

COMPLIANCE IN YOUR MARKET

FOOD PRODUCTS
REGULATIONS**Food Safety**

All business operators (BO) that take part in food production in the EU are obliged to be compliant with Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA), and outlining the procedures in matters of food safety. In connection with the roles and obligations of the different BOs, information should be disclosed through the supply chain to ensure a high level of food safety as well as:

- ▶ Ensure the free movement of food;
- ▶ Protection of the consumer's economic interests, including fair practices in food trade;
- ▶ Plant and animal health protection; and
- ▶ Environmental protection.

This regulation also covers important aspects such as:

- ▶ Traceability;
- ▶ Recall;
- ▶ Risk analysis;
- ▶ Precautionary principle;
- ▶ Rapid Alert System for Food and Feed (RASFF);
- ▶ Crisis management.

Regulation (EC) No 178/2002 defines rules for the well-known HACCP system (Hazard Analysis and Critical Control Point). Regulation (EU) No 2017/625, Regulation (EC) No 852/2004, and Regulation (EC) No 853/2004 are strictly connected with Regulation (EC) No 178/2002. They introduce the verification of compliance with feed and food law, animal health and animal welfare rules (Regulation (EU) No 2017/625), the hygiene of foodstuffs (Regulation (EC) No. 852/2004), and the specific hygiene rules for food of animal origin (Regulation (EC) No 853/2004).

Food Labeling

Regulation (EU) No 1169/2011 establishes all required information for food labeling. It applies to all business operators at every stage of the food chain. The main parts of this regulation cover:

- ▶ Mandatory food information;
- ▶ Food business operator responsibilities;
- ▶ Food naming and ingredient presentation rules;
- ▶ Allergen labeling;
- ▶ Nutritional data presentation, etc.

Food Additives

Regulation (EU) No 1333/2008 on food additives presents the list of authorized substances which can be safely used in certain food categories in the EU.

- ▶ Food additives function;
- ▶ Level of all food additives in combination.

Food producers need to comply with the listed food additives specifications.

Food Flavourings

Regulation (EU) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods, divides flavourings into specific categories:

- ▶ Flavouring;
- ▶ Natural flavouring;
- ▶ Natural „x“ flavouring (x can be for instance lemon, strawberry or any other);
- ▶ Natural „x“ flavouring with other natural flavourings.

For very specific, unique flavouring substances, such as smoke flavourings, there is a separate regulation: Regulation (EC) No 1321/2013. The classification of flavourings depends on the identity of the substances, as well as the following aspects:

- ▶ The type of flavourings and the countries in which the products will be sold. These determine the pictures allowed to be used on the packaging;
- ▶ Claims can be different based on which type of flavouring is used;
- ▶ Flavourings can be used not only for food products, but also for non-food purposes.

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Regulation (EU) 1332/2008 on food enzymes presents:

- The definition of a food enzyme;
- Labeling of food enzymes;
- Conditions of use of food enzyme in foods;
- List of approved food enzymes.

Authorization processes for substances intended to be used in food

Regulation (EU) 1331/2008 establishes a common EU authorization procedure for food additives, food enzymes and food flavourings.

The required dossier includes document preparation as well as required testing.

Claims on Food

Regulation (EC) No 1924/2006 on nutrition and health claims made on foods defines both categories of claims in order to ensure a high level of consumer protection.

There are listed definitions for claims of

- 'low'/'high'/'free'/'very' of nutritional or energy;
- 'low'/'no added'/'source' of nutritional or energy values;
- health claims.

A health claim requires an EU authorization.

Organic Food

Regulation (EU) 2018/848 on organic production and labeling of organic products, and repealing Regulation (EC) No 834/2007, imposes an obligation across the organic certification supply chain. The following are key aspects for obtaining in organic certification:

- Approval of organic raw materials;
- Cooperation with Organic Certification Bodies;
- Selling organic product across the different countries (EU & outside EU);

- Organic labeling requirements.

Novel Food

Regulation (EU) 2015/2283 on novel foods introduces the regulatory pathway for obtaining an EU authorization for novel foods. The regulation presents different categories of the novel foods. A food is considered novel, if it was not produced or used to a significant degree in the EU prior to 15 May 1997.

Our Food Regulatory Services

- Regulatory compliance checks for food ingredients and customized regulatory strategies to introduce food ingredients to the EU marketplace;
- Food product formula checks (including review of the level of added substances in accordance with the food category);
- Registration process for: novel foods, food enzymes, food additives, food flavourings;
- Preparation and Submission of the novel food, food additive, food enzyme, and food flavoring dossiers to EU Authorities;
- Label compliance check;
- Environmental labeling;
- Claim approval process;
- Organic products requirements: certifications, formula check, labeling;
- Study monitoring for analytical testing;
- Food regulatory trainings.

knoell as your go-to partner for registration – worldwide

Our strength is to be where it matters: with sites in Europe, Asia and North America and an extensive network of co-operation partners, we combine global know-how with local experience and intercultural competence.

For further information on food regulations and our services, please contact us: FfCM.NA@knoell.com



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