

## Modern food safety requirements – according to EC Regulation No. 178/2002\*

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*The European legislator has recently put forward a comprehensive new food law regulation. Although the particular food safety provisions only enter into force in the year 2005 they have already begun to overshadow food law practice. The author briefly sketches their history as well as the underlying legal and political concepts. His main concern are the essential requirements of food law – namely food safety, responsibilities and traceability – and the proper construction of the relevant new rules. He concludes that the regulation falls short of a number of its own goals: it is neither coherent nor proportional; furthermore there are considerable doubts as to its efficiency with respect to the aim of consumer confidence. The author believes that absolute safety is a myth and food consumption will always be fraught with acceptable risks.*

### A) Introduction

Food safety is a rather modern concept. Neither the Romans nor our immediate ancestors were aware of it in the sense it has now been enacted in a truly European style. The prime concern of pre-war generations was still to secure sufficient supplies of food and drink. Of course they also had to take care of the quality of their food, because nobody wanted to eat stale bread, mouldy fruit or rotten meat. When the first proper food laws were conceived and directed against deception, adulteration and passing off in the nineteenth century, people were still very close to food production and were thus trained to assess food quality themselves. They drank water from wells or fountains and they ate either what they harvested themselves or what they could buy from local shopkeepers or market traders. Processed food was hardly available, means of preservation were limited and crop failures hit the communities severely. Because of their proximity to food most consumers also knew rather well what one must not or at least should not eat at all and what type of food might cause health problems.

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Since then our habits have changed fundamentally. With the fast progress of civilisation two main characteristics of food consumed today can be identified: First food and beverage production have been far removed from those who eat and drink; e.g. few children know how milk tastes which has not been pasteurised and homogenized, some even think it comes from carton. Secondly most food is now sold via supermarkets in packaging which allow storage for a considerable time. As a consequence, original knowledge about the food is slowly receding. Instead of knowing or even being the producer of a food, buyers have to rely on information provided by the manufacturer on the food label or otherwise. And they have to trust that food they buy is safe, because for lack of competence as well as opportunity they cannot fully examine ingredients, composition or potential effects of a foodstuff prior to consumption.

It is mainly these circumstances which demand a legal approach to food safety; this new concept has thus moved into the focus of recent European food legislation. This article will briefly outline the essential ideas proposed by the Commission of the European Communities in its White Paper on Food Safety of 12 January 2000<sup>1</sup> (below B) and then centre on the general requirements demanded by the Regulation (EC) No. 178/2002 laying down general principles and requirements of food law<sup>2</sup> and their interpretation (below C). It will then throw in some critical remarks (below D) before attempting to deliver a sceptical but conciliatory conclusion (below E).

## B) Essential ideas of the White Paper

The Commission of the European Communities published its White Paper on Food Safety on 12 January 2000. It contains an executive summary, nine individual chapters, the second of which is especially dedicated to the issue of food safety, and an annex with a detailed action plan on food safety. The concept of safe food and consumer health protection runs like a thread through the document. It will not be possible in this article to present and discuss all features of the Paper<sup>3</sup>. However, the crucial food safety elements merit some closer looks.

### 1. Executive Summary

The first paragraph of the White Paper's executive summary mentions food safety twice in three lines; it reads: *Assuring that the EU has the highest standards of food safety is a key policy priority for the Commission. This White Paper reflects this priority. A radical new approach is proposed. This process is driven by the need to*

1 COM (1999) 719 final.

2 OJ L 31/1 of 1.2.2002.

3 For a detailed analysis of the White Paper cf. *Horst/Mrohs*, ZLR 2000, 125, 129-138.

*guarantee a high level of food safety.*<sup>4</sup> Apart from the establishment of an independent European Food Authority<sup>5</sup>, the essential means proposed by the White Paper to achieve the desired effect can be found here under the caption “Food Safety Legislation”. These include *a wide range of other measures to improve and bring coherence to the corpus of legislation covering all aspects of food products from “farm to table” in order to establish a high level of consumer health protection and clearly attribute primary responsibility for safe food production to industry, producers and suppliers*<sup>6</sup>. One might ask who else should be responsible? It is not surprising that neither the legislator’s nor public authorities’ responsibilities are mentioned in this context.

In addition to *appropriate official controls* one can read the following demands concerning food safety legislation: *The ability to trace products through the whole food chain will be a key issue. The use of scientific advice will underpin Food Safety policy, whilst the precautionary principle will be used where appropriate. The ability to take rapid, effective, safeguard measures in response to health emergencies throughout the food chain will be an important element*<sup>7</sup>. The Commission believes *The implementation of all the measures proposed in the White Paper will enable Food Safety to be organised in a more co-ordinated and integrated manner with a view to achieving the highest possible level of health protection* and it states *Greater transparency at all levels of Food Safety is the thread running through the whole White Paper*<sup>8</sup>.

