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Technology Neutrality in European Regulation of GMOs

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ABSTRACT

Objections to the current EU regulatory system on genetically modified organisms (GMOs) in terms of high cost and lack of consistency, speed and scientific underpinning have prompted proposals for a more technology-neutral system. We sketch the conceptual background of the notion of 'technology neutrality' and propose a refined definition of the term. The proposed definition implies that technology neutrality of a regulatory system is a gradual and multidimensional feature. We use the definition to analyze two regulatory reform proposals: One proposal from the Netherlands for improving the exemption mechanism for GMOs under Directive 2001/18/EC, and one from the Norwegian Biotechnology Advisory Board, outlining a new stratified risk assessment procedure. While both proposals offer some degree of improved technology neutrality in some dimensions compared to current EU regulation, in some extents and dimensions, they do not. We conclude that proposals for more technology-neutral regulation of GMOs need, first, to make explicit to what extent and in what dimensions the proposal improves neutrality and, second, to present arguments supporting that these specific improvements constitute desirable policy change against the background of objections to current policy.

KEYWORDS

Genetic modification; GMO; technology neutrality; European Union

Introduction

In order to responsibly protect certain cherished values, for instance, human or environmental health, privacy, or 'human dignity', societies see a need for oversight, guidance and regulation of development, use and dissemination of technology. There are numerous examples of how this need is expressed and implemented in policy and legislation. The global nonproliferation treaty for nuclear weapons, standardization criteria for electrical appliances, licensing regulation of new pharmaceuticals, workplace health and safety regulation, and regulation of genetically modified organisms (GMOs) in agriculture are all familiar examples. Such protective policies can contain measures which might be characterized as 'hard' or 'soft' with regard to their level of force (Ramachandran et al., 2011). Soft policies include voluntary moratoria, as for instance, implemented for transgenic organisms in the wake of the Asilomar conferences (Berg, 2008), various guidelines

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and industry codes of conduct, and the more recent calls for caution regarding human germ-line applications of gene editing and gene driving (National Academies of Sciences, Engineering and Medicine, 2015, 2016). Hard policies include obligatory pre-market approval processes, mandatory product standards, and complete bans. Ramachandran and colleagues hereby refer to an *arc of oversight* 'moving from problem detection to data gathering to problem formulation to negotiation over evaluation and limits, eventually leading to regulations, guidance, or some other kind of agency action' (Ramachandran et al., 2011, p. 1353).

Recently, hard technology policies have been subject to criticism. This criticism is not pushing a technological *laissez-faire* agenda, but accepts the need for regulation while questioning a combination of inconsistency and inflexibility of common hard policy solutions. In particular, it has been argued that similar types of risks and uncertainties associated with different technological applications used in the same policy area, such as agriculture, are often treated very differently. That is, different regulatory regimes are applied to different technologies developed for the same purpose(s), although they seem to pose similar potential threats to the values motivating the regulation. Moreover, it has been pointed out that hard policy solutions tend to be irresponsive to scientific or technological developments, specifically improved knowledge about the risks and uncertainties involved. The latter phenomenon tends to increase the unmotivated unequal policy treatment of different technologies lifted in the first objection. For this reason, calls have been put forward to make hard protective technology policy 'technology-neutral', for instance, in the area of ICT, climate change technology, and biotechnology. At the same time, this has given rise to concerns regarding both the desirability and feasibility of introducing technology-neutral policies (Azar & Sandén, 2011; Carton, 2016; Greenberg, 2016; Hildebrandt & Tielemans, 2013; Munthe, 2017).

The call for technology-neutral regulatory regimes has been strong in the GMO field. This is not surprising, since several hard policy measures are found in GMO regulation, not the least in the European Union (EU). Much of the criticism concerns the present EU crop legislation, which puts heavy requirements in the form of mandatory pre-authorization, risk assessment, labeling, and *ex post* control measures on GM crops, but fails to regulate conventional breeding technologies in a similar fashion although they may pose similar risks (Eriksson & Ammann, 2017). However, what is implied by this general call has not been clarified, especially as the very concept of technology neutrality has been left undefined.

In this paper, we propose a tentative definition of the term 'technology neutrality' that can be used in analyses of GMO regulation. The proposed definition suggests that technology neutrality of a regulatory system is a gradual and multidimensional feature; hence, rather than being an all-or-nothing matter, a regulatory system can be more or less technology-neutral. We demonstrate how the definition may contribute to policy assessment by analyzing two regulatory reform proposals put forward in recent years: First, a proposal from the Netherlands for improving the exemption mechanism for GMOs under Directive 2001/18/EC and second, the Norwegian Biotechnology Advisory Board's proposal for a new stratified risk assessment procedure. Analysis of the regulatory reform proposals supports our theoretical claim, namely that technology-neutrality comes in degrees and can only be determined relative to both the regulation under consideration and its rationale.

