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In the Public Interest? A Comparative Analysis of Norway and EU GMO Regulations

Apolline Roger*

The European Commission, when deciding whether the cultivation and use of genetically modified organisms (GMOs) should be authorized on European Union (EU) territory, has always limited its decision to safety considerations. Dissatisfied, Member States required the adoption of the 'GMO Package'. Its first application, Directive 2015/412, gives Member States the same opportunity that was already offered to Norway under the EEA Agreement. It allows them to invoke social grounds to opt out of EU authorizations, but maintains the competence of the EU institutions over safety issues. The interpretation of the Directive promises to be contentious. How and to what extent may the Member States use the new provisions to open a debate on when authorizing a GMO is in the public interest? Learning from the Norwegian authorities that have done so since 1994, this article offers insights both on the Norwegian system and on the potential of the new Directive.

INTRODUCTION

Genetically modified organisms (GMOs) are now widely used. In 2013, GMOs, mostly cotton, maize and soy, were cultivated on 174 million hectares of land. Genetically modified (GM) soybeans occupy 79 percent of the world soy production surface.¹ This change in agricultural practices is generally regulated. Many countries decided to submit genetically modified organisms (GMOs) to a pre-market authorization at the national level² and to cooperate on the matter at the international level.³ The identification of which GMOs can be released into nature and society has therefore been recognized not only as a matter of public interest but also as requiring the intervention of public authorities.

For a researcher in law, but more generally for social scientists, this situation raises important questions typical of the integration of new and ethically sensitive technologies in society. One of them is the way public authorities define what is in the 'public interest' in relation to new technology; the public interest that pre-release authorization procedures are deemed to protect. Indeed, the way public interest is defined, implicitly or explicitly, shapes the objective, scope and ambition of the regulation. It is therefore the core of the regulation and, as such, should be clearly identified, thoroughly debated and democratically agreed upon.

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¹See GMOcompass, 'Genetically Modified Plants: Global Cultivation on 174 Hectares' (2013), found at: http://www.gmo-compass.org/eng/agri_biotechnology/gmo_planting/257.global_gm_planting_2013.html.

² Even though these regulations display very different characteristics. See L. Bodiguel and M. Cardwell (eds.), *The Regulation of Genetically Modified Organisms: Comparative Approaches* (Oxford University Press, 2010), see also J. A. Heinemann, S. Zanon Agapito-Tenfen and J.A. Carmand, 'A Comparative Evaluation of the Regulation of GM Crops or Products Containing dsRNA and Suggested Improvements to Risk Assessments', 55 *Environment International* (2013), 43; and L. Krämer, 'Genetically Modified Living Organisms and the Precautionary Principle' (TestBiotech, 2013).

³ Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Cartagena, 29 January 2000; in force 11 September 2003).

Today, most countries limit the assessment of GMOs to the risks they might present for health and the environment. The release of a GMO considered as 'safe' is therefore assumed to be in the public interest.⁴ The protection against physical harm is undoubtedly of primary importance, and the breadth and depth of the regulation on this matter should be carefully designed. Yet, when the decision to authorize a GMO event⁵ is based purely on safety, the socio-economic, cultural and ethical dimensions of the release of GMOs into society are ignored, even though these aspects are essential. Indeed, most GMOs are technological applications meant to change two fundamental areas of human societies: agriculture and the food chain, keystones of environmental and social balance, of survival, health, culture and well-being. What is in the interest of society, or 'public interest', is therefore much wider than the protection from physical harm when it comes to GMOs. It also encompasses a debate of their impact on, for example:

- the quality, quantity and diversity of food;
- the cultural perceptions and preferences related to food, and the right to choose;
- the preservation and promotion of sustainable agriculture, i.e. agriculture capable of performing its multiple social, productive and environmental functions in the context of increasing environmental and land-use pressures, growing population and climate change;
- the power dynamics in the agriculture and food sectors;
- the preservation of rural communities;
- the preservation of the farmers' involvement in scientific innovation, the right to science, access to seeds, and the protection of traditional knowledge.

The impact of a given GMO event or trait on these aspects can be null, negative or positive and is often, in practice, an intricate mix of all of these. The considerable weakness of regulations focused on safety is the voluntary blind spot they create towards the potential societal disturbances caused, which are fully ignored. The other consequence of this orientation is the abortion of a debate on the societal benefits. The problem is that if it is assumed that the producers of GMOs receive economic benefits from their commercialization, assuming wider societal benefits seems a rather excessive shortcut. This is especially the case when looking at the mounting evidence challenging the existence of the long-term benefits of GMOs use for farmers and the environment.⁶ Against this backdrop, this article argues that GMO regulation should address the abovementioned blind spot and question the associated underlying assumptions.

⁴ See P.B. Thompson, 'Ethics and Equity', in: K. Ludlow, S.J. Smyth and J. Falck-Zepeda (eds.), *Socio-economic Considerations in Biotechnology Regulation* (Springer, 2014), 97; M. Lee, 'Beyond Safety? The Broadening Scope of Risk Regulation', 62:1 *Current Legal Problems* (2009), 242; and L. Levidow and S. Carr 'How Biotechnology Regulation Sets a Risk/Ethics Boundary', 14:1 *Agriculture and Human Values* (1997), 29.

⁵ 'When scientists develop transgenic plants, plant cells are transformed with foreign DNA individually. Every cell that successfully incorporates the gene of interest represents a unique "event". Marker genes are used to identify transformed cells, and each resulting transgenic plant is the result of one event'. See <<http://www.gmo-compass.org/eng/glossary/>>. When more than one gene is transferred the GMO is called a 'stacked event'.

⁶ See T. Kaphengst *et al.*, Final Report. Assessment of the Economic Performance of GM Crops Worldwide (Ecologic Institute, 2011).

However, the complexity of a more holistic approach also has to be taken into account. As Maria Lee rightly states, '[i]ntegrating social and ethical perspectives into innovation and its regulation is actually rather daunting'.⁷ Several studies have established the necessity to address considerations beyond risk,⁸ but have not proposed how the legal framework can be designed to support such an approach. This article seeks to contribute to the construction of a regulatory toolkit that could be used to make GMO regulation an instrument to steer innovation towards sustainable agriculture.

Because of the complexity of the process proposed, it is assumed that there is a need to learn from the legal orders with experience on this matter, while carefully considering the specificities of each social and legal culture. The objective is therefore not to develop a theory laying down the basis of a universal model, but to exploit the richness of the comparative method in order to identify best practices and evaluate their relevance as inspiration for another legal order.

Such an approach is particularly needed at this time within the European Union (EU) legal order, in light of Directive 2015/412,⁹ and more generally the recent adoption of the new GMO Package.¹⁰ This legislation, the details of which will be set out below, aims at giving Member States the possibility to opt out on social grounds from authorizations granted at the EU level. In the coming months, Member States will therefore have to refine their interpretation of the package in order to define their internal GMO policies in conformity with EU law. This process promises to be complex, especially if they intend to adopt an ambitious interpretation of their new power in order to address both the societal impacts and the societal benefits of GMOs. However, learning from the Norwegian experience might facilitate the process.

First, Norway is a pioneer in the holistic assessment of GMOs, assessing both their physical and social impacts since 1993.¹¹ Second, it has developed an innovative way to evaluate the societal benefits of GMOs. Third, Norway is partially subject to the EU GMO regulation framework that Member States have to respect.¹² An interesting

⁷ See M. Lee, n. 4 above, at 279.

⁸ Ibid.; see also M. Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology* (Edward Elgar, 2008); M. Kritikos, 'Traditional Risk Analysis and Releases of GMOs into the European Union: Space for Non-scientific Factors?', 34:3 *European Law Review* (2009), 405; A. Spök, *Assessing Socio-Economic Impacts of GMOs: Issues to Consider for Policy Development* (German Ministry of Health, 2010); D. Du, 'Rethinking Risks: Should Socioeconomic and Ethical Considerations Be Incorporated into the Regulation of Genetically Modified Crops?', 26:1 *Harvard Journal of Law & Technology* (2012), 376.

⁹ Directive 2015/412/EU of 11 March 2015 Amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of Genetically Modified Organisms (GMOs) in Their Territory, [2015] OJ L68/1.

¹⁰ Commission Proposal of 22 April 2015 for a Regulation of the European Parliament and of the Council Amending Regulation 1829/2003 as Regards the Possibility for the Member States to Restrict or Prohibit the Use of Genetically Modified Food and Feed on Their Territory, COM(2015) 177 ('Commission Proposal').

¹¹ Norway was joined later by France; see <http://www.hautconseildesbiotechnologies.fr/en>.

¹² Directive 2001/18/EC of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC, [2001] OJ L106/1, is applicable to Norway as a member of the European Economic Area (EEA) Agreement. The application of Directive 2001/18 relies on a compromise similar to the one that was later taken up by the new Package: Norway remains free to reject the authorizations on the basis of concerns other than health

parallel can therefore be drawn. This article intends to examine whether Member States have something to learn from the Norwegian approach while considering if the limits of their competence under EU law will allow them to do so.

