



The European Commission Proposal for a Regulation on Food Law and the European Food Authority: an Ambivalent Approach Leading to Missed Opportunities

On November 8, 2000, the Commission presented its proposal for a Regulation of the European Parliament and of the Council (COM (2000) 716) to lay down the fundamental principles, definitions, objectives and requirements for EU food law, create a new European Food Authority (EFA) and provide a legal basis for the Commission's comprehensive "farm to fork" food safety strategy.

As reflected by its composite title, the proposal is, indeed, an attempt by the EU Commission to achieve several goals in one go. At no surprise, given that consumer safety and health must take precedence over all other considerations, however laudable they might be, the European Commission has taken the risk of missing all of its objectives altogether.

benefit of the outcome of the ongoing discussion at the Council and Parliament – present more fully and comment on the part dealing with EFA, as shall have been substantially amended by then.

The Genesis

Back in 1997 already, at the highest of the BSE crisis and facing severe pressure from the European Parliament that ultimately led to its dismissal, the Santer Commission had to postpone the issuance of its then long awaited green paper on food law (COM(97) 176 final) until it could "balance" it with the issuance, on the very same day, of a Communication on food safety (COM (97) 183 final).

Today's proposal finds, indeed, its roots in those three fundamental previous Commission's papers: (1) the 30 April 1997 "Green Paper" on food law (2) the 30 April 1997 "Communication" on food safety and (3) the 12 January 2000 "White Paper" on food safety".

In its January 2000 "White Paper" the European Commission had noted that EU food legislation had evolved over the last thirty years "reflecting a blend of scientific, societal, political and economic forces (...) but that no overall coherence had been guiding this development". As already underlined in its 1997 Green Paper, it had announced its intention to streamline and simplify the EU decision making process for foodstuffs "in order to ensure efficacy, transparency and rapidity", suggesting that the Commission be given additional delegated powers and simplified Committee procedures for delegated legislation, individual decisions and an emergency procedure.

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common position by June, a condition for the EFA to be functioning by 2002, growing challenges to the part of the proposal laying down general principles and requirements for food law are likely to affect the outcome of the current debate and possibly delay the adoption of the long awaited common comprehensive basis and general framework for food law, while not necessarily ensuring a swift establishment of the EFA.

European industry and the enhancement of its export prospects (5) the primary responsibility for safe food on industry and (6) a coherent, rational and user friendly legislation.

This paper will mainly focus on the part of the proposal dealing with the general principles and requirements of food law, and the next issue of our Advisory will - with the

The Proposal

Principles & Requirements of Food Law

Food Law is to be based on the general objectives of protecting human life, health and safety, consumer interests and *other objectives*, such as environmental protection and animal welfare. Food Law shall *also aim* to achieve the free movement of food and feed across the Community (*emphasis added*). International standards are to be taken into consideration on the adoption of food law, but may be superseded by EU requirements if warranted by scientific justification or the appropriate deemed Community level of protection.

Health protection is to be based on risk analysis, risk assessment and risk management, a system that, in particular, shall take into account the opinions of the European Food Authority. Recourse to the precautionary principle (in line with Commission's Communication on the Precautionary Principle, COM (2000) 1) is specifically set down where a risk to public health is identified.

General provisions prohibiting fraud, adulteration and misleading practices are laid down together with the obligation to adequately label and identify food and feed to ensure proper traceability from "farm to table".

Only safe food (described as food not potentially injurious to health, unfit for human consumption or contaminated) under normal and foreseeable conditions of use shall be placed on the market. Responsibilities for providing safe food and feed lies with food and feed business operators at all stages of the production and distribution process, while Members States are required to enforce and control the application of food law. This includes notification duties to national food control authorities if a firm *considers or suspects* that a food or feed placed on the market does not comply with relevant food or feed safety requirement law and of action taken to notify consumers as well as product withdrawal and notification obligations.

