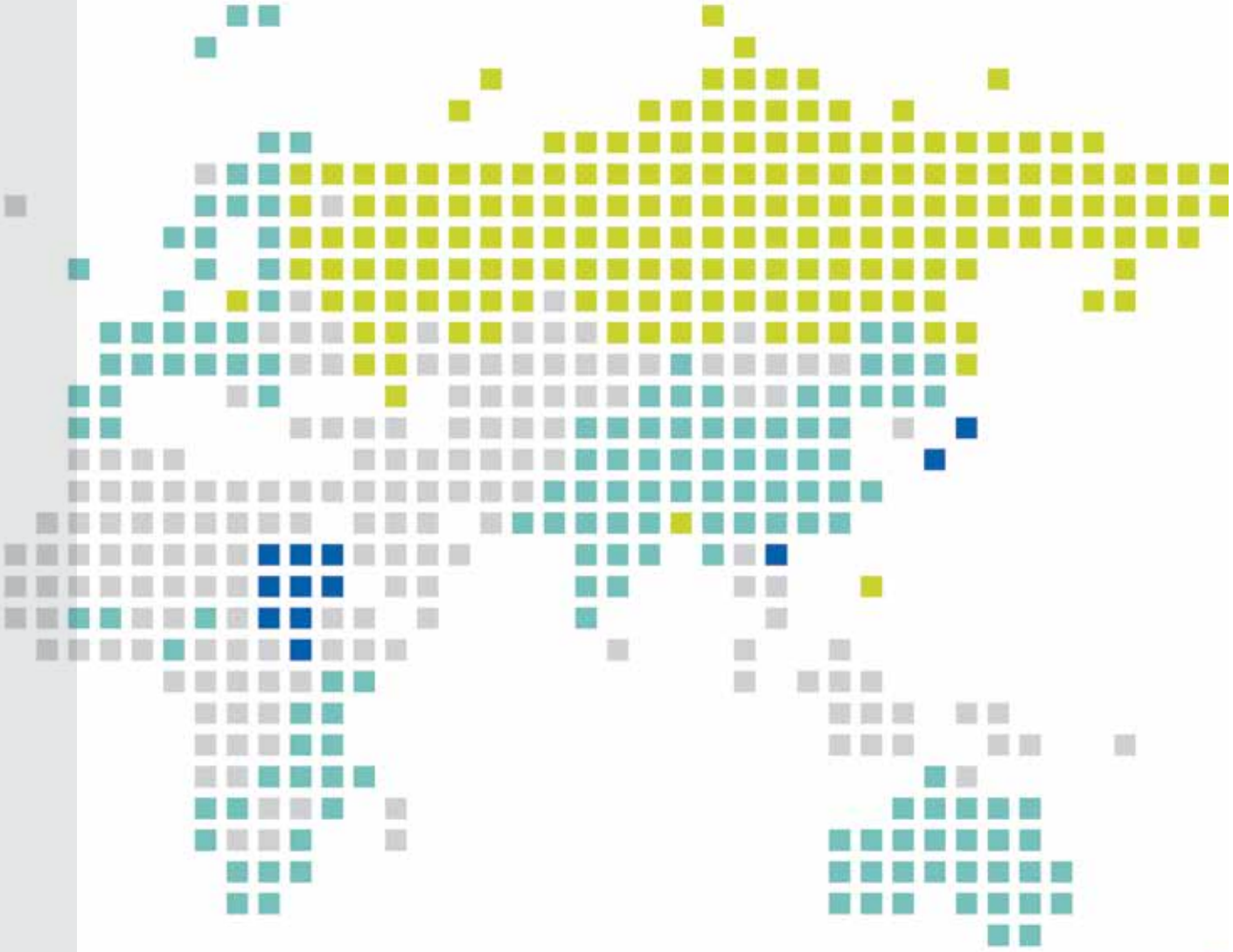
No rose without thorns

Implications of a product-based regulatory system for GM crops in the European Union



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Summary

The current legislation on genetically modified (GM) crops in the European Union (EU) is insufficiently future-proof in the light of the advances being made in genetic modification technologies. The emergence of new plant breeding techniques (NPBTs) is blurring the boundaries between genetic modification and conventional plant breeding and it is becoming increasingly difficult to determine whether or not a GM crop has been obtained by means of genetic modification. The impasse regarding the legal status of NPBTs raises questions about the appropriateness of the regulatory principle underlying EU legislation on genetically modified organisms (GMOs), which is based on the process of genetic modification and not on the products of this process.

There is also debate about the broader issues and the procedural aspects of decision-making under the GMO legislation. Questions include whether certain NPBTs should be exempt from regulation to lift the inhibitory effect on innovation and technological progress. But if these crops could not be traced in the food chain, would this not undermine consumer choice? And how can the decision-making process about marketing authorisations be made smoother?

In the EU, solutions are being sought for the problems of the current GMO legislation. Some stakeholders advocate changing the European process-based regulatory system into a product-based system. To stimulate and inform discussion on this topic, this policy report reviews the possible consequences of switching to a product-based regulatory approach for GM crops in the EU. The European regulatory system is compared with approaches taken in other countries, and in particular with the Canadian system.

Regulation

The EU has adopted specific legislation on GMOs. This GMO legislation is process-based, because the decision to require an environmental risk assessment or a food safety assessment is based on the way in which an organism is produced. The regulated GMO may be a micro-organism, a plant or an animal.

Canada has no legislation specifically for GM crops or GM food, but there is a regulatory framework for assessing the characteristics of the end-product, regardless of how it is produced. All plants with novel traits (PNTs) are covered by this legislation. This means that, depending on the nature of the novel trait, plants obtained by conventional, organic or biotechnological breeding techniques may fall under the legislation.

If the EU were to adopt a product-based regulatory system, new breeding techniques would not have to be individually assessed before introduction to determine if they fall under

the legislation and if so, that any resulting plants therefore have to comply with the regulations. Instead, each new variety would have to be assessed to establish whether or not it contains a 'novel' trait. Under such a regime, some plants varieties which in the EU are currently regulated as GMOs might be excluded from regulation, whereas some conventionally bred plants not now covered by the legislation might have to be regulated.

Risk assessment

The content of the environmental risk assessment does not depend on whether the regulatory system is process-based or product-based. The EU and Canadian regulatory systems are based on different principles, but in both jurisdictions the risk assessment examines the characteristics of the end-product. The aspects to be investigated in risk assessments for deliberate release into the environment and in food safety assessments are more or less the same in both systems. If the EU were to switch to a product-based regulatory system, therefore, this would probably have no more than minor implications for the risk assessment, assuming that the current principles, data requirements and risk assessment methods remain the same.

Innovation, production and marketing

Introducing a product-based regulatory approach could encourage plant breeders to make more use of NPBTs because crops that do not contain any significantly different traits would not be regulated under a product-based system. This could lead to an increase in the number of crops produced using these techniques. Those products with new characteristics that are clearly different from products or crops already on the market would still be regulated. In Canada, all products of genetic modification, including NPBTs, are assessed under the legislation for PNTs. Irrespective of the type of regulatory system, an increase in the number of marketing authorisations for regulated crops in the EU would seem unlikely for some time given the protracted decision-making procedures and the high costs of registration and the safety assessment.

Genetic modification is not permitted in the organic sector and as NPBTs are also considered to be GM, they are rejected. An increase in the number of crop varieties developed through the use of NPBTs that are not regulated would therefore present a problem for organic farming and the marketing of organic produce in Europe, particularly for crops in which cross-contamination is hard to prevent, such as oilseed rape. International agreements on the regulation of NPBTs could ease international trade and help to prevent unintentional cross-contamination.

Enforceability and consumer choice

The enforceability of the legislation is the degree to which oversight of compliance with the rules and required measures is possible, which depends on the possibilities for detecting PNTs and GM plants and their products. Detection is crucial for the regulation of inter-

national trade, but also for consumer choice because this is based on labelling and coexistence (no contamination of conventional and organic crops with GM crops), which in turn relies on detection.

In theory, product-based and process-based regulatory systems are both enforceable as long as the authorisation process includes the submission of reference material and a validated detection method. In practice, however, detecting NPBTs is becoming increasingly difficult owing to a lack of information and rising costs. This is particularly problematic in Europe, where labelling of GMOs is mandatory and compliance is subject to systematic supervision. Both the EU and Canada have measures in place on labelling products of GM crops and on coexistence with conventional and organic crops. These measures may be separate from the environmental risk assessment and food safety assessment of GM crops or PNTs. The difference is that labelling and coexistence is mandatory in the EU, but voluntary in Canada. Switching to a product-based approach in the EU would therefore require rethinking the regulations for traceability and the labelling of GMOs. Products developed using recombinant DNA technology but that do not possess any novel traits would no longer be subject to regulation, which would remove any obligation to provide a validated detection method or to label the products.

To continue to guarantee that organic products are GM free, a legal framework for detection would have to be drawn up or a legal duty for detection placed on the stakeholders themselves. The latter approach would represent a shift in the regulatory burden from the conventional and biotechnological sectors to the organic sector.

Procedural and political context

Several difficulties surrounding the regulation of GMOs in the EU are not just legal in nature, but concern the procedural and political context in which decisions on GMOs are taken. An important difference between the implementation of the legislation in the EU and in Canada concerns decision-making procedures. In Canada, decision-making powers lie with the mandated authority, whereas in Europe, representatives from the 28 EU Member States have to reach agreement in the decision-making procedure (comitology, or committee procedure). This throws up practical problems because the Member States do not all hold the same ideas about safety of GM crops and may have different ethical, social and economic priorities. If the EU were to switch to a product-based approach to the regulation of GM crops but retain the same decision-making procedures, it is likely that disagreements between Member States would still arise and EU decision-making on regulated plants and products would remain a laborious process.

Difficulties surrounding innovation, consumer choice and detection

Irrespective of the regulatory basis, the regulation and use of GM crops is accompanied by potential adverse effects on innovation in the plant breeding sector, consumer choice and detection. These problems cannot be resolved simply by changing the regulatory basis, but require broader political choices and decision-making.

The primary purpose of the regulation of GM crops and other GMOs is to ensure human and environmental safety. The emerging NPBTs, in particular gene editing, make it possible to create new crops that are almost indistinguishable from crops obtained by conventional breeding techniques. This prompts the question of whether these crops pose an environmental risk and, if so, what sort of risk. That is why some stakeholders view the current EU GMO authorisation process as disproportionate, protracted and costly for crops obtained by gene editing techniques. They see the authorisation process as an impediment to placing these types of new crops on the market and want them to be exempt from regulation. Exempting some GMOs from regulation would reduce their visibility in the innovation, production and marketing chain, increasing the likelihood that consumers and producers who do not want GMOs will be unwillingly and unwittingly exposed to them.

The challenges of detecting NPBTs are problematic not only for the organic sector, but for other sectors as well. NPBTs are regulated in some countries and not in others, giving them a different legal status in different jurisdictions. This presents problems in international trade. If the distinction between GMOs and conventional crops is considered to be a crucial aspect of a regulatory regime but it is no longer possible to detect certain GMOs, other possibilities will have to be found. One such possibility could be supply chain certification.

Process-based and product-based legislation: the best of both (or several) worlds

This policy report reviews the possible consequences of switching from the EU's process-based regulation of GM crops to a product-based regulatory system. The latter approach focuses on the risks and acceptability of the products of NPBTs. The survey of possible consequences underlying this report indicates that the process-based and product-based approaches to regulating GMOs are not simply interchangeable. Both approaches have their advantages, problems and disadvantages. It is also true that the practical differences between the two approaches are in some respects smaller than many people would at first think, for example with respect to the number and type of regulated crops.

The report also goes into the ways other countries outside Europe approach the regulation of NPBTs. In various countries, including Argentina, Japan and Australia, the legislation is being amended to stay abreast of the challenges of regulating new breeding techniques. These countries are looking to introduce supplementary regulations or criteria to assess the safety of new crops, to minimise the brakes on innovation, and at the same time to facilitate the visibility of NPBTs in international trade in order to safeguard consumer choice. The most favoured principle behind these proposals is that GM products containing no foreign DNA in the end-product require less stringent evaluation or can be exempt from regulation. This also lies at the heart of Dutch proposals for discussion within the EU.
To facilitate innovation and transparency in the use of NPBTs, a tiered approach to assessment is also being investigated. In this approach there is a requirement to notify new crops, which are then assessed against a number of criteria to establish whether this notification

is sufficient or a risk assessment needs to be carried out. Such an approach, if applied in the EU, could guarantee both the visibility and the safety of these crops, while imposing the least possible impediment to innovation.

Contents

1. Introduction

In the European Union (EU), new products that may present risks, such as new foods, medicines and chemicals, are assessed for human and environmental safety. The criteria used to decide whether or not a product should be subject to a form of regulation (the 'regulatory basis') are usually the characteristics of the product. The legislation on genetically modified organisms (GMOs) is an exception to this. The regulatory basis for GMOs is the way they are made: the production process.

1.1 Background

In previous advisory and policy reports, COGEM has observed that EU legislation on GMOs has not kept abreast of scientific and technological advances in plant biotechnology.[1,2,3,4] The emergence of new plant breeding techniques (NPBTs) is blurring the boundaries between genetic modification and conventional plant breeding and it is becoming increasingly difficult to determine whether or not a product has been obtained by means of genetic modification.[5] This raises serious questions about the applicability and enforceability of the legislation.

Since 2006 there has been much discussion about whether or not the plants resulting from NPBTs fall within the scope of the legislation, from both a scientific and a legal point of view. In 2018 the European Court of Justice concluded that the current GMO legislation is applicable to products of new[a] mutagenesis techniques (including gene editing using CRISPR-Cas technology).[b]

Detecting the products of NPBTs can present technical, practical and economic challenges for companies throughout the whole production chain. Even when it is technically possible, detection can still be problematic from a practical point of view (for example, if it is not known which genetic construct to look for) or be very costly.[6] Detection of GMOs is crucial for enforcement, for the regulation of international trade and for consumer choice. Genetically modified (GM) crops and foods are a politically and socially sensitive issue in Europe. Labelling is mandatory in the EU and coexistence rules are in force to facilitate producer and consumer choice, which can be compromised if the possibility of detection is weakened.

Consumer choice can also be affected if techniques are regulated in one country and not in another. Products are not identifiable as products of NPBTs and this may lead to problems in international trade and logistics if they are regulated in the importing country.

a The products of older mutagenesis techniques, including by radiation and chemicals, remain exempt from regulation because they have a history of safe use.

b European Court of Justice (2018) Case C-528/16.

Stakeholders who consider NPBTs to be genetic modification point to the importance of products from plants developed using these techniques being visible in the food chain. Companies and scientists in Europe who want to use NPBTs do not consider the products to be GMOs and experience the current strict regulatory framework, the associated costs and the time-consuming procedures to be a barrier to innovation and development. They are keen to see some techniques exempt from regulation and mandatory labelling to create an international level playing field with other plant breeding companies and put the plants on the same footing as conventionally bred varieties.

This report aims to contribute to the discussion about possible solutions to the problems in the current GMO legislation. A possibility that has been put forward for some time now is to switch from a process-based to a product-based regulatory approach.

Different regulatory systems from around the world are either based on the process used to make something or on the end-products of the process (**see text box Process-based or product-based regulation**).

Process-based or product-based regulation

The regulatory systems under which GMOs fall are generally classified as either process-based or product-based. However, opinions differ about what process and product mean exactly in this context, and as a consequence different listings of countries with process-based and product-based systems can be found in the literature. The terms are therefore not as clear-cut as they seem. The EU legislation is almost always classified as process-based, although it possesses features of both systems. EU Directive 2001/18/EC contains a definition of a GMO and a GMO product, as well as descriptions of the techniques (processes) that produce GMOs. Regulatory systems are classified as process-based or product-based primarily according to the principle or the criteria used to determine whether or not a product or organism should be regulated. In both process-based and product-based regulatory systems, an environmental risk assessment or food safety assessment is carried out on the basis of the characteristics of the product. Most countries operate a predominantly process-based regulatory system for GMOs (**see Figure 1 Countries with process-based and product-based regulatory systems for GMOs**).

