BACKGROUND

1. The 12th Session of the Codex Committee on Contaminants in Foods (CCCF12, 2018) agreed to establish an Electronic Working Group (EWG) chaired by the United States of America (USA), co-chaired by the United Kingdom (UK) and Japan, to prepare a discussion paper including a project document for a proposal for new work on the revision of the Code of Practice for the Prevention and Reduction of Lead Contamination in Foods (CXC 56-2004) (CoP) for consideration by the next session of the Committee.

2. The purpose of the work was to reflect new information available on measures to reduce lead during agricultural production and food processing. A revised CoP would complement the ongoing work by CCCF on maximum levels (MLs) for lead as well as revised MLs as contained in the General Standard for Contaminants in Food and Feed (CXS 193-1995).

3. The scope of the work would encompass the updating of the existing CoP to add new information on lead reduction in the areas of agricultural production (e.g. techniques to address lead contamination in soil and water) and food processing (e.g. filtration aids for juice manufacture, measures to reduce lead in foods during cooking, and minimizing introduction of lead from food processing equipment).²

4. CCCF13 (2019) reviewed the discussion paper and noted the following:

   (1) The discussion paper was intended to provide additional information on sources of lead in food and updated measures for reducing lead in food that have become available since publication of the CoP.

   (2) The discussion paper was not intended to establish standards for lead migration and lead composition in food contact materials used in food processing or manufacturing, but to present them as an option for consideration by regulatory bodies. As such, the establishment of standards was not within the scope of this work.

¹ Codex webpage/Circular Letters:

² REP18/CF, paras. 157-160
5. CCCF13 agreed:
   i. that there was sufficient additional information available on lead sources and mitigation measures to justify revision to the CoP;
   ii. to forward the project document to the 42nd Session of the Codex Alimentarius Commission (CAC42, 2019) for approval as new work; and
   iii. to establish an EWG chaired by USA, co-chaired by UK and Japan, to prepare a revised version of the CoP based on the document provided for consideration by CCCF14.
6. CAC42 approved the new work.
7. During the preparation of the discussion paper for CCCF13 in 2018-2019, two rounds of comments were considered from the EWG. Following approval of the new work, comments and information were received from eight members and observers participating in the EWG — Australia, Brazil, Canada, Japan, UK, USA, the European Cocoa Association (ECA) and the International Feed Industry Federation (IFIF). Based on these comments, the CoP was further revised and posted in February 2020 as CX/CF 20/14/9 for comment by CCCF14 that was to be held April 20-24, 2020.
8. Also in February 2020, CL 2020/22/OCS-CF was issued requesting comments from Codex members and observers on CX/CF 20/14/9, providing an opportunity to those member countries and observers who were not participating in the EWG to provide input on the revised CoP. The deadline for submitting comments was March 31, 2020. However, because CCCF14 was postponed to May 3-7, 2021 due to the COVID19 pandemic, the deadline for comments was extended to June 30, 2020. Comments in reply to the CL 2020/22/OCS-CF were compiled in CX/CF 20/14/9-Add.1 and posted in August 2020.

TERMS OF REFERENCE

9. CCCF13 agreed that the revisions would address measures, supported by scientific data, that have become available since adoption of the COP in 2004.
10. Completion of work is expected by 2021.

PARTICIPATION AND METHOD OF CONSULTATION

11. In addition to comments received during preparation of the discussion paper for CCCF13, comments were also received for CCC14 in response to two drafts made available on the EWG online platform in 2019-2020 and through the Codex Online Comment System (OCS) in response to CL 2020/22/OCS-CF. Comments also were received in response to two drafts that were made available on the EWG online platform in 2020-2021.
12. Comments were received from Australia, Canada, Chile, European Union (EU), India, Iraq, Japan, Kenya, Mexico, Syrian Arab Republic, Thailand, Uganda, USA, UK, Zambia, Collagen Casings Trade Association (CCTA), ECA, and International Confectionery Association (ICA).
13. The list of members and observers registered to participate in the EWG is found in Appendix II.

