inspective.

Science and Disputes in the Area of Food Safety in the European Union

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Table of Contents

1 Disputes in the European Food Sector

Food is not only a good. Food lies at the very bottom of our existence: men have to eat in order to survive. And what a man eats very often determines his health. Nowadays, foodborne diseases are widespread. About 30 percent of the European population have a food related disease.[1] Food as a prerequisite for public health is thus of concern for the European Union. However, in matters of public health the EU has only complementary competences pursuant to article 168(1) TFEU. This in turn gives the Member States a large leeway to use food safety regulations as a competitive tool for domestic markets.[2]

And the food market is an attractive market: food from Europe is worth 800 billions euros a year.[3] The internal market now is one of the core competences of the EU. Pursuant to article 28 TFEU it shall ensure the free movement of goods between the Member States, including foodstuffs. Harmonizing legislation of the EU concerning food safety and public health is therefore appropriately based on the principles of the internal market. Consequently the Food Law Regulation (FLR) of the European Parliament and the Council[4] appeals to the free movement of safe and wholesome food in article 5(2) FLR. The Regulation aims at finding a balance between health and economic concerns because measures to protect public health can equal measures having an equivalent effect to quantitative restrictions on imports and exports which are admitted as exception pursuant to article 36 TFEU.

There is an inherent conflict in safety measures and measures liberalizing trade. This conflict might grow out to a dispute on whether a measure adopted by one Member State is necessary to achieve public health or whether it only disguises its protectionist ambitions. At the centre of such disputes rests the question when and to which degree trade restricting measures that shall protect public health are justified. The Food Law Regulation tries to prevent the coming into existence of these disputes by providing principles and procedures according to which an objective ground for such justifications might be established. Its provisions shall finally lead to a consistent and transparent clarification of risks connected with the consumption of certain food which provides the ground for justifying measures restricting its trade or even banning it from the market.

The Regulation observes important differences in Member States with regard to their principles and procedures in food law whereby barriers to trade are liable to arise.[5] Indeed, disputes in the food sector increasingly revolve around different approaches of risk assessment,[6] and high profile disputes remain unresolved because the risk management principles of the Member States do not converge.[7] As a consequence several Member States even continue to ban foodstuff which the EU has approved.[8] Thus the harmonizing intentions of the Food Law Regulation were achieved when all Member States banned the same foodstuff or accepted the same dose of certain substances in their food.

[1] Birchard (2001), p.1274.
[2] Bernauer (2006), p.83.
[3] Salmon (2009), p.105.
[4] Reg 178/2002.
[5] Paras 4 and 26 preamble FLR.
[6] Ansell (2006), p.8.
[7] Roberts (2005), p.469.
[8] Grossman (2005), p.84.

2 Scientific Dispute Prevention and Resolution

The harmonization of measures protecting public health requires a common basis that the Member States cannot but share. This basis shall be established by way of a risk analysis. Prior to the adoption of protecting measures a risk analysis shall be carried out to avoid unjustified trade barriers for food. Its successful establishment then meant reducing considerably the possibility for disputes to arise – they were effectively prevented. The prevention thus depends on the quality of risk analysis which comprises pursuant to article 3(10) FLR risk assessment, risk management and risk communication. The underlying concept of risk is pursuant to article 3(9) FLR enshrined in a mathematical formula: risk equals the probability of a hazard times its severity.

2.1 Science's Role as Arbiter

The mathematical expression of risk in the Regulation epitomizes perfectly the objective, i.e. neutral, independent and transparent foundation, justifications for health protecting measures that hamper food trade have to be based on. This foundation goes by the name of science. What is almost self-suggesting because all the needed characteristics of a neutral arbiter are attributes to science. Scientific knowledge is deemed to be universal and accessible to anybody who undertakes the efforts to acquire it. Science signifies the denunciation from the powers of gentry and clergy and the implementation of the rule of reason instead.[9]

Making science the basis for the adoption of measures determines rather the procedures of how to approach a problem than the problem's solution. Therefore, the recourse to science cannot prevent disputes but it can give guidance on the way to prevention. This follows from the sceptical attitude which pervades science and which excludes any final verification. The questioning of presumed facts is a thriving force of science. This does not mean that all facts are actually questioned but it opens in principle all facts to be questioned – and therewith invites contradicting reports, for example on the toxicity of substances. The appeal to science, therefore, is objective though not unequivocal.[10]

This has implications for the risk analysis of foodstuff. The inherent lack of complete knowledge implies a persistent uncertainty in science, particularly when technological innovations outpace scientific understanding.[11] Risk analysis, therefore, cannot be a simple mechanism that delivers automatically correct measures. Rather the risk analysis itself must be regarded as a part of science what requires that methods are to be used to justify a claim instead of unjustified doctrines. Food safety is thus necessarily controversial, in science as well. A proof that food is safe is impossible. There will always be a risk associated with eating food.[12]

