CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

E

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

AGENDA ITEM NO. 5a **CX/FL 13/41/5-Rev1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD LABELLING

Forty-first Session

Charlottetown, Prince-Edward-Island, Canada, May 14 - 17, 2013

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

Use of Ethylene as Sprouting Inhibitor for Onions and Potatoes

I. BACKGROUND

The Codex Committee on Food Labelling (CCFL) held its 40th session in May 2012 and considered a proposal submitted by the European Union requesting the use of ethylene as a sprouting inhibitor for potatoes and onions (Agenda Item 5b).

At the 40th Session of the CCFL, the eWG reported that it had not made a final recommendation on this substance. The CCFL agreed to continue an electronic working group (eWG), co-chaired by the United States and Cameroon, with the terms of reference to consider the use of ethylene for sprout inhibition in onions and potatoes.

This report includes a summary of responses to additional information that was considered by eWG participants. This final report submitted to the Secretariat in advance of the 41st session of the CCFL.

II. PARTICIPATION IN eWG

In August 2012, the United States and Cameroon, as co-chairs of this eWG, invited all CCFL members to participate in the eWG on the review of the Guidelines or the Production, Processing and Labelling of Organically Produced Foods. Eighteen member countries and one member organization expressed interest in participating in this eWG. A list of participants is provided in Appendix I.

The eWG established a deadline of September 7, 2012 for submission of additional data or research information in support of proposal for ethylene for sprout inhibition of potatoes and onions. One submission from Norway was received by the deadline. A peer reviewed publication[1] was received as background information.

In November 2012, the United States, as co-chair of the working group, distributed the proposal template and additional background information to eWG members with instructions for submission of comments.

Upon receipt of the comments, a draft report was distributed to the working group members for a second round of comments which were incorporated into this final report.

An updated timeline for the work of this eWG is also provided in *Appendix III*.

III. REVIEW OF ANNEX 2 SUBSTANCES: ETHYLENE FOR SPROUT INHIBITION IN POTATOES AND ONIONS

A. Summary of Responses in Round 1

The additional background information provided by Norway was distributed to participants in response to comments received at the 40th session of the Codex Committee on Food Labelling regarding the use of ethylene as a sprouting inhibitor.

[1] EFSA Journal 2012; 10(1):2508, available at http://www.efsa.europa.eu/en/efsajournal/doc/2508.pdf

In addition to the original proposal from the EU, and the additional information submitted by Norway, four member countries (Australia, Brazil, the United States, and Uruguay) responded to the initial request for comments. All comments from the first round of responses were incorporated into the review template provided in *Appendix II*.

B. Summary of Responses in Round 2

Based upon limited number responses in the first round of comments, the co-chairs were unclear after the first round of comments whether there was sufficient consensus in the electronic working group to support or oppose the addition of ethylene to Annex 2 for purposes of sprout inhibition in potatoes and onions.

For the second round of comments on the draft report, the co-chairs issued a draft report which included three options for feedback from eWG members.

The co-chairs indicated in the request for comments that Option A may represent the best opportunity for reaching consensus and addressing the concerns raised by several members participating in the eWG. Comments on all three options were due April 19, 2013.

The co-chairs also suggested during the second request for comments that members consider next steps if a consensus cannot be reached on listing the substance under Option A.

The three options that were considered for the inclusion of ethylene into Table 2 are presented below.

TABLE 2

SUBSTANCES FOR PLANT PEST AND DISEASE CONTROL

Substance		Description; compositional requirements; conditions for use
IV. OTHER		
[Ethylene]	**Option A:**	[Need recognized by the certification body or authority for sprout inhibition of stored potatoes and onions where varieties that have long dormancy characteristics are not available, or these varieties are not suited to local growing conditions. Must be used in a manner that minimizes exposure to operators and workers.]
[Ethylene]	**Option B:**	[Need recognized by the certification body or authority for sprout inhibition of stored potatoes and onions where varieties that have long dormancy characteristics are not available, or these varieties are not suited to local growing conditions.]
	Option C:	No additional listing. If an eWG member does not support additional uses of ethylene for sprout inhibition, please indicate reason(s) in response.

Thirteen members responded to the request for a second round of comments: Argentina, Australia, Brazil, Cameroon, Canada, Chile, Costa Rica, EU, India, Mexico, Norway, United States, and Uruguay.

Comments on Proposed Options

Option A.

The majority of comments supported Option A.

