

EUROPEAN FOOD SAFETY AUTHORITY AND THE JUDICIAL REVIEW OF ITS SCIENTIFIC OPINIONS AND ADMINISTRATIVE ACTS

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Abstract: *The main goal of this paper is to provide a narrative account of the historical evolution of European Food Safety Authority and of EFSA's role in regulating European Union Food Law. Although EFSA hasn't been vested with regulatory power, its scientific opinions are likely to acquire a de facto legal binding value for the European Commission or Member States' legislative authorities when regulating. In this context, this paper also questions if EFSA's scientific opinions and administrative acts may be challenged before European Courts.*

Key words: *European Union, EFSA, food safety.*

1. Introduction

Triggered by a number of major food scandals, European and national food safety policies and regulatory structures were the subject of profound reforms. Following on the loss of confidence in European regulatory institutions caused by the BSE crisis, European Food Safety Agency (EFSA) was created as part of a general revision of the EU framework of food safety regulation through the adoption of the Regulation 178/2002 EC of 28 January 2002, considered the main source of "General Food Law".

The regulation defines the role of EFSA mainly as the responsibility of issuing scientific opinions and providing scientific and technical support to the Commission, whereas all functions of evaluating socio-economic concerns and political decision-

making remain with the Commission and its interaction with the Member States through the comitology procedure.

From its beginnings, EFSA was conceived as an independent agency entrusted with tasks mainly confined to *risk assessment* and *communication* whose main objective was to ameliorate the confidence of the consumer and of any other interested party in the European food safety system. The other important tasks, such as *risk management*, legislation and control, are left to European Commission.

In dealing with EFSA's scientific opinions and decisions reviewability, the main topic to be debated in the present essay, we should observe the economical and political context from which arrived the necessity of creating such specialized agency. Therefore, in the following, we'll point out all the remarkable moments in

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evolution of EU food law and development of European Food Safety Agency, EFSA's characteristics and main objectives, all these for creating the background required in understanding a very disputable juridical problems: can be EFSA's scientific opinions and administrative acts challenged in front of the European courts?

2. Historical Evolution of Food Safety Regulation in European Union

The Treaty of Rome signed in 1957 did not provide any guidance for food regulation because a major objective for the EC was freedom of movement of foodstuffs. Still, several years afterwards, recognizing the need to harmonize food laws, the EC issued some compositional directives. These directives, applied only to particular ingredients, including sugars, jams, chocolate products, and preserved milks, created the first EC standards of composition for certain foodstuffs. Ultimately, this formula failed because the differing culinary cultures of the Member States [1].

In 1985, the EC generated a new approach. Instead of trying to harmonize all of the food regulations, it decided to use labeling to indicate the differences in composition and production methods, allowing thus consumers to make an informed decision [2].

In the late 1980s and throughout the 1990s, the European Union was struck by several food scandals. Especially the BSE crisis induced major reforms in several national regulatory arrangements of food safety and also within the Union. The BSE crisis "created a window of opportunity for the development of a more internally integrated food safety policy (and consumer health policy in general)" [3].

The BSE crisis put the regulatory regime in Great Britain and on the European level

under pressure. Both the British government and the European institutions were confronted with severe accusations. Among other aspects, a lack of relevant expertise in committees, the systematic exclusion of critical scientists, lack of timely release of information to the public, and the blending of science and politics were criticized [4]. While the British "BSE Inquiry" of 1997 reached quite modest conclusions, the inquiry report by the European Parliament even suggested misinformation and political pressure by the British government in order to prevent further investigations and major drops in consumer demand for British beef.

To BSE crisis, other topics for public debate were joining, such as genetically modified food, "functional food", not to mention the growing interdependence in food trade both in the European internal market and in global trade. All these were major factors contributing to the need for reforming EU food system.

In this context, the regulation of food safety has become a key factor in modern consumer policies, both in the EU and in the member states.

As the member states felt that a more coherent European approach to food safety would be necessary to secure a high level of protection for consumers as well as the functioning of the Common Market, the General European Food Law (GFL) was adopted in early 2002. Accordingly, the organization of science and expertise was one of the major issues in the reform of the European system of food safety. The Commission issued a Green Paper (1997) and White Paper (2000) on food safety which eventually led to the introduction of the General Food Law (Regulation (EC) 178/2002).

