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Consistent risk regulation? Differences in the European regulation of food crops

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ABSTRACT

In the EU legal system, there is a large difference between the procedures and requirements for the introduction of crops that are classified as genetically modified (GM) and crops not so classified. In order to investigate whether this regulatory divide is compatible with real risks two cases of GM crops and two cases of non-GM crops are scrutinized. It is concluded that the regulatory divide cannot be justified from the viewpoint of risk assessment, since the GM/non-GM dichotomy is not an accurate indicator of either health risk or environmental risk. Much better such indicators are available and should form the basis of a legislation aimed at preventing the introduction of crops that are harmful for human health or the environment. If the legislator has other reasons to regulate GM crops differently than conventional crops, then those reasons should be stated in the legislation and determine the types of measures that it prescribes.

1. Introduction

In many legal systems, the introduction of new crops or cultivars is regulated differently depending on whether they are genetically modified (GM) or not. This is, for example, the case in the European Union, where the introduction of conventional crops is less stringently regulated than that of GM crops. According to EU Directive 2001/18/EC (the Release directive), a GM variety can only be introduced into the environment after a specific permission has been granted. Permissions may be granted only if cultivation and distribution do not pose a significant risk to human health or the environment. The burden of proof rests with the applicant, who must provide extensive documentation before a decision can be made. Due largely to the strict requirements, only two GM varieties have been accepted for introduction on the European market (GM maize MON 810 authorized in 1998 and GM starch potato Amflora authorized in 2010). In contrast, few demands are put on conventional crops. According to Directive 2002/53/EC (the Variety directive), conventional (and GM) crops can normally be placed on the market subject to a variety certification. Certification presumes that the variety has been included in the national...
or common EU list of varieties, which in turn requires that the variety is distinct, stable and sufficiently uniform (DUS) and has satisfactory value for cultivation and use (VCU). However, the DUS and VCU examinations do not contain any environmental or health risk assessment, and the certification process for conventional crops is therefore much less demanding than that for GM crops.

The EU legislation, with its separate legal procedures and demands for conventional and GM crops, has come under substantial criticism (Masip et al. 2013; Ricoch, Ammann, and Kuntz 2016; Davison and Ammann 2017; Tagliabue 2017). One of the arguments most frequently voiced is that the legislation is inconsistent and obsolete from a scientific point of view, since the environmental risks associated with the introduction of GM varieties could likewise be brought about by introductions of conventional varieties (Miller 2010; ACRE 2013). EU/EFSA has concluded that GM plants as such do not carry any higher risk than conventional breeding material (European Commission 2010).

In this article, we investigate to what extent the regulatory division between conventional and GM crops can be justified, given the available evidence on health and environmental risks. Four hypothetical crop introductions are used as starting points for the discussion: a GM cultivar of field cress (Case A), a GM cultivar of potato (Case B), a conventional cultivar of field cress (Case C), and a conventional cultivar of potato (Case D). In all cases we will assume that the cultivar has been developed by crop breeders in Sweden and that the application for the relevant permits is submitted to the Swedish authorities. Furthermore, the assumption is made that field trials have already been conducted, so that the application concerns the commercialization of the crop. Sweden was selected as empirical departure point, partly because of the authors’ familiarity with its national GM legislation, partly because it has incorporated ethical concerns into its national GM legislation. Because of this, the Swedish legislation is particularly instructive when developing a normative argument that concerns regulatory treatment of environmental risk. Since the pertinent Swedish legislation rests on European law, the discussion will however refer back to the EU legislation and the conclusions will have EU-wide relevance.

In the next section, the four hypothetical cases are described. In Section 3, the legal rules that apply in each case are identified and systematized on the basis of the following questions:

- Is a legal permit required? Who makes the decision?
- Must an environmental risk assessment be performed? With whom lies the burden of proof?
- Must an ethical assessment be performed? If yes, which ethical factors are included? Who is responsible for performing the ethical assessment?
- Must benefits to society be demonstrated?
- Does the public have the opportunity to participate in the decision-making process?
- What type of documentation is needed for a permission?
- Are there any provisions on labelling?
- For how long are permits valid?
- Can a permit be subjected to conditions?
- Are there established procedures for ex post control? Who is responsible and what is being controlled?

