questions for all proposals**

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

Member/ Observer	Answer
United States	The applicant has not addressed why alternative practices (e.g. cold storage) or alternative materials (e.g. plant essential oils such as caraway oil or clove oil, where registered) for sprout inhibition cannot be used. Ethylene is not permitted for post harvest use as a sprout inhibitor in potatoes and onions under the USDA National Organic Program standards.

**Are any additional conditions of use needed?**

<b>Member/ Observer</b>	<b>Answer</b>
<b>EU</b>	Yes: for sprouting inhibition in potatoes and onions.
<b>Would you support the addition of the new substance in Annex 2?</b>	
<b>Member/ Observer</b>	<b>Answer</b>
<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> </ul>

- IFOAM agrees that the requirement for periodic review of the main text of the Codex Guideline can be replaced by requests for new work items in the general Codex procedure.
- IFOAM agrees to the concept of a multi-year cycle for new work for the Annexes.
- IFOAM agrees that an Electronic Working Group (EWG) can be useful for managing revisions. The work of this EWG should be very transparent. Membership in the group should be open to both Members and Observers, and it should include significant participation from developing countries.
- IFOAM recommends that in addition to an Electronic Working Group, the EWG provide recommendations to an Organic Working Group (OWG) which should meet prior to the CCFL in the "Decision Year" of this cycle. The OWG will review the work of the EWG and make the final recommendations to the CCFL for decision.

**IFOAM Comment to the revision of the Annexes of the Guidelines in a two year cycle**

- IFOAM supports a structured review process with the two year cycle as proposed by US and EU but with more clear timelines.
- IFOAM agrees that an Electronic Working Group (EWG) is useful for managing the process.
- IFOAM recommends that for more substantial changes of the guidelines physical face to face meeting of an "Organic Working Group", meeting prior to the CCFL meeting, have shown in the past very useful and should be foreseen when necessary by the EWG.
- With regard to the request for the uptake of new substances it might be useful to take them in on an on-going basis through the EWG-process.
- IFOAM thinks that a regularly updated indicative list is very important to show to governments a broad international agreement on substances.

**A last comment relates to the proposed additional criteria for the uptake of new substances by the original US paper.**

- IFOAM is not comfortable with these proposed additional criteria for the uptake of new substances, as they would practically exclude third world countries to ask for new interesting substances for organic farming. (see detailed comment below).
- IFOAM has a comment to the terminology used in the US Paper CX/FL 10/38/11 regarding the permitted substances, where the term "illustrative listing" is used. This term has not been used until now in all the Codex discussion. IFOAM believes that the term "indicative list" should be kept as it is much more appropriate. The word "illustrative" does not express sufficiently that for these substances a world-wide consensus has been reached ("safe harbour list" for governments).

**IFOAM Comment to the revision of the whole text of the Guidelines**

- IFOAM agrees that it is unrealistic to undertake reviews of the whole text of the Organic Guidelines systematically and periodically according to the current Section 8.
- IFOAM thinks that reviews of sections of the Guidelines can be initiated through the main process for new work.
- IFOAM thinks that it would make sense to aim for a 4 year cycle of the revision of the whole guidelines, when decided as necessary by the plenary of CCFL.
- However, there should still be a system for Members and Observers to submit written comments on proposals to the full Committee. IFOAM would also support a process for the EWG to call for and accept comments from Members and Observers.
- Regarding the revision of the main guidelines text, IFOAM believes that this work should include a general review of how the content of the Guidelines accord with the functional aims of the Guidelines that are presented in the Foreword, particularly with respect to the situation of organic agriculture and trade from in developing countries.

**IFOAM Answers to questions in Document CX/FL 10/38/11**

**Do countries and observers agree that a more structured process would improve the efficiency of the review process?**

	<ul style="list-style-type: none"> <li>• IFOAM does agree with a structured process.</li> </ul> <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.

	<p>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:</p> <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	<p>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:</p> <p>a) Short information on the origin</p> <p>b) Short information on the usage (for which crops or food, with which function).</p> <p>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.</p>
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	IFOAM thinks, that the eWG should be responsible for determining whether proposed substances fall outside the scope of Annex 2 but are covered generally by Annex I. In this case the eWG should be tasked to review these substances.  Regarding the question whether substances outside the scope of Annex 2 should be subject to the 5.1 criteria or should different criterion be developed for these substances, IFOAM would propose to take the existing criteria as a basis but for certain categories of substances to include later additional criteria, in case needed. These could be later included in the Annex I text
United States	The scope of the eWG should be limited to review of substances contained in Annex 2. The United States understands that in limited circumstances the eWG might determine that such a substance under review by the eWG might fall outside of Annex 2. In this case the eWG could offer a recommendation on the substance and its appropriate placement to the Committee.  As for the determination of whether criteria similar to those detailed in 5.1 are needed for other Annexes, the United States would note that the criteria in 5.1 were developed to facilitate the development of national lists. Procedures for new work as already outlined in the Codex should adequately address additions to other annexes.