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Sustainability Council of New Zealand Trust v. The Environmental Protection Authority: Gene editing technologies and the law

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ABSTRACT. In May 2014, a New Zealand court rendered the first judicial opinion in the world about the legal classification of gene-editing techniques. The court ruled that ZFN-1 and TALEs are techniques of genetic modification and thus within the New Zealand statute and regulations governing genetically modified organisms. This article explains the facts of this legal matter, the reasoning of the court, and provides commentary about the implications of this decision for New Zealand and other jurisdictions around the world.

KEYWORDS. gene-editing techniques, legal classification, genetically-modified organisms, New Zealand

INTRODUCTION

On 20 May 2014, the High Court of New Zealand (Wellington Registry) rendered the first judicial opinion in the world about the legal classification of gene-editing techniques. The case name is *The Sustainability Council of New Zealand Trust against the Environmental Protection Authority* (The Sustainability Council of New Zealand Trust, 2014). The Wellington High Court, a trial court within the New Zealand judicial system, issued its judgment under the New Zealand Hazardous Substances and New Organisms Act of 1996 (HSNO) (Hazardous Substances and New Organisms Act of 1996, 1996). Moreover, this judgment has extra significance because neither party took an appeal from the High Court ruling. Thus, the judgment of the High Court is final, controlling and precedential within the New Zealand legal system. In light of this special issue of GM CROPS & FOOD on "Gene Editing for Crop Improvement," it is appropriate to report on this case and its implications for the use of gene-editing technologies.

BASIC FACTS

Under § 26 of HSNO, the Environmental Protection Authority (Authority) has the power, upon receipt of a petition, to determine whether or not an organism is a "new organism" for purposes of HSNO. In October 2012, Scion, the Crown Research Institute for forest resources, petitioned the Authority for a determination whether or not forest plants created by using Zinc-Finger Nuclease Type 1 (ZFN-1) and

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Transcription Activator-Like Effectors (TALEs) techniques were new organisms.[1]

In its petition, Scion argued that ZFN-1 and TALEs were equivalent techniques to genetic changes made in plants through chemical mutagenesis. Due to this claimed equivalence, Scion argued that ZFN-1 and TALEs were within the Authority's exemptions from HSNO, specifically within the exemption for "chemical or radiation treatments that cause changes in chromosome number or cause chromosome rearrangements."[2]

By considering the information provided by Scion and the Sustainability Council and by reading and interpreting HSNO and its implementing regulations, the Authority's staff recommended to the Authority's Section 26 Committee that such plants are new organisms and thus fully covered by the statute and regulations. In Section 2A of HSNO, the term "new organism" is specifically defined to include "a genetically modified organism."[3] The staff reached this decision by emphasizing the facts that both techniques are in vitro techniques and involve molecular biology. The Authority's staff concluded that plants created with ZFN-1 and TALEs would be considered genetically modified organisms.

The Authority's Committee considered the same information as the Authority's staff, plus the staff's recommendation, and concluded that the Scion-created plants would not be covered by the statute and regulations. The Committee agreed that plants created by these gene-editing techniques would be genetically modified organisms under HSNO. But the Committee decided that these plants would be exempt under the Regulations because the ZFN-1 and TALEs techniques are more similar to chemical mutagenesis than genetic modification. Under HSNO and its regulations, plants created through chemical mutagenesis are not genetically modified. Consequently, the Committee concluded that plants created using these 2 gene-editing techniques were not new organisms under HSNO or its regulations (Environmental Protection Authority, 2013).

The Sustainability Council of New Zealand Trust (Sustainability Council) appealed this Authority determination to the High Court of Wellington. It is the judgment of the High Court in response to this appeal that is the subject of this GM-in-the-Courts article.

HIGH COURT JUDGMENT

The High Court judge began the opinion by referring to and quoting from the underlying statute and regulation. The judge cited Sections 2 and 2A (definitions), Section 4 (purpose of the Act), Section 5 (principles relevant to purpose of Act), Section 6 (matters relevant to purpose of Act), and Section 7 (precautionary approach) as the substantive sections of HSNO most relevant to the legal dispute. The judge also cited and quoted HSNO Regulation Section 3 as the crucial regulatory provision because it sets forth the HSNO exemptions. More precisely, the judge decided that Regulation Section 3(1)(b) expressed the determinative language:

(1) For the purpose of the Act, the following organisms are not to be regarded as genetically modified . . . (b) organisms that are regenerated from organs, tissues, or cell culture, including those produced through selection and propagation of somaclonal variants, embryo rescue and cell fusion (including protoplast fusion or chemical or radiation treatments that cause changes in chromosome number or cause chromosome rearrangement): . . .."[4]

By selecting these specific statutory and regulatory sections, the judge properly narrowed the decision to deciding whether the Authority's staff (classifying gene-edited plants as genetically modified) or the Authority's Committee (classifying the gene-edited plants as chemical mutagens) made the correct legal interpretation.

