Chapter 3
Social Acceptability of Cisgenic Plants: Public Perception, Consumer Preferences, and Legal Regulation

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Abstract Part of the rationale behind the introduction of the term cisgenesis was the expectation that due to the "more natural" character of the genetic modification, cisgenic plants would be socially more acceptable than transgenic ones. This chapter assesses whether this expectation was justified. It thereby addresses three arenas of social acceptability: public perception, consumer preferences, and legal regulation. Discussing and comparing recent studies from four geographical areas across the globe—Europe, North America, Japan, and Australia and New Zealand—the chapter shows that the expectation was justified, and that cisgenic plants are treated as being more acceptable than other forms of genetic modification. Yet, there are considerable differences across the three arenas of social acceptability. In Australia, Canada, and the United States of America, the legal regulation of cisgenic plants is less restrictive than in Europe, Japan, and New Zealand. Also, the public perceptions are rather diverse across these countries, as are the factors that are deemed most influential in informing public opinion and consumer decisions. While people in North America appear to be most interested in individual benefits of the products (improved quality, health aspects), Europeans are more likely to accept cisgenic plants and derived

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products if they have a proven environmental benefit. In New Zealand, in contrast, the potential impact of cisgenic plants on other, more or less related markets, like meat export and tourism, is heavily debated. We conclude with some remarks about a possible new arrangement between science and policy that may come about with a new, or homogenized, international regulatory regime.

Keywords New Plant Breeding Techniques (NPBTs) · Innovation · Acceptance · Gene editing · Genetic modification

3.1 Introduction

The term cisgenesis emerged in the scientific literature about 20 years ago as one part of a notional couple that juxtaposed cis- and transgenesis (Nielsen 2003; Holme et al. 2013). The couple quickly gained currency in scientific papers and policy documents. One driver behind this successful trajectory was that the terms introduced a possibility for the public, decision-makers, and stakeholders to differentiate between different "degrees" or "depths" of genetic modification (GM) in plants. Transgenic plants contain genes from distant organisms such as bacteria, viruses, and unrelated plants and therefore differ significantly from what has been possible in conventional breeding. Cisgenic plants, however, contain genes from sexually compatible species only, i.e., from the gene pool that could be used by conventional breeding. Thus, the mutation in the cisgenic plant could theoretically also have resulted from conventional breeding, which in some legislations around the globe is an important criterion. This, for instance, is the case in Canada, where "genetic changes that are comparable to conventional breeding outcomes" are exempted from regulation; in Nigeria, applicants have to prove the absence of "recombinant DNA," and the same holds true for Japan. The differentiation between trans- and cisgenic plants therefore aligned with what had emerged as one of the major hindering factors for the social acceptability of GMOs: their perceived unnaturalness (see Sect. 3.2).

While this was the motivation to introduce the concept of cisgenesis, this chapter explores the empirical evidence if and how the public and stakeholders differentiate between trans- and cisgenic plants and derived products. Already at the time when the two terms were introduced, there was considerable heterogeneity across countries and jurisdictions with regard to social acceptability and legal regulation of GM plants and derived food/feed products. Therefore, the assumption is that this heterogeneity is also reflected in the acceptability and regulation of trans- and cisgenic plants. The chapter conducts a comparison of selected countries with differences in legal regulation, social acceptability, and market access: the USA, Canada, and Australia as cases for social and regulatory contexts that would appear to be more enabling for GM plants; and Europe, Japan, and New Zealand as cases for contexts less enabling for such products.

Acceptance versus acceptability

In the previous paragraphs, we deliberately used the term acceptability in contrast to the more widely used term "acceptance" because we consider it more appropriate. First, the term acceptance presupposes the existence of a technological product and its actual use or consumption. Most studies on technological innovations, however, address emerging technologies that are not yet available, and the term acceptability emphasizes this hypothetical character (cf. Alexandre et al. 2018). Second, acceptance is generally conceived of in terms of individual psychology, as an attitude held by a subject towards an object. In contrast, the term acceptability would move the focus away from the state of mind of an individual to the technology or its concrete manifestation, thereby emphasizing the embeddedness—or lack thereof—of technology in social and societal networks (cf. Szarka 2007). Third, it has been claimed that acceptance—as a term denoting an individual attitude—has a static touch. Once a person has accepted something, it is not very likely that s*he will question it again, unless important factors change. In contrast, the term acceptability pays more attention to the dynamics by which a state of acceptance is reached (Fournis and Fortin 2017). The relevance of paying attention to processes that lead to a particular social outcome has also been highlighted in various studies on the public perception of and the discourses surrounding plant biotechnologies (Levidow et al. 2007; Yamaguchi and Harris 2004). Finally, the term acceptability interferes less with concepts under use in other fields of scientific activity, above all market acceptance in economics and business management (e.g., Higgins and Shanklin 1992; Chiu and Tzeng 1999; Murata et al. 2019), or the user-centred Technology Acceptance Model in software engineering and IT research (Davis 1989; Venkatesh and Davis 2000; Venkatesh et al. 2003).

Dimensions of social acceptability

Inspired by the triangle of social acceptance by Wüstenhagen et al. (2007), we explore different dimensions of acceptability, which differ with regard to the subjects and object(s) of acceptance (cf. Sonnberger and Ruddat 2017).

(1) Socio-political acceptability is concerned with how a technology (e.g., cisgenesis) and the associated policy are perceived by the general public, stakeholders, and politicians.
(2) Community acceptability refers to the acceptability of a specific technological project (e.g., growing cisgenic apples on a field in Italy) by the local population, including farmers, politicians, and other stakeholders.
(3) Market acceptability is understood as the acceptability of a technological product (e.g., a cisgenic apple) by market participants across the value chain, including retailers, and consumers.

With regard to cisgenic plants, empirical evidence can only be found for some aspects of these three dimensions. Possible reasons for this are addressed in the concluding section, but the technical character of the distinction, the already widespread public hesitance towards GM, and the new narratives that came with the advent of gene editing (GE) soon after the introduction of the distinction between trans- and cisgenesis certainly play a role. The following discussion focuses on three aspects. Section 3.2 is concerned with how trans- and cisgenic plants are perceived and publicly debated—a crucial element of (1) socio-political acceptance. Section 3.3 then explores their acceptability by consumers as an element of (3) market acceptability. Finally, Sect. 3.4 discusses different regulatory regimes, which influence (1) socio-political acceptability.

3.2 Public Perception of Cisgenic Plants

In the following, we aim to describe the public perception of transgenic and cisgenic plants in several regions and countries around the globe. Despite the above efforts in establishing conceptual clarity, a direct cross-country comparison of questionnaire data is difficult. The degree to which the genetic modification of plants is perceived as a social problem differs across countries (Yamaguchi 2019), and the debates involve different meanings and cultural connotations.

Most studies assessing the social acceptability of cisgenic plants hypothetically assume the same factors as informing the public attitudes towards GM and, more recently, towards GE, namely

- the perceived naturalness (Connor and Siegrist 2010; Tenbült et al. 2005);
- the trust in the producers as well as in the agencies responsible for safety assessments (Connor and Siegrist 2010; Costa-Font et al. 2008; Lusk et al. 2018; Norwegian Biotechnology Advisory Board 2020);
- prior knowledge about plant breeding technologies (Connor and Siegrist 2010; Costa-Font et al. 2008; Kato-Nitta et al. 2019); and
- the possible positive and negative effects for the consumer, as well as the environmental and health risks of consumption (Bearth and Siegrist 2016; Connor and Siegrist 2010; Costa-Font et al. 2008; Gatica-Arias et al. 2019; Shew et al. 2018).

The thematic frame of the following discussion is provided by a series of questions: What issues were dominant in the public discourses? Do we find empirical evidence, or at least indications, that cisgenic plants and derived food/feed are (would be) perceived differently compared to transgenic?

