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REGULATORY CHALLENGES OF INNOVATION IN FOOD AND AGRICULTURE MARKET AUTHORIZATION REQUIREMENTS FOR NEW FOODS

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Abstract: Regulatory authorities face the challenge to strike a fair balance between the interests of consumers to ensure the safety of innovative foods and agricultural products and the interest of innovative businesses. Worldwide prior authorization schemes are applied. This contribution explores characteristics, pros and cons of such schemes. It identifies concerns but also best practices that may contribute to improving food safety without unduly hampering innovation.

Keywords: food law, novel food, pre-market approvals, risk assessment, WTO, Codex, food safety

Introduction

Regulatory authorities around the globe face challenges of keeping pace with innovations in the food and agricultural sectors. Without any doubt the most challenging innovations – and on those this contribution focuses – concern products not formerly known in the jurisdiction at issue.

In the 1950s and 1960s chemistry was a frontier science providing agriculture with herbicides and pesticides and food processing with synthetic additives. Later, gene technology developed crops and foods that had hitherto been unknown. Currently, innovations in food production are expected from nanotechnology and animal cloning.

New products in this sense, however, do not only come from laboratories. New foods may also originate from discoveries in other geographical areas. Products that are new to a region but have a history elsewhere are often referred to as ‘exotic’.

This wide variety of new foods presents authorities with challenges. What is their responsibility in this respect? How do they have to react? Can best practices be derived from international experience?

This article addresses these questions from the angle of legal scholarship. We apply a comparative approach gaining insights from different jurisdictions around the world. Empirics will be derived from legal-economic studies, indicating concerns experienced in practice. From this combined perspective, possible regulatory strategies will be proposed.

Core issue in the regulatory approaches to innovations in food and agriculture are prior authorization schemes requiring a proof of safety before a product belonging to a certain category of products can be placed on the market. Similar approaches are found in the areas of medicines,

veterinary drugs and pesticides. The analysis in this contribution, however, is limited to foods and agricultural products intended for human consumption.

This article addresses the following questions. How have prior authorization schemes developed? What are the critical issues? To which concerns have authorization schemes given rise? Which best practices have emerged to deal with these concerns? What can regulators do to face the challenge from product innovation in food and agriculture?

The article is structured as follows: Section II introduces the international meta-framework with which national regulatory systems should comply; Section III discusses schemes that have developed in the EU and US; Section IV describes an example of pre-market approval schemes – the EU procedure for novel foods – in more detail; Section V lays out some concerns regarding pre-market authorization requirements; Section VI discusses best practices and concludes the argument.

Meta framework

International food law

If national regulatory systems (including regional systems) want to fit into the international community, they need to comply with requirements of international law. In the international arena a framework of requirements has developed that applies (not to the behaviour of people and businesses, but) to the national legal systems, and can thus be considered a meta-framework (Meulen van der 2010).

At the global level different players contribute to this meta-framework for food and agriculture. The United

Nations (UN) lays emphasis on human rights. The Food and Agricultural Organization (FAO) and the World Health Organization (WHO) have the lead in the core elements of standard setting: risk assessment and risk management. The World Trade Organization (WTO) plays a major role in application of food standards in trade and dispute resolution. The WHO operates risk communication structures, seminal in incident management. For our analysis, the food standard developed by FAO/WHO and trade agreements concluded within the WTO are relevant.

International standard setting

Risk assessment

Risk assessment for international standard setting is undertaken in three main joint FAO and WHO panels: Joint FAO/WHO Expert Committee on Food Additives (JECFA), Joint FAO/WHO Meetings on Pesticide Residues (JMPR) and Joint FAO/WHO Meetings on Microbiological Risk Assessment (JEMRA). They advise on maximum limits for food additives, pesticide residues, microbes and on other food safety issues.

Risk management: Codex Alimentarius Commission

In 1963 the FAO and WHO established the Codex Alimentarius Commission (CAC), consisting of specialized committees, hosted by member states all over the world. Some 175 countries participate in their work. Food standards are established through an elaborate procedure of international negotiations (FAO/WHO 2006). All standards together are called '*Codex Alimentarius*' (Latin for 'food code'). Apart from standards, *Codex* also includes advisory provisions called codes of practice or guidelines, mainly addressing food businesses. At present, *Codex* comprises more than 200 standards, close to 50 food hygiene and technological codes of practice, some 60 guidelines, over 1,000 food additives and contaminants evaluations and over 3,200 maximum residue limits for pesticides and veterinary drugs (FAO/WHO 2002; Knudsen *et al.* 2008; Masson-Matthee 2007; FAO/WHO 2006).

