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JUDGMENT COMMENTARY: JUDGMENT OF 13 DECEMBER 2013, T-240/10 - HUNGARY V COMMISSION ("AMFLORA POTATO")

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Summary:

ABSTRACT

The subject matter of this commentary is a judgment concerning the annulment of two Decisions adopted by the European Commission in 2010. These authorised the marketing of a variety of genetically-modified potato and the marketing of feed produced from the same, respectively[1]. The Court awarded a judgment against the Commission and declared both Decisions null and void, as they contained

[1] Commission Decision 2010/135/EU of 2 March 2010 concerning the placing on the market in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a potato product (Solanum tuberosum L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch (OJ 2010 L 53, p. 11). And Commission Decision 2010/136/EU of 2 March 2010 which authorised the placing on the market of feed produced from the genetically modified potato EH92-527-1 (BPS-25271-9) and the adventitious or technically unavoidable presence of the potato in food and other feed products under Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ 2010 L 53, p. 15).

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infringements of essential procedural requirements pursuant to Articles 263 and 264 of the Treaty on the Functioning of the European Union (TFEU).

The judgment pursuant to well-settled case law of the Court of Justice is about that constitutes a ground said to be of 'public policy', which must be raised by the judicature of the European Union of its own motion[2].

The road that led to the two decisions being annulled was long and extremely complex, since the development of the referred legislative acts——given their object and scope of application—required a myriad of reports and scientific opinions. What was at stake was the protection of the environment and the health of the people living in the EU.

The risk assessment carried out by scientific and technical bodies is inseparable from the risk management conducted by political institutions, as the latter cannot be understood without the former, and the former is an integral part of the latter. The decision about risk management (the placing on the market of the genetically modified potato and the feed produced from it) should be based on, or motivated by, the assessment previously made by the scientific bodies (in this case, the risk involved in the transfer of genes that confer resistance to antibiotics caused by the genetic modification of this product[3]). The 'Amflora'[4] potato is the product authorised—and now prohibited—by the annulled decisions in the Judgment forming the subject matter of this commentary.

The overlap of these two risk management phases in the EU have caused a series of malfunctions, political deadlocks, moratoria, and safeguard clauses that have turned Europe into a heterogeneous space as far as plant biotechnology is concerned, as it operates at various different speeds. Consequently, since 2010 it has been almost impossible to change the regulatory framework, despite the need for a revision. As of today, six Member States (Austria, Hungary, France, Greece,

[2] Case C 367/95 P Commission v Sytraval and Brink's France [1998] ECR I 1719, paragraph 67; Case C 265/97 P VBA v Florimex and Others [2000] ECR I 2061, paragraph 114; Joined Cases T 228/99 and T 233/99 Westdeutsche Landesbank Girozentrale and Land Nordrhein-Westfalen v Commission [2003] ECR II 435, paragraph 143 and the case-law cited. The same goes for lack of competence, within the meaning of that article (see, to that effect, Case 19/58 Germany v High Authority [1960] ECR 225, 233; Case C 210/98 P Salzgitter v Commission [2000] ECR I 5843, paragraph 56; Case T 147/00 Laboratoires Servier v Commission [2003] II 85, paragraph 45).

[3] Facts (point 16 of the Judgment): The genetic modification involves introducing into the genome of the Amflora potato a gene known as 'nptII' (neomycin phosphotransferase II) (the 'nptII gene'). The nptII gene belongs to the category of antibiotic resistant marker genes ('ARM genes').

[4] Trade name of the product that the chemical company BASF sought permission to market. The company produces a range of products from chemicals to plastics performance materials, crop protection products through to oil and natural gas.

Germany and Luxembourg) have taken safeguarding measures and have prohibited the cultivation of genetically modified maize [5] in their territories. Austria, Luxembourg and Hungary have also notified the Commission of the prohibition of the cultivation of the 'Amflora' potato. Poland currently has legislation in place that prohibits the marketing of all types of genetically modified seeds.