The EU noted that it has been necessary to amend the conditions of approval of ethylene in the EU and to restrict the authorisations to indoor uses by professional users and that this restriction also applied to the organic farming production. The EU considers still needed the addition of ethylene as a sprouting inhibitor for onions and potatoes in Annex II, following Option A.

Option B.

One member (Australia) supported Option B.

Australia indicated that it supported option B because of concerns with reference to operator and workforce exposure.

Option C.

One member (Norway) supported Option C, which would not include ethylene in Annex 2.

In comments, Norway indicated that it supported Option C (no listing) because it felt that there continues to be data gaps and inconsistencies with the 5.1 criteria, e.g., points 3 and 4 about not contributing to harmful effects on environment and should have lowest effects on the environment.

Norway indicated that it is still very concerned about the use of ethylene as a plant growth regulator based on the fact that several data gaps regarding the use are published in EFSA Journal 2012; 10(1):2508[2]. All comments received from the second round of responses are included in *Appendix IV*.

C. Conclusions

The co-chairs recognize and appreciate the significant contributions made by each member participating in the eWG during the first and second round of comments on the proposed use of ethylene as a sprouting inhibitor for potatoes and onions. The majority of respondents supported inclusion of ethylene; however, given one member's concerns that remain over the data that was presented in the proposal, the co-chairs recommend a discussion at the 41st Session of the CCFL to see if consensus can be reached on the listing of the substance.

[2] http://www.efsa.europa.eu/en/efsajournal/doc/2508.pdf

APPENDIX I

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

LIST OF PARTICIPANTS

Member Country/ Observer	**Name and Contact Information**
Argentina	Ing. Agr. Juan Carlos Ramírez Coordinator or Organic Production Republic of Argentina National Agri-food Health and Quality Service (SENASA) Email address: jramirez@senasa.gov.ar Ing. Agr. Pilar Huergo Email: phuergo@senasa.gov.ar Ing. Agr. Liliana Úbeda Email: lubeda@senasa.gov.ar
Australia	Ms. Angela O'Sullivan Director, International Food Standards Department of Agriculture, Fisheries and Forestry Email: angela.osullivan@daff.gov.au Email: codex.contact@daff.gov.au
Brazil	Rodrigo Vargas Email: rodrigo.vargas@anvisa.gov.br
Cameroon	Mrs. Jeanine Nkodo Atanga Ingénieur Agronome Economiste Sous-Directeur de la Coopération Ministère de l'Agriculture et du Développement Rural Email: jeanine_nkodo@yahoo.fr Mr. Jean Martin Etoundi Ingénieur Général des Techniques Industrielles (Spécialiste de Nutrition des Technologies Alimentaires) Secrétaire Technique du CCAFRICA, Secrétaire Technique du CNCOSAC, Sous Directeur de la Promotion à l'ANOR. Email: pointfocalcodexcameroun@yahoo.fr Email: etoundijme@yahoo.fr
Canada	Ms. Elizabeth Corrigan Regulatory Standards Officer Canadian Food Inspection Agency E-mail: elizabeth.corrigan@inspection.gc.ca
Chile	Ligia Morend Profesional Subdepartmento de Agricultura Organica Division Proteccion de Recursos Naturales Renovables Servicio Agricola y Ganadero Email: ligia.morend@sag.gob.cl Roxana Vera Profesional Subdepartmento de Negociaciones Internacionales Division Asuntos Internacionales Servicio Agricola y Ganadero Email: roxana.vera@sab.gob.cl
Costa Rica	Amanda Lass Cruz Asesora Tecnología de Alimentos – Codex Alimentarius Dirección de Mejora Regulatoria y Reglamentación Técnica Ministerio de Economía, Industria y Comericio Email: mailto:alasso@meic.go.cr