The regulatory basis of product-based legislation is the characteristic of the product, regardless of the process that was used to obtain it. Some consider the idea of a product-based regulatory approach to be attractive because they say the characteristics of a product provide a verifiable and precise definition, which is much more workable than the use or otherwise of certain processes in the production of the product. In addition, a product-based regulatory system is less likely to be impaired by the introduction of new techniques and production methods, because it is the end-product that is assessed and not the process used to obtain it.

Canada is the most frequently mentioned example of a country with a strict product-based system for regulating the deliberate release of new crops. In Canada, plants are regulated if a) they possess a trait that is new in the Canadian environment, and b) they pose a poten-

tial risk to human health and the environment. This system is independent of the way the plant is produced (by genetic modification or by conventional breeding techniques).

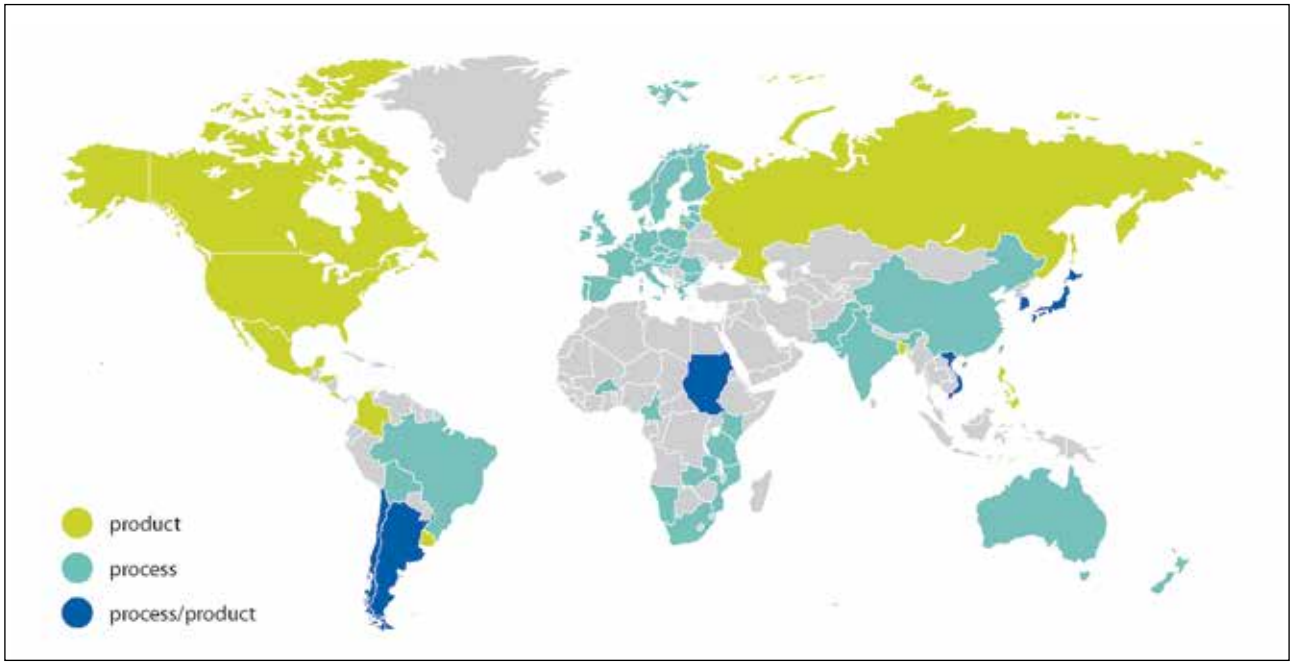

Figure 1: Countries with process-based and product-based regulatory systems for GMOs

1.2 Structure and content of this report

This report reviews the possible consequences for the EU of changing its process-based regulatory system into a 'Canadian style' product-based approach, with an emphasis on the consequences of such a switch for plants obtained by new breeding techniques. The main research questions were:

1. What are the main features of process-based and product-based regulatory systems and how are they implemented in practice?
2. What could be the consequences of adopting a product-based regulatory system in the EU, given the described features of such a system?
3. What other factors are involved in the implementation of the legislation on GMOs?
4. What potential solutions for regulating NPBTs are being explored internationally?

In Chapter 2 the features of process-based and product-based approaches are described, including issues relating to regulation, risk assessment, innovation, enforceability and freedom of choice. This is followed in Chapter 3 by a discussion of several contextual aspects which also have an impact on the regulatory system, such as political decision-making, legal traditions, agricultural history and context, and public acceptance. Finally, Chapter 4 outlines the different ways other countries and regions approach the regulation of NPBTs (including the United States, South America, South Africa, Japan, and Australia and New Zealand). This chapter also discusses the Dutch discussion document proposing an amendment of Annex 1B of Directive 2001/18/EC, which contains a list of techniques yielding organisms to be excluded from the Directive.

This report is based on literature research and interviews (**see Appendix A Consulted experts**) and focuses mainly on the authorisation for placing on the market of GM plants (cultivation and import) and products derived from them.

2. Process-based and product-based regulatory systems: features and implications

This chapter outlines the features of process-based and product-based regulatory systems, taking the EU (process) and Canada (product) as examples. The following aspects will be dealt with in turn: regulation; risk assessment; innovation, production and marketing; and enforceability and freedom of choice. For each of these aspects, the discussion will reflect on the possible implications if the EU were to change the principle underlying the legislation.

2.1 Regulation

The aim of both process-based and product-based regulatory systems is to protect humans and the environment. GM plants and PNTs that fall within the scope of the legislation must be subject to a risk assessment. The difference between the two approaches lies mainly in the legal basis (the 'trigger'): what criteria are used to determine whether or not a plant falls under the legislation?

2.1.1 Process-based regulation (EU)

The EU's GMO legislation is process-based and one of the consequences of this is that separate regulatory instruments have been adopted for GMOs.[c]

2.1.1.1 Regulation: techniques, definition and exemptions

The GMO legislation in the EU consists of several directives and regulations.[d] There is specific legislation for GMOs, including for contained use[e] (Directive 2009/41/EC), deliberate release into the environment (Directive 2001/18/EC), food and animal feed (Regulation (EC) no. 1829/2003) and traceability and labelling (Regulation (EC) no. 1830/2003/EC). In addition, there is a directive that makes it possible for each Member State to restrict or prohibit the

c For an overview of the history and establishment of the EU and Dutch GMO legislation, see, for example, COGEM research report 'Analysis of European legislation on genetically modified organisms' (CGM 2016-05, available in Dutch only).

d Directives set out specific objectives and are implemented at the national level with respect to the details needed to achieve those objectives. For some directives, guidelines have been drawn up at the European level (such as those of the EFSA). Regulations have direct force in the member states and are generally more detailed than directives.

e Contained use concerns activities involving GMOs in a containment area, such as a laboratory, animal shed, greenhouse or large installation.

cultivation of GM crops within its territory based on concerns which do not relate to safety (Directive (EU) 2015/412). The safety of medicines and therapies that 'contain' GMOs is also regulated, in addition to the GMO legislation, under the pharmaceutical legislation (Directive 2001/83/EC). As well as the directives and regulations, there are various guidelines to support applicants when preparing and submitting an application for marketing authorisation.[7] An EU Member State cannot decide independently what is or is not a GMO. The general definition of a GMO is set down in EU Directive 2001/18/EC on deliberate release. Other relevant laws and rules for GMOs refer to this or use a similar[f] definition. A GMO is defined as:

"an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination."[g]

In addition to this definition, Annex 1A of the Directive contains a list of techniques that do not lead to genetic modification (**see text box Description of techniques that result in a GMO**).

Description of techniques that result in a GMO

Directive 2001/18/EC, Annex 1A, Part 1. Techniques of genetic modification are amongst others:

1. *recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;*
2. *techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;*
3. *cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.*

Annex IB of the Directive lists techniques yielding genetically modified organisms to be excluded from the Directive on the condition that the techniques or methods do not involve the use of recombinant nucleic acid molecules or GMOs not exempt from the provisions of the Directive. These techniques include mutagenesis and cell fusion of plant cells or organisms which can exchange genetic material through traditional breeding methods. The annexes listing techniques and exemptions are intended to prevent older techniques with a 'history of safe use'[h] having to meet the conditions imposed by the legislation. Under Annex IB, plants obtained via 'traditional' mutagenesis (by irradiation or chemical means) are classified as GMOs but are exempt from regula-

f The differences are small and are in the first part of the definition. Directive 2009/41/EC refers specifically to modified microorganisms (GMMs), whereas Directive 2001/18/EC contains a definition of genetically modified organisms in general.

g 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.

h There is no strict definition of what a 'history of safe use' is, but in general it covers processes or products that have been in use for some time and are not associated with any known risks or safety incidents.

tory requirements, such as the safety assessment and labelling obligation (**see text box Mutant plant varieties**). An overview of the EU regulatory process for GMOs is given in **Figure 2**.

Mutant plant varieties

Worldwide more than 2,200 commercial plant varieties have been produced by chemical or radiation mutagenesis.[8] Other sources state that between 1930 and 2014 more than 3,200 mutant plant varieties were released into the environment, either as direct mutants (70%) or via hybridisation (30%).[9,10,11] About 75% of these plants are food crops; the remaining 25% are ornamental plants.[12] In 2014 the Food and Agriculture Organization (FAO) and the International Atomic Energy Agency (IAEA) stated that worldwide about 1,000 mutant varieties are grown as food crops, but the exact numbers are hard to track down because these crops are not labelled.[13]

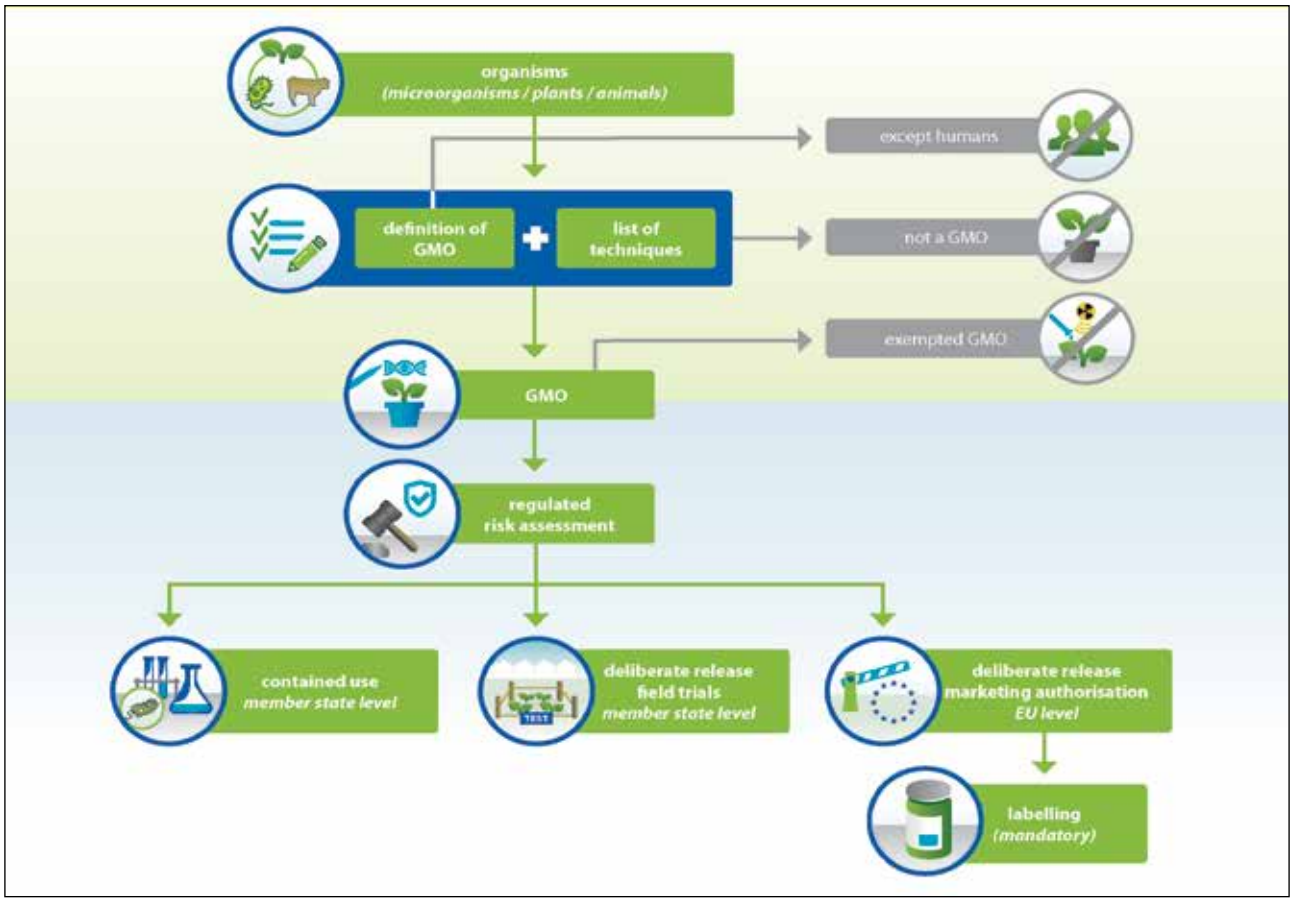

Figure 2: Schematic representation of the EU regulatory process for GMOs

Conventional breeding products and wild type organisms do not fall under the EU GMO legislation. This is explicitly stated in the Directive. Further, in Annex 1A, Part 2, it is stated that in vitro fertilisation, polyploidy induction and natural processes such as conjugation, transduction and transformation in which no use is made of recombinant nucleic acid or GMOs are not considered to result in genetic modification.[i]

Hybrids GM crops with multiple traits ('stacks') are considered to be new GMOs and have to be notified and undergo a safety assessment.[14] This does not apply to hybrids between a GM variety and a conventional variety. Authorisations for placing on the market are valid for 10 years and a further application must be made to renew the licence beyond this period. When assessing renewal applications any new information is taken into account which might lead to a different assessment of the potential risks involved. The authorisation process consists of a food safety assessment and an environmental risk assessment, followed by decision-making under the EU comitology procedure[j] (**see text box Decision-making procedure for marketing authorisation in the EU**).

Decision-making procedure for marketing authorisation in the EU

The European Food Safety Authority (EFSA) is responsible for the food and environmental safety assessment of GM crops. If the EFSA issues a positive advice based on the risk assessment, supported by input from the Member States, the European Commission makes a proposal for marketing authorisation in the EU. Applications submitted under Regulation (EC) no. 1829/2003 are voted on in the Standing Committee; applications under Directive 2001/18/EC are submitted to the Regulatory Committee. Both committees consist of representatives from the relevant ministries in the 28 Member States. Officially, the decision must be taken within three months of receipt of the EFSA advice and is made by a qualified majority vote.[k] If the required majority cannot be obtained, the dossier is sent to the Appeal Committee for another vote. If this again does not yield a qualified majority for or against the proposal, the European Commission can itself take an independent decision based on the opinion of the EFSA. However, the Commission is not obliged to do this.[15] An overview of the procedures for decision-making on marketing authorisation of GM crops is given in **Figure 3**.

i On the condition that they do not involve the use of recombinant nucleic acid molecules or GMOs made by techniques/methods other than those listed in Annex IB of Directive 2001/18/EC.

j Comitology is a set of procedures through which EU member states control how the European Commission exercises its implementing powers. Before the Commission can implement EU legislation it must propose detailed implementation proposals and consult a committee in which each EU member state is represented. The committee gives an opinion on the measures proposed by the Commission. How binding that advice is depends on the particular procedure set down in the legislation concerned. For GM crops, this is set down in Directive 2001/18/EC.

k A qualified majority vote is defined as a minimum of 55% of the member states (16 out of 28), on the condition that they represent at least 65% of the EU population.

