Food Contaminants legislation

Summary
Food chemical contaminants can be defined as substances that have not been intentionally added to food. These substances may be present in food due to environmental contamination (for example toxic heavy metals such as lead), cultivation practices (for example mycotoxins produced by moulds) or production processes (for example acrylamide formed during the baking of bread. If present above certain levels, these substances may pose a threat to human health.
That risk must be understood and managed. Depending on the market and the commodity the rules change. Some regulations are easily interpreted, and some less so. This summary covers the main contaminants and some pointers as to what has been changing recently in the law.

Content:

1. Regulatory Position

The law concerning contaminants in the UK and EU can be summarised:

- food containing an amount of contaminant 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 following recommended good working practices
- maximum levels are set for certain contaminants to ensure that food placed on the market is safe to eat and does not contain these contaminants at levels which could threaten human health.

It is the responsibility of food businesses to ensure food is safe and compliant with food legislation and to ensure due diligence measures are in place and documented to manage the risk from chemical contaminants in food.

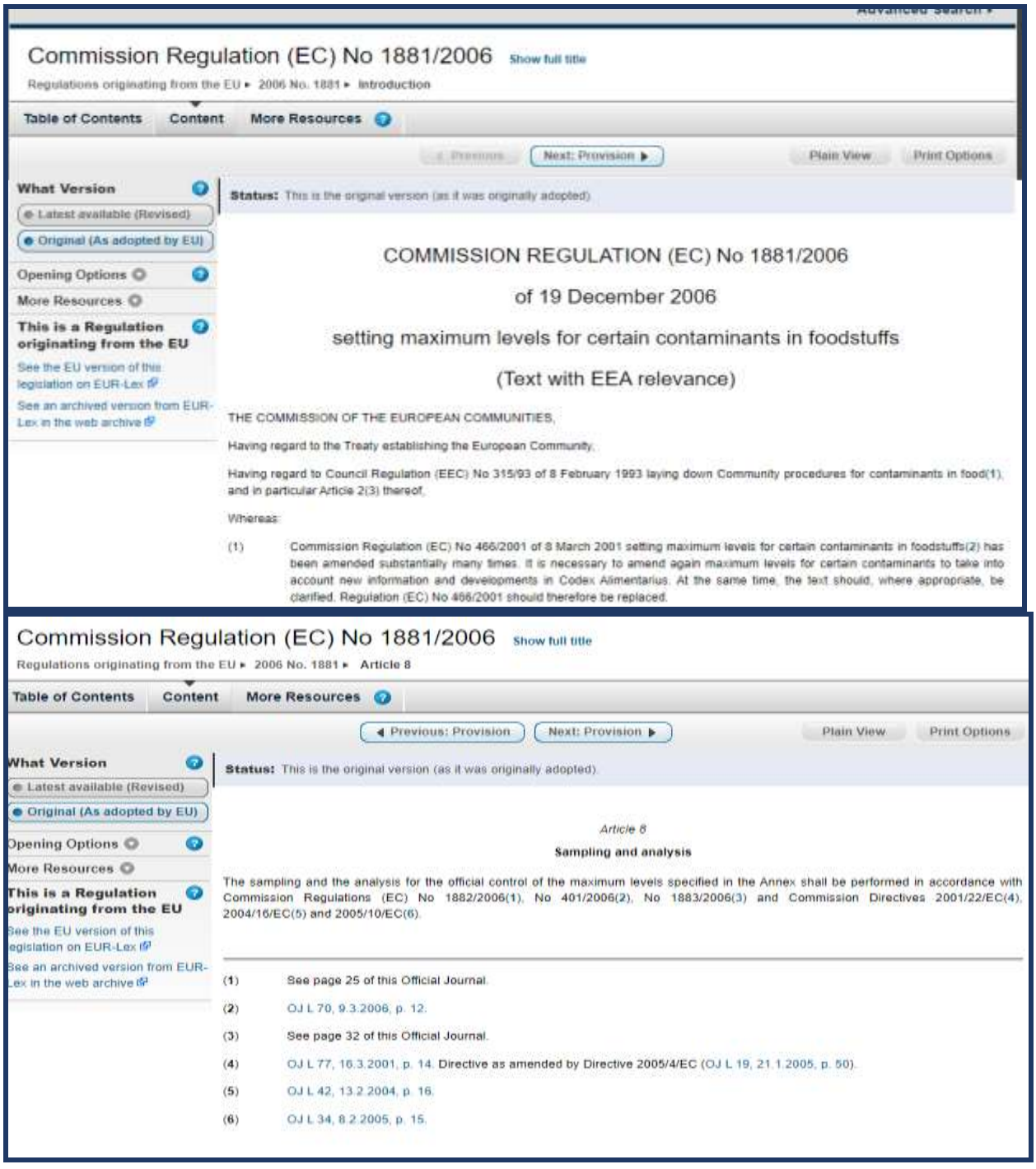
The EU General Food Law Regulation (EC) No 178/2002 sets the general rules on these requirements