With the legal issue narrowed, the judge proceeded to discuss the technologies themselves (The Sustainability Council of New Zealand Trust, 2014, para. 10–15). The judge specifically referred to 3 jurisdictions (the United States, Australia, and Germany) and one international working group that had determined that plants from the ZFN-1 technique were not genetically-modified organisms. Referring to these same jurisdictions and the working group,

the judge noted that their legal classification of plants from TALEs technology was less decisive and, therefore, much less clear (The Sustainability Council of New Zealand Trust, 2014, para. 16).

After describing the debate within the Authority between the staff and the Committee (The Sustainability Council of New Zealand Trust, 2014 para. 17–25), the judge turned attention to interpreting the statute and the regulation with respect to these 2 gene-editing techniques. The judge began by describing the competing interpretations of 2 experts, Professor Heinemann (for the Sustainability Council) and Dr. Dijkwel (for the Authority), as they gave their opinions about each of the techniques listed in Regulation Section 3(1)(b) (The Sustainability Council of New Zealand Trust, 2014, para. 26–55).

After having reviewed the expert testimony, the judge ultimately described the difference between the 2 expert opinions as follows:

> The difference between them is whether the specific techniques [listed in Regulation Section 3(1)(b)] are a closed list of techniques that are exempted, or whether they [the list] describe a category of the kind of techniques that are exempted (so that other techniques which are sufficiently scientifically similar to those techniques are also exempted)." (The Sustainability Council of New Zealand Trust, 2014, para. 57)

The High Court judge ruled that the exemption list is a closed list. The judge reached this conclusion based on a careful interpretation of the language of the Regulation itself and on the fact that HSNO and its regulations did not set forth any factors or weight of factors for the Authority to use in adding other techniques to the exemption list. The judge interpreted HSNO and the regulations as not implicitly giving the Authority discretionary power to add to the exemption list (The Sustainability Council of New Zealand Trust, 2014, para. 57–67). Hence, the judge ruled that the Authority could not expand the exemption list to include techniques similar to chemical mutagenesis.

The High Court judge buttressed the "closed list" interpretation by referring to 2 underlying principles that the judge highlighted as important to interpreting HSNO and its regulations. First, the judge emphasized that Section 4 and Section 7 of HSNO expressed the sovereign decision to be precautionary about adverse effects of new organisms and protective of the environment and the health and safety of the populace until scientific and technical uncertainty has been resolved (The Sustainability Council of New Zealand Trust, 2014, para. 68). Second, the judge noted that Parliament had provided for exemptions through the adoption of regulations "expressly" providing for exemptions. If the Authority could use its HSNO Section 26 power to add to the exemption list, the judge expressed concern that the Authority would be arrogating to itself authority that lies more appropriately through Parliamentary and Council approval of proposed regulations. In other words, the judge decided that adding to the exemption list is a political decision, not an administrative decision (The Sustainability Council of New Zealand Trust, 2014, para. 69).

Based on the language of the statute, the precautionary approach, and the allocation of power between political and administrative branches of government, the judge rendered the decision that the Authority erred in deciding that it could add the ZFN-1 and TALEs techniques to the exemption list. The judge quashed the Authority's decision of 19 April 2013 (The Sustainability Council of New Zealand Trust, 2014, para. 73–74).

IMPLICATIONS

From the author's perspective, the implications flowing from this High Court judgment can be discussed in 2 categories – legal implications and societal implications.

Legal Implications

New Zealand. Most obviously, the High Court judgment has legal implications for

New Zealand. In New Zealand, plants created by ZFN-1 and TALEs are now genetically modified organisms that come fully within HSNO and its implementing regulations. The consequences of this classification means that anyone or any entity doing plant research using these techniques will be required to comply with a very strict, costly, and time-consuming regulatory regime. Researchers using these techniques must get permission from the Environmental Protection Authority before engaging in any field trials or before any commercial release of the plants developed. If history is a worthwhile guide, getting permission will not be easy.

New Zealand has had a total of 57 outdoor experiments with genetically modified organisms (plants, animals, microorganisms) between 1988 and 2013. In 2013, there were 2 on-going outdoor experiments (field trials); 2 is the average number of outdoor experiments on-going from 1988 through 2013. Zero is the number of commercialised genetically-modified crops approved for growing by New Zealand farmers and ranchers (McGuinness Institute, 2013 at charts on pp. 6–7). In light of the High Court judgment about gene-editing techniques, New Zealand's slow pace with respect to field trials and commercial release of genetically-modified organisms will continue – at best.