The Norwegian model is often mentioned¹³ and has been the object of academic attention.¹⁴ However, the few legal analyses available in English only offer a limited overview of the legislation.¹⁵ This research therefore adds to the available literature by synthesizing the main legal characteristics of the Norwegian model. It also complements the first academic reactions to the GMO Package¹⁶ by assessing whether it will allow Member States to steer innovation towards sustainable agriculture. More generally, it aims at contributing to the identification of a regulatory framework capable of enabling and guiding public authorities when they intend to steer responsible innovation.

The article begins by explaining the most interesting feature of the Norwegian model, i.e. the utilization of a ‘test’ verifying whether the assessed GMO is needed by society to achieve sustainable development in general and sustainable agriculture in particular, both in Norway and beyond. It then exposes the tensions in the objectives of the Package, whose provisions give a considerable amount of leeway to Member States while trying to guide them towards a restrictive interpretation in order to protect the functioning of the market and of the authorization process. The article next sheds light on the underlying assumptions behind the EU and Norwegian legislation, which are reflected in a different conception of the role of public authorities towards GMOs. The article proceeds to explore whether, despite these different assumptions, a

and environment. See Decision of the EEA Joint Committee No 127/2007 of 28 September 2007 amending Annex XX to the EEA Agreement, [2008] OJ L47/58, Article 1.

¹³ See, e.g., L. Krämer, n. 2 above; A. Spök, n. 8 above; K. Ludlow, S.J. Smyth and J. Falck-Zepeda, ‘Introduction to Socio-Economic Considerations in the Regulation of Genetically Modified Organisms’, in: K. Ludlow *et al.*, n. 4 above, 3; J. Husby ‘Sustainability, Social and Ethical Considerations in Regulations’, in: T. Traavik and L. Ching (eds.), *Biosafety First – Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms* (Tapir Academic Press 2009).

¹⁴ See G.K. Rosendal, *Competing Knowledge Claims and GMO Assessment by the Norwegian Biotechnology Advisory Board* (Fridtjof Nansen Institute, 2007) (‘G.K. Rosendal, 2007’), at 4; V. Kvakkestad and A. Vatn, ‘Regulating the Release of GMOs: Contrasts between the European Union and Norway’, 26:5 *Environment and Planning C: Government and Policy* (2008), 968; O.K. Fauchald, ‘Genetically Modified Organisms and Precaution in Norwegian Law’, in: N. De Sadeleer (ed.), *Implementing the Precautionary Principle* (Earthscan 2012), 229; G.K. Rosendal, ‘Interpreting Sustainable Development and Societal Utility in Norwegian GMO Assessments’, 18:4 *European Environment* (2003), 243 (‘G.K. Rosendal, 2003’); A.I. Myhr and T. Traavik, ‘Sustainable Development and Norwegian Genetic Engineering Regulations: Applications, Impacts and Challenges’, 16:4 *Journal of Agricultural and Environmental Ethics* (2003), 317.

¹⁵ See O.K. Fauchald, n. 14 above.

¹⁶ M. Dobbs ‘Legalising General Prohibitions on Cultivation of Genetically Modified Organisms’, 11:12 *German Law Journal* (2010), 1347; L. Moore Smith ‘Divided We Fall: The Shortcomings of the European Union’s Proposal for Independent Member States to Regulate the Cultivation of Genetically Modified Organisms’, 33:3 *University of Pennsylvania Journal of International Law* (2012), 841; M. Weimer, ‘What Price Flexibility: The Recent Commission Proposal to Allow for National Opt-Outs on GMO Cultivation under the Deliberate Release Directive and the Comitology Reform Post-Lisbon’, 1:4 *European Food and Feed Law Review* (2011), 232, M. Geelhoed, ‘A Growing Impasse: the Future of the EU’s GMO Regime’ (University of Edinburgh, 2014), page 18; M. Lee, ‘GMOS in the Internal Market: New Legislation on National Flexibility’ (on file with author); M. Weimer, ‘Risk Regulation and Deliberation in EU Administrative Governance – GMO Regulation and Its Reform’, *European Law Journal* (2015, forthcoming).

Member State could exploit the margin of appreciation granted by the Package to adopt the innovative ‘tests’ developed by Norway. The article concludes by drawing lessons from a difficulty experienced by Norway that will probably be faced by Member States: the lack of data.

THE NORWEGIAN SOCIAL ASSESSMENT: A TOOL TO SELECT SUSTAINABLE GMOs

In Norway, the regulatory framework distinguishes GMOs according to their nature (living or non-living¹⁷). The importation and production of living GMOs are regulated by the Gene Technology Act (GTA).¹⁸ The regulation of ‘non-living’ GMOs depends on their utilization. Processed food¹⁹ and feed²⁰ are dealt with by the Food and the Feed Regulations.²¹ The import of non-living GMOs for industrial use or of a final non-food product derived from GMOs (e.g. a T-shirt made with GM cotton) is not submitted to a specific pre-market authorization.²²

Only the GTA requires the assessment of the social dimension of GMOs’ authorization. The other regulations are limited to safety, even though their implementation might be influenced by the GTA’s holistic approach, which takes into account the physical and social impacts of GMOs.²³ The following therefore focuses on the GTA, in order to identify its definition of the public interest as reflected by its objective and by the criteria used to implement it.

THE OBJECTIVE OF THE GTA: STEERING INNOVATION TOWARDS SUSTAINABLE DEVELOPMENT

¹⁷ A ‘living’ organism is capable of transferring material and of replicating.

¹⁸ Act of 2 April 1993 No. 38 Relating to the Production and Use of Genetically Modified Organisms (‘GTA’), found at: <<https://www.regjeringen.no/en/dokumenter/gene-technology-act/id173031/>>.

¹⁹ General Regulations Relating to the Production and Marketing of Foodstuffs (‘Generell forskrift for produksjon og omsetning mv. av næringsmidler’) (1983), found at: <<https://lovdata.no/dokument/SF/forskrift/1983-07-08-1252?q=generell+forskrift+for+produksjon+og>>.

²⁰ Regulations on Feedstuff (‘Forskrift om fôrvarer’) (2002), found at: <<https://lovdata.no/dokument/SF/forskrift/2002-11-07-1290>>.

²¹ The Food and Feed Regulations implement the Food Act (‘Matloven’), full name ‘Act on Food Production and Food Safety (‘Lov om matproduksjon og mattrygghet mv.’) (2003), found at: <<https://lovdata.no/dokument/NL/lov/2003-12-19-124?q=matloven>>.

²² They are not distinguished from products not derived from GMOs. See the explanation on the website of the Norwegian: Biotechnology Advisory Board (in Norwegian), found at: <<http://www.bioteknologiradet.no/temaer/genmodifiserte-planter-og-mat/regelverk>>. Under EU law, only non-food products derived from GMO benefit from such an exception.

²³ Before the modification of the Food and Feed Regulations in 2005, 19 feedstuffs could enter the Norwegian market because the authorizations given by the EU under Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms [1990] OJ L 117 were applicable through the EEA agreement. After the three-years transition period, it was possible to obtain a one-year derogation from the obligation to ask an authorization under the Food and Feed Regulations for ‘special circumstances’ (see Regulations on Feedstuff, n. 20 above, Section 24). The exemption was allowed every year from 2005 to 2014. However, in 2014, the Norwegian Food Security Authority refused to grant the exemption, considering that there was no ‘real need’ for such feedstuff. See

<http://www.mattilsynet.no/planter_og_dyrking/genmodifisering/bakgrunn_for_avslag_om_aa_bruke_genmodifisert_fiskefor.16613> (in Norwegian). No processed food or feedstuff has been authorized on the Norwegian market since.

The purpose of the GTA is to ensure that the production and use of GMOs ‘take place in an ethically justifiable and socially acceptable manner, in accordance with the principle of sustainable development and without adverse effect on health and the environment’.²⁴ Safety is therefore rather part of the expected result, which also has to be in line with societal values and with the political orientation towards sustainable development. The aim is not to reject biotechnologies, but to sort out which of their applications are worth accepting in light of their impacts on, and contribution to, sustainable agriculture. The GTA therefore intends to steer responsible innovation, as shown by the aim of the Act’s proposal: to ‘ensure that modern biotechnology is utilized for the common good’.²⁵

This holistic approach to public interest is confirmed by the weight given to social concerns in the final decision. The GTA affirms that when taking their decision, the competent authorities²⁶ have an obligation to give ‘considerable weight’ ‘to whether the deliberate release will be of benefit to society and is likely to promote sustainable development’.²⁷ As a result, social and safety assessments are given equal importance. They are both systematically conducted to inform the final decision. Furthermore, social grounds, like safety ones, can be used as stand-alone grounds to refuse to grant an authorization²⁸. The Ministry for the Environment could therefore, on the one hand, decide to prohibit the use of a GMO presenting no risk but whose use or production is not socially justifiable. However, so far this has not happened, and such a decision would probably be reserved for extreme cases.²⁹ On the other hand, a positive social assessment might support a more flexible application of the strict requirement of Section 10 of the GTA³⁰ requiring ‘no risk’ of adverse effects on health or the environment. Indeed, if a GMO presents a very low risk, this risk can be deemed acceptable because of very high societal benefits.