Commission Regulation (EC) No 1881/2006 (as amended) sets the specific maximum levels for chemical contaminants in foodstuffs is published on the EUR-LEX website and applies directly in all of the EU & EEA countries plus Northern Ireland.

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1881-20210831&from=EN

The EC make it remarkably easy to use by providing a list of modifications and links directly to the actual document. Includes all of the subsequent 35 amendments

Tracking changes and understanding is an essential part of ensuring raw materials and products meet regulations.



2. Brexit: GB Regulatory divergence

Following the departure of the UK from the European Single Market on 31st December 2021, the law concerning chemical contaminants in the UK/GB has become an increasingly complex regulatory picture, with Great Britain diverging from the EU27 (plus Northern Ireland).

From 1 January 2021, the 'UK retained' version of the Contaminants Regulation EC No 1881/2006 applies in Great Britain.

New European Commission Regulations amending contaminant maximum limits (ML) in the EU from this date ***do not apply in GB.***

This affects the six most recent Commission regulations setting MLs for 3-MCPD esters, pyrrolizidine alkaloids, tropane alkaloids, ergot alkaloids and amending the MLs for cadmium and lead.

However, under the NI Protocol the EU Contaminants Regulation continues to apply directly and these six new Commission

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Regulations ***do apply in Northern Ireland****.*

The link for Great Britain and can be found on the legislation.gov.uk website.
https://www.legislation.gov.uk/eur/2006/1881

Food Commodity Classification
Here is a link to Commission Regulation (EU) 2018/62 which defines the food categories used in the Pesticide MRL Regulation (EC) 396/2005.
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0062&from=EN

The useful tip is,

These are the food categories and names also used in the Contaminants Regulation 1881/2006 so a very useful document

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3. Food Chemical Contaminants - Detail

Food chemical contaminants may be divided into the following categories:

a. Environmental contaminants

- **Toxic metals / elements**

These are potentially harmful chemicals present in food adventitiously as a result of anthropogenic activities or from natural occurrence in soil and rocks. The most important ones are lead, cadmium, mercury and arsenic. These chemicals have a long history of food contamination, some of the levels found having caused serious effects on exposed populations. They can be introduced into the food chain at any point from growth through harvesting, storage and processing. Maximum permitted levels are set in Regulation (EC) No 1881/2006 (as amended) for lead, cadmium, mercury and arsenic in various foods and for tin in canned foods.

The EC last updated this on 31/08/21, it includes the new amendments for lead & cadmium from August

*Tip: It is important to remember that the limits in the regulation for lead, cadmium and mercury apply to **the total metal**, but the limits for arsenic and tin only apply to the **inorganic compounds** of these elements.*

IMPORTANT NOTE: Regulation (EU) No 2021/1317 of 9 August 2021 has newly introduced MLs for Pb in dried spices and salt and revised a few existing MLs for Pb in some other foods. The new limits entered into force on 30 August 2021, all foods on the EU market must comply with these new limits from 28 February 2022. Please note that these new limits do not legally apply within Great Britain (GB) following the UK's departure from the EU. They do however apply within Northern Ireland (NI) under the requirements of the Northern Ireland Protocol.
PAS clients may have different policies on this issue.

