Legal Requirements for the Production of Safe Food*

A Brief Outline of the Most Important Legal Provisions to be Observed by Food Business Operators in Order to Achieve Food Safety

*Moritz Hagenmeyer***

Anyone can prepare a Christmas cake and sell it. This would – still – be lawful pursuant to current European food law in principle. The manufacturer would not even have to ask anyone for permission. But would the cake be safe? Food businesses have to observe a considerable number of statutes in order to produce lawful goods, most of which address food safety. The author has tried hard, but was unable to find and list them all. Nevertheless he attempts to portray the most important legal requirements for safe food production from a practical perspective.

I. The regulatory problem of safe food

Ever since prehistoric times mankind has existed in all kinds of surroundings on our – by nature – more or less hostile planet. For the purpose of survival, reproduction and alimentation have always been paramount. Where no-one knew what was safe to eat, the trial-and-error-method will have been used extensively. Experience has presumably been gathered and passed on from generation to generation all over the world. Suspicious rulers even employed tasters from time to time in order to avoid a premature death.[1]

In the meantime there is hardly a place on earth that has not been explored and just about everything that can be reared, bred, planted, gathered, harvested, cooked, baked and otherwise prepared as food and drink is known to man. With the advent of the internet, large parts of this knowledge are accessible virtually everywhere, although not everyone can understand them, or even act accordingly.

Still, the essential food safety issue remains. If we consume unsafe food or drink, it may be detrimental to our health, if not lethal. Not only poison as such can harm; the long-term effects of the wrong type of diet have also been well documented. Hence it has always been advisable to only eat or drink safe products, if and where available. The modern concept of food safety law endorses this traditional insight. As with all legal conundrums, however, the first problem is that of a suitable definition: What food should competent legislators classify as safe?

Whilst a number of national states addressed this issue particularly during the last century, a comprehensive legal concept of food safety has only recently been developed in the European Community.[2] As will be seen, the legislator has tackled the problem in the reverse order, namely by a simple ban on unsafe food. This should actually be a matter of course. What appears to be much more difficult to define is food safety itself. A closer look will show that the relevant definition significantly depends on the prevailing circumstances to which the safety concept is meant to apply. In other words, a democratic society should normally achieve a level of safety which the majority of the citizens can agree upon.[2a] So here is the law:

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** Prof. Dr. Moritz Hagenmeyer is a Partner of the renowned German food law firm KROHN Rechtsanwälte in Hamburg, Germany (www.krohnlegal.de).

1 Instructive in this respect van der Meulen, EFFL 2009, p. 58.

2 Cf. in detail MacMaoláin, EU Food Law, 2007, p. 175 seq.

2a Cf. in particular Recuerda Girela, EFFL 2006, p. 33 seq.

II. The core provision of food safety

Roughly a year after the beginning of this millennium the European Parliament and the Council enacted Regulation (EC) No. 178/2002 on general food law principles including food safety[3]. Art. 1 of the Regulation mentions food safety as one of the Regulation's paramount aims; it even establishes a European "Food Safety" Authority. Art. 14 of the Regulation contains the core provision in this respect which is fittingly captioned "food safety requirements". Pursuant to Art. 14 para. 1 of the Regulation "food shall not be placed on the market if it is unsafe". Art. 14 para. 2 of the Regulation establishes a statutory assumption that food is unsafe "if it is considered to be" either "injurious to health" or "unfit for human consumption". This has to be observed by all food manufacturers with respect to the production of any food. Safety of a particular foodstuff is thereby essentially defined as its fitness for human consumption. Thus before embarking on producing food, a manufacturer has to analyse all envisaged ingredients, the production process with a special emphasis on its effect on those ingredients, and its potential outcome with respect to health and fitness for consumption.

Pursuant to Art. 14 para. 4 of the Regulation health effects of a foodstuff's consumption and particularly its potential toxic effects are essential parameters when determining whether a product is injurious to health. This is certainly the most important gauge in any assessment of food safety. Problems of interpretation in this respect can arise primarily in two respects, namely the term "health" which lacks precision, and the question of what is injurious and what is not. Recital 2 of the Regulation mentions a "high level of protection of human life and health" and Recital 8 emphasises that the "Community has chosen a high level of health protection". Since there is no further definition of health it can be assumed that the WHO's interpretation may be referred to which defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"[4]. Any kind of even minor deviation from such a complete state caused by the consumption of a foodstuff would thus have to indicate that the particular food in question is not safe.