Nevertheless the 2010 approval of Amflora was a surprise to many observers, as it was only the second time a genetically modified plant had been approved for cultivation in the EU. It was followed by angry responses from environmental campaigners and consumer groups opposing the technology. BASF is one of the biggest key actors in the European and global biotechnology sector and due to lack of acceptance of GM crops in Europe BASF Plant Science decided in 2012 the stop of its commercialization and research activities on the European potato varieties Amflora and others. Further it announced the relocation of the corporate headquarters from Germany to the USA.

I. LEGAL CONTEXT

Firstly, the Judgment lays out the legal framework for the case and summarises the different rules and regulations involved. The legal context consists of two sets of rules: on the one hand, all those concerning the scheme for authorising the marketing of genetically modified organisms (GMOs), and on the other hand, the regulations governing the regulatory procedure.

The first set of rules is fundamentally comprised of two legislative acts: the first relating to the intentional release into the environment of GMO in general[6], and the second specifically related to genetically modified food and feed[7].

Any applications submitted under the Directive and the Regulation must be referred to different scientific committees for risk assessment purposes. Comitology is well known and widespread in the scientific sphere. Scientific advisory committees provide policy-makers, regulators and legislative bodies with a high level of experience in highly technical areas and contribute to them being independent of vested interest.

[5] Maize MON810.
[6] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ 2001 L 106, p. 1).
[7] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ 2003 L 268, p. 1).

The legal framework is summarised in the table below, including the Committees involved in the regulatory procedure concerning the case:

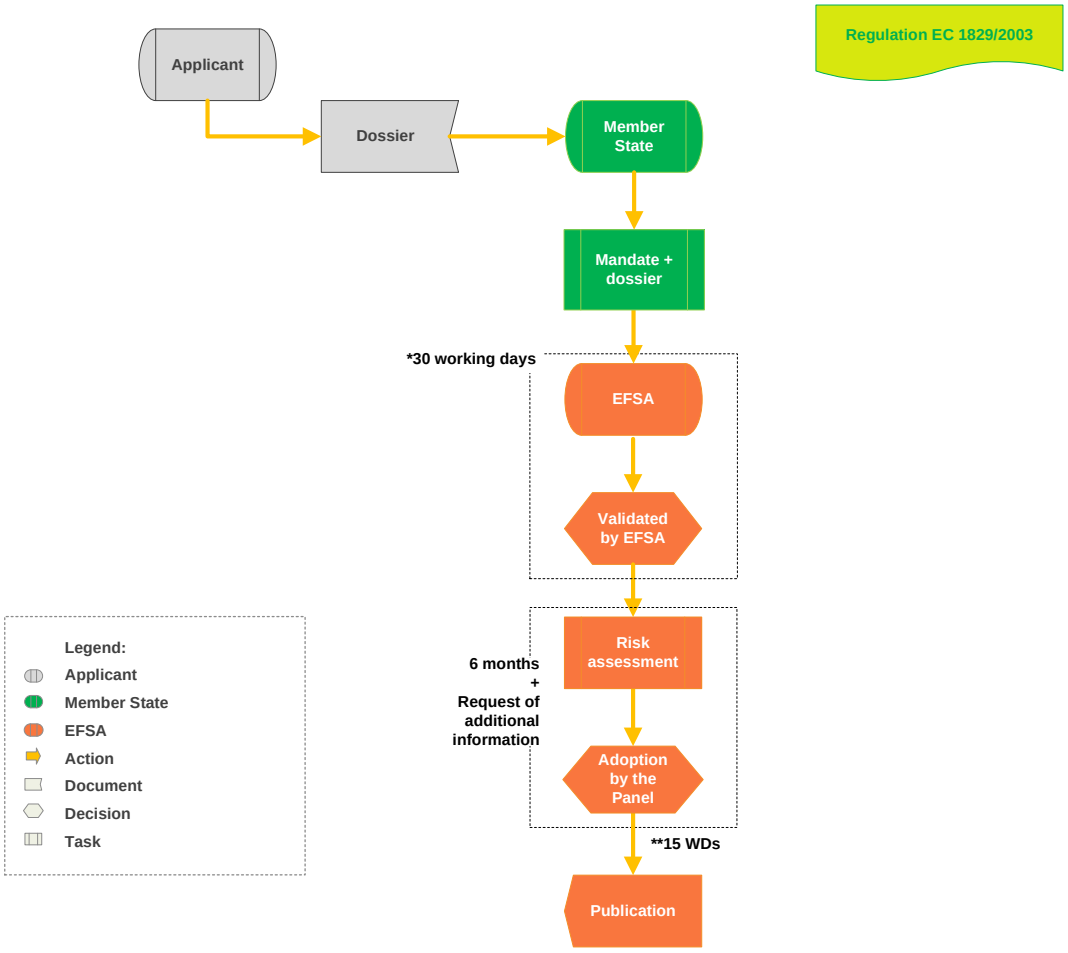
Scheme for authorising the marketing of GMOs	
Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ 2001 L 106, p. 1).	Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ 2003 L 268, p. 1).
Regulatory Procedure	
Council Decision 1999/468/EC, as amended by Council Decision 2006/512/EC. 'Regulatory procedure'. 'Comitology' Decision.	Regulatory committees competent to take part in the Commission's exercise of the implementing powers conferred upon it: REGULATORY COMMITTEE ON THE DELIBERATE RELEASE OF GMOs INTO THE ENVIRONMENT (Art. 30.1 DIRECTIVE 2001/18/EC). STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH (Art. 35.1 REGULATION (EC) No. 1829/2003).

