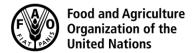
CODEX ALIMENTARIUS COMMISSION \blacksquare







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Agenda Item 8

CX/CF 18/12/8 February 2018

JOINT FAO/WHO FOOD STANDARDS PROGRAMME **CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

12th Session Utrecht, The Netherlands, 12-16 March 2018

PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF DIOXINS AND DIOXIN-LIKE PCBs IN FOOD AND FEED

(Prepared by the Electronic Working Group led by the European Union)

Codex members and Observers wishing to submit comments at Step 3 on this draft should do so as instructed in CL 2018/4-CF available on the Codex webpage/Circular Letters: http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/.

BACKGROUND

- 1. At its 80th meeting in 2015, the Joint FAO/WHO Expert Committee on Food Additives (JECFA80) assessed the toxicity of non-dioxin-like polychlorinated biphenyls (NDL-PCBs)1. JECFA concluded that none of the available studies on the NDL-PCBs known as the six indicator PCBs (PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180) and PCB 128, was suitable for derivation of health-based guidance values or for assessment of the relative toxic potency of the NDL-PCBs relative to a reference compound. Therefore, a comparative approach using the minimal effect doses was developed in order to estimate Margins of Exposure (MOEs) to provide guidance on human health risk. Owing to the long half-lives of these chemicals and to eliminate interspecies differences in toxicokinetics, JECFA considered it appropriate to estimate body burdens rather than using external dose (dietary exposure) for the risk characterization. Comparison of the human body burden estimates (derived from human milk concentrations) with the body burden estimates from animal studies derived as points of departure for each congener resulted in MOEs for adults ranging from 4.5 to 5000.
- 2. MOEs for breastfed infants, which may have a body burden up to 2-fold higher than that of adults, would be approximately half of the adult values. The MOEs for children would be expected to be intermediate between those for adults and those for breastfed infants, owing to the initial contribution from breastfeeding and the subsequent lower dietary contribution compared with human milk.
- 3. Because the MOEs are based on minimal effect doses, they were considered to give some assurance that dietary exposures to NDL-PCBs are unlikely to be of health concern for adults and children, based on the available data. For breastfed infants, the MOEs would be expected to be lower. However, based on present knowledge, the benefits of breastfeeding are considered to outweigh the possible disadvantages that may be associated with the presence of NDL-PCBs in breast milk.
- 4. The focus of efforts related to preventing exposure to persistent organic pollutants (POPs), including NDL-PCBs, is on limiting contamination of the food-chain, including exposure of food-producing animals to PCBs. With the knowledge that fish, meat and dairy product consumption makes the most significant contribution to human PCB exposure, methods of PCB reduction in animals from which these foods are derived are of primary interest. Transfer of dioxin-like (DL) PCBs and NDL-PCBs from feed to animal-based food products (e.g. milk) occurs; transfer of PCB 138, PCB 153 and PCB 180 is greater than that observed for PCB 28, PCB 52 and PCB 101. Adherence to good agricultural practices and good animal feeding practices will contribute to the efforts to reduce PCB concentrations in food for human consumption.

¹ Safety evaluation of certain food additives and contaminants. Supplement 1: Non-dioxin-like polychlorinated biphenyls, WHO Food Additives Series: 71-S1. Available at: http://apps.who.int/iris/bitstream/10665/246225/1/9789241661713eng.pdf

5. NDL-PCBs are thermally stable and resistant to degradation. Studies on the impact of processing of foods in relation to PCB concentrations have been largely focused on the cooking techniques used to prepare foods and techniques that change the fat content (e.g., PCB levels tend to be lower in skimmed milk, but higher concentrations are found in dairy foods with higher fat content, such as cheese or cream). Although the studies related to the impact of processing on PCB concentrations include both DL-PCBs and NDL-PCBs, the impact on the concentrations is similar for both types of PCBs. Ultimately, it was concluded that processing techniques, such as trimming, which result in the removal of lipids will lead to a decrease in PCB concentrations in the final food product.

- 6. The 10th Session of the Codex Committee on Contaminants in Foods (CCCF10) (2016) agreed to establish an Electronic Working Group chaired by the European Union (the list of participants to the EWG is provided as Appendix III to this discussion paper) to prepare a discussion paper on the review of the Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Food and Feeds (CAC/RCP 62-2006) to evaluate if recommendations from the JECFA assessment on NDL-PCBs could be included².
- 7. At the 11th session of the Codex Committee on Contaminants in Foods (CCCF11) (April 2017), the Committee was informed by the chair of the Electronic Working Group that it was appropriate to review the CAC/RCP 62-2006 taking into account the following elements:
 - a. Inclusion of the outcome of the risk assessment performed by JECFA at its 80th meeting in 2015 on the toxicity of NDL-PCBs in the introduction chapter under general remarks and inclusion of the provisions of the Stockholm Convention related to PCBs under source directed measures.
 - b. Most of the recommended practices to reduce the presence of DL-PCBs are also applicable to NDL-PCBs and this could be addressed by replacing the term "DL-PCBs" within the existing code of practice with the more general term "PCBs" (which includes both DL-PCBs and NDL-PCBs)
 - c. Completion of the Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Food and Feeds (CAC/RCP 62-2006) with specific measures for the prevention and reduction of NDL-PCBs in feed and food
 - d. Inclusion of information on specific analytical methods/requirements for NDL-PCBs.
 - e. Update the current recommended practices on dioxins, DL-PCBs and NDL-PCBs, taking into account experiences gained as regards new and/or unknown pathways of contamination and the new developments in science and technology.
 - f. Inclusion of relevant recent information on the carry-over of dioxins and PCBs from feed into food of animal origin.
 - a. Inclusion of cooking practices reducing the presence of dioxins and PCBs in food.
- 8. The Committee agreed with the proposal and agreed to forward the project document to CAC40 for approval. The CAC40 approved the new work. The Committee agreed to establish an EWG, chaired by the European Union, working in English only, to revise the COP for comments and consideration at its next session.
- 9. The European Union, as Chair of the EWG, prepared the proposed revision of the code of practice (COP). The proposed draft COP is provided in Appendix I. The list of participants that joined the EWG can be found in Appendix II. Comments were received from the following member countries and observers: Germany, United States of America, Kazakhstan, Switzerland, Brazil, Argentina and Canada. All comments received from members of the EWG have been taken into account. No outstanding issues have been identified.