The institutions set up by the GTA confirm that social and safety assessments equally contribute to the final decision. Indeed, two ‘mirror’ advisory bodies were created: one in charge of the safety assessment, the other of the social assessment (the Norwegian Biotechnology Advisory Board (NBAB))³¹. Both assessments are seen as requiring the same efforts in terms of data gathering, checking and synthesizing.³² The GTA, therefore, does not abide by the reductionist presentation of safety grounds

²⁴ GTA, n. 18 above, Section 1.

²⁵ Norwegian Biotechnology Advisory Board (NBAB), *Sustainability, Benefit to the Community and Ethics in the Assessment of Genetically Modified Organisms: Implementation of the Concepts set out in Sections 1 and 10 of the Norwegian Gene Technology Act*, 2nd edn (2009), found at: <http://www.bion.no/filarkiv/2010/07/2009_11_18_diskusjonsnotat_baerekraft_engelsk.pdf>, at 17.

²⁶ More precisely, the Ministry of the Environment, upon the recommendation of the Directorate for Nature Management, which coordinates the decision making process. See G.K. Rosendal, 2007, n. 14 above.

²⁷ GTA, n. 18 above, Section 11.

²⁸ Ibid., Section 10. This was confirmed by the NBAB guidance; see NBAB, n. 25 above.

²⁹ See G.K. Rosendal, 2003, n. 14 above; and G.K. Rosendal, 2007, n. 14 above; see also V. Kvakkestad and A. Vatn, n. 14 above; A.I. Myhr and T. Traavik, n. 14 above; and G.K. Rosendal, ‘Societal Utility and Sustainable Development’ (Directorate for Nature Management, 2009).

³⁰ See NBAB, n. 25 above, at 6.

³¹ <<http://www.bioteknologiradet.no/english/>>.

³² See NBAB, n. 25 above, which highlights the lack of available information; and A. Spök, n. 8 above, explaining the controversies around social data. See also T. Kaphengst *et al.*, n. 6 above, for a meta-analysis of the literature and an explanation of the gaps (lack of knowledge, uncertainties) currently left open in social data.

as ‘scientific’ and social grounds as ‘non-scientific’. The Norwegian system recognizes that it is impossible for competent authorities to form an opinion on the complex social issues at stake without the support of experts from social and natural sciences. Furthermore, the composition of the NBAB reflects that expertise is not possessed solely by scientists. A minority of relevant stakeholders also bring their knowledge and experience to the table.³³ As a result, the NBAB enjoys a very high level of legitimacy and trust from the public.³⁴

The GTA therefore aims at steering biotechnology innovation towards sustainable development, by requiring the competent authorities to give equal attention to social and safety concerns, and by giving them the appropriate institutional support to do so. However, the GTA remains silent on the exact interpretation to be given to the very malleable concepts used to formulate its objectives: ‘sustainable development’, ‘ethics’ and ‘social acceptability’. Considering that the social assessment informs and frames the final decision, the way the objectives of the GTA are translated in assessment criteria is absolutely fundamental.

THE ASSESSMENT CRITERIA

Being in charge of the social assessment, the NBAB had to quickly develop operational criteria to fulfil its task. These criteria were published in the NBAB 2000 guidance document³⁵ and later enacted in the 2005 Regulation Relating to Impact Assessment Pursuant to the Gene Technology Act (IAR).³⁶ Appendix 4 of the IAR now lists the five criteria framing the assessment:

- Risks of adverse effects on the environment and on human & animal health;
- Precautionary principle;
- Sustainable development;
- Societal benefits; and
- Ethical considerations.

³³ This is why the 15 members of the NBAB include stakeholder representatives (including from nongovernmental organizations and political parties), even though the majority is composed of scientists from relevant fields of research both from natural sciences (medicine, biology, etc.) and social sciences (philosophy, ethics, political sciences, law). France adopted a similar model in the composition of the ‘Comité économique, éthique et social’, the ‘social chamber’ of the ‘Haut Conseil des Biotechnologies’ in charge of delivering a social and a natural assessment of GMO to the competent authority. However, the majority of this committee consists of stakeholders rather than academics. See <<http://www.hautconseildesbiotechnologies.fr/spip.php?rubrique20>> (in French).

³⁴ See G.K. Rosendal, 2003, n. 14 above; and G.K. Rosendal, 2007, n. 14 above; see also the NBAB’s affirmation in its opinion of 4 July 2013

on the importation of 27 GM maize, found at: <http://www.bioteknologiradet.no/filarkiv/uttalelser/Sluttbehandling_GMOmais_import_Bioteknologi_nemnda.pdf> (in Norwegian). Furthermore, the procedure adds another legitimizing mechanism by requiring public participation before the final decision is made. See A.I. Myhr and T. Traavik, n. 14 above.

³⁵ This first guidance document was later confirmed by the slightly updated version referred to in n. 25 above.

³⁶ Regulation Relating to Impact Assessment Pursuant to the Gene Technology Act (‘Forskrift om konsekvensutredning etter genteknologiloven’) (2005) found at: <<https://www.regjeringen.no/en/dokumenter/impact-assessment/id440455/>>. The English version of the Regulation seems to be different on some points from the NBAB guidance document, but this is due to translation and not to a real difference in the meaning.

These criteria are directly derived from the objectives of Section 1 of the GTA, from Section 11 setting the ‘requirements relating to approval’, and from the aim of the Act as discussed by the parliament. Importantly, the IAR did not opt for a substantive and precise definition of each criterion, but rather for an indicative list of questions revealing how they should be understood and ‘tested’.

The first and second criteria emphasize how interlinked the social and physical dimensions of public interest are and how important the communication between the respective expert bodies is. The first one obliges the NBAB to take due consideration of the safety assessment results. The second refers to the precautionary principle as an epistemological framework. The more clouded by uncertainties the safety assumptions are, the more the applicants will have to demonstrate the utility of the GMO for society.

Criteria 3 and 5 are explicitly included in Section 1 of the GTA as the objectives of the legislation. As social assessment criteria, they mostly provide guidance on the scope of the assessment. Criterion 3 – the ‘sustainable development test’ – leads the authorities to examine both short- and long-term impacts of GMOs, within Norway and beyond. The appropriate balance between social and environmental protection and economic development is therefore understood as a fair intergenerational and intra-generational distribution of the burdens and advantages of GMOs. Complementing this approach, criterion 5 – the ‘ethics test’ – insists on the importance of giving special attention to weaker groups, in particular indigenous people, and to relevant societal values.³⁷

Criterion 4 – the ‘societal benefits test’ – involves two stages. The first one is typical of all socio-economic impact assessment (SEIA) procedures; the second one is the most innovative feature of the GTA. The first step requires comparing the anticipated economic gains induced by the production and use of the GMO with its adverse impacts on existing production. The process of comparing the anticipated negative and positive impacts of an activity in order to authorize only the predominantly beneficial ones is not new. It is at the core of the procedures of environmental impact assessment and even of the regulatory impact assessment used at the EU level as a tool of ‘simplification’ of the *acquis*.

However, the second step of the Norwegian ‘societal benefits test’ distinguishes it from more classical SEIAs. It goes beyond the analysis of the GMOs’ societal impacts by checking whether there is a societal need for the GMOs. The focus is therefore not on the consequences of the GMO but on its usefulness. It can be quite difficult to define when a GMO event is ‘needed’ by society. In economics, the market is used as a reliable indicator; demand equals need. The NBAB recognizes this by checking whether demand for the characteristics of the product exists. However, the checklist does not stop here and also asks the following questions: ‘will the product solve or possibly contribute to solving a societal problem?’; and ‘is the product significantly better than equivalent products already on the market?’

³⁷ The tests are not strictly separated; global and ethical concerns can be included in the reflection on the societal benefits even though it is primarily concerned with the Norwegian situation.

The objective of the ‘societal benefits tests’ therefore goes beyond the satisfaction of a potential demand on the market. The aim is to identify and promote the best technical solutions, i.e. those supporting the ‘best’ sustainable development in general and sustainable agriculture in particular. The inclusion of this ‘best sustainable alternative’ test in the social assessment is a game-changer compared to more classical SEIAs.

To illustrate, let’s imagine the application of such an approach to the authorization of a quarry. A classical SEIA would evaluate on the one hand the creation of jobs and the opportunities for the local shops to benefit from the arrival of workers (societal benefits). On the other hand, it would consider the social disturbances linked to the noise, traffic and pollution and the potential impact on, for example, tourism (societal impacts). A broad SEIA might also include the cultural significance of the site (ethical and cultural test). A ‘best sustainable alternative’ test would, however, question not only the impact but also the *necessity* of the project: can the current needs be satisfied by existing quarries? Can recycled materials be used instead of the raw material? Do existing policy objectives push towards the preferential use of recycled materials? It is therefore a way to link the individual decision with the current and future needs of society, appreciated in the light of sustainable development as a policy objective.