The proposal would also prevent import or export of food, which do not meet EU requirements, subject to exceptions for exports when third countries laws or governments authorise the exports. Lastly, the Commission proposes to promote transparency regarding food law through public consultation and information. This proposes to enshrine the principle of public consultation *wherever circumstances allow* during the preparation of food law as well as the right to public access to necessary information for new food safety risks, subject to the application of relevant national and Community laws on access to documents.

The Proposed European Food Authority

The mission of the new "European Food Authority" (EFA) will be to "contribute to a high level of protection of human life and health, protection of plant life, protection of animal health and welfare, protection of the environment and protection of the health of workers, while facilitating the functioning of the internal market [...]". The EFA's competence covers all issues having a direct or indirect impact on food safety, animal health and welfare, plant health as well as questions relating to nutrition or genetically modified food or feed organisms (GMOs). Its tasks range from providing scientific advice to operating the rapid alert system and communicating scientific information to the public. It would notably be composed of 8 scientific panels that would replace the existing scientific committees system. One of those panels will be dealing with food additives, flavourings, processing aids and material in contact with food; a specific panel would deal with GMOs and another will review dietetic products, nutrition and allergies. The proposal provides for confidentiality of information when requested by the party submitting the data.

Main shortcomings

While the EU Commission's commitment to develop a comprehensive and integrated approach to food safety in order to achieve the highest levels of health protection and restore and maintain consumer confidence in food safety can only be supported, one is forced to admit that the proposal represents a missed opportunity in the Commission's attempt to provide a common comprehensive basis for food law and create a general framework for food law.

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The form of a Regulation is inappropriate to establish general principles

Although, as recognized by the EU Commission in its 1997 Green Paper, the form of a Regulation is otherwise generally preferable to that of a Directive because of its direct applicability in all the 15 EU Member States, thereby "*increasing transparency of the legislation and avoiding difficulties arising from delayed or incorrect transposition*" the same does not stand true when it comes to dealing with general food law. As also stated in the 1997 Green Paper on food law "*the Directive should, however, remain the instrument of choice for framework legislation*".

Probably for those reasons, and because it did not wish to establish the "general principles and requirements of food law" as a framework legislation, the proposal fails to address properly the question of its interaction with the existing legislation. It cannot be seriously argued that the proposed wording of Article 64 of the proposal: "*Existing food law shall continue to apply until amended to ensure conformity with the provisions laid down in Chapter I and II*" could in any serious manner be the appropriate response to the stated objective in the White Paper to "*ensure efficacy, transparency and rapidity*" of food legislation. That legislation is already quite a complex and piecemeal mix of directives, regulations, decisions, case law by the European Court of Justice (ECJ), and national implementing measures, not to mention the over 80 specific legislative measures - other than the proposed Regulation itself - that are foreseen in the White Paper and of which the proposal is supposed to form the foundation. Suffice to say that certainly neither efficacy, transparency or rapidity will be enhanced when the Regulation is in force and is supposed to co-exist for many years with the pre-existing legislation.

Furthermore, noting that a Regulation should by definition leave no room for diverging interpretation one wonders how it could be reasonably expected that provisions such as the proposed article 19 of the proposal, pretending to organize public consultation as follows: "*Wherever circumstances allow there shall be effective public consultation, directly or through representative bodies, at an appropriate stage, during the preparation of food law*" would have any chance of passing that test of clarity?

Growing challenges on the chosen legal basis are likely to delay the adoption of the proposal

