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# FOOD SAFETY 101

## Regulation of chemical contaminants in food


### Abstract

Chemical contaminants in food are substances that serve no technological purpose and whose presence may lead to adverse health effects. Therefore, robust risk assessments and management options are used to reduce risk from a contaminant to as low as reasonably achievable (ALARA).

This paper describes how contaminants are regulated in Australia/New Zealand, and the key risk assessment and management considerations used to control contaminants in the food supply. Three case studies are presented demonstrating regulatory, combined regulatory/non-regulatory, and non-regulatory approaches to control specific contaminants in the food supply.



### Keywords

Contaminants – Regulation –Definition – Risk Assessment - Management – Case studies.


### Introduction

Food contaminants are substances present in food at levels which serve no technological purpose and whose presence may lead to adverse health effects. There are considerable efforts employed worldwide by both the Government and food industry to control contamination in food and keep the food supply safe for consumers.

### Standard 1.4.1 – Contaminants and natural toxicants

Contaminants are regulated in Schedule 19 of Standard 1.4.1 Contaminants and Natural Toxicants[1] of the Australia New Zealand Food Standards Code (The Code). This standard was reviewed in the late 1990s using the following key principles (ANZFA, 1998; Abbott *et al.*, 2003; Szabo *et al*., 2009):

- Levels in food should be kept as low as reasonably achievable (ALARA).
- Maximum Limits[2] (MLs) are set for a contaminant in foods that present a significant risk to public health and safety and are a significant contribution to the total dietary exposure to that contaminant.
- Where the setting of a ML for the primary commodity is judged to be ineffective, a ML may be set for nominated processed foods *e.g.,* ML for cadmium in chocolate and cocoa products.
- MLs set to be consistent with Codex levels, where appropriate, however harmonisation with Codex is secondary to measures put in place to protect the public health and safety of Australians and New Zealanders.
- Consideration must also be given to Australia and New Zealand's international trade obligations under the World Trade Organizations Sanitary and Phytosanitary (SPS) agreement and Technical Barrier to Trade (TBT) agreement.

1 https://www.foodstandards.gov.au/code/Pages/default.aspx

2 Maximum limit differs from maximum residue limits (MRLs) which are prescribed for agricultural and veterinary chemicals (AG/VET). An MRL is the maximum amount identified for the permitted residue of an AG/VET chemical in a food as prescribed in Schedule 21 of **Standard 1.4.2 – Agvet chemicals** of the Code.

In many cases, contaminants serve no nutritional function, although some, such as copper, selenium, and zinc, are essential micronutrients that may result in an adverse health effect at high levels of consumption. These micronutrients were previously prescribed MLs under an 'all other foods category' in the *Australian Food Standards Code*. However, upon review of the contaminant's standard in the late 1990s, and based on a risk assessment, no public health and safety implications were identified. Subsequently, they were removed from the contaminant's standard.

There is currently no official definition of a contaminant in The Code. However, the Codex General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995; GSCTF)[3] provides the following definition:

'*Any substance not intentionally added to food which is present in such food as a result of production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or hold of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matters*.'

The term 'contaminant' thus refers to both metal and non-metal substances, including processing chemicals (*e.g.,* acrylamide, furans, chloropropanol esters) and environmental and industrial contaminants (*e.g.,* dioxins). However, because this definition stipulates 'not intentionally added to food' it excludes agricultural and veterinary chemicals, food additives and processing aids. Certain pesticides, such as DDT, which are no longer intentionally applied to crops but are still found in foods, may also be regarded as contaminants[4].

However, compounds that occur naturally in foods derived from plants are not considered to be contaminants as they are inherent components of the plants. Such substances are referred to as 'natural toxicants' and can be found in many plant derived foods, such as edible oils, cereals, honey, and lupin products (Abbott *et al*., 2003).

## Control of contaminants in the food supply

Since many contaminants are naturally occurring substances, it is not possible to impose a blanket zero-tolerance approach to their presence (albeit sometimes at trace amounts) in food products where there is limited control over their presence in food.

