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EUROPEAN UNION ADMINISTRATIVE LAW PROJECT

SECTOR REPORT

Food Safety

Adjudication and Rulemaking

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EXECUTIVE SUMMARY

Food safety is the general responsibility of the Directorate General for Health and Consumer Protection (DG SANCO). European food safety regulation is adopted under the co-decision legislative procedure of Article 251 TEC[1], usually drawing on the authority of Articles 95 of the TEC (internal market), or 153 of the TEC (consumer protection), or in rare cases possibly 152 of the TEC (public health, phytosanitary and veterinary matters). EU food law deals with a large range of matters, including new foods ("novel foods"), genetically modified foods, food hygiene, food contact materials, food additives, food colors, food flavorings and labeling. The implementation of food safety legislation frequently uses Comitology.

In 2002, the Council and Parliament adopted the General Food Law Regulation 178/2002 to set common principles and responsibilities for all food law. Prior legislation and implementing measures are to be adapted no later than January 1, 2007 to comply with the new general principles. Regulation 178/2002 also established the European Food Safety Authority (EFSA), the Commission's scientific advisory institution for food related matters.

The General Food Law Regulation seeks to assure both a high level of protection of human life and health, and protection of consumer interests, including fair practices in food trade, protection of animal health and welfare, plant health, and the environment. All decisions must be based on risk assessment of the available scientific evidence, undertaken in an independent, objective, and transparent manner. Risk management then is to take into

[1] The Treaty Establishing the European Community (hereinafter "EC Treaty" or "TEC")

account the results of the risk assessment, other factors legitimate to the matter, and the precautionary principle.

Currently, most food safety legislation takes the form of Regulations, although major earlier continuously valid legislation uses the Directive format. Most implementing measures, involving pre-market authorization of individual products, normally by adding the product to lists in Annexes to the applicable legislation are adopted by Comitology in the form of Commission Directives or Regulations. Less often, the Commission issues Decisions to individuals (in the case of the novel foods and genetically modified foods under Regulations 258/97 and 1829/2003 respectively).[2] Under Directive 89/107 (food additives) (a revision of this Directive is currently pending), authorizations of new additives are still effected by Council and Parliament Directives. In some situations, the applicable legislation does not specify what form the authorization is to take (*e.g.* the authorization of decontaminants under Regulation 853/2004).

Traditionally, consultation on new legislation by DG SANCO has taken place in Brussels only, in various for a which were called on by DG SANCO on a largely ad-hoc and as needed basis. These usually involved only European level participants, with no consultation organized via the web or at Member State or regional level. A new development is the use of Advisory Groups or Platforms (such as the new European Platform for Action on Diet, Physical Activity and Health) initiated by DG SANCO on an ad hoc or as needed basis.

[2] European Parliament and Council Regulation (EC) 178/2002, 2002 O.J. (L 31) 1, 24 (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); European Parliament and Council Regulation (EC) No 258/97, 1997 O.J. (L 43) 1, 6 (concerning novel foods and novel food ingredients); European Parliament and Council Regulation (EC) No 1829/2003, 2003 O.J. (L 268) 1, 23 (on genetically modified food and feed).

While these groups largely consist of the normally consulted EU-level groups, representatives from individual companies have sometimes been included.

In general, DG SANCO seems to have been slower than most DGs in responding to the Commission's recent generic Communications on consultation, impact assessment, public participation, and legislation on public access to documents. With the exception of its 2002 internet consultation evaluating the Novel Foods Regulation 258/97, DG SANCO did not organize wide-range public internet consultations until very recently (2006). In the Novel Foods consultation, for the first time DG SANCO made stakeholder comments available on the Commission's homepage. Within the past two years, however, DG SANCO's practices have changed significantly, and in 2006 DG SANCO launched nine food related internet consultations.

DG SANCO's Comitology processes use a regulatory committee, the Standing Committee on the Food Chain and Animal Health (SCFCAH). Based on data gathered between 2001 and 2004, DG SANCO had the fifth largest number of Comitology committees among the DG's, the second highest number of meetings, the second highest total output in opinions, and the third highest total output in instruments. Roughly half of these involved food safety issues. Since adoption of the General Food Law Regulation 178/2002, the number of committees in the food safety area has been reduced.

As is the case in other DGs, Comitology in DG SANCO entails considerably less consultation, both in terms of the number of events and the number of participants, than secondary legislation. For implementing measures to be adopted under the Comitology rules, the minimum rules on consultation do not apply and there is therefore 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 TEC procedure. The Commission will usually only consult once a draft text has been elaborated, and then only with those stakeholders it has previously identified as having an interest in the subject, most of the time a limited number of EU industry trade and consumer organizations. Consultations will not be launched via the Internet, but by fax or mail, usually with short notice (2 to 4 weeks). Revised drafts may not be subject to consultation.

The main implementing actions adopted by Comitology are authorizations of individual products. These actions follow procedural paths that are specific to the particular legislation involved, but which have the same basic though somewhat more uniform functional steps in the wake of the passage of the General Food Law Regulation 178/2002 and the recent generic Commission Communications on Better Regulation. The main steps are as follows: Applications are filed either at the Member State level (the normal case) or with the Commission. An initial scientific assessment is then done, either at the national level (*e.g.*, novel foods) or at the Community level by the EFSA (the more common case) to determine whether the application is complete, whether it meets the relevant substantive tests in the legislation, and whether the product's use should be conditioned or restricted in light of those tests. There are provisions in some of the legislation for the adoption of guidelines with regard to various parts of this process, but in some cases no such guidelines are now in effect, or the guidelines are in existence but not formally adopted and are available only in English.

Thereafter, the Commission prepares a draft proposal that would proceed through the Comitology process for consideration by the Regulatory Committee, the SCFCAH, and then adoption by the Commission unless the matter were sent to the Council under the Comitology

process.. This normally takes between one (exceptional cases) and five years, with the majority of cases in the two to three year range.

The newer legislative instruments adopted under the framework of the General Food Law Regulation 178/2002 usually provide deadlines for the scientific assessment and most of the following administrative procedure. Some more recent Regulations also provide for an administrative review by the Commission of action and inaction by EFSA, "on its own initiative or in response to a request from a Member State or from any person directly *and* individually concerned."

The net result is that there is a large variety of procedures used for granting authorizations in the food safety sector, but the more recent pieces of legislation, especially those adopted after Regulation 178/2002, set out procedures in more detail and establish deadlines, a major improvement. Notwithstanding these positive developments, however, even these legislative instruments leave the availability of judicial review of action or inaction on the authorization often up in the air.

Direct judicial review of legislative instruments such as Regulations or Directives is generally unavailable (unless plaintiffs meet the difficult test of being directly and individually concerned), whether they are adopted by the Council and Parliament or by the Commission through Comitology; and little effective indirect judicial relief is available. This is because plaintiffs must demonstrate that they are directly and individually concerned, which is a difficult test under standing case law of the EU courts. Where a *Decision* is issued, however, the regulated entity can obtain direct judicial review of the action or inaction

involved. The general public and other possibly interested parties have no such remedy, however.

