DRAFT
Food Safety
Adjudication and Rulemaking
(Ursula Schliessner)

I. PART 1 - INTRODUCTION

A. Adjudication or Rulemaking?

In EU food law, in many ways, the distinction between adjudication and rulemaking seems somewhat artificial and to a certain extent arbitrary. With rulemaking being understood as the drafting and adoption of laws and regulations that are of general applicability, and adjudication being understood as the application of a specific law or regulation to a particular case or particular circumstances, this report will demonstrate that in many cases the form of rulemaking is used to decide very specific factual circumstances. Adjudication is used very rarely.

This report will further demonstrate that the judicial consequences of whether the forms of rulemaking or adjudication are used for a particular matter are dramatic in the EU legal system. Whereas in the case of adjudication, the concerned person or company could challenge the decision in the European Court of First Instance ('CFI'), this is generally not the case for measures taken in the form of rulemaking. These are of generally applicable nature. The individual would most likely not be considered directly and individually concerned under standing case law, because he/she is not distinguishable from a multitude of subjects targeted. The CFI would therefore most likely dismiss any judicial action as inadmissible in accordance with Article 230 Para. 4 EC Treaty (ECT).

B. The Procedure

1. Rulemaking

There are two principal ways of rulemaking in EU food safety regulation. General legislation is adopted under the general legislative procedure (Article 251 ECT), and so-called implementing legislation is passed under the Comitology procedure. No recourse is made in EU food safety legislation to the so-called New Approach, combining the setting of 'essential requirements' via Directives with voluntary standard setting by the European standardization organizations (CEN, CENELEC etc.).

(a) The Article 251 ECT Procedure

Any legislation on a new subject would be passed under the Co-Decision procedure of Article 251 ECT. This procedure is applicable to legislation in the areas of internal market (Article 95 ECT), consumer protection (Article 153 ECT), and public health, which are the Treaty provisions that are most frequently used to pass food safety legislation.

Under Article 251 ECT, it is for the European Commission (the 'Commission') to propose legislation. The decision on whether, when and what type of legislation is proposed, is entirely in the discretion of the European Commission. Early information on what the Commission's intentions are is sometimes available from

(a) multi-annual policy declarations issued by the Commission (so-called White or Green Papers),
(b) Council conclusions or resolutions; these are policy statements adopted by the Ministers of the EU Member States meeting as 'Councils' encouraging the Commission to take action;
(c) European Parliament resolutions or own-initiative reports on certain policy issues;
(d) Oral or Written questions asked by Members of the European Parliament to the Commission;

(e) National draft regulations being notified to the Commission under the Standstill Directive (98/34/EC)[1]. Under the Standstill Directive, Member States are obliged to postpone the enactment of national legislation for 12 months if the Commission declares its intention to legislate on the matter at EU level;

(f) Scientific Committees or now the European Food Safety Authority (the 'EFSA') replacing the previous Scientific Committee for Food; EFSA is the scientific advisory organ to the Commission for food safety matters, it may adopt opinions on pertinent issues and thereby morally force the Commission to act.

It is recalled though that all of the above options do not require the Commission to start the rulemaking procedure. Whether the Commission initiates legislative action is entirely in its discretion.

There is no distinct predetermined procedure for the preparation of the draft legislation and there are no set rules for stakeholder consultation.

The most organized procedure is the one on completely new larger subject areas, for example now 'obesity'. In such cases, the Commission would usually start with drafting a Green Paper, followed by a White Paper, stakeholder consultation on both, and then a Communication setting out the proposed choices.

Sometimes, the responsible Commission service (Directorate General for Health and Consumer Protection 'DG Sanco') would start the process by engaging an external consultant to provide a report on the existing national legislation or case law, its gaps, differences in application and so on, justifying the need for action at Community level. Other means of fact-finding could be the organization of conferences by the Commission or other bodies; inspections of national or EU bodies (e.g. the EU Food and Veterinary Office[2]) or reliance on the work done by international organizations (notably WHO and FAO).

Once this fact finding exercise is terminated, an individual desk officer in DG Sanco would start drafting a legislative text.

This drafting could be preceded and/or accompanied by the organization of one or several stakeholder consultation meetings. However, the size (number of participants), frequency, scope, duration, and timing is not subject to formal rules. The organization of these meetings depends to a large extent on the availability of budgets, interpreters, premises, the general timing on when the Commission would want to move forward, on whether the particular issue

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[1] 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 of 1998.

[2] The Commission, in its role as guardian of the European Community Treaties, is responsible for ensuring that Community legislation on food safety, animal health, plant health and animal welfare is properly implemented and enforced. As a Commission service, the Food and Veterinary Office (FVO) plays an important role in fulfilling this task. It conducts inspections within the Community and in third countries on matters of food safety, food and animal hygiene and animal welfare.

is contentious, and not least also on the personal style of the respective Commission heads of department, the Commissioners, Director Generals and Heads of Unit.

This rather 'loose' framework of consultation was recently slightly more formalized by the adoption of a general Commission code-of-conduct, namely the Commission Communication "European Governance: Better Lawmaking" (COM (2002) 275 final) of June 5, 2002[3]. The Commission commits in this Communication to "systemize and rationalize the wide range of consultation practices and procedures and to guarantee the feasibility and effectiveness of the operation; to ensure the transparency of consultation from the point of view of the bodies or persons consulted and from the legislator's point of view; and to demonstrate accountability vis-à-vis the bodies or players consulted, by making public, as far as possible, the results of the consultation and the lessons that have been learned." In addition, in this and previous good governance Communications, the Commission committed to carry out a formalized impact assessment for all new legislation.

As far as the implementation of these new principles is concerned, there appear to be considerable differences between the various Commission services. As far as DG Sanco is concerned, unlike other departments, it does not seem as a matter of principle to organize wide-range public consultations (for example DG Environment and DG Enterprise now organize Internet consultations). Consultations still appear to be organized on an ad-hoc and as needed basis and the number of invitees is limited to the European industry, trade, consumer organizations, other NGOs and semi-governmental organizations (e.g. European Network on Nutrition and Physical Activity; European network for public health, health promotion and disease prevention). The conclusions and transcripts of the stakeholder consultations are sometimes (e.g. the stakeholder submissions on a potential revision of the Novel Foods Regulation 258/97 were made available on the Commission's homepage), but not always, being made publicly available, usually a long time after the meetings.

What is new is the organization of so-called Advisory Groups and Platforms (see for example a new European Platform for Action on Diet, Physical Activity and Health), also more or less on an ad-hoc and an as needed basis, consisting roughly of the usually consulted stakeholder groups, albeit including representatives sometimes from individual companies.

All in all therefore it may be concluded that consultation on new legislation takes place in various fora which are called by the Commission largely on an ad-hoc and as needed basis. Consultation takes place in Brussels only and for the most part involves only the European level stakeholders. There is no consultation of stakeholders at Member State or regional level in the Member States at the time of drafting of the legislation by the Commission.

For legislation to be adopted under the Comitology rules (see below), there is usually less consultation both in terms of the number of events as well as the number of participants than for legislation to be adopted under the Article 251 ECT procedure.

Towards the end of the drafting process and sometimes at intermediate stages, the Commission would also consult the national administrations of the Member States, meeting regularly several times a year in the so-called Standing Committee on the Food Chain and Animal Health ('SCFCAH') and its various sections[4]. This Committee and its sub-sections consist of the national chief administrators in the particular subject area. For example, the section on Animal Health would consist of the national Chief Veterinary Officers. The

[3] http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002_0275en01.pdf

[4] http://europa.eu.int/comm/food/fs/rc/scfcah/index_en.html

meetings of the Standing Committee and the sections are closed and not open to the public. Agendas are published on the Commission's homepage usually a few days before but sometimes also after the date of the meeting. Summary meeting reports are also available on the Commission's website but usually only one or two months after the meeting has taken place.

Once DG Sanco has finalized its drafting, it will conduct the formal so-called interservice consultation (written consultation with a 10 work-day deadline), obtaining the views of the other Commission services. On dossiers that are considered contentious, working groups between the various Commission Directorate Generals may be set up prior to the stage of inter-service consultation.

Once inter-service consultation is terminated, the draft text will be submitted to the College of Commissioners for approval. The College usually tries to pass dossier by consensus. However, a simple majority vote suffices (Article 219 ECT). Once the Commission has adopted the proposal, it will be published in the Official Journal and submitted to Council and European Parliament for further proceedings under the Co-decision procedure. In addition it will also be published as a so-called 'ComDoc'. The ComDoc not only contains the draft provisions, but also an Explanatory Memorandum summarizing the intentions of the Commission, the results of the consultation, and a cursory economic, regulatory and financial impact assessment. The ComDoc also contains a summary explanation of the individual provisions of the legislative measure.

In addition to the above listed more or less institutionalized consultation exercises, all along the way before and during the drafting stages, the individual desk officers, their Heads of Unit, Directors and Director Generals, the members of Cabinet of the Commissioner the Commissioner him/herself, as well as the other Commission departments that will eventually get their say later in the process will be subject to informal private stakeholder advocacy actions. This is an accepted practice and its success is largely dependent on the accessibility of Commission individuals, the political and economic leverage of the advocates, and the wealth and breath of technical, scientific and legal expertise of the advocates.

(b) <u>The Comitology Procedure</u>

Article 202 ECT allows the Council[5], to confer on the Commission, in the acts which the Council adopts (e.g. Directives and Regulations) powers for the implementation of the rules which the Council lays down ('Comitology'). The Council may impose certain requirements in respect of the exercise of these powers. The Council may also reserve the right, in specific cases, to exercise the implementing powers himself. The procedures for such delegation of powers must be laid down by the Council in advance.