DISCUSSION

14. In developing this revised COP, the EWG considered comments including:
   - Information on sources of lead;
   - Additional mitigation measures; and
   - Editorial changes.

Sources of lead

15. The EWG incorporated information on additional sources of lead in the CoP. These include mention of livestock exposure to lead contaminated agricultural water and general acknowledgment in the Introduction that lead contamination of foods may exist from lingering environmental contamination and continued use of lead-containing products despite efforts to reduce lead exposures.
Mitigation measures

16. The EWG incorporated additional information on measures to reduce lead exposure. These include increasing soil pH through liming; protecting aquaculture farms from agricultural and industrial lead sources; ensuring that filtration aids for processing beverages comply with the *Guidelines on Substances Used as Processing Aids* (CXG 75-2010); and excising and discarding game meat containing lead shot fragments.

Editorial changes

17. The EWG made editorial changes, including making terminology consistent throughout the document and rearranging paragraphs so paragraphs addressing the same topic occur sequentially.

Document status

18. This CoP has been reviewed extensively over the previous two years, including six rounds of comments and subsequent revisions. The most recent series of comments have been editorial in nature, while substantive comments were previously addressed. Based on this analysis, the EWG considers the revised document to be ready for consideration for adoption at Step 5/8.

Recommendations

19. CCCF is invited to consider the revised CoP as set out in Appendix I as follows:
   a. to provide general comments on the overall content of the CoP,
   b. to provide specific comments on any provisions that may require further development, taking into account the revisions made to the CoP as summarized in paragraphs 14 to 17 of this document and the status of the CoP as summarized in paragraph 18 and
   c. Based on the guidance provided on points 19(a/b), to consider whether the CoP is ready for final adoption by CAC44 (2021)

20. CCCF is also invited to consider whether it should recommend the Codex Committee on Food Additives (CCFA) to request JECFA to:
   a. review the lead specifications for diatomaceous earth\(^6\) and charcoal (activated carbon)\(^7\) and
   b. evaluate bentonite to determine if available data support development of a lead specification.

21. In considering the points raised in paragraphs 19 - 20, CCCF is invited to take into account comments submitted by Codex members and observers in reply to the circular letter.

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INTRODUCTION

1. Lead is a toxic heavy metal that occurs in the environment both naturally, and to a greater extent from anthropogenic sources, because of its widespread industrial uses. The toxic effects of lead in food have been reviewed several times by the FAO/WHO Joint Expert Committee on Food Additives (JECFA). Lead exposure is associated with neurodevelopmental effects, mortality (mainly due to cardiovascular diseases), impaired renal function, hypertension, impaired fertility, and adverse pregnancy outcomes. Because of neurodevelopmental effects, fetuses, infants, and children are the most sensitive to lead exposures.

2. At its 73rd session (June 2010), JECFA concluded that in populations with prolonged dietary exposures to higher levels of lead, measures should be taken to identify major contributing sources, and if appropriate, to identify methods for reducing dietary exposure that are commensurate with the level of risk reduction.

3. Lead exposure can occur through food and water, and through use of cosmetics, dietary supplements, traditional medicines, and materials used in religious practices. Lead exposure also occurs in the workplace, through hobbies, from lead paint, in toys for children, and generally through exposure to lead-contaminated soil and air.

4. Lead contamination of food arises from numerous sources, including air and soil. Atmospheric lead from industrial pollution or leaded gasoline can contaminate food through deposition on agricultural crops. Agricultural crops can also take up lead from contaminated soil or contaminated soil may be deposited on plant surfaces. Lead contamination in soil may result from industrial pollution (e.g. mining); past use or inappropriate application of pesticides, fertilizers (including sewage sludge and biosolids); or lead-containing ordnance stored on former munitions sites and from ammunition used in rifle or military firing. Contaminated plants and soil are, in turn, a source of contamination of livestock.

5. Water is also a source of lead contamination of food. Surface water sources can be contaminated through runoff (drainage), atmospheric deposition, and, on a local level, by leaching of lead from game shot or fishing sinkers. Contaminated surface waters are a potential source of contamination of aquatic food producing animals. For drinking water and water for food preparation, corrosion of lead pipes or lead-containing fittings in water distribution systems and building plumbing systems is a primary source of lead contamination.