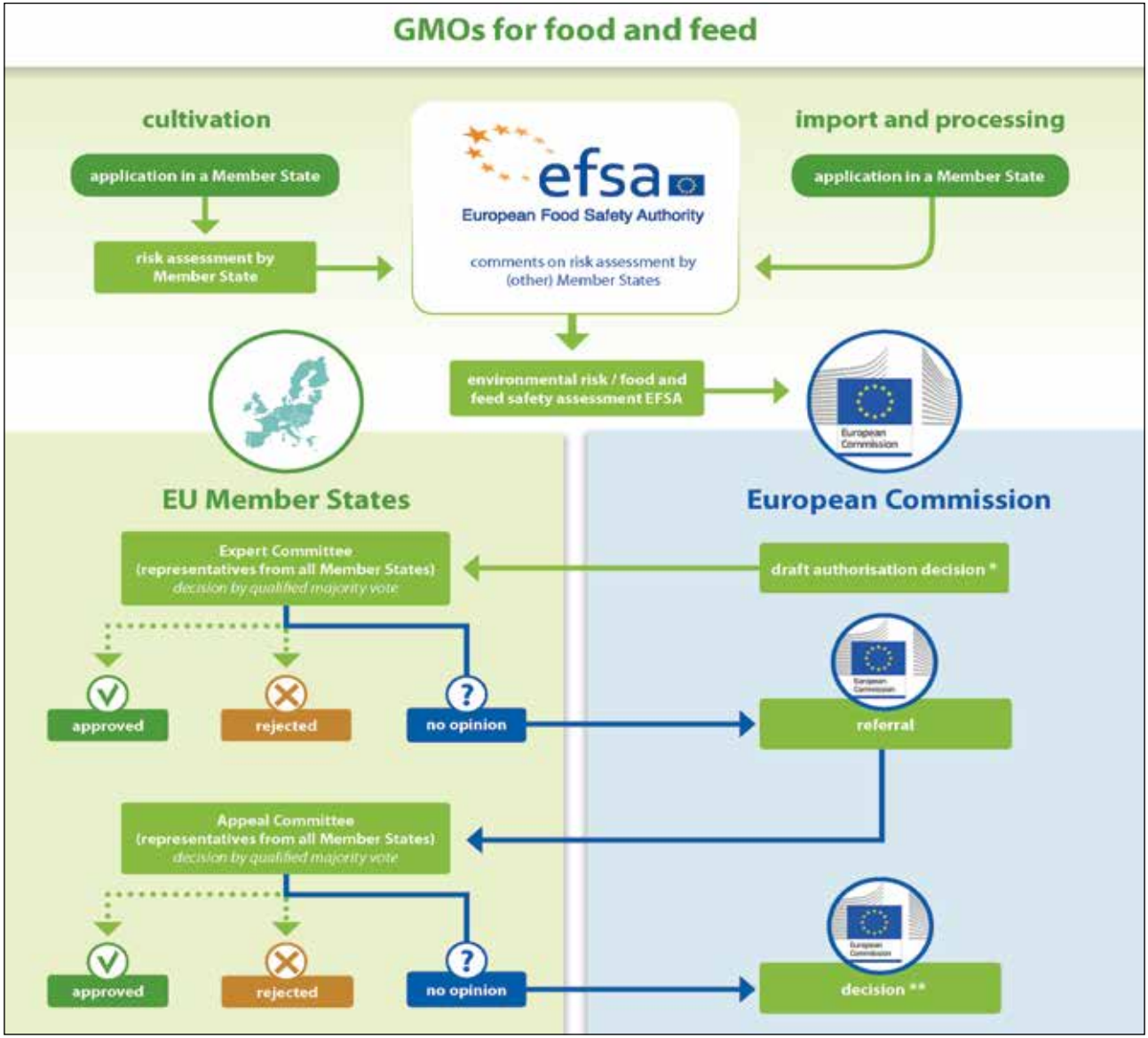

Figure 3: Overview of the decision-making procedure for marketing authorisation of GM crops in the EU.

*A draft authorisation decision may only be made if the EFSA concludes that the GM crop is safe for humans and the environment.

**The EC generally makes its final decisions on applications for import in line with the EFSA's conclusions. Decisions on cultivation have been moreover postponed.

2.1.1.2 NPBTs lead to discussion about the interpretation of the legislation

Since Directive 2001/18/EC came into force, various new techniques have been developed in the plant breeding industry and for a long time it has been uncertain if some of these fall within the definitions of the techniques as described in the Directive or not. COGEM raised this issue in 2006.[1] Taking note of this, in 2007 the European Commission appointed a working group to determine to what extent a series of eight techniques[l] fall within the scope of Directive 2001/18/EC. The working group has never made public any report on its findings.

However, various reports by the EFSA, the European Commission Joint Research Centre (JRC) and the European Commission's Scientific Advice Mechanism Group of Chief Scientific Advisors (SAM) have been published on the nature, risks and detection of some of these techniques, but they have not resulted in any decisions at the European level.[16,17,18,19,20,21,22] Since then, more NPBTs have been developed, such as TALENs and CRISPR-Cas.[m] The lack of decisions on the legal status of the NPBTs has provoked an ongoing discussion in the EU and led to several unilateral decisions in which some Member States (Germany, Sweden, the United Kingdom and Belgium) have made their own decisions about excluding specific applications for field trials from regulation. [23,24,25,26,27] A lawsuit in France led to prejudicial questions to the European Court of Justice about the legal interpretation of mutagenesis techniques in the GMO legislation (**see text box New mutagenesis techniques not exempt**).

New mutagenesis techniques not exempt

In 2018 the European Court of Justice gave a decision (C-528/16) on the prejudicial questions put by the French judge about specific NPBTs (new site-directed mutagenesis techniques, gene editing techniques such as CRISPR-Cas and oligo-directed mutagenesis (ODM)). The decision provided clarity on the legal status of organisms obtained by mutagenesis: they are GMOs. Organisms obtained by mutagenesis techniques that have been in use for some time and which are assumed to be safe are exempt from regulation. The Court did not address the question of what is needed to meet the requirement of a 'history of safe use'. According to the Court, however, new mutagenesis techniques, including CRISPR-Cas, do not meet this requirement and are not covered by the mutagenesis exemption included in Directive 2001/18/EC.

2.1.2 Product-based regulation (Canada)

Canada has no specific legislation on GM crops or GM food, but there is a regulatory framework for assessing the characteristics of the end-product, regardless of how it is pro-

l These eight techniques are zinc finger nuclease (ZFN) technology (ZFN-1, ZFN-2 and ZFN-3), Oligonucleotide Directed Mutagenese (ODM), cisgenesis and intragenesis, RNA-dependent DNA Methylation (RdDM), grafting on GM rootstock, reverse breeding, agro-inoculation (agro-infiltration, agro-inoculation, floral dip) and synthetic genomics.

m Transcription Activator-Like Effector Nucleases (TALENs) and Clustered Regularly Interspaced Short Palindromic Repeats with a CRISPR-Associated Protein (CRISPR-Cas).

duced.[n] This means that conventionally bred plants can also be regulated, depending on the new traits they possess.

2.1.2.1 Regulation: products with new characteristics

In Canada, the assessment of the risks of GMOs falls under the general regulatory framework for foods and crops. Plants, seeds and animal feed fall under the responsibility of the Canadian Food Inspection Agency (CFIA) and are regulated under the Plant Protection Act and Plant Protection Regulations, the Seeds Act and Seeds Regulations, and the Feeds Act and Feed Regulations. Foods and pharmaceutical and industrial products fall under the responsibility of Health Canada (HC) and are regulated under the Food and Drugs Act.[o] Biotechnological applications in animals and other applications that do not fall within the remit of the CFIA or HC are the responsibility of Environment Canada and are regulated under the Canadian Environmental Protection Act 1999.[p] As in the EU, guidance documents have been prepared to help applicants submitting applications for marketing approval.[28,29]

The Canadian legislation is based on the principle that plants with novel traits (PNTs) should be assessed for impacts on food safety and environmental safety (**see text box Plants with novel traits (PNTs)**).

Plants with novel traits (PNTs)

Plants with novel traits (PNTs) are defined as plants that have one or more traits that are new to that species in Canada and could have an impact on the environment. A further definition of the concept of 'newness' is given in CFIA Directive 2009-09.[q] A plant with a trait that does not yet exist in crops cultivated in Canada is considered to be a potential PNT and must be assessed for potential risks to human health and the environment. A trait that is already found in crops cultivated in Canada is not considered to be a new trait. Increasing the frequency of such a trait in the crop is also not considered to be new to the species in question (an example of this is the reintroduction of historical genetic material (germplasm) in a population). However, if a quantitative trait were to be significantly changed so that it occurs at levels far outside the natural range in cultivated crops, it may be considered new and must therefore be assessed for potential risks. This also applies to new traits that were not previously present in the crop species in question (qualitative trait).

n In Canada, activities involving microorganisms such as viruses, bacteria and fungi are regulated under the Human Pathogens and Toxic Act and Regulations. This includes both wild type and GM microorganisms, but GMOs are a distinct category. Chapter 2.8 of the Canadian Biosafety Handbook contains a similar definition to that used by the EU: GMOs are organisms (i.e., plants, animals, or microorganisms) that are created through the alteration of genetic materials in a way that does not occur naturally through mating or natural recombination.

o Food and Drug Regulations Canada. Division 28, Novel Foods.

p Canadian Environmental Protection Act 1999, Division 6 Animate products of Biotechnology.

q CFIA, Directive 2009-09: Plants with novel traits regulated under Part V of the Seeds Regulations: Guidelines for determining when to notify the CFIA. Section 2.3.1 Determination of a trait's 'newness' and Section 2.3.2 Determination of the regulatory status of a plant with a 'new' trait.

What determines whether a change is significant or not depends on the specific trait and cannot be expressed quantitatively beforehand. Products of conventional breeding must also be tested for safety if they contain new traits (e.g. herbicide tolerant crops[r] produced by conventional breeding).
In addition to the 'newness' of the trait in the population, another criterion for defining PNTs is the potential to have a significant negative environmental impact. In determining whether or not this is the case, an assessment is made of changes in weediness potential, gene flow, plant pest potential (spread of plant disease), potential negative impact on non-target organisms and potential negative impacts on biodiversity.

Some plants that meet the definition of a PNT had already been released into the Canadian environment before the rules on PNTs came into force. The Seeds Regulations therefore contain an exemption for plants released into the Canadian environment before December 1996, when the regulations came into force.[s]

There is no detailed formal definition of a 'novel trait'. This is assessed on a case-by-case basis by the Plant Biosafety Office (PBO) of the CFIA. Directives[t,u,v] have been drawn up to help applicants determine whether or not a plant is a PNT and identify the criteria for the environmental risk assessment for marketing approval and for field trials. Guidelines[w] have also been prepared on determining whether an animal feed is a novel feed or not.

Breeders and researchers are encouraged to request a pre-submission consultation to obtain clarification on regulatory requirements and the information to be submitted for the environmental risk assessment.[30] The CFIA emphasises that the communication between the regulatory authorities and applicants and the openness of this process are major contributory factors to the effectiveness of the Canadian system.[x]

The database of registered PNTs contains novel traits, including: abiotic stress tolerance; adaptations to plant growth, development or composition; herbicide tolerance; optimised biofuel production; disease resistance; production of pharmaceutical and industrial ingredients; and resistance to enzymatic browning (anti-oxidation). A number of plants produced in Canada by NPBTs have also been determined as being PNTs.[31] Examples are a po-

r Herbicide tolerant crops can be made by conventional breeding (e.g. atrazine tolerance), mutagenesis (e.g. imidazolinone tolerance) and genetic modification (e.g. glyphosate tolerance).

s Canadian Seeds Regulations, Part V, Article 108 exemptions.

t CFIA Directive 94-08 Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits.

u CFIA Directive 2009-09 Plants with novel traits regulated under Part V of the Seeds Regulations: Guidelines for determining when to notify the CFIA.

v CFIA Directive 2000-07 Conducting Confined Research Field Trials of Plants with Novel Traits in Canada.

w CFIA Regulatory guidance 1 (Feed Registration procedures and labelling standards, Chapter 2 Data requirements for single ingredient approval and feed registration. 2.6 Guidelines for the assessment of novel feeds: plant sources.

x Source: interviews (**see Appendix A Consulted experts**).

tato which is resistant to bruising ('blackspot') and which produces less acrylamide when fried,[32] and an apple which is slower to turn brown when peeled.[33] The CFIA has assessed 12 PNTs produced by NPBTs, including lucerne, maize, cotton, soybean and oilseed rape.[34]

In practice, all GMOs (in Canada called living modified organisms, LMOs[y]) have been classified as PNTs.[35] In addition, various non-GMOs have been assessed as well as products of techniques which in the EU are exempt from the GMO legislation (such as mutagenesis). So far no biological varieties have been determined as being PNTs.[x] A few examples and differences between Canada and the EU are listed in **Table 1** (**Examples of differences and similarities between the regulation of GMOs in Canada and the European Union**).

Table 1: Examples of differences and similarities between the regulation of GMOs in Canada and the European Union

		Canada	European Union	
	Method	**PNT**	**GMO**	**non-GMO**
Oilseed rape NS738, NS1471, NS1473 (Imidazolinone tolerance)	Mutagenesis (chemical)	non-LMO	X (exempt)	
Maize EXP1910IT (Imidazolinone tolerance)	Mutagenesis (chemical)	non-LMO	X (exempt)	
Lentil RH44 (Imidazolinone tolerance)	Mutagenesis (chemical)	non-LMO	X (exempt)	
Rice CL121, CL141, CFX51 (Imazethapyr tolerance)	Mutagenesis (chemical)	non-LMO	X (exempt)	
Rice HPHI2 (Provisia) (Quizalofop tolerance)	Mutagenesis (chemical)	non-LMO	X (exempt)	
Maize TUSC1 (Reduced zein expression)	Mutagenesis transposon	non-LMO		X
Maize 375IR (Imidazolinone tolerance)	Tissue culture selection on medium with herbicide	non-LMO		X
Maize DK404SR (Sethoxydim tolerance)	Tissue culture selection on medium with herbicide	non-LMO		X
Oilseed rape Cibus 5715, 5720 (Imidazolinone and sulfonylurea tolerance)	Oligo-directed mutagenesis (ODM)	non-LMO	X	

Source: CFIA Database of Plants with Novel Traits and Novel Feeds from Plant Sources approved in Canada

y Living Modified Organism (LMO) is a term from the Cartagena Protocol on Biosafety, an international treaty adopted as a supplementary agreement to the Convention on Biological Diversity. The aim of the protocol is to protect biological diversity from the possible risks presented by GMOs. An LMO is defined as 'any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.' Canada is one of the parties to this treaty and has incorporated parts of the text into its own legislation, focusing on the new combinations. The European Union and the Netherlands have also signed the Protocol.

Once PNTs have been assessed and approved for deliberate release, they are deregulated. Breeders are obliged to notify the CFIA of the production of PNT hybrids at least 60 days before the hybrid is commercialised.[36] This gives the CFIA the opportunity to make a supplementary risk assessment if it is of the opinion that the PNT potentially presents risks to the environment. In practice, for possible combinations of PNTs these notifications are done directly after the authorisation of new PNTs in order to avoid any subsequent delay.[x]

If new information becomes available on the potential risks of an already authorised PNT, the applicant is obliged to notify the CFIA, which then determines if the authorisation needs to be reassessed. Third parties are also permitted to make such notifications. To date there have been no cases in which new information has led to the revocation of an approval.[x]

2.1.2.2 Uncertainty about criteria: when is a trait novel?

The Canadian plant biotechnology sector has said that clearer guidelines are needed on when plants produced by NPBTs are deemed to be PNTs and when they are not.[31] The lack of a detailed description of novel traits and the current case-by-case approach means it is not always clear in advance if and when a plant is a PNT. In addition, it has been pointed out that all novel traits are by definition risky, but that in practice the main criteria for determining PNT status is newness.

