protection products[5], and (iii) the uniform principles for evaluation and authorisation (risk assessment) for plant protection products[6]. These regulations were adopted on 8–10 June 2011, within the framework of Article 84 of Regulation 1107, which required the Commission to adopt implementing measures on those points by 14 June 2011. In addition, the Commission adopted Regulation 547/2011 concerning labelling requirements for plant protection products,[7] as well as Regulation 540/2011 containing the list of active substances already approved through inclusion in Annex I to Directive 91/414, which are now transferred into the corresponding positive list set out under Regulation 1107/2009.[8]

Lastly, Regulation 1107/2009 contains important new provisions on data confidentiality and data sharing to avoid the duplication of testing of plant protection products on vertebrate animals. In short, as regards confidentiality, the Regulation now contains a positive list of data which are in principle regarded as confidential (e.g., manufacturing process, impurities unless they are toxicologically relevant, see Article 63). As regards data sharing, data owners and prospective applicants must *"make every effort"* to ensure that they share tests and studies involving vertebrate animals against *"fair share of the costs"* incurred by the data owner. Broadly speaking this obligation applies to both vertebrate and non-vertebrate animal tests. However, in the case of vertebrate studies, should the parties concerned fail to reach an agreement, the Member State authorities are entitled to refer to the studies for the benefit of the prospective applicant, while the data owner has a claim before a national arbitration panel or Court for a "fair share" of the costs. Regulation 1107/2009 does not define in detail the procedure, timing or criteria for data sharing, nor does it specify what constitutes a "fair share". Accordingly, unless the Commission adopts a guidance document on data sharing these critical aspects may be further clarified by arbitration panels and Court decisions.

In conclusion, the new Regulation has tightened the rules and process for the placing on the market of plant protection products. Behind the stated intention of achieving a high level of protection for human health and the environment, the EU has increased significantly the standards that industry will have to meet in order to commercialise its products in the future. While benefitting from a new, comprehensive and fully harmonised regulatory platform the agrochemical industry will be faced with many new hurdles and variable parameters such as the "substitution principle" and comparative assessment, amongst others, requiring a close coordination of business, scientific and legal considerations.

5 Commission Regulation (EU) No 545/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products.

6 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products.

7 Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products.

8 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.

Food

This section aims at updating readers on the latest developments of risk-related aspects of food law at EU level, giving information on legislation and case law on various matters, such as food safety, new diseases, animal health and welfare and food labelling.

How Much Safety Concern Makes a Food "Unsafe"?

*Kristine Lilholt Nilsson**

Article 14 of the EU's General Food Law Regulation (178/2002) specifies that food may not be placed on the market if it is unsafe. Article 19 imposes an obligation on food business operators to withdraw products from the market if they have reason to suspect that there is a health risk. But how far do these provisions stretch in terms of providing a basis for ordering recalls? How much doubt, so to speak, needs to be raised as to the safety of a product before the food business operator must withdraw it? Focusing on two recent Danish cases, this report highlights some of the weaknesses of food safety regulations and the problems that can arise when the rules are applied in practice.

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I. Introduction

Article 14 of EU General Food Law Regulation[1] 178/2002 provides that a food product may not be placed on the market if it is unsafe. Article 19 of the Regulation imposes an obligation on food business operators to withdraw a product if they have reason to believe that it poses a health risk. Though it seems obvious that unsafe foods should be withdrawn from the market, the matter of when exactly a food product can be considered unsafe often leads to discussion. How much room is there for doubt as to the safety of a product and how many obligations do the provisions impose on food business operators? While it is ultimately always up to the courts to decide, on a day-to-day basis food business operators need to navigate within the interpretations of these provisions made by national authorities.

This report will discuss the topic in the light of two recent Danish cases that have highlighted the problems that can arise in this context – especially concerning the legal rights of the food business operators involved.

II. Case I

In July 2011, the office of the Danish Parliamentary Ombudsman gave its opinion in a Danish administrative case concerning a matter of food safety.[2] The case began in autumn 2009 when the Danish Veterinary and Food Administration (DVFA) raised a safety issue as to the use of a botanical substance in food supplements. The DVFA had instructed the regional food authorities to initiate proceedings against companies marketing products with certain ingredients – and, if necessary, to make sure that the products were withdrawn from the market. In this particular case, a regional food authority contacted a company which marketed a food supplement containing a banned ingredient and asked it to withdraw the product voluntarily. The company was informed that, if it did not do so, it would be subject to sanction and an official injunction.