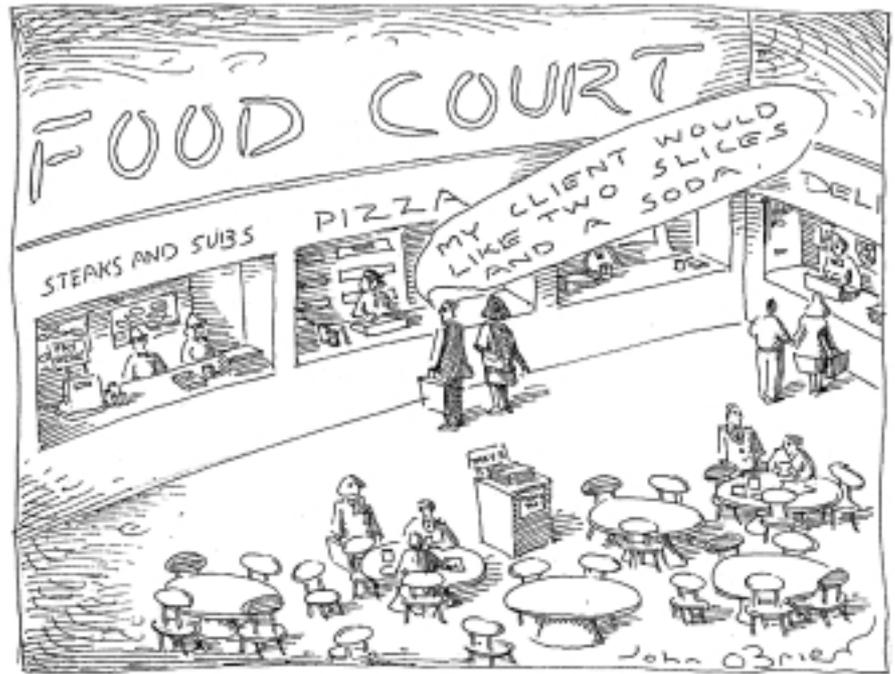
Any Community legislation needs a legal basis. As observed by Advocate General

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Fennelly in his opinion delivered on 15 June 2000 in Cases C-376/98 and C-74/99 concerning the validity of the Advertising Directive "... article 3B of the Treaty states that the Community shall act within the limits of the powers conferred upon it by this Treaty and of the objectives assigned to it therein (emphasis added). It follows from that provision that the Community only has those powers that have been conferred upon it. It is the task of the Court, inter alia, to ensure the respect by the Community of the limits of those powers". That requirement to have a strong legal basis is not absent – to say the least - from the reasons that have led the EU Commission (1) to choose the combined approach of treating in the same text, both the establishment of the EFA and the general principles and requirements of food law and (2) to prefer the form of a Regulation to that of a Directive.

The "combined approach" has been chosen because of the determination by the Commission that the legal basis for the part on general food law (article 95 of the Treaty (former article 100a) providing the basis for measures having as their object the establishment and functioning of the internal market) would be stronger than - and would therefore reinforce it if in the same text - the legal basis that would have been otherwise available for the establishment of the EFA (article 308 of the Treaty (former article 235) providing the basis for measures in the field of health). In turn, the form of a Regulation has had to be preferred to that of a Directive because the EFA - the real priority - cannot by definition be established via a Directive.

It is with those considerations in mind that the Commission has had to depart from the otherwise more obvious way to meet the very objectives of the proposal "to provide a common comprehensive basis for food law, create a general framework for food law" and "ensure a high level of protection and the effective functioning of the internal market in food" that would have been to issue two distinct proposals: One proposal for a **Framework Directive** of the European Parliament and of the Council, based on Article 95 of the treaty, laying down the general principles on food law and procedures in matters of food. That Directive would in essence cover Chapter I: "Scope and Definitions", Chapter II: "General Food Law" and most of Chapter V: "Procedures and Final Provisions" of the current proposal. One proposal for a **Regulation** of the European Parliament and of the Council, based on Article 308 of the Treaty, establishing the European Food Authority, a Rapid Alert System, Crisis Management and Emergencies. That Regulation would in essence cover Chapter III: "European Food Authority" and Chapter IV: "Rapid Alert System, Crisis Management and Emergencies" of the current proposal.



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We submit, however, that the separation of the EFA part from the rest of the proposal, as is now advocated by many Member States and commentators (not to mention the now alleged lack of competence of the Community to establish general principles for food law pursuant to article 95) would, if pursued, very likely delay for many more years the adoption of the long awaited common comprehensive basis and general framework for food law, while not necessarily ensuring a swift establishment of the EFA.

