codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 14 (c) **CX/FAC 06/38/30, Add.1**

March 2006

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-eighth Session

The Hague, the Netherlands, 24 – 28 April 2006

PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF DIOXIN AND DIOXIN-LIKE PCB CONTAMINATION IN FOOD AND FEEDS

Comments at Step 3 submitted by Canada, Japan, USA and CEFS

CANADA

Canada wishes to express its appreciation to the Working Group, led by Germany, in the preparation and revision of this discussion paper. The Canadian delegation would like to offer the following comments on the discussion paper.

General Comments:

It is Canada's view that the revised paper contains much useful information related to potential sources of dioxin and dioxin-like PCB contamination, including suggestions for preventative measures. Nevertheless, the document would benefit from some basic restructuring to place the information in a more logical sequence, reflecting a struture consistent with a "Code of Practice". Advantage could also be taken of this restructuring process to condense some of the background information and consolidate the numerous references to monitoring, currently dispersed throughout the document, under one section.

We suggest a structure that has an introductory section outlining potential sources of dioxin and dioxin-like PCB contaminates, then a section on control measures that could be implemented by each of the major participants in the food chain (e.g. farmer, feed manufacturer, food processor, etc.) followed by a section on monitoring and the role of the national authorities.

We would suggest that the monitoring section should provide some guidance on the purpose of the monitoring, e.g. a means of verifying that control measures are effective, or action that could be undertaken should limits exceed unacceptale levels where such levels have been identified. In this regard, we note that the draft document states that "*Farmers and industrial feed and food manufacturers have the primary responsibility for feed and food safety*." While we agree in principle with this statement, the next sentence states "*….they should periodically test products from areas for which elevated levels of dioxins and dioxin-like PCBs can be anticipated*." Given the cost implications for analysing for dioxins and dioxin-like contaminants, we question the practicality of expecting farmers (and some small feed and food processing establishments) to carry out such testing.

Paragraph 16:

Most of the sources listed seem more specific to dioxins than dioxin-like PCBs. We would suggest that the following be added to the list as a potential high source of PCB (including dioxin-like PCB) release to the environment:

Release from "closed" electrical equipment still in use (e.g. transformers, capacitors).

In the same paragraph, we suggest that it be explained in the document why hexachlorobenzene is mentioned. We understand that there has been some discussion around whether a TEF should be applied to hexachlorobenzene.

Paragraph 57:

We would like to suggest that allusion be made in this paragraph to "food safety programs" as a possible framework for monitoring. For example (italics indicate new text for consideration):

"Farmers and industrial feed and food manufacturers have primary responsibilities for feed and food safety. Therefore, they should periodically test products from areas for which elevated levels of dioxins and dioxin-like PCBs can be anticipated. *Testing could be conducted within the framework of a food safety program (e.g. Good Manufacturing Practices, On-Farm Food Safety programs, Hazard Analysis and Critical Control Point programs, etc.).* Competent authorities should periodically test such products as well and enforce this responsibility through the operation of surveillance and control systems *at appropriate points throughout the food continuum, from the primary production level to the retail level.*"

Paragraph 58:

This paragraph suggests that testing be periodic in consideration of the high cost of analysis. Although we recognize that paragraph 66 describes "high throughput" screening methods, we would like to suggest that the possible usefulness of *in vitro* bioassays be stated in paragraph 58 as well. Suggested additional text (in italics) is offered for consideration:

"As *chemical* analyses for dioxins are quite expensive … should be kept. *In vitro bioassays or other bioanalytical tools, which are inexpensive relative to chemical methods of analysis, may be useful in routine monitoring as a prescreening tool for large numbers of samples* (see para. 66)."

Glossary of Terms:

The "Glossary of Terms" contains a definition for "food" which is not the same as the definition for "food" contained in the Codex Procedural Manual. Given that this is a Codex document, and Codex has already defined "food", the adopted Codex definition should be used.

