European Institute for Food Law

Observations regarding the proposal for a new Novel Foods Regulation

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Contents

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1. Introduction

The European Institute for Food Law welcomes the initiative to update and improve the EU regulatory framework on novel foods. The draft proposals as presented by the European Commission are a major improvement in comparison to the current situation. The critical remarks made here below must be seen in the context of this overall appreciation of the work that has been done. Where questions are raised, the implicit suggestion is to clarify the issue in the text or in the recitals.

The new regulatory framework for novel foods consists of two proposed regulations: the Regulation establishing a common authorisation procedure for food additives, food enzymes, food flavouring and novel foods (COM(2007) 672 final)(hereafter: the Common Procedure Regulation or CPR) and the new Novel Foods Regulation (COM(2008) 872 final) (hereafter NNFR).

Comments will be made with regard to both regulations and their interrelatedness. The European Institute for Food Law wishes to point to the important report *'Competitiveness of the European Food Industry'* received by DG Enterprise and Industry in 2006 and published

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on its website in 2007.[1] This report (here after referred to as Wijnands et.al.) makes important recommendations regarding possible improvements of EU food legislation. The pre-market approval schemes are seen as the most critical parts of EU food legislation (p. 94). The observation is made that businesses try to their utmost to avoid such procedures. Partly they do so by not engaging in the type of innovation to which they apply, partly they evade compliance. If one looks at the number of innovations that have been dealt with under the current Novel Foods Regulation, the harvest is very meagre indeed. The possibility must be taken into account that scores of products will be discovered to have entered the market after 1997 without the required prior approval.

2. General remarks

2.1. The human rights perspective

The EU lays much emphasis on compliance with human rights by (candidate) Member States, however in its own policy and legislation the human rights dimension often seems to be overlooked. Content wise EU food law to a large extent can be seen as a contribution to the realisation of the human right to adequate food to which the member states are beholden as state parties to the International Covenant on Economic Social and Cultural Rights and other international treaties. The EU would make a valuable statement by placing its food law in this context through mentioning the right to food in the aim and scope article or in the recitals ('to contribute to the realisation of the human right to food within in the Community') of its legislation on food.

2.2. Procedure

The NNFR (and also the CPR) fulfils the definition of 'food law' in Article 3(1) Regulation (EC) 178/2002 aiming at a high level of protection of human life and health (Art. 5(1) 178/2002). Therefore the requirement of Article 6(1) Regulation (EC) 178/2002 applies that it is based on risk analysis. For this reason the explanatory memorandum or the recitals should express compliance with this requirements. The most likely way seems to be to indicate that an opinion given by the European Food Safety Authority has been taken into account.

2.3. Risk analysis

The proposed new regulatory framework is presented as an implementation of the risk analysis framework that is chosen as a general principle of EU food law in Regulation

[1] J.H.M. Wijnands, B.M.J. van der Meulen and K.J. Poppe (eds.) Competitiveness of the European Food Industry. An economic and legal assessment; http://ec.europa.eu/enterprise/food/competitiveness_study.pdf

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178/2002 (also known as the General Food Law).[2] This general principle implies that food law must be science based. This principle implements at EU level the same principle that is present in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement). Core of the principle is that measures restricting trade need a scientific justification. The burden of proof is on the state wishing to implement such measure. The system chosen in the Novel Foods Regulation seems to be precisely the inverse. A new product may only enter the market if scientific proof is available that the product is safe. The burden of proof is on food businesses. Rather than a statement that the latter system is an application of the former principles, an explanation would be in place that, how and why this exception to the principle is justified.

2.4. Deadline

In so far as the new regulatory framework implements the risk analysis framework that is chosen as a general principle of EU food law in the General Food Law, the applicable deadline was 1 January 2007 (Art. 4(3) Regulation EC/178/2002: "Existing food law principles and procedures shall be adapted as soon as possible and by 1 January 2007 at the latest in order to comply with Articles 5 to 10."). This date has already passed; therefore the deadline will obviously not be met. The explanatory memorandum ignores this fact. As timeliness is one of the critical issues of pre-market approval procedures (see also 2.6), some explanation would be appropriate.

2.5. Comitology

The proposed procedures under the NNFR and CPR result in regulations by the Commission through the comitology procedure. This choice of procedure gives the issue a highly political character subject to lobbying, pressure, negotiation and compromise. Politics is at its place in the setting of the general criteria for the approval of products, not in the application of those criteria to specific products.
The decision if a product meets the requirements of the NNFR or other sectoral food law should be seen as a decision of a technical-administrative nature and should be taken by the Commission in its role of executive branch of the Community in the form of a decision. The form of decision is appropriate as it regards each time a single product and a single application. There is no legal obstacle in adapting a community list – whether or not it is an annex to a regulation – by decision (see also Wijnands et. al. p. 94).