The pre-submission consultation process is only ever used for plants that are almost ready for commercialisation and not for new plants in an early stage of development. In some cases, it is only at the end of the breeding process that it becomes clear that a new variety contains a significant change in a certain trait compared with existing varieties. It would be useful for breeders to know earlier in the process whether or not their product has to be regulated.[x]

Only the regulation of the deliberate release of PNTs is strictly product-based in Canada. For novel foods, novel feeds and GM animals, both the product characteristics and the process by which it was obtained are relevant for regulation (**see Table 2 Regulatory basis for PNTs, novel foods, novel feeds and animal biotechnology in Canada**). Novel foods produced by genetic modification, for example, are a specific category in the relevant directive, but the definition is broader than that used in the EU legislation.[28] The Canadian definition also covers techniques which in the EU are not considered to be genetic modification (**see section 2.1.1.1 Regulation: techniques, definition and exemptions**).

Table 2: Regulatory basis for PNTs, novel foods, novel feeds and animal biotechnology in Canada

Responsibility	Regulation	Basis
CFIA	**Plant with novel trait (PNT)** Seeds Regulations, Part V, section 107 Regulation of environmental introduction of plants with novel traits: A novel trait, in respect of seed, means a characteristic of the seed that (a) has been intentionally selected, created or introduced into a distinct, stable population of cultivated seed of the same species through a specific genetic change, and (b) based on valid scientific rationale, is not substantially equivalent, in terms of its specific use and safety both for the environment and for human health, to any characteristic of a distinct, stable population of cultivated seed of the same species in Canada, having regard to weediness potential, gene flow, plant pest potential, impact on non-target organisms and impact on biodiversity;	Product
CFIA	**NOVEL FEEDS** Feeds Regulations, Division 2 and 4 + Guidance Regulation of feeds composed of or derived from microorganisms, plants or animal sources that are not approved as livestock feed in Canada and/or contain a new trait. Novel feeds include: • Microbial products (.e.g. forage inoculants, fermentation products) • Plants with novel traits (PNTs) • Plants with no history of use as feed • Products/by-products of biotechnology*-derived animals ***biotechnology** means the application of science and engineering to the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms.	Process (& Product)
Health Canada	**NOVEL FOODS** Food and Drug Regulations, Division 28, section B.28.001 Regulation of Novel foods, human and veterinary drugs, cosmetics, medical devices and pest control products. Novel foods include a.o. a food that is derived from a plant, animal or microorganism that has been **genetically modified*** such that: • the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism, • the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or • one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism. ***genetically modify** means to change the heritable traits of a plant, animal or microorganism by means of intentional manipulation.	Process (& Product)
Environment Canada	**ANIMATE PRODUCTS OF BIOTECHNOLOGY** Canadian Environmental Protection Act, Part 6 Animate products of biotechnology, Article 104 Regulation of environmental introduction of new substances (including living organisms, which are defined as a substance that is an animate product of biotechnology* with a significant new activity**. >>>	Process (& Product)

	*Animate products of biotechnology: **the application of science and engineering** in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms. **Significant new activity: any activity that results or may result in: (a) the entry or release of the living organism into the environment in a quantity or concentration that, in the Ministers' opinion, is significantly greater than the quantity or concentration of the living organism that previously entered or was released into the environment; Or (b) the entry or release of the living organism into the environment or the exposure or potential exposure of the environment to the living organism in a manner and circumstances that, in the Ministers' opinion, are significantly different from the manner and circumstances in which the living organism previously entered or was released into the environment or of any previous exposure or potential exposure of the environment to the living organism.	

In theory, the different regulatory bases for the release of PNTs into the environment, for their use in food and for other applications can lead to asynchronous authorisation,[37] for example, when a viable novel food is released into the environment without it having been assessed as a PNT. However, in practice these differences cause few problemsx because the various assessment agencies consult with one another and products are almost always concurrently assessed as plants to be released into the environment (PNTs) and as food products or animal feed. In practice, one approval is never issued as long as another assessment has not yet been completed. This is referred to as 'no split approval'.[z] Figure 4 is an overview of the Canadian system for the regulation of new crops for different purposes.

2.1.3 Implications of a product-based regulatory system for the EU

This section draws upon the above review to derive the possible consequences and resulting policy issues for the EU of switching to a product-based regulatory system.

- First, it must be decided which products are to be regulated and on what basis. In this report the Canadian system is taken as a model. The objects of regulation in this system are PNTs, which means that there has to be a method for deciding when a trait is novel. This can be done on the basis of a definition, criteria, age, or a combination of these.
- A broad generic definition (plants with novel traits) would provide the legal flexibility to adapt to changing situations in future, but would create uncertainty for applicants if they want to know in advance if their product is subject to regulation or not. A precise and detailed definition (what are novel traits) would provide greater clarity to applicants, but would probably be less able to accommodate future scientific developments.
- Under a product-based regulatory system, it is not necessary to assess each NPBT to determine whether or not it falls under the legislation.
- Regardless of the breeding method used (conventional, biotechnological or organic), under a product-based regulatory system every new variety has to be looked at to determine

z CFIA. Directive 94-08, Division 6.2 Harmonization of approvals under other federal acts and regulations.

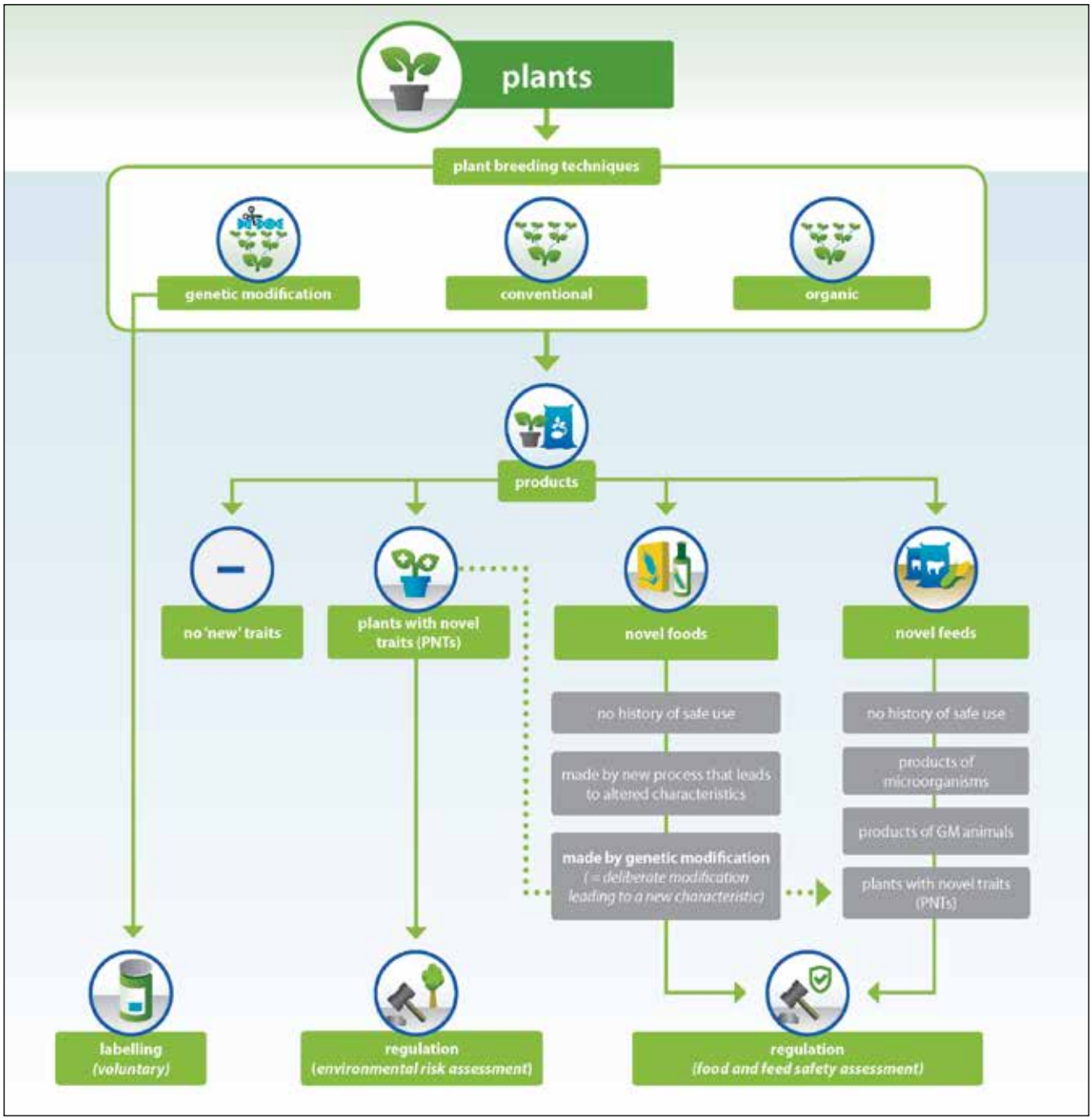

Figure 4: Overview of the regulation of plants with novel traits in Canada

whether or not it possesses a new, or significantly new, trait. It should be noted here that in the Netherlands around 2,000 new varieties are registered each year.[aa]

- Plants and plant-based products that have been obtained by site-directed or other forms of mutagenesis and possess no new traits or combination of new traits compared with existing products would probably no longer be regulated. The same goes for other techniques that do not result in significant new traits.
- Plant-based products obtained by 'traditional' mutagenesis (induced by radiation or chemicals) or other conventional breeding techniques and which do possess a new trait may well fall under the legislation and require regulation, including the preparation of an appropriate safety assessment.
- The EU adheres to more or less the same definition of a GMO for all organisms and the legislation on different types of organism and activities (contained use, deliberate release, placing on the market, labelling) and types of organisms all refer to this definition. In Canada, different regulatory bases are used for different activities. If different regulatory bases were used, the various implementing agencies would have to consult with each other and coordinate their authorisation procedures to prevent asynchronous authorisation.

2.2 Risk assessment

If a GMO or PNT falls under the legislation, it must be assessed for potential risks to human health and the environment. In both process-based and product-based regulatory systems, the risk assessment reflects the characteristics of the product. This section gives a global overview of the features of the risk assessment under both regulatory regimes.

2.2.1 European Union: broad focus on effects and detailed data requirements

In the EU, the legislation on GMOs is contained in EU directives, which are transposed into national laws, and in EU regulations, which apply directly in all Member States. Member States decide at the national level on the applications made for research under contained use and for deliberate release in field trials and clinical trials. Marketing authorisations for import and cultivation of GM crops and for gene therapy are European procedures. All these applications require authorisation and must first be subject to a risk assessment. This report is limited to providing a global overview of the risk assessment for the placing on the market of GM crops.

Directive 2001/18/EC regulates the deliberate release into the environment of GMOs. This Directive applies to GM plants, GM microorganisms and GM animals. Annex II of the Direc-

aa In order to market a variety of vegetable or other agricultural crop within the EU, it must be listed in the common catalogue of varieties of agricultural plant species. Once a variety is listed on the national list of a least one EU member state, it may be marketed throughout the EU. There are national and European catalogues. See www.raadvoorplantenrassen.nl/en

tive contains the principles for the environmental risk assessment. Part C.2 of the Annex contains a list of steps to be taken in the environmental risk assessment, including identification of potential adverse effects following deliberate release of GMOs into the environment. The EFSA has used this as a basis for drawing up more detailed environmental risk assessment guidelines specifically for GM plants (**see text box Elements of the environmental risk assessment of GM crops in the EU**). Separate guidelines have been drawn up for deliberate release into the environment of GM microorganisms and GM animals and their products.[38]

Elements of the environmental risk assessment of GM crops in the EU

The environmental risk assessment of GM plants for marketing authorisation in the EU should in any case address the following areas of concern:[39]

- persistence and invasiveness of the GM plant, including plant-to-plant gene transfer;
- probability and consequences of gene transfer from the GM plant to microorganisms;
- potential development of resistance in pest organisms;
- potential adverse effects on non-target organisms;
- effects on biogeochemical processes, such as changes in soil composition;
- potential impacts of the specific cultivation, management and harvesting techniques of the GM plant;
- effects on human and animal health.

The environmental risk assessment in the EU is carried out on a case-by-case basis and is a comparative assessment against the characteristics and performance of the non-GM comparator or variety of the same species. This assessment examines the effects of the GMO, both direct and indirect, and immediate and delayed.[ab] The marketing authorisation dossier for the deliberate release of GM plants into the environment must include a data analysis of the molecular (genotypic) composition of the plant, the phenotypic characteristics and the results of a comparative analysis with the non-transgene variety of the plant.[39] The aim of the field trials is to identify any adverse effects of the GM plant on the 'receiving environments' (such as other plants and organisms). The food safety assessment for marketing authorisation for food and feed[ac] must include certain specified analyses, including a comparative analysis of the composition of the product and the non-GM comparator and a mandatory food safety test involving a 90-day feeding trial with rodents.[40] Separate guidance documents have been drawn up for a number of these analyses setting out the data to be supplied in GMO applications dossiers.[41]

The EU legislation on GMOs is both specific and comprehensive. The Directive and the guidelines set out in detail which aspects are to be included in the environmental risk assessment

ab Directive 2001/18/EC Art 2 (8) 'environmental risk assessment'.

ac Regulation (EC) No. 1829/2003 on genetically modified food and feed and Implementing Regulation (EU) No 503/2013 on applications for authorisation of genetically modified food and feed.

and the food safety assessment and what data are needed. However, not all the data are relevant to every GMO and frequently there is confusion about which data must be included in the marketing authorisation dossier and which data are optional or have to be decided upon on a case-by-case basis. As a result, during the assessment process the EFSA regularly has to ask applicants to supply additional information.[42] The extensive and detailed data requirements for the EU's environmental risk assessment sometimes lead to questions about whether or not the identified differences with the non-GM comparator are correlated and significant.[43,44,4546,47,48,49] After placing on the market, there is a requirement to conduct general monitoring of unexpected adverse effects. The authorisation is reassessed after ten years.[ad]

2.2.2 Canada: focus on expected effects and flexible data requirements

In Canada, organisms classified as PNTs must be assessed for human and environmental safety. PNTs are only approved for deliberate release into the environment if their environmental impact is less than or equal to comparable plants. Once they are approved for environmental release, the plants are considered to be as safe as all other plants of the same species. In the environmental safety assessment, as in the European risk assessment, the PNT is compared with a comparator, a plant of the same species without the novel trait. The potential risks of PNTs and the aspects to be covered in the environmental safety assessment are defined in general terms in Directive 94-08 (**see text box Elements of the environmental safety assessment of PNTs in Canada**).[ae]

Elements of the environmental safety assessment of PNTs in Canada

The environmental safety assessment of PNTs for environmental release is based on the following five criteria:[50]

- potential of the plant to become a weed or be invasive;
- potential consequences of gene flow to sexually compatible plants;
- potential of the plant to become a plant pest;
- potential impact on on-target organisms, including humans;
- potential impact on biodiversity.

The dossier consist of information on the identity and provenance of the PNT, the characteristics of the new genes or gene products, the phenotypic characteristics of the plant and the results of a comparative study relevant to the non-GM comparator to identify potential adverse effects on other plants and organisms. The assessment also includes a molecular analysis of the PNT (genotypic characteristics), but the amount of molecular data required may vary per PNT and is determined on a case-by-case basis.[x] A guidance document is available on the sequence data to be submitted.[51]

ad The information to be supplied may include an update of the molecular analysis, monitoring reports on any unanticipated effects and a literature scan for possible new environmental and food safety risks.

ae CFIA. Directive 94-08 Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits.

