following are particularly worth recalling: (1) the need to fulfill the expectations of Polish society; (2) richness of biodiversity and the need to prevent serious disturbances to the functioning of the environment; (3) the fragmented structure of Polish agriculture; (4) specific agricultural production profile with domination of conventional traditional and organic farming; (5) following from the two previous characteristics – the impossibility of elimination of a risk of cross-contamination and preventing of potential damage that could be caused as a result of crossover of transgenes into conventional crops; (6) the need to limit the cultivation of GM plants to areas that do not contain elements of value for nature conservation, and whose agrarian structure enables the safe cultivation of transgenic plants without damaging the nature and the operations of other farmers.

Interestingly, in its decision rejecting the Polish notification, the Commission did not refer to any of these arguments, stating only that no new scientific knowledge had been presented in support of the exemption. It is therefore remarkable to see the Commission suggesting these same grounds not much more than two years later as valid concerns and as acceptable possible "opt-out" justifications. It is perhaps not possible to determine whether or not the Commission has been inspired by experiences of Member States which attempted to ban GM cultivation under the current regulatory scheme. However, it should be interpreted as a positive signal that the proposed list seems to respond to real concerns previously expressed by Member States in the context of GM cultivation restrictions.

It is too early at this juncture to draw any firm conclusions about new developments of the proposed reform of the European GM cultivation regime. However it should be said that concerns about the possible implications of use of the proposed instruments, both in the EU as well as in international context, seem to overshadow their possible positive interpretations.

To an optimistic reader, the Commission's initiative could be seen as a signal of a long-awaited transition of the EU market's regulatory philosophy towards greater flexibility, respect for local differences and acknowledgement of the validity of socio-economic context of regulation. Most commentators, however, seem to lean towards a more skeptical reading of the new developments, pointing to the underlying controversies and questioning the intentions of the Commission.

Perhaps the history of the EU regulation of GMOs, the slow pace of the current reform as well as the polemics surrounding its development, all justify this suspicion, suggesting that, instead of pointing the way forward the Commission is leading European GMO regulation into a dead end street, where it comes right up against the WTO regime. Possibly, the solution lies in the answer to the fundamental question: who is actually supposed to benefit from this reform?

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.

Faced with a Recall – How good is your Insurance?

*Susie Stærk Ekstrand and Kristine Lilholt Nilsson**

I. Introduction

Any business having experienced a product recall knows how costly this can be. Sometimes the main costs of the recall are concentrated around counteracting bad publicity, but if several or large numbers of batches are affected by the recall, the costs of the recall itself can mount up considerably.

In many large companies the overall responsibility for quality assurance and product safety is placed in a different part of the organization from the one responsible for product liability insurance and recall insurance.

As a consequence inside the organization there is not always a common understanding of what the insurance should cover and what the insurance actually does cover – or of whether and when the insurance company should become involved in the process.

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In this report we will discuss some of the many pitfalls that arise in relation to insurance when initiating a product recall, as well as the possible ways of preventing eventual disappointment.

The main problems arise out of differences in terminology, so we will start by outlining the most important definitions and differences.

II. Definitions

1. Recall

In the General Food Law Regulation, Regulation 178/2002/EC laying down the 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, article 14) it is stated that a food shall not be placed on the market if it is unsafe. A food is considered to be unsafe if it is injurious to human health or if it is unfit for human consumption. Article 19 of the General Food Law Regulation provides that "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 [...] and inform the competent authorities thereof".

Since the overall aim of the regulation is to protect human health, the obligation in article 19 can be extended to cover not only situations where a risk to human health is known and situations where there is reason to believe that there is a risk to human health, but also to cover products which may give rise to concern as to whether or not the food safety requirements are met.

2. Product liability

Under the Directive on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, 85/374/EEC (OJ L 210/ 29)[1], the two main conditions for imposing product liability are that a product is found to be dangerous or defective and has caused damage to a person or thing. The basic criterion is that the product is defective in the sense that it has qualities that during the course of normal use could cause damage to persons or things. Secondly, the defective or dangerous condition must have been caused by negligence.

3. Recall insurance

There are many "standard" types of cover for recall insurance and they generally contain the same elements. The standard Danish policy, for instance, provides that costs related to specified measures for product recall are covered provided that 1) necessary measures are taken to avoid or prevent the occurrence of health or safety hazards, and 2) that the measures have either been ordered by a competent authority under statutory provisions or approved by the insurer.

When comparing the requirement for product liability with the requirements in the General Food Law Regulation, it is clear that that a defective food must not be placed on the market – and must be withdrawn if it has already reached the market when the defect is discovered, if the defect results in a health or safety hazard.

However, if a recall is necessary due to concern over a risk to human health, the product is not necessarily defective in terms of product liability. This is where the recall insurance becomes relevant. But there are good reasons to be aware of any limitations in the coverage and to know whether the actual coverage in the individual policy meets the requirements and expectations of the company.

III. Compulsory or voluntary recall?

First of all, it is evident that the above standard insurance policy only covers a recall if it is ordered by the relevant authority. Such a provision may sound reasonable, but in practice the question will arise as to whether such a policy does indeed cover most of the situations where recall becomes necessary.

As already mentioned, the General Food Law Regulation imposes the obligation on the business operator to withdraw a product from the market if he "considers or has reason to believe that a food is not in compliance with the food safety requirements."

1 Incorporated in The Danish Product Liability Act, no. 371 of 7 June 1989, with amendments, as well as the case law-based rules on product liability which have been maintained alongside the provisions in the act.

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