To control contamination both regulatory (*e.g.,* MLs) or non-regulatory (guidelines or industry Codes of Practice (COPs)) can be considered. The most appropriate control measure for a particular contaminant depends on several factors such as the nature and severity of the potential health risk, the frequency and extent of the contamination, potential level of exposure and the size of the potentially exposed population.

[3] https://www.agriculture.gov.au/ag-farm-food/food/codex/committees/contaminants and http://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/

In respect of environmentally persistent residues, such as DDT, in Australia these are referred to as extraneous residue limits (ERLs) and relate to the presence of a residue of the agvet chemical in the food from environmental sources, and not from direct or indirect use of an agvet chemical on food. Levels are managed by maximum residue limit prescribed in Schedule 21 https://www.legislation.gov.au/Details/F2017C00330 of Standard 1.4.2 – Agvet chemicals of the Code.

MLs for contaminants in the Code are prescribed only for major dietary contributors to human exposure for a specific contaminant. Therefore, theoretically if a contaminant is *not listed* in Standard 1.4.1 it is *legally allowed* to sell that food subject to the safe and suitable provisions of the State/Territory food acts. The Code allows their presence, provided the food for sale is both safe and suitable under the general provisions of the Food Acts.

However, levels should be kept ALARA in accordance with the requirements of Standard 1.4.1 Contaminants and Natural Toxicants of the Code.

To assist both enforcement agencies and industry to maintain contaminant levels at the lowest achievable levels, generally expected levels (GELs), have been established to complement the use of MLs. GELs, while not legally enforceable, provide a benchmark against which to measure contaminant levels in foods (Abbott et al, 2003).

## International considerations

Worldwide, there is a range of policies set for contaminants in food by an individual country based on their respective risk assessment outcomes and importantly their risk appetites. Therefore, in assessment of individual contaminants, it is important to remain up to date with any changes in the health-based guidance values (HBGV). For example, the HBGVs for arsenic and lead were withdrawn by the Joint Expert Committee on Food Additives (JECFA) because they were unable to establish a safe threshold level of exposure. This means that risk assessors must then utilise other tools to determine the risk for consumers[5].

Therefore, following any updated science on risk, risk managers may then need to choose to consider whether MLs set in their own countries are still based on the best available science and evidence. A summary of changes by JECFA to the HBGVs for arsenic, lead, mercury and cadmium is presented at Appendix 1.

The Codex Committee on Contaminants in Food (CCCF)[6] of which Australia and New Zealand are represented, regularly reviews updated risk assessments by JECFA and proposes risk management options for consideration and inclusion in the GSCTF. These may consist of regulatory (standards, MLs) and/or non-regulatory options such as guideline levels or COPs.

For example, to control lead contamination in a range of foods, Codex has endorsed CXC 56-2004 Code of Practice for the Prevention and Reduction of Lead Contamination in Foods[7] and has a rolling review on MLs for lead reduction on a commodity basis, based on public health and safety and achievability by industry[8].

## Risk assessment

Risk assessment involves a process of identifying, analysing and characterising food-related health risks. Each risk assessment is done on a case-by-case basis, using the best available scientific evidence to decide whether an identified hazard might pose any public health and safety issues.

5 For example, a margin of exposure approach. FSANZ used this approach to characterise the risk of lead in foods in the 25th Australian Total Diet Survey https://www.foodstandards.gov.au/publications/Pages/25th-Australian-Total-Diet-Study.aspx
6 https://www.agriculture.gov.au/ag-farm-food/food/codex/committees/contaminants
7 http://www.fao.org/fao-who-codexalimentarius/codex-texts/codes-of-practice/en/
8 http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-meetings/en/?committee=CCCF

Risk managers use the outcomes of risk assessments to formulate responses to manage food health and safety concerns.

Risk assessments aim to estimate the likelihood and severity of an adverse health effect occurring from exposure to a hazard. A food risk assessment therefore consists of an assessment of the hazard and an assessment of exposure which together enable characterization of the risk[9].

## Risk management

Codex defines risk management as the process of weighing policy alternatives in consultation with interested parties, considering risk assessment and other factors for the health protection of consumers and the promotion of fair-trade practices, and, if needed, selecting appropriate prevention and control options.