No streamlining initiative for the food legislation

Failing to propose that the Commission be given additional delegated powers (such as the approval of new additives) and to institute a simplified Committee procedures for such delegated legislation, the proposal is a missed opportunity to streamline the decision making procedures in matters of food law (See in particular: "Streamlining and Simplifying the Procedures for the Placing on the Market of Foodstuffs in the European Union", a legal study performed for the CIAA by Jean-Philippe Montfort, Keller and Heckman LLP, September 2000).

No reinforcement of the mutual recognition principle for non harmonized areas of food law

The proposal misses the opportunity to provide a general and consolidated frame for those areas of food law that are not covered by specific harmonized rules, but where the

functioning of the Internal Market is ensured by mutual recognition, as developed by the ECJ in its "Cassis de Dijon" jurisprudence (See Case 120/78, ("Cassis de Dijon"), 1979 E.C.R. 649).

Firstly, it is submitted that consistent with its stated aim "to achieve the free movement of food or feed complying with the requirements included thereby", the proposal should be amended so that the European Court of Justice be entitled to request an opinion from the EFA as regards the scientific substantiation of national measures based on former article 36 of the Treaty.

Secondly, a codification in the proposal of the practical components of the principle of mutual recognition as developed by the European Commission in its 1989 Communication on the free movement of foodstuffs within the Community (89/C 271/03) would provide the legislative reference that is missing at the moment to ensure a smooth functioning and transform that principle of mutual recognition into reality for those non harmonized areas. Suffice to say here that at the moment, areas such as a large part of food contact legislation, food fortification, processing aids, health claims, etc. are not yet fully harmonized and still need to rely on the principle of mutual recognition to benefit from the free movement within the EU.

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GMO Labelling: Will Traceability Do Better than Detection as a Base for GM Labelling Requirements in the EU?

Issue N° 2, June 2000 of EU Advisory had concluded that detection methods were likely to have a casting vote on the interpretation and enforcement of EU's very confusing GM labelling obligations. One year later, and having had to recognise that GM labelling had not become a reality in the EU, the EU Commission is now reportedly determined to try and achieve its goal by basing its GM labelling requirements on traceability instead of detection.

The body of EU legislation covering GMOs and products that either contain or are derived from GMOs consists of (i) Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms, (ii) Regulation 258/97 on novel foods and novel food ingredients, (iii) Regulation 1138/97 on the labelling of foods derived from genetically modified soy and maize, as amended by Regulation 49/2000, and (iv) Regulation 50/2000 concerning labelling of foodstuffs containing GM additives and GM flavourings.

Regulation 1138/97, as amended by Regulation 49/2000, requires that food and food ingredients produced from *GM soy and maize* indicate that they are "produced from genetically modified soy/maize", based on appropriate analytical testing. The threshold for the presence of GM DNA or proteins as a result of adventitious contamination is fixed at 1%, provided documentation exists to prove that measures were taken to avoid contamination. Similarly, for *food and food ingredients containing GM additives and flavourings*, Regulation 50/2000 requires that labelling indicates "produced from genetically modified" (+ indication of additive or flavouring) in cases where, following a scientific assessment, products are no longer equivalent to existing ones, i.e. when GM proteins or DNA are found. This implies that labelling should be based on appropriate analytical testing. Regulation 50/2000 also provides that a threshold for adventitious contamination may be established in the future.

Because of general consumer fear and the unfortunate numerous flaws in the legislation, however, this extensive legal framework has not been sufficient to provide the necessary guarantees to consumers and regulators and has proven to be neither manageable by operators nor acceptable by the EU trade partners.

In order to regain public confidence while paving the way to lift the *de facto* moratorium on new GMO authorizations

that had been established back in 1998 by many Member States, the EU has now adopted Directive 2001/18/EC, replacing Directive 90/220/EEC and strengthening the Community authorisation procedure for genetically modified raw materials. Directive 2001/18/EC, aims at introducing better public access to information; mandatory consultation of the relevant Scientific Committees; mandatory labelling and traceability at all stages of the placing of GM materials on the market; a register of all places where GMOs are grown; a ten year limitation on the renewal of authorisations; the application of the Precautionary Principle and mechanisms for the analysis of the long-term cumulative effects of GMOs.