Modernising Canada's policy on PNTs

The Canadian government is currently in the process of evaluating and modernising its policy on PNTs and the requirements for the environmental safety assessment of PNTs in Canada have recently been reviewed. The CFIA has concluded that since the mid-1990s more than 100 PNTs have been assessed and considerable experience has been gained with certain plant species and traits, and for several varieties it has repeatedly been concluded that they are safe. Consequently, since 2017, applicants for approval of PNTs may refer to information submitted for previously approved PNTs with comparable traits and do not have to generate all the relevant data again.[af] An example would be an application for field trials with a PNT of the same plant species, with the same category of trait and a comparable mechanism for this trait. The field trials referred to must have been carried out in environmental conditions (geographical and climatological) that are similar to those found in Canada. It is still too early to say whether or not this will lighten the workload for applicants.[x]

In consultation with stakeholders, the possibility is being looked into of drawing up a set of more detailed criteria for 'novel traits'. Another possibility being examined is adopting a tiered approach based on an initial estimation of the risks. Some PNTs could then be approved by means of a form of notification, while other plants would have to be subject to a global or specific safety assessment.[x]

In Canada, food made from GM plants, animals and microorganisms forms a separate category in the assessment of novel foods, subject to a broad definition of 'modified'[ag] that includes conventional breeding, selection and mutagenesis techniques (**see also section 2.1.2.2 Uncertainty about criteria: when is a trait novel?**). The assessment includes the composition and nutritional quality of the product compared with the non-GM comparator and the potential for introducing new toxins and allergens.[52] Food trials with rats are only required if the altered trait of the PNT gives sufficient cause.[x] The assessment of feed includes the safety of the PNT for animal consumption and its nutritional value compared with conventional alternatives.

In Canada there are no standard data requirements for the environmental safety assessment of PNTs, novel foods or novel feeds. These are determined on a case-by-case basis according to the potential risks[x] and applicants are free to provide scientific arguments on why certain data are not necessary or relevant to the environmental safety assessment.[ah] A global description of the environmental safety assessment allows flexibility in the assess-

af CFIA. Directive 94-08 Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits (Appendix 5: similar PNTs).

ag Health Canada. Guidelines for the Safety Assessment of Novel foods, section 4.1.3 'Where a plant has been modified, whether by conventional breeding, selection and mutagenesis techniques or by recombinant nucleic acid technology, the relationship of the derived variety with the parent varieties should be characterised.'

ah CFIA. Directive 94-08 Appendices.

ment of individual dossiers, but it can also lead to uncertainties among applicants if they cannot determine beforehand what data they have to generate and submit.[x] This can lead to delays in the assessment if additional or supplementary data have to be provided during the process, especially if these data also have to be generated. Small breeders in particular can be put at a disadvantage. Multinationals are in a position to generate large quantities of data because they have the resources to do so and also apply for authorisation of their product in the European market. Smaller companies find it much more difficult because of the high costs involved.[x]

For disease and insect resistant crops and herbicide tolerant crops, applicants must provide a stewardship plan with a strategy for safe and sustainable use of the PNT. This plan must include a monitoring plan for unintended and unexpected environmental impacts, similar to the monitoring requirement in the EU.[ai] The responsibility for implementing these plans lies with the manufacturer, but with no active oversight by the government.[x] Approvals are only reassessed, and if necessary revoked, if new information arises that indicates a possible unexpected effect. So far this has never happened.

2.2.3 Implications of a product-based regulatory system in the EU for the risk assessment

This section draws on the above review to derive the possible consequences of operating a product-based regulatory system in the EU for the risk assessment, and the policy issues resulting from these.

- The EU and Canadian regulatory frameworks are based on different principles, but in both jurisdictions the risk assessment examines the characteristics of the end-product. The aspects to be investigated in the risk assessments for marketing authorisation of plants for cultivation and use in food and feed are more or less the same.
- The content of the environmental risk assessment does not depend on whether the regulatory system is process-based or product-based.
- If the EU were to switch to a product-oriented regulatory system, there would be only minor implications for the risk assessment if the current principles, data requirements and risk assessment methods remain the same.

ai CFIA. Directive 94-08 Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits (4.5 Stewardship Plan, 4.6 Post-release Monitoring Plan).

2.3 Innovation, production and marketing

The degree to which innovation is stimulated or inhibited by the legislation depends on the context and is influenced by historical developments. For some crops, biotechnology plays a big part in breeding programmes, whereas for other crops conventional breeding techniques dominate (at least for the time being). This section gives a global overview of several evident features of innovation, production and marketing in the plant sector in Europe and Canada.

2.3.1 Strong international position of the Dutch plant breeding sector

The activities and size of the plant breeding industry differs widely between the Member States of the EU. This section is limited to a global description of the Dutch plant breeding industry, which is of considerable importance internationally.

The Netherlands has a strong plant breeding industry for vegetables, potatoes, grasses and ornamental plants.[53],[54] The Dutch Register of Plant Varieties lists more than 12,000 varieties, of which more than 8,500 are vegetable varieties.[55] Each year about 1,000 new varieties are added. The European plant variety database contains more than 50,000 varieties, of which 23,000 are agricultural varieties and 21,000 are vegetable varieties.[56] In comparison, the Canadian Plant Variety database contains only about 6,000 agricultural varieties, although it should be noted that only the crops cultivated on a large scale, such as wheat, oilseeds, pulses and forages, are registered.[57] Crops such as maize, soy, chickpeas, fruit, vegetables and ornamental plants do not have to be registered. These figures are therefore not directly comparable.

As yet, genetic modification is little used in the breeding of these crops, but with the development of NPBTs this situation will probably change in the near future.[x] The leading position held by the Netherlands could change if NPBTs are less strictly regulated elsewhere and are used to breed crops for which the Netherlands currently occupies a strong position on the market.

Dutch companies do very little breeding of major arable crops (such as soy and maize), where genetic modification is widely used. This field is dominated by the large multinationals, such as Bayer, Corteva, Syngeta, Limagrain and KWS. One reason for this is the cost of obtaining marketing authorisation for GM crops in Europe.[58] These costs can run into the millions, whereas non-regulated crops only have to be registered[aj] with the common catalogue of varieties of agricultural plant species[ak] in the Netherlands and Europe. The costs

aj This registration procedure also involves costs (from tens of euros to a few thousand euros), but these are nothing compared with the average costs of applying for an authorisation to market a GM crop.

ak Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species and Directive 2002/55/EC on the marketing of vegetable seed.

of obtaining marketing authorisation for GM crops are often so high that only large companies and multinationals can afford them. Smaller companies therefore often experience the strict EU regulations as a constraint on innovation.

The current GMO legislation has a major influence on international trade in the Netherlands and Europe. The EU is the biggest exporter and importer of agrifoods in the world and is largely dependent on imported crops for animal feed.[59] Each year the European livestock farming industry needs 480 million tonnes of animal feed[60] and about 70% of that comes from imports of soybeans, oilseeds, etc. from outside Europe. Soy is the main protein component in animal feed and as much as 95% of it is imported. After China, Europe is the biggest consumer of animal feed and feed ingredients. The biggest exporters to Europe are North and South America (where 94–100% of the soy cultivated is genetically modified). Europe imports GM crops almost exclusively for animal feed and imports food crops mainly from countries and regions where the plant breeding techniques used are entirely or almost entirely conventional.

European food manufacturers are reluctant to use ingredients in their products that have to be labelled as genetically modified, and retailers are reluctant to stock such items.[x] The asynchronous authorisation process on the global market, the emergence of NPBTs and declining detectability make it increasingly difficult for trading partners to avoid these products.

2.3.2 Canada focuses primarily on production and marketing

The Canadian plant breeding sector is relatively small, but the country is a major producer and exporter of bulk crops. Little research is done into the development of new plant varieties. In 2017, approvals were issued for 137 field trials with PNTs. These were species such as oilseed rape and wheat, and to a lesser extent maize, potato, camelina or false flax (Brassicaceae) and poppies. The traits under investigation included herbicide tolerance and altered quantitative traits.[61]

Canada has so far approved 133 PNTs for cultivation and use in food and/or feed. Placing a PNT on the market also incurs costs. The procedure for approving a PNT for environmental release costs applicants 2,000 Canadian dollars,[62] plus the costs for generating the required data for the approval dossier. Based on an analysis of case studies, one report mentions an average of 13 years to develop a PNT and place it on the market, the total costs of which are reported as being about 136 million US dollars.[63] The costs of scientific research and registration are estimated at about 35 million dollars, a quarter of the total development costs. Breeders try to avoid certain conventional techniques they suspect carry a greater chance of resulting in products that will be classified as a PNT. To date, all GMOs have been designated as PNTs.[x] The figures on approval costs for GMOs and PNTs are not directly comparable with other studies on the costs of obtaining marketing authorisation.

In Canada, four GM crops are grown on a large scale: oilseed rape, maize, soy and sugar beet. GM oilseed rape, or canola, was introduced in 1995 and today almost all oilseed rape is genetically modified (about 95%).[64] After wheat, oilseed rape is Canada's most valuable crop. Little or no organic and conventional oilseed rape is now grown in the wake of an increasing number of incidents of cross-contamination with GM oilseed rape.[65] About 80% of the maize grown in Canada is genetically modified and is used in both food and feed, around 60% of cultivated soy is genetically modified, and virtually all sugar beet cultivated in Canada is genetically modified. In 2016 a GM alfalfa (lucerne) was introduced and is currently being cultivated on a small scale for use in animal feed.

The organic farming sector in Canada is small. The area of land used for organic production amounts to about 1.5% of the total agricultural area. Most consists of grassland for the production of animal fodder, while much of the remaining land is used to grow organic fruit and vegetables.

2.3.3 Implications of a product-based regulatory system in the EU for innovation, production and marketing

This section draws upon the above review to derive the possible consequences for innovation, production and marketing of switching to a product-based regulatory system along Canadian lines in the EU, and the resulting policy issues.

- A product-based regulatory system could stimulate the use of NPBTs in the plant breeding sector, leading to an increase in the number of crops obtained by these techniques on the European market that do not possess novel traits and so do not fall under the legislation.
- Under a product-based regulatory system, plants that do possess novel traits would be regulated. In practice, this means that products of conventional breeding techniques could also fall under the legislation if they contain novel traits.
- An increase in the number of crops with novel traits that do fall under the legislation would appear to be unlikely for some time given the protracted decision-making procedures in the EU and the high costs of registration and safety assessments.
- An increase in the cultivation of crop varieties obtained by genetic modification or NPBTs could present a problem for organic farming and the marketing of organic produce in Europe, particularly for crops in which cross-contamination is biologically hard to prevent. This problem is not new, but is being aggravated by the emergence of NPBTs that are difficult or impossible to detect.
- International agreements on the regulation of NPBTs could ease international trade, but the rules on labelling and the speed of authorisation procedures are also factors to be taken into account.

2.4 Enforceability of the GMO legislation

The enforceability of the legislation concerns the degree to which oversight of compliance with the rules and required measures and punishment of breaches is possible, which in turn depends on the ability to detect PNTs and GM plants and their products. Detection is crucial for the regulation of international trade and for consumer choice.

2.4.1 European Union: techniques not always traceable

In the current situation the main concern regarding the enforceability of the GMO legislation in the EU is the importation of GM crops. European countries import large quantities of agricultural products from countries where GM crops are grown on a large scale. More than 100 GM crops are authorised for import into the EU,[66] but just one GM crop has been approved for cultivation in the EU: a GM maize variety which is grown mainly in Spain and Portugal. From the perspective of tracing and labelling, importing GM crops only becomes problematic when they cannot be detected. This is the case for imported GM crops for use in feed and for seed destined for the European market.

In principle, the EU GMO legislation can be enforced as long as the regulated techniques result in recognisable GMOs – GMOs that can be detected. The emergence of NPBTs makes this more difficult because the end-products are sometimes hardly any different from those obtained by traditional breeding techniques or that result from natural mutations (**see text box Traceability and detection of GMOs**).

Traceability and detection of GMOs

Regulation (EC) 1830/2003 concerns the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs. It applies to plant and animal material and to food and feed as well as to living organisms. GM food and feed that has been authorised for production or import into the EU must be labelled. Applicants for marketing authorisation are required to provide sequencing information and a detection method and reference material for their product. The method must be validated by the European Joint Research Centre (JRC). Valid detection methods are essential in international trade for use in checks by customs and inspection agencies. The current detection methods for inspection and control are based on mapping the DNA of a sample of the plant or animal material and looking for general signs of genetic modification or for a specific modification. These methods can be broken down into three levels of specificity:

- **Screening methods:** These techniques look for DNA sequences that are often used to assist the process of genetic modification, such as promoters, terminators and certain resistance genes from other organisms. They can be used to establish whether or not a modification has been made, but cannot identify the modification itself.
- **Construct-specific methods:** These techniques look for combinations of elements in a transgene construct. They can establish the presence or absence of a specific construct, but cannot distinguish between specific GM crops (events) or traits introduced by means of the same or similar constructs.

- **Event-specific methods:** These techniques look for sequences unique to a certain GMO at the junction between the DNA of the host and a specific transgene from the donor. This method is highly specific and detects one specific event only.

The technical and scientific possibilities for detecting GMOs must also be examined from a practical and economic point of view. The possibilities for detection depend on the type of genetic modification made and the information that is available on the modification, for example in national and international databases on field trials, authorisations and detection methods for GM crops. One such is the European Euginius database.[al] Detection is theoretically possible, but only when it is known what to look for.[67] The European Network of GMO Laboratories (ENGL) recently concluded that detection of gene editing in plants is almost impossible if no information is available or it is not known what to look for.[6] This is the case, for example, for GMOs that have not (yet) been authorised and for GMOs that are not known in Europe. When the modification consists of a very small point mutation it is only possible to determine whether it is a spontaneous mutation or the result of genetic modification if the information needed has already been recorded for a different purpose, for example in a patent.

The EU legislation also applies to products imported from countries outside the EU. Developers of GM crops have to apply for an authorisation to import, which sets legal conditions on the transparency and provision of information about how the products have been obtained. However, enforcing these rules for imported products becomes harder if detection is more difficult or extremely time-consuming and costly, or if these products are not considered to be GMOs in the country where they were produced. Governments of countries that take a different approach to the regulation of GMOs, or have a different definition of GMOs, tend to deal with the issue of international trade by operating a central notification procedure or registration of these plants in order to provide sufficient transparency when they are exported.[x]

In the Netherlands the Human Environment and Transport Inspectorate is responsible for enforcing the GMO legislation from the environmental risk perspective. It carries out spot checks for the presence of GMOs in living material that may be released into the environment and could disperse further (such as imported living plant material). The Inspectorate carries out about 25 inspections per year under a strategy which is also used elsewhere in Europe.[68] Each year it sets priorities for specific inspections of seed and imports based on an analysis of global developments in GM crops. This prioritisation is based on potential environmental risks.[x] In practice, the presence of non-authorised GMOs rarely exceeds the detectable level during inspections of imports and these cases are almost always the result of unintentional cross-contamination. Suppliers and traders are generally well informed about what is permitted to enter the EU and what is not.

al European database of authorised GM crops for commercial use and field trials, with worldwide coverage. URL: www.euginius.eu

In addition, the Dutch General Inspection Service for seeds and seed potatoes (NAK) carries out inspections at the request of the plant breeding sector to test for the presence of GMOs in parent materials.

Regarding the interest of consumer choice, the Netherlands Food and Consumer Product Safety Authority (NVWA) is responsible for detecting GMOs in food and feed with respect to labelling requirements. Very little use is made of GM ingredients in foods and inspections focus mainly on products with a greater chance of containing GM ingredients that are not mentioned on the label, such as American products. In addition, under an EU implementing decision all rice products from China are checked in Europe, because GM material is regularly found in these products.[69] Most of the imported animal feed is genetically modified and labelled as such, and so inspections focus on the presence of non-authorised GM material. The NVWA carries out standard inspections as well as targeted sampling and each year takes about 250 samples of foods (apart from the mandatory checks on rice products from China) and 250 samples of animal feed.[x]

Besides the theoretical and practical components, there is also an economic component to the enforcement and detection of GMOs. The costs of detection[am] can rise if it becomes more difficult or if more checks are deemed necessary in response to an increase in the number of GMOs on the international market. Decisions on financing and the number of checks to be carried out are up to the government and the agriculture sector itself. Public debate cannot resolce the challenges of enforcing a process-based regulatory system for GMOs. This is because from an environmental risk and food safety standpoint it can be argued that a crop obtained by a gene editing technique that cannot be distinguished from conventional crops of the same species will present no new risks, but some consumers with objections in principle to the process of genetic modification will still insist that these are labelled when they enter the food chain.