The European Court of Justice may force the pace of change as to procedures for authorization. In its judgment of July 12, 2005,[3] the ECJ upheld Directive 2002/46 on food supplements, but laid down rules for the Commission in future cases. The ECJ held, in particular, that:

> [A] measure which, like that at issue in the main actions, includes a prohibition on marketing products containing substances not included on the positive lists laid down in the applicable legislation must be accompanied by a procedure designed to allow a given substance to be added to those lists and the procedure must comply with the general principles of Community law, in particular the principle of sound administration and legal certainty. Such a procedure must be accessible in the sense that it must be expressly mentioned in a measure of general application which is binding on the authorities concerned. It must be capable of being completed within a reasonable time. An application to have a substance included on a list of authorized substances may be refused by the competent authorities only on the basis of a full assessment of the risk posed to public health by the substance, established on the basis of the most reliable scientific

[3] Joined Cases C-154/04 and C-155/04**,** The Queen, on the application of: Alliance for Natural Health and Nutri-Link Ltd v Secretary of State for Health (C-154/04) and The Queen, on the application of: National Association of Health Stores and Health Food Manufacturers Ltd v Secretary of State for Health and National Assembly for Wales (C-155/04), 2005 E.C.R. I-6451.

data available and the most recent results of international research. If the procedure results in a refusal, the refusal must be open to challenge before the courts.

I. INTRODUCTION

A. EU Food Safety Law - Brief Overview

European Union ('EU') food safety law is a compilation of rules consisting mainly of rules related to food products, labeling, and approval of substances that are used in food. It emerged as from the end of the 1970s as a consequence to eliminating barriers to the free movement of goods, as increasing amounts of food products were shipped across EU borders that were subject to different national rules. In addition to the above, so-called "recipe" type legislation setting denomination and quality requirements for specific food products (e.g. honey, milk, fruit juices, fats and oils) (not dealt with in this Report) was adopted simultaneously as part of the common market on agriculture products.

EU food safety legislation exists in the following areas:

- Additives (including colors, flavorings, sweeteners)
- Food contact materials (packaging)
- Labeling, advertising, claims
- Contaminants
- Foodstuffs for specific dietary purposes (baby foods, supplements, fortified food)
- Maximum residue limits for pesticides
- Hygiene
- Control

- Radiation
- Extraction solvents
- Organic production, designations of origin
- Novel and biotech foods.

Traditionally, EU food safety legislation had been adopted on a more ad-hoc and as needed basis and was therefore not completely regulating all aspects of food. Within the regulated areas, regulation was not exhaustive either. For example, for certain food packaging materials, there is until this time only a general safety requirement at EU level and Member States may introduce more specific provisions.

EU food safety legislation was not very prominent until the BSE crisis highlighted for the first time that the cross-border movement of food products encompassed that a safety issue in one Member State would more or less automatically trigger food safety problems in other EU Member States, and that the EU was ill-prepared for such events. In this specific case, some time had lapsed between the first scientist making a link between the outbreak of the mad cow disease in the UK and the first human cases of the Creutzfeldt Jakob disease and the European Commission (the 'Commission') banning the export of British beef to other EU Member States pending the introduction of appropriate hygiene measures in the UK.[4]

Calls were made to introduce a strong food safety surveillance and scientific assessment system, and to include the possibility to restrict the marketing of foods on a

[4] See for a description of the E.C.J. case law, in particular case C-180/96, Schliessner, Ursula, supra note 58.

precautionary (principle)[5] basis in those cases in which the scientific basis was not conclusive but there was reason for concern.

The BSE crisis was followed briefly thereafter by another food safety event, the so-called dioxin scandal[6] and both happened shortly before the Commission was due to authorize a series of genetically modified crops (soy and maize) for import, processing and cultivation, including uses as food.

In all three cases, Member States accused other Member States and the European institutions of not sufficiently protecting their national food production and their citizens by failing to address all scientific aspects in time and comprehensively and by reacting too late. The Commission was, both from a communication and substantive point of view, not in a position to rebut the accusations made by the Member States, media, and interest groups and as a result was politically weakened. As far as genetically modified organisms were concerned, a six year halt on authorizations, the so-called "moratorium" followed.

In response to the various crisis events and following also a previous commitment to create a framework for the various items of food legislation listed above, the Commission presented a general framework Regulation on food law[7], which was adopted in record time by the Council of Ministers and European Parliament (the 'EP') in 2002. Had it not been for

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[5] For an explanation of the precautionary principle in EU law, please refer to Schliessner, Ursula; ABA Section of Environment, Energy and Natural Resources, newsletter November 2000; Application of the Precautionary Principle in the European Union – what will change. http://www.abanet.org/environ/committees/intenviron/newsletter/nov00/sch.html

[6] Waste oil contaminated with dioxins was illegally used as a feeding stuff in Belgium and chicken meat as a result was contaminated.

[7] European Parliament and Council Regulation 178/2002, supra note 1, at 24.

the crisis events that preceded, the adoption of such a wide-ranging framework legislation would likely have been much slower.

In addition to introducing a series of definitions applicable to all food legislation (including a definition of food), Regulation 178/2002 establishes a general safety requirement for food, introduces specific recall provisions for unsafe food[8], imposes traceability for all food, mandates the use of risk assessment but also establishes that "other legitimate" factors can be used in risk management, and creates a new scientific body, the European Food Safety Authority ('EFSA') to take over all the previous work carried out by the Commission's scientific committees, plus risk communication.

The Commission is currently in the process of revising all existing legislation (see further below) in order to bring it in conformity with Regulation 178/2002.

EFSA has its seat in Parma, Italy. It consists of a Management Board, an Executive Director and staff (300 expected by end of 2007), a Scientific Committee ensuring overall consistency, and scientific panels on the various food subject areas. The Panels may also form working groups and outsource some of the work. Scientists are appointed to the Panels based on public calls for interest. Scientific opinions are issued by EFSA upon request of the Community institutions or upon EFSA's own initiative.[9]

[8] Previously, the recall provisions of the General Product Safety Directive 92/59 now Directive 2001/95 were used.

[9] For an overview of EFSA's work and structure, please refer to www.efsa.eu.int.

B. Adjudication or Rulemaking? – Law Making or Implementation?

In EU food law, in many ways, the US distinction between adjudication and rulemaking seems somewhat artificial and to a certain extent arbitrary. With rulemaking being understood in US terms 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 in EU food law,[10] the form of rulemaking is used to decide very specific factual circumstances and that the form of adjudication is used very rarely.

Because of this specificity, it has been suggested to the author whether it would not be more appropriate to rather divide this report into 'lawmaking' and 'implementation'. In the 'implementation' section, it would then be possible to deal with measures that are adopted to regulate a specific case and with other technical measures implementing a base law.

To the author, this suggested distinction does not seem ideal either, because it would lump together in the 'implementation' category measures that are taken that are of a general nature with no specific product in mind (for example a potential Regulation setting approval criteria for decontaminants used on poultry adopted in pursuance of Regulation 853/2004[11] on animal hygiene) and on the other hand Regulations deciding on the approval of very specific products (for example a potential Regulation approving specific poultry carcass

[10] The same can be said also for EU environmental law, in the area of product regulation, e.g. biocides, pesticides, chemicals.

