
CHEMICAL CONTAMINANTS PRINCIPLES

Report by Steve Wearne, Director of Policy

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Summary

1.1 This paper explains the Agency's approach to managing chemical contaminant risks in food¹. It outlines what chemical contaminants are and the main risks they pose to the consumer and trade in food. The paper also outlines the current control framework.

1.2 This paper sets out the policy principles we have developed to manage risk effectively and identifies several future challenges for the regime.

1.3 The Board is asked to:

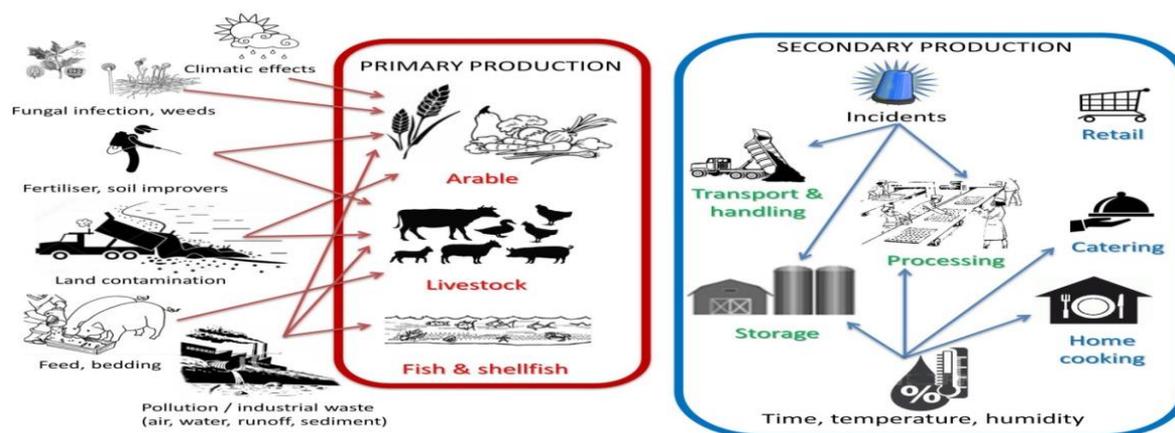
- **note** how chemical contaminants pose a complex risk to consumers and impact on the international trade in food;
- **consider** and **discuss** the current framework and roles and responsibilities, at global, regional and national levels, and in particular the division of responsibilities between the Board and executive;
- **comment** on and **agree** the principles and enablers used to manage chemical contaminants risks; and
- **comment** on the other key challenges facing this approach to the assessment and management of chemical contaminant risks.

Overview

Nature and occurrence

2.1 Food is composed of chemicals – some, like proteins, are complex while some, like salt or water, are simple; some are man-made and others are naturally-occurring. Some chemicals are not intended to be part of food, and are present only because the food has become unintentionally contaminated in some way. Chemical contaminants occur at all stages in the food system; primary and secondary food production, transportation, storage and in industrial and domestic cooking, as shown below:

¹ Defined here as food, drink and feed.



Impact on Consumers and Business

2.2 All food types can be affected by chemical contamination, and so potentially all consumers face risks. The impact on consumers may be acuteⁱ, associated with a single exposure or exposure over a short period (for example this could include exposure to high levels of hydrogen cyanide from consuming raw bitter apricot kernels which are naturally high in this contaminant), or chronicⁱⁱ, where harm arises through repeated long term exposure or the accumulation of the contaminant in the body. Details of our approach to risk assessment for chemical contaminants in food are provided in Annex 1. Most chemical contaminants have a chronic effect and the absence of an immediate impact in health terms from exposure to them presents additional challenges to risk management and risk communication. The increasing sensitivity of analytical methodology can also provide a challenge for risk communication, particularly in describing the relevance of any findings in food of traces of chemical contaminants at levels far below those which would be of any toxicological concern.