Egypt	Ms. Noha Mohammed Attia Food Standard Specialist E-mail : nonaaatia@yahoo.com Phone : 00202 22845531 Fax : 00202 22845504
European Union	Mr. Luis Martin Plaza European Commission DG Agriculture and Rural Development Unit H.3 – organic farming L130 03/245 B-1049 Brussels/Belgium Tel.: +32 229-93736 Email: Luis.MARTIN-PLAZA@ec.europa.eu Ms Maria Fladl European Commission DG Agriculture and Rural Development Unit H.3 – organic farming L130 03/236 B-1049 Brussels/Belgium Tel.: +32 2 298 04 40 E-mail: maria.fladl@ec.europa.eu
FoodDrinkEurope	Dirk Jacobs Director Consumer Information, Diet and Health Email: d.jacobs@fooddrinkeurope.eu
India	Ms. Vinod Kotwal Director (Codex) Food Safety and Standards Authority of India E-mail: vinod.kotwal@nic.in Email: codex-india@nb.nic.in
Japan	Mr. Tsuyoshi Uchida Associate Director Ministry of Agriculture, Forestry and Fisheries of Japan Email: tsuyoshi_uchida@nm.maff.go.jp Email: codex_maff@nm.maff.go.jp
Malaysia	Ms. Fauziah Arshad Deputy Director Standard and Codex Branch Food Safety and Quality Division Ministry of Health Malaysia Phone: +603 BB85 0794 Email: fauziaharshad@moh.gov.my Ms. Noraini Wahab Principal Assistant Director Codex and lnternational Section Food Safety and Quality Division Ministry of Health Malaysia Phone: +603 B8B5 0736 Fax: +603 BBB5 0790 E-mail: norawahab@moh.gov.my ccp_malaysia@moh.gov.my
Mexico	Lidia P. Barrios Alvarado Jefa de Departamento de Diseño y Gestión Regulatoria Dirección General de Inocuidad Agroalimentaria, Acuícola y Pesquera Guillermo Pérez Valenzuela No. 127, Col. Del Carmen. Del. Coyoacán, México, D.F. C.P. 04100. Tel. +52 (55) 5090 3000 Ext. 51532 Email: lidia.barrios@senasica.gob.mx codexmex@economia.gob.mx
Norway	Dr. Hanne Marit GRAN Senior Advisor Section for Plants, Organic Production and GMs Norwegian Food Safety Authority - Head Office E-mail: hamgr@mattilsynet.no

Poland	Mr. Grzegorz Ziemiecki Senior expert in the Department of Promotion and Communication of the Ministry of Agriculture and Rural Development Email: grzegorz.ziemiecki@minrol.gov.pl Email: kodeks@ijhars.gov.pl
Thailand	Ing-Orn Panyakit Senior Standard Officer National Bureau of Agricultural Commodity and Food Standards (ACFS) Ministry of Agriculture and Cooperatives 50 Paholyothin Road, Jatujak, Bangkok, 10900 Thailand Phone: +66 2 5612277 ext 1426 Fax: +66 2 5613373 Email: codex@acfs.go.th Email: p_ingorn@yahoo.co.th
United Kingdom	Nicolas Turner Senior Policy Advisor Organic Team Department for Environment, Food and Rural Affairs 8C Millbank c/o 17 Smith Square London SW1P 3JR United Kingdom Tel: +44 (0)207 238 5869 Email: Nicolas.Turner@DEFRA.GSI.GOV.UK
United States of America	Lisa M. Brines, Ph.D. Agricultural Marketing Specialist National Organic Program, Standards Division Agricultural Marketing Service U.S. Department of Agriculture 1400 Independence Ave SW, Stop 0268 Washington, DC 20250-0268 Tel: +1-202-720-3252 Email: Lisa.Brines@ams.usda.gov Jeffrey Canavan U.S. Department of Agriculture 1400 Independence Ave., SW-Stop 5273 Patriots Plaza 3, 8th Floor-161A Washington, DC 20250 Phone: (301) 504-0860 Fax: (202) 245-4792 Email: jeff.canavan@fsis.usda.gov
Uruguay	Ing. Agr. Fabiana Osorio Departamento de Promoción Comercial Dirección General de la Granja Ministerio de Ganadería, Agricultura y Pesca Avda Gral Eugenio Garzon 456, 1º Piso 12900 Montevideo - Uruguay Tel: (598) 23047422 Fax: (598) 23048051 Email: fosorio@mgap.gub.uy

APPENDIX II

CCFL ELECTRONIC WORKING GROUP ON THE REVIEW OF THE GUIDELINES FOR THE PRODUCTION, PROCESSING AND LABELLING OF ORGANICALLY PRODUCED FOOD