Europe

Large-scale opinion polls, most prominently the European Commission's EUROBAROMETER (https://www.europarl.europa.eu/at-your-service/en/be-heard/eurobarometer), have for a long time documented the attitudes and views of Europeans towards biotechnology, including its use in food production. However, the context and, as a consequence, the formulation of the questionnaire items concerning GM and GE products changed over time, and interpretation as panel data is difficult, if not impossible. In order to allow for interpretation, the following paragraphs always inform in all brevity about the context and, if feasible, about the formulation of the items in the respective EUROBAROMETER surveys.

Between 1991 and 2010, consumers became more averse to GM products. In 1991, 74% of the respondents at least tendentially agreed with the statement that genetic engineering research on plants "is worthwhile and should be encouraged," and 58% did so with regard to the use of genetic engineering in food production (INRA 1992:41). In 2005, this had changed, and the majority of the EUROBAROMETER respondents described GM foods as morally not acceptable, not useful, and risky: research in this direction should not be encouraged (European Commission 2006:17). Five years later, in 2010, 66% of EU consumers were worried about genetically modified organisms found in food or drinks (European Commission 2010:28). Comparable results emerged from various studies within European nations, e.g., in Serbia (Brankov et al. 2013), Poland (Rzymski and Królczyk 2016), Bosnia and Herzegovina (Bevanda et al. 2017), Lithuania (Lukošiutė and Petrauskaitė-Senkevič 2017), as well as in comparative studies of several countries in North and Southeastern Europe (e.g., Veličković et al. 2016; Brosig and Bavorova 2019; for an overview, see Sikora and Rzymski 2021).

More recent data at the European level indicate only small changes (Woźniak et al. 2021). When asked about the most pressing risks for food safety in 2019 with a list of fifteen topics, GM ingredients in food or drinks ranked in place 8 (27% of respondents expressed concern), while genome editing (GE) emerged as the one Europeans were least (4%) concerned about (European Commission 2019:40). To them, the most pressing issues regarding food safety were antibiotic, hormone, or steroid residues in meat (44%), pesticide residues in food (39%), and environmental pollutants in fish, meat, or dairy (37%). While taken on its own, the figures are lower than those of the earlier studies, and this might in a large part be caused by the context of the survey. The concerns about the use of GM or GE might not have decreased per se, but may appear less pressing compared to other risks for food safety. Also, even if not seen as posing risks, there might still be other fundamental reservations against GM or GE food/feed, leading to low social acceptability.

Still, across these decades, the perceptions within member states remained rather stable. Broadly stated, the public perception of GM food has been consistently favourable in Spain, Portugal, Malta, and the Czech Republic. It has been positive, although to lesser degrees, in Ireland, Italy, the Netherlands, the United Kingdom, Finland, Belgium, Denmark, Slovakia, and Hungary. Greece, Latvia, Cyprus, Luxembourg, Austria, France, Germany, Estonia, Slovenia, Hungary, and Poland have consistently shown negative attitudes towards GM food. Two European countries have shown changes in public opinion: In Sweden, public perception moved from objection to interest, whereas in Lithuania it moved in the opposite direction, from interest to opposition (cf. European Commission 2006, 2010, 2019) (Table 3.1).

These national differences notwithstanding, studies using the EUROBAROMETER 73.1 data from 2010 indicate that Europeans, after having been introduced to the two types of technological intervention, differentiate between trans- and cisgenic plants (Hudson et al. 2015; Rousselière and Rousselière 2017). Across the participating countries, 57.1% of the population think that the use of cisgenesis to require

Table 3.1 Patterns of public perception in European countries

Consistent positive public perception over time	• Spain • Portugal • Malta • Czech Republic
Positive public perception over time	• Ireland • Italy • Netherlands • United Kingdom • Finland • Belgium • Denmark • Slovakia
Consistent negative perception over time	• Greece • Latvia • Cyprus • Luxembourg • Austria • France • Germany • Estonia • Slovenia • Hungary • Poland
Changing perceptions over time	• Sweden • Lithuania

* *Sources* European Commission 2006, 2010, 2019

fewer pesticides in cultivation should be encouraged, and 31.4% approved of the use of transgenesis for this purpose (Hudson et al. 2015:306–7). However, studies carried out in Austria (Kronberger et al. 2014) and Denmark (Mielby et al. 2013) show that while cisgenic plants might be perceived as less unnatural than transgenic ones, this does not result in an increase in their acceptability. In other words, cisgenesis is still considered to be an intrusion into the plant that makes it less natural. As a consequence, the majority of the participants in the two studies thought that cisgenic plants and derived products should be labelled when marketed as food. This was also expressed in cases where genetic modification came with clear environmental and consumer benefits, e.g., growing apples with lower pesticide use and therefore, less residues on the plants (Rousselière and Rousselière 2017).

There are positive effects of prior knowledge on both the likelihood of differentiating, as has been shown in a study carried out in Denmark (Mielby et al. 2012), and on the attitude of acceptance towards trans- or cisgenic crops (Hudson et al. 2015; Mielby et al. 2012; Rousselière and Rousselière 2017). These effects, however, have not been too big, and authors have warned against over-interpreting them (Mielby et al. 2012:163). The idea of having a labelling scheme in place that allows for differentiating not only between GM and other foods but also between the type of GM food presently on the market and other ways of genetic modification such as genome editing or cisgenesis is a very controversial one—controversial in terms of need, meaningfulness, feasibility, and impacts on business. It seems to be particularly preferred by consumers and some stakeholders in GM sensitive countries (Bundesinstitut für Risikobewertung 2017; Spök and Hammer 2019; Kronberger et al. 2014; Mielby et al. 2013).

North America

Broadly speaking, publics in the USA and Canada have more favourable views of GM plants and GM food as compared to Europe (McFadden and Smyth 2019). At the same time, these two countries also have introduced lower regulatory barriers for marketing GM crops, which led to an increase in acreage used for GM crops over the last 15 years. Also, a considerable number of GM-derived food products are commercially available. This also applies to the more recent innovations in New Plant Breeding Techniques (NPBTs), like cisgenesis and GE. In 2018, the US Department of Agriculture (USDA) clarified that certain types of genome-edited plants will be considered as conventional plants. In Canada, cisgenesis is not considered to lead to novel plant properties, which would be the regulatory trigger (Dederer and Hamburger 2019; Menz et al. 2020).

Motivated by a predicted raise in demand in importing countries and by simplified and less hazardous pesticide regimes, large-scale farmers growing maize and soybean were early adopters of GM plants. The papaya industry in Hawaii was even rescued by a GM viral-resistant variety. Livestock farmers also have profited from reduced prices for feed. Environmental groups, on the other hand, opposed GM technology as fostering an industrialized agriculture and monoculture that would mainly benefit large multinational seed producers, and also because of possible environmental risks. By putting media pressure on selected value chain actors to have them pull out of using GM crops in their food products, they attempted to affect the strategies of certain food producers towards a few crops. However, their efforts did neither result in a more fundamental change in the behaviour of market actors nor in a policy change. On the contrary: the US and Canadian governments have become outspoken supporters of the cultivation and international trading of GM crops and derived products. They eventually accused the EU of violating WTO provisions in their way of hampering market access for GM crops (reviewed in Zilberman et al. 2013).

Given the rapid diffusion of GM technology into agriculture and food production in North America, it is nonetheless surprising that the public views towards GM food—as identified in recent polls—are quite negative. A 2016 survey in Canada found that 62% of the respondents agreed that they would always opt for non-GM food over GM. Only 26% expressed being comfortable with eating GM foods, and 38% stated being not comfortable (The Strategic Counsel 2016). A similar picture emerged from a multi-country survey conducted a few years later, in 2019/2020, where 38% of the US and 39% of the Canadian respondents agreed that GM foods are unsafe to eat. In both countries, only 27% agreed that they are safe to eat (Pew Research Center 2020). Foods from GM plants seem to have higher acceptability compared to foods from GM animals (Lusk et al. 2015; Runge et al. 2017). In the US, the acceptability of GM food seems to increase if it has direct consumer benefits

(Lusk et al. 2015; Rose et al. 2020). Comparative studies have shown that the positive effects of expected direct consumer benefits of GMOs are stronger with citizens in the US and Canada than they are with Europeans (Costa-Font et al. 2008).