[11] European Parliament and Council Regulation 853/2004, 2004 O.J. (L 139) 55, 205 (laying down specific hygiene rules for food of animal origin)

decontaminants under Regulation 853/2004), with both measures being subject to the Comitology procedure (further below).

The author therefore suggests, if only to assist the overall consistency of the ABA project, to keep the original distinction suggested by the ABA project leaders, but will, wherever necessary below, explicitly distinguish between measures adopted in Comitology versus those adopted by the normal legislative procedure, and within the Comitology measures, make an attempt to describe the content of the individual measures to indicate more clearly whether in the particular case at hand they relate to an individual case (and are therefore more of an 'adjudication' type) or whether they are more of general nature (and hence better fit the terminology of 'rulemaking').

This report will further demonstrate that the judicial consequences of whether the form of rulemaking or adjudication is used for a particular matter are dramatic in the EU legal system. Whereas in the case of the form of adjudication (a Decision addressed to an individual), the availability of judicial review is "automatic" because of the form of the decision taken, i.e. the concerned person or company could challenge the Decision in the European Court of First Instance ('C.F.I.'), this is generally not the case for measures taken in the form of rulemaking. These are in principle of generally applicable nature. The individual will in many cases not have the possibility of judicial review because he/she will not be considered "directly and individually concerned" under standing case law of the European courts, because he/she is not distinguishable from a multitude of subjects targeted. The C.F.I. will therefore in many cases dismiss judicial action as inadmissible in accordance with Article 230 Para. 4 TEC (for a full discussion on legal standing, see at IV. below).

C. 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 TEC), 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 TEC Procedure.

Any legislation on a new food law subject would be passed under the Co-Decision procedure of Article 251 TEC. This procedure is applicable, among others, to legislation in the areas of internal market (Article 95 TEC, used mostly), consumer protection (Article 153 TEC), and public health (Article 152 TEC for phytosanitary and veterinary matters).

Under Article 251 TEC, it is for the Commission to propose legislation. The decision on whether, when, and what type of legislation is being proposed, is entirely in the discretion of the Commission.

Very early information on what the Commission's intentions are is available from

(a) multi-annual policy plans[12] or 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) EP resolutions or own-initiative reports on certain policy issues;

(d) Oral or Written questions asked by Members of the EP to the Commission;

(e) National draft regulations being notified to the Commission under the Standstill Directive (98/34/EC)[13]. 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 EFSA; EFSA as the scientific advisory organ to the Commission for food safety matters may adopt opinions on pertinent issues and thereby factually set in motion the Commission action if a need for action is identified by it.

Once the Commission has decided to prepare proposals for new legislation or to revise existing legislation, the procedure prior to the adoption of its proposals will be

[12] For example, since 2000 the Commission carries out activity-based management and is prioritizing and grouping its activities, so-called "strategic planning and programming" http://www.europa.eu.int/comm/atwork/strategicplanning/index_en.htm. This multiannual planning is then translated into an annual policy strategy, which is adopted in the form of a Commission Communication, see for example the 2006 plan adopted in March 2005: . http://www.europa.eu.int/eur-lex/lex/LexUriServ/site/en/com/2005/com2005_0073en01.pdf With regard to the individual legislative activities, these annual policy strategies are more or less detailed. For example, on food, the 2006 plan does not mention any legislative initiative on food.

[13] European Parliament and Council Directive 98/34/EC, 1998 O.J. (L 204) 37 (laying down a procedure for the provision of information in the field of technical standards and regulations).

determined largely by the type of the legislative procedure applicable to the adoption of the legislation. If the legislation will have to be adopted by the normal legislative procedure of Article 251 TEC, the Commission will arrange for wide-ranging stakeholder consultation in line with its internal procedures.

If to the contrary, the adoption of the new/revised legislation is subject to Comitology (see further below), consultation of stakeholders will not be as wide-ranging and systematic.

On new topics and the revision of existing base secondary legislation, hence Article 251 TEC type legislation, the Commission would follow its own code-of-conduct for proposing legislation, usually starting with drafting a Green Paper, followed by a White Paper, stakeholder consultation[14] on both in accordance with the Commission's minimum standards for consultation in Communication Com (2002) 404 final[15], and then a Communication setting out the proposed choices. The Commission will also carry out a formal impact assessment.[16] (See further below Comitology)

Before or during the launch of Green and White Papers, the responsible Commission service (Directorate General for Health and Consumer Protection 'DG SANCO') would sometimes 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.

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[14] For the index of consultations, please see: http://europa.eu.int/comm/food/consultations/index_en.htm

[15] http://europa.eu.int/comm/governance/docs/comm_standards_en.pdf: Towards a re-enforced culture of consultation and dialogue – General principles and minimum standards for consultation of interested parties by the Commission.

[16] Impact assessments would only rarely be carried out for measures adopted by Comitology.

Other means of fact-finding could be the organization of conferences by the Commission or other bodies; inspections undertaken by national or EU bodies (e.g. the EU Food and Veterinary Office[17]), or reliance on the work done by international organizations (notably WHO and FAO).

Originally, once this fact finding exercise was terminated, an individual desk officer in DG SANCO would start drafting a legislative text. This drafting would have also been preceded and/or accompanied by the organization of one or several stakeholder consultation meetings. The size (number of participants), frequency, scope, duration, and timing of these stakeholder meetings were not subject to formal rules. The organization of these meetings depended to a large extent on the availability of budgets, interpreters, premises, the general timing on when the Commission wanted to move forward, on whether the particular issue was contentious, and not least also on the personal style of the respective Commission staffers, the Commissioners, Director Generals and Heads of Unit.

This rather 'loose' framework of consultation was more formalized in 2002 and also more recently in 2005 by adoption by the Commission of several codes-of-conducts, namely the Commission Communication "European Governance: Better Lawmaking" (COM (2002) 275 final) of June 5, 2002[18]. The Commission commits in this Communication to "*systemize and rationalize the wide range of consultation practices and procedures and to guarantee the*

[17] 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.

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

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."

A specific Communication was adopted on December 11, 2002 (COM(2002) 704 final) on "Minimum Standards for Consultation of Interested Parties".

Other self-commitments include

- Communication from the Commission to the Council and the European Parliament on Better Regulation for Growth and Jobs in the European Union (COM (2005) 97 final) of March 16, 2005 setting out that the Commission will submit "key legislative proposals as well as the most important cross-cutting policy-defining non-legislative proposals" to an integrated impact assessment[19], that the Commission will screen pending legislative proposals for their relevance, and that it will simplify existing legislation;
- Communication from the Commission on an EU common methodology for assessing administrative costs imposed by legislation (COM (2005) 518 final of October 21, 2005;
- Communication from the Commission to the Council and the European Parliament on the Outcome of the screening of legislative proposals pending before the Legislator (COM (2005) 462 final of September 27, 2005; and

[19] At page 5.

- Communication of the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Implementing the Community Lisbon program: A strategy for the simplification of the regulatory environment (COM ("005) 535 final) of October 25, 2005.
- US/EU 'Guidelines on Regulatory Cooperation and Transparency; April 2002; see also June 2006 'Joint Report on the Roadmap for EU-US Regulatory Cooperation.