JAPAN

We are pleased to have the opportunity to submit the following comments:

SOURCE DIRECTED MEASURES

Paragraph 16

The sentence below in paragraph 16 should read as follows:

- Part II of Annex C of the Stockholm Convention lists the following industrial source categories that have the potential for comparatively high formation and release of dioxins, PCBs and hexachlorobenzene to the environment.

Rationale

We think it more appropriate to use similar wording as Part III below of paragraph 16, "Part III of Annex C also lists the following source categories that may unintentionally form and release dioxins, PCBs and hexachlorobenzene to the environment".

1.2 Feed

1.2.3 Minerals and Trace Elements

The content of this section (paras.37- 40) should be moved to Section 1.4 and placed immediately above current para. 45.

1.2.4 Drying Process

The content of this section (paras.41- 42) should be moved to Section 1.3 and placed immediately above current para.43. In addition, the title of the Section "1.3 Special Conditions of Food Processing" should be amended to "1.3 Special Conditions of Feed and Food Processing".

Rationale

This amendment is to clarify contents what commodity categories each section of the Code of Practice covers. We separated the paragraphs describing foods from Section 1.2 Feed so that Section 1.2 covers only feeds while Section 1.3 and 1.4 cover both feeds and foods.

UNITED STATES OF AMERICA

This is in response to CX/FAC 06/38/30, requesting comments at Step 3 on the proposed Draft Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Foods and Feeds. This document will be considered at the 38th Session of the Codex Committee on Food Additives and Contaminants (CCFAC).

GENERAL COMMENTS

The United States (U.S.) supports the development of the proposed Draft Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Foods and Feeds which provides recommended practices to governments and national authorities to reduce dioxin and dioxin-like PCB contamination in foods and feeds.

The draft code of practice contains statements that are not supported by literature reference. Therefore it is unclear if there are published empirical demonstrations to support these statements, or if they are only theoretical suggestions. The U.S. has provided suggested references where available (see ATTACHMENT) and suggests that additional references be included to support statements found in the document.

SPECIFIC COMMENTS

Paragraph 2

The U.S. suggests that references be provided to support sentence 1, 2, and 4.

Paragraph 3

For clarity, the U.S. suggests restating sentence 3 as follows: "Certain commercial PCBs are known to be contaminated with PCDFs, and therefore could be a potential source for dioxin contamination (3; 4)." In addition, the U.S. suggests that references be provided to support sentence 2.

Paragraph 4

In sentence 2 it is unclear what is meant by the statement emissions via air through thermal processes are of "minor importance." The U.S. notes that it has been established that dioxin-like PCBs are formed during incineration of municipal wastes, and this may

be a primary source of dioxin-like PCBs in the environment. Moreover, other paragraphs in the document (e.g., paragraphs 2, 5, 14, 16, and 20) acknowledge the importance of thermal processes in the production of dioxin-like PCBs. Therefore the U.S. suggests that sentence 1 and 2 be revised as follows: "Today release of dioxin-like PCBs occurs from leakages, accidental spills, illegal disposal and through emissions via air from thermal processes. Migration from sealants and other old matrix applications are of minor importance." In addition, the U.S. suggests that references be provided to support sentence 1 and 2.

Paragraph 7

The U.S. suggests including the following sentence to follow sentence 1: "Other sources of dioxins in soil may be of natural origin (e.g., ball clay)." The U.S. also suggests including the following reference to support the proposed sentence: Ferrario, J.; Byrne, C.; Cleverly, D.; 2,3,7,8-Dibenzo-*p*-dioxins in mined clay products from the United States: evidence for possible natural origin, Environmental Science and Technology, 2000, 34, 4524-4532.

Paragraph 10

Sentence 1 addresses both dioxins (PCDDs/PCDFs) and dioxin-like PCBs though references an article that appears to address only PCDDs and PCDFs. In addition, the U.S. suggests that references be provided to support sentence 2.