The principle underlying the harmonised procedure in Directive 2001/18 (Articles 13 to 19) is that the competent authority of a Member State, having received a notification from a company together with an environmental risk assessment, takes the initiative of issuing consent, in relation to which the competent authorities of the other Member States, or the European Commission, may make their observations or objections known.

Company notification + ERA* ↓ MEMBER STATE authorisation * Environmental Risk Assessment	The competent authorities of the MEMBER STATES or the EUROPEAN COMMISSION may object	Objections: EU procedure in case of objection: decision within 120 days in accordance with the 'Committee' procedure (Comitology)

The Regulation establishes a special single scheme, as opposed to the harmonised general scheme of Directive 2001/18, relating to the authorisation of genetically modified food (Chapter II) and genetically modified feed. Under that single scheme, the application for authorisation is directly assessed at EU level, following consultation with the Member States, and the final decision on the authorisation lies with the Commission, or, where applicable, the Council of the European Union.

The following chart shows a summary of the steps taken in this scheme, focusing on the risk assessment sub-process carried out by the European Food Safety Authority (EFSA).



Source:
http://www.efsa.europa.eu/en/gmoapplicationshelpdesk/appworkflowgmo.htm
* EFSA: aims to provide its 1st feedback on the Completeness check within 30 working days after reception of the application (Mandate + Dossier).
** EFSA aims to publish the opinion within 15 working days after its adoption.

The existence of two legislative acts (the Directive and the Regulation) in the approval of a GMO for use as a seed has been seen to highlight the fact that the EU has abandoned its original strategy for implementing provisions for the regulation of GMOs, which consisted of the approximation of laws and harmonisation by way of Directives. After Regulation (EC) 1829/2003 entered into force, the approval of a GMO for use as a seed required the application of two regulatory schemes which authorised the marketing of the event and its varieties. However, the referred Regulation incorporated a key legal development, since it allowed the event to be approved either now or later by way of Directive 2001/18/EC, or by applying the provisions contained in the Regulation, as appropriate. This is not consistent with the strategy used by the EC in its implementing provisions, as an industry-specific rule is conferred a certain potentially horizontal rule status. This is why it has been said that the Regulation of new food and feeds allows for the authorisation of various different aspects[8].

All in all, two distinct procedures concerning the marketing of GMOs exist: one strongly Euro-centric, concerning food and feed, with the involvement of EFSA for risk assessment purposes, and the other less Euro-centric, which involves Member State authorities, for the rest of GMOs[9].