As far as the implementation[20] of these new principles is concerned, there appear to be considerable differences between the various Commission services. In DG SANCO, unlike other departments, the initial uptake of these commitments seemed slow. Until 2006, DG SANCO did not seem, as a matter of principle, to organize wide-range public consultations. Consultations appeared to be organized on an ad-hoc and as needed basis and the number of invitees was usually 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). An internet consultation evaluating the Novel Foods Regulation 258/97[21] in 2002 was an exception to this rule. In this case, also for the first time, the stakeholder comments were made available on the Commission's homepage.

[20] For a summary and critique of the European Commission's consultation policy, see "Good Governance requirements concerning the participation of interest groups in EU consultations" by Daniela Obradovic and Jose M. Alonso Vizcaino, in [2006] C.M.L.R. 43: p. 1049-1085.

[21] European and Council Regulation No 258/97, supra note 1.

This situation now has changed significantly. It would appear that on major policy initiatives, such as the revision of food labeling legislation currently pending, DG SANCO of the Commission is systematically organizing internet consultations. DG SANCO now has three different websites for stakeholder consultation and one of them is only for consultation in the food safety area. In 2006, 9 food related internet consultations were launched by the Commission[22].

In contrast, still in 2004 and 2005 several working drafts of revised legislation on food additives were circulating in the Brussels trade circles, but seemingly no official consultation exercise was launched on these.

What is also 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, or the Advisory Group on the Food Chain and Animal and Plant Health), more or less on an ad-hoc and an as needed basis, consisting roughly of the usually consulted stakeholder groups, albeit sometimes also including representatives from individual companies.[23]

Finally, in 2006, DG SANCO convoked a Peer Review Group made of a mixed representation of stakeholders affected by the different SANCO policy areas in order to review the existing consultation system and to identify areas of improvement.

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[22] http://ec.europa.eu/food/consultations/index_en.htm

[23] The European Commission's register of expert committees lists 90! expert groups within the remit of DG SANCO. However, many of these groups are not related to stakeholder consultation. They may consist of experts of the Member States for specific regulations that meet periodically to discuss on-going matters. http://ec.europa.eu/transparency/regexpert/search.cfm?l=all

All in all therefore it may be concluded that consultation on new legislation takes place in various fora. Unless consultation is organized by Internet, 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), the minimum rules on consultation do not apply and there is therefore 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 TEC procedure. The Commission will usually only consult, once a draft text has been elaborated, those stakeholders it has previously identified to have an interest in the subject, most of the time a limited number of EU industry trade and consumer organizations. Consultations will not be launched via the Internet, but by fax or mail, usually with short notice (2 to 4 weeks). Revised drafts may not be subject to consultation.

Towards the end of the drafting process and sometimes at intermediate stages, both for Article 251 as well as for legislation to be adopted by Comitology, 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[24]. 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 members of the Committees and their working groups are appointed by the respective Member States. The meetings of the Standing Committee and the sections are closed and not open to the public.

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

Agendas are published on the Commission's homepage usually a few days before but sometimes also after the date of the meeting. The documents discussed at the meetings are not published in advance of the meeting. Members of the Regulatory Committees receive the agenda and meeting documents 14 days in advance of the meetings. Summary meeting reports are made 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, for both Article 251 TEC and Comitology files, it will conduct the formal so-called interservice consultation (written consultation with a 10 work-day deadline) within the Commission, to obtain 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 dossiers by consensus. However, a simple majority vote suffices (Article 219 TEC).

As soon as the Commission has adopted the proposal, Article 251 TEC proposals will be published in the Official Journal and submitted to Council and EP for further proceedings under the Co-decision procedure. In addition, they will also be published as 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 (during interservice consultation) 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 breadth of technical, scientific and legal expertise of the advocates.

(b) The Comitology Procedure.

Article 202 TEC allows the Council[25], 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. The current typology of Comitology

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

procedures is laid down in Decision 1999/468.[26] As already mentioned in Article 202 TEC, there are several types of Comitology procedures, in which either the Commission has the sole decision-making power, or 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) consisting of high-level representatives of the Member States who have to vote on the proposal presented to them by the Commission (so-called Regulatory Committee procedure).

In the traditional, so-called Article 5 Regulatory Committee procedure, if a proposal receives a qualified majority in the Committee, the Commission must formally adopt it thereafter. 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 this during the initial part of the Comitology procedure (until the file has been assessed by the Council) because this would not be in line with the logic of Decision 1999/468 which provides for Commission amendment of the proposal only once the Council has opposed it (Article 5 (6) of Decision 1999/468).[27] Prior to having a file voted in any of the Standing Committees, the Commission must also forward the file to the EP for consultation.[28]

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[26] Council Decision 1999/468, 1999 O.J. (L 184) 23, 26 (laying down the procedures for the exercise of implementing powers conferred on the Commission); as recently amended by Council Decision 2006/512 (2006 O.J. (L 200) 11, 13) introducing an additional Regulatory Committee procedure, so-called "Regulatory Committee with scrutiny" .

[27] See also indirectly same conclusion under the old Comitology rules, in Compétences D'exécution conférées à la Commission – La nouvelle décision-cadre du Conseil; C.-D. Ehlermann; Revue du Marché Commun No. 316, Avril 1988, at p. 237.

[28] One month. Agreement on procedures for implementing Council Decision 1999/468; supra note 26.

In the case of food safety, until introduction of the new Regulatory Committee with scrutiny procedure by Decision 2006/512, so-called Article 5a procedure (see further below), recourse was almost exclusively, with one exception, made to the Regulatory Committee procedure (Articles 5, 8 of Decision 1999/468). Hence, the Council always retained the last word on any legislative competence that was delegated to the Commission and which did not gain the required qualified majority in the Committee. The Council had 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 TEC) 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.[29] 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 or possibly during several meetings, a discussion is held on the "draft" proposal to see whether there are differences of opinion. 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 voting. These practices are criticized[30] 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 TEC). However, there are a number of rather fundamental differences between the normal legislative procedure and the Comitology procedure which indeed leave a sour taste on the current practices as far as transparency and accountability are concerned:

(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;

[29] "Traditionally, however, decision-making under the Comitology procedure is very untransparent." Lenaerts, Koen and Amaryllis Verhoeven; Towards a legal framework for executive rule-making in the EU? The contribution of the new Comitology Decision; [2000] C.M.L.R., p. 645 et seq., at p. 677.

[30] It is also criticized that not all Member States are always present in the Committee meetings or Member States' representatives are not always well briefed by their national administrations on the specific files.

(b) There is little if any public knowledge[31] on the discussion and voting in the Regulatory Committee (closed meetings[32]) – hence leading to less accountability of the actual vote;[33]

(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 had 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 scored very high with a total of 465 opinions[34] and

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[31] "Traditionally, however, decision-making under the Comitology procedure is very untransparent." Lenaerts, Koen and Amaryllis Verhoeven; Towards a legal framework for executive rule-making in the EU? The contribution of the new Comitology Decision; [2000] C.M.L.R., p. 645 et seq., at p. 665.

[32] In some regulatory areas, for example in the medical devices areas, it appears that stakeholders are invited to the discussion part of the sessions of the Regulatory Committees; voting will proceed in closed session however. This practice of inviting stakeholders for discussion to part of the Regulatory Committee meetings to our understanding is not used for food safety matters.