Table 1. Example of divergence for Lead (Pb) Legislation in Infant formulae

Infant formulae and follow on formula:	*Lead Maximum (mg/Kg)*
Infant formulae and follow on formula:	
- **Marketed as powder (as sold basis)**	0.050 0.020 from 30.8.21 (not GB)
- **Marketed as liquid**	0.010

Table 2. Example of divergence for Cadmium (Cd) legislation in vegetables

Vegetable	*Cadmium Maximum (mg/Kg)*
Radishes	0.020 from 31.8.21 (not GB)
Beetroots	0.060 from 31.8.21 (not GB)
Celeriac	0.15 from 31.8.21 (not GB)
Garlic	0.050 from 31.8.21 (not GB)
Other bulb vegetables except garlic	0.030 from 31.8.21 (not GB)
Leafy brassica	0.10 from 31.8.21 (not GB)
Brassica other than leafy brassica	0.040 from 31.8.21 (not GB)
Spinaches and similar leaves, mustard seedlings and fresh herbs	0.20 from 31.8.21 (not GB)
Other leaf vegetables	0.10 from 31.8.21 (not GB)
Legume vegetables	0.020 from 31.8.21 (not GB)
Leeks	0.040 from 31.8.21 (not GB)
Celeries	0.10 from 31.8.21 (not GB)

- Nitrates

Nitrate is a natural component of vegetables although the levels present are affected by growing conditions, nitrogen-based fertiliser use and plant species / variety. There are maximum permitted levels for nitrate in lettuce spinach and rocket set out in Regulation (EC) No 1881/2006 (as amended).

- Dioxins and polychlorinated biphenyls (PCBs)

'Dioxins' is a generic term given to polychlorinated dibenzo-p-dioxins and dibenzofurans. Dioxins are very persistent chemicals which can be the unwanted by-products of the manufacture of certain industrial chemicals or are produced during various combustion and incineration processes. The dioxin 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) together with 16 other dioxins which contain chlorine at positions 2, 3, 7 and 8 of the molecules are of toxicological concern.
Polychlorinated biphenyls are mixtures of up to 209 individual chlorinated compounds (known as congeners). Large quantities of PCBs were produced world-wide for use

in electrical equipment: between 1930s and 1980 the estimated total world production was between one and two million tonnes. Of the 209 congeners of PCBs less than 10% have been reported as having toxicological effects. The global use of PCBs has been severely reduced or phased out.
Both dioxins and PCBs enter the human food chain mainly through the intake of animal fats. They cause a wide range of effects affecting the endocrine system in humans and wildlife, causing immune system effects and cancer. Maximum permitted levels are set in Regulation (EC) No 1881/2006 (as amended) for these substances in animal fats and various foods containing animal fats.

- Perfluoralkylated substances (PFAS)

PFASs have been manufactured and used in a variety of industries around the world since the 1940s including textile, carpet and leather treatment (water and dirt proofing), surfactants, firefighting foams, metal plating and paper grease-proofing treatments. They don't break down in the environment or in the human body and can accumulate over time. Exposure to PFASs may lead to adverse health effects. People can be exposed to PFASs in different ways, including from food or through food packaging containing PFASs, or equipment that contained PFASs during food processing. The European Commission is currently considering setting maximum levels of these substances in Regulation (EC) No 1881/2006

- Polyaromatic Hydrocarbons (PAHs)

PAHs are combustion products that can contaminate foods via environmental contact during e.g., heating and drying processes. Maximum levels in certain foods are in place in Regulation (EC) No 1881/2006 (as amended) for PAHs, in particular for benzo(a)pyrene.

b. **Process Contaminants (also see Neoformed contaminants paper on PAS website**
https://www.paslabs.co.uk/wp-content/uploads/2021/04/Managing-NFCs-in-the-bakery-sector.pdf)

Process contaminants are potentially toxic chemicals that are formed when foods are processed, typically during a heating process. The main process contaminants of concern are:

- Acrylamide

This is a chemical that forms naturally in starchy food products during high-temperature cooking, including frying, baking, roasting and also industrial processing, at +120°C and low moisture. The main chemical process that causes this is known as the Maillard Reaction; it is the same reaction that 'browns' food and affects its taste. Acrylamide forms from sugars and amino acids (mainly asparagine) that are naturally present in many foods. Acrylamide is found in products such as potato crisps, French fries, bread, biscuits and coffee.
Commission Regulation (EU) 2017/2158 mandates that food business operators are required to take account of strict industry codes of practice for certain foods for mitigating acrylamide formation as part of their food safety management systems. 'Benchmark' guidance values for acrylamide have been established for many of these foods. As yet no statutory maximum levels have been set, but this is planned for the future.