## 2. Chapter 2: Principles of Food Safety

The second chapter of the White Paper is rather short, it merely covers eight paragraphs on a couple of pages. They are introduced with the following headnote: *This White Paper makes proposals that will transform EU food policy into a proactive, dynamic, coherent and comprehensive instrument to ensure a high level of human health and consumer protection*<sup>9</sup>. The following features are then highlighted as essential to the concept of food safety and the relevant legislation<sup>10</sup>:

8. *Food safety policy must be based on a comprehensive, integrated approach ...*

4 White Paper, page 3.

5 Regarding the Authority and its competences cf. *Streinz/Fuchs*, ZLR 2002, 169, 181, 191.

6 White Paper, page 3.

7 White Paper, page 3

8 White Paper, page 5; cf. *Dannecker*, ZLR 2002, 19, 22; cf. also *Brenner*, ZLR 2001, 359; *David*, ZLR 2001, 625; *Grunert*, ZLR 2000, 831; *Horst/Mrohs*, ZLR 2000, 125; *Horst*, ZLR 2000, 475; *Millstone*, ZLR 2000, 815.

9 White Paper, page 8.

10 White Paper, pages 8-9.

9. ... farmers and food operators have the primary responsibility for food safety ... In this way the farm to table policy ... will be implemented systematically and in a consistent manner<sup>11</sup>.
10. A successful food policy demands the traceability of ... food and their ingredients<sup>12</sup>.
11. This comprehensive, integrated, approach will lead to a more coherent, effective and dynamic food policy. ... At the same time, the development of this approach needs to be transparent, involving all stakeholders and allowing them to make effective contributions to new developments.
12. Risk analysis must form the foundation on which food safety policy is based.
14. Where appropriate, the precautionary principle will be applied in risk management decisions.
15. ... other legitimate factors ... can also be taken into account.

Clearly, this is an assembly of rather general and not very specific demands to a food policy which in turn has to be implemented by way of legislation<sup>13</sup>. It is well known that not all policy goals can in fact be reached through direct statutory stipulations. With respect to any legal consequences following from these food safety principles it must therefore always be identified whether the principles are primarily meant to guide the legislator, or whether they are in fact suitable to mould obligations for manufacturers or operators, respectively. It should be noted that food law upon the basis of these policy principles must necessarily be *clear, simple and understandable for all operators to put into effect*. This is a fundamental idea which is obviously known to the Commission since it is thus expressed elsewhere in the White Paper<sup>14</sup>; it will become important below when the new Regulation is examined.

### 3. Annex: Action Plan on Food Safety

The action plan contained in the annex of the White Paper is an ambitious list of 80 measures proposed in order to achieve the goals of the document itself. It begins with three "Priority measures", the third of which is called "Proposal for a General Food Law Directive". This is preceded only by proposals for "setting up a European Food Authority" and "laying down procedures in matters of food safety". The express objective of the suggested directive is to *establish food safety as the primary objective*

11 Cf. Dannecker, ZLR 2002, 19, 22.

12 Cf. Horst, ZLR 2000, 475, 487.

13 Regarding the relation between food policy and legislation resulting from the White Paper cf. Millstone, ZLR 2000, 815, 817.

14 White Paper, pages 22-23; as to the consequences on food legislation cf. Grunert, ZLR 2000, 831, 840.

of EU food law and to lay down the common principles underlying food legislation (in particular: scientific basis, responsibility of producers and suppliers, traceability along the food chain, efficient controls and effective enforcement)<sup>15</sup>. There is also a reference to paragraph 67 of the White Paper where the underlying legislative idea is first mentioned: *The Commission will make proposals including a General Food Law, which will embody the principles of food safety referred to in Chapter 2*<sup>16</sup>.

The proposed directive was meant to be adopted already by December 2001. In fact the ensuing legislation was only 28 days late – in comparison with other European laws a remarkably speedy development of just about two years from conception to entering into force. However, one main characteristic of the proposal was lost on that short way; this must not be underestimated as to its practical effects: Whilst the White Paper rather prudently proposed the enactment of a directive, the actual outcome of the brief legislation process was a regulation. This has far-reaching consequences, particularly since a European regulation has direct effect in all member states of the European Union and – other than a directive – does not require any further national implementation measures<sup>17</sup>.

