

Legal aspects regarding product innovations in the food sector

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Abstract

Numerous legal bases need to be considered when developing products in the food sector, in terms of both German national law and European legislation. Additionally, various guidelines and guiding principles are used in practice to clarify legal issues. The aim of this overview is to summarize the most important legal bases applicable to food innovations, to outline their possible implications and to facilitate a methodological approach for developers. To begin with, relevant terms like ‘food’, ‘medicinal product’, ‘novel food’ etc. are defined and consideration is given to aspects of hygiene and food safety. This is followed by a focus on the opportunities and limits of food fortifications as well as the use of enzymes, aromas and additives, but also basic information on the potential to mislead through product labelling.

Keywords: food law, food industry, food startups, product innovation, product development, nutriCARD

vations, an increasing number of stakeholders are non-profit-oriented institutions like universities, technical colleges and other research facilities. Small and medium-sized enterprises, which often lack the financial or human resources to develop new and, for example, healthier or more sustainable foods, can benefit especially from this research. Furthermore, as cooperation partners they can contribute their valuable practical knowledge [3]. The four competence clusters for nutrition that have been supported by the German Federal Ministry of Education since 2015 focus on these matters. The nutriCARD cluster (♦ Box “nutriCARD”) concentrates on nutrition for cardiovascular health: Besides specializing in basic research and communication, the development of foods (which have positive effects on cardiovascular health) forms an integral area of focus. This development comprises innovative approaches to reformulation, e.g. the fortification of sausages with fibre or plant proteins, eggs with increased vitamin D content, yoghurt with long-chained omega-3 fatty acids, but also concepts for nutrition education in day-care centers or the optimization of recipes in public catering.

In view of the direct costs of 16.8 billion euros a year in Germany caused by an excessive intake of saturated fatty acids, salt and sugar [4], the production of healthier alternatives to traditional foods is a task of high social relevance, but also one of considerable political and economic importance.

Background and approach

Vegan burgers, bread with chia seeds, “Lyoner” sausages with cardiovascular benefits, locally sourced organic lemonades – the food and beverage industry invests approximately 300 million euros a year in the research and development of new foods. But of this amount, more than 60% is from large corporations which account for only approximately 10% of all companies [1]. While criteria like health and sustainability are gaining in significance for consumers [1], these are less important for the (European) food industry. The key driver of innovation here is ‘pleasure’, which is behind 56% of all innovations. Health aspects are accountable for only 20% of innovations [2]. Since primary commercial interests are not the only goal of product inno-

Citation:

Volkhardt I, Christen O, Stangl GI, Braun PG, Lorkowski S, Meier T (2017) Legal aspects regarding product innovations in the food sector. *Ernahrungs Umschau* 64(11): 158–165

The English version of this article is available online:
DOI: 10.4455/eu.2017.042

nutriCARD



The competence cluster for nutrition and cardiovascular health (nutriCARD) is a joint research project of Martin Luther University Halle-Wittenberg, Friedrich Schiller University Jena and Leipzig University supported by the German Federal Ministry of Education and Research. The interdisciplinary consortium includes numerous partners from food industry and non-profit organizations. The aim of the cluster is to develop a scientific infrastructure which investigates the relationship between nutrition and cardiovascular health and achieves an improvement in cardiovascular health by developing and optimizing foods as well as strategies for nutrition and exercise which are accompanied by actions based on communication and education policy.

However, to successfully implement new foods on the market there are numerous legal aspects to consider; these are explained in the following. This paper can be used as supporting information and a guideline on how to successfully bring to market new foods with positive cardiovascular properties. Furthermore, the paper also aims to develop a basic understanding of legal considerations, so as to pave the way for developers to elaborate a methodological procedure.

Methods

The approach of this paper is a qualitative review of relevant literature. National and European food legislation databases [5, 6] were searched to address the issues at hand (♦ Box “National law, EU legislation or guidelines?”). Aspects of particular relevance to food innovations were examined. Other documents were considered in addition to these laws, albeit ones that are not of a legally binding nature. These become significantly more relevant if e.g. public conceptions are called into question in terms of fair or unfair competition or misleading, deception and fraud. Court verdicts and associated practical examples illustrate

the legal point of view and possible chances for and obstacles to development, production and placing on the market of novel products. Advertising-related aspects, and nutritional and health claims in particular are not dealt with here. The paper also excludes issues related to the export of product innovations to non-EU countries and the associated legal provisions. Implications are presented for product innovations on the basis of the legal foundations analyzed, and unanswered questions in this field are considered.

Results and discussion

Food, functional food or medicinal product?

