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VCI-Guide for

Good hygiene practice in food additives manufacture

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Regulation (EC) No 178/2002[1] lays down the general principles and requirements of food law and food safety procedures. Food additives fall under the definition of "food" according to Article 2 of the Regulation. Consequently, the general food law rules also apply for food additives.

Regulation (EC) No 852/2004 (Food Hygiene Regulation)[2] stipulates general rules on food hygiene for food business operators. This Regulation applies for all stages of production, processing and distribution of food ("from farm to fork"). Thus, it is applicable to the manufacture of food additives too.

Quite often, the industrial manufacture of food additives differs significantly from the production processes for conventional foodstuffs. This VCI Guide is about the interpretation and implementation of the food law requirements regarding food additives manufacture. As an industry guide for good manufacturing practice (GMP) in the meaning of the Food Hygiene Regulation, it is addressed to manufacturers of food additives.

Content

[1] 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 (consolidated version of 30 June 2014)

[2] Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (consolidated version of 20 April 2009)

1. Goal of the Food Hygiene Regulation

The Food Hygiene Regulation wants to ensure a high level of health protection concerning the safety of foodstuffs – from primary production to distribution to consumers. The main responsibility for the safety of a foodstuff rests with the food business operator. Food safety must be ensured at all levels of the food chain, including primary production. Food business operators are under the obligation to comply with the relevant general hygiene rules by putting into practice the methods based on the HACCP principles[3].

According to Article 2 of the Food Hygiene Regulation, the term “food hygiene” means the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff, taking into account its intended use. In Germany, this general hygiene requirement is concretized in the national Food Hygiene Ordinance (Lebensmittelhygiene-Verordnung/LMHV): through the obligation to ward off any “adverse influence”. Therefore, in food additives manufacture all the necessary and suitable measures have to be taken to eliminate adverse influences or sources of hazards or to minimize them as far as technically possible.

2. Manufacture of food additives

2.1. Manufacture

Additives are manufactured using a large variety of different methods. These range from chemical synthesis or fermentative processes to physical methods, enzymatic reactions or the purification of natural substances.

[3] Principles of hazard analysis and critical control points (HACCP)

There is a wide range of pre-products – from natural, microbiologically sensitive products to chemical intermediates. Pre-products are processed into food additives by way of suitable methods (e.g. synthesis or purification) and subsequent substance-appropriate filling, storage and transport. Pre-products are not necessarily foodstuffs.

2.2. Borderline to other substances

Substances can be manufactured for many different uses. A food additive is given through the intended use in a foodstuff for technological purposes. At that moment in time, all the relevant legal requirements to food additives have to be fulfilled. These include, inter alia, compliance with purity criteria[4], adequate manufacture[5], as well as legally compliant packaging[6] and labelling[7].

Substances that meet these requirements can be designated and labelled as “food additives”. E numbers can be used only if all of the above-mentioned legal requirements are fulfilled. Compliance with specifications alone is not enough for an E number designation.

Pre-products for food additives manufacture do not need to meet the requirements to food additives. For example, in manufacture within chemical synthesis a pre-product can be a chemical substance that is not a foodstuff.

3. Purity criteria

Food additives have to fulfil, in particular, the purity criteria stipulated in Regulation (EU) No 231/2012. This Regulation lays down the specifications for approved food additives listed in Regulation (EC) No 1333/2008.

An important measure for the control of food additives is to check compliance with the relevant purity requirements. This can be done, in particular, by means of the following:

[4] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (consolidated version of 18 August 2017)

[5] Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (consolidated version of 20 April 2009)

[6] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (consolidated version of 7 August 2009)

[7] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (consolidated version of 18 August 2017)

- Monitoring of pre-products,
- in-process analytics,
- process control systems that enable a permanent monitoring and control of e.g. temperature, pressure and pH value,
- statistical process control, or
- analysis of manufactured additives.

When determining the extent to which measures for purity criteria control are carried out, the general quality assurance principles have to be taken into account. These include, for example, fluctuations occurring in analytical values and the differential between existing limit values for individual criteria and actual measured values.