ANNEX 2 PERMITTED SUBSTANCES FOR THE PRODUCTION OF ORGANIC FOODS

Review of New Substances proposed for inclusion in Annex 2 – September 2011

Including Responses from Round 1 of eWG Review

A. Substance: ethylene

B. Use: Sprouting inhibition in potatoes and onions

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

D. Submitted By: European Union (EU)

Assessment against Section 5.1 Criteria	
I. General Description of Substance	
Member/ Observer	**Description**
EU	Natural gas C_2H_4 (CH_2=CH_2) produced by all higher plants and therefore omnipresent in nature. The ethylene (identical to the naturally occurring ethylene) used for agricultural purposes is obtained through chemical processes. Constant exposure of stored potatoes and onions to ethylene in low concentration inhibits sprouting.
II. Section 5.1 General Criteria (all criteria in this section should be addressed)	
5.1.i) Is the substance consistent with the principles of organic production as outlined in the Guidelines?	
Member/ Observer	**Answer**
EU	This use of ethylene is consistent with the principle of careful handling of products in order to maintain their quality during the storage and contributes to the economic and ecological sustainability of organic potato and onion production, while being consistent with the other principles of organic production.
5.1.ii) Is use of the substance necessary/essential for its intended use?	
Member/ Observer	**Answer**
EU	A longer marketing period is important for the economic sustainability of farms.
Brazil	Sprout control impacts the quality of potatoes and onions and allows their storage for extended periods of time. Ethylene can help controlling sprout of potatoes and onions.
Uruguay	While several countries suggest that the use of low concentrations of ethylene inhibit sprouting of potatoes and onions, there is literature that indicates stimulation of sprouting in potatoes, among other adverse effects of its use (i.e. "Effect of ethylene on quality of fresh fruits and vegetables". Saltveit ME, Postharvest Biology and Technology 15 (1999) 279-292).[3]
5.1.iii) Does the manufacture, use and disposal of the substance result in, or contribute to, harmful effects on the environment?	
Member/ Observer	**Answer**
EU	No. Ethylene is often considered a by-product in chemical engineering process manuals, and to the extent that it is captured rather than released into the environment can be seen as reducing the ambient air pollution.
Brazil	Brazil has no data on the impact of manufacture, use and disposal of ethylene on the environment.

[3] Available at http://www.sciencedirect.com/science/article/pii/S092552149800091X

	In relation to the comments from Norway, we would like to point out that the EFSA assessment identified data gap on the environmental fate of ethylene. Thus, there is no conclusive evidence of harmful effects on the environment. Besides ethylene has history of safe use in organic and traditional agriculture and CCFL has already approved its use for the ripening of bananas and kiwi fruits, for degreening of citrus for fruit fly prevention and as a flowering agent for pineapples.

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

Member/ Observer	Answer
EU	No adverse effect known on human or animal health. No adverse effect on intrinsic food quality. Under conditions of prolonged storage, a higher external and internal quality can be maintained (absence of sprouts and wrinkles, composition of tubers).
Brazil	Brazil did not identify any study on the impact of ethylene on human or animal health. In relation to the comments from Norway, it should be noted that the EFSA assessment did not reach any conclusion on the toxicity of ethylene due to the lack of data. This data gap should not be interpreted as evidence of harmful effects on human or animal health. Besides ethylene has history of safe use in organic and traditional agriculture and CCFL has already approved its use for the ripening of bananas and kiwi fruits, for degreening of citrus for fruit fly prevention and as a flowering agent for pineapples.

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. However, both alternatives are not adequate for use in many situations. Cold storage Cold storage of potatoes increases reducing sugars. This leads to increased acrylamide when cooked (e.g. frying, baking, roasting). The Codex Code of Practice for reduction of acrylamide in food (CAC/RCP 67-2009) highlights that cold storage of potatoes at low temperatures is to be avoided and that alternatives should be determined to help reduce acrylamide in potato foods (whether processed foods, foods prepared in restaurants or at home). This Code of Practice was adopted by the Codex Committee on Contaminants in Food and CAC in 2009. Alternatives to cold storage of potatoes are therefore needed. Caraway seed oil The experience with the use of this substance is rather limited. Its use is not registered in many countries and can therefore not be used by organic producers in these countries. Use of potato varieties with high dormancy The choice of varieties is very important in organic production. The potato variety chosen should ideally have a strong resistance against potato blight and other diseases and should also have characteristics that make it suitable for organic production in the local circumstances. While high dormancy is a positive characteristic of a variety, it is not always possible to choose a variety that possesses as well the other positive characteristics sought. Therefore in many situations a variety with high dormancy can not be chosen. Conclusion Alternatives are not sufficiently available. The use of ethylene for sprouting inhibition is a useful alternative that meets the requirements for organic production.
Brazil	Brazil is aware of other alternatives to sprout control in potatoes and onions, such as the use of certain vegetable oils, cold storage and high dormancy varieties. However, these alternatives might not be available in sufficient quality and quantity for all organic producers.
Uruguay	With regard to Appendix III of the document, point 5.1.v. - Regarding refrigerated storage, at least in our conditions, this practice not always increases the content of reducing sugars, because this process typically occurs at a temperature of 4 ° C. Uruguay has also the option of storing potatoes in the ground and the use of varieties with different periods of dormancy. It is also noteworthy that the potato crop has two production cycles per year (spring and fall) in our country.