To develop innovative food (concepts), one must first define what a food actually is. Within the EU, the regulation dealing with general principles and requirements of food law is Regulation (EC) 178/2002 [7]. In Germany, the national law on food and feed (“*Lebensmittel- und Futtermittelgesetzbuch*”, [LFGB]) contains some specification [8].

According to Article 2 of Regulation (EC) 178/2002, “‘food’ (or ‘food-stuff’) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans”. While chewing gum and drinks (“mineral water” in the German version of this regulation) are explicitly included and e.g. food supplements are also covered by this definition, the regulation explicitly excludes e.g. feed, medicinal products and tobacco [7]. However, the term “functional food”, a food with a designated benefit, is not yet legally defined and does not appear in any official legal norm. The balance between food and medicinal product should be taken into account here – especially

National law, EU legislation or guidelines?

Basically, there are various legal texts that deal with different aspects of food. In general, the same legal bases apply within the EU, either in the form of EU regulations – which are directly applicable in all EU member states – or as guidelines which have to be put into action via the national law of individual states.

In addition to the European provisions, there are numerous national laws and regulations which complement or specify European law or enable its execution, while the scope of European law is broader than that of national law.

If there are no legal provisions on a subject, guidelines and public perceptions (e.g. the guidelines of the German Institute for Standardization DIN, guidelines from the food commission and the industry or the Codex Alimentarius) gain relevance.

for the development of innovative health-related products as is practiced at the nutriCARD competence cluster. Here the possibility of the new product being a medicinal product must first be ruled out; to this end, the German Act on Medicinal Products (“*Arzneimittelgesetz*” [AMG]) [9] must be consulted. Section 2 (1) of the AMG distinguishes between so-called functional medicinal products (“*Funktionsarzneimittel*”), which influence physiological functions, and presentational medicinal products (“*Präsentationsarzneimittel*”), which have characteristics that are supposedly suitable for the healing, alleviation or prevention of diseases or pathological symptoms. In the latter case, a claimed effect is sufficient to fulfil this criterion, meaning the effect does not need to be proven.

The practical relevance of the clarification of this issue is high – if a supposed food is in fact found by a court to be a medicinal product, then this product will be deemed an unauthorized medicinal product that has been placed on the market.

Case example: For example, this was the case in a verdict by the German Federal Court of Justice in 2010, where a drink containing ginkgo that was freely on sale, was classified as a medicinal product [10]. According to Section 17 of the AMG, infringements against the act can result in prison sentences or fines.

Food safety

Moreover, according to Article 14 of Regulation (EC) 178/2002, only safe foods may be “placed on the market” and according to Section 5 (1) of the LFGB only safe foods may be produced (for others) [8]. The food business operator is responsible for meeting food legislation requirements, including those pertaining to food safety, according to Article 17 (1) in conjunction with Article 3 of Regulation (EC) 178/2002, no matter whether the operator is a na-

tural or legal person.¹ According to Article 3 (2) of the Regulation (EC) 178/2002, a food business is any undertaking involving the production, processing and distribution of food, “whether for profit or not and whether public or private” [7]. This is therefore also relevant for product developers, who e.g. offer sample testing at trade fairs.

What does ‘safe’ mean in this context? According to Article 14 of Regulation (EC) 178/2002, a food must not be “injurious to health” (i.e. it must not contain ingredients that may harm a person’s health) or “unfit for human consumption” (e.g. foul). In this context, however, it is important to consider the “normal conditions of use” – and, therefore, normal consumption as opposed to excessive consumption, which applies in the case of things like sweets. Under Article 14 (4) of Regulation (EC) 178/2002, the relevant criteria for the injuriousness of food include cumulative toxic effects and particular health sensitivities of a specific category of consumers. Especially in the field of product innovations with health benefits, it is important that the levels of vitamins, minerals or secondary plant compounds that are injurious to health according to Article 14 are not exceeded.

Among other factors, whether a food is unfit for human consumption depends, according to Article 14 (5) of Regulation (EC) 178/2002, on foulness and/or contamination that have rendered the food unacceptable – even if this has no negative effect on health.

Nauseating food – a reason for complaint?

German national law goes even further in these restrictions, adding in Section 11 Para. 2 No. 1 of the LFGB that foods other than those mentioned in Regulation (EC) 178/2002 that are “unfit for human consumption” may not be placed on

the market because of protection against fraud [8]. This includes e.g. nauseating foods (like the accepted case of ‘a hair in one’s soup’) or unhygienic food production conditions (see Section 40 Para. 1 of the LFGB). This should be distinguished from subjective feelings of disgust, such as when eating algae or insects (even if there are numerous examples of their consumption).