4. Hygiene requirements and application of the HACCP concept in food additives manufacture

4.1. HACCP

The HACCP principles apply in food production. These are prescribed in Article 5 of the Food Hygiene Regulation and brought in a more precise form in the “Commission Notice on the implementation of food safety management systems covering prerequisite programs (PRPs) [8] and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses”[9].

Ensuring the safety of food additives requires not only compliance with hygiene standards but also a comprehensive risk assessment of manufacture.

In additives manufacture, HACCP must be applied at least from the last quality-relevant production step. For this production step, all raw materials and pre-products, media (e.g. water), contact materials, individual process steps and premises have to be included in the risk assessment according to the existing requirements of the Food Hygiene Regulation. Should risks be known from earlier processes, these need to be included in the assessment, too.

For example, the last purification step can be evaluated. However, decanting alone cannot be deemed a quality-relevant production step.

[8] PRPs = Prerequisite Programs (auf Deutsch „Basishygienemaßnahmen“ oder „Präventivprogramme“)

[9] Official Journal of the European Union, C 278, 30 July 2016, p. 1

4.2. Food premises

In order to check which requirements apply to premises, rooms, facilities, utensils and staff, as a matter of principle a distinction must be made between additives that can constitute a nutrient medium for microorganisms and additives that are microbiologically inert. Microbiologically sensitive additives need to undergo regular microbiological controls.

Food additives are often manufactured in closed production plants where contamination from outside is usually not possible. In open production plants and often also in filling, such contamination cannot always be ruled out.

Where closed production plants or closed parts of production plants are operated properly and without disruption, an external “adverse influence” during the production process can be excluded. Therefore, the intended protective purpose under the Food Hygiene Regulation needs to be ensured for such plants or parts of plants without having to make any additional requirements to premises or buildings.

Existing hygiene rules have to be observed for open production plants and for the filling of food additives in general. The protective purpose under the Food Hygiene Regulation can be deemed fulfilled if those parts of a building or those rooms where an open manufacture or the filling of food additives take place come up to the requirements of the Regulation. The guidance documents by the European Commission provide assistance in the implementation of special hygiene requirements[10].

4.3. Articles and equipment

The use of unsuitable materials and auxiliaries in production can lead to adverse effects on the end product.

Therefore, materials for production plants, auxiliaries and articles that come into contact with food additives have to be chosen in such a way that they have no adverse effects and, in particular, do not release any unavoidable contaminants. Guidance documents and recommendations (e.g. from suppliers) for the use and application of such materials, auxiliaries and articles as well as instructions for use, work or operating instructions elaborated for this purpose and, in particular, existing legal provisions[11] have to be complied with. Compliance must be monitored.

For waste containers, the rules of the Food Hygiene Regulation are to be applied mutatis mutandis, particularly where waste products cannot be treated as normal waste from food production due to special properties (e.g. corrosivity).

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[10] https://ec.europa.eu/food/safety/biosafety/food_hygiene/guidance_en

[11] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (consolidated version of 7 August 2009); also see chapter 4.6

4.4. Water

Where water is used in food additives manufacture, this has to be done in accordance with existing rules. In particular, regarding the last quality-relevant production step, it is referred to Annex II Chapter VII no. 3 of the Food Hygiene Regulation. Quotation:

"Recycled water used in processing or as an ingredient is not to present a risk of contamination. It is to be of the same standard as potable water, unless the competent authority is satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form."

Concerning steam, reference is made to Annex II Chapter VII no. 5 of the Food Hygiene Regulation. Quotation:

"Steam used directly in contact with food is not to contain any substance that presents a hazard to health or is likely to contaminate the food."

4.5. Personal hygiene

The need for good personal hygiene has to be expressly emphasized to staff working in open production plants or in the filling of food additives. Compliance with these hygiene rules must be monitored regularly. Personal hygiene includes, in particular, the wearing of clothing that excludes adverse effects on the products to be manufactured or filled. Here, a compromise might have to be found between wearing protective clothing and safety clothing (e.g. protective helmets).