The EU Regulation on GMOs

Legislation regarding biotechnology in plant breeding has developed in two parallel tracks. One track is sometimes referred to as 'process-based', which means that the technology of genetic modification is used as a trigger for more stringent regulatory oversight (Zetterberg & Edvardsson Björnberg, 2017). This track is followed by the EU and its member states. It can be contrasted with so-called 'product-based' regulatory regimes, according to which the organism's traits, regardless of how they were obtained, determine which legal demands must be met in order for a release permit to be granted – a legislative track followed by, for instance, the United States and Canada (Macdonald, 2014; McHughen & Smyth, 2008). Some authors caution that the 'process vs. product' distinction misses the important point that many regulatory frameworks have both process-based and product-based features (Kuzma, 2016). However, this does not diminish the overwhelmingly process-based nature of some regulatory frameworks, such as the European GMO legislation, which – as we will see – is a main source of the criticism behind the calls for technology-neutral GMO regulation.

According to EU Directive 2001/18/EC and Regulation (EC) 2003/1829, a genetically modified variety may be released into the environment or put on the European market only if it satisfies a set of licensing requirements.[1] Before an approval can be made, the GMO must undergo an extensive risk assessment conducted by the European Food Safety Authority (EFSA) aiming to, on a case by case basis, 'identify and evaluate potential adverse effects of the GMO, either direct or indirect, immediate or delayed, on human health and the environment which the deliberate release or the placing on the market of GMOs may have' (Annex II, Directive 2001/18/EC). The burden of proof falls on the applicant, who has to provide extensive documentation before an approval can be granted. Furthermore, some EU member states, such as Sweden, have enacted provisions at the domestic level, requiring that the GMO undergo ethical assessment in addition to the risk assessment performed by EFSA.[2] Thus, when an application for GMO authorization is submitted to the Swedish competent authority (the Swedish Board of Agriculture), the application is forwarded to the Swedish Gene Technology Advisory Board, which is responsible for carrying out an ethical assessment based on a set of recently adopted guidelines (Gentekniknämnden [The Swedish Gene Technology Advisory Board], 2018).

The EU legislation also requires that post-authorization measures be taken. Specifically, GMOs may not be put on the market unless they are labeled accordingly. Moreover, the licensing decision may be accompanied by demands for *ex post* control measures, such as maintaining a certain geographic distance between the GMO field and nearby fields. It is important to note that none of the abovementioned regulatory requirements – authorization involving risk assessment (and in some cases ethical assessment), labeling, etc. – apply to crops that have been developed by using conventional breeding methods or breeding methods that involve modification of the genome but fall under the exemption in Annex I B, Directive 2001/18/EC. The latter includes traditional mutation breeding (using radiation or chemicals to induce mutagenesis) but not site-directed mutagenesis.

The Core Complaints about the EU's GMO Regulation

The EU GMO legislation has been criticized by people who see large potential benefits with biotechnological applications in agriculture (for brevity, called 'biotech advocates').[3]

Biotech advocates are concerned that the present EU system will unnecessarily hamper scientific and economic development and put a halt to the benefits that biotechnology, as they argue, promises. Their main concerns are that the EU regulatory system is:

- inconsistent from the viewpoint of environmental and health risk (Miller, 2010),
- scientifically outdated (Davison & Ammann, 2017; Eriksson & Ammann, 2017; Hansson, 2016),
- slow and costly (Masip et al., 2013),
- lacking in conceptual clarity (Tagliabue, 2018), and
- hampering scientific and technological development (Callaway, 2018).

The objections are not independent of each other. If the charge of lack of clarity holds, for instance, it will also point at difficulties to ensure consistent application, since it will be difficult to assess whether application has been consistent. Moreover, if legislation is based on old, potentially outdated scientific knowledge, it is less likely that it will regulate environmental and health risks in a consistent and proportionate manner. Regardless of how valid or sound these arguments are, it is worth noticing that the critics of the EU system have a strong tendency to assume that complaints about inconsistent standards and complaints about the level of regulatory requirements are strongly linked (Sandin et al., 2018).

