
One-Door-One-Key Principle: Observations Regarding Integration of GM Authorization Procedures in the EU

Bernd van der Meulen* & Neshe Yusuf**

Abstract

Under European Union (EU) law, genetically modified organisms (GMOs) for consumption require authorizations for cultivation, for use in human food, and for use in animal feed. The recast of the legislative framework in 2003 introduced the “one-door-one-key principle.” This principle links and integrates the procedures to acquire these three authorizations partly in a mandatory and partly in an optional manner. Even though the EU legislature perceives the three authorizations as intrinsically linked, in practice considerable differences can be observed in the presence of GMOs on the EU market for cultivation, for feed use, and for food use. Partly these differences are reflected in differences in authorization.

This Article traces the one-door-one-key principle in EU GMO food law; its content is an application. Based on literature and a few interviews, it attempts to explain the gap between legal theory and business practice.

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* Bernd van der Meulen is Professor and Chair of Law Governance at Wageningen University (the Netherlands). See *Law and Governance Group*, WAGENINGEN UNIV., www.law.wur.nl (last visited May 13, 2014).

** Neshe Yusuf is Student Assistant at the Law Governance Group at Wageningen University. She participates in the MSc specialization Food Safety Law. See *Master Food Safety*, WAGENINGEN UNIV., www.mfs.wur.nl (last visited May 13, 2014). She executed the interviews reported in Part VI, *infra*.

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I.	INTRODUCTION	

In the early 2000s, the regulatory framework for genetically modified (GM) foods in the European Union (EU)¹ was recast.² The previous system had ground to a halt in what has become known as the “de facto moratorium” and—mainly for reason of this moratorium—was challenged in the World Trade Organization (WTO). The European

1. In this Article, we use EU/European Union indiscriminately. Except in quotations and references, we do not use the older names EEC/European Economic Community or EC/European Communities/Community. Also, we use American spelling in our text but the original spelling—usually British—in quotations.

2. For a detailed overview, see Bernd van der Meulen, *The EU Regulatory Approach to GM Foods*, 16 KAN. J.L. & PUB. POL'Y 286, 286–323 (2007). The EU provides two libraries on its website with documents on GMOs. See *Health and Consumers: Food*, EUROPEAN COMM'N, http://ec.europa.eu/food/food/biotechnology/evaluation/gmo_biotech_lib_en.htm (last visited May 13, 2014); *Publications*, EUROPEAN COMM'N, http://ec.europa.eu/food/food/biotechnology/resources/publications_fr.print.htm (last visited May 13, 2014).

The most prominent scholar in the United States when it comes to regulation of GMOs in the EU is Professor Margaret Rosso Grossman (University of Illinois). See, e.g., Margaret Rosso Grossman, *Traceability and Labeling of Genetically Modified Crops, Food and Feed in the European Union*, 1 J. FOOD L. & POL'Y 43, 43–85 (2005); Margaret R. Grossman, *The Coexistence of GM and Other Crops in the European Union*, 16 KAN. J.L. & PUB. POL'Y 324, 324–392 (2007); see also Helle Tegner Anker & Margaret Rosso Grossman, *Authorization of Genetically Modified Organisms: Precaution in US and EC Law*, 2009 EUR. FOOD & FEED L. REV. 3, 3–22.

In the current contribution some basic knowledge on EU law such as the relation of the EU institutions (European Commission, Council, European Parliament, Court of Justice) to each other and the Member States and the difference between regulations and directive is assumed. Readers interested in EU law generally, may want to see KLAUS-DIETER BORCHARDT, *THE ABC OF EUROPEAN UNION LAW* (Publ'n Office ed., 2010), available at http://bookshop.europa.eu/is-bin/INTERSHOP.enfinity/WFS/EU-Bookshop-Site/en_GB/-/EUR/ViewPublication-Start?PublicationKey=OA8107147 (free e-book download available).

In this Article, we refer to EU legislation by natural number only. As all EU legislation is now available at <http://eur-lex.europa.eu> both in its original form and in consolidated versions, we consider the former method of citing to the EU Official Journal outdated.

The new legislation put in place in 2003 consists of Commission Regulation 1829/2003, 2003 O.J. (L 268) 1 (EC) (on GM food and feed) and Commission Regulation 1830/2003, 2003 O.J. (L 268) 24 (EC) (on traceability and labelling of GMOs and the traceability of food and feed products from GMOs). These regulations have been further elaborated in Commission Regulation 65/2004, 2004 O.J. (L 10) 5 (EC) and Commission Regulation 641/2004, 2004 O.J. (L 102) 14 (EC).