The company disagreed with the assessment of the ingredient and indicated this to the authority. The latter insisted on the ban, however, and the company ultimately complied, while clearly stating that it did not agree on the necessity of withdrawal because it believed it could rely on a scientific safety assessment of the product to prove that it was safe to consume.

The company subsequently brought a complaint before the Danish Veterinary and Food Complaints Secretariat, partly about the decision the DVFA had taken when initially assessing the ingredient and asking the regional authorities to secure withdrawal, and partly about the administrative decision the regional food authority had made when instructing the company to withdraw the product. The complaint was rejected on procedural grounds.

It was this rejection that the office of the Danish Parliamentary Ombudsman overturned in July 2011, awarding the affected company the right to have its complaint assessed.

Apart from the procedural issues regarding the right to complain, the case also raises substantive fundamental issues related to food safety were and could not be solved through an opinion from the office of the Danish Parliamentary Ombudsman.

As mentioned above, the case began in October 2009 when a withdrawal of the products was first imposed. The formal complaints filed by the company were not given suspensive effect either initially or after the case was dismissed and the Parliamentary Ombudsman decided to look into it. As a consequence, the company has been forbidden to sell the product in the meantime. The office of the Parliamentary Commissioner published its opinion in July 2011, one year and nine months after the withdrawal. The complaint is only now being processed in the Danish administrative system and handled by the Food and Veterinary Complaints Secretariat, meaning it will take at least another year, and probably more, before the case is finally closed. During the entire period, the product has been off the market without anyone other than the DVFA having considered whether this was a justified measure to protect human health.

It is evident that, when a product is removed from the shelves, shelf space is quickly filled by other products. Anyone working within the food industry who has experienced a recall knows how costly it can be. Besides the damage to the commercial image of a company which always follows a recall, the competitive market and the need for consumers to find a sub-

1 Regulation (EC) No. 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1.

2 The opinion has not been published.

stitute for a product they like makes it highly complicated to re-enter the market after a withdrawal, even after a short period of time. Where products have limited shelf life, or there is a prolongation of the withdrawal as in this case, products in stock must be destroyed if they expire before the market is accessible again.

As mentioned above, this case also highlights the conflict between commercial interests and the protection of human health. The decision made reference to the provisions of Article 19(1) of EU General Food Law Regulation 178/2002 regarding the obligation to withdraw unsafe foods from the market:

> *"If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection."*

The provision does not leave any doubts as to its objective: protecting consumers. It does not, however, clarify what constitutes "reason to believe" that there is a health hazard. In other words, what happens when the authorities feel there is reason to believe while the food business operator does not?

In Denmark, the answer appears to be the following: if the authority has reason to believe that a food is unsafe, the food is considered unsafe, and the food business operator has an immediate obligation to withdraw. This is the case regardless of the food business operator's opinion. Such an interpretation of the rules in effect translates into unlimited powers for the authorities, which might constitute a threat to the basic legal rights of the food business operators if these powers are not exercised with care.

III. Danish guidelines on safety assessment

In October 2010, the DVFA submitted the first draft guidelines on the safety assessment of food supplements for public consultation. After the consultation procedure, the DVFA notified the Commission of the guidelines[3] in accordance with Directive 98/34.[4] Once the standstill period ended, the guidelines were ultimately published on 22 August 2011.[5]

The guidelines are intended to help enterprises in their safety assessments. However, since they are quite extensive, it could be argued that they also impose additional requirements for food establishments marketing their products in Denmark.

The guidelines are based on Article 14 of Regulation 178/02 and state that the entity responsible for the product should ensure that marketed foodstuffs are safe for consumers:

> *" for all other food products, it is the entity's responsibility to ensure that legislation is complied with, including that products are safe to consume as stipulated in Article 14 of the food regulation. The entity responsible for the product must therefore be able to document that the food, including food supplements, marketed by the entity are safe."*

In other words, Article 14 requires any food business operator to show that the food or food supplements are safe at the time of the first marketing of the product. The Danish guidelines go further, however, stating that the documentation must be made available for regular inspection by the food authorities.