In practice, this means that regularly, in Directives and Regulations, the more technical rules are left to be decided by Comitology. As already mentioned in Article 202 ECT, there are several types of Comitology, i.e. cases where the Commission has the sole decision-making power (so-called advisory or management procedure), and other cases in which the Commission forwards its proposal to a Committee (in the case of food safety, this is the Standing Committee on the Food Chain and Animal Health 'SCFCAH' as mentioned above)

[5] In areas where the European Parliament has Co-decision power this also concerns the European Parliament. The fact that the European Parliament is not mentioned in Article 202 ECT is considered a drafting error.

consisting of high-level representatives of the Member States who have to vote on the proposal (so-called Regulatory Committee procedure). If the proposal does not achieve the required qualified majority (same weighting of votes as in Council), the file is being transferred to Council for adoption by the Council. Contrary to the normal legislative procedure where the Commission is entitled to withdraw and amend its proposals at any time during the legislative procedure, the Commission is not entitled to do that during the initial part of the Comitology procedure (until file has been assessed by the Council).

Prior to having a file voted in any of the Standing Committees, the Commission must also forward the file to the European Parliament for consultation.[6]

The current typology of Comitology procedures is laid down in Decision 1999/468.[7]

In the case of food safety, recourse is almost exclusively, with one exception, made to the Regulatory Committee procedure (Articles 5, 8 of Decision 1999/468). Hence, the Council will always retain the last word on any legislative competence that was delegated to the Commission. The Council has the following options:

(a) Adopting the proposal by qualified majority within 3 months;
(b) Not reacting within three months; Commission will then adopt its original proposal;
(c) Changing the proposal with unanimity and adopting it;
(d) Indicating with qualified majority that it opposes the proposal. In this case, the Commission shall re-examine it. It may submit an amended proposal to the Council, re-submit its original proposal or present a proposal under the normal (Article 251 ECT) procedure.

Accordingly, in order for a legislative act to be adopted as quickly as possible, and as the Commission is not entitled to amend its proposal once it has been put forward to a vote in the Regulatory Committee, it is in the Commission's interest to present an "acceptable" proposal, i.e. a proposal that is likely to receive the required qualified majority in the Regulatory Committee. It is for this reason that the Commission has taken the habit that prior to putting proposals for vote in the Regulatory Committee, during a prior meeting a discussion is first held on the "draft" proposal to see where the issues are. Sometimes also, the Commission proceeds to a straw vote if majorities are close. Only once a qualified majority is expected, a final proposal is formally presented for a vote.

These practices are criticized by many EU law practitioners and stakeholders because the Commission is said to bow in front of political pressure from the Member States rather than to present a proposal based on its merits.

One could of course argue that the same argument could be made for the normal legislative procedure (Article 251 ECT). However, there are a number of rather fundamental differences between the normal legislative procedure and the Comitology procedure which indeed leave a bad taste on the current practices as far as transparency and accountability are concerned:

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[6] One month. Agreement on procedures for implementing Council Decision 1999/468; OJ L 256 of 2000.

[7] Council Decision 1999/468 of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission; OJ L 184 of 1999.

(a) The members of the Regulatory Committee are high-level national officials from the respective Ministries; hence there is little overall political control and balancing of the issues at stake at national level as far as their voting is concerned – it often goes unnoticed;

(b) There is little if any public knowledge on the discussion and voting in the Regulatory Committee (closed meetings) – hence leading to less accountability of the actual vote;

(c) As they are not known, the members of the Regulatory Committee are generally not exposed to European level advocacy, they are often just exposed, if at all, to national advocacy actions;

(d) Draft measures referred to the Regulatory Committee are not published.

As to the use of Comitology within the remit of DG Sanco, according to the Commission report (COM (2003) 530 final) on the working of committees in 2002, DG Sanco was one of the Directorate Generals with the most Comitology committees, totaling 22, only surpassed by DG Enterprise (31), DG Agriculture (29), DG Transport/Energy (39), and Environment (35). DG Sanco has 8 Advisory Committees and 9 Regulatory Committees, and 5 operating under more than one procedure. A total number of 109 committee meetings were held within the remits of DG Sanco in 2002, which is the second highest total number for 2002 after DG Agriculture with 352 meetings. On the content of the committee meetings, DG Sanco again scores very high with a total of 465 opinions and 244 other instruments (implementing measures) and comes third after DG Agriculture and DG Enterprise committees. Acknowledging that some food safety measures, in particular in the veterinary field at that time were still within DG Agriculture, the amount of committee work and legislative activity by Comitology might be even higher.

As far as the food safety related committees within the DG Sanco remit are concerned, in 2002 there were 8 Regulatory Committees which held 49 meetings. They issued 258 favorable opinions and only 1 unfavorable opinion. 184 instruments were adopted by the Commission and only 1 was referred to Council.

Since the adoption of the Food Law Framework Regulation 178/2002, the number of committees in the food area has been reduced. The number of referrals to Council though has increased because concerning the authorization of genetically modified foods, the Commission, after a six year moratorium, in 2004 re-started to process files and these, not receiving qualified majority in the Regulatory Committee, are being forwarded to Council and then pass back to the Commission for adoption.

According to the Report from the Commission on the working of the committees during 2003,[8] no case of referrals to Council was reported in 2003. For 2003, 13 Regulatory Committees were reported in DG Sanco's remit (the Standing Committee on the Food Chain and Animal Welfare with its nine sections is counted as one single committee). The number of meetings in 2003 within the DG Sanco remit was 101, opinions issued stood at 392 and instruments also at 392.

2. Adjudication (Decision-making)

As briefly mentioned above, although there are a large number of dossiers that from a substantive point of view concern individual matters (e.g. the authorization of a food additive, food decontaminant, food contact material, color, flavoring and so on; see specific samples in Part 2 of this

[8] COM (2004) 860 Final of January 7, 2005..

Report) and should therefore logically be dealt with under a specific decision-making procedure, they are all, with the exception of novel foods and genetically modified foods (Regulations 258/97[9] and 1829/2003[10]), taken in the form of rule-making.

The products and ingredients being authorized go through a regulatory and scientific assessment procedure and once they have successfully passed this procedure, will be listed in the Annex of the respective legislative instrument (which could be a Directive or a Regulation as the case may be – see further below).

Accordingly, anybody who achieves the same purities etc., can then produce and market the substances and products regardless of whether he/she previously participated and contributed to the regulatory review process. This is not the case in principle[11] for novel foods and genetically modified foods, for which authorization is granted to the individual company that filed the application, by means of a Decision addressed to the applicant.

To illustrate the above described particularity of EU food safety law, set out in the Annex is a chart listing several examples of EU food law legislative instruments providing a brief analysis of whether from a formal and a substantive point of view, the decisions taken under these legal instruments are rather decision or rule-making and whether the legal format of the measures corresponds or does not correspond to the content.

As far as the preparation and drafting is concerned, there are no major differences between those decisions that are taken in the form of rule-making and those that are taken in the form of adjudication.

Depending on the individual base legal instrument, the applicant would have to file an application either at Member State level or with the European Commission. An initial scientific assessment would then either be done at the national level (see novel foods) or at Community level by EFSA. Thereafter, the European Commission would prepare a draft proposal which then would be voted by Comitology (see above).

Depending on the type of legal instrument, such procedure would take anywhere between one (in exceptional cases) and five years, with a majority of cases in the two to three year range. The newer legislative instruments usually provide deadlines for the scientific assessment and most of the following administrative procedure. However, the deadlines are often suspended by requests for further scientific and technical information from the applicant, potential re-submission to EFSA because of new information received (also from third parties) to be assessed, and toing and froing between the Commission and the Regulatory Committee (see above).

II. PART 2 – EXAMPLES OF DECISION-MAKING

[9] Regulation No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients; OJ L 43 of 1997.

[10] Regulation No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Text with EEA relevance); OJ L 268 of 2003.

[11] With the exception of substantially equivalent novel foods equivalent to a previously authorized novel food that can be put on the market with a simplified "notification" procedure under Article 3 (4) and 5 of Regulation 258/97 (the Novel Foods Regulation).

A. Novel Foods

The Novel Foods Regulation 258/97 (the 'NFR'), as mentioned above, is, alongside the Regulation on genetically modified food and feed (Regulation 1829/2003), the only example of EU food safety law where adjudication is done in the form of adjudication, by means of issuance of a Decision addressed to the individual company that filed the application.

Any food that has not been on the Community market pre-May 15, 1997 and has not been used for human consumption to a significant degree in the Community and belongs to one of the categories listed in Article 1 (2) of the NFR (foods or food ingredients with a new or intentionally modified primary molecular structure; foods or food ingredients consisting of or isolated from micro-organisms, fungi or algae; foods or food ingredients consisting of or isolated from plants and foods ingredients isolated from animals except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use; and foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substance), must undergo a pre-market approval procedure; unless it is substantially equivalent to existing foods in which case a notification simultaneous with marketing suffices.[12]

The procedure starts according to Article 4 of the NFR with the person who wants to place the product on the Community market submitting a request to the Member State in which the product is to be put on the market for the first time. At the same time, a copy of the request has to be forwarded to the Commission.

The NFR does not contain any detailed provisions or indications on how such an application should be structured. Article 4 (4) of the NFR provides that the Commission, before entry into force of the NFR, shall publish *"recommendations concerning the scientific aspects of: - the information necessary to support an application and the presentation of such information, - the preparation of the initial assessment reports provided for in Article 6."* To date, guidance on the structure and content of applications is available from three opinions on the assessment of novel foods issued by the Scientific Committee for Food (the institution responsible for risk assessment predating the EFSA)

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[12] For a detailed discussion on the NFR, please see Schliessner, Ursula "Marketing Biotech Foods in Europe: Legal Issues and Implications", published in The Journal of Biolaw & Business, Volume 3, 1999; or Schliessner, Ursula "Borderline Products in the EU", Global Counsel Life Sciences Handbook, Practical Law, 2003.

from January 1997[13] published as a Commission Recommendation of July 29, 1997 after consultation of the Standing Committee for Foodstuffs[14].