Furthermore Art. 14 para. 5 of the Regulation draws the line with respect to unfitness for human consumption where "the food is unacceptable for human consumption according to its intended use for reasons of contamination"; accordingly no foodstuff must be putrefied, deteriorated or decayed. The standard of acceptability, however, is not expressly prescribed. Arguably, the perception of an average consumer, who is reasonably well-informed and reasonably observant and circumspect – as coined by the European Court of Justice[5] – should be employed in this respect in order to assess where the potential acceptability for consumption ends. This may vary from time to time depending on all sorts of circumstances, so that a prudent food manufacturer will have to take into account a range of possible perceptions in the attempt to produce safe food. Only if it can be reliably expected that no well-informed, observant and circumspect consumer would reasonably object to a foodstuff can it be deemed safe.

With respect to both the absence of potential health hazards as well as the fitness for human consumption some other flexible factors have to be taken into account which are also dependant on consumer perception. They are codified in Art. 14 para. 3 of the Regulation. Accordingly the assessment of food safety is gauged by "the normal conditions of use of the food by the consumer" and "the information provided to ... or ... generally available to the consumer concerning the avoidance of specific adverse health effects". It can be assumed that the average consumer, who is reasonably well-informed and reasonably observant and circumspect, knows that potatoes must be cooked or fried before consumption and should not be eaten raw; this knowledge would certainly rank as a typical example of a "normal condition of use" or as "information generally available". In either case it would follow that potatoes as such can be deemed to be a safe food. Also instructions on the preparation of herbal tea with boiling water or the recommendation to properly heat chicken breasts can serve as examples of information provided to the consumer concerning the avoidance of adverse health effects other-

3 OJ L 31/1 of 1.2.2002, last amended by Regulation (EC) No. 202/2008, OJ L 60/17 of 5.3.2008.

4 Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19–22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.

5 Cf. e.g. cases C-210/96, ECR 1998, I-4657; C 303/97, ECR 1999, I-513; C 220/98, ECR 2000, I-117; C 465/98, ECR 2000, I-2297.

wise potentially caused by salmonella. Food business operators, however, should not always put their trust in the availability of such knowledge. Arguably food safety can be best achieved by providing essential information on the avoidance of health hazards, clearly and unambiguously, on the label.

Art. 14 para. 7 of the Regulation provides a stipulation that appears clearer at first glance: "Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned"[6]. The problem in this respect, however, is that there is no comprehensive list of such safety provisions a food manufacturer could refer to. Of course specific food safety law must be observed. And it should go without saying that a product complying with the relevant stipulations must be fit for human consumption; otherwise the specific provisions would not meet the desired effect. As a consequence it remains the food business operator's obligation to identify the applicable food safety law. This is not an easy task, as a mere glance at the European Commission's "Food Safety" website reveals where an abundance of legislation can be found[7] – subdivided into the following categories: General Food Law, Animal Nutrition, Labelling & Nutrition, Biotechnology, Novel Food, Chemical Safety, Biological Safety and Official Controls. Not all the directives and regulations referred to under these captions directly concern food safety within the above meaning, some of them are even rather concerned with a healthy diet (occasionally even under the false label of food safety) which must not be confused with the concept of safe food. However, the legislation listed there certainly comprises the most important rules to be observed. Here is what a food manufacturer will find (amongst others)[8]:

III. Other food safety law

1. Novel Food

So-called "novel food" is perhaps the prototypical food category for which particular safety legislation has been enacted. The "protection of human health" by way of subjecting certain foodstuffs to "a single safety assessment" is the prime concern of Regulation (EC) No. 258/97 concerning novel foods and novel food ingredients[9] as set out in its Recital 2. The mechanism by which this goal is pursued, in principle, is the authorisation procedure defined in Art. 4 of the Regulation. The crucial criteria of the Regulation can be found in its Art. 1 para. 2: "foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community" and which fall into certain specified categories require authorisation as novel food. This rule obliges food manufacturers to examine all intended ingredients of their products as to their respective use as food or food ingredient prior to 15 May 1997, the day when the Novel Food Regulation entered into force. A helpful reference in this respect is the Commission's "Novel Food Catalogue"[10]. Where the necessary significant use as food cannot be demonstrated for a particular substance, the item in question is automatically suspicious and may not become part of the production process, unless it is supplied together with the required authorisation. In practice these rules have gained particular importance with respect to plants[11], especially from Asia and Polynesia, but also with respect to special extracts. In case of doubt it is advisable either not to use a questionable ingredient or to insist on the submission of an authorisation by the supplier. Otherwise there is a risk of producing food which is deemed unsafe (regardless of its potential fitness for human consumption). Incidentally, the novel food concept as such will remain unchanged at least with respect to the food safety implications under the planned proposal for a new regulation.[12]

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6 A parallel provision referring to national law applicable in the absence of specific Community provisions can be found in Art. 14 para. 9 of the Regulation; however, such residuary national food safety law is not subject of this article.