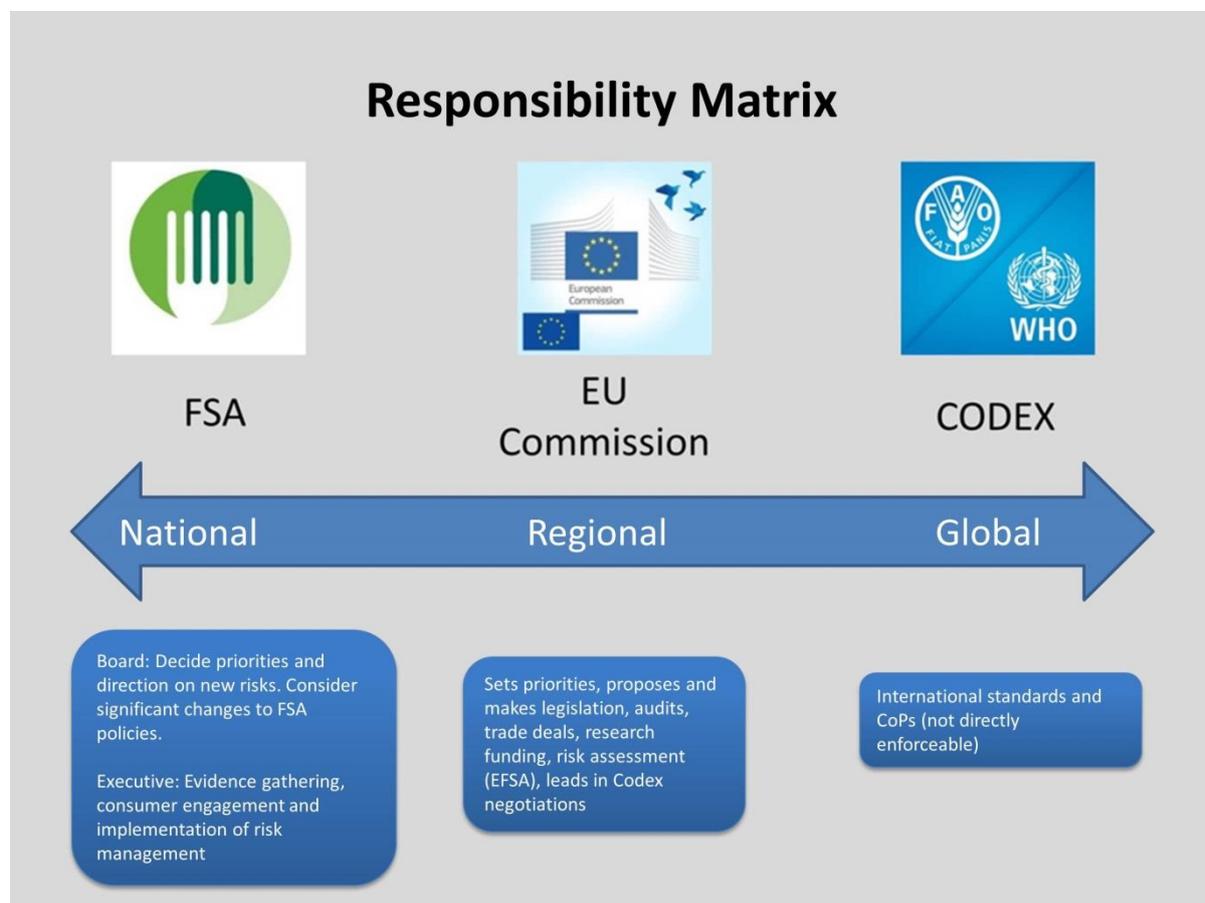
2.3 Given their chronic effects, there is very limited data on any fatalities or hospitalisations caused by exposure to chemical contaminants via food. However chemical contaminants are the cause of a considerable number of food incidents, being the cause of 19% of all incidents reported in the FSA Annual Report of Incidents 2015².

2.4 Chemical contaminants can also have a significant influence upon international trade in food, including in UK food and drink sectors which are of importance to our international trade ambitions. Effective risk management is a key part in maintaining the confidence of consumers and of trading partners in UK food products. As an example of the potential costs and impact arising from chemical contamination incidents, major incidents relating to dioxins in Belgium in 1999 and Ireland in 2008 are estimated to have cost upwards of €1 billion and € 300 million respectivelyⁱⁱⁱ in terms of their total economic costs, and the former has been credited with significantly damaging public confidence in the Belgian national government.

² <https://www.food.gov.uk/news-updates/news/2016/15190/fsa-annual-report-of-incidents-2015-published>

Management of risks from chemical contaminants in food

Risk assessment, risk management and decision-making



Nationally

3.1 The FSA is the government department responsible in England, Wales and Northern Ireland for the management of public health risks in relation to food, including those arising from chemical contaminants in food.³ The explanatory notes to the Food Standards Act 1999 identify the FSA as “the primary source of policy advice in relation to food safety and associated areas to the Government as a whole, and to the devolved authorities”. The FSA provides advice to UK Government Ministers and to the devolved administrations in Wales and Northern Ireland, for example on national positions to be taken in discussions of chemical contaminants within the EU and at Codex. Such advice draws on the analysis of evidence on risks conducted by the in-house Chemical Risk Assessment Unit (CRAU) and as required by the three relevant scientific advisory committees – the Committees on Carcinogenicity, Mutagenicity and Toxicity of Chemicals in Food, Consumer

³ This responsibility in Scotland rests with Food Standards Scotland (FSS). Collaboration and co-operation between FSA and FSS on UK-wide issues is supported and governed by bilateral discussion at all levels and by the terms of a Memorandum of Understanding.