Many of the arguments put forward by the biotech advocates are framed as if there are cases of unfairness, although the term 'unfair' is seldom explicitly used. (We understand 'fairness' in the conventional sense as implying at least nondiscrimination, requiring that like cases should be treated alike, and that differences in treatment must be justified. Fairness can be a property of agents, institutions and several other entities.) The EU GMO legislation is therefore considered unfair: It treats technologies developed for the same purpose(s) differently without good reasons, and as a consequence of this differential treatment some stakeholders are favored at the cost of others. The two stakeholders most commonly referred to in the debate are research institutions and agribiotech companies ('producers') on the one hand and farmers and consumers, primarily in low-income countries ('consumers'), on the other. (Below, we analyze the targets of unfairness claims separately.) In a statement typical of biotech advocates, Eriksson and Ammann (2017) talk about 'the regulatory discrepancy between the relatively unregulated so-called conventional breeding techniques and the overregulated transgenic techniques' (Eriksson & Ammann, 2017, p. 1).[4] The present EU system is thus perceived as falling short of treating like cases alike. Sometimes, this argument is expressed by claiming that the distinction between GMOs and non-GMOs is 'meaningless' from a scientific or risk perspective (Ricroch et al., 2016). Tagliabue (2016), one of the fiercest critics, calls the notion of GMO an 'inconsistent term', an 'incoherent expression [which] is arbitrary' and a 'bogus concept', which is 'illogical'. These authors are concerned that a particular set of technologies is singled out for special treatment without any further (or 'science-based') justification. A technology is neither a moral nor a legal subject, but a consequence of the argument is that it takes certain stakeholders to be treated unfairly as an effect of the differentiation between GMO's and other crops in the regulatory system.

Unfair Treatment of 'Producers'

The selective regulatory treatment of GMOs thus creates unequal conditions for potential producers to develop and use the technology: Agricultural producers who apply GMO technology will have a more difficult time introducing their products on the market than producers who use conventional breeding technologies, irrespective of the actual risk-benefit features of the products in question. In relation to the US GMO legislation (which in many ways is less demanding toward GMO introductions), Conko and colleagues argue that the US FDA premarket review and approval process leads to 'unnecessarily prolonged' reviews: '34 months in the case of non-browning Arctic apples [. . .] and 12 months for low-aspargine, bruise-resistant innate potatoes' (Conko et al., 2016, p. 496). They conclude that 'with development costs so high, researchers in the public sector as well as those at nonprofit organizations and small startup companies rarely have sufficient resources to navigate the complex, expensive and uncertain and regulatory process' (Conko et al., 2016, p. 502). Arguably, this holds true even more for producers who wish to introduce their products on the European market. It is worth noticing that the regulatory approval of the Amflora potato – a genetically modified potato for production of industrial starch – took 13 years.[5]

Unfair Treatment of 'Consumers'

Following the argument above, the high costs and uncertainties associated with the application process will create a situation where big companies that are able to 'fight the system' to get their products authorized enjoy a relative benefit vis-à-vis smaller companies, start-ups, and nonprofit organizations. This, in turn, creates strong incentives for having only GMO varieties that are deemed to have a high market potential to be put through the system (Conko et al., 2016). GMOs developed with the aim to sustain small-scale farming or to address public health challenges in developing countries, on the other hand, are less likely to find sufficiently resourceful agents to produce necessary authorization. In both these ways, the system is argued to unfairly favor strong economic agents (farmers and consumers) in industrialized countries at the expense of poor farmers and consumers in the global South.

What Is Technology Neutrality?

As a remedy to these problems – in particular to the unfairness charge – critics are in favor of making the regulation of biotechnologically engineered plants *technology-neutral*. The idea behind technology neutrality is ostensibly simple: Different technologies can be used to achieve similar aims, and the particular technology used should not affect the judgment if the outcomes are the same. For instance, a pen and a typewriter can be used to produce an insulting message on a piece of paper. It would be unsatisfactory to have libel laws that are *technology-specific* in the sense that it requires treating the typewritten and the handwritten insults in different ways.[6] In reality, of course, the seeming simplicity of this idea involves considerable complications. Some of these become apparent in the debate surrounding the EU regulation on GMOs, as discussed in the next section. Before proceeding to that discussion, the basic concept of technology neutrality needs to be analyzed, and we will do this in several steps.

Preliminaries

Following Greenberg (2016), we take the antonym of 'technology-neutral' to be 'technology-specific'. As an illustration, consider the highly specific protective technology regulation of the ban against so-called human reproductive cloning that is to be found in many countries. A good example of a very nonspecific regulation is common rules regarding ethics of research involving humans. In the latter case, there are typically general requirements of advance review and approval by an appointed body, such as an Institutional Review Board (IRB) or a public agency performing the same job, and some generically formulated criteria for this requirement as well as the rulings of the reviewing body.