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² REP16/CF, para. 168

APPENDIX I

PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF DIOXIN AND PCB CONTAMINATION IN FOOD AND FEED

INTRODUCTION

General remarks

- 1. Dioxins, including polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) and dioxin-like polychlorinated biphenyls (DL-PCBs) and non-dioxin-like PCBs (NDL-PCBs) are persistent organic pollutants (POPs) in the environment. Although dioxins and DL-PCBs show similarities in their toxicological and chemical behaviour, their sources are different. On the other hand while DL-PCBs and NDL-PCBs show a different toxicological behaviour, their sources are similaror the same. The NDL-PCBs account for the majority of the total PCB contamination, the remainder being DL-PCBs.
- 2. Current sources of dioxins and PCBs entering the food chain include new emissions and remobilisation of deposits or reservoirs in the environment. New emissions are mainly via the air route. Dioxins and PCBs decompose very slowly in the environment and remain there for very long periods of time. Therefore, a large part of current exposure is due to releases of dioxins and PCBs that occurred in the past.
- 3. PCBs were produced intentionally and in considerable amounts between the 1930s and 1970s and were used in a wide range of applications. PCBs are still in use in existing closed systems in certain countries and contained in solid matrices (e.g., sealing materials and electrical capacitors). Certain commercial PCBs are known to be contaminated with PCDFs and could therefore be regarded as a potential source for dioxin contamination.
- 4. Today, release of PCBs occurs from leakages, accidental spills and illegal disposal and through emissions via air from thermal processes. The emission of PCBs from paints and/or sealants into the environment e. g. during demolition and reconstruction of older buildings appears to be of some importance as a source.
- 5. Dioxins are formed as unwanted by-products from a number of human activities including certain industrial processes (e.g., production of chemicals, metallurgical industry) and combustion processes (e.g., waste incineration). Accidents at chemical factories have been shown to result in high emissions and contamination of local areas. Other dioxin sources include domestic furnaces as well as agricultural burning of harvest residues and backyard burning of household wastes. Natural processes such as volcanic eruptions and forest fires can also produce dioxins.
- 6. When released into the air, dioxins can deposit locally on plants and on soil, consequently contaminating both food and feed. Dioxins can also be widely distributed by long-range atmospheric transport. The amount of deposition varies with proximity to the source, plant species, weather conditions and other specific conditions (e.g. altitude, latitude, temperature).
- 7. Sources of dioxins in soil include deposition from atmospheric dioxins, application of contaminated sewage sludge to farm land, 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 composts). Other sources of dioxins in soil may be of natural origin (e.g., ball clay).
- 8. Dioxins and PCBs are poorly soluble in water. However, they are adsorbed onto mineral and organic particles suspended in water. The surfaces of oceans, lakes and rivers are exposed to aerial deposition of these compounds which are consequently concentrated along the aquatic food chain. The entry of waste water or contaminated effluents from certain processes, such as chlorine bleaching of paper or pulp and metallurgical processes, can lead to contamination of water and sediment of coastal ocean areas, lakes and rivers.
- 9. The uptake of dioxins and PCBs by fish occurs via gills and diet. Fish accumulate dioxins and PCBs predominantly in their fatty tissue and liver. Bottom dwelling/bottom feeding fish species are more exposed to contaminated sediments than pelagic fish species. However, levels of dioxins and PCBs in bottom dwelling/bottom feeding fish are not always higher than those in pelagic fish depending on the size, diet and physiological characteristics of the fish. Other factors that may affect accumulation of dioxins and PCBs in fish include age, weight, lipid content or environmental status of their environment.
- 10. Food of animal origin is the predominant route of human exposure to dioxins and PCBs with approximately 80–90% of the total exposure via fats in fish, meat and dairy products. Levels of dioxins and PCBs in animal fat may be related to contamination of the local environment and to contamination of feed (e.g., fish-oil and fish-meal) or to certain production processes (e.g., artificial drying).

11. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) assessed at its 57th meeting in 2002 the toxicity of dioxins and DL-PCBs. The long half-lives of dioxins and DL-PCBs mean that each daily ingestion has a small or even a negligible effect on overall body burden. In order to assess long- or short-term risks to health due to these substances, total or average intake should be assessed over months, and tolerable intake should be assessed over a period of at least 1 month. To encourage this view, the JECFA decided to express the tolerable intake as a monthly value in the form of a provisional tolerable monthly intake (PTMI). A PTMI of 70 pg/kg bw per month for dioxins and DL-PCBs expressed as TEFs was derived. In the GEMS/Food³ regional diets⁴, the median and 90th percentile estimated dietary exposures to dioxins ranged from 7 to 68 pg/kg of body weight per month and 15 to 160 pg/kg of body weight per month, respectively. Median and 90th percentile estimated exposures to DL-PCBs ranged from 7 to 57 pg/kg of body weight per month and 19 to 150 pg/kg of body weight per month, respectively. Intakes estimated from national food consumption data were lower ranging from 33 to 42 pg/kg of body weight per month at the median and 81 to 100 pg/kg of body weight per month at the 90th percentile for dioxins and from 9 to 47 pg/kg of body weight per month at the median and from 25 to 130 pg/kg of body weight per month at the 90th percentile for DL-PCBs. The above exposure estimates are on WHO-TEQ basis. Estimates could not be made for the sum of dioxins and DL-PCBs because data on concentrations were submitted separately by countries.

JECFA concluded that despite the uncertainties, the intake estimates suggest that a considerable fraction of the population has a long-term mean intake above the PTMI.