In Section 4, the results of the legislative comparison are used to develop an argument concerning the reasonableness of upholding the regulatory distinction between conventional and GM crops within the EU legislation. It is argued that the present regulatory divide cannot be justified from the viewpoint of risk assessment, since the GM/non-GM dichotomy is not an accurate indicator of either health risk or environmental risk. The prospects of adjusting the present EU legislation in the proposed direction are briefly commented on.

It is at present uncertain which crop breeding techniques should count as genetic modification and, thus, fall under the Release directive. This regulatory uncertainty is particularly acute
regarding new genome editing techniques, such as CRISPR (Jones 2015). When GM varieties are referred to it is assumed that they unambiguously fall under the definition of genetically modified organism (GMO) provided in Article 2(2) of the Release directive.

In the following, the term ‘consistent’ (as in ‘consistent risk regulation’) denotes that a legislative framework is non-discriminatory in the sense that it treats like risks (i.e. risks that are similar in all relevant respects) alike.

2. Four hypothetical introductions of new cultivars

Four hypothetical introductions of new cultivars will be used as empirical starting points for the analysis: two introductions of field cress and two introductions of potato. All cases are realistic in the sense of being based on ongoing plant breeding projects aiming at market introductions of new crop varieties in Sweden.

Field cress (Lepidium campestre) is a wild species prevalent in Europe, including its northern parts. It has many good agronomic traits, such as excellent winter hardiness and high yield potential. Compared with rapeseed, field cress is more suitable as a cover crop to prevent nutrient leaching due to its weaker growth vigour. However, it also has several drawbacks, such as low seed oil content, undesirable oil composition for food purposes or industrial feedstocks, and heavy pod shatter, which need to be improved before any commercialization of the species can take place (Ivarson et al. 2016, 2017).

Field cress and some of its close relatives grow in the wild and can cross with each other. However, one of the agricultural properties that breeders wish to introduce into cultivated field cress – highly decreased pod shatter – will substantially reduce the probability that a plant reproduces and disseminates in the wild. The ultimate goal of domesticating field cress is to provide field cress varieties with agricultural properties that make the species equally dependent on farming as the common cereals and oil crops. If this succeeds, it will not be able to outcompete wild plants whose reproductive capacity has not been impaired.

Potato (Solanum tuberosum) belongs to the family Solanaceae, which includes many thousand species all over the world. It has been one of the most important crops in Sweden for several hundred years. A major problem with potato production is its vulnerability to late blight, a disease caused by Phytophthora infestans. Many potato fields in Sweden are treated with pesticides 5–15 times during the growing season (Eriksson et al. 2016). Some potato lines with alleles resulting in improved resistance to late blight have been known for many years. They have been developed by crossing potato with wild relatives that are resistant to the disease. Unfortunately, such crossings also transfer traits from the wild species that make the crop less suitable for agriculture and for food purposes. Furthermore, the pest resistance obtained in this way has been unstable due to the evolution of new variants of the pathogen. The threat from P. infestans has increased during this millennium, due to new potato varieties with sexual reproduction in Europe, and to climate change as well as stricter regulation of fungicide use.

Potato cannot survive in the wild in Europe. Potato reproduces mainly through tubers that need open soil to grow into a vital plant. Some tubers left in the soil at harvest may start to grow next spring, but they cannot compete with the new crop sown on the field. There are no examples of escapes that survived for several generations in Sweden. There are some wild potato relatives in Sweden (e.g. Solanum dulcamara, Abreha et al. 2018), but no cases of spontaneous crosses between the domesticated potato and wild relatives have been reported in Europe.