Therefore, risk management is a consultative and decision-making process that identifies the problem; considers the risk assessment, social, economic, and other factors; and develops, weighs and selects the option of greatest net benefit to the community. This process may also evaluate the implemented decision.

Any risk associated with the presence of a chemical contaminant or a natural toxicant in food may be managed by establishing an ML for the substance, as an outcome of the risk assessment. For example, in Australia and New Zealand, MLs have been established for chemical contaminants and set at levels which are reasonably achievable from sound production and natural resource management practices[10].

Examples of other broader risk management strategies may also involve other measures:

- Labelling requirements.
- Education/awareness.
- Guidelines.
- Industry self-regulation.

## Risk communication

Some contaminants in food continue to be of high community and media interest and a communication plan is often needed to explain the risks to the public and how they will be effectively managed. The Government and industry often work closely together to ensure that public health and safety remains protected, whilst minimizing impacts on industry.

## Regulatory impact assessment

A Regulatory Impact Statement (RIS) may need to be prepared to examine the costs and benefits of various options for managing potential public health or safety issues from contaminants in the food supply.

This may include consideration of the following issues:

- A statement of the problem – explaining the need for government action.
- A statement of the objectives of any intervention.
- A statement of the possible options to address the problem.
- An impact analysis of the options.

9 https://www.foodstandards.gov.au/publications/riskanalysisfoodregulation/Documents/risk-analysis-food-regulation-ch4-pdf.pdf
10 https://www.comlaw.gov.au/Series/F2015L00408.

- Details of the consultation undertaken.
- A clear statement as to which is the preferred option and why.
- Details of how the preferred option would be implemented, monitored, and reviewed.

Three cases examples are presented of regulatory (Attachment 1), combined regulatory/non-regulatory (Attachment 2) and non-regulatory approaches (Attachment 3) to specific contaminants in Australia and New Zealand.

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## Relevant websites

http://www.codexalimentarius.org/

http://www.who.int/foodsafety/areas_work/chemical-risks/jecfa/en/

http://www.foodstandards.gov.au/Pages/default.aspx

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FSANZ (2014). Risk Analysis in Food Regulation http://www.foodstandards.gov.au/publications/riskanalysisfoodregulation/Pages/default.aspx.

## Glossary

| | |
|---|---|
| Acute Reference Dose (ARfD) | An estimate of the amount of a substance in food and/or drinking-water, normally expressed on a body-weight basis, that can be ingested in a period of 24 hours or less, without appreciable health risk to the consumer. |
| ANZFA | *Australia New Zealand Food Authority*. The predecessor agency to FSANZ. |
| FSANZ | *Food Standards Australia New Zealand.*<br>A bi-national Government agency that develops and administers the Australia New Zealand Food Standards Code. |
| HBGV | Health-based guidance values used in risk assessment. Examples are acceptable daily intakes and provisional tolerable daily intakes for contaminants (see below). |
| ML | Maximum limit legally permitted in a food (usual to express in mg/kg). |
| MRL | Maximum Residue Limit (MRLs) are prescribed for agricultural and veterinary chemicals (AG/VET). An MRL is the maximum amount identified for the permitted residue of an AG/VET chemical in a food. Levels are managed by maximum residue limit prescribed in Schedule 21 of Standard 1.4.2 – Agvet chemicals of the Code. |
| JECFA | *Joint Expert Committee on Food Additives*.<br>JECFA is an international scientific expert committee administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and WHO. |
| Margin of exposure | Margin of exposure (MOE) is the ratio of no-observed-adverse-effect level (NOAEL) obtained from animal toxicology studies to the predicted or estimated human exposure level or dose. |
| Provisional Maximum Tolerable Daily Intake (PMTDI) | The endpoint used for contaminants with no cumulative properties. Its value represents permissible human exposure as a result of the occurrence of the substance in food and in drinking-water. In the case of trace elements that are both essential nutrients and unavoidable constituents of food, a range is expressed, the lower value representing the level of essentiality and the upper value the PMTDI. |
| PTWI: | *(Provisional Tolerable Weekly Intake)*<br>An endpoint used for food contaminants such as heavy metals with cumulative properties. Its value represents permissible human weekly exposure to those contaminants unavoidably associated with the consumption of otherwise wholesome and nutritious foods. |
| PTMI: | *(Provisional Tolerable Monthly Intake)*<br>An endpoint used for a food contaminant with cumulative properties that has a very long half-life in the human body. Its value represents permissible human monthly exposure to a contaminant unavoidably associated with otherwise wholesome and nutritious foods. |