Recognising that this will not be enough to address all concerns, the establishment of reliable tracing and labelling systems throughout the food chain is now seen as a prerequisite to a lift of the moratorium. To this effect, the Commission is now envisaging to adopt:

- an amendment to Regulation 258/97 on novel foods and novel food ingredients: a draft was expected imminently when this EU Advisory went to press. Reportedly, novel foods derived from GMOs or containing ingredients, additives or flavourings derived from GMOs would have to be labelled in the ingredients list as "genetically modified" or "produced from genetically modified (name)", while foods containing not more than 1% GM-derived material would be exempt provided it can be documented that the raw materials come from GMO-free sources. Currently, for *food and food ingredients containing or consisting of GMOs*, Regulation 258/97 requires that labelling should indicate the presence of GMOs. Even though no indication is provided as to whether this should be based on testing or documentation, it is generally accepted that labelling should be based on appropriate analytical testing; for *food and food ingredients derived from GMOs*, Regulation 258/97 requires that labelling should indicate any characteristics which, following a scientific assessment, render the products no longer equivalent to existing ones, implying

that labelling should be based on appropriate analytical testing.

- a Regulation concerning "traceability and labelling of genetically modified organisms and traceability of food and feed products derived from genetically modified organisms": an internal draft by the DG SANCO of the European Commission on 23 March 2001 proposes to impose traceability requirements on products consisting of or containing GMOs and on products derived from GMOs. By contrast, it only imposes labelling obligations on products consisting of or containing GMOs; not on *products derived from GMOs*. Specifically, for *products consisting of or containing GMOs*, operators placing these products on the market would have to (a) indicate to the other operators in the chain (other than consumers) that they contain GMOs, (b) indicate the unique code of the GMO (corresponding to an authorized transformation event), and (c) keep this information for five years. For *products derived from GMOs*: operators placing these products on the market would have to (a) indicate the ingredients (including additives and flavourings), feed materials or additives which are derived from GMOs to the operator (not the ultimate consumer) receiving the products, and (b) keep this information for five years.
- a specific text on labelling applicable to food and feed products or ingredients derived from genetically modified organisms: it is now almost certain that in future, GM labelling obligations will be based on the traceability requirements of the proposed Regulation as shall be complemented by a Regulation that the Commission is intending to submit at the same time as the traceability proposal. The publication of those two proposals (traceability and labelling) was reportedly imminent when this Advisory went to press.

The concept of **traceability** itself is not new in the EU legislation: Directive 89/396/EEC requires the indication of the lot number for

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every pre-packaged foodstuff; Regulation 1760/2000 has established a traceability scheme for beef products; the proposed Regulation on the general principles and requirements of food law and the EFA refers to traceability as a general principle; article 4(6) of Directive 2001/18/EC requires Member States to ensure traceability at all stages of the placing on the market of GMOs. The draft Commission Proposal provides, however a first definition of that concept: "the ability to trace GMOs and products derived from GMOs at all stages of its placing on the market".

The European Commission has sponsored the development and validation of methods

suitable for the **detection** of GM DNA and protein both in raw materials and in food ingredients. Unfortunately, despite huge progress in the field, the few internationally validated methods available today are still not capable of providing the necessary certainty in providing unambiguous answers on the GM origin of a product. Some problems existing today, such as the lack of Certified Standard Materials for all the different transformation events or technique dependent sensitivity, could be overcome by further progress. However, other characteristics, such as false positives due to also naturally occurring modified sequences or false negatives due to DNA degradation seem more inherent drawbacks of the technique.

All in all, and although the introduction of Directive 2001/18/EC, when implemented, has the theoretical potential to break the present deadlock of EU approvals for new bio-engineered products, the future Regulations on traceability and labelling are likely, in practice, to impede for a few more years the appearance of bio-engineered products on the European market.

