IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY

CIV 2013-485-877
[2014] NZHC 1067

UNDER	the Hazardous Substances and New Organisms Act 1996 and Part 20 of the High Court Rules
IN THE MATTER OF	a determination of the Environmental Protection Authority made under s 26 of the Hazardous Substances and New Organisms Act 1996 in relation to application APP201381
BETWEEN	THE SUSTAINABILITY COUNCIL OF NEW ZEALAND TRUST Appellant
AND	THE ENVIRONMENTAL PROTECTION AUTHORITY Respondent

Hearing: 6 and 7 November 2013

Counsel: M S R Palmer and F E Geiringer for the Appellant
K M Muller and J C Haden for the Respondent

Judgment: 20 May 2014

JUDGMENT OF MALLON J

Contents

Introduction

[1] The use of genetically modified organisms in New Zealand is subject to a statutory approval regime unless they are within an exception provided for in regulations. The issue in this case is whether two particular technologies, "ZFN-1" and "TALEs", are within an exception. The Environmental Protection Authority (the Authority) determined that they were within an exception. The effect of that determination is that these technologies can be used in New Zealand without restriction. The Sustainability Council (the appellant) says that the Authority erred in making that determination by incorrectly interpreting the relevant exception in the regulations. It says that organisms that result from these technologies are genetically modified organisms which cannot be used in New Zealand unless approved by the Authority.

The legislation

[2] Hazardous substances and new organisms are subject to the Hazardous Substances and New Organisms Act 1996 (the Act). The purpose of the Act is to "protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms".[1]

[3] To achieve this purpose, all persons exercising functions, powers and duties under the Act must:

> (a) recognise and provide for the following principles: the safeguarding of the life-supporting capacity of air, water, soil and ecosystems; and the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural well-being and for the reasonably foreseeable needs of future generations;[2]

---

1 Section 4.
2 Section 5.

(b) take into account the following matters: the sustainability of flora and fauna, the intrinsic value of ecosystems, public heath, the relationship of Maori with taonga, the economic and related benefits and costs of using a particular new organism, and New Zealand's international obligations.[3]

[4] All persons exercising functions, powers or duties under the Act must also take into account "the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects" (referred to as the precautionary approach).[4]

[5] The Authority is one of the bodies with powers, functions or duties under the Act.[5] The Authority may appoint committees[6] and subcommittees[7] and delegate its functions, powers and duties to such committees and subcommittees, with some exceptions.[8] A committee or subcommittee must consist of persons who collectively have particular knowledge of, and expertise in, the subject matter of the application before it.[9]

[6] Under the Act no "new organism" can be imported, developed, field tested, or released "otherwise than in accordance with an approval issued under this Act" (or in accordance with transitional provisions which are not relevant here).[10] The Act provides for applications to be made to the Authority for various approvals, including to develop in containment any new organism or to import for release any new organism.[11]

---

3 Section 6.

4 Section 7. *National Beekeepers' Association of New Zealand v Chief Executive of the Ministry of Agriculture and Forestry* [2007] NZCA 556 at [21] to [25] discusses the legislative history and concludes (at [25]) that "[i]t is evident from both the adoption of the precautionary principle and the change to the purpose provision, that Parliament was concerned to ensure a high standard of environmental protection was the overriding goal of the new legislation."

5 Section 11. The Authority is established by s 7 of the Environmental Protection Authority Act 2011 (see s 2 of the Hazardous Substances and New Organisms Act 1996).

6 Section 18.

7 Section 18A.

8 Section 19(1).

9 Section 18C.

10 Section 25(1).

11 Section 27.

[7] An "organism" includes a human cell, a micro-organism, a genetic structure of certain kinds, an entity declared to be an organism for the purposes of the Biosecurity Act 1993 and a reproductive cell or developmental stage of an organism.[12] A "new organism" is defined as including "a genetically modified organism".[13] A "genetically modified organism" is defined as follows:[14]

> **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.