We will further assume technology neutrality (as well as specificity) to be a property of *regulatory structures*. Such structures include actual legal statutes, case law, instructions and decrees for public agencies based in these statutes, routines designed within such agencies to comply with said instructions, and orders to parties given by agencies. We will refer to the content of such regulatory structures as *regulatory measures*. Technology neutrality and technology specificity may thus be predicated of different parts of regulation: Of legislative statutes as well as of interpretations and other actions by courts and legal agents, such as administrative decisions. It is, of course, also true regarding standard pharmaceutical licensing regulation that each application for a license will have to be treated on its own conditions, but that does not preclude that the relevant regulatory structures are less specific, especially a law that basically states that pharmaceuticals may not be sold without license. This implies that the notion of technology neutrality and specificity of regulatory structures has to be understood in scalar rather than binary terms (there may be more or less of it). Technology neutrality can thus be thought of as situated on a continuum with 'full technology neutrality' and 'full technology specificity' as the opposing (ideal) end points. In the words of Paul Ohm, discussing surveillance laws: 'Most tech-centric laws lie along a spectrum from tech specificity to tech neutrality with few as close to either endpoint as [the Pen Register Act and the USA PATRIOT Act]' (Ohm, 2010, p. 1687).

A final preliminary point is that it is not technologies *per se* that are regulated by the regulatory structures which may be more or less technology-neutral. The structures regulate actions by agents that make some sort of use of a technology. Often the structure will target a wide range of activities related to a technology. In the example of EU regulation on GMOs, those actions include researching, cultivating, selling or otherwise making the GMO available to third parties, importing, keeping, transporting, destructing and disposing of GMOs. An analysis of technology neutrality must of course be sensitive to this width of scope with regard to *what* is being regulated.

The Notion of a Regulatory Rationale

In order to understand what technology neutrality is, it is necessary to understand the notion of a *regulatory rationale* (or, more broadly, a policy rationale). This is what a regulatory structure is aimed at achieving, such as a particular value that is to be protected, and that serves to justify it in policy making. For instance, the regulatory rationale behind many traffic laws is road safety, and the main rationale behind the EU regulation on GMOs is protection of human and environmental health. Obviously, a given

regulatory structure might have more than one rationale. Many traffic laws have the purpose of ensuring both safety and efficiency, for example. The EU GMO regulation is not only put in place to protect environmental and human health; it also has the purpose of ensuring a high level of protection of animal health and welfare and consumer interests, while at the same time 'ensuring the effective functioning of the internal market' (Art 1, Regulation (EC) 1829/2003). Thus, risk and consumer concerns should be attended to bearing in mind the more general values associated with the EU legal system, such as ensuring an effective market and regulatory harmonization.

Regulatory structures may have a particular *ostensible* rationale, but a different *actual* one. For instance, in an apartheid (or otherwise discriminatory) society, a law with the ostensible rationale of, say, protecting public health might have the actual purpose of denying people belonging to some particular group access to certain facilities or opportunities. Relatedly, it also happens that regulatory structures with one rationale are or are viewed to be *used* for other purposes. An example of this might be the debate between the US and Europe regarding applications of the precautionary principle. The EU's rationale for precaution was said to be protection of human and environmental health, while from a US perspective it was viewed as being motivated by trade protectionism on the part of the EU (Charlier & Rainelli, 2002). This, in turn, means that what is viewed as ostensible and actual rationales of regulations by different stakeholders may vary due to their assumptions about for what aim the regulation is being used, and lead to disagreement over policy.

We hold that technology neutrality of a regulatory structure must be understood against the background of its regulatory rationale. We can see this through the following example. Consider motorized vehicles. A pick-up truck such as the Ford F150 and a large truck such as the Scania G450XT are similar in many respects: they are apt for transporting goods, they use combustion engines, a driver controls them by way of a steering wheel and other controls, and so on. They are also different: Size, weight, and thus loading capacity differ significantly between the larger and the smaller vehicle. Thus, among other things, driving a heavier truck might require other qualifications in the form of a different category of driving license. However, how exact and exactly how a regulation thus distinguishes technology 1 (light trucks) and technology 2 (heavy trucks) may vary quite a bit.

The same regulatory rationale underlies these regulations: Ensuring that the vehicles are operated by people with adequate driving abilities. This rationale remains the same, regardless of variations in statute in terms of requirements for different types of licenses. Thus, the rationale aspect of this regulatory structure will be less specific (and more neutral) than each of the license requirements for the two types of truck.

Another reason for anchoring the understanding of technology neutrality in the notion of a regulatory rationale is that the ontological sorting of technologies into different types has no strong link to how they should be regulated. In the case of some controversial technologies, there are people who argue that there are deep differences between two technologies, even though they might be similar in terms of direct and indirect consequences. Such positions are common with regard to biotechnology. A representative of this position is the Prince of Wales, who in his commentary on the 2000 Reith Lectures on BBC Radio 4 argued:

> Above all, we should show greater respect for the genius of nature's designs, rigorously tested and refined over millions of years. This means being careful to use science to understand how nature works, not to change what nature is, as we do *when genetic manipulation seeks to transform a process of biological evolution into something altogether different* (BBC, 2000, emphasis added).

