Technology neutrality and regulation of agricultural biotechnology

P. Sandin[1], C. Munthe[2] and K. Edvardsson Björnberg[3]

[1] *Swedish University of Agricultural Sciences, Email: per.sandin@slu.se*

[2] *Dept of philosophy, linguistics and theory of science, University of Gothenburg*

[3] *KTH Royal Institute of Technology*

Abstract

Agricultural biotechnology, in particular genetically modified organisms (GMOs), is subject to regulation in many areas of the world, not least in the European Union (EU). A number of authors have argued that those regulatory processes are unfair, costly, and slow and that regulation therefore should move in the direction of increased 'technology neutrality'. The issue is becoming more pressing, especially since new biotechnologies such as CRISPR increasingly blur the regulatory distinction between GMOs and non-GMOs. This paper offers a definition of technology neutrality, uses the EU GMO regulation as a starting point for exploring technology neutrality, and presents distinctions between variants of the call for technology neutral GMO regulation in the EU.

Keywords: GMO, EU, law, ethics

Introduction

Societies have a need to oversee, guide, and regulate the development, dissemination and use of technology for reasons of protection of cherished values. Such protective policies might be characterized as hard or soft. Soft ones include measures such as voluntary moratoria, as for instance implemented for transgenic organisms in the wake of the Asilomar conferences (Berg 2008), various guidelines and industry codes of conduct, and the more recent calls for caution regarding human germ-line applications of gene editing and gene driving (Cicerone et al 2015). Hard ones include outright bans, obligatory pre-market approval processes and mandatory product standards. Many examples of the latter can be found in the European Union (EU) regulation on genetically modified organisms (GMO). In recent years, such policies have been attracting criticism of a certain kind, questioning a combination of inconsistency and inflexibility of common hard policy solutions. It has been pointed out that similar types of risks and uncertainties of different types of technology are often treated very differently, since different policy solutions are applied to different technology types, also within the same policy area, such as agriculture. It has also been pointed out that the hard policy solutions are often tardy to adapt to changes due to technological and scientific advances. This latter phenomenon moreover tends to increase the unequal policy treatment of different technologies. For this reason, calls to make hard protective technology policy 'technology neutral' have been heard, for instance in the areas of climate change technology and biotechnology, in turn provoking critical reactions regarding feasibility (Azar and Sandén 2011, Munthe 2017).

What is technology neutrality?

In this paper, we are referring to the notion of technology neutrality as a feature 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. Following Greenberg (2016), we accept the conceptual basis that such neutrality is seen as opposed to specificity.

It is never technologies *per se* that are regulated, but actions by agents that make some sort of use of a technology. The notion of technology neutrality and specificity of regulatory structures also 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. Moreover, the degree of technology neutrality must be understood as relative. One aspect of this relativity regards *what part* of a regulatory structure we focus on (general statute, derived agency decrees, or case rulings, for instance). Another aspect has to do with how technologies are individuated, and how that relates to the current state of technological development. Take vehicles. There is no radical difference in function between a small pick-up truck and a large truck. However, the quantitative difference in size and weight may be perceived to matter from certain regulatory standpoints, so that in order to operate the larger, heavier vehicle, a different type of driver's license is required. At the same time, the bottom line of this regulatory framework will be common to all types of trucks: the rule that an appropriate license is required to drive them. Moreover, the rationale behind the regulation also applies equally, typically expressed in statute in terms of requirements for different types of licenses having to ensure some standard of reliable and safe driving ability. These latter aspects of the regulatory structure will be less specific (and more neutral) than each of the license requirements for the different type of trucks.

Based on these considerations, we will in the following apply the following working criterion of technology neutrality:

> A regulatory structure, S, for a technology, T_1, is more technology neutral to the extent that
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> (a) other technologies, T_2 … T_n, that are similar to T_1 in terms of the rationale behind S, are also subjected to S, and
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> (b) S applies more similar rules to T_1 and T_2 … T_n when this similarity is greater
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> In addition, S for T_1, is more technology neutral to the extent that
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> (c) other technologies, T_2-T_n, that are similar to T_1 in terms of the rationale behind S, are subjected to some other regulatory structure, S', that applies more similar rules to T_1 and T_2 … T_n when this similarity is greater.

It is implied that technology neutrality decreases, and technology specificity increases, when these features are less present.

When we consider some regulatory structure aimed at protecting cherished values, its rationale will always consist of a combination of such values, and a normative idea of the importance of protecting them (both determined politically).