### C) General demands of the Regulation

After a considerable number of changes to the original Proposal presented by the Commission on 8 November 2000<sup>18</sup>, the European Parliament and the Council enacted the Regulation (EC) No. 178/2002 laying down general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety on 28 January 2002<sup>19</sup>. It consists of the impressive number of 66 recitals followed by merely 65 articles, which in turn are divided in five chapters, two of them containing substantive food law provisions. Chapter II captioned “General Food Law” is made up of four sections pronouncing a number of principles, obligations and requirements. Section 4 bearing the title “General Requirements of Food Law” mainly establishes fundamental food safety requirements and allocates responsibilities. It is the food (i.e. not feed) related core provisions of this section and the pertaining recitals which will be examined more closely hereunder.

15 White Paper, page 37.

16 White Paper, page 22.

17 This issue is dealt with by *Dannecker*, ZLR 2002, 19, 21; *Gorny*, ZLR 2001, 501, 513; *von Danwitz*, ZLR 2001, 209, 218 and comprehensively by *Streinz*, ZLR 2000, 803, 806-808; cf. also *Horst*, ZLR 2000, 475, 479-480.

18 COM (2000) 716 final.

19 OJ L 31/1 of 1.2.2002.

## 1. Recitals

The recitals are of considerable importance when interpreting the proper meaning of the Regulation's provisions, because they reveal the legislator's declared intentions to a large extent. The very first recital mentions food safety as follows: *The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health of well-being of citizens.* Two features can be identified here. Clearly, safe food is thus perceived primarily as one of several factors for the benefit of human health; but it is at the same time the free movement of goods, the fundamental idea of the original Common Market into which the concept of food safety is integrated.

To this intent the Regulation demands a largely uniform level of food safety within the Community (recital 3) – a feature which is reiterated and endorsed in recitals 26 and 27 – and proclaims *that it is necessary to adopt measures aimed at guaranteeing that unsafe food is not placed on the market* (recital 10). The prime goal occurs again in recital 32 which claims *the achievement of a high level of health protection within the Community.* The Regulation wishes *to take a sufficiently comprehensive and integrated approach to food safety* and envisages *a wide range of provisions with a direct or indirect effect on the safety of food* (recital 11). *In order to ensure safety of food, it is necessary to consider all aspects of the production chain as a continuum* (recital 12)<sup>20</sup>, for which purpose *it is necessary to consider the production, manufacture, transport and distribution of feed given to food-producing animals* (recital 13) and *to consider other practices and agricultural inputs at the level of primary production* (recital 14). To some extent repeating the idea of recital 10 the Regulation demands: *It is therefore necessary to establish general requirements for only safe food and feed to be placed on the market, to ensure that the internal market in such products functions effectively* (recital 27). For this purpose it is felt *necessary to establish a comprehensive system of traceability within the food and feed businesses* (recital 28). In essence that is to say all aspects of any type of food production are to be embraced by the legislation. The goal is to effectively keep unsafe food off the market so that exclusively safe food can be found there.

As a kind of general guideline the Regulation establishes: *Measures adopted by the Member States and the Community governing food and feed should generally be based on risk analysis* (recital 16), a principle further defined in recitals 17 to 19 with particular reference to the “precautionary principle” in recitals 20 and 21. Acknowledging the *increasing concern of the general public* in food safety (recital 22) the Regulation goes on to state: *The safety of and confidence of consumers within the Community, and in third countries, are of paramount importance* (recital 23). This

<sup>20</sup> Cf. Dannecker, ZLR 2002, 19, 23.

must be understood as an additional aspect of the food safety idea. Apparently it is not only the safety of the food on the market as such which is important but also the consumers' confidence in this safety<sup>21</sup>. Their trust is to be gained by way of an effective legal concept upon the basis of the available scientific information. Whether confidence can actually be produced in such a way is a question the Regulation does not openly address.

The most important feature of the Regulation's recitals as far as its practical effect on food manufacturers and distributors is concerned can be found even further on. Recital 30 unambiguously allocates responsibility for food safety<sup>22</sup>: *A food business operator is best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe; thus it should have primary legal responsibility for ensuring food safety.* This recital must be read in conjunction with the statutory definition of a food business operator in Article 3 no. 3 of the Regulation. Accordingly food business operators are *natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control*; food businesses according to Article 3 no. 2 of the Regulation comprise *any undertaking carrying out ... any activities related to any stage of production, processing and distribution of food.* Everyone manufacturing or trading food or food ingredients thus qualifies as a food business operator.