The High Court judgment also means that, if New Zealand desires to change its slow pace regarding genetically-modified organisms, political decisions will have to be adopted amending either HSNO or it regulations. The Environmental Protection Authority no longer has the legal discretion to adopt newly emerging gene-editing techniques as outside the HSNO regime for genetically-modified organisms. Of course, the political decision is precisely that – a political decision, meaning that the Sustainability Council and its allies, such as the McGuinness Institute, will provide strong political opposition to any acceptance of gene-editing techniques. Indeed, the Sustainability Counsel and the McGuiness Institute recommend that New Zealand become a dedicated GM-free food and fiber producer nation (McGuinness Institute, 2013, p. 4; Terry, 2014).

European Union. While the New Zealand High Court judgment has no binding consequences for the European Union, the High Court judgment could have persuasive impact upon the European Union as it debates and decides how to classify gene-editing techniques within its legal regime for biotechnology.

While the precise language of the relevant European Directives and Regulations differs from the New Zealand HSNO statutory and regulatory language, there also appears to be striking similarities. The European Union too has a regulatory regime that classifies modern biological techniques of breeding as genetically modified breeding and then provides exemptions from that label for certain listed breeding techniques (such as mutagenesis) (European Union Directive, 2001[5]). In other words, the European Union could approach the legal classification of gene-editing techniques as the High Court of New Zealand did, meaning is the European exemption list a closed list or is it an open list to which similar breeding techniques can be added as exempt? Moreover, the European Union has emphasized that decisions about biotechnology are primarily political decisions – an attitude that the High Court of Wellington also adopted. For these reasons, the High Court's judgment could be persuasive to European decision-makers.

Of course, at this point in time, how the European Union will classify gene-editing techniques with regard to its biotechnology legal regime is unknown. Europe has commissioned several working groups to study the issue of classification for newer breeding techniques (European Commission, Directorate-General Environment, 2013; EFSA Panel on GMOs, 2012; Lusser et al., 2011). But there has been no authoritative decision from any European Union executive, legislative, or judicial entity. Until a competent authority within the European Union officially adopts a classificatory decision, the classification is unknown and surrounded by uncertainty.

The United States of America. The High Court of Wellington was correct that the United

States Department of Agriculture, through the Animal Plant Health Inspection Service (USDA-APHIS), has issued several letters indicating that plants created by ZFN-1 and TALEs are not within the USDA-APHIS regulatory regime for agricultural biotechnology. But one must remember that in the United States, the USDA-APHIS is just one of 3 federal administrative agencies that have regulatory authority over biotechnology – the other 2 being the US Environmental Protection Agency (US-EPA) and the Food and Drug Administration (FDA). Hence, plants created by ZFN-1 and TALES, in some instances, could be regulated by US-EPA and/or FDA. Thus, the legal classification of gene-editing techniques is not entirely clear in the United States (Wolt et al., 2015).

In the United States, the Office of Science and Technology Policy (OSTP) has initiated a review of the regulatory regime presently applied to agricultural biotechnology. In a memorandum to USDA-APHIS, US-EPA, and FDA, OSTP stated that "This memorandum initiates a process to modernize the Federal regulatory system for the products of biotechnology and to establish mechanisms for periodic updates of that system" (Office of Science and Technology Policy, 2015). OSTP set a goal that this modernization review be completed within one year from the date of the memorandum (July 2, 2015). In light of this regulatory review, the legal classification of gene-editing techniques and their regulatory status should be much clearer by August 2016. During this review process, it is very likely that the High Court judgment will become part of the debate and discussion about the regulatory regime that should apply to gene-editing techniques.

Societal Implications

Looking beyond the legal implications of the High Court's judgment, there can be no question that the judgement has significant societal implications for New Zealand directly and the world indirectly.

By subjecting gene-editing techniques to regulatory oversight under HSNO, the High Court judgment imposes very costly, time-consuming, paper-intensive, and strict barriers to the field testing and the commercial introduction of plants developed by these techniques. By so doing, plants coming from molecular breeding will be delayed and hampered from entering farmers' and ranchers' lands. Of course, the evaluation as to whether the slowing of technological innovation related to plant breeding is a good thing or a bad thing is at the heart of the societal discussion concerning agricultural biotechnology. The Sustainability Council obviously thinks that slowing technological innovation is a wise and good social policy because it will protect the environment and human health and safety (Terry, 2014). Just as obviously, Scion, the Crown Research Institute, considers the slowing of innovation as unwise and harmful because it hinders scientific responses to challenging environmental problems and undermines the health and well-being of New Zealand, so heavily dependent upon forest resources as an aesthetic and productive common good (Scion Press Release, 2014). But regardless of how the debate about biotechnology is resolved, there is no doubt that the High Court judgement stifles innovation.