By Regulation (EC) 178/2002, the European Food Safety Agency (EFSA) was established which provides expertise and coordinates European risk

assessments. The responsibility for food safety was transferred from the Directorate-General Agriculture to the newly established DG Health and Consumers, thus separating the promotion of industrial interests and consumer interest. Food safety as part of public health became a horizontal issue which has to be considered in all EU policies.

On the national level, responsibilities were equally rearranged and several independent agencies were founded.

In the European case and in many national cases, risk assessment as scientific process was separated from risk management as political process.

3. European Food Safety Agency

As already mentioned above, food safety regulation in the EU has undergone tremendous changes since the mid-1990s. The strong call for an "agency solution" [5] and for a cross-cutting, "integrated policy approach" to food safety [6] was the dominant political response to the crisis. Based on the theoretical approaches on regulation and agency, in the following we shall establish the characteristics of this European agency.

The European Food Safety Agency (EFSA), based in Parma/Italy, was founded in 2002. The key legal document, "Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety" (Regulation (EC) 178/2002), gives a detailed outline of EFSA's structure and its tasks.

EFSA lacks **regulatory competencies**. As already mentioned, EFSA's task is exclusively focused on risk assessments. The whole legislative competence is reserved for the Commission and the

Regulatory Committees in the comitology process, and to a lesser extent also to the Council and Parliament. Monitoring and enforcement tasks lie with the Food and Veterinary Office (FVO) on the European level and with national bodies in the member states.

The main motif for not giving EFSA regulatory competences was generated by the fear to establish a scientifically supreme body on the European level. In the same time, there was also expressed explicitly the need to take the separation of risk assessment from risk management seriously, as stated in Article 3 of the founding Regulation (EC) 178/2002.

The **administrative independence** of EFSA is one of the main founding principles in order to avoid any bias by industrial or national interests. EFSA's main steering body is the Management Board. It establishes the internal rules of procedure and the budget code, elects the Executive Director, appoints the members of the scientific committees, steers the work of the agency by deciding on the annual work program and the multi annual strategic plan, and influences the operational work by deciding on the budget and staff of the agency. The Advisory Forum fosters the coordination and information exchange between the European and national level [7]. As provided by Regulation (EC) 178/2002, Art. 27 paragraph (1): the members are supposed to be based in "competent bodies in the Member States which undertake tasks similar to those of the Authority". For the networking function of EFSA, the Advisory Forum takes a key role.

Regarding the **scientific independence**, EFSA does not have its own scientific staff. All scientists directly employed by the EFSA are situated in the secretariat and are only supposed to assist the scientific committees. By public advertisement on

the internet, experts can apply for positions in one of the scientific committees. This has a double function of constantly exchanging the scientific experts and conciliating the member states by clarifying that there is no genuine "European" expertise based in an independent agency. Rather, the experts are regarded as national ones.

Concerning **transparency and participation of the public**, within its founding regulation EFSA was given strict rules concerning publication of documents. The very comprehensive archive of documents, requests and conducted risk assessments on the web page of EFSA demonstrates the authority to take these rules seriously. For organized interests, the Stakeholder Consultative Platform offers access. This body is composed of various European associations and is regularly re-elected. For non-organized interests, there is the chance of being brought forward in the public consultations which are launched on important issues. These calls for opinions are regularly used by individuals but also by the member states and other institutions. Hardly any other food safety agency publishes as much of its work and communicates to the public more transparently than EFSA.

4. EFSA before European Courts

The general food regulations Regulation (EC) No 178/2002 does not settle expressly the possibility of submitting the acts emanating from EFSA to legal review.

A role for European courts can be foreseen in the area of contractual and non-contractual liability of EFSA under the provisions of Art.47 of the constituent Regulation that expressly establishes the jurisdiction of the European Courts. As for EFSA administrative acts, opinions or any other scientific advice, the question related to the possibility of challenging them

before European courts can find its answer in the rules relating to actions of annulment provided by Art.230 of EC Treaty.

Still, in examining which acts emanating from EFSA can be subject of an action for annulment we must differentiate between EFSA scientific opinions and EFSA administrative decisions.

With regard to EFSA **scientific opinions**, the application of the general rule related to action for annulment under the provisions of Art.230 of EC Treaty is not quite explicit but this possibility can be foreseen under an extensive interpretation of the above mentioned article.

