

Fact or Fiction? Case C-616/17 and the Compatibility of the EU Authorisation Procedure for Pesticides with the Precautionary Principle

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This contribution analyses whether the Court of Justice of the European Union (CJEU) provides clarifications on the normative implications that the precautionary principle entails in the context of Regulation 1107/2009, laying out the EU authorisation procedure for pesticides, in its recent judgement in Case C-616/17. In this judgement, which is a response to a request for a preliminary ruling by a French criminal court on the compatibility of certain aspects of Regulation 1107/2009 with the precautionary principle, the CJEU concludes that the questions of the referring court reveal nothing capable of affecting the validity of the regulation. According to the CJEU, to ensure conformity with the precautionary principle, the EU legislature must establish a normative framework that makes available to competent authorities sufficient information to adequately assess the risks to health resulting from the pesticide in question. However, the CJEU's substantive analysis of the compatibility of the different aspects of Regulation 1107/2009 with the precautionary principle is not conducted concretely in light of this legal standard, but constitutes a mere testing of the general adequacy of Regulation 1107/2009. Furthermore, the CJEU's judgement examines Regulation 1107/2009 in a vacuum without considering problems that have occurred in its implementation or application.

I. INTRODUCTION

The circumstances leading to the request for a preliminary ruling in Case C-616/17¹ are rather curious: a number of individuals were charged with criminal offences for entering and causing damage to weed killer products containing glyphosate in a shop in Ariège, France. Before the Tribunal Correctionnel de Foix (Criminal Court of Foix or referring court), the defendants argued that their acts were meant to serve to warn shops and their customers about the dangers of weed killers containing glyphosate, to prevent sales of glyphosate products as well as to protect public health and their own health. The defendants raised necessity and the precautionary principle as defences and requested

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¹ Case C-616/17 *Blaise and others* [2019] EU:C:2019:800.

the Criminal Court of Foix to refer questions on the legality of Regulation 1107/2009 concerning the placing of plant protection products on the market² to the Court of Justice of the European Union (CJEU or Court).³ This was accepted by the public prosecution as it found that the legality of Regulation 1107/2009 may affect the legal foundation of the prosecution of the defendants.⁴ The Criminal Court of Foix thus referred to the CJEU questions on the compatibility of Regulation 1107/2009 with the precautionary principle as regards four particular aspects related to risk assessment: the lack of definition of the concept of “active substances”; the insufficient consideration of cocktail effects in the authorisation procedure of plant protection products; the scientific evidence of the safety of the products being submitted by the applicant intending to place the product on the market; and, finally, the exemption of the authorisation application for plant protection products from long-term toxicity and carcinogenicity tests.

There are a few aspects of the judgement of the CJEU’s Grand Chamber in Case C-616/17 that would be worth a more detailed discussion: first, the judgement is a continuation of the saga around glyphosate, the “omnipresent”⁵ pesticide that appears to divide politicians and scientific bodies, occupies courts, concerns the public and ultimately casts major doubts on the viability of the European Union (EU) authorisation procedure for pesticides in Regulation 1107/2009 to protect public health and the environment. Another interesting element of this judgement is the circumstances of the request for a preliminary ruling, the Court’s acceptance of the latter and the peculiar situation of a national criminal court expressing doubts as to the legitimacy of an EU regulation on the placing on the market of pesticides. This article, however, will focus on the CJEU’s testing of the compatibility of Regulation 1107/2009 with the precautionary principle. As will be explained, the concept of the precautionary principle in EU law is subject to ambiguities, due to which the concrete normative implications that the principle entails are not certain. In this article, the extent to which the Court provides clarifications on the normative implications of the precautionary principle in the context of Regulation 1107/2009 will thus be analysed.

As a first step, this article will provide a brief description of the authorisation procedure for pesticides in Regulation 1107/2009, followed by an overview of the legal status and definition (or lack thereof) of the precautionary principle in EU law. The article will then move on to analyse the CJEU’s judgement in Case C-616/17 by first examining what are, in the view of the Court, the obligations that the precautionary principle poses to the legislature in the context of Regulation 1107/2009. The findings of the Court as to the compatibility of Regulation 1107/2009 with the precautionary principle will then be analysed to finally present two observations on the reasoning of the Court.

² Regulation (EC) No 1107/2009 of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC [2009] OJ L309/1.

³ *Blaise and others*, supra, note 1, para 28.

⁴ Case C-616/17 *Blaise and others*, Opinion of Advocate Sharpston [2019] EU:C:2019:190, para 33.

⁵ European Parliament, “EU’s Pesticide Risk Assessment System: The Case of Glyphosate” (Study for the ENVI COMMITTEE 2016) <[https://www.europarl.europa.eu/RegData/etudes/STUD/2016/587309/IPOL_STU\(2016\)587309_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2016/587309/IPOL_STU(2016)587309_EN.pdf)> (last accessed 26 February 2020).

II. THE EU PESTICIDE AUTHORISATION PROCEDURE IN REGULATION 1107/2009

The EU authorisation procedure for the placing on the market of plant protection products – commonly referred to as pesticides – is set out in Regulation 1107/2009. Among the objectives of the regulation is to lay down harmonised rules on the placing on the market of plant protection products as well as their use and control and to thereby ensure a high level of protection of human and animal health as well as the environment.⁶ Pursuant to recital 8 and Article 1(4) of Regulation 1107/2009, the precautionary principle is to be applied and is underpinning the regulation. Regulation 1107/2009 lays down a prior authorisation system, according to which substances can only be placed on the market if approved or authorised, whereas the burden of proof is on the applicant to establish that the active substance or plant protection product does not have harmful effects on human or animal health or unacceptable effects on the environment.