Little evidence is available from surveys on plants and derived foods produced by new plant breeding techniques including genome editing and cisgenesis, all of which typically have much smaller genetic changes compared to traditional GM. While non-government organizations (NGOs) who hold critical views towards GMOs are lobbying to have GE and cisgenic plants and food put into the same regulatory categories as GMOs (Ishii and Araki 2016; Smyth 2019), this doesn't seem to have a relevant impact on the behaviour of value chain actors and policy development. There is some awareness in the broader public of new plant breeding techniques, with a recent study showing that about a third of US adults stated to have never heard or read anything about GE food (Peters 2021). In comparison, there is less awareness of cisgenesis. In a survey carried out in Canada, 77% of the respondents stated they had not heard about cisgenesis (Smyth 2019).

There are indications that the public appreciation of GM plants and foods in North America has decreased slightly over the last few years and that genome-edited equivalents might be perceived more favourably. A 2016 online survey in the US revealed that 39% of respondents believed that food with GM ingredients is worse for one's health compared to non-GM food (Pew Research Center 2016). This number raised to 49% in 2018 (Pew Research Center 2018). In a survey conducted in Canada by Vasquez Arreaga (2020) that invited consumers to directly compare GM and GE foods, the positive response was about 15% higher for GE foods—again with benefits as the main drivers for positive responses (see also chapter "Cisgenics and Genome Editing or Second Generation Biotechnologies: A Latin America and Caribbean Perspective").

Provided that public acceptance does not decrease further, and in the absence of a mandatory labelling regime of GM food products, there is presumably little incentive for market actors to explore and commercially exploit the differentiation between GM and GE, or between trans- and cisgenic plants.

Australia and New Zealand

In Australia, widespread planting of GM cotton, canola, and safflower has recently occurred. In several states (legislation occurs at both a federal all-of-country level and at a state-by-state level), bans on GM crops have been reversed. At present (2021), most states have lifted moratoria on GM crops, however, Tasmania still has a broad prohibition in place. Despite a rather positive public perception as described below, all GM plantings so far have been of non-food crops.

The planting of GM crops is regulated by the Office of the Gene Technology Regulator (OGTR), which does not regulate GM use in foods (Office of the Gene Technology Regulator 2021). This role is covered by Food Standards Australia New Zealand (FSANZ) who approve, or not, all foods based on safety assessments before they can be sold in Australia and New Zealand. This process appears to be well trusted: a large study of Australians in 2014 showed that the public leant positive to GM plants for food—more positive than to GM animals. It was concluded that the positive attitude towards GM food was significantly associated with higher trust in scientists and regulators, and with lower trust in environmental bodies. In this study, it was found that public trust in scientists and regulators was a predictor of acceptance of GM, but only when media coverage was low (Marques et al. 2015).

This is in stark contrast to New Zealand. Early applications to use and create transgenic organisms were met with public outrage, and led to the instalment of a Royal Commission of Inquiry into Genetic Modification and a subsequent report (Royal Commission on Genetic Modification 2001). With over 10,000 public submissions considered, this backlash led to no genetically modified crops being grown in New Zealand. Concerted political and social movements have maintained this situation; even field trials of crops that are transgenic/cisgenic or gene-edited have seen little activity. Social sentiment appears to be that remaining GM-free helps New Zealand's image as a premium destination for tourism and as supplier of high-quality food. However, this is not supported by studies. Very negative sentiment towards GM in European markets influences food industry buyers in those states. However, this study found no evidence that if New Zealand had GM crops, a country that New Zealand was exporting to would have a negative perception of non-GM food imported from that country (Knight et al. 2005a). In addition, a survey of visitors to New Zealand found no evidence that the country's image as a premium tourist destination would be harmed if GM crops were present (Knight et al. 2013).

As far as can be ascertained, a public debate on the differences between transgenics and cisgenics in Australia or New Zealand has not occurred. The definition of both as GMOs seems to have become solidified, and the public appears more fixated on this label, than on distinctions between the two.

Māori have been significant contributors to the debates on GM in New Zealand and have insisted on specific recognition of their values when making decisions on GM organisms (Cram et al. 2000; Environmental Protection Authority 2016). Māori have been considered to be positioned as more anti-GM than the general population (Gardiner 1997; Cram et al. 2000; Hudson et al. 2019). However, positive decisions appear to be possible if there is a clear cultural or environmental benefit, in particular to a local community (Roberts and Fairweather, 2004; Smith et al. 2013). Core cultural values have been analysed, which if these values were enhanced by gene editing (or gene technologies in general) would allow a more favourable decision. Such values include ancestry (whakapapa) and guardianship (kaitiakitanga). A more dynamic approach to specific uses or types of uses could then be approved on a case-by-case basis (Hudson et al. 2019).

Japan

In the mid-1990s, controversy erupted in Japan over foods derived from GM crops (Yamaguchi and Suda 2010), with the media emphasizing the unknown risks of GM foods (Shineha et al. 2008). The most pressing concern initially was the fear, expressed by consumer groups, that GM crops would enter Japan's food and feed supply chains—a fear that was not unfounded, as Japan is heavily reliant on the US for its grain supplies. In 2019, 100 per cent of Japan's corn supply and 94 per cent of its soybean supply was imported, the vast majority from the US and likely to derive from genetically engineered crops, though there are no official statistics available (USDA 2020). The International Service for the Acquisition of Agri-biotech Applications also indicates that Japan is the world's largest per capita importer of food and feed produced using modern biotechnology (ISAAA 2017). These facts present Japan with something of a contradiction: Although societal rejection of transgenic crops was powerful enough to dissuade Japanese seed makers from investing in them (Tano 2015), Japan has nevertheless been forced to rely on imports of genetically modified crops.

The position of GM food in Japan is thus complex, and there are often inconsistencies and contradictions between people's self-reported attitudes in the surveys and actual practice. Studies further suggest that a spectrum of attitudes exists towards food derived from GM crops and that the public's attitudes have changed over the course of the last two decades. Using a focus group discussion method, Nagata et al. (2006) found that research participants expressed concerns about the use of GMOs in food due to fears of interfering with nature. Comparing data from surveys conducted in 1997 and 2000, Macer and Ng (2000) suggest that their respondents hold increasingly negative views towards the application of GM in agriculture; in particular, the perception of GM crops as risky had increased in 2000 as compared with the 1997 data. Their analysis suggested that although the majority of people were optimistic about the use of biotechnology for various purposes, when it came to the use of biotechnology for agriculture and food, some people had become cautious, and that such attitudes intensified during the years in which social controversy over these issues was intense, from the mid-1990s to the year 2000.

More recent data, however, show a trend in the opposite direction. Japan's Food Safety Commission of Japan (FSCJ), mandated to carry out risk assessments concerning food safety issues, conducts annual monitoring surveys that include questions related to GM food. The reports by FSCJ suggest that approximately 75% of respondents felt "highly concerned" or "concerned" about GE foods in 2004, while approximately 40% chose the same categories in 2019, suggesting that the public's concerns about transgenic crops are to some extent abating (Food Safety Commission of Japan 2020). Further studies are required, however, a decrease in number could mean that the public are less concerned with transgenic crops because they become more concerned with other types of food safety risks.