It is no doubt that Art.230 of EC Treaty does not contain any explicit reference to the acts issued by EFSA or by any other European agency. Thus, according to Art.230 paragraph 1: "the Court of Justice shall review the legality of acts adopted jointly by the European Parliament and the Council, of the Commission and of the ECB [European Central Bank], other than recommendations and opinions, and of acts of the European Parliament intended to produce legal effects vis-à-vis third parties". As we can notice, Art.230 of EC Treaty refers to specific acts issued by specified bodies or institutions. Appliance of a restrictive interpretation of this article would lead to the conclusion that EFSA acts are not subject of an action of annulment. Still, this obstacle *per se* would not appear insurmountable under the light of European Court of Justice case-law. ECJ has shown in the past that it is ready to interpret broadly the category of acts reviewable under Art.230 EC. Let's take the Case 294/83, *Les Verts vs. Parliament* or Case 193-4/87, *Macerrissen vs Courts of Auditors*. In these judgments, the ECJ considered that insofar as the Community is based on the rule of law, acts not mentioned in Art.230 of EC Treaty are capable of forming the subject of an action

for annulment [8].

In the light of this argument, there is still a problem: EFSA can be hardly assimilated to the institutions and bodies referred to in Art.230 of EC Treaty. More than that, EFSA scientific opinions were described by ECJ as “preliminary or purely preparatory acts”, “a procedural step in an ongoing decision-making process” [9]. Therefore, they would not seem to fall within the category of acts which can be subject to an action for annulment.

Not being addressed to any individual, scientific opinions could not be assimilated into Community decisions, but fall within the scope of paragraph 4 of Art.230 EC Treaty. Under the provisions of Art.230, judicial persons can easily challenge the legality of Community decisions when these decisions are addressed to them. However, the same article provides for a very demanding *locus standi* requirement when the challenged act is not a decision [10]. Under the provisions of Art.230 of EC Treaty, paragraph 4, an individual may institute proceedings against other acts only when these are of direct and individual concern.

Despite this argument, all the cases in which EFSA scientific opinions were subject of appeals were dismissed by ECJ, the main argument being that these opinions are only an intermediate stage of a procedure intended to result in the adoption of a final decision.

Without intending to question ECJ judgments, we think that EFSA’s role among EU institutions and agencies should be reconsidered. As we have already mentioned before, EFSA’s main task is risk assessment, this task has acquired a central importance in economic and risk-generating activities. EFSA was endowed with extensive competences in this regard, as it can be brought to intervene in all fields having a direct or indirect impact on food and feed safety, as well as human

nutrition, animal health and welfare, plant health and GMOs. The general food regulation has established that risk management shall take into account the results of risk assessment and in particular the opinions of EFSA. Some recent food regulations explicitly require the Commission to take EFSA opinion into account and, if Commission’s draft decision is not in accordance with the opinion of EFSA to provide an explanation for differences. In this light, we do not mistake when we consider that EFSA scientific opinions are if not legally binding, they have a tremendous impact on the decision-making process.

With regard to EFSA administrative acts and the possibility of challenging them before European courts, we shall take into consideration the related ECJ case-law. In the case T-69/05 *Evropaiki Dynamiki SA vs. EFSA*, the former party applied for annulment of the decision of the European Food Safety Authority (EFSA) of 3 December 2004 rejecting the tender submitted by the applicant in the tendering procedure concerning the supply of IT services for establishing an extranet between Member States’ national agencies, the EFSA and the Commission, and also of the decision to award the contract to another tenderer. The Court of First Instance concluded that there was no need to adjudicate in this case since the call for tenders was cancelled by EFSA before the lodging of the application. Still, the Court of First Instance observed that “the fact that the applicant could no longer succeed by means of this action for annulment and would probably be time-barred from bringing a new action for annulment of the decision taken by EFSA following the cancellation of the disputed call for tenders does not preclude it from submitting, if appropriate, an application for compensation of the damage which it might claim to have incurred as a result of

the allegedly unlawful conduct of EFSA throughout the contested tendering procedure” [11].

This judgment of the Court of First instance does not exclude the possibility of challenging EFSA administrative acts. Therefore, the possibility of an action for annulment against EFSA administrative acts cannot be excluded in the future.

5. Conclusions

Even if there is a lack of a textual basis for arguing in favour of the judicial reviewability of EFSA scientific opinions and administrative acts, still the contemporary reality should not exclude this possibility.

In our opinion, an extensive interpretation of the principle settled by Art.230 of EC Treaty can offer an effective judicial protection in this case. Otherwise, it is the European courts duty to clarify the rules governing judicial review of EFSA scientific opinions and administrative acts.

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