7 http://ec.europa.eu/food/food/index_en.htm; most of the current legislation was conceived in the Commission's White Paper on Food Safety of 12 January 2000, COM (1999) 719 final, http://ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf.

8 This article will not deal with the following areas of law and thus not discuss whether and if so in what respect they qualify as food safety law within the meaning explained above: Animal Nutrition, Labelling & Nutrition, Biotechnology (i.e. especially Genetically Modified Organisms) and Official Controls.

9 OJ L 43/1 of 14.12.1997, last amended by Regulation (EC) No. 1332/2008, OJ L 354/7 of 31.12.2008.

10 http://ec.europa.eu/food/food/biotechnology/novelfood/nfnetweb/index.cfm.

11 Cf. the list of applications: http://ec.europa.eu/food/food/biotechnology/novelfood/app_list_en.pdf.

12 COM (2007) 872 final, http://ec.europa.eu/food/food/ biotechnology/novelfood/COM872_novel_food_proposal_en.pdf, as to which cf. Gerstberger, EFFL 2008, p. 213.

2. Food Additives

Food ingredients employed for technical purposes may only be used for the production of food under the conditions of use laid down pursuant to Art. 4 of the new Regulation (EC) No. 1333/2008 on food additives[13]. This general ban with specific authorisations has been in force all over Europe since 1989 pursuant to Directive 89/107/EEC[14] and has recently been re-codified by way of the new Regulation[15]. The ban serves, as is apparent from Art. 1 as well as Recital 2 of the new Regulation, the "protection of human life and health" and is therefore nothing but a pure food safety instrument. Recital 7 of the Regulation states accordingly: "Food additives must be safe when used ...". For this purpose the Regulation not only authorises the use of certain food additives, but also establishes "conditions of use of food additives" as set out in its Art. 1. These conditions have not yet been determined in detail so far, but Art. 6 para. 1 of the new Regulation lays down the general conditions, namely no "safety concern to the health of the consumer at the level of use proposed". Furthermore Art. 10 para. 2 of the Regulation makes it clear that the use of additives can be restricted to certain foodstuffs, and "conditions under which the food additive may be used" can be specified – these are primarily the well known maximum amounts. As long as the envisaged Community list of food additives has not been enacted, the relevant rules of current food additive law remain in force pursuant to Art. 34 of the new Regulation. So today as well as in future all additives to be employed in the production of a particular food have to be checked carefully with respect to their authorisation in principle and the observance of applicable maximum levels in particular. Only if an additive is authorised for the intended purpose in the desired quantity can the relevant food be considered as safe.

3. Vitamins, Minerals and "Other Substances"

Similar provisions apply with respect to fortification. Safety is the paramount feature of Regulation (EC) No. 1925/2006 on the addition of vitamins and minerals and certain other substances to food[16]. This can be seen from Recital 14 of the Regulation which mentions "adverse health effects" as a possible result of "excessive intakes of vitamins and minerals", concludes "it is therefore necessary to set maximum amounts for them" and accordingly demands "these amounts must ensure" that such fortified food "will be safe for the consumer". For these reasons Art. 4 of the Regulation restricts the addition of minerals and vitamins altogether with respect to a number of groups of foodstuffs whilst establishing said maximum amounts as conditions for the addition of vitamins and minerals in Art. 6. Unfortunately for manufacturers seeking orientation, no decision has yet been made on the particular levels; the scientific as well as political debate about where to fix them is still going on. As a consequence fortification with vitamins and minerals is lawful in principle. Until maximum levels have been decided, the safety of such fortification still needs to be assessed under the general rules pursuant to Art. 14 of Regulation (EC) No. 178/2002. Guidance can already be gained in this respect from various safety evaluations which are currently under consideration in the legislation process[17].

With respect to other substances the legal situation remains somewhat unclear. Art. 8 of the Regulation merely puts in place a procedure to either ban or to put them under scrutiny depending on "harmful effects on health". However, it is apparent from documents recently published by the Commission[18] that the European legislator is not prepared

13 OJ L 354/16 of 31.12.2008.

14 OJ L 40/27 of 11.2.1989, last amended by Regulation (EC) No. 1882/2003, OJ L 284/1 of 31.10.2003.

15 Similar rules have been decreed at the same time with respect to food enzymes and flavourings.

16 OJ L 404/26 of 30.12.2006, last amended by Regulation (EC) No. 108/2008, OJ L 39/11 of 13.2.2008.

17 Cf. the Commission's "Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs" of June 2006, http://ec.europa.eu/food/food/labelling nutrition/supplements/discus_paper_amount_vitamins.pdf, and the plethora of "Responses to the Discussion Paper" by member states as well as stakeholders, http://ec.europa.eu/food/food/ labellingnutrition/supplements/resp_discus_paper_amount_ vitamins.htm.