6. Lead contamination of food can also arise from food processing, food handling, and food packaging. Sources of lead in food processing areas include lead paint and lead-containing equipment, such as piping and lead-soldered machinery. In the packaging area, lead-soldered cans have been identified as an important source of lead contamination of food. Other packaging items that are potential sources of lead contamination include colored plastic bags and wrapping papers, cardboard containers that contain lead or are colored with lead-containing dyes, lead foil capsules on wine bottles, and lead-glazed ceramics, lead crystal, or lead-containing metal vessels used for packaging or storing foods.

7. There have been worldwide efforts to reduce lead exposure from food. Such efforts have focused on implementing standards for allowable lead levels in food, food additives, and food contact substances; ending the use of lead-soldered cans; controlling lead levels in drinking water; reducing leaching from lead-containing vessels or restricting their use for decorative purposes; and identifying and reacting to additional sources of lead contamination in foods or dietary supplements. Although not targeted specifically at food, efforts to reduce environmental sources of lead, including restrictions on industrial emissions and restricted use of leaded gasoline, have also contributed to declining lead levels in food. Despite efforts to reduce lead exposure, lead contamination of foods may still result from lingering environmental contamination (e.g. from leaded gasoline), continued use of lead-containing products (e.g. lead-glazed ceramic vessels erroneously used for food), and consumption of products remaining on the market (like older vintage wines).

8. The Codex Alimentarius Commission and national authorities (GSCTFF CXS 193-1995) have established or recommended standards for maximum levels of lead in various foods. Low levels of lead in foods may be unavoidable, because of the ubiquitous presence of lead in the modern industrial world. However, following good agricultural and manufacturing practices can minimize lead contamination of foods. Because many useful interventions for reducing lead rely on actions by consumers, including educating consumers about certain foods known to contain elevated levels of lead, a section with suggestions on consumer practices has also been included in this Code.
RECOMMENDED PRACTICES BASED ON GOOD AGRICULTURAL PRACTICES (GAP) AND GOOD MANUFACTURING PRACTICES (GMP)

1.1 Source directed measures

9. National or relevant food control authorities should consider implementation of source directed measures in the Code of Practice for Source Directed Measures to Reduce Contamination in Foods with Chemicals (CXC 49-2011).

1.2 Agricultural

10. Leaded gasoline is a major contributor to atmospheric lead. National or local authorities should reduce or eliminate the use of leaded gasoline in agricultural areas.

11. Agricultural lands near industrial facilities, roadways, and ordnance depots, outdoor shooting ranges and military firing ranges may have higher lead levels in soils than more isolated lands. Sources of lead on agricultural lands should be removed, including vehicle batteries; damaged or unused electric fencing batteries; and old, discarded vehicles and machinery.

12. Use of lead solder and other lead materials for repairing farming equipment should be avoided. Land near buildings with weathered exterior paint also may have high lead levels, and there is a particular concern when such buildings are situated near livestock or small gardens.

13. Where possible, farmers should test lead levels in soils, particularly for farms that are near lead sources or that are suspected of having elevated lead levels to determine if lead levels exceed recommendations for planting by national or local authorities.

14. Livestock should be prevented from grazing in areas with lead sources, including peeling paint, bonfire ash, metal roofing material, and contaminated surface waters. In addition, livestock soil consumption should be minimized, through a balanced feed diet (including mineral mixes).

15. In general, where there are potential sources of lead exposure to livestock, secure fencing and housing for livestock is a good practice to help minimize lead contamination.

16. Animal feed should meet lead standards established by national or local authorities, where available, as contaminants in feed can be transferred to food of animal origin and can be relevant for public health.

17. Dairy cows and other dairy animals found to have elevated lead levels should not be used as a source of milk until lead decreases to levels deemed appropriate by national authorities.

18. Farmers should avoid using lands that have been treated with lead arsenate pesticide, such as former orchards, to grow crops that may accumulate lead internally (e.g. root crops) or on their surface (e.g. leafy vegetables).