What has the result of the social assessment been in practice? Since its creation, the NBAB has concluded that the assessed GMOs were not needed by society.³⁸ These conclusions were motivated, for example, by the fact that the assessed GMO was not used and demanded in Norway,³⁹ such as when the pest a GMO was made to fight was not a problem on the Norwegian territory.⁴⁰ Another motivation was that the product was not significantly better than conventional alternatives,⁴¹ for example because the trait gained by genetic modification was already available through natural breeding.⁴² The NBAB has also considered certain GMO events as not needed where they required cultivation practices that appeared less sustainable than more comprehensive strategies to combat pests and weeds.⁴³ In particular, a plant modified to be used with a chemical identified as risky, or as dangerous and already banned, like glufosinate ammonium, was especially considered as not contributing to sustainable agriculture.⁴⁴ Interestingly, this decision did not deal with an authorization

³⁸ See V. Kvakkestad and A. Vatn, n. 14 above.

³⁹ This argument was used to reject several of the authorizations given by the EU under Directive 90/220, which preceded Directive 2001/18 and was applicable to Norway; see, for more detail, V. Kvakkestad and A. Vatn, n. 14 above.

⁴⁰ See, e.g., the opinion of the NBAB on the authorization of Bt Maize 1507 (2013), found at: <http://www.bioteknologiradet.no/filarkiv/2013/12/Sluttbehandling_EFSA_CS_01_01_mais_1507_Bioteknologinemnda.pdf> (in Norwegian).

⁴¹ See V. Kvakkestad and A. Vatn, n. 14 above.

⁴² This was the case for the Amflora potato; see the NBAB opinion (2010), found at: <http://www.bioteknologiradet.no/filarkiv/2010/10/2010_10_04_amflora_dyrking_industri_dn.pdf> (in Norwegian).

⁴³ See, e.g., the opinion of the NBAB on the authorization of Bt Maize 1507, n. 40 above.

⁴⁴ Ibid. See also the response by the Norwegian government to the socio-economic questionnaire of the European Commission, which defended the same conclusion concerning Maize T 25 (15 January 2010), found at: <http://ec.europa.eu/food/plant/docs/plant_gmo-socio-economic_considerations-norway_contribution_en.pdf>; and the NBAB’s opinion about 27 GM Maize (2013), found at: <http://www.bioteknologiradet.no/filarkiv/uttalelser/Sluttbehandling_GMOMais_import_Bioteknologinemnda.pdf> (in Norwegian).

to cultivate, but to import. Even though the farming practices did not directly affect the Norwegian territory, authorizing a product grown in another country from agricultural practices using a chemical banned in Norway was seen as an ethically wrong double standard.

On the other hand, it has also been accepted that even when the social assessment concludes that the GMO event is not needed by society, it could be authorized if it is reasonably certain that it presents no foreseeable risk.⁴⁵ This was the case for several cut flowers authorized for importation under Directive 2001/18,⁴⁶ which is applicable in Norway. However, the Norwegian authorities have not always followed the EU. Ten times they have used their right to reject the EU authorizations given under Directive 2001/18.⁴⁷ The reasons invoked were, however, mostly linked to safety and not to social concerns. Indeed, while no living or processed GM food and feed is currently allowed on the Norwegian territory, it is mostly because, contrary to the European Food Safety Authority, Norway considers that the health risks associated with the use of antibiotic gene markers are high enough to justify a ban.⁴⁸

To conclude, the criteria cover all aspects of the integration of GMOs in society and help define what is considered in the public interest. The ambition is set high, since the effects included in the assessment are those felt both locally and globally, in the short and long term. The ‘best sustainable alternative’ test is a core feature of the Norwegian social assessment. It goes beyond the identification of the positive and adverse impacts by investigating whether society needs the GMO event/trait. After this exploration of the Norwegian system, the way the new European package defines public interest can be analysed to enable a comparison.

SOCIAL ASSESSMENT UNDER DIRECTIVE 2015/412: A TOOL CONSTRAINED BY COMPETING OBJECTIVES

The two-tiered ‘GMO package’ is the most recent of numerous attempts to build an efficient and legitimate GMO governance system within the EU. The first tier of the

⁴⁵ See G.K. Rosendal, 2007, n. 14 above, at 22-23. Eleven cut carnations were authorized for import, despite the fact that the NBAB found an absence of utility for Norwegian Society, because of the absence of risk. See also V. Kvakkestad and A. Vatn, n. 14 above; and B.R. Heide, ‘Socio-economic Considerations in Decision-making on LMOs: Experiences from Norway’, presentation at Cartagena Protocol Workshop (14-16 November 2012), found at: <<http://bch.cbd.int/protocol/socioeconomics/presentations/norway.pdf>>.

⁴⁶ Directive 2001/18/EC, n. 12 above, recitals 9, 58 and 60.

⁴⁷ See V. Kvakkestad and A. Vatn, n. 14 above, for data from 2012. Since then, two carnations have been authorized in 2015 under the Directive and will probably not be rejected by Norway, which already has authorized a lot of carnations. The only other authorization (for the Amflora potato) was rejected in Norway in 2013. See <<http://www.miljodirektoratet.no/no/Nyheter/Nyheter/Nyhetsarkiv/2011/5/DN-sier-nei-til-GMO-potet/>> (in Norwegian). This was the same year the authorization given at EU level was invalidated by: CJEU, Case T-240/10, *Hungary v. Commission* ECLI:EU:T:2013:645.

⁴⁸ The Norwegian parliament took a clear stand on this after several opinions of the scientific committee. The result can be seen in the Regulation Prohibiting Certain Kind of Genetically Modified Foodstuff and Foodstuff Ingredients (‘Forskrift om forbud mot visse genmodifiserte næringsmidler og næringsmiddelingsredienser’) (2000) found at: <<https://lovdata.no/dokument/SF/forskrift/2000-03-04-257>>, Section 1: ‘It is forbidden to produce, import and sell food and food ingredients that contain genes coding for antibiotic resistance where these genes are introduced by genetic modification and can be detected in the final product.’ Regulations on Feedstuff, n. 20 above, Section 8, contains a similar prohibition.

package, Directive 2015/412, was adopted recently to amend Directive 2001/18 on the deliberate release of GMOs into the environment. It gives Member States the power to opt out of an authorization of cultivation given at the EU level, on all or part of their territory. The second tier is still at the first stage of the legislative procedure. Proposal COM(2015) 177⁴⁹ intends to extend the same ‘opt-out’ clause to the use of GM food and feed authorized under Regulation 1829/2003.⁵⁰

The most obvious difference between the Norwegian and EU legislation is the function of the social assessment. Under the GTA, it is systematic and as important as the safety assessment. Under the new Package, the social assessment is optional. It does not require the EU authorities to broaden the basis of their decisions, which can still address only safety issues. Societal issues are therefore seen as a marginal concern, to deal with at the national level, by the Member States inclined to do so.

Furthermore, even when a Member State is so inclined, Directive 2015/412 suggests that an open debate on the matter should be avoided. Rather, Article 26(b) gives priority to a procedure organizing the ‘consensual’ adjustment, by the applicant, of the geographical scope of an application under assessment. Member States can demand to exclude parts or all of their territory from the final decision. The applicant can decide to confirm the original scope. When he abstains from doing so or consents, the territorial adjustment is enacted.

This procedure of ‘voluntary adjustment’ reveals an underlying assumption: public authorities must abstain, as much as possible, from limiting the economic freedoms of actors involved in risky activities. An explicit reflection on the limits to economic and technological freedoms is seen as entailing political and litigation risks. This is why, in a way familiar to the EU’s administration, the debate is diverted towards a negotiated alternative.⁵¹ The priority is to obtain the consent of the applicants, which, in a way, privatizes the final decision. Not only does it give the applicants an opportunity to adapt their strategy at an early stage, but it also limits the risk for public authorities because the final result can no longer be framed as a public limitation of economic freedom.⁵²

⁴⁹ Commission Proposal, n. 10 above. See also the Joint Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 22 April 2015, Reviewing the Decision-making Process on Genetically Modified Organisms, COM(2015) 176.

⁵⁰ Under Regulation 1829/2003, the procedure is carried out at the EU level, where the EFSA is in charge of the risk assessment. The grounds chosen by the Member States must therefore not conflict the risk assessment conducted by the EFSA. See Regulation 1829/2003/EC of 22 September 2003 on Genetically Modified Food and Feed, [2003] OJ L268/1. Regulation 1829/2003 created a ‘one-door, one-key’ system by accepting applications for both the use of GM food or feed and their cultivation, normally authorized under Directive 2001/18. As a result, most of the applications are now placed under Regulation 1829/2003; see <http://gmoinfo.jrc.ec.europa.eu/gmc_browse.aspx>. Proposal COM(2015) 177 might therefore have a significant effect on the system, whereas the already adopted amendment might not be so revolutionary. This is one of the reasons why the proposal is so controversial, and debated so intensely in the European Parliament that it might be abandoned.