Commission heralded the new system as being based on the “one-door-one-key” principle. This Article aims to explore this purported principle. What is it? Can it be labeled a principle in a meaningful way? Did it bring what was expected of it? In other words, does it provide improved access to the EU market or an additional barrier to trade?

To answer these questions, in Part II, we will first trace the history of GM authorization requirements in general and in the EU in particular. Then, in Part III, we explore what is meant by “one-door-one-key principle.” Next, in Part V, we present figures showing that the current state of authorizations in the EU does not reflect the ideas set out in the new approach. To explain this state of affairs, in addition to evaluations conducted at the instigation of the European Commission and other publicly available sources, we performed a small empirical study consisting of interviews with a limited number of key players in the field, businesses as well as scholars, and the European Commission. We present our findings in Part VI. Finally, we round off this Article with a short discussion of the findings in Part VII.

II. AUTHORIZATION

In the 1950s—before the inception of the EU—responding to concerns regarding the possible relation between the use of chemicals in food and the prevalence of certain cancers, the United States banned the use of food additives. This ban could be lifted through authorization. Congress cast the concept of food additive broadly to include “any substance the intended use which results or may reasonably be expected to result—directly or indirectly—in its becoming a component or otherwise affecting the characteristics of any food,” but excluded products generally recognized as safe (GRAS).³

In the 1960s, this example was cautiously followed in the EU, at first only for colors but later for additives in general.⁴ In the EU, however, the concept of additives was limited to substances not normally consumed⁵ as a food in itself that were added for a technological purpose.⁶ This delineation proved unsatisfactory when all kinds of

3. Federal Food Drug and Cosmetic Act of 1938 § 201, 21 U.S.C. § 321 (2012). On the details, see generally NEAL D. FORTIN, *Food Additives, Food Colorings, Irradiation*, in FOOD REGULATION LAW, SCIENCE, POLICY, AND PRACTICE (2009).

4. On food authorization in the EU generally, see Bernd M.J. van der Meulen et al., *Structural Precaution: The Application of Premarket Approval Schemes in EU Food Legislation*, 67 FOOD & DRUG L.J. 453, 457–58 (2012).

5. Often, these are synthetic substances.

6. This definition can now be found in Article 3(2)(a) of Regulation (EC) 1333/2008 on food additives. Commission Regulation 1333/2008, art. 3(2)(a), 2008 O.J. (L 354) 16, 20 (EC). The technological purposes can be derived from annex I to the regulation, which lists “functional classes.” *Id.* at 29. These include sweeteners, colors,

innovative substances found their way into the food chain for other than technological purposes, genetically modified organisms among them. In response, an authorization requirement was put in place for “novel foods.” This requirement applies to all foods not consumed to a significant degree in the EU prior to 1997.⁷

The Novel Foods Regulation, however, was not the first EU measure requiring authorization for GMOs. Initial concerns mainly focused on possible environmental impacts and health impacts from GMOs released into the environment. From 1990 onwards, authorization was required for the release of viable GMOs into the environment.⁸ The 1990 legislation was recast⁹ in 2001.¹⁰ Only after environmental concerns did consumer concerns emerge. Rightly or wrongly, the authorities framed these consumer concerns as food safety concerns.¹¹

preservatives, antioxidants, carriers, acids, acidity regulators, anti-caking agents, anti-foaming agents, and many more. *Id.*

7. While the requirement applies only to foods belonging to a certain category, the categories cover most conceivable foods. *See* Commission Regulation 258/97, art. 2, 1997 O.J. (L 43) 1, 4 (EC) (the Novel Foods Regulation).

8. Directive 90/220/EEC, of 23 April 1990 on the Deliberate Release into the Environment of Genetically Modified Organisms, 1990 O.J. (L 117) 15.