19. Fertilizers (including sewage sludge and biosolids) should adhere to standards set by national or local authorities, and farmers should avoid growing crops on lands that have been treated with fertilizers that do not adhere to maximum allowable lead levels set by national or local authorities.

20. Farmers should avoid using compounds that contain lead (such as lead arsenate pesticide) or may be contaminated with lead (e.g. improperly prepared copper fungicide or lead-containing phosphate fertilizer) in agricultural areas.

21. Leafy vegetables are more vulnerable than non-leafy vegetables or root vegetables to deposition from airborne lead. Cereal grains also have been reported to absorb lead from the air at a significant rate. In areas where atmospheric lead levels are high, farmers should choose crops that are less vulnerable to airborne deposition.

22. In areas known to have higher lead levels in soil, consider planting certain types of garden plants and trees that may be less susceptible to lead contamination from soil including fruiting vegetables, vegetables that grow on vines, and fruit trees. It may be helpful to decrease the planting of leafy and root vegetables, or to relocate these crops to fields with lower lead levels.

23. Water for irrigation, livestock farming, and aquaculture should be protected from sources of lead contamination and, where possible, monitored for lead levels to prevent or reduce lead contamination of crops, livestock, and aquaculture products. For example, well water used for irrigation and livestock farming should be properly protected to prevent contamination and the water should be routinely monitored.

24. Dryers powered with leaded gasoline have been found to contaminate drying crops with lead. Farmers and processors should avoid using dryers or other equipment powered by leaded gasoline on harvested crops.

25. Crops should be protected from lead contamination (e.g. exposure to atmospheric lead, soil, dust) during transport to processing facilities.
26. Home, community, or small-scale commercial gardeners should also take steps to reduce lead contamination. Avoid planting near roadways and buildings painted with lead-based paint. Consider testing soil, where practical, particularly if gardens are located in an area with potentially high lead soil levels. Good gardening practices for soils with mildly elevated lead levels include mixing organic matter into the soil, increasing the soil pH through liming to reduce availability of lead to plants, choosing plants that are less vulnerable to lead contamination, using liners to reduce contact deposition of soil on plants, and applying mulch to reduce dust and soil splashing on plants. Some lead levels may be considered too high for gardening. It may be possible to build up gardening beds with lead-free soil in such areas and add phosphate amendments (not fertilizers) that promote formation of insoluble lead compounds to reduce availability of lead to plants. Contaminated soil can be physically removed and replaced with clean soil. Home and community gardeners should consult with local agricultural services, where available, for advice on what lead levels are too high for gardening, advice on how to garden safely in lead-contaminated soils, and recommended practices for disposal of removed soil.

27. Local and national authorities should make farmers aware of appropriate practices for preventing lead contamination of farmlands and aquaculture farms.

1.3 Drinking water

28. National or local authorities should consider establishing allowable lead levels or appropriate treatment techniques for controlling lead levels in drinking water. The WHO has established a guideline value for maximum lead levels in drinking water of 0.01 mg/L, but some national authorities may have set lower target levels.

29. Administrators of water systems with high lead levels should recommend treatment techniques, such as increasing the pH of acidic waters, to minimize corrosion and reduce leaching of lead in the distribution system. Detailed recommendations for managing high lead levels can be found in other resources, including the WHO Guidelines for Drinking-Water Quality. Because changes in water treatment practices (e.g., addition of chloramines or use of corrosion control treatment) can influence the levels of lead in drinking water, lead levels should be monitored during any system changes.

30. Given the number of potential lead sources in drinking water systems, including brass faucets, lead solder on copper pipes, lead pipes, and lead service lines, administrators of water systems should replace, where appropriate, problematic lead piping and other lead-containing fixtures.

31. National or local authorities should monitor lead levels in drinking water in schools and childcare centres and apply mitigation measures to reduce elevated lead levels.

1.4 Food ingredients and processing

32. Food producers should limit lead in foods to levels below recommended MLs in the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995) or standards established by national or local authorities for foods and food additives; this is particularly important for foods intended for infants and children.