For example, the use of the colouring agent E120 (cochineal or carmine), which uses extracted insect compounds, is common in yoghurt desserts, jams and sausage products. Special attention should be paid to names and labelling of non-pre-packed foods (e.g. in restaurants, canteens and bakeries), because a complete list of ingredients is not mandatory for non-pre-packed foods under Article 44 of the regulation on the provision of food information (“*Lebensmittelinformationsverordnung*”, LMIV) [11] and the national regulation on designation (LMIV AV), with further details which took effect on 13 July of this year [12]. It should therefore be critically determined whether any small amounts of insect protein (compared to other, more quantitatively significant ingredients) in e.g. a ‘green spelt burger’ should be announced in a company canteen.

Hygiene and HACCP

Food safety is closely connected to hygienic production conditions. Various European and national laws and regulations regulate adherence to hygienic standards. A central role is occupied by Regulation (EC)

¹ According to Section 1 of the German Civil Code (BGB), humans have legal capacity by birth. This is the meaning of the term ‘natural person’. In contrast, legal persons are legal entities such as corporate bodies, companies and associations, and they also have legal capacity.

852/2004 [13]. Pursuant to Article 5 of this regulation, every food business operator is obligated to install, perform and maintain one or more procedures based on the norms of “Hazard Analysis and Critical Control Points” (HACCP). To this end, at first there is an analysis of potential health risks in the process. On this basis, critical control points (e.g. the temperature of warm meals) are determined, limits are defined and measures for monitoring, correction, verification and documentation must be set. This is obligatory, no matter the company’s size – and it also applies to product developers who place food on the market, e.g. in the context of testing at fairs. Furthermore, there are national regulations but also non-binding norms of the German Institute for Standardization (“DIN-Normen”, e.g. for training courses in hygiene [14]) and industry guidelines (e.g. on hygienic practices, “Leitlinien für eine gute Hygienepaxis” [15]) that are considered in practice and should be maintained.

Companies’ own internal hygienic standards should also be considered when developing new products: It should be ensured that a product intended for use in gastronomy complies with the standards in this sector. For examples, eggs are often only used when already processed by heating (e.g. as ‘long eggs’) or with a pasteurized egg shell in order to fulfil the requirements of Section 20a of the national regulation on the hygiene of animal products (“Tierische Lebensmittel-Hygieneverordnung”, Tier-LMHV) on minimizing the risk of salmonella for consumers [16].

Innovation = novel food?

Another important regulation in the context of product development is Regulation (EC) 258/97 concerning novel foods [17]. Among other

requirements set out in Article 3 of this regulation, a new food product must not “present a danger for the consumer” or “mislead the consumer” [17]. Pursuant to Article 1 of Regulation (EC) 258/97, this applies to “novel foods or novel food ingredients” which had not been consumed in the European Union “to a significant amount” up to 15 May 1997. Under Article 1 Para. 2 letter f, this may also apply to foods and food ingredients “to which has been applied a production process not currently used”. The following examples illustrate how this sentence may be interpreted.

Case example: Despite the fact that rape has been well known and in use for the production of food in Europe for a long time, an isolate of rape seed protein had to be authorized as a novel food [18]. The same applied to a baking yeast which contained more vitamin D than conventional baking yeast due to a so-called bio-addition technique (in this case exposure of the yeast to UV light) [19].

The amendment of the novel food regulation, Regulation (EU) 2015/2283 [20], which provides some changes to the old regulation, took effect on 31 December 2015 and will be binding from 1 January 2018. Important topics addressed by the new regulation are the centralized approval procedure by the European Commission and the European Food Safety Agency (EFSA) and the simplified authorization of traditional foods from non-member countries as novel foods. While until now the national institutions have been responsible for the examination and authorization of novel food applications – in Germany this is the Federal Office of Consumer Protection and Food Safety (BVL) until 31 December – the European Commission is intended to be the central examination and approval authority for novel food applications from

1 January 2018. The EFSA will provide scientific assessment. If an examination is successful, the Commission will trigger an update of the so-called Union list. This Union list contains all approved novel food applications.

A different approval procedure is planned in the case of traditional food that has been consumed in a third country outside of the European Union to a significant amount before 15 May 1997. The applicant will have to prove that the new food had been used by a significant number of people in a non-EU country for at least 25 years. This could apply to foods like stevia or chia seeds, which have not been examined by the new simplified procedure so far. While the EFSA is granted nine months for the approval procedure of non-traditional foods and the Commission has seven months to publish the results, these timeframes are shortened for traditional foods to six and three months (approval procedure and publication respectively). In contrast to the former Regulation (EC) 258/97, the new Regulation (EU) 2015/2283 explicitly names insects and any products derived from insects as well as food consisting of “engineered nanomaterials” as novel food.