Paragraph 20

The U.S. believes that recommendations for measures to reduce dioxin and dioxin-like PCBs in air should be directed to appropriate national authority agencies as these measures are outside the terms of reference of Codex and suggests that sentence 1 be restated as follows: "To reduce dioxin and dioxin-like PCB contamination in the air, national food authorities should consider recommending to their national authorities responsible for air pollution measures to prevent uncontrolled burning of wastes, including the burning of landfill sites or backyard burning (9; 10)."

Paragraph 21

The U.S. notes that information contained in sentence 1 is presented in paragraphs 4 and 5 and suggests that sentence 1 be removed.

Paragraph 22

The U.S. suggests that references be provided to support sentence 2.

Paragraph 23

Sentence 2 states: "The spreading of sewage and sewage sludge should be monitored periodically." The U.S. believes this sentence is unclear and suggests that it be restated as follows: "Sewage sludge used in agriculture should be monitored, as necessary, for dioxins and dioxin-like PCBs."

Paragraph 25

The U.S. suggests that references be provided to support sentence 1.

Paragraph 26

Sentence 1 states: "On the other hand, reduction of dioxin and dioxin-like PCB levels in feed would have an immediate effect on contaminant levels in farmed fish." The U.S. notes that this sentence addresses feed but is found under Section 1.1 (Air, Soil, Water). The U.S. suggests that this sentence be moved to Section 1.2 (Feed).

Paragraph 27

The U.S. suggests that references be provided to support sentence 1 and 2.

Paragraph 30

The U.S. suggests that references be provided to support sentence 1.

Paragraph 35

Sentence 2 states: "Monitoring the dioxin content in soil as well as forage plants from treated sites may provide the necessary information to enable competent national authorities, if necessary, to take appropriate management measures in order to prevent the transfer of dioxins (and probably dioxin-like PCBs) into the food chain." The U.S. suggests revising sentence 2 as follows: "Dioxin levels in soil and forage plants from sites treated previously with dioxin-contaminated herbicides should be monitored as necessary." In addition, the U.S. suggests that references be provided to support sentence 1.

Paragraph 36

The U.S. suggests that references be provided to support sentence 1 and 2.

Paragraph 38

For clarity, the U.S. suggests restating sentence 2 as follows: “The user of such feed ingredients should verify that dioxin and dioxin-like PCB levels are within nationally-established guideline levels or maximum limits, if available, through certification by the manufacturer or supplier.”

Paragraph 39

The U.S. suggests adding the following sentence before sentence 1: “Elevated levels of dioxins were found in ball clay used as an anticaking agent for soybean meal used in feed.” The U.S. also suggests including the following reference to support the proposed sentence: Ferrario, J.; Byrne, C.; Cleverly, D.; 2,3,7,8-Dibenzo-*p*-dioxins in mined clay products from the United States: evidence for possible natural origin, 2000, 34, 4524-4532; and Hayward, D.G.; Nortrup, D.; Gardner, A.; Clower, M.; Elevated TCDD in chicken eggs and farm-raised catfish fed a diet with ball clay from a southern United States mine, Environmental Research, 1999, 81, 248-256.

Paragraph 40

Sentence 2 states: “The supplementation of copper or zinc with metallurgic cinders might be a considerable source of dioxins despite their poor bioavailability from the copper containing matrix in the gastro intestinal tract.” The U.S. believes that this sentence is unclear and suggests that it be restated as follows: “Minerals, including trace elements, which are by-products or co-products of industrial metal production have been shown to contain elevated levels of dioxins.” The U.S. also suggests including the following reference to support the proposed sentence: Bluhm, L.; Barnes, P.; Litman, V.; Shojaee, S.; Vocque, R.; Archer, J.; Polychlorinated dioxins and furans found in fish feed and related compounds, Organohalogen Compounds, 2003, 64, 144-147.

Paragraph 41

The U.S. believes that reference to “appropriate fuels” in sentence 2 is unclear. For example, what fuels are appropriate/recommended? The U.S. suggests that paragraph 41 be expanded to provide this information. In addition, the U.S. suggests that references be provided to support sentence 2.