Has the applicant adequately addressed the general criteria in section 5.1?	
Member/ Observer	**Answer**
Brazil	Brazil understands that the applicant has adequately addressed the general criteria in section 5.1. We believe that the history of use of ethylene by organic and traditional farmers without evidence of adverse effects should be taken into consideration. Additionally, CCFL has already approved the use of ethylene for the ripening of bananas and kiwi fruits, for degreening of citrus for fruit fly prevention and as a flowering agent for pineapples. Thus, we understand that the decision on the use of ethylene for sprouting inhibition of potatoes and onions should be consistent with the other approved uses for ethylene. If the available information is considered insufficient to fulfill the general criteria in section 5.1, the use of ethylene for other purposes should be review until new data is available.
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.
Australia	Australia is not confident this matter is about plant protection; rather it is more about post harvest storage treatment and marketing of potatoes and onions.
Brazil	The use of ethylene might be an alternative to the control of sprout in potatoes and onions, especially when other practices are not available.
United States	We have not observed the need for ethylene for post harvest use on organic potatoes and onions in a variety of growing regions in the United States. Organic producers can use natural plant oils and cold storage as alternatives. We recognize that plant oils may not be available in all regions, although the use of natural substances would be preferable to the use of synthetic ethylene under the criteria at 5.1.b)4).
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.
Australia	Based on current practices (e.g. de-greening) ethylene gas does not pose any major contamination risk to the environment, local ecology, or health of humans, terrestrial animals and insects.
Brazil	As explained before, we understand that the use of ethylene for sprouting inhibition in potatoes and onions takes into account these factors.
Norway	Exposure of operators and workers may occur when entering the application room, after ventilation and during maintenance works; bystanders may be exposed to leakages from the treatment rooms or during the venting of the gas into the atmosphere after treatment. No information was available to quantify the potential exposure derived from these scenarios. Therefore no conclusion could be reached on the risk assessment for ethylene exposure and a data gap was set to address this issue.
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.
Australia	Noted
Brazil	We agree with the EU comments.

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.
Australia	Noted
Brazil	We agree with the EU comments.
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.
Australia	Where varieties of potatoes and onions that have long dormancy characteristics are not available, or these varieties are not suited to local growing conditions, the inspection body may approve the use of ethylene gas to limit the sprouting of stored potatoes and/or onions.
Brazil	We agree with the EU comments.
United States	We have not observed the need for ethylene for post harvest use on organic potatoes and onions in a variety of growing regions in the United States. Organic producers use natural plant oils and cold storage as alternatives. We recognize that plant oils may not be available in all regions, although the use of natural substances would be preferable to the use of synthetic ethylene under the criteria at 5.1.b)4).
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**
Brazil	Brazil understands that the applicant has adequately addressed these aspects.
Norway	For the time being, these [data] gaps and findings are too essential for us to be able to agree upon including ethylene for various purposes in Annex 2, Table 2 to GL32-19922. They may conflict with the criteria for general inclusion of substances, point 3 and 4 saying “use and disposal of the substance should not result in, or contribute to, harmful effects on the environment and should have the lowest negative impact on human or animal health and quality of life”.
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**
Australia	There are a few claims that did not include supporting information. For example, is there evidence to: – indicate that low levels of ethylene do inhibit sprouting? – support the claim that by capturing ethylene rather than releasing it into the environment can be seen as reducing the ambient air pollution? Does controlling the amount of light (unsubstantiated information from the Internet) coupled with dry ambient temperatures provide ideal storage conditions and help reduce sprout formation in potatoes and onions? The FAO suggests that using potato varieties with long *dormancy* periods and proper *curing* methods are options to control sprouting in potatoes and onions:- www.fao.org/wairdocs/x5014e/X5014e0b.htm www.fao.org/docrep/X5415E/x5415e03.htm#3.3%20control%20of%20sprouting
Brazil	No additional comments.
Norway	A recently published scientific peer review of pesticide risk assessment of the active substance ethylene (EFSA Journal 2012; 10(1):2508) identified several data gaps regarding the use of ethylene for plant growth regulator on bananas and potatoes (point 7 in the report).[4]