9. Among other things to take into account, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity was adopted in 2000.

10. Directive 2001/18/EC, 2001 O.J. (L 106) 1.

11. On March 20, 2014, the evening before the Penn State Law Review’s GMO symposium, another interesting event took place at Penn State Law. Dan Kahan, the Elizabeth K. Dollard Professor of Law and Professor of Psychology at Yale Law School, presented his views on science communication and climate change. Dan Kahan, Professor, Yale Law School, Presentation at Penn State Law: How to Communicate Climate Science (Mar. 20, 2014). In particular, he addressed why different people approach the basic question of whether there is such a thing as climate change so very differently. His research shows a dividing line along political affiliations. Scholars who feel politically attracted to the republican way of thinking tend to be skeptical about the scientific evidence that climate change exists. Those who feel attracted to the democratic way of thinking seem more inclined to consider the evidence conclusive. He hypothesizes that on certain polarized issues such as climate change the extent to which we are open to teachings of science is a matter of group loyalty rather than of scientific relevance. His research does not indicate that within the United States the issue of GMOs is polarized in this way. Proponents and opponents to GMOs are found among all political denominations. *See* Dan Kahan, *We Aren’t Polarized on GM Foods—No Matter What the Result in Washington State*, CULTURAL COGNITION PROJECT AT YALE L. SCH. (Nov. 5, 2013, 7:39 AM), <http://www.culturalcognition.net/blog/2013/11/5/we-arent-polarized-on-gm-foods-no-matter-what-the-result-in.html>. Nevertheless, it may be worth exploring whether opposition to GM foods has become part of a group loyalty to some form of European identity.

For a meta-analysis on consumer concerns regarding GMOs, see generally Lynn J. Frewer et al., *Public Perceptions of Agri-Food Applications of Genetic Modification: A Systematic Review and Meta-Analysis*, 30 TRENDS FOOD SCI. & TECH. 142 (2013). *See also* Lynn J. Frewer et al., *Genetically Modified Animals from Life-Science, Socio-Economic and Ethical Perspectives: Examining Issues in an EU Policy Context*, 30 NEW BIOTECH. 447 (2013). For a more popular but instructive overview, see generally Carl

The Novel Foods Regulation intended to respond to these concerns by making market access incumbent on food safety risk assessment.

So since 1997, several separate but related authorization requirements applied to GMOs in the EU. Of these, our focus is on an environmental authorization based on Directive 2001/18/EC and a food authorization based on the Novel Foods Regulation.¹²

The procedure of the Novel Foods Regulation hinged on cooperation between the EU institutions with the Member States. Consensus was required. This provided Member States with the possibility to block consensus and thus with a virtual right of veto regarding individual authorization decisions. The vehement opposition to GMOs in several EU Member States¹³ made the procedure highly political. While Member State representatives did not actually use their power of veto to force *refusals* of authorization, they did act in ways that prolonged procedures almost to infinity—in particular by repeatedly requesting additional safety data to be acquired by additional studies. As a consequence, for several years not one single authorization procedure came to a conclusion. This practice has become known as the “de facto moratorium” and was contested by several states¹⁴ at the WTO. Ultimately, a panel of the WTO dispute settlement body concluded that the de facto moratorium was incompatible with some of the EU’s obligations under the WTO Agreements.¹⁵

Prior to the ruling of the WTO DSB panel, to deal with the failure of the Novel Foods Regulation for GMO authorizations, the European legislature put in place a new set of Regulations for GMOs, which

Hebden et al., *Consumer Responses to GM Foods: Why Are Americans So Different?*, 20 CHOICES 243 (2005).

12. For the current discussion, we pay no attention to scientific research, experimental releases, and releases of genetically modified microorganisms. These issues are regulated through Directive 90/219/EEC on the contained use of genetically modified microorganisms for research and industrial purposes. Directive 90/219/EEC, 1990 O.J. (L 117) 1.

13. France and Greece in particular, backed by Belgium, Denmark, Luxembourg and Austria.

14. More precisely, this practice was contested by the United States, Canada, and Argentina, and supported by Australia, Brazil, Chile, China, Chinese Taipei, Colombia, El Salvador, Honduras, Mexico, New Zealand, Norway, Paraguay, Peru, Thailand, and Uruguay.

15. For the ruling of the dispute settlement body, see Panel Report, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291–93/R (Sept. 29, 2006), available at http://www.wto.org/english/news_e/news06_e/291r_e.htm. On the developments that led to this decision, see also David Wirth, *The Transatlantic GMO Dispute Against the European Communities: Some Preliminary Thoughts* (Bos. Coll. Law Sch. Legal Studies Research Paper Series, Paper No. 100, 2006), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=920474.

removed them from the scope of the Novel Foods Regulation and centralized decision making at the EU level.