12. JECFA assessed at its 80th meeting in 2015 the toxicity of NDL-PCBs. JECFA concluded that none of the available studies on the six indicator PCBs (PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180) and PCB 128 were suitable for derivation of health-based guidance values or for assessment of the relative potency of the NDL-PCBs compared with a reference compound. Therefore, a comparative approach using the minimal effect doses was developed in order to estimate Margins of Exposure (MOEs) to provide guidance on human health risk. Due to the long half-lives and to eliminate interspecies differences in toxicokinetics, JECFA considered it appropriate to estimate body burdens rather than using external dose (dietary exposure) for the risk characterization. Comparison of the human body burden estimates (derived from human milk concentrations) with the body burden estimates from animal studies derived as points of departure for each congener resulted in MOEs for adults ranging from 4.5 to 5000.

MOEs for breastfed infants, which may have a body burden up to 2-fold higher than that of adults, would be approximately half of the adult values. The MOEs for children would be expected to be intermediate between those for adults and those for breastfed infants, due to the initial contribution from breastfeeding and the subsequent lower dietary contribution compared with human milk.

Because the MOEs are based on minimal effect doses, they were considered to give some assurance that dietary exposures to NDL-PCBs are unlikely to be of health concern for adults and children, based on the available data. Although the MOEs are lower for breastfed infants, based on current knowledge, the benefits of breastfeeding are considered to outweigh the potential disadvantages that may be associated with the presence of NDL-PCBs in breast milk.

13. In order to reduce the contamination of food from animal origin, control measures at the feed level should be considered. These may involve developing Good Agricultural Practice, Good Animal Feeding Practice (see Codex Alimentarius Commission: Code of Practice on Good Animal Feeding), and Good Manufacturing Practice guidance and measures to effectively reduce dioxins and PCBs in feed, including:

- Identification of agricultural areas with increased dioxin and PCB contamination due to local emission, accidents or illegal disposal of contaminated materials, and monitoring of feed and feed ingredients derived from these areas,
- Monitoring of dioxin and PCB content of sewage sludge and compost used as fertilizers in agriculture, as well as its compliance with nationally established guideline or maximum levels.
- Establishing recommendations for special agricultural use (e.g., limitation of grazing or use of appropriate agricultural techniques),

³ GEMS/food: the Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme, informs governments, the Codex Alimentarius Commission and other relevant institutions, as well as the public, on levels and trends of contaminants in food, their contribution to total human exposure, and significance with regard to public health and trade. WHO implements the programme in cooperation with a network Collaborating Centres and recognized national institutions located all around the world.

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⁴ Regional or cluster diets: WHO developed an approach to describe the various diets around the world based on the analysis of per capita supply available from the FAO Food Balance Sheets. The GEMS cluster diets consist in national dietary patterns grouped by similarities. These 17 cluster diets updated in 2012 are commonly used by international committees for exposure assessment to food contaminants and pesticide residues.

- Identification of possibly contaminated feed and feed ingredients,
- Monitoring compliance with nationally-established guideline levels or maximum levels, if available, and minimizing or decontaminating (e.g., refining of fish oil) non-complying feed and feed ingredients, and
- Identification and control of critical feed manufacturing processes (e.g., artificial drying by direct heating).
- 14. Similar control measures, where applicable, should be considered for reducing dioxins and PCBs in food.

Transfer of dioxins and PCBs in food producing animals

- 15. Dioxins and PCBs accumulate in tissues of food-producing animals, including fish. In addition, they can be excreted in fat-containing products such as milk and eggs. There are clear differences in toxicokinetic behaviour between the various dioxin and PCB congeners. Certain dioxins and PCBs can also specifically accumulate in the liver as shown in laboratory animals which is due to the binding to CYP1A2, rather than accumulation in fat. Since this so-called sequestration process is congener specific, it will lead to differences between the relative congener composition in liver and fat. High concentrations in liver are a particular issue in foraging animals like sheep and deer.
- 16. For most farm animal species there are data, either from controlled studies or incidents, which give insight into the transfer of dioxins and PCBs. Studies have shown that dioxins and PCBs are accumulated in body fat and liver, but also excreted into eggs and milk. This excretion contributes to lower accumulation in the body, and decreased levels after termination of the exposure. In growing animals the increase in body fat mass is also an important factor in the tissue levels obtained during exposure, which decreases after termination of the exposure. In addition, metabolism and excretion (e.g. via faeces) are expected to be involved in the accumulation and decrease of dioxins and PCBs in body fat and liver, although no specific data on these processes in farm animals were identified.
- 17. The kinetics of contaminants in the animal may be described by factors like the
- transfer rates (TRs) describing the percentage of the ingested contaminant that is excreted in milk or eggs or
- bioconcentration factor (BCF), describing the ratio between the level in tissues, milk or eggs, and that in the feed. BCFs are more suitable for tissues, since it is more difficult to obtain the information on the total weight of muscle or adipose tissues in the animal required to calculate the TRs.
- 18. Both TRs and BCFs will increase with prolonged exposure until a steady state is obtained. At that stage the TRs/BCFs have reached their maximum values. Levels in edible products will be overestimated when applying TRs/BCFs determined at steady state for only a short-term exposure. However, the major increase in the levels occurs during the first week of the exposure.

When using TRs to estimate the level in milk fat or egg fat for example, it is important to first estimate the intake level by multiplying the level in the feed (or ingredient) with the daily amount ingested. Subsequently, this intake level can be multiplied with the TR to estimate the total amount excreted into eggs or milk. Based on milk or egg production per day and their fat levels, the total amount of egg or milk fat excreted can be estimated. Combining these with absolute amounts excreted will result in an estimate of the level in milk or egg fat.

In the case of BCFs, the level in the feed can be multiplied with the BCF to obtain the level in the edible product of interest. When detected in an ingredient, the level should be extrapolated to the level in the daily ration. As in the case of TRs it is important to consider whether the BCFs were determined under steady state conditions or after a short-term exposure.