## Attachment 1

## Case study 1: Responding to an incident of a naturally occurring toxicant in food in Australia and New Zealand

This case study describes a regulatory response to a potential acute poisoning scenario from the presence of hydrocyanic acid (HCN) in a cassava-based snack food. It describes how the policy on setting MLs[11] in foods operates in Australia and New Zealand applied to an acute toxicity scenario, where the concept of an Acceptable Daily Intake (ADI) or Tolerable Daily Intake (TDI) is not appropriate. Furthermore, it demonstrates that the general principles of risk analysis can still apply in responding to rapidly emerging issues, although time constraints may affect the sequence of events and depth of information that can be obtained and assessed.

Issue

Food regulatory agencies in Australia and New Zealand found that certain cassava-based foods (chips or crackers) contained higher than expected levels of HCN. These results prompted the national recall of the implicated products in Australia and further investigation by food regulatory authorities. As part of these investigations, FSANZ prepared a risk assessment in relation to cyanogenic glycosides[12] in cassava chips[13].

The risk

HCN is a lethal acute toxin with a steep dose response curve. Doses slightly higher than those producing relatively nonspecific symptoms can be fatal. Toxicity across species is similar and animal models have clear relevance to estimation of safe human exposures. An acute reference dose (ARfD) based on death as the primary endpoint in hamsters was determined for linamarin and, by extension, HCN, its principal intestinal metabolite. Dietary modelling identified 2–4-year-old children as the highest risk group in the population.

The probability of exposure above the ARfD at total HCN levels of 10 mg/kg of cassava chips was determined to be low with the probability increasing with increasing levels of hydrocyanic acid.

As tragic and irreversible results could potentially, and rapidly, arise from a single instance of a young child consuming a moderate quantity (50 - 100 g) of cassava chips containing a somewhat, but indeterminably, higher level of HCN in a short space of time (a few minutes) without intake-limiting warning symptoms, a degree of conservatism was warranted and built into the risk assessment.

Risk management

FSANZ considered the impact of various regulatory and non-regulatory options on all sections of the community, including consumers, food industries and governments. FSANZ considered non-regulatory options of education and of encouraging the industry to reduce total hydrocyanic acid in ready-to-eat cassava chips as part of the option of maintaining the status quo.

FSANZ chose a regulatory option which included definitions for 'ready-to-eat cassava chips' and 'hydrocyanic acid, total' and a maximum level of 10 mg/kg for total hydrocyanic acid in ready-to-eat cassava chips. Compliance with these measures would reduce acute dietary exposure to hydrocyanic acid from ready-to-eat cassava chips and would address the potential public health implications that have been identified with these foods.

[11] https://www1.health.gov.au/internet/main/publishing.nsf/Content/2200FE086D480353CA2580C900817CDC/$File/Criteria-establishment-maximum-limits-food.pdf

[12] 'cyanogenic glycosides' are naturally occurring substances that produce hydrocyanic acid (hydrogen cyanide) in specific circumstances.

[13] https://www.foodstandards.gov.au/code/proposals/Pages/proposalp1002hydrocy3848.aspx

The final decision considered issues raised in public submissions, those received from a notification to the WTO and a Regulatory Impact Assessment.

Communication

Initial risk communication messages to the public were in the form of media releases issued by jurisdictions across Australia. Follow up materials were produced for the FSANZ website with advice regarding the limits set in the Code for cassava chips.