A novel food application involves considerable effort in terms of time and financial resources. It should therefore be evaluated beforehand whether a product innovation is classified as a novel food under the regulation.

Additives and food fortification

Additions play another major role in product innovations. This area is covered by the regulation for addition, Regulation (EC) 1925/2006 [21]. It regulates the addition of minerals, vitamins and “certain other substances” to foods (while according to Article 1 [3] there are also specific other regulations that apply,

e.g. for novel foods and additives); a so-called positive list names these substances. According to Article 3 of Regulation (EC) 1925/2006, such additions may even take place when the added substance is not usually contained in the food. They may in particular be added “in order to take into account” the fact that e.g. a deficiency exists, to improve the nutritional status of population groups, or to correct possible deficiencies in the future. According to Article 4 of the regulation, however, the addition to unprocessed foods is not permitted. This is of significance for labelling in particular.

Case example: If an egg for example is fortified with vitamins, it becomes a processed food (an egg product) with a corresponding list of ingredients and is no longer an unprocessed egg. On the other hand, an egg that contains a higher amount of certain substances (e.g. vitamin D) than conventional eggs due to a so-called bio-addition technique, is not covered by Regulation (EC) 1925/2006 and does not count as a processed food [22].

Furthermore, alcoholic drinks with more than 1.2 vol.% are not usually allowed to be fortified. According to Articles 6 and 14, this regulation is actually supposed to limit the maximum amounts of additions, although no such amounts have been stated thus far. As such, product developers are required to check whether a certain ingredient is subject to restrictions under national law. Such restrictions would apply until completion of the EU regulation. For example, this applies to the German Section 2 (3) of the LFGB [9] in conjunction with the German regulation on the addition of vitamins [23], which regulates and limits the use of vitamins A and D and their derivatives more precisely. According to Section 2 (3) of the LFGB, minerals, trace minerals (except sodium chloride), amino acids and their derivatives as well as vitamins A and D

are treated on a par with additives. This could mean that they have to be approved separately, and as such this matter should be examined by the food business operator. However, this equal treatment under Section 2 Para. 3 of the LFGB has been the subject of considerable controversy in legal contexts and does not apply in full, e.g. for amino acids according to a verdict of the European Court of Justice [24]. Furthermore, in the context of the addition of vitamins and minerals it is important to consider that a food must be safe and that the line between food and medicinal product must not be crossed. A product developer should therefore check the amount of added ingredients in this respect.

What needs to be considered with regard to the technological addition of enzymes, flavoring agents and additives, is settled for the EU by the “Food Improvement Agents Package” (FIAP), which includes a corresponding regulation with basic provisions such as standardized evaluation and approval processes [25]. A so-called “Verbot mit Erlaubnisvorbehalt”, a prohibition with a chance of separate approval under certain circumstances, applies here. This means that all flavoring agents, enzymes and additives are generally prohibited, unless their use is permitted for certain conditions. The three other regulations of the FIAP [26–28] contain, inter alia, terms of usage and regulation exceptions. For example, the carry-over principle applies under Article 20 letter b i of the LMIV [11], stipulating that additives that come to a product indirectly via another product do not have to be labelled if the additive has no further technical effect. Additives which are used as processing aids (e.g. gelatine for the clarification of wine) do not have to be labelled either according to Article 20 Para. b ii of the LMIV [11]. With the exception of the allergens specified in Article 9 Para. 1 letter c of the LMIV

pursuant to Article 44 LMIV, there is no European legal foundation for non-pre-packed foods. Yet pursuant to that same Article 44, the individual member states may formulate national rules for declaration. This is the reason why the German regulation on the approval of additives (“Zusatzstoff-Zulassungs-VO”, ZZuV) [29] plays an important role, as this regulation states more concrete rules for declaration in Section 9. It states that some additives, including coloring agents, must be labelled; pursuant to Section 9 Para. 6 No. 5 and No. 6 of the ZZuV, this also applies to menus in restaurants and the public catering sector. This is due to protection against fraud, and not for health reasons. Nevertheless, consumers are sceptical towards this topic. According to a survey, approximately 80% think that a food should contain as few additives as possible [30]. A product developer should therefore try to limit the usage of additives to a minimum. This also applies to the additives which must be declared in menus and public catering, if the respective food is to be used in this sector.