Codex standards do not as such have legal effect on people and businesses. To acquire such effect, they need to be implemented in national legislation.

Trade and dispute settlement

The WTO endeavours to liberalize international trade. It is a system based on negotiations. When countries face barriers to trade and want them lowered, the WTO is a platform for negotiating the opening of national markets and

removing as many obstacles to trade as possible without undesirable effects. The core of the WTO system are the WTO Agreements, providing rules for international trade. The main agreement concerning trade in goods concluded within the WTO is the General Agreement on Tariffs and Trade (GATT). In some circumstances, however, WTO rules support maintaining trade barriers – to protect higher values. Article XX(b) of GATT recognizes that exceptions to free trade can be necessary to protect human, animal or plant life or health.

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)¹ aims to ensure that countries only apply measures to protect human and animal health (sanitary measures) and plant health (phytosanitary measures) based on the assessment of risk, or – in other words – based on science. However, if the measures are in conformity with international standards, no scientific proof of necessity is required. These measures are by definition considered necessary. For food, these international standards are in the *Codex Alimentarius*. WTO members who follow *Codex* standards need not prove the necessity of their SPS measures.

WTO agreements bind WTO member states. The Dispute Settlement Understanding provides a procedure to resolve conflicts. If a party so requires, the Dispute Settlement Body forms a panel to deal with the issue. Panel decisions can be appealed to the Appellate Body. The WTO cannot enforce decisions taken in this procedure, but it can allow the winning party to implement economic sanctions if the party found at fault does not comply. These sanctions are usually additional import levies on goods coming from the state found at fault.

Developments

United States

Before the 20th century, new foods and crops were not seen as a matter of concern for authorities. One of the first pre-market approval schemes was introduced in 1958 in the United States. Concerns about the application of chemicals in food processing led to the introduction of an approval requirement for food additives (Table 1). Products within the definition of 'additive' need to be authorized or to enjoy GRAS status. Failing this, foods containing them are considered adulterated.

This concept of food additive is much wider than the concept of food additive in the *Codex Alimentarius*² (and in the EU) in that it is not limited to substances with a *technological function*. A food additive in this wide sense of the word that has not been on the US market before 1958 has to undergo safety assessment, except when it is 'Generally Recognized As Safe' (GRAS). In other words, when within

¹The SPS Agreement can be found at: http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm.

²CODEX STAN 192-1995.

the scientific community consensus has been reached on the safety of a certain product (category), it no longer needs to be assessed by the authorities.³ Separate authorization requirements apply to colour additives and dietary supplements.

Table 1. Section 201(s) FFDCFA [21 USC 321].

The term “food additive” means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

European Union

Back in 1958 when the USA introduced its scheme for food additives, the European Economic Community (now the European Union) was only just starting its activities. One of the earliest examples of harmonisation of national laws can be found in legislation on colorants. The directive concerning the colouring matters authorized for use in foodstuffs intended for human consumption set out to harmonise Member States’ legislation by establishing a single list of colouring matters the use of which is authorized for colouring foodstuffs and laying down criteria of purity which those colouring matters must satisfy.⁴ As a result, one of the first positive lists in the EU was created. The list is a part of the law (in this case an annex to the directive). To include later a product in the list (or delete it from the list), the law must be changed by the applicable procedure.

While the details differ greatly, positive lists or similar market authorization requirements exist in EU food law, as well as in Member States’ food law. Examples at EU level include food additives (including sweeteners, colourants, etc.)⁵ flavourings,⁶ extraction solvents,⁷ infant formulae and

follow-on formulae,⁸ foodstuffs intended for particular nutritional uses,⁹ food supplements,¹⁰ genetically modified (GM) food and feed,¹¹ food contact materials,¹² nutrition and health claims made on foods,¹³ and novel foods.¹⁴

Some Lists are More Positive than others

From the above follows that case-by-case risk assessments preceding the placing on the market of new products is a common feature in regulatory responses to innovations in food and agriculture in many parts of the world and – to a certain extent – also at the global level of the *Codex Alimentarius*. Within the world of positive lists, however, we find many different flavours. The most important differences are discussed below.