18 Report on the use of substances other than vitamins and minerals in food supplements of 5.12.2008, COM (2008) 824 final, http://ec.europa.eu/food/food/labellingnutrition/supplements/ documents/COMM_PDF_COM_2008_0824_F_EN_RAPPORT.pdf together with the Working Documents "Characteristics and Perspectives of the Market for Food Supplements containing Substances other than Vitamins and Minerals", SEC (2008) 2977, http://ec.europa.eu/food/food/labellingnutrition/supplements/ documents/2008_2976_F_WD1_en.pdf and "Available Scientific Information on the Use of Substances other than Vitamins and Minerals in Food Supplements SEC (2008) 2976, http://ec.europa.eu/food/food/labellingnutrition/supplements/documents/2008_ 2977_F_WD2_en.pdf.

to decree any further stipulations in this respect in the near future. Nevertheless the same considerations as with respect to vitamins and minerals should apply in practice. Hence a food manufacturer wishing to use such ingredients is well advised to have the safety of (intended amounts of) the particular substances in question evaluated as to their potential dangers to human health before commencing the production process. A potentially helpful document in this respect may be the European Food Safety Authority's most recent scientific opinion on the safety assessment of botanicals and botanical preparations.[19]

4. Contaminants, Residues and Food Contact Materials

It should go without saying under safety aspects that food which is placed on the market must not be contaminated. However, with the advent of ever more sophisticated methods of analysis it is now possible to detect all kinds of traces in most foods. It is against this background that legal provisions banning contaminants, residues and certain types of migration have been decreed. Art. 2 para. 1 of Regulation (EC) No. 315/93 on Community procedures for contaminants in food[20] demands that "food containing a contaminant in an amount which is unacceptable from the public health viewpoint and in particular at a toxicological level shall not be placed on the market". Furthermore para. 3 of that provision envisages the establishment of "maximum tolerances for specific contaminants". These thresholds havealready been introduced by Regulation (EC) No. 446/2001[21] and have in the meantime been re-enacted and constantly updated by Regulation (EC) No. 1881/2006 on maximum levels for certain contaminants in foodstuffs[22]. Art. 1 of this Regulation contains the relevant marketing ban for foodstuffs containing excessive amounts of contaminants which is accompanied in its Art. 3 by prohibitions on the use, mixing and even detoxification of such contaminated food. Additionally specific measures have been taken by the Community with respect to individual contaminants.[23]

Similar provisions have also been codified with respect to maximum residue levels of pesticides in Art. 18 and 19 of the relevant Regulation (EC) No. 396/2005[24]. Most recently a maximum residue limit concept has also been adopted with respect to pharmacologically active substances in the relevant Regulation (EC) No. 470/2009[25] which mentions "the purposes of ensuring food safety" as its prime objective in Art. 1. Moreover Art. 3 of Regulation (EC) No. 1935/2004 on materials and articles intended to come in contact with food[26] demands that such food contact material, especially all kinds of packaging, must not "endanger human health" nor "bring about an unacceptable change in the composition of the food". Particularly the latter part of this stipulation again depends on consumer protection and can thus serve to safeguard a uniform level of food safety regarding the ingredients of a food as well as its packaging.

5. Food Hygiene and Microbiological Criteria

"Experience has shown that these rules and procedures [i.e. the general rules of hygiene for foodstuffs and the procedures for verification of compliance with theses rules] constitute a sound basis for ensuring food safety"; this fundamental insight is pronounced in Recital 3 [and 4] of Regulation (EC) No. 852/2004 on the hygiene of foodstuffs[27]. This Regulation's principal objective is in fact "to ensure a high level of consumer protection with regard to food safety" as set out in its Recital 7. Accordingly Art. 3 of the Regulation obliges food business operators to "satisfy the relevant hygiene requirements laid down in this Regulation". The applicable general and specific hygiene requirements are further

19 Guidance on Safety Assessment of botanicals and botanical preparations intended for use as ingredients in food supplements, EFSA Journal 2009, 7 (9), 1249; http://www.efsa.europa.eu/cs/BlobServer/Guidance_of_Panel/sc_op_ej1249_botanicals_en,6.pdf?ssbinary=true.