Currently two authorization requirements exist side by side: the requirement for an environmental authorization based on Directive 2000/18/EC and the requirement for food and feed authorization based on Regulation (EC) 1829/2003. Both authorizations require a case-by-case assessment of safety. The objective of the environmental risk assessment is “to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment . . . with a view to identifying if there is a need for risk management and if so, the most appropriate methods to be used.”¹⁶ The objective of the assessment under Regulation (EC) 1829/2003 is to ensure that GM food does not: “(a) have adverse effects on human health, animal health or the environment; (b) mislead the consumer; (c) differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.”¹⁷ The authorization procedure is conducted at EU level. The risk assessment is performed by the European Food Safety Authority (EFSA). The decision on the application is taken by the European Commission in consultation with representatives of the Member States in the Standing Committee on the Food Chain and Animal Health.¹⁸

III. ONE-DOOR-ONE-KEY PRINCIPLE

When in 2001 the European Commission submitted its proposal for what is now Regulation (EC) 1829/2003, the Commission informed the European Parliament that:

The proposed Regulation is based on the “one door – one key” principle. Thus, it will be possible, under the proposed Regulation, to file a single application for obtaining both:

- the authorisation for the deliberate release of a GMO into the environment, under the criteria laid down in Directive 2001/18/EC;
- and the authorisation for the use of this GMO in food and/or feed under the criteria laid down in the proposed Regulation.

This authorisation, valid throughout the Community, will be granted subject to:

16. Directive 2001/18/EC, 2001 O.J. (L 106) 1. Directive 2001/18/EC, annex II ¶ A, 2001 O.J. (L 106) 1, 19.

17. Commission Regulation 1829/2003, art. 4, 2003 O.J. (L 268) 1, 7 (EC).

18. *Id.*

- a single risk assessment process (covering both the environmental risk and risks to human and animal health), under the responsibility of the European Food Authority,
- a single risk management process, involving the Commission and the Member States through a regulatory committee procedure.¹⁹

EU authorization of a GMO under Regulation (EC) 1829/2003 provides access to the entire EU. Unlike, for instance, pharmaceutical products, there is no need to acquire authorization or (mutual) recognition from each Member State where the product is brought to market. But there is more to this “one-door-one-key” principle.

The expression “one-door-one-key principle” in itself was not new when the GMO package was launched. For example, the 1997 Commission Green Paper on the General Principles of Food Law in the European Union²⁰ already uses it. The Green Paper addresses among other things the role of scientific advice in the preparation of food safety legislation. In this context, the Commission announces its intent to continue its efforts to “apply a single procedure to assess all relevant risks (the ‘one door, one key’ principle).”²¹

A Q&A sheet from 2004 further elaborates:

Clear rules are already set out in the EU for the assessment and authorisation of GMOs and GM-food, but the responsibilities are currently divided between the Member States and the EU. The Regulation replaces this with a “one door-one key” procedure for the scientific assessment and authorisation of GMOs and GM food and feed.

It puts in place a streamlined, uniform and transparent EU procedure for all marketing applications, whether they concern the GMO itself or the food and feed products derived thereof.

This means that business operators need not request separate authorisations for use of the GMO, and for its use in feed or in food, but that a single risk assessment and a single authorisation are given for a GMO and its possible uses. The Regulation also ensures that experiences such as with Starlink maize in the [United States] are avoided because GMOs likely to be used as food and feed can only be authorised for both uses, or not at all.

19. *Proposal for a Regulation of the European Parliament and of the Council on Genetically Modified Food and Feed*, at 5, COM (2001) 425 final (July 25, 2001), available at http://www.reading.ac.uk/foodlaw/pdf/com2001_0425.pdf.

20. *Commission Green Paper on the General Principles of Food Law in the European Union*, at 36, COM (1997) 176 final (Apr. 30, 1997).

21. *Id.*

The European Food Safety Authority will be responsible for the scientific risk assessment covering both the environmental risk and human and animal health safety assessment. Its opinion will be made available to the public and the public will have the possibility to make comments. On the basis of the opinion of the European Food Authority, the Commission will draft a proposal for granting or refusing authorisation.²²

In summary, the one-door-one-key principle entails one EU-level authorization procedure on the basis of a single application; applying for a single risk assessment grants access to the entire EU for all relevant uses of the GMO: food, feed, and cultivation.