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Processing Aids In The EU: Harmonisation or Mutual Recognition: A Challenge for the Free Movement of Goods

The manufacture, marketing, distribution of processing aids are not regulated at Community level. Only two pieces of legislation deal with them: a definition of processing aids in the Framework Additives Directive and a labelling exemption for processing aids used in foodstuffs in the Framework Labelling Directive. The EC Commission is considering harmonizing enzymes used as such in foods, but the process, still at a preliminary stage, will take some years before being finalized and will not affect the status of the processing aids other than enzymes. For now, all processing aids, including enzymes, remain therefore governed by national laws.

However, although EU Member States are entirely free to regulate domestic products as they wish, they are bound by EU obligations when it comes to imported products and, in particular, by the free movement of imported processing aids and the mutual recognition of national standards in force in the other Member States. They may only restrict the circulation of imported products when they successfully demonstrate on a case-by-case basis that health risks are associated with the imported products at stake. In fact, all

Member States, with the notable exception of France, consider that there is no need for legislation on processing aids because, by definition, such substances, where present in a food, may be only present in residual safe amounts and with no technological function. Hence, and although certain Member States (such as Denmark) have laid down specific requirements on enzymes used as processing aids, they allow their marketing under the condition that they comply with the EU definition. France, by contrast, subjects the marketing of processing aids to a prior approval procedure, which is set out in its Decree of April 15, 1912 (as amended) and built upon the presumption that any processing aids not on its national positive list present a health risk. This procedure is not only applicable to "domestic" processing aids, but also to imported products whether or not lawfully marketed in the Member State of export. Inevitably, the compatibility of the 1912 Decree with the EC Treaty was questioned by the EC Commission and the other Member States because of the unjustified trade barriers resulting there from, leading to the opening by the EC Commission of an infringement procedure against France in 1995.

Importantly also, the incompatibility of the French legislation on processing aids has now been recognized in a court case in France, in which Keller and Heckman's Jean Savigny and Rachida Semail acted in support of the local counsel for the defendants. The representatives of a French company were prosecuted for having violated the 1912 Decree by marketing yeast extracts manufactured with several processing aids (in that case, enzymes) that were not on the French positive list. However, the French Court has ruled that the French authorization procedure for processing aids put in place by the 1912 Decree creates trade barriers and stressed that French authorities failed to effectively demonstrate that the disputed processing aids endangered human health. Consequently, the Court held that the French legislation on the pre-market approval of processing aids is disproportionate and unjustified and is, thus, incompatible with the EC Treaty. This judgment was not appealed and, hence, became final on January 16, 2001.

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As long as this 1912 Decree is in force, importers of processing aids lawfully marketed in other Member States can legitimately rely on this jurisprudence and ignore the French authorization procedure. Of course, this conclusion is only valid for as long as it can be documented that the substance at stake complies with all requirements pursuant to which a substance is a processing aid within the meaning of the EU definition. In essence, it must be clear that the substance is not present in the finished product, or that it is only present in residual amount, that it does not have any technological function in the finished product and that the residues, if any, do not endanger human health. Of course, also, domestic producers of processing aids, cannot draw any advantage from this case law. Indeed, the free movement of goods does not benefit national products which are entirely governed, in the absence of EU harmonization, by national requirements, regardless of their incompatibility with the EC Treaty. As a consequence, national manufacturers are subject to reverse discrimination and unless the national authorities repeal the national requirements, nothing may remedy this reverse discrimination.

To remedy the trade barriers resulting from its application to imported products, France

has prepared a draft Decree repealing the old 1912 Decree that is expected to be formally adopted by end of June 2001. In essence, the future Decree aims at maintaining a pre-market approval system for processing aids, whether domestic or imported. It sets up the list of the categories of processing aids. A draft order implementing this future Decree also finalized details of the administrative and technical data that must be provided for any marketing authorization application. The main novelty of this future Decree is the inclusion of a so called mutual recognition clause. Pursuant to the French clause, imported processing aids will freely circulate in France provided that they have been subject in the Member State of origin to a risk assessment ensuring a safety level equivalent to the one put into place by the future Decree. Operators will have six months from the entry into force of the new Decree to comply with its requirements.