It is our understanding that to date all applicants that have filed novel food applications have adhered in content and structure to this Recommendation and no dispute has ever arisen as to the validity of this approach. It is noted though that Article 4 (5) of the NFR provides that *"any detailed rules for implementing this Article shall be adopted in accordance with the procedure laid down in Article 13"* (this is a reference to the Comitology procedure under the NFR) suggesting that binding rules may have to be adopted also on how to file novel foods applications, whereas Article 4 (4) NFR requests the Commission to publish "recommendations", which are non-binding in the EU nomenclature (Article 249 ECT).

Companies wishing to pursue a novel food application usually do some forum shopping when it comes to a decision on the Member State in which the application should be filed. Indeed, it is quite easy, including for importers, to decide on the place where the "novel food is first put on the market". Companies would either have a preference for the Member State in which they have their main business operations or their seat; or a Member State which they believe is easily accessible (for example for language); or a Member State they believe has a good understanding of novel foods (technical expertise required and already several files processed in a reasonable time frame). Accordingly, of the fourteen novel foods authorized to date, 5 files had their initial assessment in the United Kingdom, 4 in the Netherlands, 2 each in France and Finland, and 1 in Denmark.

The Member State of application will determine a body that will carry out the 'initial assessment'. This assessment must be carried out within three months. In practice, the deadline may be suspended if the assessment body requires additional data or studies from the applicant. There is usually regular and informal contact between the applicant and the assessment body during this three months period.

Once the initial assessment is available, it will be forwarded to the Commission who will forward it to the other Member States for comments or reasoned objections with a 60 days deadline. The comments and objections will be recirculated. Member States may also ask applicants to provide pertinent information. Some of the applicants, will, depending on the resources and contacts they have available, take up contact with the other Member States during the 60 days period, others won't. Some applicants will also have contacts with the European Commission before they file their application at the Member State of choice in order to discuss any outstanding questions they may have on their file. Such a "pre-filing" meeting would be informal. No records would be maintained and any opinions issued by Commission desk officers on the individual issues discussed would not be binding.

If no additional assessment is required (by the EU scientific body, i.e. the EFSA) and no Member State raises objections, theoretically the novel food could be marketed. In practice, however, no single novel food has ever been lucky enough to get on the market at this stage. In all cases, the Member States have raised comments or objections that were classified as "reasoned objections". In

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[13] III/5915/97. Opinion expressed on June 7, 1996; and two Opinions expressed on December 12/13, 1996.

[14] Commission Recommendation of July 29, 1997 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 Regulation (EC) No 258/97 of the European Parliament and of the Council (97/618/EC); OJ L 253 of 1997.

such case, a formal authorization decision is required. This Decision is taken under the Comitology procedure (Articles 7 and 13 of the NFR). Accordingly, unless an additional assessment is required in the opinion of the Commission and the file is being referred to EFSA for further review, the Commission will prepare a draft decision authorizing or refusing the authorization of the product, and this draft Decision will then have to receive a qualified majority in the Regulatory Committee. If not, it will be sent to Council and so on (see above).

No deadline is provided in the NFR for this second part of the procedure once the 60 days comments period for Member States has lapsed. The quickest ever novel food file (potato proteins) managed to get through the entire procedure in roughly one year. Usually, the process takes about two to three years. All, but one[15] novel food file, received the necessary qualified majority in the Regulatory Committee, but depending on the file, at times were discussed several times in the Regulatory Committee before the Commission decided to proceed to a vote.

It is common practice that applicants maintain informal contact with at least those Member States that have raised objections and provide them with information in order to ensure that these Member States will not object once the file is being voted in the Regulatory Committee. For small and medium sized companies, this can be quite a cumbersome exercise. On the other hand, if there was no EU authorization procedure for novel foods, going through a large number of national approvals would surely be worse.

To date, two novel food applications were refused authorization, and several applicants withdrew their applications during the course of the procedure.

There have been no legal challenges to any refusals or authorizations issued despite this being possible as the authorization Decisions are addressed to individuals and may therefore be challenged at the CFI.

The NFR has been subject to interpretation at the ECJ though because several Member States had started safeguard measures under Article 12 of the NFR against individual products. However, this only related to products that had undergone the "notification" rather than the authorization procedure and where the Member States had challenged the "substantial equivalence" of the notified foodstuff.[16]

For completion, it should be noted that the NFR has a specific provision allowing for Comitology procedure in those cases in which it is not clear whether a particular food or food ingredient is substantially equivalent or not (Article 3 (4) NFR at the end) or whether it is a novel food (Article 1 (3) NFR). To the best of our knowledge, this procedure has not yet been used. Rather, it appears that whenever there is doubt on whether a food is novel, it is the initial Member State of contact who issues an opinion that is then being communicated via the European Commission or directly to the other Member States. This practice of course does not provide, contrary to a decision that would be

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15 This was the Bt 11 genetically modified sweet maize (which if the application would be filed now, would be within the remit of Regulation 1829/2003 because genetically modified foods have recently been taken out of the scope of the NFR). In this particular case, the Regulatory Committee did not want to give its opinion and the Commission then had to go to Council. Council again did not give an opinion and accordingly the Commission then had to adopt the Decision.

16 C-236/01, *Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others* [2003] ECR I-8105.

taken under the Comitology procedure, any legal certainty to the concerned company about whether a Member State may later challenge (for example under the safeguard procedure) this opinion. However, there seems to be a silent understanding, a sort of gentlemen's agreement, that once a Member State has communicated its opinion to the other Member States and the Commission and none of the latter request a decision under Comitology, the initial Member States' decision is accepted and would not later be subject to safeguard measures.

B. Food Additives

EU food additives legislation is a typical example of adjudication via rule-making and it is for this reason that we have chosen food additives as an example in the present context.

EU food additives legislation consists of two main Directives, the so-called 'framework Directive 89/107 as amended[17], and the so-called 'miscellaneous' additives Directive 95/2[18] implementing the framework Directive, as well as several other Directives on purity criteria, and specific type additives.

Directive 89/107 applies to food additives the various categories of which are listed in Annex I (colors, preservatives, anti-oxidants, emulsifiers, emulsifying salts, thickeners, gelling agents, stabilizers, flavor enhancers, acids, acidity regulators, anti-caking agents, modified starch, sweeteners, raising gents, anti-foaming gents, glazing agents, humectants, sequestrants, enzymes, bulking agents, propellant gases and packaging gases) and which are used or intended to be used as ingredients during the manufacture or preparation of a foodstuff and are still present in the final product, even if in altered form.

Food additives are meant to be substances not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not they have a nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in them or their by-products becoming directly or indirectly a component of such foods.

Article 2 of Directive 89/107 provides that lists of food additives will be drawn up at Community level and only those food additives included in such lists may be used in the manufacture or preparation of foodstuffs and only under the conditions of use specified therein.

Inclusion of substances into Community lists is done by the normal legislative procedure (Article 251 ECT). Given the number of procedural steps involved (up to three Readings in the European Parliament), authorization of an additive may take anywhere from two to five years.

Article 5 also allows for provisional authorization of additives not yet included in the Community lists for a maximum period of two years. However these provisionally authorized additives can only be used on the national territory of the specific Member State. Before expiry of the two year period, the Member State may request inclusion into the Community list (Article 5 (3) of Directive 89/107) provided it presents the evidence supporting this inclusion. Inclusion into the Community list would

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[17] Council Directive 89/107 of December 21, 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption; OJ L 40 of 1989.

[18] European Parliament and Council Directive No 95/2/EC of February 20, 1995 on food additives other than colors and sweeteners; OJ L 61 of 1995.

then be done under the normal legislative procedure within 18 months. If the Council has not acted within 18 months, the national authorization must be cancelled.

Directive 89/107 also provides for a safeguard measure in case of dangers to human health from additives. These questions are then resolved by Comitology under Article 11 of the Directive.

Directive 95/2 dealing with the large bulk of additives is one of the implementing Directives of Directive 89/107. It lists in its Annex the permitted additives in the various technical use categories, their concentrations and use restrictions. It provides for the use of Comitology for questions of interpretation of the existing Annex entries and whether a particular substance is a food additive. New entries have to be adopted by the normal legislative procedure (see above).

Neither Directive 89/107 nor Directive 95/2 contain any detailed rules on the procedure for assessing additives, having them accepted and entered into the Community lists, nor do they contain detailed criteria for such listing. Annex II of Directive 89/107 contains a general list of criteria that must be fulfilled for the use of food additives:

- demonstration of a reasonable technological need the purpose of which cannot be achieved by other means which are economically and technologically practicable;
- no hazard to the health of the consumer at the level of use proposed based on available scientific evidence;
- no misleading of the consumer;

As regards the technological need, it is specified that the nutritional quality of the food must be preserved; quality or stability of the food must be enhanced or kept, or organoleptic properties must be improved provided this does not change their nature, substance or quality. The additive must provide aids in manufacture, processing, preparation, treatment, packaging, transport or storage provided it is not used to disguise the effects of use of faulty raw materials or undesirable practices. The possible harmful effects of the food additive or derivatives thereof must be subjected to appropriate toxicological testing and evaluation. This evaluation should also take into account cumulative, synergistic or potentiating effects of additives use and human intolerances to substances foreign to the body.

All food additives must be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information.