Before commencing this activity, staff working in the manufacture and filling of food additives have to be informed about the need to comply with the measures required under the Food Hygiene Regulation. In the event of changes in production processes or where disruptions become known, staff in the impacted plants or parts of plants have to be informed about measures to avoid or eliminate the problems that have occurred and they need to undergo relevant training in regular intervals.

4.6. Packaging

The packaging of food additives must meet the legal requirements for food contact materials and the labelling requirements[12]. Rules under the chemicals legislation are to be observed where applicable.

General requirements for food contact materials are laid down in Regulation (EC) No 1935/2004. These are concretized specifically for materials, for example:

[12] Regulation (EC) No 1333/2008 and specific rules for dangerous substances where applicable

- Plastics: Regulation (EU) No 10/2011[13]
- Paper: BfR recommendations on food contact materials[14] - XXXVI. Paper and Board for Food Contact (BfR = German Federal Institute for Risk Assessment)
- Silicone: BfR recommendations for food contact materials – XV. Silicones

Furthermore, food contact materials need to be manufactured according to Regulation (EC) No 2023/2006[15] on good manufacturing practice (GMP).

A comprehensive overview is given e.g. in the German standard DIN 10528:2017-08: “Food hygiene – Guideline for the selection of materials used in contact with foodstuffs – General principles".

5. In-house measures and controls

In-house measures to identify and control hazards are intended for an early detection of deviations from the normal production process and for thus avoiding adverse effects on products right from the outset or for an early identification of the impacted production batches. A monitoring of physical, chemical and microbial parameters can be necessary for this purpose.

Moreover, for each product a hazard identification and analysis concept is developed which identifies the critical chemical, physical and microbiological points for possible deviations from the normal production process and lays down appropriate controls and safety and correction measures. This concept is documented and updated in case of changes to production plants or production processes and in the light of additional findings on possible deviations.

In the above exercise, the manufacturer is to define a production stage from which the manufacture of the food additive allows a risk and hazard analysis. In multi-step processes that stage can be defined as the one of the pre-product from which all critical factors up to the end product are covered. It is up to the food additive manufacturer to define such stages at his own responsibility and to provide a written justification and substantiation for this definition.

[13] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (consolidated version of 19 May 2017)

[14] Database BfR Recommendations on Food Contact Materials
https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp

[15] Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food (consolidated version of 17 April 2008)

6. Imports

In order to protect consumers against adverse changes in the meaning of the Food Hygiene Regulation, as a matter of principle the same requirements must be made to imported goods as to food additives manufactured within the purview of the Food Hygiene Regulation.

For food additives that are not manufactured at the own responsibility of the distributor, the distributor has to take appropriate measures to ensure that the requirements in the meaning of the Food Hygiene Regulation are fulfilled. Suitable for this are, for example, supplier audits aiming to comply with the Food Hygiene Regulation combined with relevant quality assurance agreements or the proof of a hazard identification and control system at the manufacturer.

7. Example: Propylene glycol

Propylene glycol is a typical industrial chemical. The current global demand amounts to roughly 2 million tonnes annually. Out of this total, around 30% go into consumer-related applications (e.g. foodstuffs, cosmetics or medicines). Propylene glycol is approved in the EU as a carrier in food additives, food enzymes and flavourings and in nutrients with the E number designation E 1520.

Propylene glycol is continuously manufactured in a closed single-purpose system. The last step is a distillation where the mono propylene glycol is separated from the other propylene glycols and continuously collected in a storage container. The production stages that undergo a risk and hazard analysis (HACCP) start with the synthesis of the educts and end with the distillation. Additionally, all other influencing factors (inputs, equipment, packaging materials, filling, storage etc) are also included in the risk and hazard analysis (HACCP). Every batch that is placed on the market as a food additive is independently tested and released in accordance with the regulatory requirements.

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