The authorisation system in Regulation 1107/2009 follows a hazard-based approach. This means that in an assessment of a respective substance, the latter is tested for certain harmful properties, such as carcinogenicity, and in the case of a harmful property being found, it will not be authorised.⁷ This stands in contrast to a risk-based approach, according to which a substance could, despite its harmful properties, still be authorised if its harmful properties are low, manageable or simply worth accepting due to the benefits that the substance in question provides.⁸ However, Regulation 1107/2009 allows for the approval of an active substance that does not satisfy the necessary safety criteria for a limited period if the substance is necessary to control a serious danger to plant health that cannot be contained by other available means.⁹ In addition, the approval of an active substance (as well as of safeners and synergists) may be made subject to certain conditions and restrictions, such as the manner and conditions of application.¹⁰

Regulation 1107/2009 lays down a centralised EU-wide approval procedure for active substances (the active components operating against pests and plant diseases),^{11,12} safeners (substances added to plant protection products to eliminate or reduce phytotoxic effects)^{13,14} and synergists (which can give enhanced activity to active substances).^{15,16} There is a separate authorisation procedure at the Member State level for plant protection products, which are products in the form in which they

⁶ Art 1 of Regulation 1107/2009, *supra*, note 2.

⁷ E Bozzini, *Pesticide Policy and Politics in the European Union, Regulatory Assessment, Implementation and Enforcement* (Palgrave Macmillan 2017) at p 30.

⁸ *ibid.*

⁹ Art 4(7) of Regulation 1107/2009, *supra*, note 2.

¹⁰ Art 6 of Regulation 1107/2009, *supra*, note 2.

¹¹ European Commission, “Approval of active substances” <https://ec.europa.eu/food/plant/pesticides/approval_active_substances_en> (last accessed 26 February 2020).

¹² Section 1 of Chapter II of Regulation 1107/2009, *supra*, note 2.

¹³ Art 2(3)(a) of Regulation 1107/2009, *supra*, note 2.

¹⁴ Section 2 of Chapter II of Regulation 1107/2009, *supra*, note 2.

¹⁵ Art 2(3)(b) of Regulation 1107/2009, *supra*, note 2.

¹⁶ Section 2 of Chapter II of Regulation 1107/2009, *supra*, note 2.

are provided to the user (ie compounds containing actives substances, safeners or synergists) to be used to protect plant products against harmful organisms and other related uses.¹⁷

An approval procedure for the use of an active substance, safener or synergist starts with the submission by the applicant who intends to place the substance on the market of an application for authorisation to any Member State, which acts as the Rapporteur Member State for the purpose of the authorisation procedure.¹⁸ In the application for approval, the applicant must submit information that demonstrates neither the substance nor its residues have any harmful effects on human health, including that of vulnerable groups, and animal health – taking into account known cumulative and synergistic effects – or any unacceptable effect on the environment.¹⁹ The Rapporteur Member State draws up a “draft assessment report” in which it determines whether the substance in question meets the above approval requirements.²⁰ The draft assessment report of the Rapporteur Member State is then forwarded to the European Food Safety Authority (EFSA) for it to adopt conclusions on the safety of the substance in light of current scientific and technical knowledge.²¹ Taking into account the assessment of the Rapporteur Member States and EFSA, the Commission draws up a review report and a draft regulation,²² on which the Standing Committee on the Food Chain and Animal Health takes a vote.²³

The authorisation of plant protection products takes place at the level of Member States.²⁴ The applicant of the authorisation must submit certain information to prove the safety of the product to the competent authority in the Member State. The latter conducts an assessment of the application and either grants or refuses the authorisation.²⁵ The applicant may then apply for the mutual recognition of the authorisation by other Member States under a zonal system.²⁶ Pursuant to this zonal system, the holder of an authorisation of a plant protection product in one Member State may apply for mutual recognition of the authorisation in a different Member State in the same geographical zone, as determined in Annex I of Regulation 1107/2009. In order to have a plant protection product authorised in a zone other than that in which a respective plant protection product has already been authorised, a new authorisation procedure must be initiated.²⁷

According to Bozzini, EU policy is commonly criticised for the existence of a “gap between the ambition of adopted regulations and the modesty of results on the ground”.²⁸ It appears that Regulation 1107/2009 is accused of the same by a number

¹⁷ Chapter III of Regulation 1107/2009, *supra*, note 2.

¹⁸ Art 7(1) of Regulation 1107/2009, *supra*, note 2.

¹⁹ Art 4 of Regulation 1107/2009, *supra*, note 2.

²⁰ Art 11 of Regulation 1107/2009, *supra*, note 2.

²¹ Art 12 of Regulation 1107/2009, *supra*, note 2.

²² Art 13(1) of Regulation 1107/2009, *supra*, note 2.

²³ Art 13(2) of Regulation 1107/2009, *supra*, note 2.

²⁴ Art 28(1) of Regulation 1107/2009, *supra*, note 2.

²⁵ Arts 36(1) and (2) of Regulation 1107/2009, *supra*, note 2.

²⁶ Art 40 of Regulation 1107/2009, *supra*, note 2.

²⁷ Bozzini, *supra*, note 7, 43.