At closer inspection of the legislation, the different elements are, however, somewhat heterogeneous. Authorizations are indeed EU-wide; Member States have to allow authorized GMOs²³ with the sole exception of when they successfully invoke a safeguard clause based on new scientific evidence.²⁴

Under Article 27 of Regulation (EC) 1829/2003, the authorization procedure for food and feed is inextricable and mandatorily linked:

Products likely to be used as both food and feed

1. Where a product is likely to be used as both food and feed, a single application under Articles 5 and 17 shall be submitted and shall give rise to a single opinion from the Authority and a single Community decision.
2. The Authority shall consider whether the application for authorization should be submitted both as food and feed.²⁵

If a product can be used both for feed and food, it can only be approved for both uses or not at all. Thereafter the combined authorization for

22. Memorandum from the European Comm'n on Question and Answers on the Regulation of GMOs in the EU (Jan. 28, 2004), *available at* http://europa.eu/rapid/press-release_MEMO-04-16_en.htm.

23. Article 22 of Directive 2001/18/EEC states that Member States may not prohibit, restrict, or impede the placement on the market of GMOs that comply with the requirements of this directive. Directive 2001/18/EC, art. 22, 2001 O.J. (L 106) 1, 13. In several instances, the Court of Justice of the EU had to intervene to uphold this provision against non-compliant Member States. *See, e.g.*, Case C-165/08, Comm'n v. Poland, 2009 E.C.R. I-06843; Case C-121/07, Comm'n v. France, 2008 E.C.R. I-09159; Joined Cases C-439/05 and C-454/05, Comm'n v. Austria, 2007 E.C.R. I-07141; *see also* Case C-313/11, Comm'n v. Poland, 2011 EUR-Lex CELEX LEXIS 0313 (July 18, 2013) (regarding a ban on GM animal feed).

24. Directive 2001/18/EC, art. 23, 2001 O.J. (L 106) 1, 13 (safeguard clause). New scientific evidence that exists prior to the authorization should be brought forward in the procedure.

25. Commission Regulation 1829/2003, art. 27, 2003 O.J. (L 268) 1, 17 (EC).

food and for feed use is also referred to as an authorization “for consumption.”

The linking of the authorization for consumption to the authorization for cultivation, on the other hand, is voluntary. Applicants *can* combine the two issues in one application under Regulation (EC) 1829/2003, but they have the option to separate the two issues by applying only for one option and not for the other or by submitting one application for food/feed use under Regulation (EC) 1829/2003 and another for cultivation under Directive (EEC) 2001/18.

Recital 33 of Regulation (EC) 1829/2003 expresses this as follows:²⁶

Where the application concerns products containing or consisting of a genetically modified organism, the applicant should have the choice of either supplying an authorisation for the deliberate release into the environment already obtained under part C of Directive 2001/18/EC, without prejudice to the conditions set by that authorisation, or of applying for the environmental risk assessment to be carried out at the same time as the safety assessment under this Regulation. In the latter case, it is necessary for the evaluation of the environmental risk to comply with the requirements referred to in Directive 2001/18/EC and for the national competent authorities designated by Member States for this purpose to be consulted by the Authority. In addition, it is appropriate to give the Authority the possibility of asking one of these competent authorities to carry out the environmental risk assessment. It is also appropriate, in accordance with Article 12(4) of Directive 2001/18/EC, for the national competent authorities designated under the said Directive in all cases concerning GMOs and food and/or feed containing or consisting of a GMO to be consulted by the Authority before it finalises the environmental risk assessment.²⁷

If and as long as no environmental authorization is acquired, only a processed food can be placed on the market, not a viable organism.²⁸ As indicated in the recital, the integration can be procedural in that after receiving the application EFSA requests the national authority that is competent under Directive 2001/18/EC to perform the risk assessment,²⁹ but it can be substantive as well in that EFSA performs the assessment itself.³⁰

26. “The Authority” is the European Food Safety Authority (EFSA). *See generally* EUROPEAN FOOD SAFETY AUTH., <http://www.efsa.europa.eu> (last accessed May 24, 2014).

27. Commission Regulation 1829/2003, Recital 33, 2003 O.J. (L 268) 1, 4 (EC).

28. *See, e.g., id.* arts. 6(4), 7(8), at 8–9.

29. *See id.* art. 6(3)(a), at 8.