Interestingly, the Regulation's last recital endorses the principle of proportionality: *this Regulation does not go beyond what is necessary in order to achieve the objectives pursued.* This cornerstone must always be kept in mind when interpreting the individual provisions of the Regulation – including those addressing the issue of food safety.

## 2. Article 14: Food safety requirements

The central food safety provision of the Regulation is contained in Article 14 "Food safety requirements"<sup>23</sup>, which consists of altogether nine paragraphs. Only paras. 7 and 9 of the provision positively establish when a food *shall be deemed to be safe*. Para. 1 rather plainly endorses the main purpose of the Regulation, namely that *food shall not be placed on the market if it is unsafe*. Indirectly this ban also follows from paras. 7 and 9 of the provision<sup>24</sup>. They essentially require a food to comply with or conform to specific food law provisions, be it Community law (para. 7) or be it

21 This aspect was also addressed in paragraph 7 of the White Paper, page 8; cf. also *Streinz/Fuchs*, ZLR 2002, 169, 172 and footnote 20.

22 Cf. *Dannecker*, ZLR 2002, 19, 21.

23 Cf. *Dannecker*, ZLR 2002, 19, 25-26; cf. also *Staudinger*, ZLR 2001, 649, 659-662; *Gorny*, ZLR 2001, 501, 509-512 and *Köhler*, ZLR 2001, 191, 203-204 (all on Article 12 of the Draft Regulation).

24 Cf. *Gorny*, ZLR 2001, 501, 509 (on Article 12 of the Draft Regulation).

national food law (para. 9)<sup>25</sup>. This principle merits some emphasis, because it endorses all other subsisting food legislation as well as the concept of mutual recognition amongst the member states of the European Union<sup>26</sup>. Wherever a manufacturer produces a foodstuff in accordance with such law, it can market the food without restrictions on the assumption that it is deemed to be safe.

The only proviso the Regulation makes in this respect is laid down in the somewhat unclear stipulation of Article 14 para. 8. This provision allows authorities to take *appropriate measures to impose restrictions on it* [i.e. the food] *being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe*. That is to say a food which is deemed to be safe may still be suspected to be unsafe. Unfortunately Article 14 para. 8 of the Regulation does not state what type of reason might suffice to justify this type of suspicion. Of course such reasons must be sound and justified, otherwise the whole purpose of subsisting food law would become completely irrational. With respect to the recitals mentioned above, particularly recitals 16 to 21 of the Regulation, it has to be assumed that substantiation for such kind of suspicions must be based on scientific evidence. Furthermore, the same statutory criteria may be employed which are laid down in Article 14 paras. 2 to 5 of the Regulation in order to describe unsafe food. Suspicions which are not scientifically founded or do not meet these legal standards cannot thus justify an authority's assumption that a food is unsafe.

Article 14 para. 2 defines two types of unsafe food: *Food shall be deemed to be unsafe if it is considered to be (a) injurious to health; (b) unfit for human consumption*. However, the provision does not make it clear whose considerations should be decisive in this assessment. With respect to the allocation of responsibility pursuant to recital 30 of the Regulation, the food business operator's considerations must be decisive. Hence a food is not in compliance with food safety requirements if the relevant food business operator has a substantiated reason to consider it unsafe.

General criteria for determining that food is unsafe can be found in Article 14 para. 3 of the Regulation whereas criteria regarding the two particular types of unsafe food are listed in paras. 4 and 5. It is important to point out, that para. 3 refers to *the normal conditions of use of the food by the consumer* as well as to *the information provided to the consumer, including information on the label, or other information generally available to the consumer*. That is to say unusual and unexpected conditions of use need not to be taken into account. Moreover, consumers are deemed to read

<sup>25</sup> Concerning the effects of these provisions on product liability law cf. *Staudinger*, ZLR 2001, 649, 661.

<sup>26</sup> Cf. *Köhler*, ZLR 2001, 191, 204 (on Article 12 of the Draft Regulation).



essential labelling elements and to be aware of general knowledge<sup>27</sup>. For practical purposes that means: adverse effects of over-consumption or even food abuse or well known negative consequences of certain food combinations do not make such products unsafe. Similarly ignorance with respect to a product name, its ingredients list or advertised properties does not constitute a foodstuff which is unsafe.