⁵¹ See A. Roger, ‘La Transplantation des Accords Environnementaux dans l’Ordre Juridique de l’Union Européenne – Le Modèle Contractuel Hollandais Revisité’, in: M. Hautereau-Boutonnet (ed.), *Contrat et Environnement: Etude de Droit Interne, International et Européen* (PUAM, 2014), Chapter 23.

⁵² Proposal COM(2015) 177 does not contain a mechanism for voluntary adjustments (and neither did the first version of Directive 2015/412). However, the legislative process might lead to alignment with Directive 2015/412. Indeed, the Member States might favour a (more) consensual path to limit the political and legal risk of having to justify an opt-out decision.

The rationale of the optional nature of the social assessment and of this ‘voluntary adjustment’ finds its roots in the compromise between the satisfaction of some Member States’ demands for reform on the one hand and the desire to maintain the *status quo* on the other. The Package offers Member States an additional ‘safeguard’, but explicitly aims at protecting the functioning of the internal market and at providing predictability to the market actors. It also aims at preserving, as much as possible, the pre-existing procedures and improving their application.⁵³

The pre-existing decision-making procedures are indeed kept intact. As their details are now well known,⁵⁴ the following will focus on their main features. Even though the procedures organise a multi-level governance system, their implementation has always ended up at the EU level, with a safety assessment conducted by the European Food Safety Authority (EFSA).⁵⁵ However, the opinion of the EFSA has never brought Member States to a common position at the EU level.⁵⁶ As a result, the Commission has been left with the final word, which in practice has been an enactment of the (always positive) EFSA’s opinion. The Package does not change this system; it only hopes that a sufficient majority for authorizing GMOs will now be achievable, since Member States have a broader possibility to opt out at a later stage.⁵⁷

Because the Package intends to preserve the existing procedures and the free movement of goods, it submits the possibility to opt out to several conditions. First, the Package states that the national measures ‘shall, in no case, conflict with the environmental risk assessment carried out pursuant to this Directive or to Regulation (EC) No 1829/2003’.⁵⁸ This condition aims at protecting the EFSA from national intrusions by defining the grounds which cannot be invoked by Member States. It therefore leaves the question of what they can be quite open. Neither Directive 2015/412 nor proposal COM(2015) 177 provide an exhaustive list of what could be a legitimate compelling ground, although the Directive contains an indicative list.⁵⁹ According to this list, Member States can rely on grounds related to ‘socio-economic

⁵³ Commission Proposal, n. 10 above, recital 6, states it very clearly. Like Directive 2015/412, the aim of the proposal is primarily to smoothen the procedures at EU level. It is ‘intended to provide more predictability to operators and limit the recourse by the Member States to the safeguard clauses provided for in Article 23 of Directive 2001/18/EC and 34 of Regulation (EC) No 1829/2003. It [is] also expected that those amendments would have a positive impact on the decision-making process for the authorisation of GMOs for cultivation.’

⁵⁴ See, e.g., M. Lee, n. 4 above; and M. Lee, n. 8 above.

⁵⁵ The EFSA is competent to conduct the safety assessment under Regulation 1829/2003. Under Directive 2001/18, the Member State to which the application is sent first conducts the safety assessment and proposes a decision, which is communicated to all Member States and the Commission. If these actors do not agree on the decision – and they never have – the case is brought for a final decision at the EU level by the Commission, which has always asked the EFSA to give a positive opinion on the GMO safety.

⁵⁶ Gathered in the competent committee for the first step of the procedure, or in the Council (now ‘appealed committee’) for the second.

⁵⁷ The former (limited) possibility to opt out on safety grounds, which has been used by several States, is also maintained.

⁵⁸ Directive 2015/412, n. 9 above, Article 26b(3); Commission Proposal, n. above, Article 34(a).

⁵⁹ The list is indicative as Directive 2015/412, n. 9 above, Article 26b(3) states: ‘based on compelling grounds *such as* those related to: ...’ (emphasis added). Regulation 1829/2003 does not contain such a list, but it has been conceived as an extension of the Directive. Therefore, the guidance of the former will probably be relevant to the latter.

impacts’, ‘environmental policy objectives’, ‘land use’, ‘town and country planning’ or ‘agricultural policy objectives’ and, ‘public policy’, which can only be invoked in association with another ground. These grounds, broadly formulated, seem to leave a considerable margin of appreciation to Member States.

Furthermore, in addition to invoking a legitimate ground which does not conflict with the European assessment, Member States will also have to demonstrate that their measure respects the other, more severe, conditions set by both texts of the Package. The opt-out has to be reasoned. Article 26b of Directive 2015/412 and Article 34a in proposal COM(2015) 177 also state that opt-out has to be ‘in conformity with Union law’, proportional⁶⁰ and non-discriminatory.⁶¹ These three conditions are an implicit but very clear reminder of Member States’ obligations under internal and/or international trade law.⁶² It is not certain whether a restriction on the right to cultivate GMOs on one’s territory would be seen as a restriction to trade.⁶³ However, it is very likely that somebody who intends to challenge an opt-out will invoke trade law to support his claim. If the measure is indeed seen by Courts (national or European) as impairing the free movement of goods, the Member States will have to demonstrate that they meet the conditions to legally do so.⁶⁴ The exact margin of appreciation for Member States under the new Package read in conjunction with trade law is a complex issue, which deserves a detailed analysis which cannot be conducted within the limits of this article.⁶⁵ The existing literature on the derogations to free circulation

⁶⁰ Member States will have to clearly explain not only that the means fit the aim, but also that the pursued objective could not be attained by less restrictive measures. Depending on the scrutiny of the Courts, their control might lead to finding Member States in breach of their obligations, especially for bans that Member States intend to apply nationally rather than locally. See CJEU, Cases C-452/01, *Margarethe Ospelt and Schlössle Weissenberg Familienstiftung*, [2003] ECR I-09743; and C-192/01, *Commission of the European Communities v. Kingdom of Denmark*, [2003] ECR 2003 I-9693.

⁶¹ The non-discrimination test might easily be passed if GMOs and non-GMOs as or in products are considered different. European Commission, Complementary Considerations on Legal Issues on GMO Cultivation Raised in the Opinions of the Legal Service of the Council of the European Union of 5 November 2010 and of the Legal Service of the European Parliament of 17 November 2010, SEC(2011) 551. However, the debate might not be as straightforward under WTO law.

⁶² Article 216.2 of the Treaty on the Functioning of the European Union (TFEU) submits Member States to the international agreements concluded by the EU, including the WTO agreements. Consolidated Version of the Treaty on the Functioning of the European Union, [2012] OJ C326/47 (‘TFEU’), Article 216.2. The Commission refused to see WTO law as a barrier. See European Commission, Complementary Considerations on Legal Issues on GMO Cultivation Raised in the Opinions of the Legal Service of the Council of the European Union of 5 November 2010 and of the Legal Service of the European Parliament of 17 November 2010, SEC(2011)0551. But Member States nevertheless expressed legitimate concerns. See Council of the European Union, Press Release 7478/12, 3152nd Council Meeting, Environment (9 March 2012). Furthermore, the national opt-outs might also be challenged under the other trade obligations of the EU, for example bilateral treaties.

⁶³ Its impact would be indirect and probably very limited if the restriction does not cover the whole territory. This seems to be the position of the Commission. See European Commission, Considerations on Legal Issues on GMO Cultivation Raised in the Opinion of the Legal Service of the Council of the European Union of 5 November 2010, SEC(2010) 1454, at 11. Arguably, the Commission seems even to be willing to extend the *de minimis* rule to the free movement of goods. Even in this case however, the Court of Justice of the European Union could still qualify the opt-outs as measures having an effect equivalent to a quantitative restriction on imports and a broader restriction might very well be more contentious under internal and/or international trade law. See M. Geelhoed, n. 16 above.

⁶⁴ According to the conditions of Article 36 of the TFEU, n. 62 above.

⁶⁵ But see M. Lee, n. 16 above. See also N. de Sadeleer, *EU Environmental Law and the Internal Market* (Oxford University Press, 2014); and M. Geelhoed, n. 16 above.

obligations can be used as a useful starting point in the matter.⁶⁶ For the purposes of this article, it suffices to acknowledge that the Member States might perceive trade law as a political and legal risk in the design of their opt-out policy and that they will have to carefully explain the nature, necessity and coherence of their measures.

The Norwegian GTA clearly pursues a single aim: steering agro-biotechnology innovations towards sustainable development. The Package aims at three potentially conflicting aims: preserving the functioning of the market, improving the application of the decision-making procedures and broadening the assessment of GMOs to social concerns. The potential tensions are well illustrated by the scope of the Package. Indeed, even if proposal COM(2015) 177 is adopted, the Member States would not have control over the presence of GMOs on their territory: the circulation of GM food, feed and seeds will still have to be left free.⁶⁷ In practice, the Member States who opt out will therefore have to bear the risk of spillage and unauthorized use associated with free circulation. Similarly, a State which opts out, but which is surrounded by GMO-cultivating countries, will have to face a risk of contamination. A high compliance cost might have to be paid if just a few States decide to opt out.⁶⁸

Because of the tension resulting from competing objectives, it is uncertain whether the Package will result in a more holistic approach of what is in the public interest or in further delaying the (re)coupling of physical expertise with a political judgement on the social value of GMOs. The competing objectives open the way for various interpretations, with varying degrees of ambition. Settling on one might very well depend on the underlying assumptions of the text.