There are no studies comparing public attitudes to cisgenics and transgenics in Japan. This is due in part to the fact that research and development of food using cisgenics are not taking place in Japan as widely as in Europe (correspondence with a plant scientist, spring 2021), and in part to the fact that the advent of gene editing technologies drew more societal attention in Japan than cisgenic plants (Ministry of Health, Labour and Welfare 2021). However, there are studies that compare attitudes towards transgenics and other types of breeding technologies, and we will look at them in turn with the goal of gaining some insights into how social acceptance might differ between transgenics and cisgenic breeding technologies. Kato-Nitta et al. (2019) studied expert and public attitudes towards the application of gene editing to agricultural crops compared with attitudes towards transgenic crops and crops developed by the use of conventional breeding technologies, and found that although the lay public tended to have more favourable attitudes towards gene editing than towards genetic modification, such differences were much smaller than the differences between attitudes towards conventional breeding and genetic modification. Looking more closely into the ways in which consumers perceive various types of breeding technologies, Otsuka (2021) examines the correlation between the perceived naturalness and safety of various breeding technologies. In this survey, consumers were asked to rank scores for foods derived from crops developed by five breeding technologies: epigenome editing, genome editing, genetic modification, mutagenesis by chemicals or irradiation, and crossing as conventional breeding. With regard to the perception of safety, conventional breeding was seen as the safest, followed by mutagenesis, epigenome editing, and genome editing; genetic modification was the last. This study suggests that consumers perceive gene-edited crops as less natural, and more similar to GMOs, than those with mutagenesis achieved by chemicals or irradiation.

3.3 Consumer Acceptability of Cisgenic Plants

Consumer acceptability can be defined as a subset, or as one of several constitutive elements, of market acceptability as described in Sect. 3.1. In consumer acceptability, the object of acceptability is a technological product that can be purchased by a consumer (the subject of acceptability) on the market. In the case of cisgenic plants, the type of products addressed in studies on consumer acceptability is basically always food. Methods to measure consumer acceptability include the willingness-to-pay (WTP) and the willingness-to-consume (WTC). Initially developed as a way to support pricing decisions in marketing, willingness-to-pay (WTP) and willingness-to-consume (WTC) became used as indicators of the consumer acceptability of a real or hypothetical product. Study participants are offered a set of product descriptions and invited to either, in a direct survey, state the price they would pay for it or, in an indirect survey, rank a series of product-price-bundles according to their individual preferences (Breidert et al. 2006). This section explores whether there are indications that consumers in the selected regions might differentiate between food products derived from cisgenic plants and products derived from plants that have been created by other means.

Key factors that shape consumers' actions are awareness and knowledge. That such knowledge cannot be assumed has been taken to be a major hindrance to the consumer acceptability of cisgenic plants (Ishii and Araki 2016). However, as discussed above, it has been disputed whether beyond the mere awareness that a difference exists between cisgenic and other forms of plant breeding, to what extent knowledge is important (Connor and Siegrist 2010; Fernbach et al. 2019; Siegrist and Hartmann 2020). In studies on the consumer acceptability of cisgenic plants, prior knowledge about the difference between cisgenesis and other breeding techniques introduces a methodological difficulty, requiring such studies to introduce their participants to the very difference they would like to assess. Therefore, when discussing various studies indicating the extent to which the techniques of plant breeding cause differences in consumer acceptability, we also report how the techniques were presented in the research instrument (e.g., the questionnaire) and whether measures were taken to assess or control the degree to which the measured differentiation on behalf of the consumer was indeed an artefact of the difference introduced by the instrument.

Earlier studies on consumer acceptability consistently found a lower WTP for GM food, indicating that consumers would pay extra in order to avoid GM food and instead receive a "conventional" product (see Costa-Font et al. 2008, for an overview). Similarly, studies found that consumers tended to rank gene-edited (GE) food higher than GM food, but still lower than "conventional" food (e.g., An et al. 2019; Muringai et al. 2020; Siegrist and Hartmann 2020). However, a study carried out in Germany that used questionnaires interspersed with focus group discussion found that people were more open to purchasing GM food than GE food (Bundesinstitut für Risikobewertung 2017). Most of the relevant studies on cisgenic food thus hypothesized that the situation for the trias conventional—cisgenic—transgenic was similar to the trias conventional—GE—GM (Haller 2009; Marette et al. 2021).

The European Union

This hypothesized preference order

conventional—cisgenic—transgenic

was confirmed in several studies carried out in European countries. In a study directly assessing the WTP for cisgenic rice across five European countries, Delwaide et al. (2015) found significant discrimination effects between GM and cisgenic crops. The countries covered were Belgium (N = 500), France (N = 750), the Netherlands (N = 602), Spain (N = 399), and the United Kingdom (N = 751; N_{total} = 3002). Participants were interrogated via an online questionnaire, and the WTP item was constructed in such a way that it assessed in the first round how much more money people would be willing to spend when purchasing 2.25 kg of traditional rice instead of 2.25 kg of either a GM variant, a cisgenic variant, or a variant with clear environmental benefits. No specific information was provided to the study participants to describe the GM variant. The plant variety with environmental benefits emphasized the lower amount of Greenhouse Gas emission due to disease resistance:

> New breeding techniques can result in a rice variety that is resistant to rice blast disease and that would not require fungicide sprays. Rice blast is a disease that decreases yields and increases Greenhouse Gas emissions because of the fungicide sprays that are required to treat the disease. […] (Delwaide et al. 2015:6)

As regards the cisgenic variant, the description reads:

> Cisgenic rice is bred using a process in which genes are transferred between crossable organisms (the same species or closely related species). The same result could be obtained by cross-breeding that occurs in nature or by traditional breeding methods but it would require a longer time frame. (Delwaide et al. 2015:6)

Table 3.2 Results from a 2015 study on cisgenic rice*

	Willingness to pay extra to avoid		Difference		Willingness to consume: Yes	
Country	GM rice	Cisgenic rice	Absolute	Relative	GM rice (%)	Cisgenic rice (%)
Belgium	€10.68	€3.05	€7.63	−71.4%	38	38
Netherlands	€16.02	€9.20	€6.82	−42.6%	32	30
Spain	€16.97	€15.00	€1.97	−11.6%	46	52
United Kingdom	€18.46	€10.78	€7.68	−41.6%	47	46
France	€29.83	€14.11	€15.87	−53.2%	23	27

Source Delwaide et al. (2015:8); own calculations

In later rounds, the three alternative options were coupled.

In interpreting the results, it should again be emphasized that in this study, the WTP was used as an indicator of consumer acceptability, not as a means of price estimation.[1] On average, the amount to be paid in order to avoid GM rice was €10.68 for consumers in Belgium, €16.02 for consumers in the Netherlands, €16.97 for consumers in Spain, €18.46 for consumers in the UK, and €29.83 for consumers in France (Delwaide et al. 2015:10). However, these differences were lower when cisgenic rice was the alternative product. Here, the price to be paid extra to avoid a cisgenic rice variant was €3.05 in Belgium, €9.20 in the Netherlands, €15 in Spain, €10.78 in the United Kingdom, and €14.11 in France (see Table 3.2). With the exception of Spain, the differences between the GM and the cisgenic variants are statistically significant at the 1% level.

Apart from the WTP, the questionnaire also asked for the willingness to consume (WTC) GM or cisgenic food. It turned out that across the countries covered, consumers did not differentiate significantly between the two alternatives. The willingness to consume cisgenic food was at 38% (36% for GM) for the complete sample ($N = 3002$), with the country figures ranging from 27% (23% for GM) in France to 52% in Spain (47% for GM in the UK). However, in all countries covered, the largest share of respondents said they had not enough information to give a definite answer. For the complete sample, this applied to 49% (46%) of the respondents (Delwaide et al. 2015:9). As mentioned above, thus, it appears quite likely that a considerable share of the respondents learned about the distinction between trans- and cisgenesis only in the survey instrument. This underscores the hypothetical, indicatory character of WTP/WTC results.