2.4.2 Canada: PNTs deregulated following assessment

Canada is a major agricultural producer and exporter of agricultural commodities, including to Europe. GM crops are grown on a large scale. Enforcement and detection focus mainly on production and export, with particular regard to the international market. For Canada itself it can be problematic if a viable PNT or novel food is imported but not recognised as such. However, given the limited volume of imports, this is not considered to be an urgent problem.

The enforceability of the Canadian legislation differs from that of the EU legislation. So far almost all GM crops in Canada have been assessed as being PNTs (**see section 2.2.2 Canada:**

am The cost of analysing a single sample amounts to about 800 euros and can rise further the more information for specific search criteria is missing or when repeat analyses have to be made (Source: interviews).

focus on expected effects and flexible data requirements). Developing and supplying a detection method and reference material for PNTs is also mandatory under the Canadian assessment procedures for marketing approval.[70]

The Canadian government does not operate a formalised monitoring regime for detecting the presence of illegal PNTs or GM crops.[x] It argues that its pre-submission consultation process and its communication with the sector gives it a good grasp of developments in the plant breeding industry and it is confident that there is no desire to deliberately release illegal PNTs or GMOs into the environment.[x] However, this could happen unintentionally via imported crops or seeds of PNTs that are not GMOs and are not recognised to be PNTs in other countries.

One of the basic principles of the organic farming sector is that it is GMO free. The Canadian national standard for organic production, Organic Production Systems – General principles and management standards, are currently under revision. The revised version explicitly mentions NPBTs and states that gene editing is not permitted in organic agriculture.[71] The Canadian organic sector is responsible for conducting inspections to check for the presence of GMOs and to this end makes use of information it holds itself and information from other NGOs, such as the Non-GMO Project.[an] Information from the Canadian government database of approved PNTs is of limited use to the organic sector because it is not always clear which PNTs are GMOs[ao] and because approved GMOs have not all by definition been commercialised.[x] The organisations responsible for organic certification may carry out inspections when they suspect that GM material may be present, and producers may sample material to demonstrate that they do not make use of GMOs in their production processes. Cross-contamination between convention or organic crops and GM crops does occur. Unintentional cross-contamination with GMOs has come to light in the past mainly via third parties, such as international trading partners (Europe) or producers.[65]

In Canada, labelling of GMOs is voluntary and may consist of either a positive or negative statement (contains GMOs or GMO free). For parties that make use of this type of labelling (mostly 'GMO free' labels), detection is important because legally they may be required to demonstrate the truth of their claim.

an The Non-GMO Project is a non-profit organisation for North America that provides information on and labelling of non-genetically-modified food and other products. URL: www.nongmoproject.org

ao The database makes a distinction between PNTs and LMOs, but some products made by gene editing, such as Cibus Canola (a product of ODM), are classified as non-LMO whereas this is not permitted in the organic sector.

2.4.3 Implications of a product-based regulatory system in the EU for enforceability

This section draws upon the above review to derive the possible consequences for enforceability of switching to a product-based regulatory system in the EU, and the resulting issues.

- Switching to a product-oriented approach in the EU would require rethinking the regulations for traceability and labelling of GMOs. Products created using recombinant DNA technology but which do not possess any novel traits would no longer be subject to regulation, removing any obligation to provide reference materials and a validated detection method. If providing these materials and a detection method are not required under the marketing authorisation procedure, tracing and labelling will have to be regulated under a separate legal framework or be made the responsibility of other parties. The latter option could involve a shift in the administrative burden from the conventional and biotechnological sectors to the organic sector.
- Under a product-based regulatory system, some of the plants obtained by NPBTs will still have to be regulated (if they contain novel traits). This means that detection methods would also have to be submitted for these plants. A reduction in the detectability of some NPBTs will therefore present a challenge in future regardless of the type of regulation.

2.5 Consumer and producer choice

In most countries consumer and producer choice is considered to be in the public interest. The underlying idea is that producers should have access to innovations and new development possibilities in the conventional, organic and biotechnological sectors, and by the same token, individual consumers should be able to make choices in line with their personal preferences and convictions. Many countries therefore have specific measures on GMOs designed to facilitate consumer and producer choice.

2.5.1 European Union: government responsible for choice

To facilitate consumer and producer choice, the EU has introduced mandatory legal measures governing the production, marketing and sale of GMOs.

2.5.1.1 Mandatory labelling, coexistence and national competence on cultivation

In the EU, food that has been produced from GMOs or contains genetically modified ingredients must be labelled as such (Regulation (EC) 1830/2003) (**see text box Labelling of GMOs in food in Europe**).[ap] The label on these products must contain the words 'This

ap Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' (**see Figure 5**). Labelling is not mandatory for food produced from GMOs but which contains no traces of GMOs.

Figure 5: Example of labelling food made from GM ingredients in the EU

Labelling of GMOs in food in Europe

Labelling is mandatory for:
- food that is not itself a GMO but consists of GMOs (e.g. GM plant, GM animal);
- food ingredients or additives produced from GMOs (e.g. oil from GM soybean);
- food ingredients or additives that contain GMOs (e.g. GM yeast in beer, GM mould in cheese or yoghurt).

Labelling is not mandatory for:
- food produced by GMOs, but no longer contains GMOs (e.g. vitamins);
- food that contains amounts of GMOs below the threshold of 0.9% per ingredient;
- substances not subject to mandatory labelling;
- substrate or culture mediums for microorganisms that produce a substance.

Using 'GMO free' labels is not prohibited in the EU, but such labels must meet certain rules and must not be misleading. The 'GMO free' label is used mainly on products of animal origin (milk, meat, eggs) from animals that have not been fed with GM feed.[aq] These products do not have to be labelled under the rules for mandatory GMO labelling. Such 'GMO free' labels are used in some Member States, including Germany, France and Austria (**see Figure 6**).[72]

aq This often applies for a limited period during the life of the animal, for example several days or weeks before slaughter. The rules differ per animal and type of certification.

Figure 6: Examples of (voluntary) labelling of food produced without GM in Germany and France

Labelling of foods made from GMOs guarantees the freedom of choice of those consumers who do not want to buy GM food. This labelling is entirely separate from the certification of organic products, which in the EU must also be free from GMOs, but must meet various other requirements as well.[ar]

In addition, coexistence measures are in force to facilitate producer choice in the cultivation, production and marketing of crops. Article 26(a) of Directive 2001/18/EC states that Member States must take appropriate measures to avoid any unintended presence of GMOs in other products and in particular the presence of GMOs in other crops such as conventional and organic crops.[as] Between 2003 and 2010 the European Commission

ar Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products.

as Directive 2001/18/EC, Art. 26 Labelling of GMOs.

made various recommendations and published reports to facilitate the implementation of measures at the national level.[73,74] A network group was also set up to coordinate the exchange of information about coexistence of genetically modified, conventional and organic crops. The European Coexistence Bureau,[75] established in 2018, has drawn up various best practice documents on crop-specific measures (e.g. maize, soybean, cotton) for effective coexistence. The Directive and recommendations by the European Commission are global and the precise measures taken to implement them can differ between Member States, but effective and sufficient measures must be taken. In the Netherlands an agreement on coexistence in the primary sector was made in 2004 between various parties (Biologica, LTO Nederland and Platform Aarde Boer Consument).[76] This agreement has been incorporated into the Cultivation Regulation (*Regeling Teelt*)[at] which contains requirements for informing neighbouring farms or market gardens and maintaining isolation distances for specific crops.

2.5.1.2 Labelling difficult to enforce

Guaranteeing consumer and producer choice under a process-based approach faces several challenges. Some believe the mandatory labelling of GMOs in foods does not go far enough. They take a strict view of the process-based approach and would like to see labelling extended to products from animals that have been fed on GM feed (such as dairy products, eggs and meat) and to products that are produced by GM microorganisms (such as certain vitamins). One of the reasons for not making it mandatory to label these products is that they do not contain any genetically modified material, making oversight impossible (**see section 2.4 Enforceability of the GMO legislation**).

Mandatory labelling becomes problematic when there is little or no possibility of detecting GMOs. This is the case for processed products that no longer contain any DNA (such as oil from GM soybeans) and to an increasing extent for products of NPBTs in which it is hard to determine whether or not they have been obtained by means of genetic modification. As a result, consumers may unintentionally come into contact with products they perceive as GMOs. In turn, this could damage the credibility and trustworthiness of government and the inspection agencies responsible for labelling GMOs, especially when consumer and producer choice is enshrined in the legislation. The thresholds for labelling GMOs in the EU are strict.[au] If cross-contamination occurs producers may suffer financial losses and in the worst case scenario organic producers can lose their certification.

The jury is still out on whether or not the coexistence rule is an effective way of facilitating consumer and producer choice in Europe. At the moment very few GM crops are grown in

at Regeling van de Minister van Economische Zaken van 10 december 2014, nr. WJZ/14148909, houdende regels inzake de teelt van gewassen (Cultivation regulation).

au In theory there is a zero toleration threshold for non-authorised GMOs. In practice it is impossible to demonstrate the total absence of GMOs. For this reason a practical detection limit of 0.1% is used for zero tolerance. The threshold for authorised GMOs is 0.9%. Products containing more than this must be labelled.

Europe. Just one GM maize (MON810) has been authorised for cultivation in the EU and it is grown mainly in Spain and Portugal.[77] Besides the safety assessment, since 2015 Member States have the possibility to restrict or prohibit the cultivation of GM crops in their territory based on concerns relating to issues other than safety (Directive (EU) 2015/412),[av] such as national agricultural policy, coexistence or social and economic aspects. This directive was adopted because Member States could not agree on the marketing authorisation of GM crops (**see section 3.1 The role of political decision-making)**. The European Commission wanted to permit considerations other than safety concerns in order to smooth decision-making on marketing authorisation for cultivation at EU level. However, restricting or prohibiting the cultivation of GM crops at the national level can limit the freedom of choice of individual producers because they are then unable to grow certain crops in these countries. It should be noted, though, that the current situation in which few if any decisions have been taken to authorise crops also creates a situation which restricts producer choice.

2.5.2 Canada: responsibility for freedom of choice lies with the sector

The importance of consumer and producer choice is also acknowledged in Canada. There are guidelines for voluntary labelling GM foods and agreements have been made to facilitate coexistence between the organic, conventional and biotechnological sectors.[78]

2.5.2.1 Voluntary positive or negative labelling

Health Canada is responsible for the labelling of foods with respect to health and safety risks (such as allergens and nutritional content). This applies to all foods, including GM products. Labelling is compulsory for all novel foods, including GMOs, if there is a health risk or the composition of a product has significantly changed. The CFIA is responsible for labelling not related to health and safety and ensures information about foods on labels is objective and not misleading.

Over the years various consultation rounds have been held on labelling GM foods, resulting in 2004 in a national standard for the voluntary labelling of GM foods (**see text box Canadian standard for the labelling of GM foods**).[79,80]

av Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.

Canadian standard for the labelling of GM foods

A global description of the Canadian rules for the labelling of GM foods:

- Food may be labelled with the claim 'product of genetic engineering,' 'genetically engineered (name of product),' or '(derived) from genetically engineered (name of product)' when genetic modification has been used in the production of one or more ingredients.
- Food made from GMOs may be labelled, regardless of whether or not it still contains DNA (such as oil, where this is not the case).
- Food may also be labelled as 'not a product of genetic engineering' if none of the ingredients has been produced by genetic modification or the ingredients contain less than 5% GMOs.
- A 'non GMO' claim can only be made for single ingredients; a product that consists of multiple ingredients (such as a cake) may not be labelled as a GMO-free cake, because it is the ingredients that are or are not modified.
- Products for which there are no genetically modified variants on the market may not be labelled as GMO free.
- Claims may not be made that products are GMO free or 100% free; this applies also to the use of terms such as entirely, completely and absolutely.
- The definition of 'genetic engineering' in the standard for labelling specifically excludes NPBTs which result in end-products that are indistinguishable from products of conventional breeding.

The standard contains guidelines for wording that is understandable and not misleading, for both positive and negative labelling (contains/made from GMOs versus GMO free) and for whole products as well as products consisting of several ingredients. **Figure 7** shows an example of a GM label that can be used in Canada under the voluntary standard. In practice, very few companies use this label on their products.

Figure 7: Example of a label that can be used for food products containing GM ingredients in Canada

The government does not actively monitor the presence of GMOs in food products. An initiative is underway to modernise the guidelines for labelling foods in Canada.[81] Although the labelling of GMOs was not included in the proposed amendments and modernisation, the CFIA has received various requests for both mandatory labelling of GMOs and a firmer response to misleading[aw] 'non GMO' labels.[82]

Coexistence

Conventional and GM crops make up the majority of cultivated crops in Canada, along with a relatively small market for organic produce.[83] The responsibility for coexistence with GM crops lies with the producers, who have drawn up their own standard, which has been adopted by the authorities. In its management standards for organic production systems, the Canadian organic sector stipulates that no use should be made of genetic modification in the production of animal-based and plant-based products.[ax] The definition of genetic engineering in the organic production system standards[ay] is in line with the European definitions of GMOs. Producers that comply with the standard may apply for an Organic Standard certification mark. If inspections show that the conditions have not all been met, the licence to use the certification mark is revoked.

In some regions of Canada routine inspections are made of certified organic products.[84] Certified organic farmers must be able to demonstrate that they have done everything in their power to prevent contamination, such as late planting and establishing buffer zones. Industry organisations and individual companies have themselves recommended coexistence and drawn up best practice documents for organic farmers and farmers who grow GM crops. An example is the Stewardship First programme of Croplife Canada, which has produced various guidelines, including a 'Best management practices guide for growers of GE crops'.[85,86] Another example is the 'Standards for organic agricultural production' by the Canadian General Standards Board (CGSB).[87]

2.5.2.2 Limited transparency of voluntary labelling

Consumer and producer choice is not strictly regulated in Canada because the rules for labelling and coexistence are voluntary. Consumers who have objections in principle to GM food and who do not want to buy any such products must turn to organic products. This is because the voluntary labelling standard contains a 5% threshold value (products containing less than 5% GM ingredients may be labelled as not genetically engineered) whereas the organic sector aims to be entirely GMO free.

aw Labelling products of which there are no genetically modified variants (e.g. water and salt) is considered to be an incorrect or misleading form of labelling. The Canadian government has not yet taken any measures against this practice.

ax Canadian Organic Products Regulations, 2009 (SOR/2009-176).

ay 'Techniques by which the genetic material of an organism is changed in a way that does not occur naturally by multiplication and/or natural recombination.'

The voluntary labelling standards are based on the willingness of producers to provide information on GMOs and to separate GMOs from non-GMOs. It is mainly those parties with a declared interest that use labels, such as the organic sector and NGOs opposed to GMOs. Few if any companies in Canada voluntarily label GM food products,[88] but 'non GMO' claims are made on some labels. A well-known example is the Non-GMO Project Verified label, which is used on about 35,000 products across the whole of North America (**see Figure 8**).

Figure 8: Example of labels used for products that do not contain GM ingredients in Canada

This label has been a source of controversy, because in some cases the labels do not seem to meet all the requirements of the Canadian labelling standard. For example, sometimes products that consist of multiple ingredients are labelled as 'non GMO' in their entirety, as are some products with no GM variants.[89,90] However, there is no legislative obligation to label products and so far the CFIA has not taken any measures against the label.