NORWAY AND THE EU: DIFFERENT UNDERLYING ASSUMPTIONS

Our comparative analysis reveals different conceptions of GMOs and of the role of public authorities in their governance. The opposition to GMOs in Norway is strong. The Norwegian biotechnology industry is quite weak and its lobbying cannot compete with the influence of the associations opposed to GMOs.⁶⁹ Furthermore, Norway's climate restrains the attractiveness of its fields, and the size of its market is of limited interest. This social and physical context probably contributed to the consolidation of the assumptions underlying the regulation: GMOs should not be released unless there is a good reason to do so (i.e. they do not present any physical or social risk and/or they are needed by society). The role of public authorities is to steer sustainable innovation, by addressing the question 'is the GMO answering a societal need better than available sustainable alternatives?' The focus is therefore on the realization of the policy objective, i.e. sustainable development and sustainable agriculture.

⁶⁶ See M. Lee, n. 4 above; see also L. Moore Smith, n. 16 above; S. Poli, 'Continuity and Change in the EU Regulatory Framework on GMOs, after the WTO Dispute on 'Biotech Products'', 37:2 *Legal Issues of Economic Integration* (2010), 133, at 137; N. Thayyil, *Biotechnology Regulation and GMOs. Law, Technology and Public Contestations in Europe* (Edward Elgar, 2014); N.N. Shuibhne and M. Maci, 'Proving Public Interest: The Growing Impact of Evidence in Free Movement Case Law', 50:4 *Common Market Law Review* (2013), 965; M. Lee, n. 8 above, at 84.

⁶⁷ This is a huge difference with Norway. However, Member States will be able to engage in a social assessment of not only all living GMOs, as under the GTA, but also of processed GM food and feed which is currently not allowed under Norwegian regulation.

⁶⁸ See L. Moore Smith, n. 16 above.

⁶⁹ See G.K. Rosendal, 2003, n. 14 above; G.K. Rosendal, 2007, n. 14 above.

At the EU level, public opinion is much more divided, with some countries strongly in favour of GMOs (e.g. Spain, the Netherlands) and some strongly opposed (e.g. Austria, Hungary). The potential market is very attractive and the preservation of the free movement of goods is one of the core *raison d'être* of the EU. The pro-GMO lobbies are accordingly generously endowed and very active. The regulation therefore logically, but not necessarily rightly, is built on different assumptions than the Norway's. EU regulation assumes that GMOs should benefit from the free movement of goods except when they are reasonably suspected as harmful; the question whether they are needed is ignored. From this perspective, the public authorities' role is to contain the harm potentially caused by GMOs while disrupting, as little as possible, the functioning of the market. To do so, they have to answer the question: does the GMO have a worse impact than the most commonly used alternatives? This is obvious when looking at the EFSA's risk assessment policy. The EFSA uses conventional agriculture as a benchmark,⁷⁰ even though it officially recognizes the 'high diversity' of agriculture models in its guidance documents.⁷¹ The focus is therefore on the functioning of the internal market and on the smooth functioning of the EU procedures. It is also on preserving the *status quo* for environmental and health protection, which is regarded as satisfactory even though 'the unsustainability of the green revolution shows it will not be the model for future agriculture.'⁷²

Despite these differences, could Member States draw inspiration from the Norwegian model in implementing the Package?

LEARNING FROM NORWAY'S INNOVATIONS: THE POTENTIAL BARRIER

As discussed above, the two most original and ambitious features of the Norwegian model are the scope of the assessment, including global and long-term effects, and the 'best sustainable alternative' test. The new Package is presented by the Commission as a measure of de-harmonization; Member States regain the power to adopt a

⁷⁰ See COGEM, *Socio-economic Aspects of GMOs. Building Blocks for an EU Sustainability Assessment of Genetically Modified Crop* (COGEM, 2009); Convention on Biological Diversity, 'Summary Report on the Survey of the Application of and Experience in the Use of Socio-economic Considerations in Decision-making on Living Modified Organisms (UN Doc. UNEP/CBD/BS/COP-MOP/5/INF/10, 17 September 2010); and A. Spök, n. 8 above. For examples of this practice, see: EFSA Panel on Genetically Modified Organisms (GMOs), 'Applications (EFSA-GMO-RX-MON810) for the Renewal of Authorisation for the Continued Marketing of (1) Existing Food and Food Ingredients Produced from Genetically Modified Insect Resistant Maize MON810; (2) Feed Consisting of and/or Containing Maize MON810, Including the Use of Seed for Cultivation; and of (3) Food and Feed Additives, and Feed Materials Produced from Maize MON810, all under Regulation (EC) No 1829/2003 from Monsanto, 1149 *EFSA Journal* (2009), 1; and Panel on Genetically Modified Organisms (GMOs), 'Opinion of the Scientific Panel on Genetically Modified Organisms on a Request from the Commission Related to the Notification (Reference C/ES/01/01) for the Placing on the Market of Insect-tolerant Genetically Modified Maize 1507, for Import, Feed and Industrial Processing and Cultivation, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/Mycogen Seeds, 181 *EFSA Journal* (2005), 1.

⁷¹ EFSA Panel on Genetically Modified Organisms (GMO), 'Scientific Opinion on Guidance for Risk Assessment of Food and Feed from Genetically Modified Plants, 9:5 *EFSA Journal* (2011), 1, at 70.

⁷² D. Quist *et al.*, 'Hungry for Innovation: Pathways from GM Crops to Agroecology', in: European Environment Agency (ed.), *Late Lessons from Early Warnings* (European Environment Agency, 2013), 458.

national policy on the matter. But to what extent? Could they decide to develop a system inspired by the Norwegian approach?

The answer depends on the interpretation of the conditions that Member States need to respect when exercising their competence. As explained above, the most obvious potential barriers are trade law and the necessity to provide evidence for the need and proportionality of the measure, even though these requirements leave space for interpretation. A less obvious and equally difficult and predictable constraint is the clause which delimits the respective competences of the EU institutions and Member States. The Package specifies that national measures ‘shall, in no case, conflict with the environmental risk assessment carried out pursuant to this Directive or to Regulation (EC) No 1829/2003’.⁷³

A strict separation between the realms of social and safety assessment could pose a threat to a State willing to find inspiration in the Norwegian model. Indeed, the Norwegian experience shows how interlinked the social and physical dimensions of GMOs are. Determining the socio-economic impact of GMOs, for example, requires an understanding of their physical impacts. Questioning whether the GMO is the best sustainable alternative involves a potentially deeper intrusion in the realm of safety. Indeed, the performance and physical impacts of the GMOs have to be known, as well as those of their alternatives. Similarly, addressing the intra-generational equity implications of the release requires knowledge on their impact in the producing, neighbouring or importing countries. This interconnection has not caused issues in Norway, even though the country is, like EU Member States, subject to a competence clause which aims at protecting the unity of the (European) safety assessment. The Decision adding Directive 2001/18 to the EU law applicable to Norway under the EEA Agreement inserted a provision which states that:

[t]he Contracting Parties agree that the Directive only covers aspects relating to the potential risks to humans, plants, animals and the environment. The EFTA [European Free Trade Agreement] States therefore reserve the right to apply their national legislation in this area in relation to other concerns than health and environment, in so far as it is compatible with this Agreement.⁷⁴

However, this clause did not constitute a strict obstacle because it exists alongside a ‘safety’ safeguard clause that is much more flexible than the one available to the Member States if they want to depart from the EFSA’s assessment. The EEA decision states that Norway should have the possibility to restrict the circulation of a GMO if it has ‘detailed grounds’ for considering a risk for health of the environment. This restriction can be permanent, and might be discussed in the EEA joint committee.⁷⁵ On this matter, the EEA agreement harmonizes Norwegian and EU law, but to a far lesser degree than within the EU, where Member States have a higher threshold to meet when using the safety safeguard of the Directive or Article 114 TFEU.⁷⁶ An

⁷³ Directive 2015/412, n. 9 above, Article 26b(3); Commission Proposal, n. 10 above, Article 34(a).

⁷⁴ Decision of the EEA Joint Committee, n. 12 above, Article 1, inserting Article 23(c).

⁷⁵ See O.K. Fauchald, n. 14 above; Decision of the EEA Joint Committee, n. 12 above, Article 23.

⁷⁶ The EU GMO regulation’s legal basis is TFEU, n. 62 above, Article 114. When Member States want to derogate from the harmonized measures adopted at the EU level, they have to respect either the conditions set by the Directive itself or the even stricter conditions set by the general safeguard clause detailed by Article 114.5 TFEU: ‘if, after the adoption of a harmonisation measure by the European

intrusion of Member States in the topics covered by the EFSA mandate is therefore less acceptable under EU law than under the EEA agreement. It is therefore important to determine the extent of Member States' leeway under the new provision.