- 19. TRs and BCFs differ for each congener but in practice those for the lower chlorinated and more persistent congeners are more relevant because they contribute most to the TEQ, like PeCDD, 2,3,4,7,8-PeCDF, TCDD, TCDF (in the case of chickens) and to a lesser extent the hexachlorinated PCDD/Fs. Only in some cases, like where pentachlorphenol (PCP) is the contamination source, will higher chlorinated congeners like HpCDD make a significant contribution to the TEQ level. In the case of DL-PCBs, PCB-126 and to some extent PCB-169 are the most relevant congeners in terms of contribution to the TEQ levels.
- 20. PCDD/Fs and PCBs are accumulated to a greater extent in fillet of oily fish (such as salmon and trout) than leaner fish, the latter having higher concentrations of these compounds in the liver tissue. The main feed-related sources of dioxins and DL-PCBs in farmed fish are often fish oil and fishmeal. In addition to the feed composition, the transfer of dioxins and PCBs to fillets depends on other factors such as species, and animal growth and levels of dioxins and DL-PCBs in the environment (water and soil).

Source directed measures

21. Reducing sources of dioxins and PCBs is an essential prerequisite for reduction of contamination. Measures to reduce dioxin emission sources should be directed to reducing the formation of dioxin during thermal processes as well as the application of destruction techniques. Measures to reduce PCBs emission sources should be directed to minimizing releases from existing equipment (e.g. transformers, capacitors), prevention of accidents and better control of the disposal and destruction of PCBs containing oils and wastes.

- 22. The Stockholm Convention on Persistent Organic Pollutants (Stockholm Convention) is a global treaty to protect human health and the environment from POPs including dioxins and PCBs. It includes a number of possible source-directed measures that national authorities can consider.
- 23. Part II of Annex A of the Stockholm Convention lists the following priority measures:
- a) with regard to the elimination of the use of PCBs in equipment (e.g. transformers, capacitors or other receptacles containing liquid stocks) by 2025:
 - (i) identify, label and remove from use equipment containing greater than 10 % PCBs and volumes greater than 5 litres;
 - (ii) identify, label and remove from use equipment containing greater than 0.05 % PCBs and volumes greater than 5 litres;
 - (iii) Endeavour to identify and remove from use equipment containing greater than 0.005 % PCBs and volumes greater than 0.05 litres;
- b) consistent with the priority measures under a), to reduce exposures and risk to control the use of PCBs:
 - (i) Use only with intact and non-leaking equipment and only in areas where the risk from environmental release can be minimised and quickly remediated;
 - (ii) Do not use in equipment in areas associated with the production or processing of food or feed;
 - (iii) When used in populated areas, including schools and hospitals, all reasonable measures to protect from electrical failure which could result in a fire, and regular inspection of equipment for leaks;
- c) that equipment containing PCBs, as described under a) shall not be exported or imported except for the purpose of environmentally sound waste management;
- (d) Except for maintenance and servicing operations, not allow recovery for the purpose of reuse in other equipment of liquids with polychlorinated biphenyls content above $0.005\,\%$
- (e) Ensure environmentally sound waste management of liquids containing PCBs and equipment contaminated with PCBs having a PCB content above 0.005 %, as soon as possible but no later than 2028.
- (f) Identify other articles containing more than 0.005 % PCBs (e.g. cable-sheaths, cured caulk and painted objects) and manage them in an environmentally sound manner.
- 24. 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 and PCBs to the environment.
- a) Waste incinerators, including co-incinerators of municipal, hazardous or medical waste or of sewage sludge;
- b) Cement kilns firing hazardous waste;
- c) Production of pulp using elemental chlorine or chemicals generating elemental chlorine for bleaching;
- d) Thermal processes in the metallurgical industry, i.e. secondary copper production; sinter plants in the iron and steel industry; secondary aluminium production; secondary zinc production.
- 25. Part III of Annex C also lists the following source categories that may unintentionally form and release dioxins and PCBs to the environment:
- a) Open burning of waste, including burning of landfill sites;
- b) Thermal processes in the metallurgic industry not mentioned in Part II, Annex C;
- c) Residential combustion sources;
- d) Fossil fuel-fired utility and industrial boilers;
- e) Firing installations for wood and other biomass fuels;
- f) Specific chemical production processes releasing unintentionally formed POPs, especially production of chlorophenols and chloranil;

- g) Crematoria;
- h) Motor vehicles, particularly those burning leaded gasoline;
- i) Destruction of animal carcasses by burning;
- j) Textile and leather dyeing (with chloranil) and finishing (with alkaline extraction);
- k) Shredder plants for the treatment of end of life vehicles;
- I) Smouldering of copper cables;
- m) Waste of oil refineries.
- 26. Adopting technologies to minimize formation and release of dioxins and PCBs from these source categories can be considered by national authorities when developing national measures to reduce dioxins, DL-PCBs and NDL PCBs.
- 27. Sources of PCB contamination in food and feed may also inlcude intake of contaminated soil (free ranging laying hens, flooded land, burned areas), waste oil (transmission oil leakage, paintings with waste oil), sisal (bags, binding twine), car tyre used as feding troughsor plaything, open applications of PCB such as paints or coatings and releases from caulk.

Scope

- 28. This Code of Practice focuses on measures (e.g., Good Agricultural Practices, Good Manufacturing Practices, Good Storage Practices, Good Animal Feeding Practices, and Good Laboratory Practices) for national authorities, farmers, feed and food manufacturers as well as consumers to prevent or reduce dioxin and PCB contamination in foods and feeds.
- 29. This Code of Practice applies to the production and use of all materials destined for feed (including grazing or free-range feeding, forage crop production and aquaculture) and food at all levels whether produced industrially, on farms or in households.
- 30. Since the global limitation and reduction of dioxins and PCBs from non food / feed related industrial and environmental sources may lie outside of the responsibility of CCCF, these measures will not be considered within this Code of Practice.