Food additives must comply with the approved criteria of purity (for which specific Directives have been issued). Any approval must be limited to the lowest level of use necessary to achieve the desired effect and take into account any acceptable daily intake, or equivalent assessment, established for the food additive and the probable daily intake of it from all sources.

Because there is no whatsoever language in the text of Directive 89/107 on the procedure for assessing a food additive, the Commission has issued a three page guidance document for this purpose.[19] This guidance document does not take the established forms of Commission non-binding instruments under Article 249 ECT (recommendation or opinion).

The guidance document provides that requests for authorization of a new food additive, modifications of conditions of use of an authorized food additive, or modification of the purity criteria should be addressed to the European Commission. The application for authorization of a new food additive should consist of a letter clearly specifying the request and of a technical dossier following the guidelines entitled “Guidelines for submissions of additive evaluations by the Scientific Committee

[19] http://europa.eu.int/comm/food/food/chemicalsafety/additives/flav16_en.pdf

on Food prior to its authorization". The dossier should also contain a summary document that can be separated. The guidance document further specifies that the letter and two copies of the summary document should be addressed to Unit D3 of DG Sanco, and that at the same time, the full application (a copy of the letter, 30 copies of the Summary Document, 3 copies of the full dossier), should be sent to the Secretariat of the Panel on food additives, flavorings, processing aids and materials in contact with foodstuffs of EFSA. In addition, the full information shall also be submitted in a searchable version in electronic format (CD Rom). The petitions should be sent by registered mail.

Interestingly, the Guidance Document also contains rules on confidentiality. It specifies that the application in itself cannot be considered as confidential. Sections considered as confidential by the applicant should be kept to a minimum. Applicants are encouraged to make publicly available a maximum of the information submitted for example by posting the content of the application on the Internet.

It is also noteworthy that this Guidance Document is not published in the Official Journal of the EU but only on the Commission's homepage, and that it is currently only available in English, and not in the other EU official languages.

The second document also only published in electronic format on the Commission's homepage is the Guidance for submissions for food additive evaluations by the Scientific Committee for Food (opinion expressed on July 11, 2001) mentioned above.[20] It sets out in 42 pages a description of the process of evaluations, the content of the dossier to be submitted, which toxicological and other studies should be carried, and use criteria for food additives.

Hence, it follows from the above that the authorization of individual food additives at this time is taken in the form of the normal legislative procedure (Article 251 ECT) and that the details of how an application is filed and how an assessment is conducted are not provided for in the secondary Community legislation, but only in the form of informal documents, published on the Commission's website in only one of the Community languages.

C. Smoke Flavorings

We have chosen the example of the smoke flavorings Regulation because it is an example of the new type of food legislation passed after adoption of the General Food Law Regulation 178/2002.[21]

Regulation 178/2002 sets common principles and responsibilities for all EU food law applicable to all foods and food ingredients, including food packaging. It also establishes the EFSA. Existing food law principles and procedures have to be adapted as soon as possible and by January 1, 2007 at the latest in order to comply with the general principles (Article 4 of Regulation 178/2002).

According to Article 5 of Regulation 178/2002, food law shall pursue a high level of protection of human life and health, the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment.

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[20] SCF/CS/ADD/GEN/26 Final/July 11, 2001. http://europa.eu.int/comm/food/fs/sc/scf/out98_en.pdf

[21] Regulation No 178/2002 of the European Parliament and of the Council of January 28, 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 of 2002.

In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure. Risk assessment shall be based on the available scientific evidence and undertaken in an independent objective and transparent manner. Risk management shall take into account the result of the risk assessment, other factors legitimate to the matter and the precautionary principle[22] (all Article 6 of Regulation 178/2002).

The smoke flavorings Regulation 2065/2003[23] is a prime example[24] of this new approach. As a first particularity of this new approach, it is striking that regulation of flavorings is conducted by means of a Regulation, rather than via a Directive, thereby centralizing and streamlining the regulation of these substances and elevating their assessment to EU level.

Regulation 2065/2003 applies to smoke flavorings used or intended for use in or on foods, and source materials for the production of smoke flavorings, the conditions under which smoke flavorings are prepared, and foods in or on which smoke flavorings are present (Article 2 of Regulation 2065/2003). To this end, the Regulation lays down a Community procedure for the evaluation and authorization of primary smoke condensates and primary tar fractions for use as such in or on foods, in the production of derived smoke flavorings for use in or on foods; and a Community procedure for the establishment of a list of primary smoke condensates and primary tar fractions authorized to the exclusion of all others in the Community and their conditions of use in or on foods.

The use of smoke flavorings shall only be authorized if its sufficiently demonstrated that they do not present risks to human health and do not mislead consumers. No smoke flavoring may be used unless it is authorized under this Regulation (Article 4).

The application for authorization of a primary product in the list requires an application. This application has to be sent to the competent authority of a Member State, who in turn shall acknowledge receipt in writing within 14 days. It shall inform without delay EFSA and make the application and any supplementary information supplied by the applicant available to EFSA. EFSA shall inform the other Member States and the Commission of the application and shall make the application and any supplementary information submitted by the applicant available to them (Article 7).

The application shall be accompanied by

- the name and address of the applicant;
- the information listed in Annex II (type of wood; detailed information of production methods of primary products and further processing; qualitative and quantitative chemical composition

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[22] See also, Schliessner, Ursula "Application of the Precautionary Principle in European Life Science Regulation", Global Counsel's Life Sciences Industry Report 2001, Second Edition, published May 2001; or Schliessner, Ursula "Application of the Precautionary Principle in the European Union ('EU') - What Will Change", published in The ABA IELC Newsletter, Volume 3, No.2, November 2000.

[23] Regulation No 2065/2003 of the European Parliament and of the Council of November 10, 2003 on smoke flavorings used or intended for use in or on foods; OJ L 309 of 2003.

[24] The Commission is currently working on a renewal of the additives legislation and on a Regulation on enzymes that mirror the approach taken in Regulation 2065/2003.

of the primary product and characterization of the portion which has not been identified.; validated analytical method for sampling, identification and characterization of the primary product; information on the intended use levels in or on specific foods or food categories; toxicological data following the advice of the Scientific Committee on Food given in its report on smoke flavorings of June 25, 1993 or its latest update;

- a reasoned statement affirming that the product complies with Article 4 (1) first indent;
- a summary of the dossier.

Article 7 (4) also states that EFSA shall publish detailed guidance concerning the preparation and the submission of the application. In a footnote to Article 7 (4), it is noted that until publication of this guidance, applicants should follow the Guidance on submission of food additive evaluations (see above). The web address for this guidance document is given. As noted above, this guidance is only available in the English language rather than in all official EU languages.

Under Article 8, EFSA shall give an opinion on the dossier within six months of the receipt of a valid application. EFSA may extend this period provided it issues an explanation for the delay to the applicant, the Commission and the Member States.

EFSA may also request the applicant to supplement the particulars accompanying the application within a time limit specified by it and which in no event shall exceed 12 months. Where EFSA request such supplementary information, the time limit above shall be suspended until such time that this information is supplied. Likewise, the time limit shall be suspended for the time allowed to the applicant to prepare oral or written explanations.

In order to prepare its opinion, EFSA shall verify that the particulars and documents submitted by the applicant are complete in which case the application shall be regarded as valid. If not complete, EFSFA shall inform the applicant, the Commission and the Member States that the application is not valid.

In the event of an opinion in favor of authorizing the evaluated product, the opinion shall include any conditions and restrictions that should be attached to the use of the product and an assessment of the analytical method.

EFSA shall forward its opinion to the Commission, the Member States and the applicant. Under Article 8 (6), EFSA shall also make its opinion public, after deletion of any information identified as confidential in accordance with Article 15.

Within three months of receiving the opinion from EFSA, the Commission shall prepare a draft of the measure to be taken in respect of the application for inclusion of a primary product in the list, taking into account the requirements of Article 4 (1), Community law, and other legitimate factors (!) relevant to the matter under consideration. Where the draft measure is not in accordance with the opinion of EFSA, the Commission must provide an explanation for the reasons for these differences. The measure will be adopted by means of Comitology (Regulatory Committee procedure).

Very interestingly, Article 9 (1) establishes two different legal formats for the measure to be taken depending on whether the decision is positive or negative. If the product is authorized, this shall be done by means of a Regulation entering the product into the list set up under the Regulation. Hence, it will be generally applicable and anybody may produce and market the substance provided he/she fulfills the specifications. If authorization of the product is refused, this shall be done by means of a Decision, addressed to the applicant, refusing authorization. Obviously, the fact that a negative measure is issued by means of a Decision is a significant improvement of the current situation for many other food ingredients (see e.g. additives above) because it will allow the applicant to challenge the negative Decision with an action at the CFI. On the other hand, the fact that two types of measures are foreseen, demonstrates for the first time clearly that there is a mix-up between adjudication and rulemaking and that the form of the measure does not always correspond to its

content. It is understandable from a legislator's point though that the positive decision is issued by means of a generally applicable instrument because this makes also the use specifications applicable to anybody using the product which would not be granted if the decision was just addressed to the applicant (unless two separate measures were to be adopted, the use specifications being adopted by a generally applicable measure). In the latter case it would be the applicant who would have to ensure that his/her customers comply with the conditions of use. Enforcement at national level of the use specifications would thus be rendered more difficult.

The authorization is granted for 10 years and may be renewed thereafter. This is also new because previously authorizations were generally unlimited in time.

After an authorization has been issued, the authorization holder or any other food business operator using the authorized primary product or derived smoke flavoring shall comply with any condition or restriction attached to such authorization.

Article 10 provides a specific procedure for setting up the initial list of authorized primary products (transitional period).