30. *Id.* art. 5(5), at 8.

The documents addressing the one-door-one-key principle do not elaborate why it should be applied and much less why it should be considered a principle. One has to assume that the approach is based on considerations of efficiency and clarity of legislation.

IV. FUTURE CHANGES IN THE SCOPE?

A group of thirteen Member States asked the European Commission to limit the scope of the “key” to cultivation in the EU by returning to them the freedom to decide whether or not they wish to cultivate GM crops on their territory. In response, the European Commission submitted a proposal to the European Parliament to amend Directive 2001/18/EC in such a way that “Member States may adopt measures restricting or prohibiting the cultivation of all or particular GMOs authorized.”³¹ Such measures must be “based on grounds other than those related to the assessment of the adverse effect on health and environment which might arise from the deliberate release or the placing on the market of GMOs.”³² The Commission has in mind “grounds relating to the public interest other than those already addressed by the harmonised set of EU rules which already provide for procedures to take into account the risks that a GMO for cultivation may pose on health and the environment.”³³ In the public debate, these grounds are loosely referred to as “social-economic.”

The European Parliament, however, has proposed to connect the competence of Member States to restrict cultivation to “duly justified grounds relating to local or regional environmental impacts.”³⁴

The opinions of the European Commission and the European Parliament seem to differ fundamentally. For this reason, it does seem likely that the procedure will be lengthy before any actual amendment will occur.

V. SITUATION ON THE EU MARKET

From the above follow three potential uses of GMOs that deserve our attention: for food, for feed, and for cultivation. Prior to the introduction of the new GMO package, 18 GMOs had been approved for commercial release into the environment under Directive 90/220/EEC,

31. *Proposal for a Regulation of the European Parliament and of the Council Amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of GMOs in Their Territory*, at 13, COM (2010) 375 final (July 13, 2010), available at http://ec.europa.eu/food/food/biotechnology/docs/proposal_en.pdf.

32. *Id.*

33. *Id.* at 12 (draft recital ¶ 8).

34. *Position of the European Parliament*, PARL. EUR. DOC. 2010/0208(COD).

two of which were also approved for food use. Under the Novel Foods Regulation an additional 13 GM foods have been approved.³⁵

Since the new system went into force, in total, 45 GMOs have successfully passed an authorization procedure in the EU. Of those authorized, 45 are approved for food and feed use and have been included in the register.³⁶ Thus, under the new system, food authorizations have significantly increased while cultivation authorizations have dramatically decreased.

With regard to the presence of these products on the market, the situations on the food and feed market differ dramatically from each other. On the food market, GMOs are virtually absent. GM labels have become collectors' items. Of all compound feeds, by contrast, the vast majority—between 85 and 90 percent—is labeled as GM. Up to 95 percent of imported soy is labeled GM and used for feed.³⁷ Non-GM feed is mainly used in organic production.

The European Commission sees the large presence of GM feed on the EU market as evidence of the functionality of the regulatory framework. The absence on the food market, in the view of the Commission, is not caused by this framework but by market forces.³⁸

In our understanding, only one factor can explain this state of affairs: consumer preference. Human consumers in the EU seem adamant in their rejection of GM food. Non-human consumers—and in particular the farmers feeding them—base their choice on other priorities, such as price.

35. The figures have been taken from a Commission document: Memorandum from the European Comm'n on Question and Answers on the Regulation of GMOs in the EU (July 1, 2003), available at http://ec.europa.eu/dgs/health_consumer/library/press/press298_en.pdf. This document takes stock of the existing situation at the eve of entry into force of the new package.

36. *Health and Consumers: EU Register of Authorised GMOs*, EUROPEAN COMM'N, http://ec.europa.eu/food/dyna/gm_register/index_en.cfm (last visited May 17, 2014).

37. FOOD CHAIN EVALUATION CONSORTIUM, EVALUATION OF THE EU LEGISLATIVE FRAMEWORK IN THE FIELD OF GM FOOD AND FEED xvii, 118 (2010) [hereinafter FCEC EVALUATION REPORT], available at http://ec.europa.eu/food/food/biotechnology/evaluation/docs/evaluation_gm_report_en.pdf; see also FOOD CHAIN EVALUATION CONSORTIUM, EXECUTIVE SUMMARY: EVALUATION OF THE EU LEGISLATIVE FRAMEWORK IN THE FIELD OF GM FOOD AND FEED 6 (2010), available at http://ec.europa.eu/food/food/biotechnology/evaluation/docs/executive_summary_food_feed_en.pdf.