²⁸ Bozzini, *supra*, note 7, 109.

of civil society and regulatory initiatives launched with the aim of improving Regulation 1107/2009. Following the controversy around glyphosate and the application of the renewal of its authorisation, a Special Committee – the PEST Committee – was set up in the European Parliament to conduct an assessment of the EU’s authorisation procedure for pesticides and to focus on, among other things, the independence of the procedure from industry and its transparency.²⁹ According to the findings of the PEST Committee, which were relied on by the defendants in the proceedings of Case C-616/17,³⁰ the EU has one of the most stringent systems for the authorisation of pesticides in the world, but “both [Regulation 1107/2009] as such and its implementation need to be improved for it to achieve its purpose”.³¹ Similarly, a coalition of stakeholders and scientists called “Citizens for Science in Pesticide Regulation” criticises that “the rules [of Regulation 1107/2009] are not implemented properly and the regulatory system is allowing private interests to be given priority over health and the environment”, and it calls for “[a] full reform of the current pesticide risk assessment and risk management systems”.³²

In another development, a European Citizen’s Initiative called for, among other things, the ban of glyphosate and the reform of the EU procedure to approve pesticides.³³ In particular, the European Citizen’s Initiative expressed concern about the reliability and transparency of the risk assessment and demanded that scientific studies in support of pesticide approval should be commissioned by public authorities and should be published.³⁴ The European Commission responded with Regulation 2019/1381³⁵ on the transparency and sustainability of the EU risk assessment in the food chain, which will be applicable as of 2021 and stipulates that EFSA is to “carry out its activities with a high level of transparency” and “make public . . . scientific data, studies and other information supporting applications, including supplementary information supplied by applicants”.³⁶ Regulation 2019/1381 is also establishing “an additional verification tool” by way of which “the Commission, in exceptional circumstances of serious controversies or conflicting results, may request [EFSA] to commission scientific studies with the objective of verifying evidence used in its risk assessment process”.³⁷ Arcuri and Hendlin argue that Regulation 2019/1381 is “a first

²⁹ European Parliament decision of 6 February 2018 on setting up a special committee on the Union’s authorisation procedure for pesticides, its responsibilities, numerical strength and term of office (2018/2534(RSO)).

³⁰ *Blaise and others*, Opinion of Advocate Sharpston, *supra*, note 4, para 82.

³¹ European Parliament resolution of 16 January 2019 on the Union’s authorisation procedure for pesticides (2018/2153(INI)).

³² “Citizens for Science in Pesticide Regulation – A European Coalition” <<https://citizens4pesticide-reform.eu/>> (last accessed 26 February).

³³ European Citizens’ Initiative: Ban Glyphosate and Protect People and the Environment from Toxic Pesticides <<http://www.banglyphosate.eu/>> (last accessed 26 February).

³⁴ “Annex to the European Citizens’ Initiative: Ban Glyphosate and Protect People and the Environment from Toxic Pesticides” <https://europa.eu/citizens-initiative/initiatives/details/2017/000002_en> (last accessed 26 February).

³⁵ Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC.

³⁶ Art 1(7) of Regulation (EU) 2019/1381, *supra*, note 35.

³⁷ Recital 25 and Art 1(6) of Regulation (EU) 2019/1381, *supra*, note 35.

step in changing the current system towards more stringent accountability and transparency”, but it “fails to meet the requests of the European citizens”.³⁸

Notably, Regulation 1107/2009, together with Regulation 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin,³⁹ is currently subject to the European Commission’s Regulatory Fitness and Performance (REFIT) programme. The REFIT programme aims to assess “the accomplishment of the objectives, the efficacy of the enforcement as well as the effectiveness of the pesticides legislation”, as well as to “identify the problems of compliance and underline which factors hinder the achievement of the objectives of the legislation”.⁴⁰

III. THE PRECAUTIONARY PRINCIPLE IN EU LAW

Pursuant to Article 191(2) of the Treaty on the Functioning of the European Union (TFEU),⁴¹ the policy of the EU on the environment must aim at a high level of protection and be based on, among other principles, the precautionary principle. The latter was added to the foundational environmental principles that are to guide environmental policies in the EU by the Maastricht Treaty⁴² in 1992. However, long before the formalisation and codification of the precautionary principle in the Maastricht Treaty, the principle was – albeit not being named as such – tacitly endorsed in the jurisprudence of the European Courts and in the legislation of the European Economic Community.⁴³

Although the only express reference to the precautionary principle in the EU treaties is made in Article 191(2) TFEU in the field of environmental policy, the scope of application of the precautionary principle is not limited to the environmental field. Article 11 TFEU stipulates that “environmental protection requirements must be integrated into the definition and implementation of the Union’s policies and activities”. Relying on the “horizontal nature”⁴⁴ of Article 11 TFEU in combination with Article 191(2) TFEU, the EU Courts extended the scope of the principle beyond environmental policy. In *Artegodan*, the Court of First Instance (CFI) found that the precautionary principle is intended to be applied in order to secure a high level of human health, environmental and consumer protection in the definition and

³⁸ A Arcuri and YH Hendlin, “The Chemical Anthropocene: Glyphosate as a Case Study of Pesticide Exposures” (2009) 30 King’s Law Journal 248.

³⁹ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC [2005] OJ L70/1.

⁴⁰ European Commission, “Evaluation and Fitness Check (FC) Roadmap” <https://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_197_evaluation_plant_protection_products_en.pdf> (last accessed 26 February 2020); at the time of writing, the adoption of the draft Report to the Council and the European Parliament on the REFIT evaluation is still pending.

⁴¹ Consolidated Version of the Treaty on the Functioning of the European Union [2012] OJ C326/47.

⁴² Treaty of Maastricht [1992] OJ C191.

⁴³ For examples of jurisprudence, see Case C-174/82, *Officier van Justitie v Sandoz BV* ECR 2445 and Case C-83/80, *Officier van Justitie/Kaasfabriek Eysen* ECR 409; for examples of legislation, see Council Decision 80/372/EEC of 26 March 1980 concerning chlorofluorocarbons in the environment [1980] OJ L 90/45 and Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms [1990] OJ L 117.