RECOMMENDED PRACTICES BASED ON GOOD AGRICULTURAL PRACTICES (GAPS), GOOD MANUFACTURING PRACTICES (GMPS), GOOD STORAGE PRACTICES (GSPS), GOOD ANIMAL FEEDING PRACTICES (GAFPS), AND GOOD LABORATORY PRACTICES (GLPS)

Control measures within the food chain

Air, Soil, Water

- 31. To reduce dioxin and PCB contamination in the air, national food authorities should consider recommending to their national authorities responsible for air pollution measures to restrict uncontrolled burning of wastes, including the burning of landfill sites or backyard burning, and the use of PCP treated wood for domestic heaters.
- 32. Control measures to prevent or reduce contamination of the environment by dioxins and PCBs are important. To reduce possible contamination of feed or food, agricultural land with unacceptable dioxin and PCB contamination due to local emission, accidents, or illegal disposal of contaminated materials should be identified.
- 33. Agricultural production on contaminated areas should be avoided or should be restricted if a significant transfer of dioxins and PCBs to feed or food produced on these areas is anticipated.
- 34. The spreading of sewage sludge contaminated with dioxins and PCBs can lead to dioxins and PCBs adhering to vegetation which can increase livestock exposure. Sewage sludge used in agriculture should be monitored, as necessary for dioxins and PCBs and treated, as necessary. National guidelines should be adhered to where applicable.
- 35. Livestock, game, and poultry exposed to contaminated soil, may accumulate dioxins and PCBs by consumption of contaminated soil or plants. These areas should be identified and access by certain food producing animals controlled. If necessary, the outdoor production in these areas should be restricted.
- 36. Source-reduction measures may take many years to reduce contamination levels in wild fish due to the long half-lives of dioxins and PCBs in the environment. To reduce exposure to dioxins and PCBs, highly contaminated areas (e.g., lakes, rivers or contaminated marine catching areas) and relevant fish species should be identified and fishing in these areas should be controlled and, if necessary, restricted.

Feed

37. The bulk of human dietary intake of dioxins and PCBs is due to the concentration of these substances in the lipid component of animal derived foods (e.g., poultry, fish, eggs, meat and milk). In lactating animals dioxins and PCBs can be excreted with milk fat, and in laying hens they may concentrate in the fat content of the egg yolk. To reduce this transfer, control measures at the feed and feed ingredients level should be considered. Measures to reduce dioxin and PCB levels in feed would have a rapid effect on their concentrations in food of animal origin originating from farm animals, including farmed fish. Such measures may include:

- identification of possibly contaminated areas in the feed supply ecosystem,
- identification of the origin of frequently contaminated feed or feed ingredients, and
- monitoring the compliance of feed and feed ingredients with nationally-established guideline levels or maximum levels, if available.
- 38. National authorities should periodically sample and analyse suspect feed and feed ingredients using recognized international methods to verify dioxin and PCB levels. This information will determine actions, if needed, to minimize dioxin and PCB levels and allow alternative feed and feed ingredients to be located, if necessary.
- 39. The purchaser and user should pay attention to:
- origin of feed and feed ingredients to ensure that producers and/or companies have certified production facilities, production processes and quality assurance programs (e.g., HACCP-like principles);
- accompanying documents confirming compliance with nationally-established guideline levels or maximum levels, if available, according to national requirements.

Feed of animal origin

- 40. Due to the position of their precursors in the food chain, animal derived feed has a higher risk for dioxin and PCB contamination compared to plant derived feed. Attention should be paid to avoid dioxins and PCBs from entering the food chain through the feeding of animal derived feed to food producing animals. Animal derived feed should be monitored, as necessary, for dioxins and PCBs.
- 41. Accumulation of dioxins and PCBs in adipose tissues of livestock, where there is a potential to exceed nationally established guideline levels or maximum levels for animal feeds. ,Therefore, feed of animal origin that exceeds nationally established guideline levels or maximum levels, if available, or contains elevated levels of dioxins or PCBs should not be fed to animals unless the fat has been removed.
- 42. If intended for use in feed, fish-oil and other products derived from fish as well animal fats should be monitored to the extent practicable for dioxins and PCBs. If there are nationally established guideline levels or maximum levels for animal feeds, the feed manufacturer should ensure that the products are in compliance with these provisions.

Feed of plant origin

- 43. If potential sources of dioxins and PCBs are anticipated in the vicinity of fields, attention should be paid to monitor these areas, as necessary.
- 44. Cultivation sites irrigated with water or treated with sewage sludge or municipal compost that may contain elevated dioxin and PCB levels should be monitored, as necessary, for contamination.
- 45. Prior treatment of fields with herbicides from the chlorinated phenoxyalkanoic acid type or chlorinated products like pentachlorophenol should be considered as a potential source for dioxin contamination. Dioxin levels in soil and forage plants from sites treated previously with dioxin-contaminated herbicides should be monitored as necessary. This will enable national authorities to take appropriate management measures in order to prevent the transfer of dioxins (and PCBs) to the food chain.
- 46. Typically, oilseeds and vegetable oil are not significantly contaminated with dioxins and PCBs. This also applies to other by-products of oilseed processing (e.g., oilseed cakes) used as feed ingredients. However, certain vegetable and animal oil refining by-products (e.g., fatty acid and deodorizer distillates) and spent products used in oil refingin (e.g. bleaching clays) may contain increased levels of dioxins and PCBs and should be analysed, as necessary, if used for feed.

Feed and food processing

Drying processes

47. Certain processes for the artificial drying of feed and food (and feed or food ingredients) and the heating of indoor growing facilities (e.g. greenhouses) requires a flow of heated gases, either a flue gas-air mix (direct drying or heating) or heated air alone (indirect drying or heating). Accordingly, fuels not expected to generate dioxins and dioxin-like compounds should be used. Feed, food and feed or food ingredients that are dried or subjected to heated air should be monitored as necessary to ensure that drying or heating processes do not result in elevated levels of dioxins and PCBs.