Article 11 allows the authorization holder to apply for a modification of the existing authorization using the same procedure as for the first authorization. A decision is again to be taken by Comitology but contrary to Article 9 on the initial authorization, Article 11 does not specify which legal form the modification, suspension or revocation of the authorization shall take. Article 11 merely specifies at the end that the Commission shall without delay inform the authorization holder of the measure taken.

Concerning access to documents, Article 14 specifies that applications for authorization, supplementary information from applicants and opinions from the EFSA, excluding confidential information shall be made accessible to the public in accordance with the general Regulation on access to information (Regulation 1049/2001).[25] According to Article 15 on confidentiality, the applicant may indicate which information submitted under Article 7 should be treated as confidential because disclosure may significantly harm his or her competitive position. Verifiable justification must be given in such cases. The Commission shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant and the Authority of its decision. Certain types of information, in accordance with Article 39 (3) of Regulation 178/2002 cannot be considered as confidential, including the information of direct relevance to the assessment of the safety of the product and the analytical method.

Article 16 also contains rules on data protection, namely that the information in the application submitted according to Article 7 may not be used for the benefit of another applicant, unless the other applicant has agreed with the authorization holder that such information may be used.

Finally, we note that despite the rather, compared to earlier type approval legislation, comprehensive regulation of the procedure, Regulation 2065/2003 does not contain any rules for administrative appeals in relation to the different steps of the procedure.

D. Food Contact Materials

[25] Regulation No 1049/2001 of the European Parliament and of the Council of May 30, 2001 regarding public access to European Parliament, Council and Commission documents; OJ L 145 of 2001.

The new food contact material Regulation 1935/2004[26] consolidating and revising the existing food contact legislation is another noteworthy example of legislation passed after adoption of the General food law Regulation 178/2002 and is discussed here as first example of the introduction of an administrative review procedure into EU food safety law.

Materials and articles, including active and intelligent materials and articles shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health or bring about an unacceptable change in the composition of the food (so-called general safety requirement); or bring about a deterioration in the organoleptic characteristics thereof. Labeling, advertising and presentation of a material or article shall not mislead consumers. For the groups of materials and articles set out in Annex I (active and intelligent materials and articles, adhesives, ceramics, cork, rubbers, glass, ion-exchange resins, metals and alloys, paper and board, plastics, printing inks, regenerated cellulose, silicones, textiles varnishes and coatings, waxes, wood), combinations of those materials and articles or recycled materials and articles used in the manufacture of those materials an articles, specific measures may be adopted or amended under the Comitology procedure (Article 5) (reference to Regulatory Committee procedure).

These specific measures may include

- a list of substances authorized for use in the manufacturing of materials and articles;
- lists of authorized substances incorporated in active or intelligent food contact materials and articles;
- purity standards for substances referred to in the first indent above;
- specific conditions of use for substances;
- specific migration limits of certain constituents or groups of constituents into or on to food, taking due account of other possible sources of exposure to those constituents;
- an overall limit on the migration of constituents into or on to food;
- provisions aimed at protecting human health against hazards arising from oral contact with materials and articles;

and many more.

According to Article 7, any provisions liable to affect public health shall be adopted after consultation of EFSA.

When it comes to the authorization procedure, Article 8 of Regulation 2035/2004 provides that anyone seeking an authorization for a substance not yet included in the Community lists shall submit an application in accordance with Article 9 (1). The application shall be submitted to the competent authority of a Member State accompanied by the name and address of the applicant, and a technical dossier containing the information specified in the guidelines for the safety assessment of a substance to be published by EFSA, and a summary of the technical dossier. The competent authority shall acknowledge receipt of the dossier in writing within 14 days. The national competent authority shall inform EFSA without delay and shall make the application and any supplementary information supplied by the applicant available to EFSA. EFSA then must inform the other Member States and the Commission without delay of the application and must make the application and any supplementary information supplied by the applicant available to them.

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[26] Regulation No 1935/2004 of the European Parliament and of the Council of October 27, 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC; OJ L 338 of 2004.

Article 9 (2) provides that EFSA must publish detailed guidelines concerning the preparation and the submission of the application. As for the smoke flavorings (see above), there is a footnote to Article 9 (2) mentioning that pending such publication, applicants may consult the 'Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorization with a reference to the homepage of the Commission where this guidance note is published (again only in English).

EFSA must give an opinion on the file within six months of receipt of a valid application. This period may be extended by another six months provided an explanation of the delay is given to the applicant, the Commission and the Member States. EFSA may request the applicant to supply supplemental information, in which case the deadlines are being suspended until the information has been provided. The same applies if the applicant has to prepare oral or written explanations. Under Article 10, EFSA must verify all documentation submitted and must make a formal statement as to whether the application is valid or not.

If EFSA is of the opinion that the substance may be authorized, it shall issue an opinion including where appropriate recommendations for any conditions or restrictions of use and an assessment of the analytical method. The opinion shall be forwarded to the Commission, the Member States and the applicant. EFSA shall also make its opinion public after deletion of all confidential information.

The form of authorization itself is not specified in Article 11. Article 11 merely states that it shall *"take place in the form of the adoption of a specific measure"*. The measure shall take into account the opinion of the EFSA, relevant provisions of Community law and other legitimate factors. If the draft measure is not in accordance with the opinion of EFSA, the Commission must provide without delay an explanation for the reasons for the differences. The Commission is also under a duty to provide reasons if it does not intend to prepare a draft specific measure despite a favorable opinion by EFSA.

The actual adoption of the authorization is done by Comitology (Regulatory Committee procedure). Article 11 (4) then goes on to state that after the authorization, any business operator using the authorized substance or using articles containing the substance shall comply with any conditions or restrictions attached to the authorization.

Under Article 12, the applicant or any business operator using the authorized substance or materials may apply for modification of the existing authorization. Again, any decisions to that extent are taken by Comitology.

Article 14 provides that *"any act adopted under, or failure to exercise, the powers vested in the Authority (EFSA) by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly or individually concerned. To this effect a request shall be submitted to the Commission within two months from the day on which the party concerned became aware of the act or omission in question. The Commission shall take a decision within two months requiring, if appropriate the Authority to undo its act or to remedy its failure to act."* As mentioned above, this administrative review procedure is new, as yet unused and its practical application and impact is yet to be seen.

Concluding from the above, whilst Regulation 2035/2004 is a major improvement in terms of clarity of procedure, it still has shortcomings, including the lack of clarity on the legal nature and hence appealability of the authorization and refusal decisions, the lack of binding criteria on the content of the scientific assessment and the fact that factually binding criteria are not available in all EU languages.

III. PART 3 – SPECIFICS OF THE ADJUDICATION PROCEDURE

As can be seen from the above examples, there is a rather large variety of procedures, with a tendency among the more recent pieces of secondary Community legislation to set out the procedures in more detail and with more deadlines.

However, there are also new instruments of Community legislation that continue, despite Regulation 178/2002, to not provide any detailed rules on the procedure for adoption of an authorization decision, see for example the approval of decontaminant products for fresh meat under Regulation 853/2004.[27]

Despite this tendency to be more detailed and increase accountability, there are still steps in the administrative procedure for which no deadlines are set, for example on the maximum of time that can be allocated to the Regulatory Committee to take a decision. On occasion also, no time limit is set for the Commission to prepare its draft measures.

No details are provided, even in the newer legislative instruments, on the interaction between applicants on one side and EFSA and/or the Commission on the other, once an application has been filed. For example, there is no specific language as to whether an applicant would be entitled to comment on an EFSA opinion or a draft Commission measure. No rule is provided on interaction between the applicant or third parties with the Regulatory Committee, and no rules are provided on public consultation of any draft measure.

Hence, the current practice of informal contacts between the Commission and the applicants will likely continue.

Whether the previous practice of informal contacts between the Scientific Committee and the applicants will continue under EFSA remains to be seen. It is our recent experience that EFSA is more formalized in its dealings with petitioners than the previous scientific committees and that individual contacts between scientific panel members and applicants are discouraged by the EFSA secretariat. We would therefore expect a formalization in this area. The administrative review procedure for EFSA acts included for example in the new food contact legislation (Regulation 2035/2004) may actually accelerate this trend.

There is as yet no case law on this issue. However, EFSA has recently come under considerable scrutiny with the Advocate General opinion in joined cases C-154/04 and C-155/04 which is a request for a preliminary ruling concerning the validity of Directive 2002/46 on food supplements[28]. Because of its importance, the relevant paragraphs of the Opinion of Advocate General Geelhoed are here cited in full:

> *"The selection of a legislative instrument using positive lists of allowed substances that, on the one hand, aims at securing a high level of protection of public health, and, on the other, imposes far-reaching restrictions on the freedom of market operators in certain Member States to produce and market foodstuffs enriched with minerals and/or vitamins, cannot as such be regarded as being contrary to the principle of proportionality. However, as such a choice significantly affects the freedom of market operators by impeding the continuation of activities previously regarded as permissible and safe, and subjects the development and production of new products to prior assessment by the Commission before inclusion in the positive list, the*

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[27] Regulation No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin; OJ L 139 of 2004.

[28] Directive 2002/46 of the European Parliament and of the Council of June 10, 2002 on the approximation of the laws of the Member States relating to food supplements; OJ L 183 of 2002.

legal instruments employed must be designed with prudence and precision. Without calling in question the substantive assessment made by the Community legislature, I must conclude that it has seriously failed in its duty to design such a far-reaching measure with all due care. In its present form, Directive 2002/46 is seriously deficient in three respects.