[2] Explanatory memorandum CPR.

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2.6. Timeliness

The new regulatory framework addresses the concerns of stakeholders regarding delays by deadlines and by procedures at Community level only.
Businesses show concern in particular regarding timeliness of EFSA given its shortage in financial means and staff and its geographical inaccessibility both for co-operators and for applicants from outside Italy. Legislative measures alone may not be enough to address this concern. In particular not where the measures are being presented as budget neutral (explanatory memorandum NNFR at 4), instead of ensuring availability of the means necessary for the proposed system to function as envisaged.

3. The draft New Novel Foods Regulation

3.1. On terminology

3.1.1. Harmonisation

In the explanatory memorandum, the recitals and the articles, the NNFR speaks of 'harmonisation' as its aim and subject matter. Harmonisation is a term usually applied to the effect of directives on national legislation, not to regulations. Harmonisation is the approximation of national legislation. If harmonisation is the aim it is difficult to understand why the bullet 'choice of instruments' does not address the directive as alternative to the regulation. The term usually associated with a regulation is 'uniformity'.

3.1.2. Enforcement

Art. 10(1) NNFR holds the authorisation-holder responsible for 'enforcement'. Usually the term 'enforcement' is used for sanctions and other coercive measures applied by public authorities (vide Art. 17(2) Regulation (EC) 178/2002). Probably Art. 10(1) has 'compliance' in mind.

3.2. Definitions

Article 10 addresses the 'producer'. This concept should be defined. It seems that a category is intended more narrow than producer in the Product liability directive[3] or food business operator in the General Food Law (Art. 3(3) Regulation (EC) 178/2002).

[3] Directive 85/374 as amended by Directive 1999/34.

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3.3. Subject matter

The meaning of Article 1 is unclear. EC legislation usually begins with 'aim and scope'. This statement is difficult to understand as a provision of law. It seems to have more the character of a policy statement. Such statement is best placed in the recitals.

3.4. Concept of novelty

3.4.1. Timeline

Art. 2(2)(a) NNFR keeps the timeline at 15 May 1997. With regard to production process, however, this provision uses the rather unclear concept of 'currently'. Best would be either to refer explicitly to the entry into force of this new regulation or also to 15-5-1997.

3.4.2. History of use

In determining if a food has a history of food use Article 3(4) deems a use as or in a food supplement insufficient (recital 11 even calls this 'non-food supplement use'). This seems to be counter intuitive and should be explained in the recitals. The whole idea in recital 11 seems extreme.

3.4.3. Geographical dimension

A product is considered novel if it does not have a history of use in the Community prior to 15 May 1997. Since that date the Community has been enlarged considerably and may enlarge further in the future. It should be clarified that a history of use in a new member state prior to its accession keeps the product out of the scope of the NNFR. This subject should not be left to accession treaties as it regards all innovating food businesses.

3.4.4. Processed innovations

Application of a production process not currently used brings a product under the NNFR only if the process gives rise to significant changes in the composition or structure of the food which affect its nutritional value, metabolism or level of undesired substances. The NNFR seems to work from the presumption that most novel foods (except exotics) are produced by conventional techniques (production processes that are currently used). The NNFR does not answer the question how to distinguish novel foods from conventional foods. How much reduction in size of particles (through nano technology) is needed to make a product new? Which high concentration of an ingredient or nutrient hither to used in low concentrations, brings a product within the ambit of the NNFR? Is the criterion different from "significant

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changes in the composition or structure of the food which affect its nutritional value, metabolism or level of undesired substances ”? If so, in what way? If not, what is the relevance of separately mentioning “production process not currently used”?

3.4.5. Novel processing

Application of a novel processing technique brings a product under the NNFR only if the process gives rise to significant changes in the composition or structure of the food which affect its nutritional value, metabolism or level of undesired substances. What is the benchmark to decide if there are significant changes? May the product be compared to a similar product after application of a conventional process? If the benchmark must be taken from the raw material to which the new process is applied, the standard will be met almost in every case, as such changes usually are the aim of processing.
A second question regarding the criterion for novel processing is if a positive effect on the level of undesired substances also brings a changed product within the ambit of the NNFR – if so, why? – or only a negative effect.

3.5. Procedure for applicability

The explanatory memorandum seems to promise a general procedure to determine if a food falls within the scope of the NNFR. Article 4(7) however seems to provide only for a procedure in case the history of food use is uncertain. The novel food status may however be uncertain for numerous of other reasons. For instance are the changes resulting from a new production process ‘significant’ or not?[4] Such questions should be covered as well. Furthermore, the applicability of an approval procedure may be unclear not only in relation to the NNFR but also between NNFR and other sectoral food laws. Therefore it would improve the system if this applicability procedure were included in the CPR. This would be very much in line with the single application procedure! (See also Wijnands et.al. p. 95)

3.6. Community list

According to Art. 2 CPR the community list must be published in the Official Journal. According to Art. 5 NNFR it must be published on the Commission’s website. The tension between these two provisions should be lifted. As far as the European Institute for Food Law is aware, this would be the first time that the Internet is designated as official means for publication of a Community Act. From a timing point of view, entry into force through publication on the Internet is laudable. It seems doubtful however if another official source of food law should be added to the Official Journal. Accessibility of food law is already very

[4] See more in general the issue raised in § 3.4.