Object of authorization

Different categories of foods are submitted to premarket approval. Some products are subject to premarket approval based on certain *processes* that have been applied to them. An example of such a procedure is the regulation on GM foods in the EU. The pre-market approval responds to consumers’ concerns to ensure the safety of food products which have been produced with help of modern biotechnology. Another category of pre-market approvals refers to food or food ingredients new to the market and which will be used for a certain *purpose*, e.g. food additives or processing aids. The Regulation on novel foods in the EU provides an example of a regulatory scheme for foods that are new because they have no history of safe use prior to a single cut-off date (15 May 1997).¹⁵

Subject of authorization

To whom does the authorization grant rights? Generally speaking, authorization schemes come in two different forms. Some schemes are *specific* in that they address the applicant (applicant-linked). Others are *generic* in that they address the product. In a generic scheme, the product is

³ On a voluntary basis, Food and Drug Administration’s opinion can be sought.

⁴ OJ 1962, pp. 2645-2654.

⁵ Reg. 1333/2008 on food additives, OJ 2008, L 354/16.

⁶ Reg. 1334/2008 on flavourings, OJ 2008, L 354/34.

⁷ Dir. 2009/32 on extraction solvents, OJ 2009, L 141/3.

⁸ Dir. 2006/141 on infant formulae and follow-on formulae, OJ 2006, L 401/1.

⁹ Dir. 2009/39 on foodstuffs intended for particular nutritional uses, OJ 2009, L 124/21.

¹⁰ Dir. 2002/46 on food supplements, OJ 2002, L 183/51.

¹¹ Reg. 1829/2003 on genetically modified food and feed, OJ 2003, L 268/1.

¹² Reg. 1935/2004 on materials and articles intended to come into contact with food, OJ 2004, L 338/4.

¹³ Reg. 1924/2006 on nutrition and health claims made on foods, OJ 2007, L 404/3.

¹⁴ Reg. 258/97 concerning novel foods and novel food ingredients, OJ 1997, L 43/1.

¹⁵ Regulatory framework based on similar criteria exist also in Australia and New Zealand. To some extent, food additives regulation in the US is also based on a cut-off date.

placed on the (positive) list. All businesses are allowed to bring the authorized product to the market. In a specific scheme, the authorization decision addresses the applicant, authorizing the applicant to bring the product at issue to the market. All others who would want to bring an identical product to the market need an authorization as well (usually through a simplified procedure).

Applicant-linked schemes reward the applicant for the investment made in the safety assessment and in the procedure by granting him an exclusive right. The downside is that repeated procedures are required, even though the outcome of the risk assessment is already known to the authorities (the product is safe and allowed on the market). Generic schemes reward the second to come to the market who benefits from the investment made by the applicant, without having made the effort.

Currently, the EU is experimenting with an in-between form: data protection. If the application is based on proprietary data, these data can be used only to the benefit of the applicant for a certain period. Thus, innovative foods based on considerable product development could be granted a specific authorization to protect the applicant. Only after the data protection period has elapsed, the authorization could become generic. Applicants who would like to enter the market before that time would have to provide their own data. Data protection rewards the investment made in scientific research, not in the approval procedure as such.

Assessment

A decided advantage of a prior authorization procedure on a case-by-case basis is that all the uncertainties that surround food and agricultural innovations can be given a place. In all procedures, be they positive lists or authorizations for specific foods, applicants have an interest to actively contribute to solving problems. In the case of applications for the authorization of a new food additive (positive list), a full technical dossier must be submitted showing that a reasonable technological need exists for the proposed food additive, that it presents no hazard to the health of consumers and does not mislead them (EC 2001). Similar requirements are set for businesses sponsoring a novel food (individual authorization). An application must scrupulously identify the product and present evidence that a product is safe to consumers and – if need be – adequately labelled not to mislead them.¹⁶

Finally, it has to be mentioned that most prior authorization schemes apply only negative criteria, that is to say they focus on risks and do not take into account benefits. One of the current debates on risk assessment raises the issue if benefits can be accepted to outweigh certain risks such as (potential) allergenic properties (EFSA 2006). In

pharmaceutical law, for example, usually it is accepted that a beneficial medicine may have certain side-effects. In foods, side effects are usually not accepted.