Product labelling and misleading

In addition to their formal product designation, foods may also carry other invented names under Article 9 Para. 1 letter a in conjunction with Article 17 of the LMIV. Here, however, protection against misleading and fraud (cf. Article 16 of Regulation [EC] 178/2002 [8], Section 11 of the LFGB [9] in conjunction with Article 7 of the LMIV [11]) and the rules on unfair competition (cf. Section 3 of the German act on unfair competition, UWG [31]) still need to be taken into consideration.

For some food categories, formal designations are strictly regulated – the German regulation on milk products [32] for example declares what cha-

racteristics define a 'yoghurt'. For food without such legally binding specifications, a "customary name" ("verkehrsübliche Bezeichnung") has to be used according to Article 17 of the LMIV. Tools used in Germany to specify what a customary name is include the guidelines from the national commission on foodstuffs ("Lebensmittelbuch-Kommission") – e.g. there are guidelines for meat and meat products [33], which further define German "liver sausage". This commission consists of representatives from the industry, research and science, consumers and the food control administration. Furthermore, stipulations of the Codex Alimentarius also need to be considered [34]. If no such customary name exists or the developers do not want to use it, it is also possible to use a descriptive name. Food developers should be especially careful here. For example, it should be considered whether a modification in the recipe of a sausage (e.g. exchanging fat for fibre or protein) will necessitate a modification in the product name.

Limitations

The present summary primarily addresses food developers. Individual cases should always be examined with a lawyer specializing in foodstuffs. This overview cannot be exhaustive due to the sheer quantity of legally relevant texts concerning foods, but instead aims at providing an overview of food law, especially all relevant facts for food innovations. A basic understanding of legal aspects is the focus. Topics such as advertising, especially nutrition and health claims as well as exports, were not explored.

Conclusion

The paper shows that, when developing new foods, it is important to already check during the conception phase whether the planned product qualifies as a food and not a medi-

Excursus: Vegetarian and vegan product innovations

One area where so far only few legal stipulations exist, but where a lot of innovations are brought to market in Germany in particular, is vegetarian and vegan foods [35]. While the EU Commission aims to provide "information related to suitability of a food for vegetarians or vegans" according to Article 36 Para. 3 letter b of the LMIV [11], there are no comprehensive legal bases for the terms "vegetarian" and "vegan" (yet). This has been the source of repeated legal disputes.

In a verdict issued in June of this year, the European Court declared that designations such as milk, cheese and yoghurt may not be used for solely plant-based products. This even applies when such designations are supplemented with clarifying or descriptive information (e.g. "vegan cheese") [36]. Milk and milk products are subject to the rules of the European regulation on the organization of markets (1308/2013) [37], which protects terms like "cheese". Furthermore, legislation applicable within Germany includes the regulation on cheese ("Käse-VO") [38], which defines what products may be designated as "cheese".

Products labelled and placed on the market as "vegan sausage" etc. are not covered by the regulation on the organization of markets. Nonetheless, these foods are also not allowed to be suitable for fraud or misleading. This means that the product designation must make it clearly recognizable that no meat is included. Furthermore, there is uncertainty about whether and how processing aids or traces of animal origin may be contained within vegetarian and vegan foods. One definition from the conference of ministers of consumer protection ("*Verbraucherschutzministerkonferenz*") in April 2016, according to which, for example, traces are acceptable but processing aids are not [39], is not legally binding – but may be used as a guideline.

Concepts by developers dealing with these issues, such as the checklist for a vegan menu in catering [40] to which the present authors contributed, should take this into account and always define transparent and plausible terms.

cial product. Products with health benefits and functional foods in particular are not easy to differentiate from medicinal products. After this, all aspects of food safety and hygienic production must be considered. This includes all sectors, including those from potential buyers in public catering or gastronomy. Possible dangers of fortifications are also of relevance. It is essentially important to consider what substances, such as additives (as well as flavoring agents, enzymes etc.) or additions (minerals, vitamins or amino acids) may be used at all, and under which circumstances. Provisions on labelling also apply

in part to non-pre-packed food, which is important because of general consumer scepticism towards additives. Furthermore, it should be examined whether product innovations count as novel foods; under certain conditions, even new production technologies like bio-additioning lead to novel foods. Protection against fraud and misleading are to be taken into account, e.g. for food designations. Particular attention is needed for vegan and vegetarian product innovations (or concepts), because this topic has yet to be adequately addressed by legislation (♦ Box "Excursus: Vegetarian and vegan product innovations").

Funding

This paper was realized in the context of the competence cluster for nutrition and cardiovascular health (nutriCARD) Halle-Jena-Leipzig and supported by the German Federal Ministry of Education and Research (funding number 01EA1411C).

Conflict of Interest

The authors declare no conflict of interest.

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DOI: 10.4455/eu.2017.042