2.1.1 Regulating Risk: Assessment

The first stage in risk analysis is risk assessment. Risk assessment means pursuant to article 3(11) FLR to identify a hazard, to characterize a hazard, to assess exposure to a hazard and finally to characterize the risk. Ideally there is no room for subjective evaluations of a hazard. The whole assessment shall be undertaken in an objective, independent and transparent

[9] Polanyi (1962) p.56.
[10] Kitcher (2001) p.81.
[11] Salmon (2009), p.108.
[12] Lindsay (2001), p.101.

manner which is pursuant to article 6(2) FLR based on scientific evidence. As science cannot provide final and definite evidence so the risk assessment cannot be required to provide conclusive scientific evidence of an actual risk.[13] Rather coherently the sceptical attitude entails that the methods involved in a risk assessment, for example to identify a hazard, are themselves criticized.[14] Not being unequivocal however does not mean that the risk management were an inaccurate process of measuring risk.[15] Inaccuracies only result from systematic errors connected with a method, not from applying the wrong method because the right method has to be established scientifically, too.

It is one of the tasks of the European Food Safety Authority (EFSA), instituted by the Food Law Regulation in 2002, to establish the right methods in risk analysis. Pursuant to article 22 FLR the EFSA shall be an independent scientific reference point on contentious issues concerning food safety and deliver scientific opinions in respect of the issues. Therewith the EFSA shall operate as a neutral facilitator of a smooth functioning of the internal market. It disposes pursuant to article 28 FLR over a Scientific Committee which ensures the consistency of the scientific opinion procedure, and over scientific Panels which consist of independent experts.

When the EFSA requests a scientific opinion from one of its Panels it must comply with that opinion unless it has further or more exact scientific data at its disposal to set aside the Panel's opinion.[16] The opinion is treated as a fact, and the EFSA has to comply with that fact. However, this fact is still subject to the 'general assessment of the risk'.[17] The general risk assessment puts the scientific opinion of a Panel in the concrete context of a scientific investigation. It not only reflects what conclusions can be drawn from the data but also takes into account how the data are gathered to ensure a consistent risk management. Thus, the Panel's risk assessment is theoretical, whereas the EFSA, when carrying out the same assessment, has to consider the practical contingencies connected with the management of those risks.[18]

From the EFSA the European Parliament, the Commission and the Member States can request scientific opinions. And they do quite frequently. The demand for scientific opinions became that high that more Panels had to be instituted.[19] The high demand demonstrates the wide acceptance of science as a neutral arbiter with regard to justifications of food-trade restricting measures. Nevertheless or just for that reason diverging scientific opinions are unavoidable. Else it would be no scientific opinion. It would be a doctrinal opinion gained by decree. In this context the complementary competence of the EU becomes an asset for the regulation of risk connected with food. Because there is no hierarchy with supreme decisions on top, the EFSA has to work out the right assessment with the Member States what amounts to the scientific enterprise where no authority exists but the evidence. Thus, a common basis can be established authentically.

In this respect the EFSA is called upon to exercise actively vigilance over scientific opinions concerning food safety, over its own opinions and those issued by authorities of the Member States. Wherever it identifies a potential source of divergence of scientific opinions it shall pursuant to article 30(2) FLR contact the relevant authority to ensure that all scientific data

[13] T-334/07 *Denka International BV v. Commission* [2009], para 116.
[14] Lindsay (2002), p.108.
[15] Rosa (2008), p.749.
[16] T-334/07 *Denka International BV v. Commission* [2009], para 68.
[17] T-334/07 *Denka International BV v. Commission* [2009], para 70.
[18] T-334/07 *Denka International BV v. Commission* [2009], para 75.
[19] Reg 575/2006; Reg 202/2008.

are shared. Thus, the EFSA sees to it that the risk assessments take off from the same knowledge base. Still however, divergent scientific opinions might arise out of these assessments. Where the EFSA then identifies a substantive divergence of scientific opinions the relevant authorities are pursuant to article 30(3-4) FLR obliged to cooperate in order to resolve the divergence, or else publish a joint document that clarifies the contentious scientific issues and identifies uncertainties in the scientific data.