In the case under consideration, BASF initially submitted an application to the Swedish authorities through a subsidiary company, to request that the marketing of the genetically modified potato 'Amflora' be authorised for cultivation and industrial use. Given that several Member States made observations in relation to the application, the EU authorities were relied upon in order to make the final decision. BASF also initiated an authorisation procedure directly before the European Union authorities for the production of feed obtained from this potato. This last application also covered the case of unintended presence of traces of GMOs in human food and animal feed.

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[8] MANTECA VALDELANDE, V., "Nueva regulación de los transgénicos", *Unión Europea Aranzadi,* Vol. 32, Nº 6, 2005, pages 11-18. Pages 13 and 14.
The difficulties in the interpretation and coexistence of both regulations (Directive and Regulation) currently persist. An example of this can be seen in the following report: Final Report (EPEC), Evaluation of the EU legislative framework in the field of cultivation of GMOs under Directive 2001/18/EC and regulation (EC) Nº 1829/2003, and the placing on the market of GMOS as, or in, products under Directive 2001/18/EC. For DG SANCO, European Commission Main Report. March 2011. European Policy Evaluation Consortium (EPEC).
Accessible on:
http://ec.europa.eu/food/food/biotechnology/evaluation/docs/gmo_cultivation_report_en.pdf

[9] URRUTIA LIBARONA, I., "Comercialización de transgénicos y medio ambiente". In: *Libre mercado y protección ambiental. Intervención y orientación ambiental de las actividades económicas.* F. JAVIER SANZ LARRUGA, F. J., GARCÍA PÉREZ, M. and PERNAS GARCÍA, J. J. (Directors). INAP, 2013. Pages 281-316. Page 292.

Briefly the German Ministry of Education and Research provides the following information about the process taken by BASF to obtain authorization: "The first applications for approval for the newly developed potato were submitted already in 1996. In 2003, after the approval moratorium expired in the EU, a new application for the Amflora potato was filed for cutlivation, and two years later its utilisation as food and feed stuff. For the safety appraisal and approval process it was decisive that the new significantly tightened EU regulations for gene technology were then in force. However, politically there was more than one single approval application at stake. The Amflora potato would be the first genetically modified plant that had received approval in the EU since 1998. It had become a symbolic, charged issue, in which a political conflict of basic principles about green gene technology was being carried out.

After the expert panel responsible for gene technology in European food safety had assessed the Amflora potato as being safe for the environment as well as for the health of both people and animals, the start for commercial cultivation was expected in 2007.

Since the Member States could not agree with the necessary relative majority on either acceptance or rejection of the Amflora potato, according to EU law it fell to the EU commission to make the decision. However, in contrast to similar cases, the Commission hesitated"[10].

II. RISK ASSESSMENT, COMITOLOGY PROCEDURES AND LAW

Following the description of the legal context, the Court proceeded to provide details in chronological order about all of the statements[11] and opinions of the scientific bodies concerned in the case as Facts[12]. In summary, it was explained that, after receiving favourable opinions from the EFSA, the Commission submitted some authorisation proposals to the committees and later, in the absence of opinions from these, to the Council, which in turn failed to make a decision. Consequently, at that time the Commission could have granted the approvals requested.

[10] Accessible from the web and sponsored by Federal Ministry of Education and Research in Germany:
http://www.gmo-safety.eu/science/potato/263.amflora-potato-industrial-applications-starch-potatoes-renewable-raw-material.html

[11] Up to 5 EFSA opinions and one opinion from the European Medical Agency (EMA).

[12] Point 17 of the Judgment under analysis established 1996 as the date when the first notification was received by the Swedish competent authority. The company waited 14 years before obtaining authorisation to market the 'Amflora' potato.