[8] The Act provides for regulations to be made which prescribe organisms that are or are not genetically modified organisms for the purposes of the Act.[15] The relevant regulation for present purposes is:[16]

> **3 Organisms not genetically modified**
>
> (1) For the purposes of the Act, the following organisms are not to be regarded as genetically modified:
>
> (a) organisms that result solely from selection or natural regeneration, hand pollination, or other managed, controlled pollination:
>
> (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 rearrangements):
>
> (c) organisms that result solely from artificial insemination, superovulation, embryo transfer, or embryo splitting:
>
> (d) organisms modified solely by –

---

12 Section 2. It does not include a human being.

13 Section 2A(1)(d). However a genetically modified organism that has the same taxonomic classification as an organism that has been approved or prescribed as not a new organism, is not a "new organism" (s 2A(2)(b)).

14 Section 2.

15 Section 140(1)(a) and (b).

16 Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998.

(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 organism is a genetically modified organism for the purposes of the Act.

[9] An application can be made for a determination from the Authority as to whether or not any organism is a "new organism".[17] Before making such a determination the Authority must have regard to any information it holds, any information held by public service[18] departments and Crown entities and information provided by the applicant. A party to an application for a determination as to whether an organism is a new organism, or any person who made submissions in respect of such an application, may appeal against the Authority's decision on a question of law.[19]

The technologies at issue[20]

[10] ZFN-1 stands for Zinc Finger Nuclease Type 1. It is an artificially created fusion protein that contains a Zinc Finger DNA binding domain and a DNA cleavage domain. The zinc finger domain can be designed and customised to recognise a specific DNA sequence in a cell and bind to that sequence. The DNA cleavage domain causes a single stranded break in the DNA chain. The technique involves using two custom designed ZFN proteins that will recognise neighbouring sequences on opposite DNA strands, causing a double stranded break.

---

17 Section 26.

18 That is, those departments, ministries or other entities that are listed in Schedule 1 of the State Sector Act 1988.

19 Section 126.

20 This information comes from the information before the Authority. Further information about the technology was provided in the affidavit of Dr Dijkwel. The Sustainability Council objected to this evidence on the basis that it was not within the scope of the leave that was granted to file expert evidence. I agree with that objection. As set out in my minute dated 17 June 2013, the evidence was intended to be directed to the relevant technical scientific terms in reg 3(1)(b). I have therefore not considered Dr Dijkwel's evidence about the ZFN-1 and ALEs techniques in setting out the description of these techniques.

[11] The proteins are introduced into the cell "in vitro" through standard in vitro techniques (such as micro-injection, electroporation, or gold gun). The proteins cause a double stranded break in the DNA chain. The cell's natural DNA repair mechanisms then fix the break. The repair process is relatively inefficient and prone to errors. It therefore may introduce small changes in base pairs or small sequence insertions or deletions in the DNA chain. Sometimes the break may become joined to another unrelated site. These changes that arise in the repair process generate site specific mutations.

[12] TALEs stands for Transcription Activator-Like Effectors. TALE proteins can be customised and linked to a nuclease protein to form TALEN proteins. They are able to recognise and bind to specific DNA sequences, causing a double stranded break in the DNA chain. As with the ZFN-1 technique, the natural repair process fixes the break but in so doing errors (mutations) occur.

[13] In short, both the ZFN-1 and TALEs techniques result in site specific but random changes in the cell. They therefore alter the genetic code of an organism. They do so without incorporating foreign genetic material into the genome of the cell. The protein that causes the break is made for a short period before being degraded by the cell. Because no foreign DNA is expected to be introduced into the genome of the cell naturally occurring mutations and those induced by ZFN-1 or TALEs are expected to be indistinguishable.