Interpreting these figures, one has to have in mind what has been said in Sect. 3.2 on the heterogeneous public perception across European countries. It is thus not surprising

[1] Also, the authors used a fixed scale in the questionnaire—the multiple price list (MPL)—with the highest option being at €50; further, the questionnaire did not include an "I would not purchase at all" option, so people rejecting the alternatives altogether presumably felt compelled to select the €50 option (Delwaide et al. 2015:5).

to see for instance that consumers in France are willing to pay much more than consumers in other European countries in order to avoid GM food. France is among those countries where a negative attitude towards GMO food is widespread. It is however surprising that consumers in France differentiate stronger between GM and cisgenic plants than in any other country covered. Their WTP for avoiding the cisgenic variant is even slightly below those of the Spanish respondents. That, in turn, is a surprise also on its own, given that Spain is one of those countries where the public perception has traditionally and consistently been very favourable to GM plants. In this study, Spanish consumers also have been those who differentiated the least between GM and cisgenic rice. Further, while the acceptability of cisgenic rice among the French respondents is decisively higher than it is for GM rice, the willingness to consume this rice is still low. Shew et al. (2018) also report findings from Belgium and France which corroborate the results by Delwaide et al. (2015).

Environmental benefits. There are, however, indications that the reluctance to purchase cisgenic food can change and that consumers are ready to consider other arguments in their purchasing decisions. In said study, the coupling of cisgenesis with environmental benefits (and with GM) led to an increase in acceptability as measured via WTP. The results were especially explicit for France, where consumers even stated to prefer a cisgenic variant with clear environmental benefits over the traditional variant, suggesting that cisgenesis would be accepted by consumers if it had clear and proven environmental benefits.

This suggestion was confirmed in a study assessing the consumer acceptability of cisgenic food in Denmark. Denmark is an interesting case, since it is among those countries in Europe where a considerable market for organic food exists (cf. Edenbrandt et al. 2017:123). Comparing bread from traditional bread rye with transgenic, cisgenic, and organic variants, the study found a consumer's preference order as below (Edenbrandt 2018; Edenbrandt et al. 2017):

organic—cis- or transgenic + env. benefits—conventional—cisgenic—transgenic.

Here again, the environmental benefit was pesticide-free crop cultivation. A study carried out with Indian rice consumers found a similar preference order defining fungicide-free cultivation as the environmental benefit (Shew et al. 2016; for further remarks on India, see Basnal and Gruère 2015). However, compared to more immediate consumer benefits, like better taste, nutritional quality, or increased health benefits, the appreciation of environmental benefits presupposes consumers with a low time preference (De Marchi et al. 2020).

Origin of food or ingredients. A series of studies in European countries suggested that consumer acceptance of cisgenic food depended on the country of production, with consumers preferring their own countries over others. This would be very much in line with studies on the consumer acceptance of GE food (Norwegian Biotechnology Advisory Board 2020). The effect of the country of origin has been assessed in studies of consumers in Denmark (Edenbrandt 2018; Edenbrandt et al. 2017) and Italy (De Marchi et al. 2019), yet not in methodological designs that informed about how this would play out in terms of the preference order. In light of earlier mode conceptualizations of consumer acceptance (e.g., by Costa-Font et al. 2008), this can be interpreted as a dimension of trust. Despite EU-wide regulations, consumers still have a higher trust in domestic, i.e., national food products than in products imported from the other Member States.

North America

Studies in North America show that despite the differences in statutory regulation, the preference order of consumers is similar to those found in European countries. Consumers are willing to pay extra to avoid cisgenic food—yet, given the choice, they prefer cisgenic over transgenic food. This was confirmed in a study that assessed the consumer acceptance of two sorts of grapes, table and muscadine grapes (Edenbrandt et al. 2018). Using the WTP as an indicator of consumer acceptability, the study design started with a short description of cisgenesis and later added a more extensive one (below in italics):

> The development of new plant varieties by inserting genes only from the same species or sexually-compatible relatives into a plant to add desirable traits.
>
> *For example, taking a disease resistance gene from a wild grapevine and transferring it into a cultivated variety of grape. This approach is similar to breeding in that only genes from sexually-compatible species are used. However, it differs from breeding in that only one or a few traits are transferred, resulting in greatly enhanced predictability of results in less time.* (Edenbrandt et al. 2018:51)

The study found that the WTP ranged from -\$0.12 to -\$0.33 for a pound of cisgenic grapes and from -\$0.61 to -\$0.84 for a pound of transgenic grapes. The effect of the longer descriptions was partly statistically significant and in favour of the technology, but never really big.

<u>Consumer benefits:</u> However, the cited study also set out to assess the effect of a specific consumer benefit on the acceptability of cisgenic food. It could show that US consumers valued the trait of small or no seeds higher than the fruits' trans- or cisgenic character. The respondents declared to be willing to pay \$0.22 more for a pound of cisgenic Muscadine grapes with small seeds as compared to conventional ones, which have rather large seeds (Edenbrandt et al. 2018:50). Thus, while consumers in some countries are willing to accept cisgenesis (and sometimes even transgenesis) in exchange for rather indirect environmental benefits, the more direct consumer benefits also might lead to comparable results.

> cisgenic + cons. benefits—conventional—transgenic + cons. benefits—cisgenic—transgenic.

Australia and New Zealand

In Australia, a 2017 survey (Cormick and Mercer 2017) found that around 13% of the population was strongly opposed to GMOs, especially in food and agriculture. However, support for GMOs in this sector was around 38% conditional on the type of modification; there was more support for modifications that are perceived to be less radical. This included gene editing as being more likely to "improve our way of life in the future". Considering the challenges Australia faces with the climate crisis, it is interesting that GM plants which could be made more drought-resistant were thought of as “very valuable” by 43% of respondents. The report also suggested that there had been little change in awareness and understanding of GM issues and concerns, since previous surveys.

This is likely to be the case with NZ consumers, with acceptability varying according to the trait targeted and a guarantee of safety. However, in one New Zealand-based purchasing experiment (Mather et al. 2012), it was found that consumers do not necessarily act in the way they have indicated they will. People who indicated that they would not buy GM foods actually buy GM foods in real-life situations. If “organic” fruit has a higher price, while “GM fruit” is cheaper, this category became the most popular, or second most popular, choice. Approximately 27% of consumers were willing to purchase GM-labelled cherries when all fruit types were priced the same, while 60% would purchase GM-labelled fruit that were discounted (Knight et al. 2005b). All fruit in this study was actually non-GM, but labels were applied for the purpose of the study.

In a decision from the pan-Australia/New Zealand regulatory authority, FSANZ, food derived from “Golden Rice” (Provitamin A rice line GR2E) can now be sold in both Australia and New Zealand (Food Standards Australia New Zealand 2017). Their study on the safety of this transgenic grain concluded that “food derived from provitamin A biofortified GR2E rice is as safe and nutritious as food derived from conventional rice varieties”. This decision proved contentious with several groups threatening further legal action.

Japan

Unlike the situation with regards to the EU, there are no studies that specifically examine consumer acceptability of cisgenic plants in Japan; however, one can gain insights into how consumer acceptability of cisgenic plants may compare with that of transgenics plants by looking into how consumers responded to transgenic crops and gene-edited crops. The assumption here is that consumer reaction to the latter (gene-edited crops) will be somewhat similar to attitudes towards cisgenic plants.

Using a framework that relies on consumer willingness to pay (WTP) for genetically modified foods, Chern and Rickertsen (2001) compared consumers in Japan, Norway, Taiwan, and the U.S. They found that American consumers are more willing to consume GM foods than their Japanese, Norwegian, and Taiwanese counterparts. Similarly using a comparative framework and studying the perception of food safety issues in the US (Seattle) and Japan (Kobe), Jussaume and Judson (1992) suggested that residents of Kobe are significantly more concerned about food safety than residents of Seattle. Looking at consumers’ responses to genetically modified food by reviewing and comparing surveys in Japan, Germany, India, and Australia, Masaki and Sassa (2009) indicate that consumers in Japan and Germany tended to be more cautious about genetically modified food than those in India and Australia, who are influenced by varying economic and industrial structures as well as the climatic conditions of each of these countries (on India, see also Kumar and Mallick 2021). Indeed, other studies also point out the roles that contextual factors and individual attributes play in determining consumer acceptability. Studying factors which influence Japanese consumers to choose GM foods, McCluskey et al. (2003)

further suggested that in order to increase the willingness to accept compensation for choosing GM foods among members of consumer cooperatives who have higher self-reported knowledge about biotechnology, self-reported risk perceptions towards GM foods, income, and education, a greater discount is required.