Case A: A GM cultivar of field cress

In Case A, an improved GM cultivar has been obtained that has significantly reduced pod shatter, synchronized maturity, increased oil yield, and oil composition appropriate for food purposes. It is suitable
as a catch crop in combination with spring barley or wheat, with significantly reduced nitrogen leakage and decreased need for tillage. Field trials have shown that due to its agricultural properties such as low pod shatter, the modified field cress cannot compete with wild species outside the agricultural fields. Furthermore, since the modified or inserted genes are unfavourable for surviving in the wild, the risk of gene transfer to related wild species is minimal.

Case B: A GM cultivar of potato

In Case B, plant geneticists have transferred three genes from resistant potato lines to a modern potato line and thus developed a high producing potato with high and more sustainable resistance to late blight, in addition to all the qualities expected from a modern potato line performing well in the Nordic countries.

Case C: A conventional cultivar of field cress

In Case C, through a combination of conventional crossing and selection with modern non-GM breeding methods such as effector screening (Lenman et al. 2016), DNA markers or genomic selection, plant breeders have achieved a variety with all the properties mentioned in Case A.

Case D: A conventional cultivar of potato

In Case D, through a combination of conventional crossing and selection with modern non-GM breeding methods such as genome selection and DNA markers, plant breeders have achieved a variety with all the properties mentioned in Case B.

3. Legislative comparison

The results of the legislative comparison related to the four hypothetical market introductions are presented in Table 1. Below, we summarize the legislative differences between GM and conventional crop market introductions as regards environmental risk assessment (Section 3.1) and ethical assessment (Section 3.2). We also comment on assessment of benefits to society (Section 3.3). The GM legislation, which applies exclusively to Cases A and B, is first described, followed by a description of the Variety directive, which applies to all cases (A–D).

3.1. Must an environmental risk assessment be performed?

Cases A and B: According to the Release directive, the applicant must conduct an environmental risk assessment before a GM cultivar of field cress or potato can be put on the market. The objective of the risk assessment is

on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release or the placing on the market of GMOs may have.

The burden of proof lies with the applicant, who must provide extensive documentation before a decision can be made.

All cases (A–D): To be admitted to the national or EU list of varieties, a new cultivar of field cress or potato must satisfy the DUS and VCU requirements, as specified above. They do not involve any assessment of the environmental or health risks associated with the introduction of the cultivar.

3.2. Must an ethical assessment be performed?

Cases A and B: A major difference in how conventional and GM crop introductions are regulated concerns whether or not ethical considerations are attended to in the licensing process. The Release directive does not require that an ethical assessment be completed before a GM variety is put on the European market, but it allows member states to consider such aspects in their
<table>
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<th>Case</th>
<th>Is a legal permit required?</th>
<th>Must an environmental risk assessment be performed?</th>
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<th>Are there established procedures for ex post control?</th>
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<tr>
<td>A</td>
<td>Yes, according to Part C of the Release directive (see also Article 4 of Regulation (EC) 1829/2003). The licensing decision is made by the European Commission following a voting procedure. See also C</td>
<td>Yes, according to Article 4(2) of the Release directive. The applicant has the burden of proof (see sect 3.1 for details).</td>
<td>Not required by the EU legislation, but Swedish law requires that both risks and opportunities are taken into consideration as part of the ethical assessment (see sect 3.3 for details).</td>
<td>Yes, according to Article 9 of the Release directive, the member states consult the public on any proposed introduction of a GM variety.</td>
<td>Extensive documentation is required according to Article 13(2) of the Release directive, including environmental risk assessment, plan for monitoring, and proposal for labelling, etc.</td>
<td>Yes, Article 21 of the Release directive requires that GM varieties are labelled before they are placed on the market (see also Article 9(5) of the Variety directive).</td>
<td>A maximum period of 10 years according to Article 15(4) of the Release directive.</td>
<td>Yes, according to Article 19 of the Release directive a permit to place a GM variety on the market can be subject to conditions regarding use, handling and packaging.</td>
<td>Yes, according to Article 20 of the Release directive, the permit holder has to carry out monitoring and reporting as specified in the permit.</td>
<td></td>
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<tr>
<td>B</td>
<td>Yes, see A and C</td>
<td>Yes, see A</td>
<td>Yes, see A</td>
<td>Yes, see A</td>
<td>See A</td>
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<td>Yes, see A</td>
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<td>C</td>
<td>Yes, see A</td>
<td>No</td>
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<td>D</td>
<td>Yes, see C</td>
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national GM legislations (Preamble 9). In Sweden, the Parliament has decided that ethical considerations should be part of the licensing process for GM varieties. The Environmental Code thus prescribes that ‘special ethical considerations’ should be taken before a GM variety is placed on the market. It furthermore requires that any such placing be ‘ethically justified’.