48. The quality of commercial dried feed materials, in particular green fodder and commercially dried foods depends on the selection of the raw material and the drying process. The purchaser should consider requiring a certificate from the manufacturer/supplier, confirming that the dried goods are produced applying Good Manufacturing Practice, particularly in the choice of the fuel used for drying or heating and are in compliance with nationally-established guideline levels or maximum levels, if available.

Smoking

49. Depending on the technology used, smoking can be a critical processing step for increased dioxin content in foods, especially if the products show a very dark surface with particles of soot. Such processed products should be monitored for dioxins and PCBs, as necessary, by the manufacturer.

Milling / Disposal of contaminated milling fractions

50. Airborne external deposition of dioxins and PCBs on the surface of all parts of the grain plants as well as the adherent dust fraction from the standing crop is widely removed during the milling process and before the final grinding process. If present, most particle-bound contamination is removed in the loading chute with the remaining dust. Further external dioxins and PCB contaminations are significantly reduced during aspiration and sieving. Certain grain fractions, especially dust, chaff and mixed screenings can have increased dioxin and PCB levels and should be monitored, as necessary. If there is evidence of elevated contamination, such fractions should not be used in food or feed and should be treated as waste.

Cooking practices

- 51. Food selection, preparation, and cooking practices can reduce exposure to dioxins and PCBs
- 52. Dioxins and PCB levels in green vegetables can be reduced by washing and during cooking. Consequently, normal cooking processes can be expected to reduce dioxins and PCB levels in these foods.
- 53. Selecting low fat foods (lean cuts of meat, low fat dairy products), cooking foods and removing the fat portion of the foods during food preparation can significantly reduce dioxin and PCB levels
- 54. Household food preparation and cooking methods such as skinning, trimming the fat, in addition to the disposing of pan drippings and poaching/boiling liquids) are practical approaches to reduce exposure to dioxins and PCBs from fish. Although removal of fat can reduce dioxin and PCB levels significantly, such practices also reduce fat-soluble nutrients and other beneficial compounds (such as omega-3 fatty acids). Therefore, it is essential to carefully consider both risks and benefits in any public health message regarding food consumption.

Substances added to feed and food

Minerals and trace elements

- 55. Some minerals and trace elements are obtained from natural sources. However, experience has shown that geogenic dioxins may be present in certain prehistoric sediments. Therefore, dioxin levels in minerals and trace elements added to feed or food should be monitored as necessary.
- 56. Reclaimed mineral products or by-products from certain industrial processes may contain elevated levels of dioxins and PCBs. The user of such feed ingredients should verify that dioxin and PCBs are within nationally established guideline levels or maximum levels, if available, through certification by the manufacturer or supplier.
- 57. Elevated levels of dioxins have been found in ball clay used as an anticaking agent in soybean meal in feed. Attention should be paid to minerals used as binders or anticaking agents (e.g., bentonite, montmorillonite, kaolinitic clay, diatomaceous earth) and carriers (e.g., calcium carbonate) used as feed ingredients. As assurance to the user that these substances do not contain minerals with elevated levels (e.g., exceeding nationally- established guideline levels or maximum levels, if available) of dioxins and PCBs, the distributor should provide appropriate certification to the user of such feed ingredients.

58. Feed of some food producing animals is supplemented with trace elements (e.g., copper or zinc). Minerals, including trace elements, which are by-products or co-products of industrial metal production have been shown to contain elevated levels of dioxins. Such products should be monitored for dioxins and PCBs, as necessary.

Ingredients

59. Feed and food manufacturers should ensure that all ingredients in feed and food comply with nationally established guideline levels or maximum levels of dioxins and PCBs, if available.

Harvesting, transport, storage of feed and food

- 60. To the extent feasible, it should be ensured that minimal contamination with dioxins and 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.
- 61. After flooding, crops harvested for feed and food should be monitored for dioxins and PCBs, if there is evidence of dioxin and/or PCB contaminaiton in the flood water.
- 62. To avoid cross-contamination, the transport of feed and food should only be performed in vehicles (including ships) and in containers that are free of dioxins and PCBs. Storage containers for feed and food should be painted only with dioxin and PCB-free paint.
- 63. Storage sites for feed or food should be free from dioxins and PCB contamination. Surfaces (e.g., walls, floors) treated with tar-based paints may result in transfer of dioxins and PCBs to food and feed. Surfaces that come in contact with smoke and soot from fires always bear a risk of contamination with dioxins and PCBs. These sites should be monitored as necessary for contamination before use for storage of feed and food.

Special problems of animal keeping (Housing)

- 64. Food producing animals may be exposed to dioxins and PCBs found in certain treated wood used in buildings, farm equipment and bedding material. To reduce exposure, animal contact with treated wood containing dioxins and PCBs should be minimized. In addition, sawdust from treated wood containing dioxins and PCBs should not be used as bedding material.
- 65. Due to the potential for soil contamination, eggs from free living or free-range hens (e.g., organic farming) may have higher levels of dioxins and PCBs compared to eggs from caged hens and should be monitored, as necessary.
- 66. Attention should be paid to older buildings as they may have building materials and varnishes that may contain dioxins and PCBs. If they have caught fire, measures should be taken to avoid contamination of the feed and feed chain by dioxins and PCBs.
- 67. In housings without a floor covering, the animals may take up soil particles from the ground. If there are indications of increased levels of dioxins and PCBs, contamination of the soil should be controlled as necessary. If needed, the soil should be exchanged.
- 68. Pentachlorophenol-treated wood in animal facilities has been associated with elevated levels of dioxins in beef. Wood (e.g., railroad ties, utility poles) treated with chemicals such as pentachlorophenol or other unsuitable substances should not be used as fence posts for enclosures of free-range animals or feed lines. Hay racks should not be constructed from such treated wood. The preservation of wood with waste oils should also be avoided.
- 69. In case there is a risk of adding dioxin to the housing environment for the livestock by cleaning or disinfecting the housing with chlorine-containing agents, special attention should be paid thereto and the use of such cleaning/disinfecting agents should be avoided.