⁴⁴ A Alemanno, *Trade in Food: Regulatory and Judicial Approaches in the EC and the WTO* (Cameron May 2007) at p 111.

implementation of all EU policies, as is required by the treaties, and “can be defined as a general principle of Community law”.⁴⁵

Despite the pronouncement of the precautionary principle as a general principle of EU law by the EU Courts, there does not exist a universally accepted definition of the precautionary principle in EU law.⁴⁶ While it is argued that this is because the application of the precautionary principle is contextual, dependent on the policy area concerned and by its nature discretionary,⁴⁷ the ambiguity around its precise meaning is a particular issue of contention for its critics, who have argued that the precautionary principle can lead to arbitrary decision-making and protectionism.⁴⁸

The lack of a universally endorsed definition of the principle creates ambiguity around its normative implications. The majority of definitions of the precautionary principle in EU law put forward an understanding of the principle as providing public authorities with the discretion to take protective measures in situations of scientific uncertainty. For example, a frequently reiterated articulation of the concept of the precautionary principle was provided by the CJEU in the BSE judgements and constitutes one of the first times that the CJEU expressed the essence of the principle.⁴⁹ According to the CJEU, “Where there is uncertainty as to the existence or extent of human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent”.⁵⁰ Article 7 of Regulation 178/2002, the General Food Law Regulation,⁵¹ contains the first definition of the precautionary principle in EU legislation.⁵² According to Article 7(1), “In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment”.

⁴⁵ Joined Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00 *Artegodan v Commission* [2002] ECR II-04945, paras 183–84.

⁴⁶ J Zander, “The Application of the Precautionary Principle in Practice: Comparative Dimensions” (Cambridge University Press 2010) at p 93; E Stokes, “The EC Courts’ Contribution to Refining the Parameters of Precaution” (2008) 11 *Journal of Risk Research* 493; D Bourguignon, “The Precautionary Principle: Definitions, Applications and Governance” (European Parliamentary Research Service 2015) at p 6; R Lofstedt, “The Precautionary Principle in the EU: Why a Formal Review Is Long Overdue” 16 *Risk Management* 140; J Scott, “Legal Aspects of the Precautionary Principle” (A British Academy Brexit Briefing 2018) at p 7.

⁴⁷ N de Sadeleer, “The Precautionary Principle in European Community Health and Environment Law: Sword or Shield for the Nordic Countries?” in N de Sadeleer (ed.), *Implementing the Precautionary Principle: Approaches from the Nordic Countries, EU and USA* (Earthscan 2007) p 12; Stokes, *supra*, note 46, 492.

⁴⁸ G Majone, “What Price Safety: The Precautionary Principle and Its Policy Implications” (2002) 40 *Journal of Common Market Studies* 89.

⁴⁹ Curiously, the CJEU in the BSE judgements did not refer to the precautionary principle by its name, even though the two judgements were issued following the codification of the precautionary principle by the Maastricht Treaty.

⁵⁰ Case C-157/96 *The Queen v Ministry of Agriculture, Fisheries and Food and Others ex parte: The National Farmers’ Union and Others* [1998] ECR I-02211, para 63; Case C-180/96 *United Kingdom v Commission of the European Communities* [1998] ECRI-02265, para 99.

⁵¹ 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 [2002] OJ L31/1.

⁵² Alemanno, *supra*, note 44, 122.

However, there are also instances in the jurisprudence of the EU Courts where the precautionary principle is defined as an imperative *requiring* action to be taken in certain situations of scientific uncertainty. For example, in *Pfizer*, the CFI found that “by reason of [the precautionary principle] a public authority can be required to act even before any adverse effects have become apparent”.⁵³ In *French Republic v European Commission*, the CFI stated that “where [a risk faced] exceeds the level of risk deemed acceptable for society, the institution is bound, by reason of the precautionary principle, to adopt provisional risk management measures necessary to ensure a high level of protection”.⁵⁴ There is thus a variety of definitions expressing the precautionary principle with a range of normative implications, leaving ambiguous the precise positive obligations that derive from the principle under EU law. For example, in the case of a regulation setting out a regulatory framework for the authorisation procedure for a specific object of substance – such as Regulation 1107/2009 – in a policy field in which the precautionary principle applies, it is clear that pursuant to Article 191(2) TFEU such a regulation has to be based on the precautionary principle. Less certain, however, are the concrete normative implications that derive from Article 191(2) TFEU in such cases (ie what the obligation to be based on the precautionary principle actually entails).

The questions of the referring court – concerned with the compliance of several risk assessment aspects in Regulation 1107/2009 with the precautionary principle – also touch upon the role of the precautionary principle in risk assessment. According to the European Commission, the precautionary principle is exclusively part of risk management and, in particular, weighs in on the questions of whether to act and how to act. The European Commission emphasises that views according to which the precautionary principle is also part of risk assessment policy confuse the precautionary principle with a prudential approach to risk assessment.⁵⁵ de Sadeleer, on the other hand, argues that “[f]rom a legal point of view, nothing precludes that the risk assessment stage has to be carried out in accordance with the obligations stemming from the precautionary principle”, as well as that “in order to deal effectively with uncertainty, ambiguity, and ignorance, assessors should apply precaution at an early stage”.⁵⁶ Similarly, Stirling finds that “insisting that precaution relates only to risk management entirely misses its real value in highlighting more diverse ways to gather relevant knowledge”, such as by “draw[ing] attention to a broader range of non-reductive methods, which avoid spurious promises to determine ‘science-based’ policy”.⁵⁷ According to Peel, the implementation of the precautionary principle in the context of risk assessment “will require attention to the issue of

⁵³ Case T-13/99 *Pfizer Animal Health v Council* [2002] ECR II-03305, para 444.

⁵⁴ Case T-257/07 *French Republic v European Commission* [2011] ECR II-05827, para 81.

⁵⁵ European Commission, “Communication from the Commission on the Precautionary Principle” (Communication) COM (2000) 1 final.

⁵⁶ N de Sadeleer, “The Precautionary Principle in EC Health and Environmental Law” (2006) 12 *European Law Journal* 139, 148.