Turning now to the individual principles for the evaluation of a foodstuff's safety, the following can be observed: Article 14 para. 5 declares food "unfit for human consumption" if it is in any way contaminated. Of course a wide range of food law provisions does not allow contaminations in any event so that contaminated food would not meet the requirements established in Article 14 paras. 7 and 9. A considerably larger number of criteria regarding food which is "injurious to health" is listed in Article 14 para. 4 of the Regulation. Accordingly regard shall be had *(a) not only to the probable immediate and/or short term and/or long term effect of that food on the health of a person consuming it, but also on subsequent generations; (b) to the probable cumulative toxic effects; (c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.*

It is clear that no manufacturer or even distributor of a foodstuff can seriously claim to be in full possession of all the necessary knowledge in this respect<sup>28</sup>. The long term effects of a food on subsequent generations cannot be established with sufficient precision, because it is practically impossible to carry out tests for say three generations and come to clear and unambiguous results regarding the effect of a particular foodstuff or even a particular ingredient only<sup>29</sup>. Furthermore the scope of possible cumulative toxic effects is far too wide to be fully determined for reasons of the variety of individual diets consumed by any number of people over any given period of time. Hence Article 14 para. 4 of the Regulation can only be interpreted as an appeal to the legislators' scientific advisers. The scientific evidence they come up with must be taken into account when developing new food law. But the provision does not impose any direct obligations on food manufacturers over and above their reasonable diligence. In effect a food can only be deemed unsafe, where a food business operator knows of or has a sound and justified reason to suspect failure of a food to meet with the requirements of Article 14 paras. 2 and 3 to 5 of the Regulation at the time of placing it on the market.

27 Cf. *Gorny*, ZLR 2001, 501, 511-512 who points out: "volenti non fit inuria"; cf. also *Schipper*, EFLR 1997, 445.

28 Convincing criticism from a criminal law perspective is voiced by *Dannecker*, ZLR 2002, 19, 26 and from a general food law perspective by *Gorny*, ZLR 2001, 501, 509, 511; cf. also *von Danwitz*, ZLR 2001, 209, 219.

29 Cf. *Gorny*, ZLR 2001, 501, 511 who asks whether it should be three, four or even five generations and states: "ultra vires nemo obligari potest".

### 3. Article 17: Responsibilities

Article 17 of the Regulation allocates “Responsibilities”<sup>30</sup>. Pursuant to Article 17 para. 1 food operators *at all stages of production, processing and distribution within the businesses under their control shall ensure that foods ... satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met*. This provision endorses the concept of holding food manufacturers and distributors fully responsible for the all safety aspects of what they produce or distribute. At the same time the responsibility is confined to the particular activities of a food operator; as a consequence an operator cannot be made liable for safety aspects outside its own control. The provision, however, does not specify in any detail, how the responsibility approach is meant to work in practice. Particular aspects of this feature will become more apparent from Articles 18 and 19 which are presented further below.

Public authorities are not entirely forgotten. Article 17 para. 2 of the Regulation obliges member states to *enforce food law and monitor and verify that the relevant requirements of food law are fulfilled*, meaning those of the food business operators mentioned in Article 17 para. 1. Member states shall therefore *maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food ... safety and risk*. Such a system shall include *effective, proportionate and dissuasive* penalties for infringements of the relevant law. The underlying concept is clear: Food manufacturers and distributors bear the responsibility for their products; public authorities must control food production, processing and distribution, in cases of violations of the law they have to impose fines or submit the offenders to court. These ideas are not truly new and have existed in similar shapes in all member states already before the Regulation entered into force. However, the efficiency of controls and monitoring depends on a number of aspects not addressed in this particular provision. Experience shows that no safety concept can be better than those who operate it – its quality is in fact determined by an appropriate, sensible, diligent and conscientious application of the law.

### 4. Article 18: Traceability

A very important feature of the new concept of food safety is the “Traceability” principle laid down in Article 18 of the Regulation<sup>31</sup>. Pursuant to para. 1 of the article traceability *shall be established at all stages of production, procession and distribution*. This should be a matter of course, because a gap at any stage would make the traceability impossible. It is also coherent with the approach of holding all operators

<sup>30</sup> Cf. Dannecker, ZLR 2002, 19, 27.

<sup>31</sup> Cf. Dannecker, ZLR 2002, 19, 28-29.

involved in the food chain responsible individually. Para. 2 of the article describes more closely what is meant by traceability: *Food ... business operators shall be able to identify any person from whom they have been supplied with a food ... or any substance intended to be, or expected to be, incorporated into a food.* The responsibility for establishing relevant *systems and procedures* lies with the food business operators themselves, because they know best how to do it. They must also be able to submit information about their suppliers *to the competent authorities on demand* pursuant to para. 3 of the article. In order to make the origin of a foodstuff's components clear or easily accessible, Article 18 para. 4 demands that food *shall be adequately labelled or identified to facilitate its traceability.* In other words: sufficient information about the supplier of a food and its ingredients must either be presented on the product label or kept ready for inspection by the food business operator responsible for placing the food on the market.