[33] The Commission has consistently argued, and is supported to some extent by scholars, that the efficiency of the Comitology committees would suffer ("confidentiality of deliberations") if full transparency would be applied. This is the same argument as used pleading for closed Council of Ministers meetings. Lenaerts, Koen and Amaryllis Verhoeven; Towards a legal framework for executive rule-making in the EU? The contribution of the new Comitology Decision; [2000] C.M.L.R., p. 645 et seq., at p. 683 and 684.

[34] Opinions delivered by the committees may be of various kinds (e.g. draft legislative acts, decisions designed to regulate specific legal situations or to approve financial projects, or just position statements). This explains

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244 instruments (implementing measures) and came 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 have been 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.

According to the Report from the Commission on the working of the committees during 2003,[35] 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 Health 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.

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

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why the total number of favorable opinions may be greater than the total number of legal instruments adopted in a specific sector. See COM (2003) 530 final, at p. 12.

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

receiving qualified majority in the Regulatory Committee, are being forwarded to Council and then pass back to the Commission for adoption.

For food safety matters, the Regulatory Committee within DG SANCO is the so-called Standing Committee on the Food Chain and Animal Health (SCFCAH). It has eight sections:

(a) General Food Law;

(b) Biological Safety of the Food Chain;

(c) Toxicological Safety of the Food Chain;

(d) Controls and Import Conditions;

(e) Animal Nutrition;

(f) Genetically modified Food and Feed and Environmental Risk (2004);

(g) Animal Health and Animal Welfare;

(h) Phytopharmaceuticals.

Each of the sections consists of representatives from the 27 Member States appointed by the Member States, usually high ranking officials from the respective national Ministries of Health and Consumer Protection or national food safety agencies.

As mentioned above, Decision 2006/512[36] introduced an additional Regulatory Committee procedure, the so-called Article 5a or "Comitology with scrutiny procedure". In short, whenever the Scrutiny procedure is imposed in the secondary legislation, where there is a qualified majority in the Regulatory Committee, the Commission must nevertheless forward the proposal to both the EP and the Council for scrutiny. The EP has three months to possibly oppose it with a majority of its component members and the Council has the same

[36] Council Decision 2006/512, supra note 26.

time to oppose by qualified majority – provided in both cases that the draft measure proposed by the Commission exceeds the implementing powers provided in the base legislation, or that the draft is not compatible with the aim or the content of the basic instrument, or does not respect the principles of subsidiarity or proportionality. In other words, the scope of scrutiny is large.

If the proposal does not obtain qualified majority in the Regulatory Committee, as previously it would be submitted to Council and if the Council intends to adopt it or does not act, again the EP is called upon and may act within four months on the same grounds as above.

Because the EP has considerably increased rights under the Scrutiny procedure compared to the normal Regulatory Committee procedure, the EP is now systematically requesting the insertion of the Scrutiny procedure both into new as well as into existing legislation, including in food law. For example, the recently adopted Regulations on health and nutrition claims and fortified foods (Regulations 1924/2006[37] and 1925/2006[38]), are already undergoing revision to replace the Article 5 procedure by the Article 5a procedure.

The impact of the replacement of the Article 5 by the Article 5a procedure for the approval of foods and food ingredients remains to be seen. The author predicts that the authorizations / listings of new products will take more time than they do today already (on average currently under the Article 5 procedure at least 12 months, but in many cases 24 to

[37] European Parliament and Council Regulation 1924/2006, 2006 O.J. (L 404) 9, 25 (on nutrition and health claims made on food).

[38] European Parliament and Council Regulation 1925/2006; 2006 O.J. (L 404) (on the addition of vitamins and minerals and of certain other substances to foods).

36 months). Second, it is conceivable that decisions that by their nature are mainly technical in nature will be politicized with EP involvement and may be burdened with non-food safety related considerations. Third, and as a result thereof, the food industry may have to spend more resources on advocacy to having its products pass the Scrutiny procedure successfully. Lastly, the proliferation of considerations and stakeholders involved may make it even more difficult than today to challenge any negative product decisions in the EU courts.

It is unclear at this stage whether the EP will use its scrutiny right systematically or not. The author predicts that the EP will guard and test its Scrutiny rights rather systematically in the next several years, despite the heavy workload involved with this. A slowdown and less product authorizations in several areas are therefore to be expected.

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 examples in Part 2 of this 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[39] and 1829/2003[40]), taken in the form of rule-making.

The products and ingredients being authorized go through a scientific assessment (EFSA) procedure, then regulatory approval either by Co-Decision or mostly Comitology,

[39] European and Council Regulation No 258/97, supra note 1.

[40] European Parliament and Council Regulation No 1829/2003; supra note 1 (on genetically modified food and feed).

and once they have successfully passed both, 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[41] 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 Commission. An initial scientific assessment would then either be done at the national level (see novel foods) or at Community

[41] 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, supra note 1 (the Novel Foods Regulation).

level by EFSA. Thereafter, the 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. EXAMPLES OF DECISION-MAKING

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)[42], 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.

[42] European Parliament and Council Regulation No 1829/2003; supra note 1 (genetically modified food and feed).

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.[43]

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*

[43] 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.

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) from January 1997[44] published as a Commission Recommendation of July 29, 1997 after consultation of the Standing Committee for Foodstuffs[45].

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 TEC).

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

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

[45] 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); 1997 O.J. (L 253).

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). Of the 75 novel food applications filed between May 15, 1997 and May 31, 2007, 28 novel foods were authorized by May 2007, 5 were refused, and 14 withdrawn. Of the 28 authorized novel foods, 8 had their initial assessment in the Netherlands, 7 in the United Kingdom, 4 in Finland and Belgium respectively, 3 in France and 2 in Germany.

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 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, only once, in 2005, a novel food has been lucky enough to get on the market at this stage. In all other cases, Member States did raise comments or objections that were classified as "reasoned objections". In 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 (which happens from time to time), 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, Comitology).

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) that had received reasoned objections managed to get through the entire procedure in roughly one year. Usually, the process takes about two to three years. All, but one[46] novel food file, received the necessary qualified majority in the Regulatory Committee, but depending on the file, at times the proposals for authorizing novel foods were discussed several times in the Regulatory Committee before the Commission decided to proceed to a vote.

[46] 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.

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.

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 C.F.I.

The NFR has been subject to interpretation at the European Court of Justice ("E.C.J.") though because several Member States had started safeguard measures under Article 12 of the NFR against individual products. However, these 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.[47]

For completion, it should be noted that the NFR has a specific provision allowing for the 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

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

the initial Member State of contact who issues an opinion that is then being communicated via the Commission or directly to the other Member States. This practice of course does not provide, contrary to a decision that would be 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[48]) 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 one main Directive, the so-called "Framework Directive 89/107" as amended[49], the so-called "miscellaneous" additives Directive 95/2[50], Directives 94/35 on sweeteners[51], 94/36 on colors[52] as well as several Directives on purity criteria for additives.