The French mutual recognition clause introduced in the legislation departs fundamentally from the mutual recognition clause as affirmed and interpreted by the European Court of Justice (ECJ). Indeed, the mutual recognition principle as issued by the ECJ requires that Member States accept the marketing on their territory of imported goods under the sole condition that the latter have been lawfully marketed in the Member

State of origin. It does not subject the effectiveness of the mutual recognition of national laws to the condition of equivalence of national laws. This is not necessary since national authorities have always the right under article 30 of the Treaty to adopt safeguard measures. While the mutual recognition principle puts the burden of proof of the health risk on Member States, the French clause places it on the operators. In our view, because there are no national equivalent procedures in the other Member States, the French pre-market approval with a mutual recognition clause that in effect will not be applicable remains excessive and thus disproportionate and unjustified. Consequently, like the 1912 Decree, the future Decree should be regarded as violating the Treaty, but should be valid as regards French products. Under such circumstances, if adopted with this conditional mutual recognition clause, importers of processing aids should have detailed grounds to challenge its compatibility with the EC Treaty.

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Advertising to Children: a Matter of National Competence but for How Long?

The debate on the need for strict regulations on advertising to children has come into the spotlight this year under the Swedish Presidency of the EU. Talks of regulating advertisements for children at EU level have been tentatively held and although no specific EU initiative is currently foreseen, the revision of general advertising rules, notably under the TV Without Frontier Directive (TWF Directive), is likely to fuel the debate.

At the moment there is no harmonized legislation regulating specifically advertising to children at EU level and member states have taken different approach towards the issue. The type of measures adopted by members states range from an outright ban on TV ads for children toys in Greece, or strict rules on TV ads for children under 12 in Denmark and even a ban of such ads in Sweden, to the absence of any specific regulatory measures and the reliance on self-regulation or Codes of practice developed and enforced by Industry as in the Netherlands or by Statutory Authorities, as in the UK.



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At EU level, the TWF Directive (Directive 89/552/EEC as amended) is the main legislation that addresses the issue of children advertising by setting rules regarding the possibility and length of ads in children TV programmes (article 11-4) and providing for the protection of minors against pornography and gratuitous violence (article 22). This Directive is to be reviewed in 2002 and the Commission has launched a series of studies to evaluate its implementation and efficiency, notably in view of new media developments. In 1999, the Commission released a study on parental control of TV broadcasting, followed up in October 2000 by a study on parental control in a converged communication environment. These reports led the Parliament to adopt a report calling for an EU wide self regulatory Code. Then in 2001, a study on the impact of TV advertising and teleshopping on minors was issued. The TWF Directive is complemented by the 1997 Commission Green Paper and subsequent 1998 Council Recommendation (Recommendation 98/560/EC) on the protection of minors and human dignity, that sets guidelines for national legislation and advocates the development of parental control tools and self-regulation for on-line services. An evaluation report on the implementation of

the Recommendation by member states, issued by the Commission in February 2001, has highlighted the satisfactory recourse to self-regulation. These studies and reports will serve as a base to launch the debate on the revision of the TWF Directive and the broader issue of new media regulation.

The Commission has indicated no intention to go forward with regulating children advertising at EU level, and seems to favour relying on self-regulation where possible. However, the future review of the TWF Directive and the outcome of the study on development of new advertising techniques, expected early 2002, may trigger a change of attitude towards the need to regulate advertising to children in various media. The forthcoming Presidency of the Union by Denmark and Greece, in the second half of 2002 and first half of 2003 respectively, may provide these states with an opportunity to re-launch the debate and advocate a more restrictive approach at EU level.