#### 5. Article 19: Responsibilities for food: food business operators

A new and in some aspects comparatively heavy burden of "Responsibilities for food" is put on food business operators by Article 19 of the Regulation<sup>32</sup>. Again the essential general rule can be found in the last of the provision's paragraphs, namely para. 4: *Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.* Paras. 1 to 3 of the provision specify the risks mentioned here as well as the type of co-operation which is required. These distinguish between the degree of risk on the one hand and the kind of operator on the other hand, para. 2 being limited to the participation of retailers and distributors in withdrawal procedures only.

Pursuant to Article 19 para. 1 of the Regulation a food business operator is obliged to withdraw a food from the market if it *considers or has reason to believe that a food ... is not in compliance with the food safety requirements* and to inform the relevant authorities thereof. *Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers* and under certain circumstances also recall products supplied. The compliance with food safety requirements is a direct reference to the relevant provisions of Article 14 of the Regulation. It follows from the above explanation of food safety within the meaning of Article 14 that not any consideration or unsubstantiated belief of the operator will suffice to consider a food unsafe. Only positive knowledge or an actually justified reason can lead to the relevant requirement, namely a substantiated suspicion of a food being unsafe<sup>33</sup>.

Hence any food manufacturer or distributor who positively knows or reasonably suspects with substantiation that a food is either "injurious to health" or "unfit for

<sup>32</sup> Cf. Dannecker, ZLR 2002, 19, 29.

<sup>33</sup> Against an extensive interpretation of the provision is also Dannecker, ZLR 2002, 19, 27.

human consumption” must undertake safety measures to withdraw that particular food from the market. According to Article 14 para. 6 of the Regulation this duty comprises all items of the same lot, batch or consignment<sup>34</sup>. However, the obligation only arises where the food *has already left the immediate control* of the food business operator, i.e. where the products are no longer on its premises. In addition to that the food business operator is obliged to inform the competent authorities of the withdrawal procedures, but the provision does not say when. A comparison with the parallel provision of Article 19 para. 3 of the Regulation leads to the following conclusion: depending on the extent to which the food is believed to be unsafe the information about the withdrawal can be provided sooner or later. In circumstances where there is no immediate danger to human health the authorities may be informed even after completion of the withdrawal. There is no such duty of information where the food in question has not yet left the food business operator’s immediate control.

If a food business operator reasonably expects that its food has reached consumers, it is obliged to inform them accurately and effectively why the food is deemed unsafe. It must ensure that the consumers concerned are reached by such information and that they can understand it. No irrelevant details need to be communicated. Furthermore the food business operator has to resort to adequate measures *to achieve a high level of health protection*. The decision what is an adequate measure in any given circumstances remains with the operator. A duty to carry out a product recall arises only if other measures cannot achieve the desired effect.

Pursuant to Article 19 para. 3 of the Regulation *A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has put on the market may be injurious to health*<sup>35</sup>. Again the trigger-criterion is taken from Article 14 of the Regulation, but confined to the more serious of the two categories defined there. As in case of Article 19 para. 1 only positive knowledge or an actually justified reason can lead to the relevant requirement, namely a substantiated suspicion of a food being injurious to health. In this case, however, the information must be furnished forthwith, i.e. directly after the operator responsible becomes aware of the problem. Furthermore, Article 19 para. 3 demands that *Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer*. This provision does not actually oblige food manufacturers or distributors to take any action at all, but they have to tell their relevant authority so. However, *reasonable grounds to suspect that a food . . . may present a risk for human . . . health* justify public information by the authority under certain

34 This allocation of the burden of proof is criticised as unlawful from a criminal law perspective by *Dannecker*, ZLR 2002, 19, 26 and as problematic from a product safety law perspective by *Staudinger*, ZLR 2001, 649, 661; cf. also *Gorny*, ZLR 2001, 501, 512.

35 As to the advance German “implementation“ of this provision cf. *Schroeter*, ZLR 2002, 532, 533 (in this issue).

circumstances pursuant to Article 10 of the Regulation. In any event the operators must not obstruct an authority in its lawful pursuit *to eliminate a risk arising from a food*.

All measures stipulated in Article 19 of the Regulation are serving a dual purpose. Not only are they directed at maintaining food safety by keeping unsafe and dangerous food off the market. They also try to reinforce consumer confidence in food safety by creating transparency and enabling authorities to take appropriate measures. Nevertheless it has to be pointed out again that the primary responsibility for the safety of their products remains with the food manufacturers and distributors.

