

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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

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INFORMATION PAPER ON EMERGING ISSUES: A PROPOSED RISK MANAGEMENT APPROACH TO ADDRESS DETECTION IN FOOD OF CHEMICALS OF VERY LOW PUBLIC HEALTH CONCERN

Prepared by New Zealand

1. The following was presented at the recent Codex Committee on General Principles meeting and New Zealand would like to raise awareness of this paper with relevant Codex Committees.
2. One of the strategic objectives of the Codex Alimentarius Commission (CAC) is to proactively identify emerging issues and members' needs, and where appropriate, develop relevant food standards¹.
3. The purpose of this paper is to inform members of the value of promoting an internationally harmonised risk management approach to address detections in food of traces of chemicals presenting very low exposure and very low potential public health concern. Many of these chemicals may have already been determined by different national regulatory authorities as chemicals of very low health concern and of little or no public health or food safety consequence.
4. The potential for chemicals to inadvertently be present in food at various stages of production and processing has long been recognised by regulatory authorities around the world e.g. use of cleaning agents. Regulatory authorities and scientific bodies, both at national and international levels have, over the years, developed pragmatic approaches to responding to detections of such chemicals that constitute a very low exposure and very low public health concern. There is already a sound body of science that can be drawn upon to assist with developing a harmonised international approach.
5. The CAC is ideally placed to consider and promote an internationally harmonised approach for regulators to address potential public health and trade issues when responding to detections of traces of chemicals in food.

Chemicals of very low public health concern: scientific issues

6. There are many chemicals that can be present in food following proper and legitimate use in the food chain. The traditional focus on standards for residues of pesticides, veterinary drugs and contaminants remain important for Codex and regulators². There is, however, a growing imperative to look beyond those chemicals already dealt with by existing Codex processes and address issues arising from the use and detection of chemicals of very low exposure and very low potential public health concern, that may be inadvertently present in food at trace levels.
7. These chemicals include:
 - chemicals that inadvertently get into food during production and processing. Typically these chemicals could include cleaning agents, and surface coatings e.g. quaternary ammonium compounds;
 - chemicals that are being developed for use in agriculture to address specific environmental and climate change related issues e.g. nitrification or urease inhibitors; and

¹ Codex Alimentarius Commission Strategic Plan 2014-2019, Strategic Goal 1, Objective 1.2

² Codex Committees on Pesticide Residues (CCPR), Residues of Veterinary Drugs in Food (CCRVDF), and Contaminants in Foods (CCCF) are the traditional bodies responsible for establishing maximum limits and establishing international guidelines for risk management. Pesticides in animal feed are managed by CCPR, CCRVDR has responsibility for veterinary drugs in feed and the feed additive ethoxyquin, an antioxidant. CCCF has responsibility for contaminants in feed if they lead to residues in food.

- *fertilisers* and other chemicals that are commonly used to promote plant growth and improve yields; traces of these chemicals and/or impurities within them might be detected in food.

8. Advances in analytical methods and testing technologies mean that compounds are now able to be detected at very low concentrations (parts per billion) with hundreds of compounds able to be screened simultaneously. At the levels detected these chemicals are highly unlikely to represent any risk to public health but may lead to restrictions on trade at the border.

9. There is an important need to promote internationally-agreed guidelines to address this generic risk management issue.

Contemporary approaches

10. In the United States, the Department of Agriculture's Food Safety and Inspection Service (FSIS) recently announced a standardised approach to address chemicals without established public health tolerances³. Under this approach, FSIS will derive a *de minimis* level (DML) for the given chemical, below which FSIS is confident that any public health concern is non-existent or negligible⁴.

11. The approach that appears to have the most international attention is the Threshold of Toxicological Concern (TTC). This can be used to assess potential human health concerns for chemicals (for which there is little if any toxicology data) based on their chemical structures and potential human exposures.

12. The TTC approach has been recently reviewed by an expert consultation convened by the European Food Safety Authority (EFSA) and the World Health Organization (WHO), with the support of the US Food and Drug Administration (FDA) to update and extend the TTC framework.⁵ The report of this consultation was released in March 2016, and recommends a globally harmonised decision tree framework for the application of the TTC in the risk assessment of chemicals.

13. The TTC approach is not a substitute for the risk assessment of regulated compounds such as pesticides and food/feed additives but it does appear to be best placed as a means of assessing human health risks associated with the finding of an inadvertent presence of traces of chemicals in foods.

Strategic options in Codex

14. Codex has a clear interest and responsibility to take a proactive approach to address the issues raised in this paper and support the development of an internationally harmonised risk management approach.

15. The issues raised in this paper are likely to be of growing relevance and interest to many countries. It is against this background that New Zealand is proposing a harmonised risk management approach to address detection in food of chemicals of very low public health concern.

16. New Zealand will be working closely with parent bodies, members and other interested parties, as we move forward with the development of a new work proposal for consideration at 71st session of the Executive Committee and the 39th session of the CAC in June 2016.

³ Federal Register, Vol. 80, No. 249, Tuesday, December 29, 2015, *National Residue Program: Monitoring Chemical Hazards* <http://www.fsis.usda.gov/wps/wcm/connect/0387871c-201a-45a5-854e-4e717788baed/2015-0002.pdf?MOD=AJPERES>, (18 March 2016)

⁴ Congressional and Public Affairs, Julie Schwartz, (202) 720-9113, *USDA's Food Safety and Inspection Service Announces Standardized Approach to Residues without Established Public Health Tolerances* <http://www.fsis.usda.gov/wps/portal/fsis/newsroom/news-releases-statements-transcripts/news-release-archives-by-year/archive/2015/nr-122315-01>, (18 March 2016)

⁵ <http://www.efsa.europa.eu/en/supporting/pub/1006e>