The grounds for the ethical assessment of GM varieties are elaborated at length in the preparatory work to the Code. The government emphasizes the general responsibilities of humans to manage and take care of the environment and to prevent serious ecological disturbances. These responsibilities attach to all activities that fall under the Code, including introductions of GMOs. However, as is evident from the legislator’s choice of the phrase ‘special ethical considerations’, something more is required when assessing the ethical appropriateness of GM varieties than simply meeting the general provisions of the Code. These ‘special’ ethical considerations are three-fold.

First, the government acknowledges that genetic engineering touches on the issue of humanity’s right to transform the natural environment. In the government’s words, genetic applications ‘must not be perceived as offensive or against public policy and morality’. It is evident from the decisions of the Swedish Board of Agriculture that in the application of the Code genetic modification as such is not regarded as offensive or against public policy and morality. Instead, there must be something offensive about the particular application under consideration. There are to date only two rejections made by the Swedish Board of Agriculture concerning GM crop introductions (field trials), both of which were rejected due to lack of information about the environmental risks involved, and not on ethical grounds. Therefore, it is unclear how the phrase ‘offensive or against public policy and morality’ should be interpreted.

Second, the applications of gene technology must not cause unnecessary suffering to animals. This goes beyond the general obligation that humans have to manage and take care of the environment, as enshrined in Chapter 1 Section 1 of the Environmental Code. In the latter provision, the term ‘the environment’ includes populations of animals but the protection of individual animals does not fall within its scope.

Finally, introductions of GM varieties should only be allowed if they involve benefits to society. Benefits to society are specifically defined as benefits that are not restricted to the operator but extend to the general public (see Section 3.3).

The ethical assessment is to be carried out by weighing risks and opportunities in the individual case, taking the latest scientific facts into consideration. Among the values that form the basis of the ethical assessment are: animal and human health values, environmental values such as biological diversity, reduced climate impact, and efficient resource use, religious and existential values, scientific values, economic values, and justice and autonomy (justice in a national and global context, freedom of choice and co-existence aspects). The Swedish Gene Technology Advisory Board is responsible for conducting the ethical assessment.

**Cases C and D:** The Variety directive does not require that any ethical assessment be performed before a new conventional variety is admitted to the national/EU list of varieties.

**3.3. Must benefits to society be demonstrated?**

**Cases A and B:** The Release directive does not require that potential benefits to society be assessed before a permit is granted. Consequently, the risk assessment performed as part of the approval process is strictly focused on identifying and categorizing potential risks and does not include any balancing of those risks against potential benefits. In contrast, Swedish law requires that both risks and benefits are taken into consideration (as part of the ethical assessment) before a GM crop is placed on the market. The Swedish legislation is intended to make sure that a GM crop will only be put on the market if it involves benefits to society, that is, ‘benefits that are not restricted to the operator but extend to the general public’.
All cases (A–D): For a new cultivar of field cress or potato to be approved and admitted to the national or EU list of varieties, it must have VCU. A variety's VCU is satisfactory if, compared to other varieties accepted in the national catalogue of varieties,

its qualities, taken as a whole, offer, at least as far as production in any given region is concerned, a clear improvement either for cultivation or as regards the uses which can be made of the crops or the products derived therefrom.16

Notably, this does not include any assessment of potential benefits to society in broader terms. Instead, the phrase should be understood as referring only to the farmers’ needs for harvest security (van Waes 2004).