There is no mention, in the text of the Directive itself, of the substantive norm which the Commission must follow as a guiding principle in exercising its powers under Articles 4(5) and 13 of the Directive. The Directive thus contains no standard for assessing whether the Commission has, in taking decisions concerning modifications of the positive list, remained within the limits of its legal powers;
It is not clear whether the Directive allows private parties to submit substances for evaluation with a view to having them included in the positive lists. Recital 10 in the preamble to the Directive refers unambiguously to this possibility, yet Article 4(6)(b) of the Directive would seem to suggest the contrary;

On the supposition that private parties are indeed able to submit substances for an evaluation with a view to inclusion in the positive lists, there is no clear procedure for this purpose which provides minimum guarantees for protecting those parties' interests.

The first deficiency is a particularly serious shortcoming, because it relates to the substantive norm governing the exercise by the Commission of the most far-reaching power provided for in the Directive, namely the decision to add to the as yet incomplete positive lists. The way in which this power is exercised determines the scope for interested parties to exercise their existing economic activities, as well as the restrictions to which they will be subject in the future. Even if we take as a basis only the minimum requirements of the legal certainty necessary in economic relations, it is indispensable that the legislative instrument should itself lay down a substantive standard. Without such a standard there is no basis for effective legal protection.

This deficiency is even more striking in view of the fact that the Directive does contain clear norms in respect of less intrusive decisions to be taken by the Commission and which provide guidance for the exercise of its powers, as in the case of labeling (Article 7, first sentence) and quantities (Article 8(1), first sentence).

Although the preamble to the Directive, at recital 5, provides a certain substantive point of reference for the decisions on the composition of the positive lists, where it states that 'the products that will be put on the market must be safe', such a recital in the preamble does not constitute a substitute for a standard which should appear in the corpus of the Directive.

The legislative technique applied here, if it merits such a title, is furthermore in direct conflict with points 10 and 13 of the Interinstitutional Agreement of 22 December 1998 on common guidelines for the quality of drafting of Community legislation[29].
The striking conflict between recital 10 in the preamble and Article 4(6) of the Directive led to some confusion at the hearing, particularly on the part of the representatives of the Council and the European Parliament.
It is clear that the text of Article 4(6)(b) of the Directive does not provide a solution for that confusion. This provision refers to 'an unfavourable opinion (of the European Food Safety Authority) … on the basis of a dossier supporting use of the substance in question to be submitted to the Commission by the Member State (my italics) …'. It may be inferred from this that it is the Member State which is to take the initiative and submit the dossier to the

29 OJ C 73 of 1999.

Commission. In turn, the Commission must forward the file to the EFSA which subsequently carries out the evaluation resulting in its 'opinion'.

This plainly contradicts the terms of recital 10 in the preamble:
'There is a wide range of vitamin preparations and mineral substances used in the manufacture of food supplements currently marketed in some Member States that have not been evaluated by the Scientific Committee on Food and consequently not included in the positive lists. These should be submitted to the European Food Safety Authority for urgent evaluation, as soon as appropriate files are presented by the interested parties.'

The recital refers to neither the nor the Commission. It does expressly mention 'the interested parties' who, it would appear, must compile and present the necessary dossiers, not, as Article 4(6) of the Directive would seem to indicate, with a view to obtaining a derogation for the period up to 31 December 2009, but for the purpose of evaluating the substances concerned to be included in the positive list.

Some assistance in seeking a solution to this contradiction is provided by the 'Administrative Guidance on Submissions for Safety Evaluation of Substances added for Specific Nutritional Purposes in the Manufacture of Foods.') These technical, administrative official guidelines expressly apply to Directive 2002/46. They contain instructions for 'petitioners' submitting an application, a description of the administrative acceptance process and of how the dossier is to be composed when submitting 'the full application'.

The following section of point 2.1. of the 'Administrative Guidance', entitled 'Application for the authorisation of a nutritional substance for inclusion in the appropriate EU legislation', is particularly noteworthy. It reads as follows:
'An application for the authorisation of a nutritional substance should consist of the following separate elements:
– a letter clearly specifying the request with regard to nutrient(s) categories and, if appropriate, the specific nutrient(s) that the nutritional substance is intended to be used as a source of. In addition the specific Community legislation that the petitioner would like the substance to be included in should be specified, namely: (..)

This section seems to confirm what is expressed in recital 10 in the preamble to the Directive, namely that:
a. interested parties (petitioners) are private parties, who
b. may request the 'inclusion of a substance on a positive list', within the meaning of the Directive
c. the Member States play no role in that part of the procedure which precedes the evaluation by the EFSA.

It follows from the above that an administrative practice undeniably exists which conforms to the terms of recital 10 in the preamble to the Directive, but which deviates from the text of Article 4(6)(b) of the Directive, as to both procedure and substance, in that it goes further than merely obtaining a temporary derogation for a substance. It is also undeniable that private parties ('petitioners' and 'applicants') are considered to be 'interested parties' in the context of that administrative practice.
Such an obvious contradiction between the text of a provision in the Directive and the corresponding recital in the preamble which, in turn, accords with an administrative practice, clearly results in legal uncertainty for the interested parties who have an evident interest in the prudent and transparent application of the Directive.

As a passing comment, I would add that a legislative act leading to an administrative practice which is not based on the provisions of that act, but on its preamble, is incompatible with points 10, 14 and 15 of the Interinstitutional Agreement of 22 December 1998 referred to above. It is

also at odds with the Court's case-law which requires the reasons given for an act of an institution to cover the substance of that act.

These observations are in themselves sufficient to cast doubt on the validity of the extra legem procedure available to 'interested parties', in view of the fact that it is also, at least in part, contra legem. However, even assuming that it is valid, it does not comply with the minimum standards which apply to such procedures under the principles of sound administration.

Indeed the 'Administrative Guidance' indicates with some precision which requirements apply to 'petitions' and, subsequently, to 'full applications'. However, an 'interested party' never gets beyond the EFSA's front door. It must patiently await the 'scientific opinion' of this body, following which, under Article 13 of the Directive, a decision is taken by the Commission or the Council in accordance with the so-called regulatory procedure of the Comitology Decision. Once they have submitted their application with the accompanying dossier, interested parties have no right to be heard. Nor are they given the opportunity to express their views on the EFSA's (draft) 'scientific opinion'. According to the 'Administrative Guidance' an applicant must consult the EFSA's website to learn of the EFSA's final judgment. If this judgment is favourable, the Commission remains free to decide whether to follow it up by submitting a proposal to the Standing Committee on the Food Chain and Animal Health, which acts as the regulatory committee referred to in Article 5(1) of the Comitology Decision. Neither the Directive nor the Administrative Guidance obliges the Commission to inform the interested party of its decisions and the reasons on which they are based.

In short, this procedure, in so far as it may exist and in so far as it may deserve this title, has the transparency of a black box: no provision is made for parties to be heard, no time-limits apply in respect of decision-making; nor, indeed, is there any certainty that a final decision will be taken. The procedure therefore lacks essential guarantees for the protection of the interests of private applicants.

At the hearing, the representative of the Council, responding to a question, remarked that the decisions on the composition of the positive lists are of general application and that it was not necessary, therefore, to accord procedural rights to individual interested parties at the preparatory stage. That position, it would appear to me, is based on a misunderstanding. Even though decisions relating to the extension or the shortening of the positive lists have effect erga omnes, plainly they may also affect the vital interests of individual parties. In order to ensure that these interests are taken into account in the decision-making process in a manner which is open to judicial scrutiny, the basic legislative act ought for that purpose to provide for the minimal guarantee of an adequate procedure. The Community legislature recognised this requirement in, e.g., Regulation (EC) No 384/96) which provides, in precise terms, for guarantees for balanced decision-making in the procedure leading to the adoption of protective anti-dumping measures. Those measures, too, are generally applicable.
The claimants in the main proceedings in this case observed, in both their written and their oral submissions, that preparing an 'admissible' application within the meaning of the 'Administrative Guidance' is a costly matter and that the final decision – or the lack of such a decision – may have the consequence that the company concerned will have to cease (part of) its economic activities. These observations were not contradicted. In this light, the Community legislature in drafting a legislative act may at least be expected to act with such care as to make express provision for minimum conditions of prudent decision-making in that legislative act. The fact that these conditions were not included in Directive 2002/46 is in itself sufficient to conclude that the Community legislature has failed in this respect. The Directive does not comply with essential requirements of legal protection, of legal certainty and of sound administration, which are basic principles of Community law. Thus, lacking appropriate and transparent procedures for its application, the Directive infringes the principle of proportionality. It is, therefore, invalid.

I would make one further observation on the Interinstitutional Agreement of 22 December 1998, to which I referred above. The mutual obligations which the institutions entered into in respect of the quality of drafting of Community legislation are not intended primarily to achieve the linguistic aestheticism dear to legislative draftsmen. In a Community of law, such as the European Union, which is governed by the principles of the Rechtsstaat, there are two aspects to a legislative act as an expression of the legislature's will. On the one hand, it is an instrument for pursuing and, if possible, achieving justified objectives of public interest. On the other hand, it constitutes a guarantee of citizens' rights in their dealings with public authority. Qualitatively adequate legislation is characterised by a balance between both aspects. The wording and the structure of the legislative act must strike an acceptable balance between the powers granted to the implementing authorities and the guarantees granted to citizens. Directive 2002/46 does not comply with this essential quality requirement of proper legislation.

It should also be noted that the consequences of declaring the Directive invalid on these grounds would remain limited. Such a declaration would not, after all, affect the substantive assessment made by the Community legislature which led to the selection of a restrictive system with positive lists for marketing nutrients enriched with minerals or vitamins. A declaration of invalidity would, however, compel the Community legislature to take better account in such a system of the interests of private parties and to provide for the necessary guarantees for their protection. As the Directive only requires the Member States to prohibit trade in products which do not appear on the positive lists as from 1 August 2005 at the latest, the practical consequences of a declaration of invalidity will be limited if the necessary improvements and amendments to the text of the Directive are adopted quickly.