⁵⁷ A Stirling, “Risk, Precaution and Science: Towards a More Constructive Policy Debate. Talking Point on the Precautionary Principle” (2007) 8 *EMBO Reports* 312–13.

how regulatory frameworks incorporate broader input – most usually from the general public – into processes for the selection and assessment of health and environmental risks”.⁵⁸

IV. THE JUDGEMENT

1. Testing conformity of Regulation 1107/2009 with the precautionary principle

Due to the above-mentioned ambiguity as to the concrete normative implications of the precautionary principle, it is worth taking a closer look at what are, in the view of the Court, the obligations that derive from the precautionary principle in the context of Regulation 1107/2009.

Firstly, the Court confirms the applicability of the precautionary principle to Regulation 1107/2009 as constituting a policy protecting public health within the common agricultural policy or internal market policy.⁵⁹ According to the Court, “There is therefore an obligation on the EU legislature, when it adopts rules governing the placing on the market of plant protection products, such as those laid down in Regulation 1107/2009, to comply with the precautionary principle, in order to ensure . . . a high level of protection of human health”.⁶⁰ The Court then defines the precautionary principle as providing the possibility of taking protective measures in a situation of uncertain risk, without having to wait for the materialisation of that risk.⁶¹

The CJEU proceeds to elaborate how the legislature can ensure compliance with the precautionary principle in the context of Regulation 1107/2009. First of all, the Court finds that mere references to the precautionary principle within the Regulation – such as those in recital 8 and Article 1(4) of Regulation 1107/2009 – are insufficient to prove compliance with the principle.⁶² According to the CJEU, “A correct application of [the precautionary principle] in the area covered by Regulation No 1107/2009 presupposes, first, identification of the potentially negative consequences for health of the use of the active substances and plant protection products falling within its scope, and, second, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research”. The CJEU finds that in order to be able to undertake these two steps in the application of the precautionary principle, it is for the EU legislature to establish a “normative framework” that makes available to competent authorities “sufficient information in order to adequately assess . . . the risks to health resulting from the use of those active substances and those plant protection products”.⁶³ Thus, according to the Court, for the legislature to be in conformity with the precautionary principle, the regulatory framework that the legislature sets up must ensure that the competent

⁵⁸ J Peel, “Precautionary Only in Name? Tensions between Precaution and Risk Assessment in the Australian GMO Regulatory Framework” in E Fisher, J Jones and R von Schomberg (eds), *Implementing the Precautionary Principle, Perspectives and Prospects* (Edward Elgar 2006) p 203.

⁵⁹ *Blaise and others*, supra, note 1, para 41.

⁶⁰ *Blaise and others*, supra, note 1, para 42.

⁶¹ *Blaise and others*, supra, note 1, para 43.

⁶² *Blaise and others*, supra, note 1, para 45.

⁶³ *Blaise and others*, supra, note 1, para 47.

authorities have all of the information to properly assess the risks involved. The Court is silent as to whether this is the only obligation that the legislature needs to fulfil in order to be in conformity with the precautionary principle. Nonetheless, unlike the European Commission, according to which the precautionary principle only applies in risk management, the Court clearly regards the precautionary principle as having a role in risk assessment.

Finally, the standard of review that the Court is applying to test the validity of Regulation 1107/2009 is whether the EU legislature committed a manifest error of assessment in adopting Regulation 1107/2009 in that the general rules of the regulation do not satisfy the requirements arising from the precautionary principle.⁶⁴

2. Findings of the CJEU

The Criminal Court of Foix referred four questions on the compatibility of the risk assessment aspects of Regulation 1107/2009 with the precautionary principle for a preliminary ruling to the CJEU. In particular, the questions of the Criminal Court of Foix are concerned with the lack of definition of the concept of “active substances”, the insufficient consideration of cocktail effects in plant protection products in the authorisation procedure, the scientific evidence on the safety of the product being submitted by the applicant and, finally, the exemption of the authorisation application for plant protection products from long-term toxicity and carcinogenicity tests. The Court, after having examined the latter aspects of Regulation 1107/2009, concludes that the questions of the referring court reveal nothing capable of affecting the validity of the regulation.⁶⁵ In the following, the reasoning of the Court is analysed in more detail.

a. Designation of “active substances”

The first question referred to the CJEU by the Criminal Court of Foix is concerned with the compatibility with the precautionary principle of the lack of precise definition of “active substance” in Regulation 1107/2009. According to the Criminal Court of Foix, the ambiguity as to the meaning of the concept of “active substance” in Regulation 1107/2009 could enable the applicant in an authorisation application for a plant protection product to freely designate what is the active substance in a given product and focus the dossier for its authorisation application only on one substance, despite the end product being made of several substances.

The CJEU finds that the concept of “active substance” is sufficiently delineated for the purposes of Regulation 1107/2009 and also rejects the concern of the referring court that the applicant has the discretion to freely choose a substance of a product to be regarded as the active substance. Although the term “active substance” is not defined in Article 3 setting out various other definitions, Article 2(2) gives sufficient meaning to it. According to Article 2(2), “active substances” for the purpose of Regulation 1107/2009 are “substances, including micro-organisms having general or

⁶⁴ *Blaise and others*, supra, note 1, paras 50–51.