[4] Report is available at http://www.efsa.europa.eu/en/efsajournal/doc/2508.pdf

Are any additional conditions of use needed?	
Member/ Observer	**Answer**
Australia	Yes: Need for ethylene recognised by the certification body or authority for sprout inhibition of stored potatoes and onions where varieties that have long dormancy characteristics are not available, or these varieties are not suited to local growing conditions. [Option 2]. If there is strong support for option 1, Australia would be open to considering certain restrictions, such as limiting the time the treatment may be applied.
Brazil	No additional comments.
Uruguay	Uruguay suggests including ethylene in Table 2 and proposes supporting option 2, leaving to national authorities the possibility of permitting its use in each country.

Would you support the addition of the new substance in Annex 2?	
Member/ Observer	**Answer**
Australia	If supported, ethylene for sprout inhibition not be listed as a substance for plant pest and disease control (Annex 2, Table 2), but be appended to the current reference to ethylene for ripening (Annex 1, para 82) or be listed as a processing aid (Annex 2, Table 4).
Brazil	Yes.
Norway	[No.] For the time being, these gaps and findings are too essential for us to be able to agree upon including ethylene for various purposes in Annex 2, Table 2 to GL32-19922. They may conflict with the criteria for general inclusion of substances, point 3 and 4 saying “use and disposal of the substance should not result in, or contribute to, harmful effects on the environment and should have the lowest negative impact on human or animal health and quality of life.”
Uruguay	Uruguay suggests including ethylene in Table 2 and proposes supporting option 2, leaving to national authorities the possibility of permitting its use in each country.

APPENDIX III

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

UPDATED Timeline

Completed	Letter of invitation to join the eWG sent to member countries and observers; Request for any data or research information on ethylene to be considered by working group.
Completed	Deadline for submitting interest to participate in eWG. Deadline for submission of data or research information on ethylene to be considered by eWG.
Completed	Proposal and new data and research information sent to eWG members for consideration using structured work approach and review templates
Completed	Comments on proposal due
Completed	eWG Draft Report distributed to participants
Completed	Comments on eWG Draft Report due
April 30, 2013	eWG Final Report submitted to Codex Secretariat for distribution and consideration of the 41th Session of the CCFL in May 14-17, 2013

Appendix IV

COMPILATION OF COMMENTS SUBMITTED FOR THE SECOND ROUND OF COMMENTS ON THE DRAFT REPORT

ARGENTINA

Comments from Argentine to the Draft Report of the Electronic Working Group on the Review of the Guidelines of Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999) specifically on use of ethylene as a sprouting inhibitor for potatoes and onions

Argentine agrees to include ethylene as allowed substance within the Guidelines like a sprouting inhibitor for potatoes and onions

Argentine maintains its earlier position about the location where the substance should be included in the Annexes – Tables. Argentine supports the inclusion of the ethylene in a new Table to be incorporated in the Annex 2 as follows:

ANNEX 2 PERMITTED SUBSTANCES FOR THE PRODUCTION OF ORGANIC FOOD

Table 2' "Substances permitted for the post harvest management".

Justification: Is understood that the inclusion of the ethylene in the Table 2 "Substances for plant pest and disease control". IV "Other" is not right. The purpose of the use of ethylene is not the control of pests and diseases but to make the management of sprouting of potatoes and onions in the post harvest

Regarding to the three options presented in the final report of the electronic working group, **Argentine agrees with the Option A** as follows:

"Need recognized by the certification body or authority for sprout inhibition of stores potatoes and onions where varieties that have long dormancy characteristics are not available, or this varieties are not suited to local growing conditions. Must be used in a manner that minimizes exposure to operators and workers."

AUSTRALIA

Australia does not support the recommendation of accepting proposed Option A. Australia considers that the wording at the end of Option A *'...Must be used in a manner that minimizes exposure to operators and workers'* represents an issue that is related to occupational health and safety, which is the responsibility of each member country and we believe is outside the scope of Codex. Further, Australia supports Brazil's comments in section 5.1.iv of Annex 2 of the draft eWG report, which highlight that *'...the EFSA assessment did not reach any conclusion on the toxicity of ethylene due to the lack of data. This data gap should not be interpreted as evidence of harmful effects on human or animal health.*'

Australia supports proposed Option B, which does not have the additional occupational health and safety wording.