To summarize: existing studies suggest in comparative terms that consumers in Japan tend to exhibit a more cautious stance towards genetically modified food than consumers in the other countries studied, and that these attitudes are shaped in part by respondents' individual attributes, such as their household situation, whether they have children, their income, and other socio-economic variables. At the same time, it is important to note that these types of concerns, particularly with regard to genetically modified foods, are strongly influenced by the activities of consumer and environmental movements which have mobilized people to generate societal debates about genetically modified foods (Jussaume et al. 2001). These studies suggest that Japanese consumers may take a more cautious approach to gene editing technologies (or cisgenics) than consumers in other countries. Because consumer acceptance of a particular breeding technology is affected by both individuals' attributes and the social context within which gene editing technologies (or cisgenics) will be embedded, it is to be expected that consumers in Japan will differ from those in other countries with respect to whether and how they will accept or reject a particular breeding technology.

Surveys about consumer attitudes towards gene editing foods are only beginning to emerge, and thus it is not possible to make any conclusive statements about how consumers would respond to gene edited foods, especially those that are not subject to regulatory evaluation and are thus unlike genetically modified foods, which are subject to regulation. However, one can at least see some signs of how gene edited food would be perceived. A report published by the National Institute of Science and Technology Policy compared consumer attitudes to various technologies such as hydrogen energy, the use of robots, autonomous cars, etc.; it indicates that consumer responses to gene edited foods are somewhat similar to responses to genetically modified food (Hosotsubo et al. 2020). Similarly, Ishii (2017) speculates that gene edited food and genetically modified food are "bracketed" in the same food category, and that a segment of consumers respond to these two technologies in a similar way and might reject the use of gene edited foods. On the other hand, in a study of WTP for apples altered by the use of agroinfiltration, Saito et al. (2017) point out that although consumers will pay a slightly lower price for agroinfiltrated apples, providing information about the ecological benefits of planting those apples will cause some consumers to change their attitudes and express wiliness to pay more for agroinfiltrated apples. As suggested earlier, contextual factors are quite important in trying to understand consumer acceptability of a breeding technology. In Japan, there are early signs of consumer movements in which people voice demands for regulation of the cultivation of all gene edited crops, as well as safety reviews and labelling of all gene edited foods so that consumers can make informed choices (Mainichi 2018), but the influence (if any) of such movements on the social acceptability of gene edited foods has yet to be observed.

3.4 Legal Regulation

An important factor for the regulatory scoping of cisgenic plants is a clear definition of cisgenesis and a clear differentiation between cisgenesis, intragenesis, and allelic-swap (see also chapter "The Origin of Cisgenesis, and Its Evolving Definition").

So far, working definitions for these categories seem to have been proposed for the EU context only.

Already in 2012, the European Food Safety Authority (EFSA) proposed an official definition of cisgenesis and intragenesis. The other jurisdictions covered in this chapter have not published comparable official definitions.

The EFSA defined intragenesis as "a genetic modification of a recipient organism that leads to a combination of different gene fragments from donor organism(s) of the same or a sexually compatible species as the recipient. These may be arranged in a sense or antisense orientation compared to their orientation in the donor organism. Intragenesis involves the insertion of a reorganised, full or partial coding region of a gene frequently combined with another promoter and/or terminator from a gene of the same species or a crossable species."

The definition for cisgenesis reads as followed: "…the genetic modification of a recipient organism with a gene from a crossable—sexually compatible—organism (same species or closely related species). This gene includes its introns and is flanked by its native promoter and terminator in the normal sense orientation. Cisgenic plants can harbour one or more cisgenes, but they do not contain any parts of transgenes or inserted foreign sequences. To produce cisgenic plants any suitable technique used for production of transgenic organisms may be used. Genes must be isolated, cloned or synthesized and transferred back into a recipient where stably integrated and expressed." (EFSA 2012: 5).

This definition clearly marks two points: (i) a cisgene does not contain any parts of transgene or foreign sequence; (ii) the techniques to produce a cisgenic plant are the same as for a transgenic plant, with the genes/nucleic acid being produced outside an organism.

Cis- and intragenesis make both use of techniques used for transgenesis, e.g., *Agrobacterium* mediated or biolistic transfer; these techniques lead to a random integration of the genetic elements into the genome with all its consequences such as gene disruption, formation of new open reading frames, and others. In contrast to this, the use of side directed nuclease technology such as CRISPR-Cas allows the introduction of a cisgene of a donor organism in exactly the same spot of a recipient. These so-called "allelic-swaps" are a special case of cisgenesis and have to be seen as such. An allelic-swap contains nucleic acids which have been prepared outside an organism, but the origin of the allele is a crossable species and no new genetic element is introduced into the recipient. Therefore, the outcome is also possible to achieve by the means of conventional breeding. That's why these allelic-swaps are the main point of discussion when it comes to regulation of genome edited organisms. The legal situation of cisgenic plants is not globally harmonized and differs between countries.

The European Union

In the European Union, GM plants and derived food/feed products require a risk assessment and authorization before marketing as specified in statutory EU legislation (Directive 2001/18/EC or Regulation 1829/2003). According to this legislation and as specified by a recent ruling of the Court of Justice of the European Union, all organisms, "*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*", are considered GMOs (Directive 2001/18/EC, Art. 2). Mutagenesis is considered to result in a GMO, but these organisms are exempted from regulation (ibid: Directive 2001/18/EC; Annex IB,). Risk assessment is done by the European Food Safety Authority (EFSA) together with Member States' national Competent Authorities. Authorization for marketing or cultivation requires a majority vote of EU Member States. Different view across Member States and recently established legal option for national/regional bans for cultivation have, however, effectively blocked commercial cultivation of GM crops (one event authorized and cultivated on ca. 100,000 hectares in two Member States only).

In 2006, a *Nature Biotechnology* paper by Jacobsen and Schouten triggered a debate in the EU whether cisgenic plants should still fall under the strict jurisdiction of the Directive 2001/18/EC especially when transformation has been made without any selection marker. Already then, they proposed to add cisgenesis to the Annex 1B of the Directive 2001/18/EC which defines techniques/methods of genetic modification which are excluded from the Directive. In 2008, they also addressed theoretical drawbacks and limitations of cisgenesis showing less hazards associated with cisgenesis compared to transgenesis (Schouten et al 2006; Jacobsen and Schouten, 2008; see also chapter "Cisgenesis: Enabling an Innovative Green Agriculture by Deploying Genes from the Breeders' Gene Pool"). In 2012, an EU level Expert Group on NBPTs concluded that cisgenic and intragenic fell under the harmonized EU legislation. In the same year, the EFSA stated that the hazard of cisgenic organisms is comparable to their conventionally counterparts, while novel hazards may arise from intragenic plants. The EFSA GMO panel stated further that the general approach and all elements in the guidance for risk assessment of food and feed as well as the guidance on environmental risk assessment of GM plants are applicable and do not have to be developed further for cisgenesis. But it might be that on a case-by-case basis lesser, amounts of event-specific data are necessary (European Parliament 2020).

Since then, the debate in Europe is ongoing. There are still different views across Member States about the risk status of cisgenic crops, especially on allelic-swaps, which has not been addressed by EFSA so far. Especially, detection and identification of such events will be challenging if not impossible making an enforcement of the law almost impossible (Grohmann et al. 2019).