## D) Critical Evaluation

Admittedly, the new Regulation has been and still is a very ambitious legislation, not only with respect to its extensive scope and the speed with which it has been passed, but also particularly with respect to the aspiring goals it aims at. A critical analysis of the food safety requirements decreed must address the question whether the whole concept is a coherent and proportional piece of codification. It is also worthwhile to examine whether the targets set up by the White Paper have in fact been reached, i.e. whether the new provisions will make food as safe as the Commission would like it to be. In that context one has to ask as well if and in which conditions the law will actually work, particularly with respect to the (re-)establishment of consumer confidence.

### 1. Coherence and proportionality of the provisions

It is already doubtful whether the above mentioned provisions of Chapter II Section 4 of the Regulation form a coherent or even proportional set of rules. The four articles are neither fully convincing in themselves nor do they make up a complete and sound set of rules. The most striking feature in this respect is the definition of food safety as such in Article 14 when read in conjunction with the food business operators' responsibilities set out in Article 19 of the Regulation. Whilst the operator is under considerable duties to inform authorities, the conditions which demand such information hinge on criteria no conscientious business can actually fulfil. It remains unclear what degree of suspicion makes the information compulsory. Neither is it apparent what type of scientific evidence must be taken into account when assessing the potential effects of a foodstuff's consumption on human health. As a consequence no food business operator can be entirely sure in what circumstances it has to notify the relevant authorities. Neither is it determined by the Regulation what measures the authorities have to take in case they receive information on uncertain suspicions.

Another example of inadequate coherence and proportionality in the food safety requirements is the rather imprecise provision on enforcement in Article 17 para 2 of the Regulation with respect to the traceability obligations codified in Article 18. What if a foodstuff is evidently safe, but the chain of suppliers cannot be traced to its origin, i.e. the necessary information cannot be provided on demand? There is no clue in the Regulation as to whether such a foodstuff may be marketed or whether the authorities are in fact entitled to take it off the market although the manufacturer or distributor can prove that it conforms with food law provisions as set out in Article 14 paras. 7 and 9 of the Regulation.

The whole relation of subsisting food law addressing the issue of food safety and the new definition of food safety are at considerable odds. On the one hand a food manufacturer is obliged to obey the law – complicated as it is –, and on the other hand a diligent producer still runs the risk pursuant to Article 14 para. 8 of the Regulation that its products are withdrawn from the market upon a mere suspicion. This cannot be lawful in any democratic legal system based on the rule of law. Either one follows statutory demands; then one has to be allowed to rely on remaining unscathed. Or the relevant food safety law is inadequate; then it must be changed. But it cannot be in anyone's interest to have unrestricted suspicions prevail over parliamentary legislation. Clearly such rules cannot be called proportional in any respect either.

## **2. Conformity of the Regulation with the original proposals**

If measured with the original demands of the White Paper, however, the new statutory food safety requirements can – to a comparatively large extent – be seen as a success. The relevant provisions do in fact attempt to create a comprehensive system of food safety rules allocating responsibility to all operators along the food production chain safeguarded by traceability measures and supported by scientific risk analysis. Thus it appears well possible that the current level of food safety may improve as a consequence of the Regulation. However, this is not something the food safety requirements of the Regulation can achieve on their own. For an integrated food safety concept it is important that other food safety related legislation – e.g. rules on additives as well as residues or contaminations – defines lawful compositions of food and makes it unlawful to market unsafe food.

Only where the White Paper proposed transparency, consistency and clarity there appear to be some shortcomings. The problem of coherence including clarity has already been mentioned above. The question of transparency, however, remains largely in the dark. The same applies more or less to the demands that the law should be simple and understandable. Perhaps these goals were too aspiring in the first place. Perhaps the application and the implementation of the new Regulation has got to be tried and tested for some time before one can see how the issue of transparency

develops in practice. Since the Articles 14 to 20 of the Regulation only apply from 1 January 2005 pursuant to Article 65, this may take some time. In any case, it remains doubtful whether an additional aim mentioned in the Regulation itself may be reached, namely consumer confidence. This aspect merits a closer look when turning to the question of efficiency.