⁶⁵ *Blaise and others*, supra, note 1, para 117.

specific action against harmful organisms or on plants, parts of plants or plant products”. Moreover, in the view of the Court, the specific information required for the dossiers to be submitted by the applicant for the authorisation application for a plant protection product enable the identification of the respective active substances. The Court further refers to the task of the competent authority of the Member States to assess whether the identification of the active substance by the applicant has been carried out and to verify whether each of the active substances contained in the plant protection product has been subject to prior approval (as a precondition for the authorisation of a plant protection product). Finally, the holder of an authorisation risks the withdrawal of the authorisation if not all active substances have been identified in the authorisation application.

b. Disregard of “cocktail effects” in plant protection products

The referring court also asks about the compatibility of the precautionary principle with Regulation 1107/2009 given that it disregards the presence and cumulative effect of multiple active substances and, in particular, there being no analysis at the EU level of the cumulative effect of several active substances in a plant protection product.⁶⁶

The CJEU holds that both the authorisation procedure for active substances (Chapter II) and the procedure for plant protection products (Chapter III) in Regulation 1107/2009 set out requirements according to which the potential effects of the combination of various constituents need to be considered. In the approval procedure for active substances, the safety of one or more representative uses of at least one plant protection product containing the respective active substance must be established. In the view of the CJEU, this assessment “cannot be carried out in an objective fashion while failing to take into account the effects deriving from a possible combination of various constituents of a plant protection product”.⁶⁷ Moreover, the regulation mandates taking into account the cumulative and synergistic effects of an active substance in the assessment of its safety, which must also be considered in the assessment by EFSA.⁶⁸

In the assessment of the safety of plant protection products, the Court finds that cumulative and synergistic effects are again sufficiently considered pursuant to the general approval criteria, as well as by way of the uniform principles for the evaluation and authorisation of plant protection product that are to be adopted by Member States.⁶⁹

Furthermore, according to the Court, based on applicable data requirements, the applicant of the authorisation must submit information on likely cumulative and synergistic effects caused by interactions between active substances, safeners, synergists and the co-formulants.⁷⁰ The Court further finds that the specific rules on

⁶⁶ Notably, while it has also been criticised that the assessment of the cumulative effects of several plant protection products on one crop is disregarded by the authorisation procedure in Regulation 1107/2009, the question of the referring court is limited to the cumulative effects of various active substances in one plant protection product.

⁶⁷ *Blaise and others*, supra, note 1, para 68.

⁶⁸ *Blaise and others*, supra, note 1, paras 68–69.

⁶⁹ *Blaise and others*, supra, note 1, paras 71–72.

⁷⁰ *Blaise and others*, supra, note 1, para 73.

safeners, synergists and co-formulants in Articles 25 and 27 further ensure that if there are any safeners, synergists and co-formulants contained in a product, the safety of those must also be assessed.⁷¹

c. Bias in studies, tests and analyses submitted by the applicant and confidentiality rules

The Criminal Court of Foix further asks whether in the authorisation procedure of Regulation 1107/2009 – in which tests, analyses and evaluations for the dossier are conducted by the applicant of the authorisation alone – the precautionary principle is observed and impartiality is maintained. According to the Criminal Court of Foix, the applicant may be biased in the presentation of the scientific evidence and there is no independent counter-analysis of the material submitted by the applicant, nor are the application reports published for reasons of protecting industry secrets.

According to the Court, the rules setting out that it is the applicant – intending to place the product on the market – who for both active substances and plant protection products submits the studies, tests and analyses are “the corollary of the principle . . . that it is for the applicant to prove that the active substance or plant protection product that is the subject of an application for approval or authorization fulfils the relevant criteria laid down by that regulation”.⁷² These rules ensure that it is not presumed that the substances in question have no harmful effects and therefore “contribut[e] to achieving compliance with the precautionary principle”.⁷³

The Court sees sufficient safeguard against potential bias in a number of information requirements Regulation 1107/2009 sets out: the summary dossiers submitted as part of the authorisation application must contain specific information (eg results of tests and studies, the names of their owners and of the persons or institutes that have carried out the tests and studies), the methods of analysis of an active substance must be validated, its sufficiency must be demonstrated and the tests and analyses submitted need to be official or officially recognised. In addition, evidence has to be submitted that tests, studies and analyses have been carried out by a reliable institution and with models that meet recognised scientific principles. Finally, the applicant is obliged to submit scientific peer-reviewed open literature on the active substance published within the last 10 years.⁷⁴

According to the Court, the competent authorities and EFSA must take into account in their assessment evidence beyond that submitted by the applicant and must not “give in all cases preponderant weight to the studies provided by the applicant”.⁷⁵ EFSA also has the option of consulting experts or a Community reference laboratory.⁷⁶

Regarding the applicable disclosure rules, the Court concedes that increased transparency could enable the public to put forward arguments against the approval

⁷¹ *Blaise and others*, supra, note 1, para 74.

⁷² *Blaise and others*, supra, note 1, para 79.

⁷³ *Blaise and others*, supra, note 1, para 80.

⁷⁴ *Blaise and others*, supra, note 1, paras 83–91.

⁷⁵ *Blaise and others*, supra, note 1, para 94.

⁷⁶ *Blaise and others*, supra, note 1, para 98.

of a substance and therefore have the potential to improve the assessment of the risk.⁷⁷ However, according to the Court, there already exists ways for the public to get access to the authorisation or approval application dossier. In the approval procedure for active substances, EFSA must make a summary dossier (which includes summaries and results of tests and studies) and the draft assessment report by the Rapporteur Member States available to the public.⁷⁸ Moreover, a person requesting any of the latter information to remain confidential must prove that disclosure would undermine commercial interests.⁷⁹ The Court also refers to Directive 2003/4 on public access to environmental information,⁸⁰ which provides that Members States cannot deny access for information on emissions into the environment due to concerns around the protection of confidentiality. Referring to its judgement in *Bayer CropScience and Stichting De Bijenstichting*,⁸¹ the Court states this covers “to a great extent” studies that assess harm that could be caused by the use of plant protection products as well as residues following the application of plant protection products.⁸²

d. Testing of long-term carcinogenicity and toxicity of plant protection products

The final question of the referring court asks whether the compatibility of Regulation 1107/2009 with the precautionary principle is affected by Regulation 1107/2009 exempting plant protection products from toxicity tests and requiring only summary testing performed by the applicant.