- Glycidyl esters

Glycidyl fatty acid esters (GE) are process contaminants generated during the high temperature deodorisation step of edible oil refining. GEs are found at the highest levels in palm oil/fat, but most refined vegetable oils/fats contain significant quantities.
Maximum levels for glycidyl esters (based on glycidol) are set in Regulation (EC) No 1881/2006 (as amended) for vegetable fats & oils & fish oils sold as such or used as food ingredients.

- 3-MCPD esters

3-MCPD esters are also formed in refined vegetable oils (particularly palm oil), infant formulae, fast foods and certain thermally treated and fermented foodstuffs.
Maximum levels for glycidyl esters (based on glycidol) are set in Regulation (EC) No 1881/2006 (as amended) for vegetable fats & oils & fish oils sold as such or used as food ingredients and infant foods.

- Furans

Furans are chemical contaminants that form naturally during heated food processing, including cooking. Highest concentrations of furan have been found in coffee, particularly in roasted beans/powders. Other foodstuffs with significant but lower levels of furan include beer (from roasted malt) and products such as baby foods and vegetables that have been heat-treated in sealed containers. So far, no regulatory maximum levels of furans in foods have been set, although this is under consideration. (21.6.2021) The European Food Safety Authority (EFSA) recommended collecting additional data on such occurrence. Therefore, the Commission is considering adopting a Recommendation on the monitoring of the presence of furan and alkylfurans in food, in order to gather the necessary occurrence data, in view of regulating the presence of furans and methylfurans in food, including baby food, to ensure a high level of public health protection.

c. Mycotoxins

Mycotoxins are natural toxins produced by certain fungi infecting agricultural crops during growth. These toxins occur at very low levels from parts per million down to parts per billion (µg/kg). Some toxins cause acute illness such as vomiting, but the major concern is the long-term chronic effects - some of the mycotoxins may be associated with cancer in humans. Mycotoxins are important chemical contaminants in the food chain and unacceptably high levels are a major reason for imports being rejected on entry into the EU and UK.
Most mycotoxins are heat stable and will survive food processing temperatures and be present in finished product.
There are many mycotoxins but the most significant are:

- aflatoxins - associated with nuts, cereals and spices,
- ochratoxin A - linked to cereals, coffee beans, grape products such as wine, juice and dried fruit, cocoa and some spices,
- trichothecene toxins, fumonisins and zearalenone - are typically associated with cereals,
- patulin - has historically been a significant problem in apple juice.
- ergot alkaloids - in cereals

There are UK/EU legislative limits for these toxins set in Regulation (EC) No 1881/2006 (as amended) for a variety of foodstuffs.

*Note that new EU food regulations entering into force from 1 January 2021 (including Regulation 2021/1399) do not apply directly in Great Britain ('GB' - England, Wales and Scotland), following the end of the Brexit transition period. They do apply in Northern Ireland under the terms of the Northern Ireland Protocol.
It is currently unknown whether the Authorities in Great Britain will eventually pass domestic legislation to introduce these new ergot sclerotia / ergot alkaloid limits.
Food manufacturers will all make their own decision as policy that consider ingredients used to manufacture and where their foods are sold.