33. Where standards are not available, national or local authorities should consider establishing standards limiting the concentration of lead allowed in foods, including the traditional foods of their countries. In the absence of standards, national or local authorities or industry should monitor selected foods, including dietary supplements, to ensure that lead levels do not rise above normal background levels or are as low as reasonably achievable.

34. Food processors should choose food and food ingredients, including ingredients used for dietary supplements, that are below the recommended MLs, or where no MLs are available, that are as low as reasonably achievable. Where feasible, they should also consider whether the land used to produce crops has been treated with lead-containing pesticides and fertilizers (including sewage sludge and biosolids).

35. Food processors should consider having control measures in place to monitor incoming ingredients or verify that suppliers are providing ingredients that are below the recommended MLs or where there are no MLs available, that levels are as low as reasonably achievable. Food processors should consider occasional testing of incoming raw materials and finished products for lead to verify that their control measures are functioning effectively.

36. More focused testing should be considered for ingredients or products known to contain high lead levels or that are intended for infants and children. This is particularly important for ingredients or products that may have a history of economic adulteration.

37. For foods for infants and children, consideration should be given to sourcing of raw materials and ingredients used in the manufacture of finished products to ensure levels of lead are as low as reasonably achievable.

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38. During processing, maximum removal of surface lead from plants should be practiced, e.g. by thoroughly washing vegetables, particularly leafy vegetables; removing the outer leaves of leafy vegetables; and peeling root vegetables, where appropriate. Home gardeners should also follow such steps if their soil has elevated lead levels.

39. Food processors should ensure that the water supply for food processing complies with MLs for lead established by the national or local authorities.

40. Food processors should examine piping within facilities to ensure that older piping is not adding lead to water supplies inside the facility, and should replace, where appropriate, outdated piping, fittings, and old containers as they may contain brass alloys and lead soldering.

41. Food processors should use food-grade metals for all metal surfaces that come into contact with food and beverages.

42. Food processors should not use lead solder to repair broken equipment in food processing facilities. They also should not substitute non-food-grade equipment that may be present in a food processing facility for broken food-grade equipment.

43. Food processors should ensure that lead paint peeling do not become a source of lead contamination in processing facilities. If food processors carry out lead paint abatement in their facilities, they should also ensure that appropriate cleanup procedures are followed to prevent further dispersion of lead paint and dust, which could create a greater hazard.

44. Because filtration aids (specifically diatomaceous earth, bentonite, and charcoal filtration) used in processing fruit juices, wines, and beer can contain lead, selecting filtration aids with lower lead levels or washing filtration aids with solutions such as ethylenediamine tetraacetic acid (EDTA) or hydrochloric acid solution, can reduce lead levels in the beverages. Alternative filtration methods also may be used, for example, ultrafiltration. Filtration aids used for processing beverages should comply with Guidelines on Substances Used as Processing Aids (CXG 75-2010).

45. Metal detectors and X-rays are commonly used in food facilities for detecting physical hazards. Metal detectors or X-rays can be used in food establishments such as slaughterhouses and fish processing facilities to detect and facilitate removal of lead shot (pellets) or fishing sinkers in wild game and fish.

1.5 Production and use of packaging and storage products

46. To provide maximum protection against lead contamination, food processors should not use lead-soldered cans. Alternatives to lead-soldered cans are discussed in the Guidelines for can manufacturers and food canners. Prevention of metal contamination of canned foods, FAO Food and Nutrition Paper No. 36 (Rome, 1986) as well as JECFA Monograph 622. These alternatives include using two-piece cans (which lack side seams) rather than three-piece cans, using cementing and welding to bond seams instead of soldering, using lead-free (tin) solders, and using alternative containers, such as lead-free glass.

47. Where it is not feasible to avoid the use of lead-soldered cans, methods for reducing lead exposure from lead-soldered cans are discussed in depth in FAO Food and Nutrition Paper 36. Lead can be released from the solder surface itself, or from solder dust or solder splashes deposited inside the can during the can-making process. Methods for reducing splashing and dust formation include avoiding the use of excess flux, controlling exhaust over the work area to minimize dust deposition, controlling the temperature of the fluxed can body and solder, post-solder lacquering of the interior surface or interior side seams of cans, careful wiping of excess solder from finished cans, and washing soldered cans before use. For a detailed description of proper manufacturing practices with lead-soldered cans, the FAO paper should be consulted.