BRAZIL

Brazil supports the use of ethylene as sprouting inhibitor for onions and potatoes and its inclusion in Table 2. We understand that Option A, as suggested by co-chairs, covers adequately the conditions that should be taken into consideration for the use of ethylene as sprouting inhibitor for onions and potatoes.

CAMEROON

Comments from Cameroon to the Draft Report of the Electronic Working Group on the Review of the Guidelines of Production, Processing, Labeling and Marketing of Organically Produced Foods (CAC/GL 32-1999) specifically on use of ethylene as a sprouting inhibitor for potatoes and onions

Cameroon is a producer of potatoes and onions. The varieties of these crops produced have high dormancy characteristics and, the post harvest process for inhibition of germination is natural specially, through sun drying. In fact, more the sun is, better the products are stored, and less it is, greater are the losses related to post-harvest sprouting. Then, natural drying solution is not sufficient.

Considering the discussion of the first round of the EWG and studies previously carried out by the EU which led to introduce the adoption of the standard project in discussion, we infer that it is essential to have an alternative and economically viable solution such as the use of ethylene.

Furthermore, Cameroon is a producer of bananas where ethylene is used as a retarder of ripening. We have not so far observed on workers, animals and environment, adverse effects of this product for the simple reason that it is used in very small quantities from which workers are generally protected.

In addition, potatoes are produced in regions of Cameroon where climate is relatively cold with less temperature. Ethylene thus presents itself as an effective alternative for many post harvest losses observed in these growing areas because of low intensity of sunlight.

Regarding the risks faced by workers due to the use of ethylene, it is necessary to require Member States to implement the establishment of a manual of additional procedures for their protection. However, if the risks appear forward, it would be quite recommended reviewing these procedures manuals, where necessary.

In conclusion, Cameroon supports the use of ethylene as a sprout inhibitor for potatoes and onions, and agrees to option A as recommended by the co-chairs.

CANADA

Canada is pleased to provide the following comments.

Canada would like to remind the Committee that the Annex in the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods* is an indicative list intended to provide guidance on substances which might be used by national authorities. Each country must evaluate, against the established criteria, whether or not it is appropriate to use a particular substance, given their regional circumstances.

As stated in the Guidelines, "The following lists do not attempt to be all inclusive or exclusive, or a finite regulatory tool, but rather to provide advice to governments on internationally agreed inputs. A system of review criteria as detailed in Section 5 of these Guidelines for products to be considered by national governments should be the primary determinant for acceptability or rejection of substances."

Thus Canada could support Option A provided the "authority" determines that it meets the criteria established in Section 5.1 of the Guidelines. However, as this is the case with all substances, Canada questions whether listing this or other substances in this manner is necessary.

Canada looks forward to reviewing further justification which will be presented in the report of the electronic working group.

CHILE

Chile considered the three proposed conditions for use for ethylene and we agree with the Option A.

COSTA RICA

Costa Rica desea externar su agradecimiento por la oportunidad de emitir los siguientes comentarios:

El etileno y los usos propuestos en las diferentes modalidades que se han planteado ante el CODEX, no encajan en ninguno de los anexos de las normas orgánicas. Debe proponerse una lista de productos permitidos en pos-cosecha y que en este momento no existe.

Lo anterior por cuanto no es fertilizante, no es producto fitosanitario y tampoco coadyuvante ni ingrediente. Debe ser un anexo aparte que también incluya otras sustancias que se han identificado como necesarias para la protección de los productos durante la pos-cosecha tanto de origen vegetal como animal.

Como comentario general cabe mencionar que Costa Rica argumentó para la justificación del uso de etileno en la inducción de floración en piña:

- el etileno es un gas naturalmente producido por las frutas en su proceso de maduración, por lo que está presente siempre en la naturaleza.

-el sistema de utilización del etileno en espacios cerrados, tampoco provoca mayor contaminación a la atmosfera, que vale aclarar que tampoco existen muchos datos en la literatura sobre este aspecto.

- su uso está en concordancia con los principios de la producción orgánica.

- aunque en Costa Rica en la producción orgánica no se está utilizando en papa orgánica, sería un factor que ayudaría a conservar la calidad del producto por un tiempo más prolongado.

- los principios que se utilizaron para aceptar el etileno en otros usos, aplican en este caso también, ya que las posibilidades de otras alternativas son limitadas o en algunos casos no existen y en el caso de la papa las variedades utilizadas en Costa Rica , requerirían del uso del etileno.