This is the ergot alkaloids regulation:
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R1399&from=EN
A simple excerpt

Table 3: Excerpt from new EU legislation of Ergot Alkaloids

The Annex to Regulation (EC) No 1881/2006 is amended as follows:

(1) In section 2, the entries '2.9 Ergot sclerotia and ergot alkaloids' are replaced by the following:

Foodstuffs [1]		Maximum level
'2.9	**Ergot sclerotia and ergot alkaloids**	
2.9.1.	**Ergot sclerotia**	
2.9.1.1.	Unprocessed cereals([18]) with the exception of — maize, rye and rice	0,2 g/kg
2.9.1.2.	Unprocessed rye([18])	0,5 g/kg until 30.6.2024 0,2 g/kg as from 1.7.2024
2.9.2.	**Ergot alkaloids** (*)	
2.9.2.1.	Milling products of barley, wheat, spelt and oats (with an ash content lower than 900mg/100g)	100 µg/kg 50 µg/kg as from 1.7.2024
2.9.2.2.	Milling products of barley, wheat, spelt and oats (with an ash content equal or higher than 900mg/100g) Barley, wheat, spelt and oats grains placed on the market for the final consumer	150 µg/kg
2.9.2.3.	Rye milling products Rye placed on the market for the final consumer	500 µg/kg until 30.6.2024 250 µg/kg as from 1.7.2024
2.9.2.4.	Wheat gluten	400 µg/kg
2.9.2.5.	Processed cereal based food for infants and young children (3) (24)	20 µg/kg

However, the UK retained legislation has not been amended and so looks very different, in particular note that cereals are now named

Table 4.Table 3: Excerpt from UK retained (GB) legislation of Ergot Alkaloids

The Annex to Regulation (EC) No 1881/2006 is amended as follows:

(1) In Section 2, the following entry 2.9 is added:

'2.9	Ergot sclerotia and ergot alkaloids	
2.9.1.	Ergot sclerotia	
2.9.1.1.	Unprocessed cereals ([18]) with the exception of corn and rice	0,5 g/kg[a]
2.9.2.	Ergot alkaloids[b]	
2.9.2.1.	Unprocessed cereals ([18]) with the exception of corn and rice	—[c]
2.9.2.2.	Cereal milling products excluding corn and rice milling products	—[c]
2.9.2.3.	Bread (including small bakery wares), pastries, biscuits, cereal snacks, breakfast cereals and pasta	—[c]
2.9.2.4.	Cereal-based food for infants and young children	—[c]

[a] The sampling shall be performed in accordance with point B of Annex I to Commission Regulation (EC) No 401/2006 (OJ L 70, 9.3.2006, p. 12).
The analysis shall be performed by microscopic examination.

[b] Sum of 12 ergot alkaloids: ergocristine/ergocristinine; ergotamine/ergotaminine; ergocryptine/ergocryptinine; ergometrine/ergometrinine; ergosine/ergosinine; ergocornine/ergocorninine.

[c] Appropriate and achievable maximum levels, providing a high level of human health protection, shall be considered for these relevant food categories before 1 July 2017.'

(2) Footnote 18 replaced by the following:

d. **Other chemical contaminants in foods:**

- **Inherent Plant Toxins**

These are substances that naturally occur in plants used as foods that are potentially harmful when present at high levels, Regulation (EC) No 1881/2006 (as amended) sets maximum levels for the following:

- Erucic Acid – In vegetable oils
- Tropane Alkaloids – In maize, millet, sorghum, buckwheat or their derived products and in herbal infusions. Just published is: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R1408&from=EN
- Pyrrolizidine Alkaloids – In tea, herbal infusions, dried herbs, cumin seeds
- Hydrogen Cyanide – Currently a limit is set for unprocessed apricot kernels. The European Commission is now proposing to set MLs in unprocessed linseeds, unprocessed almonds (placed on the market for the final consumer), cassava and cassava flour.
- Opium alkaloids – The European Commission is proposing to set MLs for poppy seeds as sold and breads / fine bakery wares containing poppy seeds

- **Pesticides and veterinary medicines residues**

Residues of these are sometimes considered to be chemical contaminants, however they result from authorised intentional use by farmers in the growing of crops or the raising of animals. Regulations are in place setting maximum residue limits for these substances in foods.

- **Residues from Food Packaging**

Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food sets out a general requirement that all food contact materials and articles should not transfer their constituents to food in quantities that could endanger human health or cause unacceptable changes in the composition of food or a deterioration to its organoleptic properties. Regulation (EU) No 10/2011 on plastic food contact materials sets out a positive list of authorised substances that may be used in their manufacture together with migration limits from the plastic into the food.