Case: The EU regulatory system on GMOs

The legislative work on biotechnology in plant breeding has developed along two parallel tracks (Zetterberg and Edvardsson Björnberg, 2017). One track is commonly referred to as 'process-based', which means that the technology of genetic modification is used as a trigger for regulatory oversight. This track is followed by the EU and its Member States. According to EU Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and Regulation 2003/1829 on genetically modified food and feed, 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. This is to be contrasted with 'product-based' legislation according to which the organism's traits, regardless of how they were obtained, in combination with the environment into which the organism will be introduced, determine which legal demands must be met in order for a release permit to be granted. This legislative track is followed by the United States and Canada, among other countries (McHughen and Smyth, 2008; Macdonald, 2014). The EU GMO legislation can be said to be more technology specific, since it singles out new crops developed by use of a certain technology (genetic modification) and subjects them to more stringent licensing requirements than other crops, while the US and Canadian legislations are in various degrees more technology neutral.

Proponents of agricultural biotechnology often argue that current EU regulatory processes are unfair, costly, and slow (Masip et al 2013). In a typical statement, Eriksson and Ammann (2017) talk about 'the regulatory discrepancy between the relatively unregulated so called conventional breeding techniques and the overregulated transgenic techniques' (Eriksson and Amman 2007, p. 1). They hereby imply a case for unfairness, due to a perceived violation of the basic requirement of justice that similar cases should be treated uniformly, and that differences in treatment must be justified. Critics of current regulation argue in this way by claiming that the distinction between genetically modified organisms and non-GM organisms is 'meaningless' (Ricroch, Ammann and Kuntz 2016). One particularly fierce critic, Tagliabue (2016), calls

GMO an 'inconsistent term', an 'inchoherent expression [which] is arbitrary' and a 'bogus concept', which is 'illogical' – all accusations fitting within one paragraph. However, also parties who are opposed to the extended use of industrial agricultural biotechnology have voiced dissatisfaction with the GMO regulation of the EU when realizing that it may not apply to most biotechnology as the methods used are moving from old school hybrid DNA technology to the latest 'gene editing' technology of CRISPR (Kim and Kim 2016). At the time of writing, the issue remains undecided (Abbott 2018). This criticism of the EU regulation of GMOs has a strong tendency to mix rather different messages, namely complaints about inconsistent standards and complaints about the level of regulatory requirements. A requirement of coherence in EU law (Winter 2016) can be used as a basis for requiring that similar regulatory arrangements apply to relevantly similar technologies. But that does not answer either what makes different technologies relevantly similar or what level of regulatory force should be thus equally applied across some set of technologies. We note that the biotechnology advocates apparently would like to see regulatory force to be uniformly relaxed, while biotechnological skeptics desire the opposite move. We may thus distinguish the following variants of the call for technology neutral GMO regulation in Europe:

> TN1: Agricultural technology regulation in the EU should become more technology neutral.
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> TN2: Non-GMO biotechnology should be subject to the same level of regulatory force as GMO technology in current regulation.
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> TN3: GMO technology should be subject to the same level of regulatory force as non-GMO biotechnology in current regulation.
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> TN4: Both GMO technology and non-GMO biotechnology should be subject to more forceful regulation than what is the case in current GMO regulation.
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> TN5: Both GMO technology and non-GMO biotechnology should be subject to less forceful regulation than what is the case in current non-GMO biotechnology regulation

TN1 is consistent with each of TN2-TN5, but all of these are, in turn, mutually incompatible. It is obvious that the standard arguments summarized above do not settle the question to what extent T1 enjoys support, and if this support in that case speaks for any of TN2-TN5.

Discussions about technology neutral regulation often revolve around tensions between the effectiveness of regulatory structures and generic qualities thought to be required by legal systems to be justified. One central feature of a good legal system in both of these respects is the system's ability to regulate actions and behavior over time and among agents in a consistent way. This feature is captured by the requirement of 'legal certainty'. Legal certainty means that the regulatory system is precise and understandable and that the implications of the system can be foreseen by those to whom it applies. As noted above, it has been argued that the present EU process-based regulatory system for GMOs fails to meet the requirement of legal certainty, since it is unclear whether plants that have been developed through genome editing fall under the regulation or not. More technology-specific regulatory systems are generally more vulnerable to this type of objection than more technology-neutral systems, especially in areas where there is rapid advancement in science and technology and where the boundaries of the technology are in need of continuous redefinition as a consequence of this. This means that the classification of technologies in relation to regulatory structures is critical for ascertaining its legal certainty. If technologies are classified as relevantly similar, they should be regulated