38. *Report from the Commission to the Council and the European Parliament on the Implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on Genetically Modified Food and Feed*, at 13, COM (2006) 626 final (Oct. 25, 2006), available at <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52006DC0626&rid=1>.

How is the situation with regard to cultivation? On the 2013 global map, showing the 19 biotech mega-countries growing 50,000 hectares or more of biotech crops,³⁹ no less than five EU Member States appear: Portugal, Spain, the Czech Republic, Slovakia, and Romania. Surprisingly, in the EU register we find only one GMO approved for cultivation after 2003, GM maize MON810. In 2010, a second GMO was authorized for cultivation—namely a GM starch potato known as the “Amflora” potato—but Hungary, supported by Austria, France, Luxembourg, and Poland, successfully appealed the authorization decision at the EU Court of Justice.⁴⁰ As a consequence, the number of GMOs authorized both for consumption and for cultivation has decreased from two to one by the end of 2013.⁴¹

The one-door-one-key principle leaves businesses the choice to apply both for an authorization for consumption and for cultivation in one combined application, to do it in two separate applications, or to apply only for one of these uses. The number of authorizations found indicates that since the introduction of the new framework businesses almost unanimously choose to apply for consumption only and not in combination with cultivation, or indeed at all for cultivation. Literature does not provide a satisfactory explanation for this state of affairs. Therefore, we approached stakeholders to find out which factors have influenced their decisions.

VI. STAKEHOLDERS' CONSIDERATIONS

As the group of stakeholders actively involved in the authorization of GMOs is very small, the number of interviews we could conduct was limited. We spoke with an academic researcher active in gene technology, an academic researcher specialized in risk regulation, and a representative from the European Commission. Businesses were very reluctant to discuss their policies regarding GMOs. Nevertheless, we did manage to speak to representatives from four businesses involved in one or more GM authorization procedures in the EU, including one former employee of such a business who was willing to share his or her personal opinion. Despite the relatively small number of interviewees, we gained some interesting boardroom insights shared here below. As we promised

39. CLIVE JAMES, ISAAA BRIEF NO. 46, GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2013 (2013), *available at* <http://www.isaaa.org/resources/publications/briefs/46/default.asp> (prepared and updated annually).

40. Case T-240/10, Hungary v. Comm'n, 2013 EUR-Lex CELEX LEXIS 645 (Dec. 13, 2013).

41. Apparently, the earlier authorizations have expired and have not been renewed.

confidentiality, we will not trace the information provided here below back to recognizable persons or businesses.⁴²

A. Observations Regarding the Authorization Decision

All interviewees agreed that the possibility of an unfavorable outcome on the application for an authorization is always present. Thus, this possibility is taken into account in strategic business decisions.

Several interviewees pointed out that the single procedure as envisaged under the one-door-one-key principle results in one decision authorizing all requested applications of the GMO at issue or none at all. By consequence, if on the basis of the dossier and the risk assessment one use could be authorized while the other could not, the application would be rejected in its entirety—not partially granted. For this reason, the businesses considering an application both for consumption and for cultivation will submit them separately.

The representative from the European Commission pointed out that, at any stage of the procedure, the applicant can decide to split the application and continue as two separate applications.

B. Observations Regarding the Procedure

Interviewees noted some attractive elements in the integrated procedure. For example, preparing one file and dealing with the same people may be faster and less costly than submitting different files to different people. However, one business interviewee pointed out that the opposite can be true as well. The authorization procedure for cultivation under Directive 2001/18/EC is conducted at Member State level. This gives the applicant the option to select a favorable forum and/or language.⁴³

Interestingly, the representative of the European Commission expects that the number of applications for cultivation may increase when the proposal to amend Directive 2001/18/EC⁴⁴ is enacted. The proposal is to return to the Member States the power to restrict or prohibit cultivation of approved GMOs in its own territory based on

42. As the number of interviews is insufficient for any meaningful quantitative observations, we will only derive qualitative observations from the responses received.