This procedure again amounts to the scientific enterprise: Scientific claims must stand the public test, scientific knowledge is neither exclusive nor esoteric – in principle it is shared by all people bestowed with reason. Consequently, the EFSA is generally open for the public, for consumers like for other interest groups. This public stance gives the European food safety regulation an even wider legitimation based on a sound public foundation. When a contentious scientific issue on food safety reaches the public, the EU citizens participate in characterizing a risk and effectuate a wide consensus on the matter.[20] And that is the way to go: There is little empirical evidence that experts assess risk differently or more accurately than the public.[21]

2.1.2 Regulating Risk: Management and Communication

While risk assessment carves out the objective characteristics of a risk, the final selection of the appropriate health protecting measure belongs to the realm of risk management. Risk management also considers pursuant to article 3(12) FLR cultural, ethical or environmental factors and the feasibility of control. In other words, risk assessment is open for subjective elements that determine the individual level of risk acceptance.[22] Contrary to scientific opinions the acceptance of risk is allowed to diverge because there appears to be no need of an overarching consensus on the level of acceptable risk. And indeed the acceptance of risk differs from culture to culture. In some Member States it is more important that certain food is tasty than that it is germfree, others care more about the food's price than about its sanitary quality.[23] A zero-risk level however is not admitted.[24]

The lower the level of acceptable risk the higher is the level of precaution. Thus, precaution is central to risk management. The respective principle is enshrined in article 191 TFEU in the context of environmental policy but expressly includes protecting human health, too. Two versions of the precautionary principle can be identified in international law. Both become applicable when the degree of scientific uncertainty about a risk is so large that it only amounts to a potential risk. The weak version then contends that a potential risk does not prohibit an authority to act. The strong version however requires that a potential risk obliges an authority to act, i.e. to take a precautionary measure.

Facing the controversy on precaution the European Parliament took a very remarkable and felicitous approach. It declared that the precautionary principle was only one of several tools for risk management and that the principle should be part of an overall policy based on factors such as traceability and labelling.[25] The Food Law Regulation hereafter implemented this

[20] Todt (2004), p.146; Rosa (2008), p.747.
[21] Rowe (2001), p.341.
[22] Salmon (2009), p.107.
[23] Waarden (2006), p.42; Rosa (2008), p.748.
[24] T-13/99 *Pfizer Animal Health SA v. Council* [2002], para 152.
[25] European Parliament. *Resolution on the Precautionary Principle* (2001), p.345.

holistic approach and wiped away legal uncertainties concerning the principle and its application without coming into conflict with the Courts' jurisprudence on the matter.

Article 7(1) FLR defines precaution such that if after an assessment of all available information a possibility of a hazard is identified and scientific uncertainty persists then risk management measures may be adopted which are necessary to health protection and which are subject to later risk assessments when scientific data are available. Hence a measure of precaution may be adopted when no probability of risk can be calculated, however the realization of a hazard is not implausible, i.e. it exists a mere possibility for it. The measure might be due to be withdrawn when later on data are on hand that narrow the scientific uncertainty and make a calculation of the risk possible, particularly when the measure then turns out to be disproportionate, i.e. no longer necessary to protect health because less onerous measures can be chosen.

Even though it is a corollary of the precautionary principle that the protection of public health prevails over economic interests,[26] the measure adopted must be proportionate pursuant to article 7(2) FLR, which means it must be no more restrictive of trade than is required to achieve public health, and, again, it must be reviewed within a reasonable period of time. This is in full accordance with the Courts' jurisprudence and provides a clear guidance for future rulings.[27]

Basically, the European Court of Justice framed precaution such that where there is uncertainty to the existence or the extent of risks to human health, the authorities may adopt protective measures 'without having to wait until the reality and seriousness of those risks become fully apparent.'[28] Nevertheless, the protective measures may only be adopted when risk management was carried out.[29] The risk management then is based on a less objective appraisal of risk but still 'adequately backed up by the data available at the time when the measure was taken.'[30] Notwithstanding any existing scientific uncertainty, the risk assessment must be 'on the basis of the best scientific data and most recent results of international research' to assess 'whether matters have gone beyond the level of risk that the authority deems acceptable for society.'[31] In sum, the authority needs 'detailed grounds' for considering that a food endangers public health.[32]

Where scientific uncertainty is high a wide public discussion is useful to determine the level of risk acceptance.[33] This requires a risk communication that goes beyond the labelling of food products as of article 18(4) FLR, comparable to the mechanisms in case of divergent scientific opinions. In addition, where conventional plant products are not subject to the same risk assessment as genetically modified organisms the risk communication on labels becomes pretty one sided.[34] Hence, slight amendments in the procedures of the European risk regulation could bestow the consumer more fully with his right to know. The current Regulation already respects the informed choice of the consumer pursuant to article 8(1) FLR

[26] Joined cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00 *Artegodan GmbH v. Commission* [2002], para 174.
[27] Cazala (2004), p.544.
[28] C-157/96 *The Queen v. Ministery of Agriculture, Fishery and Food, ex parte National Farmers' Union* [1998], para 63.
[29] C-236/01 *Criminal Proceedings against Monsanto Agricultura Italia SpA and others* [2003], para 132.
[30] T-13/99 *Pfizer Animal Health SA v. Council* [2002], para 144.
[31] T-13/99 *Pfizer Animal Health SA v. Council* [2002], para 162.
[32] C-236/01 *Criminal Proceedings against Monsanto Agricultura Italia SpA and others* [2003], para 108.
[33] Houghton (2008), p.23.
[34] Lindsay (2002), p.101.

and defers by way of prescribed labelling much of the actual risk acceptance on the citizens of the European Union.