Monitoring

70. Farmers and industrial feed and food manufacturers have the primary responsibility for feed and food safety. Testing could be conducted within the framework of a food safety program (e.g. Good Manufacturing Practices, On-Farm Safety programmes, Hazard Analysis and Critical Control Point programs, etc.) In previous sections of this Code, it is mentioned where it could be appropriate to perform monitoring. Competent authorities should enforce the primary responsibility of farmers, feed and food manufacturers for feed and food safety through the operation of surveillance and control systems at appropriate points throughout the food chain, from the primary production to the retail level. In addition competent authorities should establish their own monitoring programs.

71. As analyses for dioxins are relatively expensive, 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. 80). The frequency of sampling should be considered by the results from previous analyses (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 PCBs, farmers and other primary producers should be informed about the contamination and the source should be identified and the necessary measures taken to remediate the situation and reduce or prevent further contamination.

72. Monitoring programs dealing with contaminations originating from the environment, accidents or illegal disposals should be organized by operators in the feed and food chain and by competent national authorities in order to obtain additional information on food and feed contamination. Products or ingredients at risk or found with elevated concentrations should be monitored more intensively. For example, monitoring programs may include major fish species used in food or feed that have been shown to contain elevated levels of dioxins and PCBs.

Sampling, analytical methods, data reporting and laboratories

- 73. Advice concerning analytical requirements and qualification of laboratories is given in the literature. Furthermore, methods considered fort he analysis of dioxins and PCBs is addressed by the Codex Committee of Methods of Analysis and Sampling.
- 74. Traditional methods for the analysis of dioxin and DL-PCBs rely on gas chromatography coupled to high-resolution mass spectrometry (GC-HRMS) which is time-consuming and expensive. Methods based on gas chromatography coupled to tandem mass spectrometry (GC-MS/MS) can also be used to quantify dioxins and DL-PCBs. Alternatively, bioassay techniques have been developed as high throughput screening methods which can 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 DL-PCBs.

Gas chromatography (GC) coupled to Electron Capture Detection (ECD) and mass spectrometers (including ion trap, low-resolution (LRMS), high-resolution (HRMS) and tandem mass (MS/MS) spectrometers) are used in the analysis of NDL-PCBs. The analysis of NDL-PCBs generally does not require as extensive a clean-up procedure as the DL-PCBs or dioxins. For screening purposes, GC-ECD is often used. GC/MS may also be used for screening purposes.

Sampling

75. Important aspects of sampling for dioxin and PCB analysis are collecting representative samples, avoiding cross contamination and deterioration of samples and unambiguously identifying and tracing back samples. To avoid cross-contamination, samples should be put in containers or other receptacles that are not reactive and that have been chemically cleaned or certified to be free of contaminants. All relevant information on sampling, sample preparation and sample description (e.g., sampling period, geographic origin, fish species, fat content, size of fish) should be recorded.

Analytical methods and data reporting

- 76. Analytical methods should be applied only if they are fit for purpose meeting a minimum of requirements. If nationally-established maximum levels are available, the limit of quantification (LOQ) of the method of analysis should be in the range of one fifth of this level of interest. For adequate time trend measurements, the limit of quantification of the method of analysis should be clearly below the mean of the present background ranges for the different matrices.
- 77. Performance of a method of analysis should be demonstrated in the range of the level of interest, e.g. 0.5 x, 1 x and 2 x level of maximum level with an acceptable coefficient of variation for repeated analysis. The difference between upper bound and lower bound levels (see next para.) should not exceed 20% for feed and food with a dioxin concentration of about 1 pg WHO-PCDD/PCDF-TEQ/g fat. If needed, another calculation based on fresh weight or dry matter could be considered.
- 78. Except for bioassay techniques, the results of total dioxin and DL-PCB levels in a given sample should be reported as lower bound, medium bound and upper bound concentration by multiplying each congener by their respective WHO Toxic Equivalency Factor (TEF) and subsequently summing them up to give the total concentration expressed as Toxic Equivalency (TEQ). The three different TEQ values should be generated reflecting assignment of zero (lower bound), half the limit of quantification (medium bound), and limit of quantification (upper bound) values to each non-quantified dioxin and DL-PCB congener.

For the analysis of NDL-PCBs the analytical result should also be reported as lower-bound, medium bound and upper-bound and indicate clearly to what the analytical result refers to (sum of six indicator PCBs, total PCBs, etc.)

79. Depending on the sample type, the reported information may also include the lipid or dry matter content of the sample as well as the method used for lipid extraction and for the determination of dry matter. This report should also include a specific description of the procedure used to determine the LOQ.

80. A high throughput screening method of analysis with proven acceptable validation could be used to screen the samples with significant levels of dioxins and PCBs. Screening methods should have less than 1% falsenegative results in the relevant range of interest for a particular matrix. Use of ¹³C-labelled internal standards for dioxins or PCBs allows for specific control of possible losses of the analytes in each sample. As such,, false-negative results can be avoided thus preventing contaminated food or feed from being used or marketed. For confirmatory methods, use of these internal standards is mandatory. For screening methods without control of losses during the analytical procedure, information on correction of losses of compounds and the possible variability of results should be given. Levels of dioxins and PCBs in positive samples (above the level of interest) should be determined by a confirmatory method.

Laboratories

- 81. Laboratories involved in the analysis of dioxins and PCBs using screening as well as confirmatory methods of analysis should be accredited by a recognized body operating in accordance with ISO/IEC Guide 58:1993⁵ as revised by ISO/IEC 17011:2004⁶ 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 standard "General requirements for the competence of testing and calibration laboratories" or other equivalent standards.
- 82. Regular participation in interlaboratory studies or proficiency tests for the determination of dioxins and PCBs in the relevant feed and food matrices is highly recommended according to ISO/IEC/17025 standard.