Another example is views on reproductive genetic technologies such as IVF or preimplantation genetic testing, which see them as related to fundamental features of human nature, for instance, freedom or natural procreation, and therefore special in relation to other technologies that also impact on child birth and the features of children born (such as pregnancy care and education).[7] The presence (or absence) of such ideas has bearing on how technologies are individuated, that is, how they come to be seen as ontologically distinct, or as *different types* of technology. If a deep difference of this sort is thought to exist between technology 1 and technology 2, these technologies are likely to be perceived as (properly being counted as) ontologically distinct, and individuated as different types of technology. Such individuation *could* lead to more specific regulation, but it does not *have to* preclude technology neutrality – this depends on the rationale of the regulation, hence the need to spell this out. To see that, let us return to the vehicle case. A new type of engine is introduced (say, electric), and driving license requirements remain the same for electric and fossil-fuel cars, albeit they are perceived as ontologically distinct types of cars (e.g., due to climate-change-related concerns). In this case, the technologies are still similar from a regulatory rationale of road safety: Licensing requirements will therefore remain the same. The technologies might of course be regulated very differently in the light of some *other* regulatory rationale, such as the one motivating emission limits, CO_2 taxation, and so on. However, it might very well be that two technologies that are categorized as ontologically separate are, and should be, treated in the same way in regulation. In the vehicle case, this happens when, for instance, it is decided that some piece of regulation that applies to cars, such as ordinary traffic rules, also applies to, say, bicycles. Similarly, the fact that two things or procedures are counted as being of the *same type* of technology is compatible with regulating them in different ways. Thus, in the case of the EU regulation of GMOs, plants developed using mutagenesis are classified as GMOs, but nevertheless explicitly exempted from the GMO assessment requirements according to Annex 1B of Directive 2001/18/EC.

Against the background of the above considerations, we have adopted the following working definition of technology neutrality of a regulatory structure[8]:

> A regulatory structure, S, for a technology, T_1, is more technology-neutral to the extent that other technologies, $T_2 \ldots T_n$, are subjected to regulatory structures similar to S in proportion to their similarity to T_1 in terms of the rationale behind S.

In accordance with the observations earlier, this definition makes technology neutrality into both a *gradual* and a *relative* concept. Depending on the presence of different technologies with more or less similar rationales for the structures regulating them, one and the same technology regulation may be more or less technology-neutral. Thus, the degree of technology neutrality may vary with both the content of the regulatory structure, with what other technologies that are regulated, and the rationales behind these regulations. Note also that the definition assigns degrees of technology neutrality across arbitrary divisions of different types of legal statute, e.g. between the 'Technology 1 Act' and the 'Technology 2 Act'. The degree of neutrality will depend on the similarity

between prescribed regulatory action for these acts and between the rationales behind the respective acts.

Moreover, the definition does not say anything about the *substantive* content of the regulatory structure S, for instance, whether it is more or less permissive. Historically, proponents of technology neutrality have typically argued that one – usually new – technology is being unjustifiably restricted relative to some other – usually older – technology, and that implementing technology-neutral regulation would amount to removing the perceived restrictions. However, subjecting both technologies to the restriction would be just as technology-neutral (Sandin et al., 2018, p. 225).

Neither does technology neutrality have anything to do with whether the regulatory rationale is desirable, good, or morally acceptable. For instance, it would be quite possible to have a technology-neutral regulatory structure that applied to iron maidens, thumbscrews and other instruments of torture, with the regulatory rationale of ensuring their efficiency in causing pain. Of course, a (more reasonable) regulatory rationale banning such instruments could also be technology-neutral.

Changes in the regulatory rationale behind a technology regulation may affect the content of the regulation. How do such changes interplay with the degree of technology neutrality of this regulation? For instance, since a few years, the EU regulatory system on GMOs contains an 'opt-out' mechanism: Directive 2015/412 allows Member States to restrict or even ban cultivation of GM crops that have been approved by the EU, within their territories.[9] This option has been used by some states, hitherto 17 member states and two autonomous regions (Eriksson et al., 2019).[10] The scope of possible grounds for 'opting out' is quite broad:

> Those grounds may be related to environmental or agricultural policy objectives, or other compelling grounds such as town and country planning, land use, socioeconomic impacts, coexistence and public policy (Directive 2015/412).

What this does is that it *widens* the regulatory rationale very significantly, so that more regulatory responses to one and the same technology become possible. However, this does not as such decrease the technology neutrality of European GMO regulation, as long as the content of the regulation applies similarly to all technologies relevant for the regulatory rationale.