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difficult as it is (Wijnands et al. p. 76). If updating the list is done by regulation (Art. 3(3) CPR) this way of publication seem difficult to reconcile with Article 254 of the EC Treaty.

3.7. Monopolisation

The monopolising effect of the NNFR is limited to the situation where an application is based on new knowledge. This is laudable. The willingness of food businesses to engage in a novel foods procedure, however, is already very low (Wijnands et. al. p. 11, 61, 83, 86). According to Graham Brookes[5] under the current NFR it is better to be second than to be first. This effect is likely to increase under the NNFR. If the NNFR does not grant a bonus for the business who takes to burden (considerable in time and money) to go through the procedure, the evasive strategies will probably increase instead of decrease. In this context it is very positive that the burden to collect information regarding history of use is shifted from the applicant to the Member States. Maybe similar creative solutions can be found for other burdens as well.

3.8. Application

The application must be submitted to the Commission. The explanatory memorandum says to this point that this is in line with the separation of risk management and risk assessment. This reasoning seems slim. If the Commission does not act as more than a letter-box (see also hereafter 4.5.2) than valuable time may be gained by allowing applications to be submitted to EFSA directly.

3.9. Criteria

3.9.1. Standard of proof

Art. 6 NNFR gives the criteria ('conditions') for inclusion in the list. The first (a) is the novel food 'does not, on the basis of the scientific evidence available, pose a safety concern to health of the consumer'. The NNFR does not provide a basis here or elsewhere to require a certain level of available scientific evidence. To put it extreme: if no evidence at all would be available, nothing would be known about safety risks, therefore under this wording of the provision the product would have to be included in the list. This cannot be the idea. If, however, the applicant is required to provide proof of the safety of the product, the NNFR

[5] Graham Brookes, Economic impact assessment of the way in which the EU novel foods regulatory approval procedures affect the EU food sector. Briefing paper for the Confederation of the Food and Drink Industries of the European Union (CIAA) & the Platform for Ingredients in Europe (PIE), July 2007: http://www.pgeconomics.co.uk/pdf/novelfoods.pdf.

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should explicitly say so. The more so as this shift of burden of proof to the applicant derogates from Art. 6 Regulation 178/2002 as discussed above in 2.3.

3.9.2. Mutual recognition

Part of the burden of pre-market approval schemes, is in the duplication of efforts to acquire access to different markets. In other parts of the world high level food safety regimes exist. It would help industry considerably if the Commission would be willing to name foreign authorities who's risk assessments or approval decisions can be recognised for the EC market. Do not JECFA and FDA for example enjoy a good reputation? (On this issue see also Wijnands et. al. p. 82).

3.9.3. Balancing risks and benefits

The NNFR does not provide for the possibility to accept certain risks if the advantages of a product warrant it. It has been said for example (the point here is the conceivable example, not the specific product) that stevia as sweetener has certain advantages for diabetics. It does however not meet the safety standard due to its allergenic properties. Why exclude beforehand the option that (at least for some consumers) the advantages outweigh the risk?

3.10. Procedure

Art. 7(2) NNFR is unclear. It says to derogate from Art. 7 CPR but seems to be identical.

3.11. Notification procedure

This procedure seems to be a great improvement for exotic foods. It is unclear however why Art. 8(6) establishes a separate list.

3.12. Unnecessary provision

Art. 6(2) does not seem to add anything to Art. 1 of Directive 89/938. Furthermore it is incorrect. This directive – being a directive – does not address foods but national legislatures.

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4. Common Procedure

4.1. Application

4.1.1. Interested party

The commission can act on its own initiative or on application by an interested party. The concept 'interested party' is not defined. Is this a way for an inspection agency that is unsure whether to act against a certain product to get certainty about its status? Does the risk exist that businesses delay each other's market introductions by filling a NNFR application regarding the competitors product?

4.1.2. Valid application

EFSA's deadline starts at the moment of a valid application. What makes an application valid? Who decides if the application is valid? Is this why the Commission is granted 14 days to acknowledge receipt (see 4.5.2)?

4.2. Risk assessment

The explanatory memorandum states that the procedure is based on risk assessment carried out by EFSA. This starting point may lead to confusion. In practice EFSA reviews the dossier submitted by the applicant, so in reality the risk assessment is performed by businesses. See also: 2.3.