[14] ZFN technology is relatively new and still in the development phase. The technique has been used in fish to create individuals carrying a targeted gene. It has been shown to produce targeted gene disruption in various mammalian cell types. The use of the techniques has only recently been developed as a plant breeding tool. A survey of plant breeding companies referred to applying the ZFN-1 (and related techniques) for breeding maize, oilseed rape and tomatoes.[21]

[15] New Zealand Forest Research Institute Limited (Scion) is the licensee of the technology in New Zealand. It proposes to use the techniques in relation to conifer

---

[21] Maria Lusser and others *New Plant Breeding Techniques: State-of-the-Art and Prospects for Commercial Development* (Publications Office of the European Union, Luxembourg, 2011) at 33 (provided with Scion's application).

(for example, *Pinus Radiata*) protoplasts.[22] It proposes to introduce an mRNA molecule encoding a protein capable of introducing breaks in a specific target gene (the mRNA would be designed using either a ZFN or TALE technique). After introducing the breaks the mRNA and protein would be degraded by normal cellular mechanisms. In a percentage of these protoplasts the cellular repair mechanisms will create mutations. Scion would then use tissue culture procedures to regenerate plants from these protoplasts and screen for individuals with mutations in the targeted gene. The only change in the genome of these plants would be within the targeted gene, introduced by the repair mechanism.

[16] The position in other jurisdictions is:[23]

(a) As at 2012 the United States' Department of Agriculture informed crop companies that the techniques lay outside the scope of current legislation and did not require regulatory oversight.

(b) As at 2012 Australia's Office of the Gene Technology Regulator had not publically given guidance on whether the techniques result in genetically modified organisms. However it was considered likely that they would not be regarded as genetically modified organisms.

(c) As at 2011 the relevant authority in Germany had stated that it did not consider organisms using ZFN-1 to be genetically modified organisms if the mutagenesis reaction was mediated by protein or mRNA.

(d) The consensus at a 2012 international working group was that it was very likely that organisms from the use of ZFN-1 would be classed as not genetically modified organisms, and that such organisms cannot be distinguished from crops derived through mutagenesis induced by chemicals or irradiation and should be regulated in the same way.

---

22 Protoplasts are cells with the cell wall removed.

23 The Sustainability Council provided further information about the position in other jurisdictions and possible consequences if organisms from the ZFN-1 and TALEs techniques are not regarded as genetically modified organisms in New Zealand. This information was objected to. It is not necessary that I consider the information an in light of the objection I have not done so.

The Authority's decision

The process

[17] In this case Scion made an application to the Authority for a determination that the ZFN-1 and TALEs techniques did not result in genetically modified organisms. It provided information about what the techniques involve. It also provided some information on how the techniques are regarded internationally.

[18] The Sustainability Council made submissions in respect of that application.[24] It submitted that the resulting organisms from the techniques were genetically modified organisations under the legislation. In making that submission it noted that the techniques involved the introduction of artificial restriction enzyme activity to cleave and thereby alter genes. Although the mRNA may be eventually degraded, the natural repair mechanisms would not occur without the in vitro step of injecting mRNA or proteins into the cell. The interventions cause permanent, heritable changes to an organism.

[19] The decision making committee appointed by the Authority received a report from its staff. In that report the staff recommended that organisms arising from the use of the ZFN-1 and TALEs techniques be regarded as genetically modified organisms. In reaching this view the report considered the following:

(a) The techniques result in organisms in which the genetic material has been changed. It therefore seems that the resulting organisms are considered to be genetically modified under the Act unless excluded by reg 3(1)(b) (referred to above).

(b) Scion has suggested that the ZFN-1 technique is comparable to traditional mutagenesis induced by chemical treatment. That process involves exposing cultured cells or tissues to chemical mutagens (such as nitrous acid and ethyl methane sulfonate). The mutagen is applied

[24] The Sustainability Council is a charitable trust with objectives that include the realisation of a sustainable New Zealand; the protection and enhancement of New Zealand's ecosystems and ability to derive income from established land uses; promotion of the health of New Zealanders; research into issues related to sustainability (including genetic modification); and the provision of information to facilitate community decision making on sustainability issues.

externally to the cell and affects the whole genome. Generally the changes induced are random but some mutagens may be used to target specific nucleotides. The process may induce changes by altering or disrupting the cell's natural repair mechanisms.