Paragraph 42

As in paragraph 41, the U.S. believes that recommendations for fuels for “drying processes” are unclear. For example, are light heating oil and natural gas being recommended for all drying processes? The U.S. suggests that paragraph 42 be rewritten to include specific recommendations. The U.S. also questions why these recommendation are specific to only "dried green fodder" and if they could be applied to other products. In addition, the U.S. suggests that references be provided to support sentence 2.

Paragraph 44

Paragraph 44 states: “Special nationally-used food preparation practices that could lead to elevated levels of dioxins or dioxin-like PCBs should be identified and, if necessary, measures for minimization should be considered.” The U.S. is not aware of studies to support this statement and requests that specific nationally-used food preparation practices that lead to elevated levels of dioxins or dioxin-like PCBs be identified and supported by reference. Otherwise the U.S. suggests this paragraph be removed.

Paragraph 47

The U.S. questions whether contaminated flood waters have resulted in elevated dioxin and dioxin-like PCBs in food and feed and suggests including a reference to support this statement.

Paragraph 49

The U.S. suggests that references be provided to support sentence 2 and 3.

Paragraph 50

Paragraph 50 states: "Some string for baling straw may be contaminated with dioxin-like PCBs due to certain manufacturing processes." The U.S. suggests including a reference to support this statement.

Paragraph 53

Sentence 3 states: "Removal of ashes and remaining fire-fighting water and flushing with freshwater should reduce the risk of high PCB levels." The U.S. believes that this sentence is unnecessary and suggests that it be removed. In addition, the U.S. suggests that references be provided to support sentence 1.

Paragraph 54

The U.S. suggests that references be provided to support sentence 1.

Paragraph 55

The U.S. suggests including the following sentence to precede sentence 1: "Pentachlorophenol-treated wood in animal facilities has been associated with elevated levels of dioxins in livestock." The U.S. also suggests including the following reference to support the proposed sentence: Fries, G.F.; Feil, V.J.; Zaylskie, R.G.; Bialek, K.M.; Rice, C.P.; Treated wood in livestock facilities: relationship among residues of pentachlorophenol, dioxins, and furans in wood and beef, Environmental Pollution, 2002, 116, 301-307. In addition, the U.S. suggests that references be provided to support sentence 4.

Paragraph 56

The U.S. suggests that references be provided to support sentences 1, 2, 3 and 4.

New Paragraph to Follow Paragraph 60

The U.S. suggests including the following discussion in Section 2 (Sampling, Analytical Methods, and Data Reporting and Laboratories): "Traditional methods for the analysis of dioxin and dioxin-like PCBs rely on high-resolution mass spectrometry which is time-consuming and expensive. Alternatively, bioassay techniques (e.g., CALUX) have been developed as high throughput screening methods which may be less expensive than traditional methods. However, the cost of analysis remains an impediment to data collection thus research priority should be given to the development of less costly analytical methods for the analysis of dioxin and dioxin-like PCBs." The U.S. suggests that the following reference be included to support sentence 2 of the proposed paragraph: Dioxins and Dioxin-like Compounds in the Food Supply: Strategies to Decrease Exposure, Institute of Medicine of the U.S. National Academy of Science, 2003, Washington DC.

Paragraph 65

The U.S. suggests that the following sentence be included after sentence 1: "This report should also include a specific description of the procedure used to determine the level of quantification (LOQ)."

Paragraph 67

Certain U.S. government laboratories may not be formally accredited although they have thorough quality assurance programs that address all of the critical elements of accrediting agencies. Therefore, the U.S. suggests revising paragraph 67 as follows: "Laboratories involved in the analysis of dioxins and dioxin-like PCBs using screening as well as confirmatory methods of analysis should be accredited by a recognized body operating in accordance with ISO/IEC Guide 58: 1993 (39) or have quality assurance programs that address all critical elements of accrediting agencies to ensure that they are applying analytical quality assurance. Accredited laboratories should follow the ISO/IEC/17025:1999 standard "General requirements for the competence of testing and calibration laboratories" (40) or other equivalent standards."