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[48] The so-called Safeguard procedure is a procedure included consistently in EU internal market legislation allowing a Member State to temporarily restrict the marketing of a product otherwise in compliance with the harmonized legislation that is thought not to being compliant with health, safety or environmental requirements. The Member State must then bring this matter in front of the Commission who must rule on it.

[49] Council Directive 89/107, 1989 O.J. (L 40) 27, 33 (on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption).

[50] European Parliament and Council Directive No 95/2/EC, 1995 O.J. (L 61) 1, 40 (on food additives other than colors and sweeteners).

[51] European Parliament and Council Directive 94/35, 1994 O.J. (L 237) 3, 12 (on sweeteners for use in foodstuffs).

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 agents, anti-foaming agents, 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 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.

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[52] European Parliament and Council Directive 94/36, 1994 O.J. (L 237) 13, 29 (on colors for use in foodstuffs).

Inclusion of substances into Community lists is effected by the normal legislative procedure (Article 251 TEC). Given the number of procedural steps involved (up to three Readings in the EP), 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 then be done under the normal legislative procedure. If the Council has not acted within 18 months of the Commission having proposed the inclusion or the Commission has not proposed the inclusion within the two year period specified above, 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. Article 2 (3) and Annex II of Directive 89/107 contain 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.[53] This guidance document does not take the established forms of Commission non-binding instruments under Article 249 TEC (recommendation or opinion).[54]

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 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 "Guidance on submissions for food additive evaluations by the Scientific Committee on Food". The dossier should also contain a summary document that can be separated. The guidance document further specifies that the

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

[54] The Commission argues that it is not necessary that this specific guidance document has the same format as other guidance documents or is published in the Official Journal or is translated into all Community languages because it is an 'administrative' rather than 'technical guidance' document only.

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 on submissions for food additive evaluations by the Scientific Committee for Food (opinion expressed on July 11, 2001) mentioned above.[55] 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 out, and use criteria for food additives.

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

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 TEC) and that the details to file an application 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.[56]

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.[57]

Regulation 178/2002 sets common principles and responsibilities for all EU food law applicable to all foods and food ingredients, including food packaging. 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.

[56] A proposal for revision of the additives legislation is currently pending in Council and EP and is expected to deal with some of the procedural shortcomings highlighted above.

[57] European Parliament and Council Regulation 178/2002, supra note 1, at 24.

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[58] (all Article 6 of Regulation 178/2002).

The smoke flavorings Regulation 2065/2003[59] is a prime example[60] 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

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[58] 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.

[59] European Parliament and Council Regulation No 2065/2003; 2003 O.J. (L 309) 1, 8 (on smoke flavorings used or intended for use in or on foods).

[60] 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, supra note 59.

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.[61] 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 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

[61] Informally, this type of procedure is called "mail box" procedure because the tasks of the Member State in the initial stage are reduced to post office functions. It is argued that this type of procedure giving a contact point in Member States is more convenient for small and mid-size companies.

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. EFSA published such guidance on October 7, 2004. 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, EFSA 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 C.F.I.. 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 the case 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).[62] 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.

[62] European Parliament and Council Regulation No 1049/2001; 2001 O.J. (L 145) 43, 48 (regarding public access to European Parliament, Council and Commission documents).

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 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

The new food contact material Regulation 1935/2004[63] 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

[63] European Parliament and Council Regulation No 1935/2004; 2004 O.J. (L 338) 4, 17 (on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC).

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 and 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, and shall be accompanied by the name and address of the applicant, 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.

Article 9 (2) provides that EFSA must publish detailed guidelines concerning the preparation and the submission of the application. A Guidance document was published by EFSA's AFC Panel on December 2, 2004 (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 of 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 effected 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. In particular, there is no definition of the term 'act'. It is therefore unclear whether this term also encompasses EFSA 'opinions' or just administrative actions taken by EFSA. In its own various internal procedures, EFSA itself seems to distinguish between 'acts' and 'opinions' thereby indicating that 'opinions' may not be challengeable by the administrative review procedure.

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, and the fact that the factually binding criteria for scientific assessment by EFSA are not available in all EU languages.

III. 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.[64]

Despite this tendency to be more detailed and to increase accountability, there continue to be 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 wording 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

[64] European Parliament and Council Regulation No 853/2004; supra note 11 (laying down specific hygiene rules for food of animal origin).

Committee, and no rules are provided on public consultation of any draft measure (except in the case of GMOs).

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 strongly discouraged by the EFSA secretariat. For example, EFSA scientific Panel coordinators do not routinely release the names of Panel or working group members that act as rapporteurs. Correspondence on the status of files is often sketchy and takes time. We have also had the experience that upon question by the applicant whether further data was needed, the Panel coordinator responded that this was not the case and contrary to that, the EFSA opinion subsequently issued stated that certain data was missing.

Concluding from the above therefore, contacts with EFSA are more formalized than under the previous system. The administrative review procedure for EFSA acts included for example in the new food contact legislation (Regulation 2035/2004) may actually accelerate this trend.

EFSA has recently come under considerable scrutiny with the Advocate General opinion in joined cases C-154/04 and C-155/04 which was a request for a preliminary ruling concerning the validity of Directive 2002/46 on food supplements[65].

Advocate General Geelhoed opined in this case as follows:

"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 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.

(……);

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

[65] European Parliament and Council Directive 2002/46; 2002 O.J. (L 183) 51, 57 (on the approximation of the laws of the Member States relating to food supplements). The Food Supplements Directive provides, among others, for a positive list of vitamins and minerals and their purity criteria that can be used in the production of food supplements to the exclusion of all others.

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.

(……..)

. 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.

(……)

Unfortunately, the ruling of the E.C.J. in this matter was less progressive than the Advocate General opinion. In its judgment of July 12, 2005, the E.C.J. upheld the Directive. However, the E.C.J. nevertheless made a number of useful comments and set prerogatives for the Commission to adhere to in future cases.

The E.C.J. ruled in particular[66] that *"a measure which, like that at issue in the main actions, includes a prohibition on marketing products containing substances not included on the positive lists laid down in the applicable legislation must be accompanied by a procedure designed to allow a given substance to be added to those lists and the procedure must comply with the general principles of Community law, in particular the principle of sound administration and legal certainty. Such a procedure must be accessible in the sense that it must be expressly mentioned in a measure of general application which is binding on the authorities concerned. It must be capable of being completed within a reasonable time. An application to have a substance included on a list of authorized substances may be refused by*

[66] At paragraphs 72 and 73.

the competent authorities only on the basis of a full assessment of the risk posed to public health by the substance, established on the basis of the most reliable scientific data available and the most recent results of international research. If the procedure results in a refusal, the refusal must be open to challenge before the courts."

The E.C.J. also stated[67] that *"it would, no doubt, have been desirable, as regards the stage between the filing of a dossier seeking modification of the positive lists, and the time when the matter is brought before the committee…for the Directive to have included provisions which in themselves ensured that that stage be completed transparently and within a reasonable time. The absence of any such provisions cannot, however, be regarded as such as to jeopardize the proper functioning of the procedure for modifying the positive lists within a reasonable time. It is none the less the responsibility of the Commission, by virtue of the implementing powers conferred on it by Directive 2002/46 concerning, inter alia, the way the procedure is operated, to adopt and make accessible to interested parties, in accordance with the principle of sound administration, the measures necessary to ensure generally that the consultation stage with the European Food Safety Authority is carried out transparently and within a reasonable time. By providing for the procedure established in Article 5 of Decision 1999/468 to apply, Article 4 (5)[68] of Directive 2002/46 also ensures that an application for inclusion on the positive lists of a vitamin, a mineral or a vitamin or mineral substance can be rejected only by a binding legal act, which may be subject to judicial review."*

[67] At paragraph 81 et al.