(c) A comparison of the characteristics of ZFN-1 and TALENs modifications with traditional chemical mutagenesis and with traditional genetic modification (that is, the direct manipulation of an organism's genome using biotechnology and where new DNA may be inserted into the host genome and genes may be removed or knocked out) shows that the ZFN-1 and TALENs techniques share characteristics with each of these.

(d) A difference between the ZFN-1 technique and chemical treatment is that ZFN-1 techniques do not cause changes in chromosome numbers and rarely cause chromosome rearrangements. The ZFN-1 technique of breaking the DNA and allowing the cell to repair the break is a more moderate change than a change to chromosome number or significant chromosome rearrangement. However the Act and the Regulations do not comment on the severity or scale of modifications.

(e) The question is whether the ZFN-1 and TALENs techniques "are sufficiently similar to chemical mutagenesis (which is permitted by the Regulations) to qualify organisms arising from these process[es] as not genetically modified". On balance the techniques used to achieve the modifications are most similar to the techniques employed by traditional genetic modification. However the biological outcomes of the treatments are most similar to those resulting from chemical mutagenesis.

(f) The Act and the Regulations tend to regulate genetically modified organisms on the basis of the techniques and processes giving rise to the organism rather than the scale or nature of the modifications introduced. On this basis the organisms arising from the ZFN-1 and

> TALENs techniques should be considered to be genetically modified organisms.

[20] The staff report included a summary of how other regulatory jurisdictions around the world have regarded this technology (as set out above). The staff report noted that ultimately the question was, however, whether organisms generated using these techniques met the definition of a genetically modified organism as defined in the Act and the Regulations. This was distinct from a consideration of whether the organisms should be regulated. However regulating these techniques may present challenges if they are subject to regulation in some jurisdictions but not others. That is because the genetic changes from these techniques are indistinguishable from natural mutations. There is therefore the potential for organisms using this technology to be imported into New Zealand from countries that do not regulate this type of mutagenesis.

[21] Scion was given an opportunity to comment on the staff report. It did so. It advised that it disagreed with the staff recommendation. It said that ZFN-1, when supplied as a protein, acts as a chemical mutagen. It said that the genes in this procedure are not modified by in vitro techniques. Rather they are modified *in vivo* (within the treated cell) by the protein. It also said that insufficient weight had been given by the staff to the fact that no foreign genetic material is introduced and to the differences in the mRNA and protein versions of the process. It set out its interpretation of the legislation. It contended that reg 3(1)(b) did not set out an exhaustive list.

[22] Further staff advice was prepared for the decision making committee determining the application. The advice suggested that the committee ask two questions. The first question was to ask whether the techniques described in the application give rise to a genetically modified organism as defined in the Act. If the answer to that question is "yes", the second question was to ask whether the organisms are within the scope of the Regulations. As to that, the staff advice was:

> [I]f a technique is scientifically similar to a technique listed in the Regulations, and the organism produced by the technique is similar to one produced by a listed technique, then that organism is not to be regarded as a [genetically modified organism].

[23] The staff advice went on to set out why the staff considered that the answer to the first question was yes. As to the second question, the advice said:

(a) That the role of the Regulations was to exclude certain commonly used techniques that might be inadvertently captured under the broad definition of a genetically modified organism.

(b) There was no particular pattern to the exclusions other than that they were commonly used techniques at the time the Regulations were promulgated that could otherwise have been captured by the definition of genetically modified organisms.

(c) If the technique is scientifically similar to a technique listed in the Regulations and the product is similar then an organism produced should not be regarded as genetically modified.

(d) The earlier staff advice set out the similarities with both chemical mutagenesis and traditional genetic modification and a key issue for the decision making committee would be which factors if any should be given more weight.