4. Discussion and conclusions

The legislative comparison shows that the main differences between the two regulatory frameworks relate to the scope of the assessment performed as part of the licensing process. All varieties (A–D) must be certified and admitted to the national/EU list of varieties before they can be marketed in the EU. However, GM varieties must in addition go through a comprehensive environmental assessment before an application can be filed for admission to the list of varieties. The office turn-around time is therefore much longer for GM varieties than for conventional varieties. The high cost in combination with the high level of commercial unpredictability has led leading companies to refrain from trying to introduce GM cultivars on the European market (Kanter 2012; Eriksson et al. 2018).

The environmental risks associated with a crop depend on its properties, not on how the properties were obtained. For instance, the potential for invasiveness depends on the crop's ability to survive outside of an agricultural field. This, in turn, depends on properties such as pod shatter and germination capacity, which can be changed with either conventional or GM breeding methods (Sukopp and Sukopp 1993; Hails 2002; Buddenhagen, Chimera, and Clifford 2009). As our examples show, the current legislation requires extensive environmental assessments of GM cultivars but not of conventional cultivars with similar potentials for developing invasiveness. This means that the legislation is not consistent in the sense of apportioning measures against environmental damages in proportion to the risk of such damages.

Furthermore, the European GM legislation is based on a risk assessment that only considers risks and not the associated benefits. It thus differs from many other risk-related legislations in which risks are required to be weighed against the benefits (Pearce 1998; Turner 2007). The difference seems to be difficult to defend from the viewpoint of the principle of non-discrimination. For instance, one would expect stricter requirements to be put on a (GM or conventional) crop that lacks substantial benefits for the public than on a GM product such as that in our Case B that has a substantial environmental benefit (reduced use of harmful pesticides). In the current EU legislation, no such distinction is made.

In addition to the environmental risk assessment, some EU/EEA member states include wider socio-economic considerations in their national GM legislations, which can further delay the licensing process. Sweden, France and Norway are some examples (EPEC 2011; Roger 2015). In France, the High Council of Biotechnology has a broad mandate to evaluate the economic, ethical and social aspects of GM crop introductions.17 In Norway, socio-economic consequences, including ethical and positive and negative sustainable development impacts, are assessed by the Norwegian Biotechnology Advisory Board (Kvakkestad and Vatn 2008; Roger 2015). In Sweden, socio-economic considerations are part of the licensing process via the Gene Technology Advisory Board’s ethical assessment.18

In addition to the differences in the scope of the assessment, conventional and GM crops are regulated differently after a permit to place the variety on the market has been granted. The most significant difference relates to the mandatory labelling of GM seeds and other propagation material. There is no such labelling requirement for non-GM products with the same properties.
Its purpose is not to inform consumers of the properties of the products (which it does not) but to inform them of the process used when they were bred.

The application of special precaution to GM varieties originates in the endeavours of pioneer researchers in the 1970s to investigate potential risks before they proceeded with their research. In July 1974, 11 researchers published a letter in *Science* proposing that scientists should ‘voluntarily defer’ two types of experiments with biologically active recombinant DNA molecules. They did so because there was ‘serious concern that some of these artificial recombinant DNA molecules could prove biologically hazardous’ (Berg et al. 1974, 303). This was a precautionary measure. As far as we can see, it was justified given the state of knowledge at the time about potential risks. However, today our knowledge in genetics, plant biology and ecology has increased dramatically. It is now known in considerable detail how genetic modifications affect the traits of a plant, and we can also learn from naturally occurring horizontal gene transfer that has been detected in some cases. Today, precautionary measures against potential environmental risks with new cultivars can be apportioned with much more precision than what was possible in 1974. The oversimplified dichotomy between GM and non-GM products can be replaced by much more nuanced criteria based on biological knowledge of the ecological consequences of different properties in the plants (Hansson 2016). Although safety legislation often has to rely on simplified criteria that are more easily implementable than ideal, more precise criteria, the difference in this case is so large that the efficiency of the legislation has become questionable.