48. Tinplate used for food cans should meet international standards for maximum allowable lead concentration. ASTM International has set a maximum concentration of 0.010 percent lead for “Grade A” tinplate.

49. Lead dyes or lead-based printing inks should not be used for food packaging, such as for brightly colored candy wrappers. Even if such wrapping does not come in direct contact with foods, children may be tempted to put the brightly colored wrappers in their mouths.

50. Plastic bags or boxes with exteriors treated with lead-based dyes or lead-based printing inks should not be used for packaging food. Handling of these items during cooking or reuse by consumers for storing other food items can cause lead contamination.

51. Packaging foods for sale in traditional lead-glazed ceramics should be avoided because these ceramics may leach significant quantities of lead into the foods.
52. Lead foil capsules should not be used on wine bottles because this practice may leave lead residues around the mouth of the bottle that can contaminate wine upon pouring.

53. National and local authorities should consider setting standards for lead migration from lead-glazed ceramic ware, lead crystal, and other lead-containing items that might potentially be used for food storage or preparation by consumers.

54. As one regulatory option, national and local authorities could consider setting standards for lead migration and lead composition in food contact substances used in food processing or manufacturing.

55. Decorative ceramic ware that has the potential to leach unacceptable quantities of lead should be clearly labeled as not for food use.

56. Ceramic ware producers should use manufacturing procedures and quality control mechanisms that minimize lead leaching.

1.6 Consumer practices and consideration of certain foods

57. National and local authorities should consider educating consumers about the hazards of lead, particularly to children; sources of lead; and appropriate practices to reduce lead contamination from food prepared in the home or grown in the garden.

58. Consumers should wash vegetables and fruit thoroughly to remove dust and soil that may contain lead. Removing outer leaves from leafy greens and peeling root crops can reduce lead levels. Washing hands before preparing food will also help remove any lead-contaminated dust or soil from hands.

59. Consumers should store food and eating/cooking utensils in sealed containers or closed cabinets to protect them from falling dust. Consumers should avoid storing foods, particularly acidic foods or foods for infants and children, in decorative ceramic ware, lead crystal, or other containers that can leach lead. Foods should not be stored in opened lead-soldered cans or stored in reused lead-dyed bags and containers. Consumers should avoid frequent use of ceramic mugs when drinking hot beverages such as coffee or tea, unless the mugs are known to have been made with a lead glaze that is properly fired or fired with a non-lead glaze.

60. Where lead in water distribution systems is a problem, consumers should let water run from faucets before use to allow corroded lead from piping to be flushed out of the system, particularly if they are preparing foods for infants or children. Hot water from the faucet should not be used for drinking, cooking or food preparation. If filters are used, consumers should ensure they are properly installed and replaced regularly according to manufacturer specifications. Another option is to use an alternative water source for food preparation.

61. Consumers should be educated about the concerns surrounding geophagia (the practice of consuming clay or soil) that is practiced mainly by children and pregnant and lactating women. Various clay products, known by names such as calabash chalk, mabele, sikor, and pimbpa, have been found to contain elevated lead levels. Pregnant and lactating women, and children who frequently engage in geophagia, should be discouraged from this practice.

62. Consumers should be educated that foods sold as traditional medicines, including herbs and spices, may be sources of lead exposure.

63. Meat from game killed with lead shot (pellets) or from waterfowl that have ingested lead shot may be a source of lead exposure. Therefore, children and women of childbearing age should reduce or avoid consumption of game killed with and containing lead shot. When hunting game intended for consumption, consider using a rifle or using a slug rather than buckshot in a shotgun, as this may reduce lead contamination of the meat; although there is the potential for lead fragments to remain in the game meat. Meat containing lead fragments or shot should be excised and discarded.

64. National or local authorities should educate people about the potential risks of consuming local specialty foods or collected wild foods (e.g. mushrooms) that could contain elevated lead levels.
APPENDIX II

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