Determination

[24] The Authority, by its decision making committee, gave its determination on 19 April 2013. It determined that the use of ZFN-1 and TALEs techniques resulted in genetically modified organisms as defined by the Act. It then considered whether they were exempted by reg 3(1)(b). It referred to the staff advice and concluded as follows:

…

> The Committee reviewed the Authority staff advice, and considered feedback from the applicant on the staff advice. The committee considered the experimental process and the products of the ZFN-1 and TALEs techniques and compared them to the processes and products of conventional chemical mutagenesis and genetic modification. The Committee noted that ZFN-1 and TALEs techniques show close similarities to both chemical mutagenesis and genetic modification. However, they considered that because these techniques involve the exposure of the cell to a chemical agent

> (in this case, a protein) that induces changes to the genetic sequence without the introduction of foreign DNA and without the use of homologous recombination, the use of ZFN-1 and TALEs proteins to induce changes in the genetic code is more similar to chemical mutagenesis. The Committee noted that the Regulations exclude products of chemical mutagenesis from consideration under the Act.
>
> The Committee considered that the Regulations should not be considered as an exhaustive list. Techniques that are comparable and sufficiently similar to those listed in the Regulations should also be excluded, and organisms arising from them should not be considered GMOs.
>
> The Committee determined that organisms arising from the use of mutagenic techniques using ZFN-2 and comparable TALEs technology are exempt by the Regulations.
>
> …

Appeal

[25] The Sustainability Council has brought this appeal. Scion was served with the appeal but did not wish to take an active part in it. Dow Agrosciences LLC, which holds a global licence to use the ZFN-1 technology, sought but was declined leave to intervene.[25] The Authority made submissions on the appeal to inform and assist the Court on matters of interpretation and application of the legislation.[26]

Possible interpretations

[26] In this case the parties are agreed that organisms resulting from the use of ZFN-1 and TALEs are organisms in which the genes or genetic material have been modified by in vitro techniques (that is, they are within paragraph (b) in the above definition of "genetically modified organisms"). Therefore organisms that result from the use of ZFN-1 and TALEs are genetically modified organisms "unless expressly provided otherwise by regulations." Whether organisms resulting from ZFN-1 or TALEs techniques are genetically modified organisms under the Act therefore depends on whether reg 3(1)(b) expressly exempts them.

---

[25] *Sustainability Council of New Zealand Trust v The Environmental Protection Authority* [2013] NZHC 2608.

[26] Consideration was given to whether an amicus should be appointed but in the event the parties did not seek that.

[27] There are three possible interpretations that are put forward:

(a) The first possible (and broadest) interpretation is that reg 3(1)(b) exempts from the definition of genetically modified organisms, organisms that are regenerated from organs, tissues, or cell culture, with the balance of the words in reg 3(1)(b) being techniques which are simply examples of how such organisms may be produced. This interpretation is the one that arises from an ordinary reading of the regulation.

(b) The second possible (and strictest) interpretation is that reg 3(1)(b) is a closed list. This is the interpretation advanced by the Sustainability Council. On this interpretation, the regulation exempts from the definition of a genetically modified organism, organisms that are regenerated from organs, tissues, or cell culture, and which are created using the following techniques: somaclonal variation, embryo rescue, cell fusion, protoplast fusion, chemical mutagenesis, and radiation mutagenesis.

(c) The third possible interpretation is a "middle ground" approach which is put forward by the Authority for the Court's consideration. On this interpretation reg 3(1)(b) exempts from the definition of genetically modified organisms, organisms that are regenerated from organs, tissues, or cell culture; and which are produced through:

(i) selection and propagation of somaclonal variants, embryo rescue, cell fusion, protoplast fusion, or chemical or radiation mutagenesis; or

(ii) techniques scientifically similar to the listed processes.

