

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

Aim and scope

1 This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the ^{F1}... market. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.

2 For the purposes of paragraph 1, this Regulation lays down the general principles governing food and feed in general, and food and feed safety in particular, ^{F2}...

^{F2}...

It lays down procedures for matters with a direct or indirect impact on food and feed safety.

3 This Regulation shall apply to all stages of production, processing and distribution of food and feed. It shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption.

Textual Amendments

F1 Word in Art. 1(1) omitted (31.12.2020) by virtue of [The General Food Law \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/641\)](#), regs. 1, **6(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Words in Art. 1(2) omitted (31.12.2020) by virtue of [The General Food Law \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/641\)](#), regs. 1, **6(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 2

Definition of ‘food’

For the purposes of this Regulation, ‘food’ (or ‘foodstuff’) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

‘Food’ includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes

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water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

‘Food’ shall not include:

- (a) feed;
- (b) live animals unless they are prepared for placing on the market for human consumption;
- (c) plants prior to harvesting;
- (d) medicinal products within the meaning of Council Directives 65/65/EEC⁽¹⁾ and 92/73/EEC⁽²⁾;
- (e) cosmetics within the meaning of Council Directive 76/768/EEC⁽³⁾;
- (f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC⁽⁴⁾;
- (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;
- (h) residues and contaminants.

Article 3

Other definitions

For the purposes of this Regulation:

1. ‘food law’ means the laws, regulations and administrative provisions governing food in general, and food safety in particular, ^{F3} ...; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals;
2. ‘food business’ means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food;
3. ‘food business operator’ means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control;
4. ‘feed’ (or ‘feedingstuff’) means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;
5. ‘feed business’ means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding;
6. ‘feed business operator’ means the natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control;
7. ‘retail’ means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;

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8. ‘placing on the market’ means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves;
9. ‘risk’ means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;
10. ‘risk analysis’ means a process consisting of three interconnected components: risk assessment, risk management and risk communication;
11. ‘risk assessment’ means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;
12. ‘risk management’ means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;
13. ‘risk communication’ means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;
14. ‘hazard’ means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;
15. ‘traceability’ means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution;
16. ‘stages of production, processing and distribution’ means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed;
17. ‘primary production’ means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products;
18. ‘final consumer’ means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity.
- [^{F4}19. “appropriate authority” means—
- a in relation to England, the Secretary of State;
 - b in relation to Wales, the Welsh Ministers;
 - c in relation to Scotland, the Scottish Ministers;
20. “third country” means any country or territory other than the British Islands.]

Textual Amendments

- F3** Words in [Art. 3\(1\)](#) omitted (31.12.2020) by virtue of [The General Food Law \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/641\)](#), regs. 1, [7\(a\)](#); 2020 c. 1, Sch. 5 para. 1(1)

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F4 Art. 3(19)(20) inserted by [The General Food Law \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/641\)](#), regs. 1, [7\(b\)](#) (as substituted by [S.I. 2020/1504](#), regs. 1(2), [10\(3\)](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

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- (1) OJ 22, 9.2.1965, p. 369. Directive as last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).
- (2) OJ L 297, 13.10.1992, p. 8.
- (3) OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2000/41/EC (OJ L 145, 20.6.2000, p. 25).
- (4) OJ L 359, 8.12.1989, p. 1. Directive as last amended by Directive 92/41/EEC (OJ L 158, 11.6.1992, p. 30).

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