For consumers it can be difficult in practice to find out whether products do or do not contain GMOs. The database of PNTs provides only limited information on the GM status of approved plants and the labelling of products is inconsistent because it is voluntary. Even with organic products, consumers cannot be completely certain that these are completely GMO free. Various labels for organic products can be used even if the products do allow some GM ingredients (such as 'Certified Organic' and 'Made with Organic').[az]

2.5.3 Implications of a product-based regulatory system in the EU for freedom of choice

This section draws upon the above review to derive the possible consequences for freedom of choice and labelling of switching to a product-based regulatory system in the EU, and the resulting policy issues.

- In the EU, the principle of consumer and producer choice is taken seriously. The regulations on the safety assessment of GMOs are directly linked to the mandatory labelling of these GMOs. If a switch were made to a product-based regulatory approach, this direct linkage would no longer be possible because some GMOs would not fall under the product-based legislation. Legal obligations for labelling and coexistence with GMOs would then no longer be linked to the environmental and food safety assessments. If labelling is considered necessary, free-standing legislation will have to be introduced.
- Freedom of choice would increase for some producers, and eventually for consumers, if certain applications of genetic modification no longer fall under the rules for marketing authorisation. This is because reducing the costs of marketing authorisation may make it more attractive for smaller companies to use these techniques in the development and marketing of new crops.
- The increasing difficulty of detecting NPBTs presents challenges for enforcing both voluntary and mandatory labelling schemes. The financial consequences may be less severe for a voluntary labelling requirement because producers can choose not to use this option.
- Supply chain certification could provide an answer and is an accepted approach in other non-safety-related food preferences, such as organic food. But even this form of certification is subject to traceability problems.[91] The lengths to which society should go (technically, practically, economically) to enforce the separation of GMOs from other crops to satisfy a particular preference is a political choice.
- The Directive on the possibility for Member States to restrict or prohibit cultivation of GMOs (Directive (EU) 2015/412)) is linked to Directive 2001/18/EC. If the legislation on de-

az 100% Organic: Must contain 100% organically produced ingredients. These products are completely GMO free. Certified organic: At least 95% of content is organic by weight. The remaining 5% of the ingredients must consist of substances approved on the USDA's National List. GMOs are not on this list. Made with Organic: Up to 70% of the ingredients are organic. The remaining non-organic ingredients are produced without prohibited practices, including genetic engineering. URL: https://gmo-awareness.com/2011/05/05/is-organic-always-gmo-free.

liberate release is changed to a product-based approach this may mean that conventional crops with novel traits, which will then also be regulated, could be prohibited for cultivation by Member States. GM crops that fall outside the scope of the product-based approach, however, could not be subject to such restrictive measures.

3. Context: process-based and product-based regulatory systems are not simply interchangeable

The choice between a process-based and a product-based regulatory system is not an arbitrary one and is inextricable bound up with the national legal system. Moreover, how the legislation is actually implemented in practice is influenced by the decision-making rules and by which bodies have the authority to take the decisions.

The situations in Canada and the EU with respect to innovation, production and marketing are influenced by the regulation of GMOs and PNTs, but are also products of history, culture and geography. Moreover, public acceptance and policy influence each other.

3.1 The role of political decision-making

The average time taken to decide on an application varies considerably between Canada and the EU. In 2015 a marketing authorisation for the EU took on average about 6.5 years (with a range of from 2 to 5 years, and in some cases as long as 8 years).[93,92] In Canada the time taken to decide on an application for a PNT is from 2 to 3 years, with an average of 2 years.[x] These differences appear to be largely due to the different decision-making procedures in Canada and the EU.

In Canada applications are assessed by the CFIA or HC. If the outcome of the safety assessment is positive, the responsible minister delegates the approval decision to the CFIA or HC. Applications for novel foods are discussed at the highest official level in monthly meetings to review the proposed decisions. Applications for PNTs or novel foods may be discussed by government ministers if the dossier is politically sensitive, but this is rare.[x]

In contrast to the situation in Canada, all the EU Member States are involved in the decision-making. Following the food safety or environmental safety assessment, decisions are made by senior civil servants in the Regulatory Committee; if that does not yield a qualified majority for a positive or negative advice, the dossier goes to the Appeal Committee (**see section 2.1.1, text box Decision-making procedure for marketing authorisation in the EU**). These committees consist of representatives from the 28 Member States. The Member States each have their own historical and cultural background as well as different economic and political interests, which can all influence how they vote. In practice, a qualified majority for a positive or negative advice is seldom reached for marketing authorisations for GMOs.[93] On import dossiers the European Commission takes the final decision if no

qualified majority can be reached; for cultivation dossiers the Commission has postponed any decision-making until further notice.

Although the assessment under Directive 2001/18/EC is limited to safety considerations, in the committees representatives from Member States regularly put forward non-safety arguments for voting against marketing authorisation or abstaining. In 2015 a directive was adopted to give Member States the possibility, over and above the safety assessment, to restrict or prohibit the cultivation of GM crops in their territory on the basis on non-safety arguments, but so far this has not led to a faster decision-making on marketing authorisation for the cultivation of GM crops in the EU.

The question, therefore, is whether voting on marketing authorisations for crops under a different type of regulatory system (for example a product-based system) would yield a qualified majority if the decision-making process remains the same as in the current situation. Some stakeholders believe it is the comitology system itself that is the main problem.[94] Questions surrounding the safety of regulated crops (PNTs) or when a trait is novel (equivalent to the current discussion about whether certain techniques lead to a GMO or not) could lead to just as much discussion as at present and slow down the authorisation procedure.

3.2 Integration into different legal traditions

The decision to have a process-based or a product-based regulatory system generally follows from the specific type of legal system in operation. Throughout history various different systems have arisen across the world and some have disappeared again. Legal systems[ba] are generally divided into the common law tradition and the civil law tradition. However, the distinction is not always as rigid as this would imply and many countries work with a combination of both systems. About 150 countries have a predominantly civil law system and about 80 countries have a predominantly common law system.[95]

In common law traditions the process of reaching a verdict has a more inductive character. General rules are inferred from particular instances. Law arises as precedent: decisions on comparable individual cases form the basis for future decisions. This system has its roots in the early English monarchy, when judicial precedent formed the basis for legal decision-making and legislation was based on judicial decisions that had been taken in the past on similar cases. Laws are still made in common law systems, but judges have a duty to take previous decisions into account when coming to a verdict. In this system, the judge not only administers justice, but forms law as well. Countries that have common law jurisdictions include the United Kingdom, Australia, India, the United States, Canada (except Quebec) and some African countries.

ba There are more legal systems, such as Islamic law, Halakha and canon law, and subdivisions of these. However, these other systems are not relevant for this report and are therefore not discussed further.

In civil law traditions, judicial decisions are made by a more deductive process in which the opinion of the judge is formed by the application of general rules to specific cases. Judicial decisions are based predominantly on codified laws and rules. This legal system is used in most European countries, Sri Lanka, the Philippines, Russia, China, Japan, Mexico and South American countries. Jurisprudence also plays a role in these systems, but only if the law does not adequately cover the case in question. In such cases the judge interprets the existing law with the help of judgments in other cases. This tradition has its origins in Roman law and the function of the judge is limited to administering justice by drawing conclusions from the law.

In a continental European civil law system based on laws and rules that codify procedures and general principles, a process-based regulatory approach is the more obvious choice. The emphasis in this legal tradition is on the legal process rather than the final outcome of a specific case. A product-based approach is the more obvious choice in common law systems, which look to individual cases and the situation and context of each case play a greater role. The law is made by precedent, by judicial decisions on concrete cases. In a product-based approach under a continental European legal system, difficulties in the interpretation of the legislation would have different consequences than in a common law system.

3.3 Innovation, production and marketing in historical context

Innovation and the production and marketing of agricultural crops are affected not only by the legislation, but also by geography, climate and historical context. Among other things, these determine which crops are grown where. The Netherlands is densely populated and has a relatively small agricultural area with many crops grown on a small scale. The Dutch plant sector is geared primarily to research and breeding and has acquired a strong international position, particularly in vegetable varieties. Few bulk crops are grown and many plant-based products are imported. Canada, on the other hand, is much more thinly populated, has a large agricultural area and is primarily a production country which grows a number of major crops on a large scale.

The big difference between the agricultural sectors in the two countries leads to differences in impact and issues of regulation. In Europe, the main problems are about innovation in the plant breeding sector and the detection of GMOs in imported products. In Canada coexistence is a more important problem. In Europe this is not yet an issue because hardly any GM crops are grown.

The trade in crops is influenced by economic and political factors, which may change as the international balance of economic and political power shifts. In the past, the approval of GM crops in various countries outside the EU was brought into line with authorisations in

the EU to avoid incurring high costs as a result of cross-contamination with non-authorised GMOs. However, shifts in global markets and the increasingly powerful position of China as an importing country have led countries such as the US and Argentina to abandon their policy of keeping in step with Europe.[x]

3.4 Public opinion hardly affected by regulatory basis

The European public has always been sceptical about genetic modification. Older public opinion surveys (2010) showed that in no European country was the majority of the population enthusiastic about GM food.[96] Respondents saw no advantage and had doubts about the safety of these products. They thought GM food was unnatural, felt uneasy about it and thought it presented a risk. They were less negative about medical applications of GMOs and could see clear advantages of these applications. Recent studies (2019) reveal a more ambivalent and indifferent attitude.[97,98] European citizens do not consider biotechnology to be such a big issues and have few strong opinions about it.[99,100] Industry and other stakeholders conclude from this that the public now has fewer objections to GMOs. NGOs, however, conclude that the subject is being swept under the carpet and is too complicated for the general public to fully understand, and that there really are significant objections.[101,102] These conflicting interpretations can be found in the political discussions and are reflected in the laborious European decision-making on GM crops.

Governments respond to the objections to GMOs by offering a choice in the form of a labelling requirement and coexistence measures. In both Canada and the EU the public can make representations or lodge objections in some application procedures for research and marketing authorisation.[103,104] These public consultation procedures can only take representations on risk into consideration. Most of these representations are made by a standard group of NGOs, are of a general nature and follow a consistent pattern.[x]

In Canada, too, there is little support for GMOs. Over the years, public opinion surveys have shown that Canadians are sceptical or even opposed to GMOs in food. Opinion is divided about whether or not GM food is safe to eat and a large majority of the population are for labelling products that contain GM ingredients.[105,106] Another study shows that a majority of respondents have negative associations with GM food.[107] They associate GM food with Frankenstein, food in extreme forms or formats and with injected chemicals and hormones. A quarter of the respondents feel comfortable eating GM food. This public opinion research in Canada and the opposition to GMOs among NGOs suggests that a product-based regulatory system does not stimulate greater public acceptance, although there seems to be no fallout on the production and marketing of GM crops. Various GM crops are grown in Canada, some even on a large scale. But this does not means that genetic modification is a non-issue in Canada.

Public acceptance and legislation influence each other. The legislation and the visibility of regulation can influence the ideas people have about biotechnology (safe or unsafe) and, vice versa, public opinion regularly informs political debate and policymaking on GMOs.

However, it is not possible to establish a clear correlation between public acceptance and the legislation. Society is a collective of individuals with diverse opinions and perceptions; public opinion is not consistent or uniform. Public acceptance of technology is generally influenced by a multiplicity of social and cultural factors and there is little sign of active support; people accept the status quo. Public acceptance is visible when it is lacking, because then individuals or groups resist the use of a technology by uniting in groups as platforms for providing critical information and organising protests or objections. This can obstruct the implementation of the regulations.

4. NPBTs in process-based and product-based legislation

Various countries outside the EU have already amended their legislation to accommodate the emergence of NPBTs or are in the process of doing so. This chapter provides a brief overview of how a number of countries other than Canada and the EU are adapting their legislation.

4.1 Adapting legislation in other countries

Countries outside the EU also face the problem of regulating NPBTs and are looking for ways to do this. This section outlines the approaches being considered or already being put into practice in several other countries.[108]

Argentina has a predominantly product-oriented regulatory system for GMOs in which the focus is on new traits rather than the process used to obtain the plant.[109] *Null segregants* – plants from which the end-products do not contain any transgene modifications – are exempt from regulation (in contrast to the situation in the EU). Regarding NPBTs, each application has to be examined individually to determine if it falls under the legislation. To support this process a supplementary resolution (Resolution no. 173/2015) was adopted in 2015 which contains criteria for use in the case-by-case assessment of NPBTs. These criteria are designed to help determine whether or not foreign DNA is introduced and are used to regulate 'SDN-3 applications' in which recombinant DNA is introduced.[bb] Applications of SDN-1, SDN-2 and ODM that do not insert any foreign DNA are not regulated. As of June 2018, 12 NPBTs have been assessed under this resolution. Most were not regulated.

In the **United States** plants can be regulated if they can be considered to be a veterinary pharmaceutical product or a plant disease. They are assessed by the Food and Drug Administration (FDA), the US Department of Agriculture (USDA) and the Environmental Protection Agency (EPA).
The USDA-APHIS regulates plants with plant disease traits. If during the creation of a GM crop use is made of a plant pathogen or DNA from a plant pathogen, it falls under

bb Gene editing techniques using site-directed nuclease (SDN) systems can be categorised according to the degree to which the DNA is altered. A division is usually made into three categories of SDN. SDN-1 and SDN-2 do not make use of recombinant DNA. A single break is repaired (SDN-2 with an altered template) which can lead to a mutation or deletion (gene silencing or knockout). Oligo Directed Mutagenesis (ODM) also does not involve the insertion of recombinant DNA. In SDN-3 a gene or other sequence is inserted after a break, which means that new genetic material is introduced into the genome.

the legislation. Plants also fall under the legislation if DNA sequences from pathogenic bacteria and viruses are inserted (such as T-DNA borders, 35S promoter of the Cauliflower mosaic virus, NOS terminator of *Agrobacterium tumefaciens*) or if a plant pathogenic bacterium, such as *A. tumefaciens*, is used for the transfer of DNA. This means that the basis for regulating plants is the process of genetic modification in combination with the presence of traits of plant pathogens.[110] Products of gene editing techniques in which the edited sequences are not present in the end-product do not fall under the legislation.[111]

The FDA regulates all food and animal feed of plant origin that poses a potential risk. Regulated foods and feeds are those whose composition has been substantially changed, such as an increase or decrease in nutrients, minerals, fibre, toxins, allergens or other components. The regulatory basis is the characteristics of the end-product. Whether a plant must undergo a safety assessment or not is determined on a case-by-case basis in a pre-consultation process. In practice, all products of genetic modification are put forward for this pre-consultation process. GM animals are regulated as veterinary pharmaceutical products by the FDA's Center for Veterinary Medicine (CVM). The definition of a pharmaceutical product in the Federal Food, Drug and Cosmetic Act (FFDCA) covers recombinant DNA constructs that causes a change in the structure or function of the body of a GM animal, regardless of the intended use of the products of these animals, and non-heritable rDNA constructs that influence the structure or function of an animal for the purpose of preventing or curing a disease.

The EPA regulates, among other things, toxic substances (such as pesticides) in the interests of human and environmental safety. A pesticide is any substance that is used to prevent, destroy, repel or control pests. Regulation is required for the use of new pesticides, changed use patterns of pesticides and pesticides produced by the plant itself. To bring plants that have been made resistant to pests and diseases under regulation, the category of 'plant-incorporated protectants' (PIPS) has been included in the legislation. These are substances produced by the plant to provide protection against pest and diseases and the genetic material needed to produce these substances.

To assist breeders who have questions about the use of NPBTs, the US operates a voluntary consultation process called 'Am I Regulated?' which helps applicants early in the development of a product to determine whether or not the product will have to be regulated.[112] It has also been decided that certain NPBTs will not be regulated. Studies are ongoing to determine if certain techniques, such as cisgenesis, can be deregulated.

Japan is mentioned in the literature both as having a process-based regulatory system and as having a product-based regulatory system.[113,114,108] The initial regulatory basis is the process, but it is the nature of the product itself that finally determines whether or not it is subject to regulation.[115] In June 2019 the Japanese Ministry of Health, Labour and Welfare

(MHLW) published a draft proposal for regulating food and food additives made using genome editing.[116] Possibilities are being investigated for amending the legislation to exempt food consisting of organisms made by NPBTs, or their products, that do not contain any recombinant nucleic acids. A tiered approach is proposed in which such cases would be subject to a notification requirement. If recombinant nucleic acids are present in the end-product, authorisation and an environmental risk assessment would be required. These genome editing products are GMOs and in Japan fall under the Food Sanitation Law.