It remains to be seen whether and to which extent the ECJ will follow the Advocate General in the given case. Unless the ECJ manages to evade a ruling on these particular statements made by the Advocate General, which is not excluded, the judgment in this case should provide a much clearer picture on the minimum procedural requirements and practices in dealings with the European Commission and EFSA and on the standards for regulatory approval of products.

IV. PART 4 - LEGAL REVIEW OF COMMUNITY ACTS – AVAILABILITY AND SCOPE OF JUDICIAL REVIEW

The judicial review of Community acts for private individuals is limited. Under Article 230 fourth paragraph ECT, *"any natural or legal person may, under the same conditions (*review of legality of acts*), institute proceedings against a decision addressed to that person or against a decision which, although in the form of a regulation or a decision addressed to another person, is of direct and individual concern to the former.*[30]*"* The legal challenge has to be brought within two months after publication of the act.

The fourth paragraph of Article 230 ECT gives individuals the right to challenge any decision which, albeit in the form of a regulation, is of direct and individual concern to them. The particular objective of that provision is to prevent the Community institutions from being able, merely by choosing the form of a regulation, to preclude an individual from bringing an action against a decision which

[30] The same applies under Article 232 ECT for any failure to act according to which any natural or legal person may complain to the ECJ that an institution of the Community has failed *"to address to that person any act other than a recommendation or an opinion"*.

concerns him/her directly and individually and thus to make it clear that the nature of a measure cannot be changed by the form chosen.[31]

The ECJ has held that if the contested measure is a legislative measure which does not constitute a decision within the meaning of Article 189 ECT, it is necessary to determine if the applicant may be regarded as directly and individually concerned by it and that "*in certain circumstances, even a legislative measure which applies to the economic operators generally may not be of direct and individual concern to some of them (Case C-358/89, Extramet Industrie v Council, [1991] ECR I-2501, paragraph 13; Case C-309/89 Codorniu v Council, [1994] ECR I-1853, paragraph 19, and order in Japan Tobacco and JT International, cited above, paragraph 29).*"[32]

A Community act has been held to directly affect the legal position of an applicant when it leaves no discretion to the Member States which are entrusted with the task of formally implementing it, such implementation being purely automatic and resulting from Community rules[33].

In the *Boehringer v. Council and Commission* Case,[34] the Court stated that "*The Court's case law shows that, for a person to be directly concerned by a Community measure, the latter must directly affect the legal situation of the individual and leave no discretion to the addressees of that measure who are entrusted with the task of implementing it, such implementation being purely automatic and resulting from Community rules without the application of other intermediate rules*."[35]

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31 See, *inter alia*, Joined Cases 789/79 and 790/79 *Calpak and Società Emiliana Lavorazione Frutta* v *Commission* [1980] ECR 1949, paragraph 7, and Case T-298/94 *Roquette Frères* v *Council* [1996] ECR II-1531, paragraph 35.

32 Case T-321/02, *Vannieuwenhuyze-Morin v. Parliament and Council* (not yet published), paragraph 24.

33 Case C-404/96 P, *Glencore v. Commission* [1998] ECR I-2435, paragraph 41; Case C-386/96 P, *Dreyfus v. Commission* [1998] ECR I-2309, paragraph 43.

34 Joined Cases T-125/96 and T-152/96, *Boehringer v. Council and Commission* [1999] ECR II-3427, paragraph 170.

35 See also Case 92/78, *Simmenthal* v. *Commission* [1979] ECR 777, paragraphs 25 and 26; Case 113/77, *NTN Toyo Bearing Company and Others* v. *Council* [1979] ECR 1185, paragraphs 11 and 12; Case 118/77, *ISO* v. *Council* [1979] ECR 1277, paragraph 26; Case 119/77, *Nippon Seiko and Others* v. *Council and Commission* [1979] ECR 1303, paragraph 14; Case 120/77, *Koyo Seiko and Others* v. *Council and Commission* [1979] ECR 1337, paragraph 25; Case 121/77, *Nachi Fujikoshi and Others* v. *Council* [1979] ECR 1363, paragraph 11; Joined Cases 87/77, 130/77, 22/83, 9/84 and 10/84, *Salerno and Others* v. *Commission and Council* [1985] ECR 2523, paragraph 31; Case 333/85, *Mannesmann-Röhrenwerke and Benteler* v. *Council* [1987] ECR 1381, paragraph 14; Case 55/86, *Arposol* v. *Council* [1988] ECR 13, paragraphs 11 to 13; Case 207/86, *Apesco* v. *Commission* [1988] ECR 2151, paragraph 12; and Case C-152/88, *Sofrimport* v. *Commission* [1990] ECR I-2477, paragraph 9.

On individual concern, according to the *Plaumann* case, parties to a procedure must be viewed as individually concerned by a Community measure where it affects them *"by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons"*.[36]

According to the ECJ, this is the case in particular where the applicant belongs to a "closed category" of persons, *i.e.*, a category which was fixed when the measure was adopted.[37]

It is well established that the existence of a closed and well established group of individually affected companies demonstrates the presence of individual concern. In the *International Fruit Company* case,[38] the ECJ held that "*By adopting these distinguishing criteria, the contested measure affects a fixed number of traders identified by reason of the individual course of action which they pursued or are regarded as having pursued during a particular period"*. It added that *"Such a measure, even if it is one of a number of provisions having a legislative function, individually concerns the persons to whom it applies in that it affects their legal position because of the factual situation which differentiates them from all other persons and distinguishes them individually just as in the case of the person addressed. The application is admissible.*"[39]
The Court held in the *Roquette Frères* Case that undertakings are directly and individually concerned by a measure, if the latter identifies and mentions them individually.[40]

In the field of state aid, the ECJ constantly held that a decision "*is of individual concern to any undertaking which was at the origin of the complaint which led to the opening of the investigation procedure, and whose views were heard during that procedure and largely determined the conduct of that procedure, provided, however, that its position on the market was significantly affected by the aid which is the subject of the decision.*"[41]

Legal practitioners argue in this context, albeit mostly unsuccessfully, that in procedures of review of substances for inclusion or not in Community positive lists or withdrawals from those positive lists where the petitioners are somewhat involved in the review, legal standing should be granted.

In the *Alpharma* case,[42] the CFI held that the Applicant benefited from legal safeguards offered by Directive 70/542/EEC, and in particular Article 9c(1), which held that "*the scientific data and other information in the initial dossier submitted for the purpose of the first authorization may not be used*

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36 Case 25/62, *Plaumann & Co. v. Commission* [1963] ECR 95.

37 Judgment of 6 November 1990, Case C-354/87, *Weddel & Co. BV v. Commission*, ECR [1990] I-03847; Joined Cases 41-44/70 *NV International Fruit Company and others v. Commission* [1971] ECR 411.

38 Case 41 to 44/70, *NV International Fruit Company and others v. Commission*, [1971] ECR 411, paragraph 21.

39 Case 100/74, *CAM v. Commission* [1975] ECR 1393, paragraphs 18-20.

40 Case 138/79, *SA Roquette Frères v. Council* [1980] ECR 3333, paragraph 16.

41 Case T-11/95, *BP Chemicals Limited v Commission*, [1998] ECR II-3235.

42 Case T-70/99, *Alpharma Inc. v. Council*, [2002] ECR II-3495.

for the benefit of other applicants for a period of 10 years" from the date of first authorization by means of regulation.[43] The CFI continued that, under these circumstances, Alpharma enjoyed a "*particular legal situation*" and that "*even before the end of the transitional period, Alpharma was affected by withdrawal of the authorization of bacitracin zinc following on the adoption of the contested regulation by reason of certain attributes which were peculiar to it and which differentiated it from all other persons.*"

In the above-mentioned *Alpharma* case, the CFI also held that Directive 70/524, as amended by Directive 96/51, allowed *Alpharma* to submit a scientific dossier with a view to the re-evaluation of an additive, and that this specific procedure "*confers on that person procedural guarantees. The operator concerned must be notified, through the various stages of that procedure, if the application does not comply with the relevant provisions, if it is rejected or even if processing of it is merely postponed.*"[44] The CFI concluded that the contested regulation "*affects Alpharma by reason of a legal and factual situation which differentiates it from all other persons. That fact is also such as to distinguish Alpharma for the purposes of the fourth paragraph of Article 173 of the Treaty (now Article 230 EC).*"

In Case C-309/89, *Codorniu v. Council*, the ECJ stated that "*natural or legal persons may claim that a contested provision is of individual concern to them only if it affects them by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons"*[45] *and added that "Codorniu [which had a registered trademark] has established the existence of a situation which from the point of view of the contested provision differentiates it from all other traders.*"[46]

All in all, the CFI which has jurisdiction on these private party actions, continues to be very restrictive on the issue of 'direct and individual concern' and on the few occasions it has tried to broaden the concept[47] was overturned by the ECJ on appeal.

In addition to the above challenges, individuals can also have EU law assessed by ways of a preliminary ruling whereby a national court refers a matter to the ECJ for the interpretation of Community law (Article 234 ECT), and seek damages for unlawful acts of the Community under Article 235 in conjunction with Article 288 ECT ("*in the case of non-contractual liability, the Community shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its institutions or by its servants in the performance of their duties.*").

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43 The *Alpharma* case, paragraph 90.