In the Danish guidelines it is further described what a dossier for the safety assessment of a food supplement should comprise. This includes:

1) A toxicological evaluation based on comprehensive scientific toxicological studies on plant ingredients, plant extracts, relevant substances linked to the use of plant ingredients, well-defined substances and other relevant substances and/or ingredients in the product, as well as the combination of ingredients in the product;
2) Information as to side effects or adverse reactions, contra-indications and experiences with special population or patient groups, including pregnant or lactating women, should be given if known or available; and

3 Notification No. 2011/142/DK.

4 Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, OJ L 204, 21.7.1998, pp. 37–48.

5 Guideline No. 9381 of 22 August 2011 on the Safety "As Assessment of Food Supplements".

3) Other significant data material relevant for the assessment of the safety of the product.

Furthermore, the guidelines elaborate on the manner in which the data should be presented and how it should be documented that a full search of all relevant databases has been performed.

The guidelines impose more safety-related requirements than Regulation 178/02 and thus go far beyond anything that was previously required for food supplements. Indeed, the guidelines require that the food business operator prepare a scientific dossier on the food supplements before they are first brought to market. This scientific dossier must contain a full toxicological review of the ingredients, both by themselves and in combination. The dossier also has to contain proof that a comprehensive search for information has been made in all relevant databases, and include a discussion and conclusion on the results of this search. All these steps resemble the requirements for the clinical evaluation of medical products.

IV. Case II

In another recent administrative case,[6] a Danish manufacturer of food supplements was asked to submit to the authorities its safety assessment of a certain food supplement containing a botanical substance in early 2011. A few weeks later the food business operator forwarded what it believed to be the relevant documentation. Some weeks later, the Danish authorities imposed a prohibition and ordered the company to withdraw the product under Article 14 of the General Food Law Regulation (178/2002).

The basis for this decision was the fact that the company had made an insufficient safety assessment. The order to withdraw the product referred to an assessment of the botanical substance made by the Danish Food Institute on behalf of the DVFA a few days prior to the recall. This assessment had only been presented to the company shortly before the recall was ordered and concerned an ingredient similar – but not identical – to the botanical ingredient in question. At the same time, the assessment made by the Danish Food Institute on behalf of the DVFA analysed a much larger quantity of the active substance than was proportionally present in the product. Nonetheless, the authorities concluded that there were "doubts" as to the safety of the product to an extent that justified the imposition of a prohibition and an order to withdraw the product from the market.

Danish Executive Order no. 1287 of 14 December 2004 makes it a criminal offence to infringe Regulation 178/2002. Following the order to recall, the company was, accordingly, presented with a fine of DKK 60,000 for breaching Article 14 of said regulation by selling a product the safety of which could be placed in "doubt".[7] The fine was imposed during the standstill period after the notification of the abovementioned guidelines and before they were actually issued.

V. Concluding remarks

As we have seen, Article 14 of Regulation 178/2002 states that "unsafe" foods must not be placed on the market. Furthermore, the Article refers to a number of criteria in defining when a food can be considered "unsafe".

In light of the above examined cases it seems that the Danish authorities understood Article 14 of Regulation 178/2002 in the following way: even when a food business operator has performed a safety assessment of a product, the fact that any type of doubt can be raised as to its safety can be interpreted to mean that that the food business operator has infringed Article 14 and thereby committed a criminal offence.

Due to such far-fetched interpretation and the length and expense of Danish administrative proceedings, many companies are likely to resign themselves to accept the relevant decisions and invest in the manufacture and sale of other products.

From a practising lawyer's perspective it does appear that the application of the abovementioned provisions of Regulation 178/2002 in Denmark threatens the basic legal rights of food companies. It also appears that the above interpretation lacks reference to the balancing of the interests at stake and the principle of proportionality, with the result that, in matters of food safety, Danish authorities appear to have almost unlimited powers. There is a valid question as to whether this is truly acceptable in a modern society.

6 The case is still pending in the administrative complaint system. The product has been withdrawn.

7 This case is still pending.