The inadequacy of the present legislation comes out clearly from our four cases. Beginning with the potato cases (B and D), it is well known that conventional potato breeding can lead to inadvertent increase in toxic substances such as solanine. In the past, there have been cases where new cultivars have had to be removed from the market due to high solanine content (Van Gelder 1990; Hellenäs et al. 1995). A good case can be made for a precautionary approach to this risk. This would mean that all new potato cultivars should be carefully tested in field trials under varying agricultural conditions in order to make sure that the solanine concentration stays below levels of concern. This will have to apply equally to GM and conventional potato cultivars. The current legislation that requires extensive health risk assessment in case B (GM) but not in case D (non-GM) does not satisfy reasonable requirements of consistency in risk legislation.

Field cress (cases A and C) is a wild species that plant breeders are currently domesticating. When a wild species is domesticated, it is important to evaluate whether the domesticated variety can plausibly become invasive. The risk of invasiveness depends on several traits that are well known to botanists and plant breeders. Essentially, this boils down to whether the crop will depend on farming for its reproduction or survival, and whether it can outcompete wild plants outside of the farmland. This will have to be seriously assessed for field cress cultivars, regardless of the breeding method used. In this assessment, specific traits such as pod shattering will be at focus. How these traits have been obtained is irrelevant from a risk perspective. For instance, a conventional cultivar with considerable pod shattering will incur a much higher risk than a GM cultivar with very low pod shattering of becoming invasive and threatening the integrity of wild ecosystems. Therefore, the current legislation, which requires an extensive environmental risk assessment in case A but no such assessment in case C, does not satisfy reasonable requirements of consistency.

These examples show that neither health risks nor environmental risks justify a regulation that puts high demands on GM cultivars but no demands on conventional cultivars. From the viewpoint of risk assessment and management, a unified legislation is needed that focuses on potentially harmful traits rather than on the techniques used for obtaining the traits.

However, it can be argued that although neither health risks nor environmental risks justify the current legislative dichotomy, it can be justified on other grounds. The most plausible such justification seems to be that considerable segments of the population prefer conventional products for reasons unrelated to scientifically plausible risks or uncertainties. They may for instance be against ‘tampering with nature’, or have other existential or religious grounds for rejecting GM products. Such concerns may justify legislation, but the legislation would have to be tailored to deal with
those particular issues. With a separation of issues, it will be possible to reconsider what type of legislation on agricultural crops is needed in order to prevent risks to health and the environment. Such considerations should be based on the best available scientific information, and they should ideally be continuously updated as science progresses. The prospects for reforming the pertinent EU legislation in this direction depend on complex policy issues in the member states, related to public opinion as well as to agricultural policies in general, that fall beyond the scope of this paper.

Notes
3. Article 4(2), Directive 2001/18/EC.
5. Chapter 13 Section 10 and 13, Swedish Environmental Code.
7. Chapter 1 Section 1, Swedish Environmental Code, see also Chapter 2 of the Code.
14. This is different from established practice in virtually all other areas of application for risk analysis. In the early days of modern risk analysis (the 1960s and early 1970s), it was often assumed that there is a general ‘probability limit’ below which risks are acceptable, independently of the associated benefits (if any). For a rebuttal, see Hansson (2011).
18. However, it should be noted that the impact of this national legislation is reduced when placing a product on the market by the fact that the Swedish decision depends on a foregoing EU process that does not include such considerations.

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