The Court finds that although Regulation 1107/2009 does not contain detailed requirements on the nature of tests, analyses and studies as regards the authorisation of plant protection products (while there are some specific tests required for active substances), there is no exemption with respect to the submission of long-term carcinogenicity and toxicity tests. According to the Court, the applicant has the burden of proof to establish that the plant protection product intended to be placed on the market has no immediate or delayed harmful effect on human health, whereas the applicant’s burden of proof is not met if the product in question exhibits any long-term carcinogenicity and toxicity. The Court concludes that the material submitted by the applicant (ie tests, analyses, studies and other material) must therefore be sufficient to exclude risks of toxicity and carcinogenicity, which will be verified by the competent authorities in their examination of the application for the authorisation. cursory tests or summary tests, as the Court emphasises, are not sufficient to exclude these risks.

⁷⁷ *Blaise and others*, supra, note 1, para 102.

⁷⁸ *Blaise and others*, supra, note 1, paras 103–04.

⁷⁹ *Blaise and others*, supra, note 1, para 105.

⁸⁰ Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC [2003] OJ L41.

⁸¹ C-442/14 *Bayer CropScience and Stichting De Bijenstichting* [2016] EU:C:2016:890; for other jurisprudence on the access to risk assessment information in the context of pesticides, see, for example, Case T-716/14 *Anthony C Tweedale v European Food Safety Authority* [2019] EU:T:2019:141; Case T-329/17 *Heidi Hautala and Others v European Food Safety Authority* [2019] EU:T:2019:142; Case C-673/13 P *Commission v Stichting Greenpeace Nederland and PAN Europe* [2016] EU:C:2016:889.

⁸² *Blaise and others*, supra, note 1, paras 106–08.

3. Observations on the reasoning of the Court

a. The Court does not explicitly apply the standard that it has established for Regulation 1107/2009 to be in conformity with the precautionary principle

As explained above, in its judgement, the Court lays down the standard that Regulation 1107/2009 has to meet to ensure conformity with the precautionary principle. According to this standard, the normative framework set up by Regulation 1107/2009 must make available to the competent authorities sufficient information for the assessment of the risks to health that are posed by an active substance or plant protection product. When the Court proceeds to assess the different aspects of Regulation 1107/2009, however, it does not specifically and explicitly examine those aspects in the light of how they contribute to or compromise such a normative framework. Instead, the CJEU appears to merely test the general adequacy of Regulation 1109/2009.

For example, when the CJEU discusses the potential bias in the presentation of the scientific evidence by the applicant, the Court does not appear to concretely assess the extent to which the applicant producing the scientific evidence and studies on which the risk assessment largely relies could affect the competent authorities' availability of sufficient information. A potential concern that the Court could have considered here is the risk of industry applicants omitting from the submission of scientific evidence possible negative health effects, as was alleged in the context of the approval of glyphosate and the Monsanto Papers.⁸³ In a White Paper of the "Citizens for Science in Pesticide Regulation" coalition, it is argued that "bias [on the part of the applicant] could lead to toxic effects being hidden, misrepresented, or misinterpreted (as not exposure-related, spontaneously occurring, or irrelevant to humans, etc.)".⁸⁴ According to the European Parliament, although "the Regulation requires the applicant to add scientific peer-reviewed open literature on the active substance . . . for new active substances, normally only data from regulatory studies generated by the applicant are available".⁸⁵ In particular, in such situations, the possibility of the applicant omitting evidence of harmful health effects in an authorisation application for a new substance and how the regulation is or is not able to counteract against the risk of this happening would have been important aspects for the Court's assessment. Indeed, the fact that this is addressed in Regulation 2019/1381 – which, among other things, obliges business operators to notify EFSA of the title and the scope as well as the laboratory or testing facility of any study commissioned or carried out by them to support an application – shows that this aspect had been recognised as problematic by the EU legislator.⁸⁶ The Court could have also addressed how the procedure according to which scientific evidence as to the safety of a substance is presented by the applicant relates to the main

⁸³ Citizens for Science in Pesticide Regulation, Letter to EU Ministries Concerning: Action needed to ensure a higher level of protection from pesticides in Europe (Brussels 2018) <<https://citizens4pesticidereform.eu/wp-content/uploads/2018/12/Coalition-letter-to-Permanent-Representatives-20181123.pdf>> (last accessed 26 February 2020).

⁸⁴ "Ensuring a Higher Level of Protection from Pesticides in Europe – The Problems with Current Pesticide Risk Assessment Procedures in the EU – And Proposed Solutions", White Paper prepared for "Citizens for Science in Pesticide Regulation" (2018) p 10.

⁸⁵ European Parliament resolution of 16 January 2019, *supra*, note 31.

⁸⁶ Recital 21 and Art 1(6) on "Notification of Studies" of Regulation 2019/1381, *supra*, note 35.

objective of a company to generate profits independently of the effects on public health and the environment.⁸⁷

In another instance, when responding to the referring court's concern about the lack of definition of the concept of "active substance" in plant protection products, the Court makes the general finding that it is "not clearly evident that the criteria set out in [Article 2(2) of Regulation 1107/2009] are insufficient to permit an objective determination of the substances concerned".⁸⁸ However, if the Court strictly applied the standard it set for testing the compatibility of the regulation with the precautionary principle, the question it should ask is not whether it is clearly evident that criteria are insufficient, but rather whether it is clear that they are indeed sufficient for the competent authority to properly assess the risk. Here, the Court could have also discussed the extent to which a flexible and open definition of the concept of active substance could be beneficial for risk assessment in compliance with the precautionary principle, as it could encompass novel types of active substances that may fall out of a static definition.