[68] Comitology.

IV. 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 TEC, *"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."*[69] The legal challenge has to be brought within two months after publication of the act.

The fourth paragraph of Article 230 TEC 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 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.[70]

The E.C.J. has held that if the contested measure is a legislative measure which does not constitute a Decision within the meaning of Article 189 TEC, 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,*

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

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

Extramet Industrie v Council, [1991] E.C.R. I-2501, paragraph 13; Case C-309/89 Codorniu v Council, [1994] E.C.R. I-1853, paragraph 19, and order in Japan Tobacco and JT International, cited above, paragraph 29)."[71]

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[72].

In the *Boehringer v. Council and Commission* Case,[73] 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*."[74]

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

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

[73] Joined Cases T-125/96 and T-152/96, *Boehringer v. Council and Commission* [1999] E.C.R. II-3427, paragraph 170.

[74] See also Case 92/78, *Simmenthal* v. *Commission* [1979] E.C.R. 777, paragraphs 25 and 26; Case 113/77, *NTN Toyo Bearing Company and Others* v. *Council* [1979] E.C.R. 1185, paragraphs 11 and 12; Case 118/77, *ISO* v. *Council* [1979] E.C.R. 1277, paragraph 26; Case 119/77, *Nippon Seiko and Others* v. *Council and Commission* [1979] E.C.R. 1303, paragraph 14; Case 120/77, *Koyo Seiko and Others* v. *Council and Commission* [1979] E.C.R. 1337, paragraph 25; Case 121/77, *Nachi Fujikoshi and Others* v. *Council* [1979] E.C.R. 1363, paragraph 11; Joined Cases 87/77, 130/77, 22/83, 9/84 and 10/84, *Salerno and Others* v. *Commission and Council* [1985] E.C.R. 2523, paragraph 31; Case 333/85, *Mannesmann-Röhrenwerke and Benteler* v. *Council* [1987] E.C.R. 1381, paragraph 14; Case 55/86, *Arposol* v. *Council* [1988] E.C.R. 13, paragraphs 11 to 13; Case 207/86, *Apesco* v. *Commission* [1988] E.C.R. 2151, paragraph 12; and Case C-152/88, *Sofrimport* v. *Commission* [1990] E.C.R. 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"*.[75]

According to the E.C.J., 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.[76]

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,[77] the E.C.J. 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.*"[78]

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[75] Case 25/62, *Plaumann & Co. v. Commission* [1963] E.C.R. 95.

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

[77] Case 41 to 44/70, *NV International Fruit Company and others v. Commission*, [1971] E.C.R. 411, paragraph 21.

[78] Case 100/74, *CAM v. Commission* [1975] E.C.R. 1393, paragraphs 18-20.

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.[79]

In the field of state aid, the E.C.J. 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.*"[80]

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 "positive list" cases of legislation briefly discussed above (additives, flavorings, supplements, food contact), practitioners would argue this to be the case in all cases in which interested stakeholders have submitted data to the Commission or EFSA for review of their substances for being introduced or remaining in the positive lists. It is uncertain however whether the C.F.I. and E.C.J. would follow this reasoning in all cases, in particular in the case of additives. As the newer regulations (smoke flavorings, food contact) provide for a more formalized procedural involvement of the interested stakeholders, those cases may be easier to argue.

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[79] Case 138/79, *SA Roquette Frères v. Council* [1980] E.C.R. 3333, paragraph 16.

[80] Case T-11/95, *BP Chemicals Limited v Commission*, [1998] E.C.R. II-3235.

There is no legal standing issue for novel foods (see above) because decisions are taken in the form of 'Decisions' and are therefore challengeable by reason of their form.

In the *Alpharma* case,[81] the C.F.I. 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 for the benefit of other applicants for a period of 10 years*" from the date of first authorization by means of regulation.[82] The C.F.I. 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 C.F.I. 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.*"[83] The C.F.I. concluded that the contested regulation "*affects Alpharma by reason of a legal and factual situation which*

[81] Case T-70/99, *Alpharma Inc. v. Council*, [2002] E.C.R. II-3495.

[82] The *Alpharma* case, paragraph 90.

[83] The *Alpharma* case, paragraph 94.

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 TEC)."

In Case C-309/89, *Codorniu v. Council*, the E.C.J. 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"*[84] *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*."[85]

All in all, the C.F.I. 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[86] was overturned by the E.C.J. 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 E.C.J. for the interpretation of Community law (Article 234 TEC), and seek damages for unlawful acts of the Community under Article 235 in conjunction with Article 288 TEC (*"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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[84] This was a repetition of the formula used in Case 25/62, *Plaumann v. Commission* [1963] E.C.R. 95.

[85] Case C 309/89, *Codorniu v. Council*, [1994] E.C.R. I-1853.

[86] Case T-177/01, *Jégo-Quéré & Cie SA v Commission*, [2002] E.C.R. II-2365.

V. CONCLUSION

Food safety is the general responsibility of the Directorate General for Health and Consumer Protection (DG SANCO). European food safety regulation is adopted under the co-decision legislative procedure of Article 251 TEC, usually drawing on the authority of Articles 95 of the TEC (internal market), or 153 of the TEC (consumer protection), or in rare cases possibly 152 of the TEC (public health, phytosanitary and veterinary matters). EU food law deals with a large range of matters, including new foods ("novel foods"), genetically modified foods, food hygiene, food contact materials, food additives, food colors, food flavorings and labeling. The implementation of food safety legislation frequently uses Comitology.

In 2002, the Council and Parliament adopted the General Food Law Regulation 178/2002 to set common principles and responsibilities for all food law. Prior legislation and implementing measures are to be adapted no later than January 1, 2007 to comply with the new general principles. Regulation 178/2002 also established the European Food Safety Authority (EFSA), the Commission's scientific advisory institution for food related matters.

The General Food Law Regulation seeks to assure both a high level of protection of human life and health, and protection of consumer interests, including fair practices in food trade, protection of animal health and welfare, plant health, and the environment. All decisions must be based on risk assessment of the available scientific evidence, undertaken in an independent, objective, and transparent manner. Risk management then is to take into

account the results of the risk assessment, other factors legitimate to the matter, and the precautionary principle.

Currently, most food safety legislation takes the form of Regulations, although major earlier continuously valid legislation uses the Directive format. Most implementing measures, involving pre-market authorization of individual products, normally by adding the product to lists in Annexes to the applicable legislation are adopted by Comitology in the form of Commission Directives or Regulations. Less often, the Commission issues Decisions to individuals (in the case of the novel foods and genetically modified foods under Regulations 258/97 and 1829/2003 respectively).[87] Under Directive 89/107 (food additives) (a revision of this Directive is currently pending), authorizations of new additives are still effected by Council and Parliament Directives. In some situations, the applicable legislation does not specify what form the authorization is to take (*e.g.* the authorization of decontaminants under Regulation 853/2004).