The competence clause allows Member States to consider issues explicitly excluded from the EFSA mandate: the 'ethical and socio-economic aspects'⁷⁷ of the cultivation and use of GMOs. Other 'purely' social issues, for example religious concerns, could also be accepted if sufficient evidence of their relevance can be provided. However, it is less certain whether the clause also allows Member States to venture into dealing with social issues deeply connected with physical ones.

The answer depends on the way the clause prohibiting 'conflicts' between the national measures and the European safety assessment is interpreted. Interpreted strictly, it could involve a complete exclusion of Member States from questions dealing directly or indirectly with safety. Some elements of the Package encourage this interpretation. The recitals of Directive 2015/412 and proposal COM(2015) 177 affirm that it is necessary 'to avoid any interference with the competences which are granted to the risk assessors and risk managers'⁷⁸ under Regulation 1829/2003 and Directive 2001/18. Directive 2015/412 further specifies that this would be done by using grounds 'distinct from and complementary to those assessed according to the harmonized set of Union rules',⁷⁹ whereas the proposal adds that the solution would be to use grounds 'not related to risks to human and animal health and to the environment, as those are already assessed at Union level'.⁸⁰

In addition, recital 15 of Directive 2015/412 refers to a report of the Commission which also points towards a strict interpretation.⁸¹ This report is indeed limited to socio-economic impacts, i.e. the impacts on production and consumption patterns. It ignores wider social concerns, such as the distribution of advantages and burdens of GMOs or their societal benefits. The cultural or ethical dimensions of GMOs are similarly set aside by the report.⁸² In the context of the Directive, such an interpretation would considerably constrain the scope for reform. It would exclude the most contentious social issues, which are always intertwined with the safety assessment of GMOs, as shown by the Norwegian experience.

Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.'

⁷⁷ See, e.g., EFSA Panel on Genetically Modified Organisms (GMO), 'Guidance on the Environmental Risk Assessment of Genetically Modified Plants, 8:11 *EFSA Journal* (2010), 1879; and EFSA Panel on Genetically Modified Organisms (GMO), 'Scientific Opinion on Guidance for Risk Assessment of Food and Feed from Genetically Modified Plants, 9:5 *EFSA Journal* (2011), 2150.

⁷⁸ Directive 2015/412, n. 9 above, recital 14; Commission Proposal, n. 10 above, recital 10.

⁷⁹ Directive 2015/412, n. 9 above, recitals 13-14.

⁸⁰ Commission Proposal, n. 10 above, recital 7.

⁸¹ Report from the Commission to the European Parliament and the Council of December 2008 on Socio-economic implications of GMO Cultivation on the Basis of Member States Contributions, as Requested by the Conclusions of the Environment Council, found at: <http://ec.europa.eu/food/plant/gmo/reports_studies/docs/socio_economic_report_gmo_en.pdf> ('Report from the Commission').

⁸² Even though Directive 2001/18 already mentioned ethical issues as a matter reserved for the Member States.

However, several Member States denounced the narrow scope of the report, and some Member States advocated the Norwegian model in response to the questionnaire used in preparing the report.⁸³ Furthermore, the narrow interpretation does not seem to fit the breadth of the legitimate grounds listed by Directive 2015/412. If, as authorized by the Directive, Member States are using grounds related to their environmental, agriculture or land-use policy, social and safety issues will necessarily be tightly connected. In addition, recital 14 of Directive 2015/412 also leans towards a more flexible interpretation when it provides the ‘maintenance of local biodiversity, including certain habitats and ecosystems, or certain types of natural and landscape features, as well as specific ecosystem functions and services’ as an example of legitimate ground. Finally, the wording of the competence clause accommodates more flexible interpretations: requiring an absence of ‘conflict’ is not excluding Member States from any question related to the physical impacts of GMOs; it simply asks for their action to be compatible with the EU decision.

This more flexible interpretation opens up new possibilities for Member States. First, Member States could be allowed to use the information present in the EU risk assessment to translate the safety data in social terms. This would take into account the interconnection of issues, without authorizing a ‘conflict’ with the EFSA assessment. For example, a reference to a more targeted protection against pests might mean less yield loss for farmers, and therefore more economic gains and available biomass; an identified risk of increasing resistant pests or super weeds might lead to yield loss, or threaten the maintenance of agricultural models which do not rely on chemical inputs. The power of Member States would then be to identify the social impacts linked to the GMO characteristics identified at the EU level. They would then be free to rank the burdens and benefits according to their values as well as their environmental and agricultural policies. For example, some Member States may consider that saving carbon dioxide emissions by not using tillage (a possibility with Bt⁸⁴ GM plants) is a benefit compensating for the increase in pest resistance or for the difficulty of maintaining non-GMO chains.

However the significance of the competence clause is less clear when the EU risk assessment does not provide the physical data related to the specific concern of a Member State. May a Member State act upon social concerns grounded on physical impacts not covered by the EU risk assessment? Such an interpretation could be accepted, even though it is pushing the boundary further. When a Member State includes an issue not covered by the EFSA in its assessment, national authorities would examine safety issues, but would not create a ‘conflict’ with the EU process that ignored the question. This would, for example, allow a Member State to consider the impact of the cultivation of a GMO imported but not grown in the EU if proposal

⁸³ See Commission Report, n. 81 above, at 5, as well as the detailed contributions from the Member States. France is a clear example of a country denouncing the restrictive framing. See Haut Conseil des Biotechnologies, ‘Réaction du Comité Économique, Éthique et Social au “Questionnaire Socio-économique” Proposé par la Commission Européenne’ (2010), found at: <http://ec.europa.eu/food/plant/gmo/new/reports_studies/contribution_en.htm>.

⁸⁴ *Bacillus thuringiensis* or Bt, bacterium used as pesticide.

COM(2015) 177 is adopted⁸⁵. Indeed, the EFSA considers this question as being outside its remit.

More controversially, could a Member State invoke grounds closely related to safety concerns that the EFSA mentions, but does not fully examine? Again, since the safety issues are not exhausted by the EFSA, the national measure would not *per se* conflict with the European one; it would just deal with physical impacts which were not assessed. Recital 14, which accepts the preservation of local biodiversity as a legitimate ground for opting out, corroborates this view. The EFSA sometimes mentions local conditions but does not examine in detail the specificities of each particular region in which a GMO could be cultivated. This interpretation would also allow Member States to compare the assessed GMO to other available sustainable options, which is encouraged by recital 14 of Directive 2015/412 authorizing the States to promote ‘the maintenance and development of agricultural practices which offer a better potential to reconcile production with ecosystem sustainability’. Finally, this flexible interpretation should be preferred because the alternative would give a disproportionate power to the EFSA. The agency would have the power to exclude Member States from regulating an issue without thoroughly assessing it. The example of a Member State which would like to apply a ‘best sustainable alternative’ test to a GMO event illustrates this point well. Such a test touches upon two aspects covered by the EFSA mandate. The first one is the selection of the benchmark against which GMOs are evaluated, knowing that the EFSA uses conventional agriculture and not the most sustainable alternative available. The second potential ‘overlap’ is the analysis of whether the use of a GMO brings changes in management practices. It is part of the EFSA mandate,⁸⁶ even though its opinions do not always analyse this issue in depth.

The last potentially contentious point in the interpretation of the competence clause concerns whether the existence of scientific uncertainties could have an impact on the extent to which the related issue might be considered as harmonized. This is a crucial point in light of the considerable uncertainties remaining regarding the physical impact of some GMOs, in particular in the long term. Is it possible to consider that when the conclusions are clouded by uncertainty, the EFSA opinion does not exhaust the question, meaning that the Member States are allowed to differ in their appreciation of the acceptability of the risk according to their social and political contexts? Does the risk management decision adopted at the EU level in that case set a minimum level of harmonization, leaving Member States free to adopt a more precautionary approach towards uncertainty? As this would equal authorizing Member States to adopt another definition of what is ‘safe’, this is highly improbable.

⁸⁵ This would be in line with several environmental actions of the EU, which has been keen on expanding the influence of its environmental regulation in other contexts. See J. Scott, ‘Extraterritoriality and Territorial Extension in EU Law’, 62:1 *American Journal of Comparative Law* (2014), 87. Examples include the EU’s Forest Law Enforcement, Governance and Trade programme, its biofuels regulation or its (now suspended) decision to extend the EU’s emissions trading scheme to international flights. See J. Scott and L. Rajamani, ‘EU Climate Change Unilateralism’, 23:2 *European Journal of International Law* (2012), 469. However, Member States might be limited by trade law on this matter. See M. Dougan, ‘Minimum Harmonisation and the Internal Market’, 37:4 *Common Market Law Review* (2000), 853.

⁸⁶ Directive 2001/18/EC, n. 12 above, Annex II C.3.