The controversy over the need for strict and extensive regulation versus the efficiency of self-regulation goes beyond the issue of advertising to children and must be read in the wider context of the regulation of marketing practices between consumers and

businesses, in particular with the development of e-commerce. The Commission's current work programme for 2001/2002 foresaw the adoption in February 2001 of a Communication on a general framework on "fair trading" that would examine the possibility to provide a coherent approach to regulate marketing practices between consumers and businesses. It also planned the adoption of a proposal for a Directive on a general duty to trade fairly in November 2001. If adopted, such a scheme would have a broad impact, as it would apply to all relations between businesses and consumers. Both initiatives are still under discussion within the Commission services and the idea of a general framework on fair trade has already triggered criticism from Industry. Concerns have been voiced over the possible overlapping of such a scheme with existing rules regulating specific marketing practices, such as the E-commerce Directive (Directive 2000/31/EC), the TWF Directive and the Distance Selling Directive (Directive 97/7/EC).

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Slovak Legislation on Cosmetic Products: Towards Harmonization with EU Rules

Slovak Republic's Ministry of Health and Ministry of Agriculture have jointly adopted a new cosmetic legislation – Decree of 15th December 1999 No. 4312/3/1999-100 – forming the Chapter on Cosmetic Products of the Food Codex of the Slovak Republic. The Decree, which had to come under the Food Codex because the Act N° 152/1995 on Foodstuffs also covers cosmetic products, entered into force on 1st of March 2000 and is in fact the first ever piece of legislation in this field. Further, because of that specific structure of the Slovak legislation, amendments to the regulations laying down pre-market requirements for food products have also had to be introduced for cosmetics so that such products are now exempted from mandatory conformity assessment. Indeed, since 1 February 2001, requirements in terms of certification or approval procedure have been repealed for all cosmetic products, except "new cosmetic products": Article 2(2) of the Decree provides an exhaustive list of cosmetic types/categories and specifies that any product that does not fall under any one

of those categories, must be approved by the Ministry of Health prior to its placing in the market. Although the new legislation is generally in line with EU Cosmetics Directive, quite a few discrepancies remain, mostly related to labelling, the major part in the legislation.

- Probably a legacy of the framework Act on Foodstuffs (its Article 9 sets the obligation to put the production date on the label of the product) the new legislation requires that indication as well for cosmetics
- The trade name of the cosmetic product must contain an indication of the "category" name as laid down in article 2 (2) of the Decree. How that specific labelling requirement will apply to those so-called "new cosmetic products" (subject to pre market clearance by the Ministry of Health under Article 19 (3)) of the Decree

remains to be clarified

- The requirement to declare the name of the producer, distributor or importer will trigger confusion as to its interpretation: it is indeed stipulated that such declaration must be made "according to the record in "Trade Registry". How foreign producers who do not otherwise carry out business in the Slovak Republic – and have accordingly no record in the Trade Registry - will be expected to meet that requirement remains to be clarified as well
- Unlike the EU, the quantity declaration requirement provides no exemption for products with content lower than 5 ml/g, free samples and single application packs, which is likely to cause problems with the labelling of such small products

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- Although ingredient declaration may be carried out using INCI nomenclature, the word “ingredients” itself will only be accepted in Slovak language
- Exemptions from labelling requirements set out in article 15 are worded differently compared to their EU counterparts: the Decree states that “Small consumer packages, the surface of which is smaller than 25 cm², need not to be labelled for batch identification, instructions for use and list of ingredients.

Besides the labelling provisions in the Decree, that shall fully enter into force on 1st January 2002, consistent with the temporary allowance to permit the marketing of products labelled in compliance with the previous rules, there are other requirements, already in force, that are equally not in line with the EU Cosmetic Directive, e.g. article 20 that lays down requirements for pH value of certain cosmetic products and article 21 sets forth limits for heavy metals.

It is a fact that this new legislation, although it represents significant progress towards full harmonisation with the EU, is by far not fully satisfactory. Moreover, marketing of

EU cosmetic products in Slovakia is likely to be further restricted by the coexistence of not less than two governmental bodies dealing in the Slovak Republic with inspection and enforcement, paving the way for different interpretation and enforcement, and leading ultimately to trade barriers.

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