2.2 Science's Role as Mediator

Where the recourse to science is not able to prevent disputes, it might still be of help resolving it in the course of mediation by the Commission. The proceedings of mediation are laid down in article 60 FLR. It says that where a Member States alleges that a protective measure by another Member State infringes the Food Law Regulation or impairs the functioning of the internal market, it shall refer the matter to the Commission which mediates between the Member States. The prospect of success of such mediation likely depends on the stage of the risk analysis from which the dispute arises. Most successful will be the mediation of a dispute arising from risk assessment where scientific issues are controversial. Then the Commission may request a scientific opinion from the EFSA on the issue which is obviously deemed to be agreeable. Otherwise the competent authorities of the Member States would have to publish a joint document on their disagreement pursuant to article 30(4) FLR.

If the dispute sparks from risk management the success of mediation depends on what the concerned Member States have to offer each other because very often mediation results in a deal of the parties. The deal then comprised the lowering of one's level of risk acceptance in exchange for some service in return. If no deal can be arranged by the Commission then even a legal settlement of the dispute becomes unlikely because the Courts regularly refrain from reviewing how risk is assessed in risk management. The judicial review is deemed to be limited to an appraisal of whether an authority has examined the scientific facts impartially.[35]

3 Conclusions on Science and Safety

No question, the regulation of food safety requires precaution. To achieve a high level of public health enshrined in article 168(1) TFEU authorities have a wide discretion at their disposal to adopt precautionary measures, which is not to the least a consequence to the fact that the EU only has complementary competences on the matter. The discretion is wide, however far from arbitrariness. The food safety regulation system of the EU does not allow for decrees, it is disciplined by the rigor of science. The scientific model puts the precautionary principle in a comprehensive conceptual framework of risk analysis in which an authority has to consider all relevant data before adopting a protective measure and then to reconsider the adopted measure.

The FLR frames precaution such that the absence of scientific certainty cannot be used to justify a protective measure.[36] This means an abrupt negation of the strong version and denies the precautionary principle an extra status within risk management. In contexts of scientific uncertainty, risk management and the protection of health, the precautionary principle adds nothing to the content.[37] It does no more than to widen the discretion of an authority. In the Regulation's decision making and re-examination procedure numerous elements can be taken into account, encompassing pursuant to article 14(4) FLR not only probable immediate effects

[35] T-75/06 *Bayer CropScience AG and others v. Commission* [2008], paras 84 and 141.
[36] Cazala (2004), p.546.
[37] C-1/00 *Commission v. France* [2001], para 83.

but also effects on subsequent generations and various categories of consumers and consumption. And the least negligible element is the level of acceptable risk.[38]

Thus, the precautionary principle must be seen as part of a scientifically framed decision making procedure. The framework of science unifies with respect to food safety the principles and procedures and the knowledge base gained from them. The unification makes protective measures and their justifications comparable and therewith rationally prevents disputes from arising. The framework operates as neutral arbiter without providing decisive grounds because science itself is inherently not decisive. Alleging that the EFSA's procedures won't prove decisive in overcoming the difficulties from diverging scientific opinions[39] is therefore begging the question.

Rather the framework provides the approved dynamic balance between ascertained and questioned facts of science giving health concerns sound consideration, that is restricting it to proportionate measures with regard to the relevant scientific evidence available. This approach then enables a reasonable balance between precaution and profit, between health and economy. The balance being dynamic it is no surprise that opposing ratings of the framework can be found. One side sees the producers' interest privileged over the public interest in food safety to an extent that precludes precaution in face of uncertain risks, 'even where the degree of uncertainty is such that it equates to ignorance.'[40] The other side complains a 'repressive and restrictive regulatory framework' dominated by precaution and potential risks.[41]

Such extreme positions however find no support, neither in the Food Law Regulation nor in case law. The truth lies literally in the middle: in a proportionate balance. The balance is very well safeguarded by science, providing a neutral ground for decision making on which it is hard to contradict an established fact because it is the power of the evidence that counts and not the power of an authority or company. Entering the ground requires a thorough analysis and stringent argumentation that not only is in the public interest but also appears to be very effective in preventing disputes on food safety. The clear obligation to base protective measures on science has led to resolutions of many disputes before they could advance to dispute settlement mechanisms such as mediation or adjudication.[42]

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[38] Cazala (2004), p.544.
[39] Alemanno (2006), p.250.
[40] Salmon (2009), p.113; cf. Schofield (2000), p.531.
[41] Ramessar (2009), p.109.
[42] Roberts (2005), p.485.

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