Furthermore, in its discussion of long-term carcinogenicity and toxicity studies in the authorisation procedure for plant protection products, the Court states that authorisation applications for plant protection products are not exempt from testing long-term carcinogenicity and toxicity. Despite it not being explicitly demanded in the regulation, according to the Court, by way of the applicant's burden of proof to establish the safety of plant protection products, the applicant must provide sufficient evidence to include long-term carcinogenicity and toxicity. The Court does not, however, consider if in practice this is the case, and scientific evidence on long-term carcinogenicity and toxicity is in fact submitted by the applicant or, if not initially submitted, requested to be submitted by the competent authorities. In her opinion, Advocate General (AG) Sharpston paints a different picture about why long-term carcinogenicity and toxicity tests are not explicitly requested by Regulation 1107/2009. AG Sharpston finds that requiring the applicant to submit an assessment of long-term toxicity would involve additional costs and a longer authorisation procedure. According to AG Sharpston, the non-existence of such a requirement is thus a result of a balance that was struck between achieving an appropriately high level of protection and the added value of authorised products with the ability of enhancing agricultural productivity.⁸⁹ The Court, however, has not tested whether this balance was struck correctly and in conformity with the precautionary principle. Again, testing whether this balance was struck correctly would have been material in the assessment of whether the normative framework set out by Regulation 1107/2009 makes available to competent authorities sufficient information to assess the risks. In particular, it would have been interesting to see whether the Court – when balancing obligations to submit evidence on long-term

⁸⁷ H Vainio, "Public Health and Evidence-Informed Policy-Making: The Case of a Commonly Used Herbicide" (2020) 46 *Scandinavian Journal of Work, Environment & Health* 107.

⁸⁸ *Blaise and others*, *supra*, note 1, para 57.

⁸⁹ *Blaise and others*, Opinion of Advocate Sharpston, *supra*, note 4, para 79.

carcinogenicity and toxicity – distinguishes between first-time authorisations and renewals of authorisations for plant protection products.

b. The Court adopts an analysis of the text of Regulation 1107/2009 in a vacuum and disregards concerns around its implementation and application

Before the Court presents its findings in response to the questions of the referring court, it clarifies that general criticism around the approval of glyphosate cannot – by itself – be taken to mean that Regulation 1107/2009 is unlawful. According to the Court, “[T]he validity of a provision of EU law is to be assessed according to the characteristics of those provisions themselves and cannot depend on the particular circumstances of a given case”.⁹⁰ However, experiences of past cases could make visible potential problems with the regulation, just as the case of glyphosate has put the shortcomings of the regulation into focus and led initiatives, such as the European Parliament’s PEST Committee, in their aim to improve the regulation. In her opinion, AG Sharpston acknowledges this, stating that concerns relating to glyphosate do not affect the integrity of the regulation “[u]nless concerns relating to glyphosate are shown to be representative of a systemic and fundamental failure undermining the [Plant Protection Product] Regulation and the aim that that regulation seeks to achieve”.⁹¹ There are certainly lessons to be learnt from the glyphosate saga – as elaborated in other contributions in this Special Issue – that are nevertheless not considered by the Court. As can be seen from all of the above examples, instead the Court adopts a purely mechanical interpretation of the text of Regulation 1107/2009 in a vacuum, without any reference to frequently raised issues around the practical implementation and application of its respective provisions.

V. CONCLUSIONS

By establishing that for Regulation 1107/2009 to be compatible with the precautionary principle it needs to contain a normative framework that provides to competent authorities sufficient information to assess the risk of a substance, the Court’s judgement has provided helpful clarification about the normative implications of the precautionary principle. The latter obligation is likely applicable to similar regulations setting out authorisation procedures for substances or objects. However, the standard established by the Court has not been explicitly applied to the different aspects of Regulation 1107/2009 that the Court is examining in its judgement, and the judgement therefore lacks guidance as to the practical application of this standard. Furthermore, the CJEU’s judgement examines Regulation 1107/2009 in a vacuum without considering problems that have occurred in its implementation or application and therefore constitutes a rather limited assessment of the authorisation procedure.

⁹⁰ *Blaise and others*, supra, note 1, para 48.

⁹¹ *Blaise and others*, Opinion of Advocate Sharpston, supra, note 4, para 44.

In a Postscript to her opinion, AG Sharpston refers to the conclusions of the report of the PEST Committee of the European Parliament, according to which the regulation as such and its implementation need to be improved for it to achieve its purpose, and she states that nothing in the AG's opinion should be taken as meaning that there are no areas of improvement. Her findings merely relate to whether the Regulation is vitiated by a manifest error and therefore invalid, which she concludes is not the case.⁹² Possibly, the Court adopted a rather cursory analysis of Regulation 1107/2009 – as is also evidenced by the relative brevity of the judgement considering the complex subject matter at hand – as it took account of the fact that the authorisation procedure has already been reviewed by the European Parliament, improved by Regulation 2019/1381 and is currently undergoing the European Commission's REFIT programme.⁹³ It is further important to note that the Court finding Regulation 1107/2009 invalid due to its incompatibility with the precautionary principle would have had vast consequences, as it would remove the legal basis of numerous substances approved and authorised under Regulation 1107/2009. Thus, the question of whether the conformity of the EU authorisation procedure for pesticides in Regulation 1107/2009 with the precautionary principle is a fact or merely fiction is not settled with the CJEU's judgement in Case C-616/17.

⁹² *Blaise and others*, Opinion of Advocate Sharpston, *supra*, note 4, paras 82–83.

⁹³ In its Resolution of 16 November 2019, the European Parliament “calls on the Commission . . . to submit a specific legislative proposal to amend the Regulation outside of the ongoing REFIT procedure, with a view to enabling a rigorous high-quality fast-track evaluation, authorisation and registration process”, see European Parliament resolution of 16 January 2019, *supra*, note 31.