South Africa has a process-based regulatory system for GMOs that closely resembles the EU system. All GMOs, including NPBTs, fall under the legislation and must undergo an environmental risk assessment.[108,113 ,117]

New Zealand also has a process-based regulatory system Mutagenesis by radiation or chemicals is excluded from regulation. In principle, all NPBTs fall under the legislation, at least for the time being.[118] The government has designated NZ-EPA as the competent authority responsible for deciding the legal status of NPBTs.

In **Australia**, each application of an NPBT has to be assessed to determine whether or not it falls under the legislation.[119] Following an evaluation of the existing legislation, various amendments will be made to the Gene Technology Regulations 2001, including the exclusion from regulation of genome editing (SDN-1) which does not introduce foreign DNA. This and other changes will take effect from October 2019. Other NPBTs will remain regulated for the time being.[120]

Brazil is seen as a country with a predominantly process-based regulatory system. In 2018 a resolution was adopted (Normative Resolution No. 16/2018) similar to that in Argentina to support assessment of NPBTs to determine whether or not they fall under the legislation.[121] Techniques that do not add any new recombinant DNA/RNA are not considered to be GMOs. This in effect adds product-based features to the regulatory system.

4.2 Amending the EU legislation: Dutch discussion document

In 2017 the Netherlands submitted a proposal for discussion in the EU that aims to bring the legislation better in line with the development of NPBTs, with respect to both innovation and safety.[122] The proposal is for an amendment to Annex IB of Directive 2001/18/EC (organisms excluded from the Directive) (**see text box Dutch proposal for amending Annex IB of Directive 2001/18/EC**). At the request of the Dutch Minister of Infrastructure and Water Management, COGEM has published advice on the potential environmental risks associated with this amendment.[123]

Dutch proposal for amending Annex IB of Directive 2001/18/EC

The Netherlands has submitted a discussion document proposing to amend Annex IB of Directive 2001/18/EC and include criteria for determining whether or not techniques can be excluded from the Directive. Under the proposal, products of all NPBTs would be excluded if they:

- contain no recombinant DNA used for genetic modification;
- contain no GMOs (with the exception of GMOs obtained by techniques already excluded from the Directive: mutagenesis and cell fusion);
- contain no foreign DNA that has not been obtained by traditional hybridisation.

The burden of proof for meeting these criteria would lie with the producer. According to the proposal, Annex IB would be periodically updated (every 5 years) to keep abreast of technological and scientific developments.

A large number of Member States support the call to revise the legislation.[124] A new European Commission will be installed at the end of 2019 and it is expected to put a revision of the GMO legislation on the agenda for the coming years. However, the outcome is hard to predict, particularly given the long-running and painstaking discussion on GMOs in Europe.

5. Observations and conclusion

The current GMO legislation in the EU is insufficiently future-proof in the light of the advances being made in genetic modification technologies. Under the process-based regulatory approach, in which certain techniques are subject to regulation and others are not, each new NPBT must be assessed to determine whether or not products obtained by the technique fall under the legislation or not. This problem raises questions about the principle behind the EU's GMO legislation.

At the same time, there is discussion about the wider (social and economic) and procedural (decision-making) aspects of the regulatory process. Is it necessary or desirable to exempt certain NPBTs from regulation to avoid hampering innovation? Or would this compromise the freedom of choice for consumers and the organic farming sector? And how does the rest of the world approach the regulation of NPBTs, and what influence does that have on international trade and importing products into the EU? A product-based regulatory system such as the approach taken in Canada is regularly promoted as a solution.

This report has analysed the possible consequences of switching from the current process-based regulatory system to a product-based system for GM crops in the EU.

5.1 The procedural and political context of regulating GMOs and NPBTs

Quite apart from the regulatory principle behind the legislation on new GM crops, there are several difficulties inherent in the regulation of GM crops which either constrain or steer the choice of options for improving the regulatory system. These difficulties cannot be resolved simply by changing the regulatory basis, but require broader political consideration.

Protracted political decision-making: A significant difference between the way the legislation is put into practice in the EU and Canada is the decision-making process. In the EU the scientific safety assessment is followed by a voting round in which all the Member States have to agree on the proposed decision. This process almost never produces a qualified majority on either a positive or negative advice on the authorisation of GM crops. In Canada, decisions on the approval of PNTs are made by a mandated agency on the basis of a scientific safety assessment. This limits the politicisation of the process and the marketing authorisation procedures seem to run more smoothly and more quickly. If the EU switched to a product-based regulatory system for GMOs, but the current decision-making procedures were retained, it is likely that the current problems of protracted decision-making and disagreement would remain for regulated crops.

Negative impact on innovation: Human and environmental safety is the guiding principle for the regulation of crops bred with use of genetic modification techniques. The availability of NPBTs, in particular gene editing, makes it possible to develop new crops that are almost indistinguishable from crops obtained using conventional breeding techniques. This prompts the question of whether these crops pose an environmental risk and, if so, what sort of risk. That is why some stakeholders view the current EU authorisation process for crops obtained by gene editing as disproportionate, time-consuming and costly. They want these new crops to be exempt from regulation so that the authorisation process no longer presents an impediment to placing them on the market.

Freedom of choice under pressure: For the organic sector it is important that all plants and their products made using genetic modification and related biotechnological techniques are visible and transparent in the food supply chain so that these crops can be avoided if desired. The organic sector is concerned that its core values will be eroded if GMOs developed using NPBTs are exempt from regulation. These crops would become less visible in the innovation, production and marketing chain, increasing the likelihood that consumers and producers who do not want GMOs will nevertheless be unknowingly and unwittingly exposed to them.

Problematic enforcement: The increasing difficulty of detecting NPBTs in combination with the differences in regulatory practices around the world present problems for parties in the food supply chain (biotechnological, conventional and organic).

5.2 Implications for regulation and the safety assessment

- In the EU's process-based regulatory system each new genetic modification technique must be assessed to determine whether or not it has to be regulated. The legislation meets the demands of those who hold objections in principle to GMOs, because all GMOs (including NPBTs) are regulated and must be labelled as such (with the exception of exempted GMOs such as those obtained by traditional mutagenesis).
- A product-based regulatory system based on new traits is more future-proof with respect to the development of new techniques, because it is not necessary to assess every new technique to determine whether or not it falls within the scope of the legislation. Because both conventionally bred products and GM products can fall under this regulatory system, more crops may be regulated.
- In both systems the regulatory basis leads to questions and uncertainties. In the EU the definition of a GMO and the description of techniques in the relevant Directive lead to discussions about whether techniques do or do not lead to GMOs and therefore should be regulated. In Canada there is a lack of clarity about when a trait is new and when it is not. In both cases, the uncertainty can inhibit innovation.
- Both the European process-based approach and the Canadian product-based approach involve a thorough safety assessment. Some of the details may differ, but overall the assessments are more or less the same.

5.3 Implications for enforceability and consumer choice

- In the EU, the mandatory labelling requirement and strict thresholds for cross-contamination ensure a considerable degree of consumers' freedom of choice. However, consumer choice is becoming increasingly hard to guarantee due to the growing problems of detecting NPBTs, which could lead to a loss of trust in the government.
- The Canadian system has a mandatory safety assessment of PNTs and voluntary rules for labelling and coexistence. The responsibility for these lies with the producers. The voluntary labelling and coexistence rules are less demanding for producers, but can lead to uncertainty among consumers, for example if there are many different labels.
- In practice, coexistence of crops that easily outcross, such as oilseed rape, proves to be very difficult and as a consequence may lead to shifts in the production sector. In Canada, for example, cultivation of organic oilseed rape has declined considerably as a result of an increase in the cultivation of GM oilseed rape.
- Safety and consumer choice (labelling and coexistence) can, in theory, be regulated separately. It is possible to maintain two systems with different regulatory bases: one set of regulations for safety assessment for GMOs that meet certain criteria and another set of regulations on tracing and labelling all GMOs.
- Providing reference material and a detection method are a condition of the marketing authorisation for GMOs in the EU. The traceability and labelling of GMOs is therefore in the hands of government and the organic sector makes use of these data to avoid the presence of GMOs in its products and processes. Under a product-based regulatory system this information would become fragmented and sectors that claim to be GMO free, such as the organic sector, would have to resort to their own systems, which could place additional administrative burdens on this sector.

5.4 Implications for innovation, production and marketing

- A product-based regulatory system in the EU could encourage the use of NPBTs by the plant breeding industry and, as far as the new traits obtained as a result do not fall under the new regulations, may lead to an increase in the number of GM crops.
- Under a product-based regulatory system, products with novel traits would still be regulated. This may also include some crops that are currently not regulated. The question, though, is what impact would switching from a process-based to a product-based system have on innovation.
- International agreements on the regulation of NPBTs could facilitate international trade and reduce problems of unintended cross-contamination.

5.5 The best of both (or several) worlds

This report shows that the process-based and product-based approaches to regulating GMOs are not simply interchangeable. The principles underlying each of the approaches have their advantages, problems and disadvantages. Moreover, the legal framework is the start-

ing point for effective regulation and changes to the process, such as implementation and compliance, can also contribute towards more effective and efficient regulation.

It is also true that the practical differences between the two approaches are in some respects smaller than many people would at first think, for example with respect to the number and type of regulated crops. **Figure 9** presents several key facts and figures about the regulation and use of new crops in the EU and Canada.

Various countries outside the EU are amending their legislation to facilitate the regulation of NPBTs. Countries with a product-based regulatory system do not need to make many changes for the time being. They apply their current regulations and develop additional criteria where necessary to assess new applications.

Countries with a process-based regulatory system have to develop additional legislation and criteria for determining whether or not a product should be regulated. These criteria concern the characteristics of the end-product and the type of modification made to the DNA. The most favoured principle behind these proposals is that genetic modifications resulting in end-products that contain no foreign DNA require less stringent evaluation or can be exempt from regulation. The Dutch proposal for discussion within the EU takes this line as well.

To facilitate both innovation and transparency in the use of NPBTs, various countries (including Canada, Australia and Japan) are investigating the option of using a tiered approach to assessment. Under this approach, new crops would have to be notified and then assessed against a number of criteria to establish whether or not a risk assessment needs to be carried out.

This approach could be a viable option for the EU, too. In the interests of detection and freedom of choice, NPBTs that produce crops which contain no foreign DNA could be subject to a notification procedure, which would trigger an appraisal to determine whether a risk assessment is needed. Such an approach could ensure the visibility and the safety of these crops as well as imposing the least possible impediment to innovation.

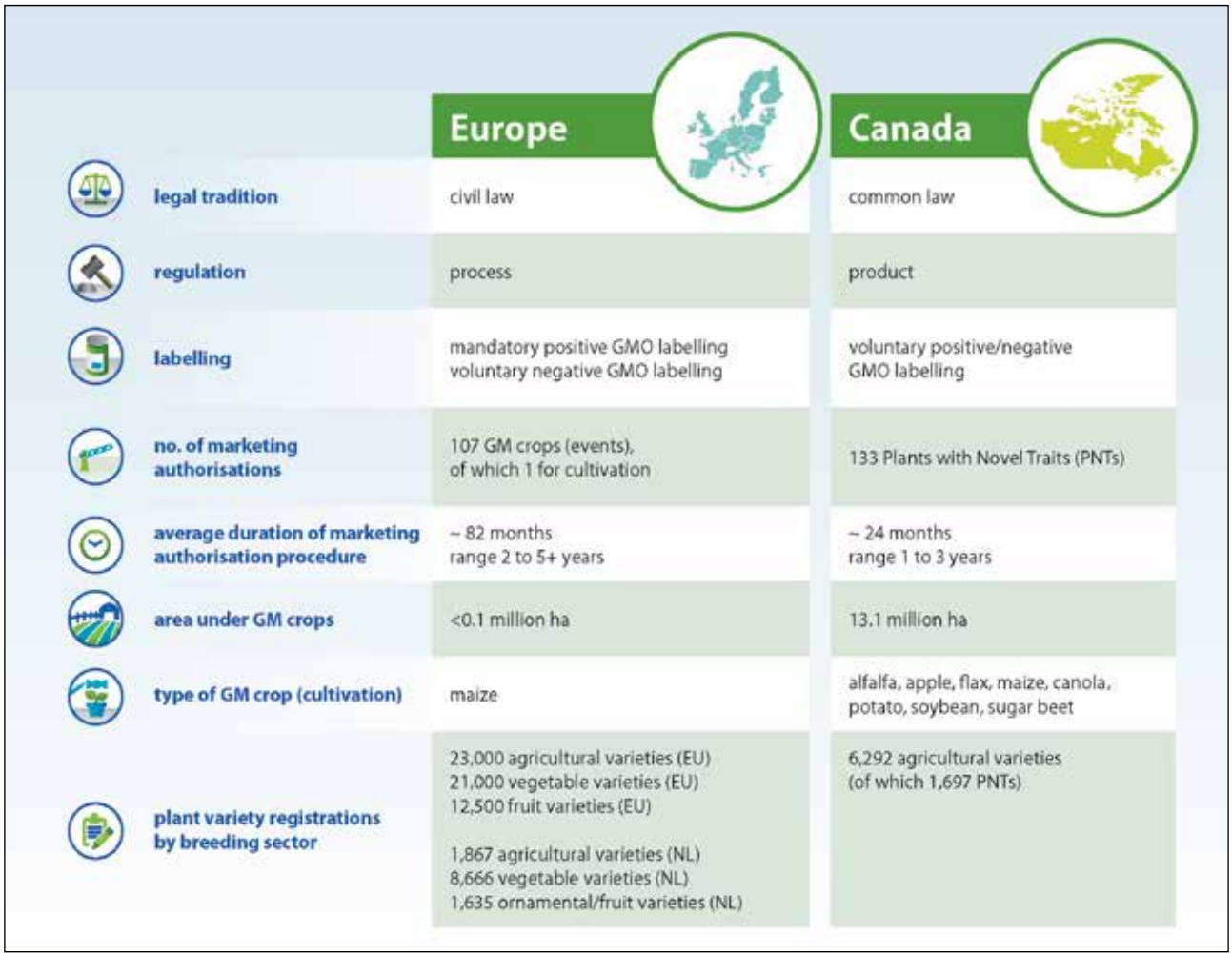

Figure 9: Overview of some key features of regulation and production of new crops in the EU and Canada

APPENDIX A: Consulted experts

- **Amanda DeBruyn,** Plant Biosafety Policy Analyst, Canadian Food Inspection Agency (CFIA)
- **Claudio Feulner,** Manager Regulatory Affairs and Trade, Canadian Seed Trade Association (CSTA)
- **Robert Hoek,** Senior Inspector, Human Environment and Transport Inspectorate (ILT, Netherlands)
- **Jennifer Hubert**, Director, Plant Biotechnology, Croplife Canada
- **Frans Köster,** Senior Manager, Trade Policy and Biotechnology, MVO – The Netherlands Oils and Fats Industry
- **Emile Laurensse**, Senior Inspector, Netherlands Food and Consumer Product Safety Authority (NVWA)
- **Niels Louwaars,** Managing Director, Plantum, Netherlands
- **Tia Loftsgard**, Executive Director, Canada Organic Trade Association (COTA)
- **Luis Luque,** Science and Regulatory Affairs Officer, Croplife Canada
- **Laurens Nuijten,** Junior Project Manager, Bionext, Netherlands[bc]
- **Emily Silk,** Deputy Director, Agriculture and Agri-food Canada
- **Margot Spreuwenberg,** Senior Inspector, Human Environment and Transport Inspectorate (ILT, Netherlands)
- **Stephen Yarrow,** Independent plant biotech policy consultant, Canada

bc The report of this interview has not been formally approved. For this reason, input that could not be verified in the literature has not been used in this report.

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