20 OJ L 37/1 of 13.2.1993, last amended by Regulation (EC) No. 1882/2003, OJ L 284/1 of 31.10.2003.

21 OJ L 77/1 of 16.3.2001, last amended by Regulation (EC) No. 199/2006, OJ L 32/32 of 4.2.2006.

22 OJ L 364/5 of 20.12.2006, last amended by Regulation (EC) No. 629/2008, OJ L 173/6 of 3.7.2008.

23 Cf. http://ec.europa.eu/food/food/chemicalsafety/contaminants/index_en.htm.

24 OJ L 70/1 of 16.3.2005, last amended by Regulation (EC) No. 299/2008, OJ L 97/67 of 9.4.2008.

25 OJ L 152/11 of 16.6.2009.

26 OJ L 338/4 of 13.11.2004.

27 OJ L 139/1 of 30.4.2004, as corrected OJ L226/3 of 25.6.2004.

specified in Art. 4 of the Regulation and in the relevant Annex. These rules are very comprehensive and in effect make it necessary for a food manufacturer to examine premises, equipment, packaging and all kinds of details in relation to the whole production process. Such examination is the core part of the hazard analysis and critical control points procedure (HACCP) prescribed by Art. 5 of the Regulation. This is in turn mirrored by Recital 5 of Regulation (EC) No. 2073/2005 on microbiological criteria[28] where it is stated that "the safety of foodstuffs is mainly ensured by a preventive approach, such as implementation of good hygiene practice and application of procedures based on hazard analysis and critical control point principles". Accordingly "microbiological criteria can be used in validation and verification of HACCP and other hygiene control measure". For these purposes Art. 3 of the Regulation demands that "foodstuffs shall comply with the relevant microbiological criteria" set out in the pertaining Annex. Additional legislation in this respect applies in particular with respect to fighting salmonella[29].

IV. Practical implications of food safety

So what are the practical implications these (and many more) different legal safety provisions have on the operations of a prudent and diligent food business operator? A food manufacturer must find all the applicable law and ensure compliance. After all, it is patent from Recital 30 of Regulation (EC) No. 178/2002 that the food business operator has the "primary legal responsibility for ensuring food safety", because the operator "is best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe". It is for this reason that Art. 17 of that Regulation establishes the obligation of food business operators to "ensure that foods ... satisfy the requirements of food law". This responsibility must comprise the obligation to only place on the market food which is safe within the meaning of Art. 14 of the Regulation and other European food safety law as set out above. This conclusion does not only follow from the structure of the Regulation itself and its Art. 19 which contains an operator's duty to withdraw food "not in compliance with the food safety requirements", i.e. the requirements codified in Art. 14 of the Regulation. The responsibility and the pertaining burden of proof, namely the duty to show that a foodstuff is safe, can also be drawn from all the above mentioned individual food safety stipulations. In fact, Art. 1 para. 1 of Regulation (EC) No. 852/2004 endorses that the "primary responsibility for food safety rests with the food business operator". And even more so, Recital 20 of Regulation (EC) No. 1925/2006 expressly declares that "food business operators, responsible for the safety of the foods they place on the market, assume the burden of proof in relation to their safety".

V. Safe food by way of conclusion

At the end of this brief overview it is possible to conclude: If a food business operator does in fact observe all safety provisions, its product should be fit for human consumption. Even a breach of minor obligations does not necessarily have to lead to a danger to human health, because altogether there are so many rules and regulations to adhere to. What is more, food safety should not be confused with a healthy diet, because the absence of potential health hazards for consumers in general is not the same as sound nutrition of a particular individual. In any event, food scandals with health concerns do still occur from time to time. It can be safely assumed in such cases that the relevant law will have been violated and that sanctions will apply (pursuant to the relevant national food law). However, all law can only be as good as those who practice it: "In a society of gentlemen we would not need any law"[30]. Unfortunately we have to admit that we do not live in such a society – for whatever reasons. Hence it is necessary that we have food safety law and it is good that this law is observed by the vast majority of food business operators. Whether all the above details are necessary to achieve the desired effect may well be doubted. But as long as we agree on a certain level of food safety we should also be able to benefit – when consuming food and drink – from the law that safeguards that safety level. This should be the prime concern in food law practice.

28 OJ L338/1 of 22.12.2005, last amended by Regulation (EC) No.1441/2007, OJ L 322/12 of 2.12.2007.

29 Cf. http://ec.europa.eu/food/food/biosafety/salmonella/legisl_en.htm.

30 Tony Weir, at a lecture in Cambridge during the Summer of 1988, witnessed by the author.