To see this, suppose that some country has adopted a technology for duplicating text and images (like the printing press), and that use of this is restricted so that it might not be used for producing pornographic texts. We can call the regulatory rationale 'avoidance of obscenity'. In this imaginary country, there emerges a new technology that also duplicates text (like photocopiers). The society's obscenity restrictions are technology-neutral, so that they apply also to photocopiers. Suppose now that the society decides that provinces have an opt out possibility – even when a duplicator technology has been considered 'safe' from an obscenity perspective, they may adopt measures to restrict the use of it with reference to a widened regulatory rationale, so that in addition to 'avoidance of obscenity', it also includes 'avoidance of criticism of local politicians'. This might be a very bad idea, of course – but it seems that it makes no difference in terms of technology neutrality. Again, this underlines the observation that the degree of technology neutrality of a regulation does not determine whether or not it is a desirable regulation, or that its rationale is. At best, (more) technology neutrality appears to be *a desirable feature of otherwise justified regulations and regulatory rationales*.

The EU GMO Regulation Revisited

As we have seen, the rapid development in gene-editing technology has pointed to shortcomings of the current EU regulatory framework. It is therefore not surprising that there have been concrete proposals for regulatory reform. We will consider two such recent proposals that, arguably, go some way in the direction of technology neutrality, albeit in slightly different ways.

The first – 'the Dutch Proposal' – was put forward by the Netherlands Ministry of Infrastructure and the Environment (2017) and directly concerns reform of the current EU regulatory system for GMOs. The second – 'the Norwegian Proposal' – was presented in a discussion paper from the Norwegian Biotechnology Advisory Board in 2018 (Bioteknologirådet [The Norwegian Biotechnology Advisory Board], 2018). Of course, Norway is not an EU member, and thus the proposal has no direct consequences for the EU regulatory system. However, it is included here as it is potentially very relevant in case of forthcoming revisions of the EU system.[11] In addition, there is considerable overlap between cases handled by the EU and those that have been considered by Norwegian authorities. The overlap holds both for what cases have been dealt with – until now, there have not been any applications for marketing GMOs that have been directed specifically toward Norway – and the outcome of the decisions. The Norwegian decision is at odds with those of the EU only in a handful of cases (Myskja & Myhr, 2020, p. 2609).

The Dutch Proposal

The 'Dutch Proposal' concerns Directive 2001/18/EC, specifically Annex I B in which the exemptions to the directive referred to in Article 3 are outlined. As presently worded, Annex I exempts conventional mutagenesis and cell fusion on the condition that they do not involve the use of recombinant nucleic acid molecules or GMOs other than those that are produced by one or more of the exempted techniques/methods. The Dutch proposal is explicitly limited to plants, and it involves extending the exemption mechanism to all techniques used in plant breeding provided that: (i) no other genetic material than what could be transferred through traditional breeding methods is introduced, and (ii) the end-product does not contain any recombinant nucleic acid molecules (Eriksson, Harwood et al., 2018; see also Part III B of the proposal). Crucially, the proposal does not involve any changes to the definition of GMO in Article 2; instead, the drafters propose that the definition remains unchanged and applied to its full extent. Moreover, the burden of proof for justifying compliance with the exemption provision will remain with the applicant.

Today, we know that the Court of Justice of the European Union (CJEU) has ruled against amending the directive along the lines of the Dutch proposal, although it is not completely clear what the legal and political implications of the ruling are. In its ruling, the Court argues that the exemption mechanism in Annex I B should only apply to mutagenesis techniques that have 'conventionally been used in a number of applications and have a long safety record'. This appears to rule out the exemption of 'New Breeding Technologies' such as genome editing. However, as pointed out by the legal scholar Kai Purnhagen, the ruling leaves open a possible loophole: If scientists can prove that a certain biotechnological application has indeed a long safety record, it may earn an

exemption (Callaway, 2018). Further to the point, the CJEU's decision does not rule out the possibility that the EU Commission will one day decide to initiate a review of the EU legislation, although it is admittedly unlikely that this will happen in the foreseeable future. For this reason, we argue that it is still meaningful to investigate to what extent a hypothetical implementation of the Dutch proposal would work in the direction of a more technology-neutral EU regulation on GMOs.[12]

As already mentioned, the proposal does not involve any changes to the legal definition of GMO. Nor does it question the validity of the EU legislation as regards traditional GMOs. Any changes in an organism's genome that involves permanent inclusions of recombinant nucleic acid still counts as genetic modification and will be subject to all the usual requirements and demands. Thus, even if the suggested amendments were to be incorporated into EU law, the legislation would still be technology-specific to a significant degree. However, it would be *less* technology-specific than what is presently the case.