Nevertheless, other arguments arose during the authorisation procedure which sought to refute the EFSA's statements[13] and revealed inconsistencies between the different scientific opinions from the Food Authority. The Commission did not grant any authorisation and opted instead to consult the Authority again, with the aim of having those opinions clarified. In June 2009, the EFSA adopted a consolidated scientific opinion which confirmed (despite minority rulings that disagreed with its findings) that the 'Amflora' potato did not present risks to either human health or the environment. Based on this opinion, the Commission did not submit any new draft authorisation decisions to the competent committees and granted the two authorisations requested, by way of the Decisions of 2 March, 2010.

The mandate sent to EFSA by the Commission, to clarify certain inconsistencies between the earlier opinions and to reduce the pervading scientific uncertainty, by attempting to respond to the substantive objections expressed in the letters from an NGO and from the Danish Ministers, was intended to obtain a response from the EFSA to such substantive objections, which is an essential element in the statement of reasons on which those decisions were based, and carries with it an amendment of the substance of the measure and of the decision[14].

The previous paragraph made reference to the Court's decision with respect to Hungary's petitions. In support of its action, Hungary submitted two pleas in law. Its principal claim rests on a manifest error of assessment and on an infringement of the precautionary principle, as well as on the breach of Article 4(2) and Annex II to Directive 2001/18, in that the GMO marketing authorisation decisions are based on a risk assessment that is deficient, inconsistent and incomplete.

Finally, it is important to highlight that the Court considers it necessary to note, as the Commission did, the 'great political sensitivity' and the 'complexity of the subject matter' of the marketing authorisation of GMOs (…). This is precisely why it is the Commission's obligation to submit the amended drafts of the authorisation decisions in relation to the 'Amflora' potato to the competent regulatory committees and, where applicable, to the Council[15]. The Commission failed to take these steps, as emphasised in the Judgment.

[13] Letters from an NGO and from the Danish Government. See Sections 34, 77, 83, 97 and 103 of the Judgment analysed in this commentary.
[14] See point 95 in the Judgement.
[15] Section 110 of the Judgment.

CONCLUSION

Whilst the comitology procedure is complex and cumbersome, there exists a legal obligation to follow it, since what is at stake is the balance of power between the institutions, and consequently, the proper functioning of the EU. Community Law on the interaction between the political institutions and bodies such as the committees provided for in the Comitology Decision are excellent examples of the rules regarding the division of powers. The Court of Justice declared in the *Vreugdenhil* judgement that 'the aim of the system of the division of powers between the various Community institutions is to ensure that the balance between the institutions provided for in the Treaty is maintained, and not to protect individuals'[16].

The comitology reinforces the supranational dimenssion represented by the Commission, rather that the intergubernamental one, traditionally attributed to the Council. This, to the extent that the national experts possition included in the committees is, in most cases, merely advisory.

This is an endless discussion that needs to be addressed and closed, as there are further outstanding authorisation requests concerning other GMOs. One of these products is maize 1507, on which the General Court of the European Union[17] has already taken a position. It declared that the Commission had failed to comply with Directive 2001/18/EC by not submitting a proposal to the Council pursuant to Article 5.4 of Comitology Decision 1999/468/EC of the Council. Three months later the Court issued a similar judgment on the 'Amflora' potato case discussed in this paper.
The ability of the administrative procedure to integrate and involve an unlimited number of agents (in this particular marketing authorization procedure for GMOs) makes it an essential to properly articulate this networking administration, the plurality of interests and data that deserve to be considered in making management complex decisions, giving satisfaction to democratic principles, policy and effective decentralization.

It is for that reason that should be further explored by administrative law in order to reflect on the current configuration of the procedure for obtaining marketing authorizations for GMOs. Is it adequate to satisfy all interests, given what happened in the case commented?; or if it is not able to cover all this networking

[16] Opinion of Advocate General Fennelly delivered on 27 January 2000 (1). (Laboratoires Pharmaceutiques Bergaderm SA and Jean-Jacques Goupil v Commission of the European Communities). Case C-352/98P.
[17] Judgement of the General Court, 26 September, 2013. In Case T-164/10, Pioneer Hi Bred International, Inc. versus the European Commission.

called (pluricentric) Administration and plurality of interests and data that deserve to be considered in making complex administrative decisions in the XXI century.