44 The *Alpharma* case, paragraph 94.

45 This was a repetition of the formula used in Case 25/62, *Plaumann v. Commission* [1963] ECR 95.

46 Case C 309/89, *Codorniu v. Council*, [1994] ECR I-1853.

47 Case T-177/01, *Jégo-Quéré & Cie SA v Commission*, [2002] ECR II-2365.

Legal Measure	Actual Function	Related Articles	Procedure	Format of Rule/Decision
General Food Law (GFL) Regulation (EC) 178/2002	Rule-Making	Art. 18: Provides procedure for applying traceability requirements to specific sectors	Comitology	Not specified
	??	Art. 60: Provides mediation procedure for MS disagreement	Collaboration between COM, MS & EFSA	
	Rule-Making			
		Art. 29: Provides procedure for adopting implementing rules for application of scientific opinions	Comitology	Not specified
		Art. 36: Provides procedure for adopting implementing rules for application of a networking of organizations within the field	Comitology	Not specified
		Art. 50: Provides procedure for adopting implementing rules for the Rapid Alert System	Comitology	Not specified
	Decision-Making?	Art. 53: Provides procedure for adopting emergency measures for food posing a serious risk which cannot be contained at MS level	Emergency Measures through Commission, thereafter Comitology	Not specified
		Art. 54: Provides procedure for MS emergency interim protective measures	MS informs COM; Comitology	
Novel Foods Regulation (EC) 258/97	Decision-Making			
		Arts. 4-6, 7: Establish application procedure for authorization of novel foods	Request by applicant to MS & COM; initial assessment by MS; COM publication; implementing rules adopted by COM	COM Decision
		Art. 10: Provides a protection procedure for information provided in applications to authorize novel foods	Comitology	Not specified – was done in form of Regulation
		Art. 12: Allows MS with detailed grounds to temporarily restrict or suspend trade of questionable novel foods pending further review by the COM	Immediate measures; inform all MS & COM; Comitology	COM Decision

Legal Measure	Actual Function	Related Articles	Procedure	Format of Rule/Decision
Additives Directive 89/107/EEC	Decision-Making	Art. 3: Provides procedure for authorization of additives	Commission proposal to be adopted under Co-decision	Council and EP Directive
		Art. 3a: Provides procedure for authorization of MS' traditional foodstuffs	Notification by MS to COM; review of measure by COM; Co-Decision	Council and EP Directive
		Art. 4: Allows MS with detailed grounds to temporarily restrict or suspend trade of questionable additives pending further review by the COM	Immediate measures; inform all MS & COM; Comitology	COM Directive
		Art. 5: Provides MS with a provisional authorization procedure for additives from an Annex I category & not included in the relevant list, to be later included into Community list	Notification by MS to COM; review of measure by COM; Community list inclusion by Co-decision	Council and EP Directive
	Rule-Making / Decision Making	Art. 3: • Provides authorization procedure for criteria of purity for additives, methods of verification, methods of analysis & other necessary rules	• Notification by MS to COM; review of measure by COM • Comitology	• Com Directive COM Directive
		Art. 13: Provides procedure for adaptation to technical progress	Comitology	COM Directive
Genetically Modified Foods (GM-food) Regulation (EC) 1829/2003	Decision-Making	Art. 3: Provides procedure for determination of whether GMOs for food use, food containing or consisting of GMOs & food produced from or containing ingredients produced from GMOs fall within its scope	Comitology	Not specified
		Art. 5-7: Provide application procedure for authorization of GM foods	Submission of application to MS authority; EFSA notification to MS; Comitology	Com Decision
		Art. 10: Provides modification, suspension & revocation procedures by Commission for authorizations of GMOs	EFSA opinion, followed by Comitology	Com Decision
		Art. 12: Provides procedure for establishing lower thresholds in respect of GMOs or to utilize scientific & technological advances	Comitology	Not specified

Legal Measure	Actual Function	Related Articles	Procedure	Format of Rule/Decision
		Art. 15: Provides procedure for determination of whether GMOs for feed use, feed containing or consisting of GMOs & feed produced from GMOs fall within its scope	Comitology	Not specified
		Art. 17-19: Provide application procedure for authorization of GM feed	Comitology	Com Decision
		Art. 20: Provides procedure for authorization of GMOs in feed lawfully placed on the market before this Regulation	Comitology	Com Decision
		Art. 22: Provides modification, suspension & revocation procedures for authorizations of GMOs in feed	Immediate measures followed by Comitology	Com Decision
		Art. 24: Provides procedure for establishing lower thresholds in respect of GMOs in feed or to utilize scientific & technological advances	Comitology	Not specified
		Art. 34: Provides procedure for adoption of emergency measures	Immediate measures Commission followed by Comitology	Not specified
	Rule-Making	Art. 8(8): Provides procedure for adoption of implementing rules regarding the authorization of existing products	Comitology	Not specified
		Art. 11: Provides procedure for establishing implementing rules for the renewal of authorizations for GMOs	Comitology	Not specified
		Art. 14: Provides procedure for implementing detailed rules regarding labeling & provision of information to consumers requirements for GMOs	Comitology	Not specified
		Art. 20(8): Provides procedure for adoption of implementing rules regarding the authorization of existing products	Comitology	Not specified
		Art. 23: Provides procedure for establishing implementing rules for the renewal of authorizations for GMOs	Comitology	Not specified
		Art. 26: Provides procedure for implementing detailed rules regarding labeling & provision of information to consumers requirements for GMOs in feed	Comitology	Not specified
		Art. 32: Provides procedure for establishing of a national reference laboratory & adopting detailed rules for its implementation	Comitology	Not specified

Legal Measure	Actual Function	Related Articles	Procedure	Format of Rule/Decision
	Administrative Review	Art. 36: Provides a COM review procedure for EFSA decisions relating to GMOs	COM review	COM Decision
Food Contact Material Regulation (EC) 1935/2004	Decision-Making	Art. 5: Provides adoption & amendment procedure for materials intended to come into contact with food listed in Annex I & specific directives	Comitology	Not specified
		Arts. 8-11: Provides application procedure for authorization of a new substance intended to come into contact with food	Comitology	Not specified
		Art. 12: Provides modification, suspension & revocation procedures for authorizations of materials & Arts. intended to come into contact with food	Comitology	Not specified
		Art. 18: Provides procedure for adoption of emergency measures	Immediate measures Commission followed by Comitology	Not specified
	Rule-Making			
		Art. 22: Provides procedure for amending the Annexes	Comitology	
	Administrative Review	Art. 14: Provides COM review procedure for EFSA decisions relating to GMOs	COM review	COM Decision
Food Hygiene Regulation (EC) 853/2004	Decision-Making	Art: 3: Provides approval procedure for substances used to remove surface contamination	Comitology	Not specified
		Art. 11: Provides decision making procedure for specific implementing measures & amendments to Annex II & III	Comitology	Not specified
	Rule-Making	Art. 7: Provides procedure for establishment of model documents & provision of electronic documents	Comitology	Not specified
		Art. 8: Provides procedure for updating & extending requirements regarding specific MS control programs	Comitology	Not specified
		Art. 9: Provides procedure for implementing measures & transitional arrangements	Comitology	Not specified
		Art. 10: Provides procedure for adapting, exempting from & updating Annexes II & III and MS adoption of national measures	Comitology	Not specified

Legal Measure	Actual Function	Related Articles	Procedure	Format of Rule/Decision
Labeling Directive 2000/13/EC	Decision-Making	Art. 6: Provides procedure for determination on whether items are regarded as ingredients	Comitology	Not specified
		Art. 7: Provides procedure for determinations regarding quantities of ingredients listed	Comitology	Not specified
		Art. 10: Provides procedure for deciding whether foodstuffs are highly perishable	Comitology	Not specified
	Rule-Making	Art. 2: Provides procedure for drawing up list of prohibited or restricted events for labeling & methods	Notification by MS to COM; review of measure by COM	
		Art. 4: • Provides rulemaking procedures for Community provisions applicable to labeling specified foodstuffs • Provides rulemaking procedures for MS provisions applicable to labeling specified foodstuffs	• Notification by MS to COM & other MS; COM consultation with MS; COM approval or Comitology • Comitology	
		Art. 6: • Provides alteration procedure for the list of categories contained in Annex I & other amendments to Annex I based on scientific & technical knowledge • Provides rulemaking procedures for Community provisions regarding mentioning of particular ingredients • Provides rulemaking procedures for MS provisions regarding mentioning of particular ingredients	• Comitology • Notification by MS to COM & other MS; COM consultation with MS; COM approval or Comitology • Comitology	
		Art. 8: • Provides rulemaking procedures for Community provisions applicable to the net quantity of prepackaged foodstuff • Provides rulemaking procedures for MS provisions applicable to	• Notification by MS to COM & other MS; COM consultation with MS; COM approval or Comitology • Comitology	

Legal Measure	Actual Function	Related Articles	Procedure	Format of Rule/Decision
		the net quantity of prepackaged foodstuff • Provides procedure for supplementing the list of liquid mediums & checking the net weight of solid foodstuffs in liquid medium • Provides procedure for the Community provision paragraphs in the Art.	• Comitology • Comitology	
		Art. 9: Provides procedure for the manner of indicating the date of minimum durability	Comitology	
		Art. 11: • Provides rulemaking procedures for Community provisions applicable to the way in which instructions are indicated • Provides rulemaking procedures for MS provisions applicable to the way in which instructions are indicated	• Notification by MS to COM & other MS; COM consultation with MS; COM approval or Comitology • Comitology	
		Art. 12: Provides procedure for indication of alcoholic strength by volume	Comitology	
		Art. 19: Details procedure for MS' adoption of new legislation	Notification by MS to COM & other MS; COM consultation with MS; COM approval or Comitology	
		Art. 20: Provides reference to the Comitology procedure	Comitology	
		Art. 21: Provides procedure for adoption of emergency measures	Comitology	

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