We see this by applying the above definition of technology neutrality. In the light of this definition, The Dutch proposal entails that other technologies that are similar to the one in question in terms of the rationale behind the regulation are also subjected to the regulatory structure (S). It proposes exempting technologies for the reason that they are similar to 'traditional' mutagenesis with respect to the regulatory rationale of safety. The suggested reformulation of the exemption provision would apply to all products demonstrating the indicated properties, regardless of breeding technique, which is a big step in the direction of a more technology-neutral legislation. This would align the legislation with the policy rationale (arguably, environmental and human safety) and subject technologies that are similar to each other *in this respect* to similar legislation – thus being more technology-neutral than the current situation.

The Norwegian Proposal

The 'Norwegian proposal' (Bioteknologirådet [The Norwegian Biotechnology Advisory Board], 2018) suggests differentiation of the requirements for risk assessment and approval of biotechnological products into levels. The proposal considers two versions of this differentiation.

The *first version* has four levels of regulatory action: no action (exempt), requirement of notification to competent authorities, expedited assessment, and standard assessment. The assignment into levels in this version is based on the *type of genetic change*. According to the proposal, all organisms for which temporary and non-heritable changes in the genome have been made are exempted from oversight. For all other organisms, certain demands must be met before the organism can be released. At the 'notification' level, we find changes that 'exist or can arise naturally, and can be achieved by using conventional breeding methods'. At the next level, an approval is needed; however, the risk assessment would be expedited. This applies to 'other genetic changes within the same species' (p. 29). At the highest level, a full risk assessment corresponding to the one presently in force in the EU is required. This applies to all other genetic changes, including transgenic changes and those that involve synthetic DNA-sequences. In addition, all organisms that are covered by the legislation and thus have to meet the demands of either notification or approval, are subject to socio-economic assessment. That is, they must still (as is the case in Norway but not in the EU generally) be assessed on the basis of sustainability, societal benefit, and ethical concerns.

This version of the level-based system retains elements that are strongly technology-specific, in that its scope of application is determined by the type of technology applied: The nature of the genetic change is what triggers regulation. Thus, in the light of the definition above, it appears that technologies that are similar to each other in terms of the regulatory rationale (of safety/risk reduction) are nevertheless regulated differently. However, the level-based system can be seen as an attempt at making the regulation more technology-neutral, since more similar regulatory measures are applied to technologies that are alike with respect to the regulatory rationale *within* the levels.

The *second version* of a level-based system in a sense turns the procedure on its head. It starts with a 'public morals review'. This review proceeds in three steps: In step 1, it is reviewed whether the product fits policy objectives for agriculture and the environment and is 'not in violation of any foundational ethical values and norms of Norwegian culture' (Bioteknologirådet [The Norwegian Biotechnology Advisory Board], 2018, p. 35) – values and norms that have to be decided in a political process. However, the Council offers some examples of what such norms and objectives could be: use of antibiotic resistance genes, lack of monitoring system, and engineered resistance to chemicals that are not approved in Norway. The first step acts as a filter, stopping products that are not in accordance with some fundamental value or norm. In Step 2, 'an integrated ethical evaluation on aspects relating to both the product and the process', is to be performed (ibid.). This evaluation is very broad and apparently concerns most ethical aspects that go beyond the 'foundational ethical values and norms' covered in the first step, even though this distinction is not entirely clear. The Council proposes that existing guidelines for assessment of, for instance, sustainability might be used. Notably, the evaluation is to consider uncertainties and available alternatives, and consider both the product and the process. The evaluation results in a ranking of the ethical justifiability that is performed in Step 3. There are three categories: *Strong, moderate* and *weak* ethical justifiability. On this basis the public morals review is followed by risk assessment: 'Strongly justified' products are to be subject to an expedited risk assessment and 'moderately justified' ones to a standard risk assessment. 'Weakly justified' products are not assessed, but the application is simply declined.

It seems that the second version of the level-based system is more technology-neutral than the first, at least at first glance. The policy rationale is, as we noted, broader than that of the EU, and a 'public morals review' with its many components as described in the Norwegian Proposal does not necessarily hinge on specific technologies – at least not in theory.

However, it is possible, or perhaps even likely, that it can be more technology-specific *in practice*. This will depend on the content of the 'integrated ethical evaluation on aspects relating to both the product and the process'. Thus, a complication remains with the model: Technology specificity might actually be part of the 'public morals' that are in turn part of the regulatory rationale of the model. When that is the case, the concerns about consistency and fairness raised by biotech advocates might not be addressed, at least not addressed in the manner those advocates desire.