Products and the Environment. The FSA is also responsible for the implementation of EU harmonized regulatory controls, including activities such as risk communication, engagement with the food industry on their risk management approaches, provision of guidance and support to local authorities, and response to incidents involving the chemical contamination of food.

3.2 Within these responsibilities, the FSA Board:

- takes decisions on priorities and direction if and when new risks or issues related to a chemical contaminant arise and are likely to require substantial commitment of additional resources to further understand the issue and/or mitigate the risk;
- considers significant changes to FSA policies or positions, for example where establishing or adapting a maximum level could significantly impact on consumer choice or significantly affect UK industry; and
- seeks and gains assurance relating to the work of the executive in these area, as in all others.

The Board is updated on issues of public or political interest relating to chemical contaminants in food through the Chief Executive's reports to Board meetings and through the weekly update to Board members.

3.3 The Board has a particular responsibility – in relation to our work in general, and not just in relation to chemical contaminants in food – for deciding whether an issue significantly effects consumers' capacity to make informed choices. Where the Board's decision is that an issue does have this effect, this brings into play Section 7(2) of the *Food Standards Act 1999* which says that we shall deliver our "function of providing advice and information to the general public" "with a view to ensuring that members of the public are kept adequately informed about and advised in respect of matters which the Agency considers significantly affect their capacity to make informed decisions about food".

3.4 The executive team implements the decisions taken by the Board, designing and executing activities which include:

- reviewing and commissioning science and evidence on global food chain risks and on key chemical contaminant hazards;
- engagement with both consumers and industry to support the delivery of effective risk management and communication; and
- the implementation of risk management interventions such as industry guidance and advice to Ministers on the need for statutory limits for chemical contaminants in food.

3.5 The FSA currently dedicates 14 FTE to work on chemical contaminants issues, across risk assessment, food policy and incident management. This is supported by further expenditure, which totalled £367,000 in 2016/17, including spend on evidence generation, and on expert advice from Scientific Advisory Committees.

Consumer-facing risk communication

3.4 Between 2015 and 2017 the FSA undertook two research projects to improve its insight into customer awareness of contaminants and identify how consumers

wished to be informed about risks. The research concluded that consumers were more concerned about risks relating to other regulated chemicals in food such as additives and pesticides. Furthermore, the research identified that consumers generally had low levels of knowledge around specific chemical contaminants and, where they were knowledgeable, their concerns focussed on manmade chemicals rather than natural contaminants.

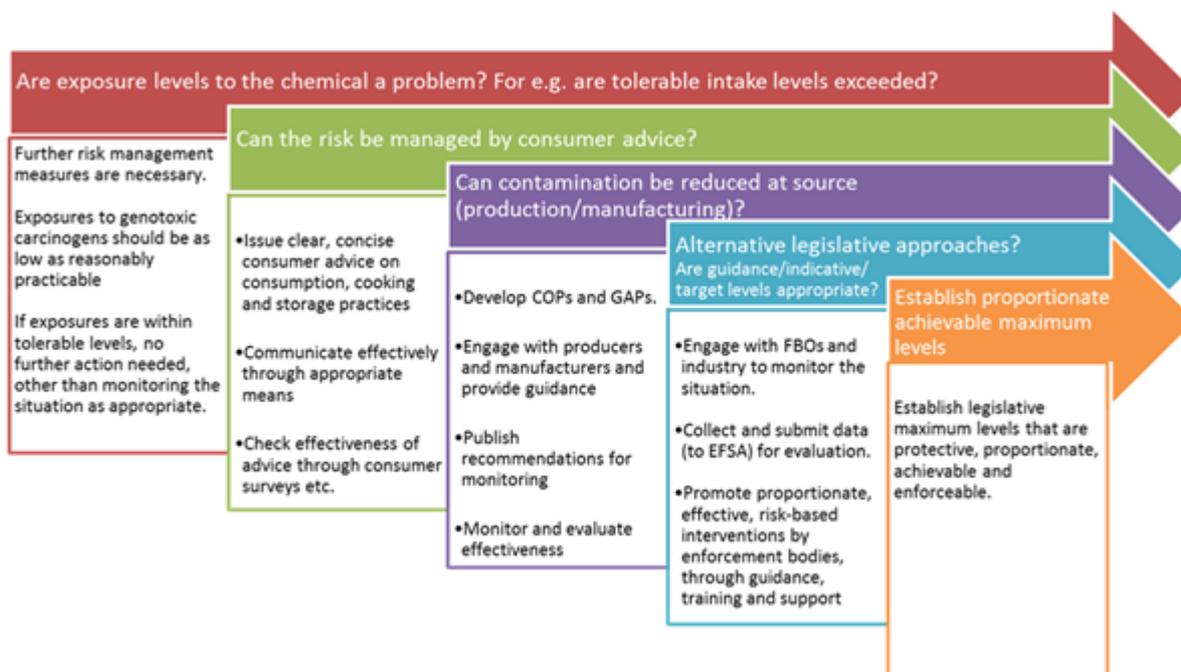
3.5 The research also showed that consumers had a desire to be reassured that risks are being managed, and found the current Government advice on chemical contaminants clear and useful. The research concluded that consumers want appropriate consumer advice and messaging where they can take feasible action at an individual/domestic level, mostly to inform decisions on what to buy, how much to consume and cooking practices.