### 3. Efficiency of the new law with respect to consumer confidence

Time will tell whether the food safety rules of the new Regulations are efficient. However, from the outset it seems questionable whether some of them can indeed properly function to serve their purpose. Particularly where suspicions trigger off legal consequences (as in Article 14 paras. 4 and 8 and in Article 19 paras. 1 and 3) and the information of authorities is involved (cf. Article 10), scandals are likely to occur. An operator informing an authority early about its suspicions always runs the risk of the authority reacting prematurely, i.e. without fully confirmed and scientifically sound information, because the authority will of course feel under pressure to avoid potentially unsafe food entering the market. This is even more so where the term risk is rather extensively defined in Article 3 no. 9 of the Regulation as *a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard* and the authorities wish to prevent all conceivable risks. So measures may be taken where there is no actual but only a possible issue of unsafe food with the probable result of the operator concerned suffering considerable harm.

Perhaps responsible food business operators will therefore try to quickly solve safety problems themselves, as they are obliged to do, and be reluctant to fully co-operate with the authorities. This may lead to serious problems e.g. where undetected contaminations are concerned. In either case it is very difficult to gain consumer trust. Neither authorities which do not efficiently control nor manufacturers or distributors who do not adequately ensure the safety of their products merit consumer trust. But faults in the detection of unsafe food as well as inaccurate information and inappropriate measures can cause far greater loss of consumer confidence than is actually justified in such instances. As is well known, businesses can be ruined and authorities dismantled in the aftermath of food scandals which turn out to be based on unjustified suspicions. This can surely not be the desired effect of the new food safety law.

## E) Conclusion

The quality of the Regulation's food safety rules depends largely on their proper application by those they bind. An ineffective enforcement cannot be improved through any kind of law. Nor can fraudsters or other ruthless criminals be effectively deterred by legislative means. Food safety is, after all, an issue everyone should be

interested in as well as concerned about. Therefore the law can in effect only ever be as good as those who follow it. In other words: European food will always be as safe as the Europeans actually want it to be. If no manufacturer produces and no distributor offers unsafe food, the new provisions are unnecessary anyway. If no authority controls effectively, breaches of the current or the new law may remain undetected. If the consumers knowingly buy unreliable food they cannot truly complain about it. However, every society is prepared to take some risks – as long as they are known. All parties involved should agree upon the standards of safety they wish to have and then try to stick to those standards and actively participate in controlling themselves and monitoring others. When such consensus is not reached, it remains an open question whether the new law will work well. A democratic society has to accept deviating opinions – also with respect to the risks concerning food safety. In a certain sense the consumption of food will thus always remain dangerous, because absolute safety is a myth which can never be achieved; but the informed and understanding consumer will be aware of and accept the remaining risks<sup>36</sup>.

### Zusammenfassung

Die neue europäische „Verordnung (EG) Nr. 178/2002 zur Festlegung allgemeiner Grundsätze und Anforderungen des Lebensmittelrechts, zur Errichtung der Europäischen Behörde für Lebensmittelsicherheit und zur Festlegung von Verfahren zur Lebensmittelsicherheit“ enthält eine Reihe von Vorschriften zur materiellen Lebensmittelsicherheit im engeren Sinne. Der Autor befaßt sich mit diesem gesetzgeberischen Konzept, das Anfang des Jahres 2005 in Kraft treten soll.

Zunächst geht er dem Ursprung der neuen Vorschriften im Weißbuch zur Lebensmittelsicherheit aus dem Jahr 2000 nach und zeigt, was aus dessen Forderungen geworden ist. Anschließend stellt er die gesetzlich vorgesehenen Anforderungen an die Lebensmittelsicherheit (Art. 14), die Zuständigkeiten (Art. 17), das System der Rückverfolgbarkeit (Art. 18) und die Verantwortlichkeiten der Lebensmittelunternehmer (Art. 19) näher vor und unterzieht die einzelnen Normen sowie ihren Gesamtzusammenhang einer kritischen Würdigung.

Der Autor kommt dabei zu dem Ergebnis, daß die vorgesehenen Regelungen zwar vom Grundsatz her die Ziele des Weißbuchs in die Tat umsetzen, daß im Detail aber viel zu wünschen übrig bleibt. Er meint, die neuen Vorschriften seien weder besonders kohärent noch in jedem Fall verhältnismäßig; vor allem könnten sie das Ver-

<sup>36</sup> Cf. Gorny, ZLR 2001, 501, 512 who speaks of a socially adequate remaining risk.



trauen der Verbraucher in die Lebensmittelsicherheit letztlich nicht wesentlich stärken. Nach Ansicht des Autors wird es trotz aller Bemühungen keine absolute Lebensmittelsicherheit geben, dieser Wunsch bleibt ein Mythos. Es wäre darum besser, wenn man sich allgemein darauf verständigen und generell akzeptieren könnte, daß der Verzehr von Lebensmitteln stets mit einem Restrisiko behaftet sein wird.