Costa Rica want to externalize their appreciation for the opportunity to provide the following comments: Ethylene and the proposed uses in the different modalities that have been raised before the CODEX, do not fit in any of the annexes of organic standards. Should be offered a list of products allowed in post-harvest and at this time there. This is because fertilizer is not plant protection product or adjuvant either ingredient. You must be a separate annex that also includes other substances that have been identified as necessary for the protection of products during postharvest both plant and animal.

As a general comment it should be mentioned that Costa Rica argued for the justification of the use of ethylene in the induction of flowering in pineapple:

- Ethylene gas is produced naturally in the fruit ripening process, so it is always present in nature.

-the use of ethylene system indoors, not causes more pollution into the atmosphere, that it is clear that there are not many data in the literature on this aspect.

- Their use is in accordance with the principles of organic production.

- Although in Costa Rica in organic production is not being used in organic potato would be a factor that would help preserve the quality of the product for a longer time.

- The principles that were used to accept the ethylene in other applications, apply in this case also, since the chances of other alternatives are limited or in some cases do not exist and in the case of potato varieties used in Costa Rica, require the use of ethylene.

EUROPEAN UNION

The EU agrees with your recommendation for listing the substance in Annex 2 following Option A.

[I] would like to stress that in the light of current scientific and technical knowledge, it has been necessary to amend the conditions of approval of ethylene in the EU and to restrict the authorisations to indoor uses by professional users. This restriction also applied to the organic farming production. Therefore, the EU considers still needed the addition of Ethylene as a sprouting inhibitor for onions and potatoes in Annex II, following Option A.

INDIA

India would like to mention that Option A is the most suitable which is "Need recognized by the certification body or authority for spout inhibition of stored potatoes and onions where varieties that have long dormancy characteristics are not available, or these varieties are not suited to local growing conditions. Must be used in a manner that minimizes exposure to operators and workers", since ethylene, a naturally produced chemical / plant hormone during ripening of fruits is used as growth regulator and also for artificial ripening of fruits. Residues of gaseous ethylene in agricultural or horticulture products may not pose health alert.

MEXICO

Thank you for the information, we support option A.

Substance		Description; compositional requirements; conditions for use
IV. OTHER		
[Ethylene]	**Option A:**	[Need recognized by the certification body or authority for sprout inhibition of stored potatoes and onions where varieties that have long dormancy characteristics are not available, or these varieties are not suited to local growing conditions. Must be used in a manner that minimizes exposure to operators and workers.]

NORWAY

In consideration of the criteria at section 5.1. of the guidelines, the eWG has identified three options, please find our comments below.

Norway is still very concerned about the use of ethylene as a plant growth regulator based on the fact that several data gaps regarding the use are published in EFSA Journal 2012; 10(1):2508[5].

We strongly support Option C, as we consider this the most appropriate option for ethylene.

The reason for this is that data gap is identified for toxicological information allowing to set reference values for ethylene if the levels of exposure of consumers, operators, workers and bystanders are shown to exceed natural background exposure levels. Based on this EFSA could not reach a conclusion on the potential genotoxic or carcinogenic effect of ethylene exposure.

Similar data gap is also identified for ethylene oxide derived from the use of ethylene. Ethylene oxide is of toxicological concern and appears to be more toxic than ethylene, and is considered as a category 2 carcinogen and mutagen. The EFSA publication also points out a potential for long-range transport of ethylene oxide through the atmosphere, and appoint this as a critical area of concern.

It is our opinion that these gaps and findings are too essential to support the inclusion of ethylene for various purposes in Annex 2, Table 2 to GL32-1992[6] at this time, even when including conditions for use as described in option A and B.

We also consider the inclusion of ethylene to be in conflict with the criteria for general inclusion of substances, point 3 and 4 saying "*use and disposal of the substance should not result in, or contribute to, harmful effects on the environment and should have the lowest negative impact on human or animal health and quality of life*".

To conclude: We do not support the proposal from the co-chairs that option A is the way forward as it is our strong opinion that ethylene, based on current data, cannot be included in the list of substances for plant, pest and disease control for organically produced foods.

URUGUAY

Uruguay comments on the Draft Report of the Electronic Working Group on the Review of the Guidelines for the Production, Processing and Labeling of Organically Produced Food. Uruguay considers that the option A is the most adequate.

[5] http://www.efsa.europa.eu/en/efsajournal/doc/2508.pdf
[6] Guidelines for the production, processing, labelling and marketing of organically produced foods, GL 32-1999.