3.6 In view of the relatively low consumer interest in learning about chemical contaminant risks, the FSA's current consumer engagement activity is focussed on providing a limited range of specific advice on both the FSA and NHS Choices websites, especially to more vulnerable risks⁴. No new activity is currently planned.

Principles

4.1 We have developed a set of principles to guide activity on managing chemical contaminants risks. These principles have at their core the protection of the consumer using science and evidence based research to achieve practical and proportionate outcomes. These principles are used when a chemical contaminant is first identified, and then throughout the process of risk management approach, as a consistent framework for determining the action that is needed and justified in each case.

⁴ <https://www.food.gov.uk/science/arsenic-in-rice>,
<https://www.food.gov.uk/news-updates/news/2015/13461/eating-fish-efsa>



4.2 The application of these principles is underpinned by three key capabilities:

- **Technical Knowledge:** Of the chemicals themselves, industrial processes and best ways to reduce exposure.
- **Influence:** With industry, international partners and consumers to drive change and secure effective proportionate controls.
- **Persistent engagement:** To build evidence and shape meaningful policy interventions.

Challenges and opportunities

5.1 The current regime faces a number of challenges and opportunities over the near to medium term:

- **Regulating our Future:** The food industry is responsible for complying with the contaminants legislation and ensuring that the food they sell is safe. Enforcement of the legislation is undertaken by enforcement officers inland and by Port Health at import. It is important that activity continues to be supported by effective risk based prioritisation to ensure maximum impact. We will need to ensure that assurance and validation approaches incorporate the need for effective identification of chemical contaminant risks and their mitigation by food business operators.
- **Horizon Scanning:** Surveillance and horizon scanning are key to understanding what contaminants may pose a heightened risk in the future. Effective identification and management of chemical contaminant risks will draw on both the new surveillance approach and the proposals in relation to understanding food system risks which are described in a separate paper for this meeting.

- **Consumer information:** Delivering relevant, impactful, cost effective and proportionate information to consumers will remain a challenge for the FSA. Whilst research has shown consumers prioritise other risks, we will look to build on our existing communication of chronic risks.

Conclusion and Recommendation

6.1 Chemical contaminants present a difficult challenge for the FSA in terms of understanding and quantifying the risks, continuing to ensure a relevant regulatory framework and delivering proportionate and impactful consumer advice, especially on chronic risks. The Board is asked to:

- **note** how chemical contaminants pose a complex risk to consumers and impact on the international trade in food;
- **consider** and **discuss** the current framework and roles and responsibilities, at global, regional and national levels, and in particular the division of responsibilities between the Board and executive;
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ANNEX 1

FSA RISK ASSESSMENT APPROACHES

Scientific experts assess these health effects by reviewing relevant data and derive tolerable levels of exposure (health-based guidance values or HBGVs) to chemicals of potential concern. Dietary exposures to these are then estimated to check whether they are within these HBGVs, sometimes described as tolerable daily intakes (TDI)⁵ or acute reference doses (ARfD)⁶. In some instances - for example inorganic arsenic and aflatoxins - the chemical may be known or suspected to be a genotoxic carcinogen i.e. it causes cancer by modifying the genetic material. In these cases, there are no tolerable intake levels and exposure from levels in food should be as low as reasonably achievable (ALARA).