4.3. List

In its wording the CPR is not precise regarding the question if there is one list or several. Apparently the latter is intended.

4.4. Implementation

Like the NNFR the CPR speaks of harmonisation. It goes so far to claim harmonisation of national law and – p. 8 – to require implementation. Generally it is understood that regulations need not and may not be implemented. Experience with Regulation (EC) 178/2002 shows that member states have great difficulty in grasping the concept of regulations that require implementation (see also Wijnands et. al. p. 73). If the CPR indeed means to be implemented by the national legislatures, this should be clarified in detail.

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4.5. Deadlines

4.5.1. General

It is an improvement that the CPR sets deadlines. One of the biggest problems in the current novel foods procedure is in the delays. In average the procedure takes 3 years (Wijnands et. al. p. 86). The proposed deadlines go a little over half that time (14 days + 6 month + 9 month + 3 month + publication time + possible extension of the 6 and 9 month deadline + possible additional time if extra information is required).

4.5.2. Receipt

Art. 4(a) grants the Commission 14 days for acknowledging receipt of the application. It is unclear what the Commission needs this time for. A professional organisation should be capable of acknowledging the same day or the next working day at the latest. If it is the idea that the Commission decides that the application is valid (Art. 5(1)) this should be stated explicitly. If the Commission needs 14 days to act as letter-box, it should not play this role.

4.5.3. EFSA

Six month from valid application. See above 4.1.2. May be extended by the Commission Art. 10.

4.5.4. Additional information

The Commission is granted the power to object to extension of the deadline (Art. 6(1)). Why not the applicant?

4.5.5. Commission

Nine months. May be extended by the Commission Art. 10. Why does the Commission need more time than EFSA?

4.5.6. Additional information

If additional information is asked by EFSA or the Commission, this may result in an extension of the deadline. How does this provision relate to the requirement of a valid application? If ‘the clock stops’ when additional information is asked, there does not seem to be much need to wait to start the clock until the application is ‘valid’. If the procedure only starts after the applicant has provided all the information required, the procedure should

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proceed uninterrupted. If there is the option to interrupt the procedure each time additional information is required, the deadline should start from the receipt of the application.

4.5.7. Decision

After the draft decision is finalised by the Commission, the decision must be taken in comitology. For this step another 3 month is reserved (Art. 14(2)).

4.5.8. Sanctions

Taken together the deadlines in the NNFR are very long given the concern that exists. No sanctions apply if the deadlines are not met. This makes them very soft indeed, apart from the fact that they can be extended in different ways. Wijnands et. al. (p. 95) suggest to follow the example set in competition law to introduce fatal deadlines.[6] That is to say if EFSA or the Commission do not meet their deadline, the application is automatically granted. Experience in DG Competition shows that if such is the consequence, deadlines are never missed.

4.6. Confidentiality

It is not very clear how Art. 12 relates to Regulation (EC) 1049/2001.
The applicant is granted a three weeks term de grace to withdraw the application if he does not agree to the Commission interpretation of the confidentiality requirements. Should it not also be made explicit that the Commission will not disclose information if the decision to do so is contested with the Court of Justice?

[6] See Article 10(6) of Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (the EC Merger Regulation), *OJ L 24, 29.1.2004.* See also Commission Regulation (EC) No 802/2004 of 7 April 2004 implementing Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (OJ L 133, 30.4.2004). Other examples of fatal deadlines can be found in: Article 95 (6) of the EC Treaty and Article 16 (3) of Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products, *OJ L 204, 11.8.2000, p. 1–10* and Commission Regulation (EC) No 1825/2000 of 25 August 2000 laying down detailed rules for the application of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the labelling of beef and beef products, *OJ L 216, 26.8.2000, p. 8–12.*

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4.7. Unnecessary provisions

4.7.1. Transparency

What does Art. 11 add to Art. 38 Regulation (EC) 178/2002? Does it imply that the latter provision does not apply automatically?

4.7.2. Emergency measures

What does Art. 13 add to Art. 53 and 54 Regulation (EC) 178/2002? Does it not provide the false impression that these articles only apply if sectoral legislation says so?

4.8. Expanding the scope

Wijnands et.al. recommend to integrate all pre-market-approval procedures.
Recital 16 promises a medium-term examination as to whether to extend the scope of the CPR to other food legislation. This is very important. A provision to this effect should be included in the articles.

5. Conclusion

The Commission has presented a very promising proposal for a new regulatory framework for novel foods. It is the opinion of the European Institute for Food Law that several details need some clarification and that the system can be improved considerably, by:

- abolishing the comitology procedure;
- introducing a general procedure to decide on the applicability of a sectoral pre-market approval scheme;
- introducing the possibility to balance risks and benefits;
- recognition of foreign risk assessments;
- introducing fatal deadlines.

On behalf of the European Institute for Food Law

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