Traditionally, consultation on new legislation by DG SANCO has taken place in Brussels only, in various fora which were called on by DG SANCO on a largely ad-hoc and as needed basis. These usually involved only European level participants, with no consultation organized via the web or at Member State or regional level. A new development is the use of Advisory Groups or Platforms (such as the new European Platform for Action on Diet, Physical Activity and Health) initiated by DG SANCO on an ad hoc or as needed basis. While these groups largely consist of the normally consulted EU-level groups, representatives from individual companies have sometimes been included.

[87] European and Council Regulation No 258/97, supra note 1 (concerning novel foods and novel food ingredients); European Parliament and Council Regulation (EC) No 1829/2003, supra note 1 (on genetically modified food and feed).

In general, DG SANCO seems to have been slower than most DGs in responding to the Commission's recent generic Communications on consultation, impact assessment, public participation, and legislation on public access to documents. With the exception of its 2002 internet consultation evaluating the Novel Foods Regulation 258/97, DG SANCO did not organize wide-range public internet consultations until very recently (2006). In the Novel Foods consultation, for the first time DG SANCO made stakeholder comments available on the Commission's homepage. Within the past two years, however, DG SANCO's practices have changed significantly, and in 2006 DG SANCO launched nine food related internet consultations.

DG SANCO's Comitology processes use a regulatory committee, the Standing Committee on the Food Chain and Animal Health (SCFCAH). Based on data gathered between 2001 and 2004, DG SANCO had the fifth largest number of Comitology committees among the DG's, the second highest number of meetings, the second highest total output in opinions, and the third highest total output in instruments. Roughly half of these involved food safety issues. Since adoption of the General Food Law Regulation 178/2002, the number of committees in the food safety area has been reduced.

As is the case in other DGs, Comitology in DG SANCO entails considerably less consultation, both in terms of the number of events and the number of participants, than secondary legislation. For implementing measures to be adopted under the Comitology rules, the minimum rules on consultation do not apply and there is therefore 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 TEC procedure. The Commission will usually only consult

once a draft text has been elaborated, and then only with those stakeholders it has previously identified as having an interest in the subject, most of the time a limited number of EU industry trade and consumer organizations. Consultations will not be launched via the Internet, but by fax or mail, usually with short notice (2 to 4 weeks). Revised drafts may not be subject to consultation.

The main implementing actions adopted by Comitology are authorizations of individual products. These actions follow procedural paths that are specific to the particular legislation involved, but which have the same basic though somewhat more uniform functional steps in the wake of the passage of the General Food Law Regulation 178/2002 and the recent generic Commission Communications on Better Regulation. The main steps are as follows: Applications are filed either at the Member State level (the normal case) or with the Commission. An initial scientific assessment is then done, either at the national level (*e.g.*, novel foods) or at the Community level by the EFSA (the more common case) to determine whether the application is complete, whether it meets the relevant substantive tests in the legislation, and whether the product's use should be conditioned or restricted in light of those tests. There are provisions in some of the legislation for the adoption of guidelines with regard to various parts of this process, but in some cases no such guidelines are now in effect, or the guidelines are in existence but not formally adopted and are available only in English.

Thereafter, the Commission prepares a draft proposal that would proceed through the Comitology process for consideration by the Regulatory Committee, the SCFCAH, and then adoption by the Commission unless the matter were sent to the Council under the Comitology process. This normally takes between one (exceptional cases) and five years, with the majority of cases in the two to three year range.

The newer legislative instruments adopted under the framework of the General Food Law Regulation 178/2002 usually provide deadlines for the scientific assessment and most of the following administrative procedure. Some more recent Regulations also provide for an administrative review by the Commission of action and inaction by EFSA, "on its own initiative or in response to a request from a Member State or from any person directly *and* individually concerned."

The net result is that there is a large variety of procedures used for granting authorizations in the food safety sector, but the more recent pieces of legislation, especially those adopted after Regulation 178/2002, set out procedures in more detail and establish deadlines, a major improvement. Notwithstanding these positive developments, however, even these legislative instruments leave the availability of judicial review of action or inaction on the authorization often up in the air.

Direct judicial review of legislative instruments such as Regulations or Directives is generally unavailable (unless the plaintiffs meet the difficult test of being directly and individually concerned), whether they are adopted by the Council and Parliament or by the Commission through Comitology; and little effective indirect judicial relief is available. This is because plaintiffs must demonstrate that they are directly and individually concerned, which is a difficult test under standing case law of the EU courts. Where a *Decision* is issued, however, the regulated entity can obtain direct judicial review of the action or inaction involved. The general public and other possibly interested parties have no such remedy, however.

The European Court of Justice may force the pace of change as to procedures for authorization. In its judgment of July 12, 2005,[88] the ECJ upheld Directive 2002/46 on food supplements, but laid down rules for the Commission for future cases. The ECJ held, in particular, that:

> [A] measure which, like that at issue in the main actions, includes a prohibition on marketing products containing substances not included on the positive lists laid down in the applicable legislation must be accompanied by a procedure designed to allow a given substance to be added to those lists and the procedure must comply with the general principles of Community law, in particular the principle of sound administration and legal certainty. Such a procedure must be accessible in the sense that it must be expressly mentioned in a measure of general application which is binding on the authorities concerned. It must be capable of being completed within a reasonable time. An application to have a substance included on a list of authorized substances may be refused by the competent authorities only on the basis of a full assessment of the risk posed to public health by the substance, established on the basis of the most reliable scientific data available and the most recent results of international research. If the procedure results in a refusal, the refusal must be open to challenge before the courts.
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> …

[88] Joined Cases C-154/04 and C-155/04**,** The Queen, on the application of: Alliance for Natural Health and Nutri-Link Ltd v Secretary of State for Health (C-154/04) and The Queen, on the application of: National Association of Health Stores and Health Food Manufacturers Ltd v Secretary of State for Health and National Assembly for Wales (C-155/04), 2005 E.C.R. I-6451.

It remains to be seen whether the above judgment will lead to a more uniform regulatory regime for the various food products and food ingredients, whether it will improve the availability of judicial review, and whether it will lead to more transparency, accountability, and to quicker decision-making in food safety matters.

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ANNEX 1

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
		Art. 15: Provides procedure for determination of whether GMOs for feed use, feed containing or consisting of GMOs & feed produced	Comitology	Not specified

Legal Measure	Actual Function	Related Articles	Procedure	Format of Rule/Decision
		from GMOs fall within its scope		
		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
	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

Legal Measure	Actual Function	Related Articles	Procedure	Format of Rule/Decision
		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
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	

Legal Measure	Actual Function	Related Articles	Procedure	Format of Rule/Decision
			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 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.	• Notification by MS to COM & other MS; COM consultation with MS; COM approval or Comitology • Comitology • 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	• Notification by MS to COM & other MS; COM consultation with MS; COM approval or Comitology	

Legal Measure	Actual Function	Related Articles	Procedure	Format of Rule/Decision
		• Provides rulemaking procedures for MS provisions applicable to the way in which instructions are indicated	• 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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