For the time being, cisgenesis, intragenesis, and allelic-swaps are regulated the same way as transgenesis which all its objections under the Directive 2001/18/EC just like their transgenic pendants due to the use of transgene technologies, e.g., transformation vectors which fulfil the obligations of Annex 1(A) of the Directive 2001/18 (see also chapter "Cisgenesis: An European Union (EU) Perspective"). However, at the time of writing this chapter (29 April 2021), the European Commission published a study regarding the status of New Genomic Techniques under Union law. This study concluded that the extant regulations are not fit for the purpose of some NPBTs, and they suggested entering a political process of revising them, with, important to the context of this book, an explicit mention of cisgenesis (and targeted mutagenesis). Also, in accompanying media statements, representatives of the European Commission underlined the possible contribution of NPBTs as one potential means in the structural transformation towards a more sustainable European agriculture, and called for an open dialogue with citizens, Member States, and the European parliament. It is therefore quite likely that there will be a general increase in public awareness of cisgenesis within the EU.

North America

In Canada, plants are not regulated solely based on the method with which they have been developed, but on the novelty of the trait (different from what is already available in Canada) they have obtained. In this case, it does not matter whether the trait has been introduced via biotechnology (e.g., transgenesis or genome editing) or via conventional breeding. Pre-market risk assessments are conducted by the Canadian Food Inspection Agency (CFIA) and Health Canada. As of 2018, 78 events were approved for commercial cultivation, grown on ca. 11 million hectares (Hamburger 2019).

Cisgenic plants in most cases are not in the scope of the Canadian legislation as the trait is already inherent in the population of the species and therefore is not considered novel. In some cases, most likely resulting from intragenesis, a trait might be considered as novel. There is no definition of novelty as all products are being evaluated on a case-by-cases basis, but a change of ~ 20% in the characteristics of a trait is considered as novel in many cases (Menz et al. 2020). Due to this, a general statement on the legal regulation of cisgenic plants in Canada cannot be made (see also chapter "Social Concerns and Regulation of Cisgenic Crops in North America").

In the United States of America, plants developed with biotechnology are regulated under the Coordinated Framework for the Regulation of Biotechnology (CFR). Three agencies oversee the use of biotechnology, namely USDA APHIS (United States Department of Agriculture, Animal and Plant Health Inspection Services), FDA (Food and Drug Administration), and the EPA (Environmental Protection Agency). APHIS regulates importation, interstate movement, and environmental release of certain organisms developed using genetic engineering. While FDA evaluates plant-derived foods and feed products, EPA oversees products generating pesticides (e.g., Bt toxins) or food containing pesticide residues. USDA regulates plants containing foreign DNA from plant pests. Regulation by FDA is triggered by "pesticide chemical residues considered unsafe" and thereby also applies to plant-incorporated protectants, such as genes for Bt toxin (Hamburger 2019).

As of 2018, 123 events were authorized and cultivation was ongoing on ca. 73 million hectares (ibid.).

In 2020, USDA reiterated its statement not to regulate plants which could also have been obtained by conventional breeding (USDA APHIS 2020). Also, the FDA committed in the context of its Plant and Animal Biotechnology Innovation Action Plan to pursue advances in policy priorities in order to establish a science-and-risk-based approach for product developers and to remove barriers to future innovation in plant and animal biotechnology. In 2019, these guidelines have been implemented into the new SECURE (Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient) rule which comes into place in 2021. The SECURE rule exempts categories of products developed through biotechnology under most conditions from obligations under §7 CFR part 340 when changes in the plant genome are "solely introductions from sequences derived from the plant's natural gene pool or edits from sequences which are known to correspond in the plant's natural gene pool." This leads to an exemption of cisgenic plants from the regulation. However, the degree to which the procedures defined in the SECURE rule will promote justified public trust is a matter of contention (Wolf 2021).

Australia and New Zealand

New Zealand and Australia have both chosen to regulate GM and GMOs in a process-based fashion (Ishii and Araki 2017). Even though these countries share process-based regulations, the outcomes have been very different. Australia had over 700,000 hectares under GM cultivation in 2015, while no GM crops were, or are, being grown in New Zealand.

In New Zealand, the definition and regulation of GM have been provided for by the HSNO Act of 1996 (HSNO 1996). The Act defines that if DNA changes are made "in vitro", then this triggers regulation under HSNO Act. The Act has been the primary means of regulating for over 20 years with little amendment. Some local councils (regional and city authorities) have further sort to regulate GM without really defining the term. The Royal Society of NZ Te Apārangi has suggested the Act is no longer fit for purpose (Royal Society Te Apārangi 2019; Everett-Hincks and Henaghan 2019), as it fails to take into account new techniques (such as CRISPR-Cas9) which could alter DNA not "in vitro".

Minor amendments to the regulations associated with the HSNO Act (1996) have been made. In 2016, one regulation was amended after the High Court overruled the Environmental Protection Authority (EPA) decision, and in 2014, transgene-free plans produced via NHEJ genome editing could be deregulated (Ishii and Araki, 2016). The amendment meant that genetic technologies could be exempt from regulation, such as chemical and irradiation mutagenesis, but only if they were in use before July 1998. Therefore, NHEJ genome editing and CRISPR-Cas9 technology (being developed after July 1998) are still regulated as GM under the Act. Cisgenics remains a technique that is regulated as a GMO, due to its development "in vitro". The approach of having a date stamp on what is an acceptable technique (in common use before 1998) and what is regulated as GMO because it is "newer" has been criticized.

Importantly, several other large pieces of legislation have to be considered in the New Zealand regulatory framework when developing or even suggesting implementing a GM organism. These include Acts covering human tissues, animal ethics, biosecurity, conservation, and resource management. Terminology and definitions are not consistent across these Acts.

In addition, food safety is regulated by another body—Food Standards Australia New Zealand (FSANZ). This body makes decisions on food safety for both Australia and New Zealand (Heinemann et al. 2020), leading to the ambiguous situation where a plant, not regulated in Australia but which would be in New Zealand, could be made into food not regulated in either country. Half of New Zealand's domestic food supply is imported, while it is also a major food exporter. This lack of clarity may have implications for both imports and exports.

In Australia, the regulatory framework is quite different (apart from the previously mentioned group, FSANZ). An independent regulator—Office of the Gene Technology Regulator (OGTR)—is appointed by the Governor-General with the agreement of the Federal and State Governments. This body is responsible for administering the Gene Technology Act 2000 and the Gene Technology Regulations 2001 (Office of the Gene Technology Regulator 2020a). It considers new organisms that have resulted from DNA manipulation techniques. This body has accepted applications for the release of GM crops, on the basis of its responsibility to protect the health and safety of people, the environment, and manage the risks of GMOs (Robold and Mitchell 2020). During this time (since 2000), several State Governments have instigated bans or moratoria on GM technologies, which have been reversed in several cases.

A technical review of the Australian Gene Technology Regulations (2001) was begun in 2016 (Office of the Gene Technology Regulator 2018). This was in order to take into account new developments in GM technologies, which can produce organisms where it is not clear whether they are GMO or not. It was proposed, and accepted by the Government, that gene editing events which do not introduce "templates" (e.g., plasmid sequence, transgenes, and cisgenes) are not regulated as GMOs. Also, organisms modified by introduced RNA to block gene expression (RNAi) are not defined as GMOs, provided the RNA does not change the genome sequence. Cisgenic plants are likely to be regulated, as they have introduced "templates" even though these may be part of the organism's own DNA. These amendments (Office of the Gene Technology Regulator 2020b) were made by 2020, but it is not yet apparent what effect these changes have had on releases or applications.

Japan

In Japan, the commercialization of transgenic crops and food products requires specific approvals under the existing food, feed, and environmental regulations. Four ministries are involved in the regulatory framework: the Ministry of Agriculture, Forestry and Fisheries (MAFF); the Ministry of Health, Labor and Welfare (MHLW); The Ministry of Environment (MOE); and the Ministry of Education, Culture, Sports, Science and Technology (MEXT). Food and feed safety risk assessments for MHLW and MAFF are carried out by the Food Safety Commission (FSC), an independent risk assessment body. When it ratified the Cartagena Protocol on Biosafety to the Convention on Biological Diversity in 2003, Japan adopted the "Act Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms" also called the "Cartagena Act" (Ministry of Justice, 2003). The Act in Article 2 (2) defines LMO as

> …an organism that possesses nucleic acid, or a replicated product thereof, obtained through use of the any of the following technologies: (i) Those technologies as stipulated in the ordinance of the competent ministries, for the processing of nucleic acid extracellularly (ii) Those technologies, as stipulated in the ordinance of the competent ministries, for fusing the cells of organisms belonging to different taxonomical families.