# Attachment 2

## Case study 2: Methyl mercury in fish

This case study describes the following:

- how a contaminant with a neurotoxic profile has assigned MLs in the Code but in parallel can be effectively managed by non-regulatory measures.
- risk management responses need to be reviewed and updated as new scientific evidence becomes available, particularly for vulnerable population sub-groups such as pregnant women, children, and consumers with high levels of fish consumption.

Issue

Mercury is a heavy metal released into the environment from a range of natural and human made sources. Methylmercury (an organic form of mercury) is formed from inorganic mercury by microbial action in aquatic systems (both fresh and marine water), sediments and soils; accumulates in the aquatic food chain, with predatory and long living species higher up the food chain accumulating higher levels. These species include marlin, swordfish, and shark.

The consumption of fish and seafood is the major source of human exposure to methylmercury in most populations. Methylmercury levels will differ significantly across different fish species. Typical levels in some types of fish can cause potential health risks to consumers.

The risk

The toxic effects of methylmercury in humans are well documented. Methylmercury is readily absorbed following ingestion and can induce toxic effects in several organ systems. However, the nervous system (central and peripheral) is the most sensitive to methylmercury toxicity, with the developing nervous system the most vulnerable. Therefore, methylmercury in fish has been a known hazard for many years and is the subject of previously completed risk analyses at the international

The most recent ATDS (2019[14]) indicated that dietary exposures to inorganic mercury for most Australian consumers are acceptably low with exceedances for children aged 2 to 5 years were up to 110% and 220% of the PTWI for mean and P90 consumers, respectively. However, exceedances of the PTWI for certain subpopulations should be considered in the context of the health benefits of fish consumption in accordance with the **FSANZ Mercury in Fish: Advice on fish consumption**.

Risk management

The risk management of methylmercury exposure is complex as the risks associated with exposure to methylmercury through the consumption of certain types of fish must be considered also noting the benefits of consuming fish as part of a healthy diet. Fish consumption has many nutritional benefits. Fish are considered a good source of protein, omega 3 fatty acids and iodine. Fish are also low in saturated fat. As a result, fish consumption is often encouraged by health professionals.

In considering the risks and benefits, the aim is to restrict the level of methylmercury in fish to protect public health and safety, while not setting the levels so low to restrict the availability of fish in the marketplace (and their concomitant nutritional benefits).

In relation to risk management options, levels of mercury in the fish are difficult to control in their natural environment, and MLs for mercury are in place in the Code. It was determined that providing advice to the population (and pregnant women and women intending to become pregnant) on fish consumption would be the best way of managing potential health risks of methylmercury in fish.

[14] https://www.foodstandards.gov.au/publications/Pages/25th-Australian-Total-Diet-Study.aspx

An advisory statement on mercury in fish, detailing the number of serves of different types of fish pregnant women and women planning pregnancy could safely consume was first issued by FSANZ in 2001 and this has been updated in 2020:
https://www.foodstandards.gov.au/consumer/chemicals/mercury/Pages/default.aspx

FSANZ continues to participate in international assessment and standards-setting work on methyl mercury through the CCCF (Codex).

# Attachment 3

## Case study 3: Acrylamide

This case study describes how a contaminant assessed as a genotoxic carcinogen[15] can be managed by non-regulatory measures.

Issue

In 2002, Swedish scientists found acrylamide can form in some foods during high-temperature cooking e.g., frying, roasting, and baking. Acrylamide forms from sugars and an amino acid (asparagine) that are naturally present in food[16], and has a ubiquitous presence in a range of foods consumed daily (*e.g.*, coffee; coffee substitutes from chicory (European Food Safety Authority[17], FSANZ, 2016[18]).

The risk

Assessment of the potential risk from acrylamide exposure in foods has been undertaken by regulatory agencies in several countries. JECFA (2005) concluded that acrylamide may cause cancer in long-term feeding studies in rats; and in 2010, determined that acrylamide is a human health concern, and suggested additional long-term studies. US FDA experts participated in the evaluation and provided data from new research studies on acrylamide risk and acrylamide levels surveyed the US food supply[19].