43. Also, a 2011 EPEC evaluation report notes that the procedure under Directive 2001/18/EC provides “more opportunities for direct discussion between notifiers and those conducting the appraisal of the risk assessment.” EUROPEAN POLICY EVALUATION CONSORTIUM, EVALUATION OF THE EU LEGISLATIVE FRAMEWORK IN THE FIELD OF CULTIVATION OF GMOs 75 (2011), available at http://ec.europa.eu/food/food/biotechnology/evaluation/docs/gmo_cultivation_executive_summary_en.pdf.

44. See *supra* Part IV.

other considerations than risk to the environment or to human health. Probably the spokesperson believes that to have this power will reduce the incentive for some Member States to oppose authorizations.

As there will be one single decision in the integrated procedure, a decision will only be forthcoming after all aspects of the procedure have been addressed. In this way, the slower procedure will delay the faster one. Interviewees from two businesses both indicated that risk assessment for consumption can be completed in three to four years, while risk assessment for cultivation may take ten years or more. And risk assessment is only one element of the procedure. Authorization for cultivation can easily take thirteen years. Apart from the intrinsic differences between the authorizations involved, in individual cases one procedure may inexplicably run more smoothly than another, making it preferable not to have them depend on each other.

The average cost of discovery, development, and authorization of a new plant trait was estimated by one interviewee as \$136 million USD over 2008–2012.⁴⁵ If there is no return on investment within five years or if the innovation is outdated before authorization is achieved, in the long run this is not sustainable.

C. Observations Regarding European Conditions

One of the business interviewees pointed out that pest resistance in crops is developed with certain pest-related problems in mind. There is no economically sound reason to apply for authorization in the EU if the crop is designed to deal with a pest not prevalent in Europe.

Another of the business interviewees considered the situation regarding the cultivation of GMOs in the EU unpredictable. For this reason, this business focuses on imports into the EU.

One interviewee, finally, observed that in the global arena, Europe is not well placed for agricultural production. Cost in labor and taxes are high and regulatory requirements on environmental and other issues are strict. Social opposition to GMOs is also a risk factor. The calculation is economic. Europe is much more attractive for sales (in animal feed in particular) than for production. Incomes are high and prices are good. In other words, it is an attractive sales market, but not an attractive production market. Sales do not depend on production in Europe; they can be achieved via imports as well. By consequence, the economic option is to produce in China and other low-cost countries and export to

45. According to the 2010 FCEC Evaluation Report, costs in the EU are about 25% above costs in the United States. FCEC EVALUATION REPORT, *supra* note 37, at XV, 65.

Europe. To make this export possible, market authorization is needed but cultivation authorization is not.

VII. DISCUSSION

In 2006, the first author had the honor to be a guest of the American Soybean Association.⁴⁶ The hosts were so kind to explain why the Association and its members highly value GM produce. They consider GM soy a more uniform, controllable, and predictable product and therefore a higher quality product than conventional soy. They also indicated that as long as the EU and other markets are willing to pay a price premium of at least ten percent, it remains commercially feasible to maintain conventional production for these markets and to ensure strict systems of segregation and identity preservation. The main position taken towards the EU, however, was: “we have given up on your consumers; we want to feed your cattle.” It now seems that “they”—or at least the innovative GM businesses—have given up on the European crop farmers as well. It appears that for those who have the resources to invest in GM approvals, the EU is a sales market (for feed uses), not a production market. The reasons are legal and economic, but mainly political.

With the recast of the GM legal infrastructure the EU legislature intended to create a door, one that could be opened with a single key. It does not seem that a door has been welcomingly opened. Some bridges have indeed been made less precarious to pass over but solid walls are still in place.⁴⁷

The one-door-one-key principle is a tool designed to streamline procedure. It does not seem to have any fundamental attributes justifying the label “principle.” Thus, no matter of principle should stand in the way of reconsidering this tool if it fails to serve its purpose. And with regard to cultivation of GM crops, fail it did.

From the point of view of access to the EU market, combining the authorization into one procedure resulting in one decision has been counterproductive. Combining the procedure could be attractive for businesses only if it could lead to partially positive outcomes in the sense of authorization for a single use in the event that not all requirements are satisfied, rather than a full rejection.

46. See generally AM. SOYBEAN ASS'N, <http://soygrowers.com> (last visited May 23, 2014).

47. In choosing this wording, we took inspiration from John Lennon. When in 1974 he released his album WALLS AND BRIDGES (Apple Records), in an interview he explained the title to be about human relations. Walls separate, bridges connect. Applied to this Article, we ask the question: has the gap to the EU been bridged or rather another wall erected?