Scientific meaning of words

[28] The meaning of reg 3(1)(b) is to be ascertained from the text of the regulation and in the light of its purpose.[27] The words used in reg 3(1)(b) are, however, technical words. They are words used in science rather than in ordinary use. To assist with interpreting reg 3(1)(b) expert evidence has been filed by both parties as to the meaning of the terms used in the regulation.[28] The main expert evidence comes from Professor Heinemann (the expert instructed by the Sustainability Council) and Dr Dijkwel (the expert instructed by the Authority).[29] Professor Heinemann has endeavoured to keep his evidence simple (and has intentionally left out matters of detail which he considers unimportant to an understanding of the words in the regulation). Dr Dijkwel has largely agreed with the explanations Professor Heinemann has provided but has tended to provide more detail (which Professor Heinemann does not consider to be material for present purposes nor in some instances to be accurate).

Organisms that are regenerated from organs, tissues, or cell culture

[29] Professor Heinemann explains that the genome of a living organism is the full set of instructions needed to make every cell, tissue, and organ in the organism (usually this refers to DNA, but it can also refer to RNA). Most cells in living organisms contain a copy of the organism's entire genome. Organs and tissues are larger collections of cells.

[30] Because most cells contain a copy of the organism's entire genome, it is possible to regenerate an entire organism from just one of its cells given proper conditions. For example, nearly any cell from a plant can be used to recreate the entire plant. All genetic modification processes have a step where the organism is generated from organs, tissues or cell culture. Therefore "organisms that are regenerated from organs, tissues, or cell culture" is not a description that

---

27 Interpretation Act 1999, s 5(1).

28 Leave was granted by consent to file expert evidence limited to the meaning of relevant scientific terms. An issue arose between the parties as to whether some of the evidence went beyond the leave granted. I have considered the expert evidence as within the leave granted to the extent that it explains what is meant by each of the technical terms as used in reg 3(1)(b) including whether they have common characteristics.

29 Each party filed an affidavit from a second expert who confirmed their agreement with the evidence given by Professor Heinemann and Dr Dijkwel respectively.

distinguishes between different genetic modification processes involving plants, nor that distinguishes between processes that are genetic modification and those that are not. Dr Dijkwel essentially agrees with this.[30]

[31] Professor Heinemann says that the important question is therefore how the cells from which the organism is generated come into being. In vitro techniques (meaning literally "in glass")[31] are used as the touchstone for genetic modification legislation. In vitro techniques may be used to alter the genome of a cell and generate an organism from that altered cell. The generated organism will be different from the original organism according to the changes the techniques introduced into the genome.[32] The changes will be a potentially significant factor influencing the organism's physical characteristics.

[32] Dr Dijkwel agrees that "in vitro" techniques are the key words in the definition of genetically modified organisms in the Act. He refers to genetic alterations as being any change in a DNA sequence, and genetic modifications as being a subset of genetic alterations.[33] Using this terminology, he defines genetic modifications as being alterations linked to in vitro techniques, which in turn are techniques caused by human intervention.[34]

[33] As to the link between genetic modification and in vitro techniques, Professor Heinemann makes the point that the in vitro technique must be the cause of the modification. An organism is not genetically modified by an in vitro technique merely because the organism was in a petri dish and underwent natural mutations.

---

30 The difference is that Dr Dijkwel considers it important to distinguish between "regeneration" and "generation". Professor Heinemann agrees that it is possible to distinguish between these terms (with generation involving creating a new organism and regeneration involving recreating a previously existing organism from one of its cells) but says that this is not a well-established distinction. Dr Dijkwel says that the distinction means that some embryo rescue techniques and reproduction of genetically altered plant cuttings do not require a regeneration step. He also gives an example of a particular genetic modification procedure that does not require a regeneration step. The distinction, however, does not bear upon the meaning of reg 3(1)(b).

31 That is, laboratory techniques where materials are treated in a container, for example a test tube. In modern times, it is more likely that the container will be some form of plastic.

32 In contrast with cloning, where an unaltered genome is used to regenerate another organism that is physically identical to the original organism.

33 Professor Heinemann notes that this is not accurate in that there are other genetic material (not just DNA) which may be modified by in vitro techniques.