EFSA (2015) published its first full risk assessment of acrylamide in food, examining levels of acrylamide in a range of foods and concluding that exposure potentially increases the risk of developing cancer for consumers in all age groups.

Australia and New Zealand have kept a watching brief on this contaminant and over many years participated in considerations of acrylamide by the CCCF. Estimated dietary exposures of Australian consumers to acrylamide in food were investigated as a part of the first phase of the 24th Australian Total Diet Study. The study found that the levels of acrylamide were generally lower than, or comparable to, those reported in previous Australian and international studies.

The New Zealand Ministry for Primary Industries (MPI) reassessed dietary exposure with a survey of foods contributing to acrylamide intake in New Zealand. The ministry updated its survey in 2012, finding dietary exposures have remained fairly constant since a previous survey in 2006[20].

In summary, while there is no direct evidence that acrylamide can cause cancer in humans, there is evidence it can cause cancer in laboratory animals. Therefore, FSANZ believes it is prudent to reduce our exposure to acrylamide in food.

Risk management

No MLs are prescribed for acrylamide in food; however, the EU uses benchmark levels for foods including potato, bread, cereals, coffee, biscuits and specific foods for infants and children[21].

Currently, acrylamide exposure is managed by a range of non-regulatory measures:

[15] a chemical capable of producing cancer by directly altering the genetic material of target cells.
[16] https://www.fda.gov/food/chemicals/acrylamide-questions-and-answers#:~:text=Acrylamide%20is%20a%20chemical%20that,food%20packaging%20or%20the%20environment
[17] https://www.efsa.europa.eu/en/topics/topic/acrylamide
[18] Food Standards Australia New Zealand (FSANZ) Acrylamide Fact Sheet (2016). https://www.foodstandards.gov.au/consumer/chemicals/acrylamide/Pages/default.aspx
[19] https://www.fda.gov/food/chemicals/survey-data-acrylamide-food.
[20] Acrylamide in New Zealand food and updated exposure assessment, MAF Technical Paper No: 2011/19
[21] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32017R2158

- Utilizing the Codex CXC 67-2009 Code of Practice for the Reduction of Acrylamide in Foods[22].
- Consumer advice aimed at ensuring a balanced diet[23] and varying how food is cooked.
- Consideration of new farming and processing techniques to produce lower levels of acrylamide.
- Industry adoption of an "acrylamide toolbox" produced by Food and Drink Europe.

[22] http://www.fao.org/fao-who-codexalimentarius/codex-texts/codes-of-practice/en/
[23] that emphasizes fruits, vegetables, whole grains, and fat-free or low-fat milk and milk products; includes lean meats, poultry, fish, beans, eggs, and nuts; and limits saturated fats, trans fats, cholesterol, salt (sodium) and added sugars.

## APPENDIX 1: Changes by JECFA to the Health Based Reference Values for arsenic, lead, mercury, and cadmium[24]

| Contaminant | Previous reference health level | JECFA toxicological consideration | Revised HBGV and reason |
|---|---|---|---|
| Arsenic | 15 µg/kg bw (PTWI) | JECFA 72 (2010) | ***Withdrawn*** because the PTWI could no longer be considered health protective |
| Cadmium | 7 µg/kg bw (PTWI) | JECFA 73 (2011) | Changed from a **PTWI** to a ***PTMI of 25 µg/kg bw*** to account for the long half-life of cadmium |
| Lead | 25 µg/kg bw (PTWI) | JECFA 73 (2011) | ***Withdrawn*** because the PTWI could no longer be considered health protective |
| Mercury | 5 µg/kg bw (PTWI) for total mercury for adults was withdrawn | JECFA 72 (2010) | JECFA established a PTWI for ***inorganic mercury of 4 µg/kg bw*** for the whole population. Previously there were two HBGVs applicable (relating to adults and children separately). JECFA assigned a separate HBGV (PTWI) for methylmercury of 1.6 µg/kg bw based on the estimated exposure that would be expected to have no appreciable adverse effects on children. |

[24] GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED CXS 193-1995 Adopted in 1995 Revised in 1997, 2006, 2008, 2009 Amended in 2010, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019