Conclusion

There have been a number of complaints of the EU regulatory system for GMOs from biotech advocates. The main arguments are that the EU regulatory system is

inconsistent from the viewpoint of environmental and health risk, scientifically outdated, slow and costly, lacks conceptual clarity, and hampers scientific and technological development. As a remedy for some of these problems, it has been suggested that regulation should be (more) technology-neutral. We have argued that technology neutrality should be seen as a property of regulatory structures, a broad notion that includes actual legal statutes, case law, and instructions and decrees for public agencies based in these statutes, among other things. Technology neutrality should be understood in scalar rather than binary terms and may be thought of as situated on a continuum with 'full technology neutrality' and 'full technology specificity' as the opposing ideal end points. Technology neutrality does not imply anything in particular about the content of the regulation, and it does not imply that either the regulatory rationale or the regulation it supports is desirable, good, or even minimally morally acceptable. At best, (more) technology-neutral regulation is desirable only if this regulation and its rationale is independently justified. We also showed how changes of a regulation that may appear to decrease technology neutrality need not do this, if only the regulatory rationale is appropriately adjusted. While such 'gerrymandering' of regulatory rationales might appear sneaky by those who dislike the regulatory change, from a technology neutrality standpoint they mostly illustrate how technology neutrality is always relative to *both* the regulation and its rationale.

We illustrated our theoretical points in our discussion of two recent proposals for regulatory reform: The 'Dutch Proposal' and the 'Norwegian Proposal'. Using the proposed definition of technology neutrality, we showed that both proposals go some way in the direction of increased technology neutrality compared to the present EU system. The analysis also showed that the proposals might be more technology-neutral in *some* respects but not in others. To assess these and future proposals for regulatory reform in the GMO area, the degree and dimension of improved technology neutrality needs to be made more explicit. On such a basis, it may then be more easily determined to what extent such proposals meet the critical objections to the current regulation.

Notes

1. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106/1 and Regulation (EC) No 1829 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268/1.
2. Swedish Environmental Code (Miljöbalken), Chapter 13, paras.10, 13.
3. Also, parties who are opposed to the extended use of industrial agricultural biotechnology have voiced dissatisfaction with the present system when realizing that it may not apply to most biotechnology as the technique is moving from old school hybrid DNA technology to genome editing technologies, such as CRISPR (Kim & Kim, 2016). The motivation for voicing such criticism has lately diminished, due to a decision by the Court of Justice of the European Union (CJEU) not to let organisms produced by site-directed mutagenesis fall under the exemption in Annex I B of the Directive (Court of Justice of the European Union, 2018).
4. This argument is not new. Neither is it unique to the EU. For instance, in 2002, the US National Research Council's Committee on Environmental Impacts Associated with Commercialization

of Transgenic Plants wrote: 'There is currently no formal environmental regulation of most conventionally improved crops, so it is clear that the standards being set for transgenic crops are much higher than for their conventional counterparts. The committee finds that the scientific justification for regulation of transgenic plants is not dependent on historically set precedents for not regulating conventionally modified plants. While there is a need to reevaluate the potential environmental effects of conventionally improved crops, for practical reasons, the committee does not recommend immediate regulation of conventional crops.' (National Research Council, 2002, p. 3, bold type in original).

5. Three years after the Commission's decision to approve the cultivation of Amflora, the decision was overturned by the General Court of the European Union (2013). By then Amflora had already been withdrawn from the European market by BASF. The stated reason for the withdrawal was lack of acceptance by consumers, farmers and politicians (Kanter, 2012).
6. This has been the subject of much discussion in the area of regulation of information and communication technologies (see, e.g. Koops, 2006; Reed, 2007).
7. Two examples might be the Catholic Church's traditional criticism of reproductive technologies that bypass the standard of procreation through sexual intercourse between married couples of male and female sex (Vatican Congregation for the Doctrine of the Faith, 1987), and Jürgen Habermas' idea that genetic selection or modification of human beings means that they are deprived of the fundamental feature of freedom defining human nature (Malmqvist, 2007).
8. This is an improved version of the definition in Sandin et al. (2018).
9. For a critical discussion of the moral grounds for some possible opt-out arguments, see Christiansen et al. (2019).
10. It has recently been proposed that the opt-out mechanism should be supplemented with an *opt-in* mechanism that would allow Member States to authorize cultivation of GM crops in cases where there is a regulatory stalemate – the common situation where the Regulatory Committee is unable to reach the required qualified majority for approval or rejection of a GM event (Eriksson, De Andrade et al., 2018; Eriksson et al., 2019).
11. We might also mention the recent statement from the Danish Ethics Council [Det Etiske Råd]. Denmark, in contrast to Norway, *is* an EU Member State. It does not propose specific regulatory change, but a large majority of the Council's members stand behind a system for approving GMOs that is based on the properties of the organism and not the technology used (Det Etiske Råd, 2019, pp. 20–21). In effect, the Council is arguing for increased technology neutrality against a regulatory rationale of risk reduction.
12. Political initiatives in this direction occasionally occur. For instance, in January 2021, the French minister for agriculture Julien Denormandie is reported to have said that that New Breeding Technologies 'are not GMOs' (Reuters, 2021)

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