GRAS

In the EU system of prior authorization for novel foods no exception exists to the requirement that all foods that were not on the market before the cut-off date must be explicitly approved. There is no possibility to exclude certain categories from this requirement when it has been sufficiently established that the category as such does not pose a relevant risk. If over time science would establish that a certain new type of process does not give rise to safety concerns, in theory each next product made with this process would still have to undergo safety assessment. To put it more simply, in the EU system there is no way out of novelty. The American system may hold a solution to this problem in the concept of 'GRAS'. A food additive that has not been on the US market before 1958 has to undergo safety assessment, *except* when it is 'Generally Recognized As Safe' (GRAS). This is the case when consensus has been reached within the scientific community on the safety of a certain product or category of products. In that case, risk assessment is no longer required by the authorities.

Concerns

Trade barriers

In literature it has been argued that prior authorization schemes hamper innovation. Brookes in his analysis of the economic impact of the novel foods approval procedures on the EU food sector finds that it is fairly common for the costs associated with meeting regulatory requirements to be between € 0.3 million and € 4 million, and that the considerable additional time taken to authorize novel foods in the EU adds an extra € 0.3 million to € 0.75 million per application (Brookes 2007). Further, he concludes that the rate of return of the costs made on these investments would be around 25% if the procedure were to take 6 months. If delayed to 2.5 to 3 years, the rate decreases to 17%-18%, and if it is extended to five years (60 months), it becomes negative as the rate is then 14.6%, which is lower than 15%, the commonly used baseline for determining whether investments take place.

These concerns are supported by the little empirical evidence that is available from the EU. In the period 2003 – 2008 a total of 25 genetically modified foods were approved. Nineteen novel foods were approved and some 30 new additives. It seems that less than one hundred product

¹⁶ Commission Recommendation 97/618/EC concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Reg. 258/97, OJ 1997, L 253/1.

innovations in the food sector requiring prior authorization have actually been approved under EU prior authorization schemes. This small quantity is in striking contrast to the total number of innovations. Data for the entire food sector are not available, but for the dairy sector alone *Poppe et al.* identified over 1,400 innovations in the same period (*Poppe et al.* 2009).

Also in the world of exotic foods – these are foods that have a history outside the EU, but, due to a lack of history of use inside the EU, are considered novel – the potential is huge but hardly used. Worldwide, some 7,000 plants are known to be used in the human food supply. About 300 of these are likely to be considered traditional in the EU. Most of the rest would come within the ambit of prior authorization requirements if anyone tried to bring them to the EU market (Knudsen et al. 2008). Thus, with the potential of over 6,000 already existing food sources, only five or six exotic plants or oils derived from such plants have been approved for the EU market under the Novel Foods Regulation.

WTO

From the above follows that, with regard to innovations in food and agriculture, regulatory authorities face the challenge to strike a fair balance between the requirements of safety – that is consumer protection – and the interests of the business sector. The considerable burden that pre-market approvals place on businesses must be scientifically justified and not constitute disguised restrictions on international trade.

According to the WTO SPS Agreement, members have the right to adopt sanitary or phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are based on scientific principles and not maintained without sufficient scientific evidence (Article 2 SPS). This requirement is further elaborated in Article 5 SPS, which also provides for one exception: Article 5.7 SPS allows to adopt provisional SPS measures in cases where the scientific evidence is not sufficient.¹⁷

Hence, although the choice of an appropriate level of protection is perceived as a democratic choice of each WTO member, food safety measures must meet rather strict risk assessment requirements to be considered justified barriers to trade.

Pre-market approval schemes are not forbidden under WTO law, provided that certain conditions are met. Article 8 permits procedures aimed at ‘checking and ensuring the fulfilment of SPS measures’ and undertaken in the context of ‘control, inspection, or approval’.¹⁸ Annex C sets out requirements for these procedures. They have to be, i.a., undertaken and completed without undue delay and in no less favourable manner for imported than for like domestic products, the applicant has to be duly informed by the competent authorities about the progress of the application at all stages at the procedure, and any requirements for control, inspection and approval of individual specimens of a product must be limited to what is reasonable and necessary.

Concerning the Novel Foods Regulation, the Panel stated in the *Biotech Products* case that the granting of marketing approval for these foods is conditional, i.a., on a satisfactory demonstration that the product for which approval is sought not present a danger for the consumer. To the extent the Novel Foods Regulation is applied for this purpose, it meets the purpose element of the definition of an ‘SPS measure’.¹⁹ In consequence, the pre-market approval procedure for novel foods constitutes a procedure ‘to check and ensure the fulfilment of SPS measures’ within the meaning of Annex C.²⁰

Thus, in the SPS Agreement pre-market authorizations fall within the category of procedures aimed at checking and ensuring the fulfilment of SPS measures. The risk analysis paradigm is applied to individual authorization decisions taken within the framework of the Novel Foods Regulation.²¹ However, the main issue that begs the question here is whether the regulatory framework setting out the pre-market approval requirement itself should be based on scientific evidence.