Indeed, the Directive and the Proposal reaffirm the importance of preserving a ‘uniform high level of protection of health, the environment and consumers’.⁸⁷

However, if Member States are not able to adopt a more precautionary approach, several changes at the EU level are required. First, the EFSA should explicitly mention the degree of uncertainty associated with its evaluations, in order to leave space for debate on the acceptability of the risk. Second, it requires greater inclusion of factors other than safety not only at the national level, but also at the EU level by the representatives of the Member States involved in comitology decisions and by the Commission. Indeed, the very purpose of the risk management phase is to develop a political appreciation of the risk, not to give a legal seal of approval to the results of the risk assessment. If the political acceptability of uncertainties cannot be discussed at the national level, it has to be done at the European level. Not only does Regulation 1829/2003 allow the Commission to integrate concerns beyond safety, but policies related to GMOs command the EU institutions to do so.⁸⁸ Although the social impacts of GMOs are often best assessed at a local level since they depend on the cultural, political, physical and social context of a given territory, several social issues related to GMO use and cultivation are common to all States and should be discussed at a higher level of governance.⁸⁹ Finally, it has been demonstrated that responsible innovation is better steered as far upstream as possible.⁹⁰

Thus, the Package should not be seen as a form of de-harmonization, not least because it is not clear whether social concerns were actually harmonized before.⁹¹ On the contrary, it could be implemented as an opportunity for all the authorities involved in the EU GMO multi-level governance system⁹² to finally engage in a more holistic approach to public interest in GMO policies. This perspective would enrich the system by both allowing a more comprehensive management of the integration of GMOs in society and, in the spirit of subsidiarity, increasing respect for the various political viewpoints of the Member States. The challenges of this process should not be forgotten; nevertheless, the Norwegian experience helps to anticipate one of the main problems that the actors will face when assessing the social impacts of GMOs:

⁸⁷ Directive 2015/412, n. 9 above, recital 2, also referred to in Commission Proposal, n. 10 above.

⁸⁸ Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions, Life Sciences and Biotechnology. A Strategy for Europe, COM(2002) 27, at 18, suggesting that ‘life sciences and biotechnology should be developed in a responsible way in harmony with ethical values and societal goals’. It also suggests that biotechnologies should address ‘society’s needs’ related to ‘health ..., food and the environment and to sustainable development’, within the EU and globally. *Ibid.*, at 9. This is confirmed by the objectives of the Common Agriculture Policy; see Regulation 1305/2013/EU of 17 December 2013 on Support for Rural Development by the European Agricultural Fund for Rural Development (EAFRD) and Repealing Council Regulation (EC) No 1698/2005, [2013] OJ L 347/387, containing 54 occurrences of ‘sustainability’ or ‘sustainable’, and see in particular recitals 4-5 and Article 4. Finally, see Council of the European Union, Conclusions 16882/08,(5 December 2008).

⁸⁹ For example, the impact of intellectual property rights on bottom-up innovation is a common issue, as is the oligopoly of a handful of firms over the production of seeds and associated chemical inputs. The co-existence of production is in a similar situation.

⁹⁰ R. Owen, P.M. Macnaghten and J. Stilgoe, ‘Responsible Research and Innovation: from Science in Society to Science for Society, with Society’, 39:6 *Science and Public Policy* (2012), 751; see also R. Owen, J. Bessant and M. Heintz, *Responsible Innovation* (John Wiley & Sons, 2013).

⁹¹ See M. Lee, *EU Environmental Law, Governance and Decision-making*, 2nd edn (Hart, 2014), at 234.

⁹² M. Lee, ‘Multi-level Governance of GMOs in the EU: Ambiguity and Hierarchy’, in: M. Cardwell and L. Bodiguel (eds.), *The Regulation of GMOs: Comparative Approaches* (Oxford University Press, 2010), 101.

the lack of data.

LEARNING FROM NORWAY'S DIFFICULTIES: LACK OF DATA

Understanding the social dimension of the integration of GMOs in society is a complex and resource-intensive process. However, neither the amended Directive 2001/18 nor Regulation 1829/2003 requires the applicant to provide the authority with relevant social data. The NBAB suffered from this data gap when examining whether the European authorization should be rejected for the Norwegian territory. The Norwegian market is not considered interesting enough to convince the applicants to provide the supplementary information not required by EU regulation, even after repeated demands by the authorities.⁹³ The new Package also does not oblige applicants to provide supplementary information, and might therefore lead to a situation where Member States may face similar challenges. The problem is acute since the literature does not offer sufficient material for an extensive social assessment. Social data is plagued, as is physical data, by ignorance⁹⁴ and uncertainties.⁹⁵ Most research involves farm-level studies, focused on yield performances⁹⁶ and a strong funding bias has been identified.⁹⁷ Overreliance on these studies could therefore distort the final result of the social assessment. Furthermore, the GMO Package does not promote future improvement of the situation, because it does not require the applicant to monitor social impacts, but only safety concerns. Finally, the quality and depth of the social assessment very much depend on the integration of safety and socio-economic analyses. To be useful, safety data needs to be articulated through criteria which can be used for the purpose of the social assessment.⁹⁸ For example, the toxicity of a product needs to be expressed in cancer incidence rates, its impact on the soil in terms of fertility, etc. The relative performance of agricultural models has to be known. The fragmentation of the assessment procedures might become an important obstacle to their effective implementation if the EFSA does not adapt its risk assessment policy to the more holistic appreciation of what is in the public interest permitted by the new Package.⁹⁹

CONCLUSION

The new GMO Package empowers Member States to engage in a holistic assessment of public interest in relation to GMOs. However, EU regulation still seems to perceive public authorities only as a 'guardrail' against harm. The new Package does not change the vision of public authorities' role, but just allowed to broaden the scope of

⁹³ This issue is expressed in the NBAB guidance (NBAB, n. 25 above), but also in nearly all its opinions. This forced the NBAB to consider whether the precautionary principle is applicable to the social assessment. It answered negatively, worrying that this extension would weaken the principle.

⁹⁴ When no data is available.

⁹⁵ When the data is not precise, not conclusive enough or heavily debated.

⁹⁶ See T. Kaphengst *et al.*, n. 6 above; and Report from the Commission, n. 81 above.

⁹⁷ See T. Kaphengst *et al.*, n. 6 above.

⁹⁸ A. Péry *et al.*, 'Perspectives for Integrating Human and Environmental Risk Assessment and Synergies with Socio-economic Analysis', 456-457 *Science of the Total Environment* (2013), 307; see also M. Kritikos, n. 8 above.

⁹⁹ The request to update the assessment guidelines of the EFSA might, however, open up an opportunity to debate the issue. Directive 2015/412, n. 9 above, Article 3 requires that no later than 3 April 2017, 'the Commission shall update the Annexes to Directive 2001/18 ... as regards the environmental risk assessment, with a view to incorporating and building upon the strengthened 2010 Authority guidance on the environmental risk assessment of GMOs'.

the safeguard which can now be exercised against social harm as well as physical harm. On the other hand, Norway's authorities take on the role of 'switch operator', guiding technological innovation towards the satisfaction of societal needs in a sustainable way. This is quite a difference, but the conflicting aims of the Package might open space for an interpretation allowing Member States to get inspiration from Norway.

Should they do so? It is sometimes argued that the agro-technologies currently in use might present as many risks as GMOs or more, and that GMOs are unjustifiably stigmatized.¹⁰⁰ Looking at the debate surrounding the risks for pollinators associated with neonicotinoid-coated seeds¹⁰¹ or the endocrine-disrupting effects of some herbicides (including the one to which GM crops are tolerant)¹⁰² and pesticides,¹⁰³ this implicit preference is indeed confirmed. However, concluding from this that regulation of GMOs should be lighter would start a race to the bottom. On the contrary, this difference in treatment calls for reinforced scrutiny on the effects of available techniques through interdisciplinary monitoring and, if necessary, regulation. It is indispensable to learn from the failures of the 'green revolution', and promote agro-technologies supporting a more resilient, locally adapted and environmentally friendly agricultural model. To do so, every opportunity to identify and exchange good practices should be seized.

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¹⁰⁰ See, e.g., R. Batista *et al.*, 'Microarray Analyses Reveal that Plant Mutagenesis May Induce More Transcriptomic Changes than Transgene Insertion', 105:9 *Proceedings of the National Academy of Sciences of the United States of America* (2008), 3640.

¹⁰¹ L. Maxim and J. van der Sluijs, 'Seed-dressing Systemic Insecticides and Honeybees', in: European Environment Agency, n. 72 above, 369; D.L. Kleinman and S. Suryanarayanan, 'Dying Bees and the Social production of Ignorance', 38:4 *Science, Technology & Human Values* (2012), 4492.

¹⁰² C. Gasnier *et al.*, 'Glyphosate-based Herbicides are Toxic and Endocrine Disruptors in Human Cell Lines', 262:3 *Toxicology* (2009), 184.

¹⁰³ A. Kortenkamp *et al.*, 'State of the Art Assessment of Endocrine Disruptors' (2011), found at: <http://ec.europa.eu/environment/chemicals/endocrine/pdf/sota_edc_final_report.pdf>.