The High Court judgment affects not just New Zealand but also the broader debate about agricultural biotechnology occurring around the world. If New Zealand delays and hampers plants from gene-editing techniques, New Zealand sets an example, for good or ill, for other nations. New Zealand may prove to be in the forefront of world-wide decisions about gene-editing technologies or may prove to be a hindmost in using these techniques and growing the plants created. New Zealand may be the future or the past – and New Zealand will only learn when other countries begin to clarify their legal and social positions about plants from gene-editing techniques. In the meantime, disruptions in primary production (agricultural and forest) trade are likely to increase as different nations adopt different legal classifications for different gene-editing techniques.

At the broadest, most abstract level, the High Court judgment has highlighted the significance and impact of the precautionary approach to science and technology. By the High Court's rejection of the Authority's Committee's plausible interpretation of HSNO and its regulations, the

High Court showed a very cautious approach to technology and a distrustful attitude toward science. While the High Court rendered a judgment that is also a very plausible interpretation of HSNO and its regulations, the High Court's choice of the legally-correct plausible interpretation does not look favorably or approvingly toward science and technology. Rather, the High Court judgment would rather delay and hamper science than embrace science to address the challenges that face the modern world. At the deepest level, the High Court judgement shows the choice facing the modern world: do we hamper and delay science to deal reassuringly with our uncertainties and fears? Or, do we embrace science to assist us in facing our uncertainties and fears? (Fedoroff & Kershen, 2014)

DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST

No potential conflicts of interest were disclosed.

NOTES

1. In the Environmental Protection Authority decision and in the Court opinion, the documents name the two procedures under discussion as ZFN-1 and TALEs. However, the Authority and the Court considered TALEs to be the same as TALENs (Transcription Activator-Like Effectors Nucleases). The Court makes this identification particularly apparent in paragraph [12] of its opinion. See the citation in The Sustainability Council of New Zealand Trust, 2014. Hence, this author is convinced that the Authority and the Court, by using the term "TALEs" in the decision and opinion, did not intend to make any legal distinction between TALEs and TALENs for purposes of the HSNO statute and it regulations.

2. Readers may locate the Regulations under HSNO at http://www.mfe.govt.nz/more/acts-and-regulations/hsno-act-1996. The High Court opinion (The Sustainability Council of New Zealand Trust, 2014) quotes in full all relevant regulations. However, in light of Scion's argument for exemption, it is appropriate to quote the EPA exemptions in full:

"Organisms not genetically modified

(1) For the purposes of the Act, the following organisms are not to be regarded a genetically modified:
  (a) Organisms that result solely from selection or natural regeneration, hand pollination, or other managed, controlled pollination;
  (b) Organisms that are generated from organs, tissues, or cell culture, including those produced through selection and propagation of somaclonal variants, embryo rescue and cell fusion (including protoplast fusion or chemical or radiation treatments that cause changes in chromosome number or cause chromosome rearrangements);
  (c) Organisms that result solely from artificial insemination, superovulation, embryo transfer, or embryo splitting;
  (d) Organisms modified solely by –
    (i) the movement of nucleic acids using physiological processes, including conjugation, transduction, and transformation; and
    (ii) plasmid loss or spontaneous deletion
  (e) Organisms resulting from spontaneous deletions, rearrangements, and amplifications within a single genome, including its extrachromosomal elements.

(2) Despite anything in subclause (1)(d), if nucleic acid molecules produced using *in vitro* manipulation are transferred using any of the techniques referred to in subparagraph i. or subparagraph ii of subclause (1)(d), the resulting organisms is a genetically modified organism for purposes of the Act."

3. HSNO Section 2 Interpretation defines the term "genetically modified organism" as follows:

"**genetically modified organism** means, unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic material –(a) Have been modified by *in vitro* techniques; or (b) Are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques."

4. The Sustainability Council of New Zealand Trust, 2014, para. 8 contains the textual quotation. The judge ruled that the drafters of the regulation placed the end parenthetical mark incorrectly. The judge decided that the regulation should be read as placing the end parenthetical after the second use of the word "fusion" – i.e., "cell fusion (including protoplast fusion) or chemical or radiation treatments that cause changes in chromosome number or cause chromosome rearrangement" (The Sustainability Council of New Zealand Trust, 2014, para. 47).

5. The most relevant provisions of this directive are Article 2 (Definitions) and Article 3 (Exemptions) and the accompanying Annexes, specifically Annex 1A (Techniques referred to in Article 2(2)) and Annex 1B (Techniques referred to in Article 3). The Annex 1B exempted techniques include mutagenesis; and, cell fusion, including protoplast fusion, of plant cells or organisms which can exchange genetic material through traditional breeding methods.

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