Glossary of Terms/Fat Fish

The term "fat fish" is defined as a "fish with a fat content of more than 5% in the muscle tissue." The U.S. questions whether including this unique term and definition is required.

CEFS

CEFS (Comité Européen des Fabricants de Sucre), on behalf of all sugar manufacturers in the EU and Switzerland, would like to present comments on the proposed Draft Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Foods and Feed at step 3 (CX/FAC 06/38/30).

CEFS would like to propose the following modifications to the current draft that could not be sent on time for consideration by the electronic working group in which CEFS participated:

- **"Proposed Draft Code of Practice" (pages 3-5) :**

Draft Text	Proposed change(s)	Rationale
7. Sources of dioxins in soil include deposition from atmospheric dioxins, application of **contaminated** sewage sludge to farm land (15), flooding of pastures with contaminated sludge, and prior use of contaminated pesticides (e.g., 2.4.5-trichlorophenoxy acetic acid) and fertilizers (e.g., certain compost) (13; 16).	Insert "contaminated" before "sewage sludge".	Consistency with the rest of the text and avoidance of possible misunderstandings.
19. Since the global limitation and reduction of dioxins and dioxin-like PCBs from **non-food related** industrial and environmental sources may lie outside of the responsibility of CCFAC, these measures will not be considered within this Code of Practice.	Insert "non-food related" before "industrial and environmental sources".	Food (and feed) production often falls under the definition of "industrial activity".

- **"Recommended Practices" (pages 6-13) :**

Draft Text	Proposed change(s)	Rationale
42. The quality of commercial dried green fodder depends on the selection of the raw material and the drying process. The purchaser should consider requiring a certificate from the manufacturer/supplier, that the dried goods are produced according to Good Manufacturing Practice, especially in the choice of the fuel ~~**(e.g., light heating oil, natural gas, by no means treated wood)**~~ and are in compliance with nationally-established guideline levels or maximum limits, if available.	Delete the examples (or eventually, further develop the Draft Code with a more detailed section on fuels)	The examples given are potentially confusing since there are other "dioxin-safe" quality fuels such as bituminous coal or pulverised coal and on the other hand there are likely to be "undesirable" fuels other than treated wood.
46. To the extent feasible, it should be ensured that minimal contamination with dioxins and dioxin-like PCBs occurs during the harvest of feed and food. This can be achieved in possibly contaminated areas by minimizing soil deposition on feed and food during harvest by using appropriate techniques and tools according to Good Agricultural Practice. Roots and tubers, grown on contaminated soil, should be washed to reduce soil contamination. If roots and tubers are washed, they should be sufficiently dried before storage **or be stored following techniques (e.g. ensilage) aiming** to prevent mould formation.	Introduce the idea that drying is not the only alternative to prevent mould formation.	As an example, a significant fraction of sugar beet pulp (a feed material) is not dried after sugar extraction but is either used within a short time-period or stored following techniques such as ensilage.

58. As analyses for dioxins are quite expensive in comparison to determination of other chemical contaminants, periodic tests should be performed to the extent feasible at least by industrial feed and food manufacturers including both incoming raw materials and final products and data should be kept (see para. 66). **The frequency of sampling should be related to HACCP analysis with due consideration being given to results from previous analysis by individual companies and/or via a pool of industry results within the same sector.** If there are indications of elevated levels of dioxins and dioxin-like PCBs, farmers and other primary producers should be informed about the contamination and the source should be identified.	Introduce the idea of HACCP- related frequency of sampling and the cost-sharing mechanism of "pools" of industry sector analyses results.	The frequency of sampling should be commensurate to the level of risk. On the other hand, due to the cost of dioxin analyses, industry-wide sector-specific initiatives such as a pool of laboratory results from individual companies conducted under similar parameters should be encouraged.

We thank you in advance for taking our comments into consideration.