QUALITY MANAGEMENT AND EDUCATION

83. Good Agricultural Practices, Good Manufacturing Practices, Good Storage Practices, and Good Animal Feeding Practices are valuable systems for further reduction of dioxin and PCB contamination in the food chain. Farmers as well as feed and food manufacturers should consider educating their emplyees on how to prevent contamination by the implementation of control measures. Good Laboratory Practices is a valuable system to ensure high quality of the analytical outcome.

⁵ https://www.iso.org/standard/21678.html

⁶ https://www.iso.org/standard/29332.html

⁷ https://www.iso.org/obp/ui/#iso:std:iso-iec:17025:en

ANNEX GLOSSARY OF TERMS

(for the purpose of this code of practice)

Term Explanation

anticaking agent Substance that reduces the tendency of particles of a feed or food to stick

binder Substance that increases the tendency of individual particles of a feed or

food to stick

coefficient of variation Statistical parameter expressing:

100 x standard deviation of a set of values/mean value of set

confirmatory method of

analysis

Method of analysis with high quality parameters capable of confirming analytical results produced from screening methods with lower quality

parameters

congener One of two or more compounds of similar chemical structures with respect

to classification

dioxins (PCDD/PCDF) Include 7 polychlorinated dibenzo-p-dioxins (PCDDs) and 10

dibenzofurans (PCDFs) with similar toxicological properties and belong to a group of lipophilic and persistent organic substances. Depending on the degree of chlorination (1–8 chlorine atoms) and the substitution patterns, 75 different PCDDs and 135 different PCDFs ("congeners"), can be

distinguished.

dioxin-like PCBs (DL-

PCBs)

Include 12 non-ortho and mono-ortho substituted polychlorinated biphenyls (PCBs) showing toxicological properties (dioxin-like activity)

that are similar to dioxins

fish Poikilothermic vertebrate animals including Pisces, Elasmobranches and

Cyclostomes. For the purpose of this code of practice, molluscs and

crustaceans are also included

feed Any single or multiple materials, whether processed, semi-processed or

raw which is intended to be fed directly to food producing animals

food Any substance, whether processed, semi-processed or raw which is

intended for direct human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics, tobacco, medicinal products, narcotic or psychotropic substances, residues and

contaminants

feed or food ingredient A component or constituent of any combination or mixture making up a

feed or food, whether or not it has a nutritional value in the diet, including additives. Ingredients are of plant, animal or aquatic origin, or may

originate from other organic or inorganic substances.

guideline levels The maximum concentration of a substance which is recommended by a

national or international authority to be acceptable in feed or food,

however not legally binding

HACCP Hazard Analysis Critical Control Point (HACCP) is a system that identifies,

evaluates and controls hazards which are significant for food safety

limit of quantification (LOQ) (valid for dioxins and PCBs

only)

The limit of quantification of an individual congener means the lowest concentration of the analyte that can be measured with reasonable statistical certainty, fulfilling the identification criteria as described in internationally recognised standards such as in EN 16215:2012 and/or EPA methods 1613 and 1668 as revised. The limit of quantification of an individual congener may be identified as the concentration of an analyte in the extract of a sample which produces an instrumental response at two different ions to be monitored with an S/N (signal/noise) ratio of 3:1 for the less sensitive signal and fulfilment of the basic requirements such as e.g. retention time, isotope ratio according to the determination procedure as described in EPA method 1613 as revised.

Term	Explanation
maximum levels	Legally binding maximum concentration of a substance in feed or food, established by a national or international authority
minerals	Inorganic compounds used in food and feed being required for normal nutrition or used as processing aids
non dioxin-like PCBs (NDL-PCBs)	Includes the 197 PCB congeners other than the 12 non-ortho and mono- ortho substituted PCBs. The NDL-PCBs account for the majority of the total PCB contamination, the remainder being DL-PCBs. The Stockholm Convention on POPs recommends the measurement of six indicator PCBs (PCB 28, PCB52, PCB 101, PCB, 138, PCB 153 and PCB 180) to characterise contamination by NDL-PCBs.
PCBs	Polychlorinated biphenyls belonging to a group of chlorinated hydrocarbons, formed by direct chlorination of biphenyl. Depending on the number of chlorine atoms $(1-10)$ and their position at the two rings, 209 different compounds ("congeners") are theoretically possible. The 209 congeners of PCBs include the dioxin-like PCBs (12 congeners) and the non-dioxin-like PCBs (197 congeners).
PCP	Pentachlorophenol
pelagic fish species	Fish species living in free water (e.g., ocean, lake) without contact to the sediment
persistent organic pollutant (POP)	Chemical substance that persists in the environment, bioaccumulates through the food web, and poses a risk of causing adverse effects to human health and the environment
Stockholm Convention (POPs Convention)	The Stockholm Convention on Persistent Organic Pollutants is a global treaty to protect human health and the environment from persistent organic pollutants (POPs) including dioxins and dioxin-like PCBs. It entered into force on 17th May 2004. In implementing the Stockholm Convention governments will take measures to eliminate or reduce the release of POPs into the environment.
screening method of analysis	Method of analysis with lower quality parameters to select samples with significant levels of an analyte
trace elements	Chemical elements essential for plant, animal and/or human nutrition in small amounts
Toxic Equivalency Factor (TEF)	Estimates of the toxicity of dioxin-like compounds relative to the toxicity of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), which is assigned a TEF of 1.0.
	WHO-TEFs for human risk assessment are based on the conclusions of the World Health Organization (WHO) – International Programme on Chemical Safety (IPCS) expert meeting which was held in Geneva in June 2005 ⁸
Toxic Equivalency (TEQ)	Relative toxicity value calculated by multiplying the concentration of a congener by it's toxic equivalency factor (TEF)
WHO-TEQ	TEQ value for dioxins furans and dioxin-like PCBs, established by WHO and based on established Toxic Equivalency Factors (TEFs)

⁸ Martin van den Berg et al., The 2005 World Health Organization Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Toxicological Sciences 93(2), 223–241 (2006)

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