Some local governments established local ordinances at the prefectural level that restrict commercial plantings of genetically modified crops. These multiple layers of statutory requirements suggest that Japan takes a "precautionary" stance on the commercial planting of gene-modified plants (Law Library of Congress 2014).

On February 8, 2019 (Notification No. 1902081), following up on guidance given by the Central Environment Council, an advisory body to the Ministry of the Environment, notifications were sent to the government ministries to indicate how gene edited food is to be regulated. The notification sent to MAFF indicates:

> …(i) any organisms that has inserted extracellularly processed nucleic acid (including RNA) is regarded as a living modified organism (LMO), even those obtained by using genome editing technologies, and is subject to the regulations stipulated in the Cartagena Act, in principle, (ii) such organisms are subject to the Cartagena Act unless complete removal of the inserted nucleic acid (including RNA), or its replicated product, is confirmed, and (iii) when using organisms obtained through genome editing technologies, applicants are requested to submit information to the competent government agencies, even when the organisms are not subject to the Cartagena Protocol.

Based on these legal definitions, some gene edited crops such as foods derived from Site-Directed Nucleases 1 (SDN-1) are exempted from regulation. Though there are no specific mentions of food derived by cisgenics or intragenesis in the Act, when the final products do not contain extracellularly processed nucleic acid (null segregant), they are not subject to regulation. In other words, recombinant microorganisms obtained by using self-cloning or natural occurrences are exempt from regulation by the Cartagena Act. Similarly, the Food Sanitation Commission of Pharmaceutical Affairs and Food Sanitation Council published guidance on March 27, 2019, indicating that insertion of one to a few bases will not be regarded as LMOs.

Discussion of the regulation of New Plant Breeding Techniques (NPBTs) can be traced back to a report published by the Science Council of Japan in 2014, entitled "New Plant Breeding Techniques (NPBT): Current and Future Challenges." In this report, a range of plant breeding techniques such as cisgenesis, intragenesis, and agroinfiltration was introduced as promising technologies for breeding new plant varieties which would remain productive even under adverse and changing climatic conditions (Science Council of Japan 2014).

In 2018, the Japanese government issued a ruling that gene editing techniques that do not leave extracellularly processed nucleic acids such as SDN-1 will not be subjected to regulation. This policy is not an amendment of the regulatory framework but an authoritative interpretation of enforcement of the Cartagena Law with respect to genome edited plant varieties. Pursuant to that guidance, some of the genome edited crops are not considered to be LMOs and therefore are not subject to stricter regulation. Also excluded are processes using the nucleic acid of an organism belonging to the same species as that of the target organism or the nucleic acid of an organism belonging to a species that exchanges nucleic acid with the species of the target organism (Ministry of Agriculture, Forestry and Fisheries 2018). Hence, cisgenic and certain types of intragenic plants would be exempted from regulation.

Under this framework, those who use gene editing technologies are responsible for notifying the government of information such as the details of their production processes and any knowledge of their impact on biodiversity (Ishii 2019; Tsuda et al. 2019). The recommendations by the government have not yet addressed labelling requirements for gene-edited foods. Despite the authorization of 133 varieties, there has been no commercial cultivation of GM crops in Japan (Hamburger 2019), but gene-edited food products will go on sale in 2021.

3.5 Discussion and Conclusions

This chapter addressed the social acceptability of cisgenic plants and derived food/feed. It did so for a selected group of countries and especially focused on three aspects of social acceptability: public perception, consumer acceptability, and legal regulation. Comparisons were made between the European Union, Canada, the USA, Japan, Australia, and New Zealand. A comparative framework is useful for gaining insights into plant technologies that are emerging (only very few cisgenic plants have ever entered the food market) as well as into the heterogeneity in acceptability and regulation across different countries.

The countries studied represent two different social and regulatory contexts: one that is more enabling for biotechnology (North America and Australia), and one that is less enabling (European Union, Japan, and New Zealand). While comparative analysis provides valuable insights into phenomena and differences, it has some limitations. For instance, the EU as a comparator is a tricky case: Member States differ widely in terms of political, public, and consumer acceptability of GM crops, and derived food. At the moment, this internal split is reflected in EU legislation, which offers Member States the option to ban cultivation on their territory of GM crops legally authorized in the EU. The harmonized legal regulation is fully functional only with respect to GM food and feed. Given the reluctance of retailers in many EU Member States to have food labelled as GM on their shelves, a common market exists for GM feed only. This situation has led some stakeholders, in particular plant breeders and the biotechnology industry, but also some Member States, to express their dissatisfaction with the current regulation and lobby for change in legislation.

These difficulties of comparison notwithstanding, interesting insights and perspectives emerge from the juxtaposition of these countries. For instance, direct consumer benefits seem to be more important for consumers in the US and Canada than they are for consumers in Europe. In Europe, especially in countries that are heavily opposed to GMOs, arguments related to sustainability and the protection of the environment are more likely to have a positive impact on consumers' acceptability than any direct consumer benefit might have. While certainly it can be questioned how such choice experiment studies translate into real-life purchasing behaviour, there is a possibility that European consumers may accept cisgenic plants in their foods if they had a proven environmental benefit. In New Zealand, part of the public debate has centred on another topic, the negative impact that any cultivation of GMOs might have on trade and export (even of non-GM plants), as well as on the tourism industry. In Japan, consumers seem to be more concerned with food safety issues than issues related to the environmental effects of GMOs.

The comparison between Australia and New Zealand is also interesting. Both have followed process-based regulations on GM and gene editing, and both have an extensive shared history and historical relationships, but outcomes have varied considerably. Australia has considerable plantings of transgenic crops and de-regulation of certain categories of gene edits, while New Zealand has seen no GM plantings and has toughened its regulations (in existence since 1996) to include new developments in gene editing technologies in scope as GM organisms. In this context, it is also interesting to note that Australia has not signed the Cartagena Protocol, while New Zealand has.

All these trends have been studied with regard to GM in general, and some of them also addressed a possible differentiation between transgenic and cisgenic plants. However, data for the social acceptability of cisgenesis does not exist for all the countries covered in this chapter. We hypothesize that these blank spaces in empirical research are not accidental, but follow from the political/legal thrust that informed the introduction of the differentiation between transgenesis and cisgenesis. The promise of cisgenesis was to define a type of genetic modification that is perceived to be closer to traditional breeding. This promise is of course more attractive in contexts where the unnaturalness of GM plants is a major source of concern. Similarly, in countries that had a more enabling stance towards GM in biotechnology, the differentiation of trans- and cisgenesis might have had less traction.

The available data does not allow for a profound investigation of this hypothesis. Also, with the advent of gene editing (GE) soon after the introduction of the distinction between trans- and cisgenesis, the focus shifted and new narratives have emerged. Under the pressure of international trade, the legislative frameworks in several jurisdictions are presently in the process of being modified.

An emerging regulatory regime might also involve changes in the relationship between science and the public (Malyska et al. 2016; Wirz et al. 2020). In this new arrangement, the public might ascribe a different role to the scientists. "Although the importance to proactively engage in 'post-research' issues by researchers […] is emphasized and arguably contributes to the recognition of broader concerns, these are often phrased in the sense of 'educating' or 'informing' public, rather than listening and acting upon their concerns." (van Hove and Gillund 2017, 8). It is by measures that ensure (1) fairly and effective risk management, (2) the systematic uptake of scientific results, (3) truthfulness, (4) transparency, and (5) responsiveness to public input that decision-makers can create a regulatory regime that justifiably hopes to be publicly trusted (Wolf 2021). It will be up to the involved scientists—from all disciplinary branches—to find where and how they can constructively contribute to this process.

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