Concerns over the legality of the Novel Foods Regulation in the WTO forum were first raised in 2006 by a few developing countries, including Peru, Ecuador and Colombia, supported by interventions from other South American and African countries. Peru in its communication highlighted that, as a consequence of the implementation of the regulation, exports of dehydrated lucuma meal (‘harina de Lúcumá’) and yacon had been stopped.²² According to Peru, the Novel Foods Regulation is therefore an unnecessary and unjustified barrier to international trade because of the very high costs of producing the scientific studies required and a lengthy authorization procedure.²³

As already mentioned, the main problem of the Novel Foods Regulation is that it makes no distinction between

17 See also WTO Appellate Body Report, Japan – Measures Affecting Agricultural Products, WT/DS76/AB/R, adopted 19 Mar 1999 (Japan – Agricultural Products II) for conditions that have to be met if Art. 5.7 SPS is to be applied.

18 WTO Reports of the Panels, European Communities – Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R; WT/DS292/R; WT/DS293/R, adopted 29 Sept. 2006, at para. 7.424.

19 Ibid., at para. 7.427.

20 Ibid., at para. 7.1491.

21 Ibid., at paras 1525-1526.

22 G/SPS/GEN/681 (5 Apr. 2006).

23 G/SPS/GEN/713 (12 July 2006). The trade concerns regarding Reg. 258/97 were raised again in 2011, after the EU institutions failed to agree on the revision of the regulation, which aimed, i.a., at making the procedure for exotic novel foods simpler. See G/SPS/GEN/1087 (7 June 2011).

strictly novel foods, i.e. those that have not been consumed anywhere in the world, and those that are novel only in the EU, e.g. exotic traditional products with a history of safe use outside the EU. Such products are submitted to pre-market authorization procedure in which the applicant has to prove that a product is safe to consumers. These safety considerations refer to a category of products determined solely on the basis of an arbitrary date (May 1997), despite the fact that some of them have been used safely for human consumption for centuries in the country of origin and elsewhere in the world.

Discussion and conclusion

The figures show that a side effect of the authorization requirements is that comparatively few truly innovative foods and crops become available for businesses and consumers. If regulatory authorities want optimally to protect consumers without unduly hampering innovation, they should apply authorization schemes in the least intrusive way possible to mitigate heavy burdens placed on industry.

The safety approach via prior authorization schemes seems to be truly global. The schemes themselves, however, remain national or regional. This means that the same product has to be submitted to multiple risk analysis procedures for the same purpose to acquire access to different markets. Obviously, burdens both on authorities and on businesses would be much reduced if authorities could trust each other's judgement on the safety of products to the extent that they dare rely on them. To the extent risk management authorities can recognise risk assessments performed by (certain) foreign risk assessment bodies, one single risk assessment procedure would provide a key to many markets.

International trade law and international food standards do not provide much guidance on pre-market approvals. Most food safety pre-market approvals do, however, fall under the SPS Agreement, which means that they have to be scientifically justified. Legislatures are thus given a strong incentive to exercise self-restraint in setting up prior authorization schemes. These schemes should only be required when scientific evidence shows that a risk to human, animal or plant life or health exists.

Positive lists instead of individual authorizations should be applied where possible. Similarly, flexible authorization schemes, i.e. generic in principle, granting a specific authorization only in justified cases, would help avoid duplicating work.

Furthermore, pre-market approval schemes should contain mechanisms to keep them up to date with the current progress of science, by providing the option to exclude certain categories of foods which can be 'generally recognized as safe' in light of new scientific evidence. Technologies that were 'new' in 1997 do not necessarily need to raise safety concerns 15 years later. Updating the regulation can also be done through issuing guidance documents explaining which categories of foods fall within the scope of broad legal definitions.

Finally, setting clear deadlines for authorities to complete authorizations procedure is a minimum requirement (still lacking in, e.g., the Novel Foods Regulation) that could greatly increase the efficiency and predictability of the system and decrease the costs of placing new products on the market.

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