Risk assessors use the Margin of Exposure (MOE) approach to consider possible safety concerns arising from presence in food of chemicals which are both genotoxic and carcinogenic. The MOE is a ratio of two factors and examines, for a given population, the dose at which a small but measurable adverse effect is first observed and the level of exposure to the substance under consideration. The MOE approach may be used not only for genotoxic carcinogens but also for other contaminants for which HBGVs cannot be derived and which may have other toxic endpoints, such as lead and polybrominated diphenyl ethers (PBDEs), both of which are developmental toxins. Use of the MOE can help support risk managers in defining possible actions required to keep exposure to such substances as low as possible.

⁵ **Tolerable Daily Intake (TDI)**: An estimate of the amount of contaminant, expressed on a body weight basis (e.g. mg/kg bodyweight), that can be ingested daily over a lifetime without appreciable health risk

⁶ **Acute reference dose (ARfD)**: Estimate of the amount of a substance in food or drink, expressed on a body weight basis, that can be ingested in a period of 24 hours or less without appreciable health risk

ANNEX 2

EUROPEAN UNION REGULATORY PROCESSES

The basic approach of EU legislation on chemical contaminants begins with EU Regulation 178/2002, setting out the General Principles of Food Law, and is reinforced by Council Regulation (EEC) No 315/93 laying down Community procedures for controlling contaminants in food, as well as other general food safety and hygiene legislation. The key principles can be summarised as:

- All food placed on the market must be safe.
- It is primarily industry's responsibility to ensure that a food is safe.
- Food containing a contaminant to an amount unacceptable from the public health viewpoint shall not be placed on the market.
- Contaminant levels shall be kept as low as can reasonably be achieved (ALARA) following recommended good working practices.
- It is the responsibility of Food Business operators (FBOs) to ensure that appropriate measures are in place and documented in food safety management systems/HACCP to manage the risk from chemical contaminants in food. This is known as due diligence.

Since 1993, the list of chemical contaminants covered by the legislation has expanded as new risks are identified. At present, specific maximum levels for certain contaminants in food are laid down in Commission Regulation (EC) No 1881/2006. A recent example is the EU process of establishing maximum levels for arsenic in foods. Rice was identified as a significant contributor to exposure and the FSA engaged in the EU discussions to ensure that a practicable level was established for rice and rice products reflecting achievability and promoting ALARA. Whilst rice was an important starting point the FSA has supported further monitoring of other foods to gather the necessary occurrence data to be used for discussion on the appropriateness of setting maximum levels for arsenic in other foods.

The EU is also developing other regulatory and related measures such as Recommendations to collect data or to investigate exceedances of performance indicators, as well as regulations promoting specific activity under the scope of the Hygiene Regulation (EC) 852/2004 (which covers HACCP). An example would be the current work to agree an approach at EU level to tackling the issue of acrylamide exposure from the diet. Acrylamide is a process contaminant naturally formed when certain foods are cooked at high temperatures. The UK has been influential in steering EU negotiations away from the setting of strict limits and towards a more proportionate approach which would legally require FBOs to implement reasonable acrylamide mitigation steps from codes of practice as part of their food safety management system.

The Directorate General for Health and Food Safety (DG SANTE) of the EU Commission holds regular working groups, chaired by a Commission representative and attended by national representatives. These expert meetings are specific to a range of contaminant issues. There are expert meetings on agricultural contaminants and plant toxins, environmental and industrial contaminants and Persistent Organic Pollutants. After discussion of proposed legal measures at

working group, votes are taken at meetings of the Standing Committee on Plants, Animals, Food and Feed (SCOPAFF). The FSA represents the UK in this process, attending relevant meetings and liaising with stakeholders to develop UK positions. When considering appropriate levels for maximum limits in food, the Commission and Member States are required to take account of international standards, such as those produced by Codex Alimentarius Commission (CAC), where they exist.

ⁱ Acute adverse effects result from exposure to the contaminant in a short period of time (usually less than 24 hours) whereby severe symptoms develop rapidly and lead quickly to a health crisis

ⁱⁱ Chronic adverse effects result from long term exposure to low concentrations of a contaminant with symptoms that develop slowly

ⁱⁱⁱ Costs of incidents can be difficult to establish but a good analysis of these two major incidents, together with others, is available in *Thomson, Poms and Rose, Quality Assurance and Safety of Crops & Foods 2012, 4, 77–92*