similarly. If not, it is easier to justify differences in regulatory requirements. But what should be considered as relevant similarity? Here, it becomes necessary to go beyond the legal structure under consideration and look to underlying assertions thought to justify it. These may be more basic legal rules (such as principles found in constitutions or international conventions), but ultimately they will as a rule force us to consider the basic ethical rationale of law, legal systems and the considered areas of regulation, in our case, GMO. This brings us to moral philosophy (Gregorowius et al 2012).

Technology neutrality and ethics: a way forward?

We can broadly distinguish between *consequentialist* and *non-consequentialist* concerns that are invoked to justify different variants of technology neutrality or technology specificity, depending on what value the regulation intends to protect. Of course, a particular piece of regulation need not be justified solely with regard to one such concern. Multiple ways of justifying a given regulatory item are possible.

Both technology neutrality and technology specificity can be justified on straightforwardly consequentialist grounds depending on circumstances. A decidedly technology-specific policy (say, subsidies for vehicles using a particular kind of fuel) can be argued for on the basis that such a policy contributes to technological development that would otherwise never get off the ground due to high initial costs, low demand, and so on. However, many standard ways of arguing for technology neutrality are consequentialist. Typical examples include Tagliabue's (2018) call for 'product, not process'. Such arguments state that a particular technology ought to be regulated since doing so, or not doing so, will have certain desirable or undesirable consequences. Thus, if different technologies would have similar regulatory consequences, they should be treated similarly. If the (valid consequentialist) rationale of a regulatory structure for some specific technology is satisfied by some other technology, this would therefore seem to provide a *pro tanto* reason for subjecting the latter technology to similar regulation as the former. That is, they should be classified as relevantly similar from a legal standpoint. In terms of our criteria for technology neutrality, this, in turn, would seem to be a case of calling for more technology neutrality rather than less.

Another familiar ethical stance is that certain technologies are subject to strong non-consequentialist considerations. Ronald Sandler has argued that agricultural biotechnology ought to be resisted, since it is contrary to some virtues such as 'humility', which human beings ought to display in their relationship with nature (Sandler 2004). In a similar vein, there are familiar objections to modern biotechnologies in the form of 'playing God' or 'unnaturalness' arguments (Siipi 2015). They express the notion that certain qualitative features of a sub-class of technologies make them subject to some strong moral restrictions and that, therefore, there should be specific regulation for this sub-class, in spite of the fact that the technologies may be very similar to other technologies to which other regulatory solutions apply.

Autonomy and freedom provide a further ethical base that may be played out in either a consequentialist or a non-consequentialist version. It is interesting here because of its role to support regulation regarding very specific uses of biotechnology, but not others, namely commercial retail of goods containing some sort of biotechnologically manufactured element (such as a GMO). The idea is that producers and retailers should be legally forced to provide information to facilitate informed consumer choice on the basis of preferences and values related to GMO (positive or negative), usually in the form of mandatory labeling. Here, the reasons for the regulation will depend on the presence of differences of preference and values

that are considered to be important enough to justify regulation from a perspective of autonomy and freedom.

A final ethical perspective concerns the regulatory handling of ignorance and uncertainty about facts of relevance from any of the other ethical perspectives, often expressed in terms of a precautionary principle (Munthe 2011). In this area, Munthe (2017) has recently presented an idea for how biotechnologies may be classified as more or less similar in a number of ways of importance from a precautionary standpoint, and concluded that the current EU GMO regulation could and should probably be made more technology neutral from a precautionary ethical standpoint by subjecting more traditional agricultural practices and more modern biotechnology, such as GMO, to similar regulatory requirements. Hansson (2016) has argued that the current special regulatory arrangements for GMOs in Europe originally had a rationale based in lack of knowledge that no longer applies with equal force, likewise concluding that general agricultural technology regulation and that of traditional GMOs should be made more similar. However, both authors hold that new technological developments, for instance in the field of synthetic biology, present vast uncertainties and areas of ignorance, thereby possibly being apt for more specific regulatory attention. Again, a regulatory structure may very well be viewed as both quite technology specific from some standpoint, and at the same time more technology neutral in relation to a specific regulatory rationale (where the rationale might be, for instance, precaution).

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