34 Dr Dijkwel sets out the kinds of changes that may occur in DNA as being single base pair changes, small and large deletions, small and large insertions, chromosome duplications and chromosome rearrangements.

For example if two elephants were to mate in an enormous test tube the off-spring would be no more genetically modified than if those elephants had mated under a tree.

Selection and propagation of somaclonal variants

[34] Both experts regard the words "selection and propagation of" as relating to "somaclonal variants". That is, the words after "organisms that are regenerated from organs, tissues, or cell culture," are to be read "including those produced through [selection and propagation of somaclonal variants], [embryo rescue], [and cell fusion] …".

[35] Professor Heinemann explains that "soma" in "somaclonal variants" refers to somatic cells. Somatic cells are fully-differentiated cells (that is, specialised cells). In human beings, for example, skin cells are somatic cells. Some somatic cells in organisms naturally experience variation. An example of how this can occur is through environmental factors changing their genomes (for example, the sun's radiation may cause human skin cells to mutate).

[36] Somaclonal cells are present in plants. As discussed above, it is possible to take a cell from an adult plant and use it to regenerate a whole plant. If the cell that is taken has a heritable variation then this mutation will be reflected in the regenerated plant. This is known as somaclonal variation. It is a process by which material can be sourced from which an organism can be generated.

[37] Dr Dijkwel provides further detail about this technique. In particular he notes that "selection and propagation of" somaclonal variants refers to processes after the regeneration process. He also says that somaclonal variation is the result of two separate processes that induce genetic alterations (namely, the process of de-differentiation and the process of regeneration). Professor Heinemann does not agree with this. He says that what makes an organism a genetically modified organism is the in vitro technique used to modify the genes (whether they are applied before or after the de-differentiation phase). He also notes that although a high degree of DNA alterations do occur during the regeneration of plant cells, he is unaware of evidence that the regeneration process is the cause of those changes.

Embryo rescue

[38] Professor Heinemann explains that embryo rescue is the process of placing an embryo into a special medium that allows it to continue to develop. Like selection and propagation of somaclonal variants, it is therefore a process by which material is sourced from which an organism can be generated. Professor Heinemann says that embryo rescue does not by itself effect genetic change but it can enable some recombinations of genomes and could thereby be seen as enabling genetic change.

[39] Dr Dijkwel considers Professor Heinemann's explanation to be incomplete. Dr Dijkwel says that, while embryo rescue can involve the process of developing an embryo in a special medium, it can also involve a regeneration process. That involves the culture of the rescued embryo to induce de-differentiation and subsequent plant generation. He says that the specific purpose of embryo rescue is to introduce genetic alterations.

Cell fusion

[40] Professor Heinemann explains that cell fusion is another process by which material is sourced from which an organism can be generated. He says that it is a means of introducing genetic change. He says that cell fusion can occur in various ways, including naturally in a number of biological processes. He says that in the present context it is a process by which cells from two different organisms are fused or hybridised resulting in an organism containing the genetic information from both parental cells. This produces hybrid cells. Professor Heinemann also explains that a variety of techniques can be used to promote fusion. For example, cells without rigid walls can be placed in solutions that promote the blending of the membranes. Special enzymes can be used to remove walls from cells with rigid walls allowing the cells to be fused. Dr Dijkwel does not disagree with this explanation.[35]

---

[35] A difference between Dr Dijkwel and Professor Heinemann relates to whether the process disrupts the integrity of the cell. In Professor Heinemann's view it does not. In Dr Dijkwel's view it does. This difference in view is not, however, material for the purposes of understanding reg 3(1)(b).

Protoplast fusion

[41] Professor Heinemann and Dr Dijkwel say that protoplast fusion is a type of cell fusion. It involves the fusion of cells that do not contain rigid cell walls. When somatic cells are fused some process of removing the rigid cell walls is required. Protoplast fusion can therefore be thought of as cell fusion where the fused cells are somatic cells.

[42] Professor Heinemann says that protoplast fusion does not usually result in changes to chromosome number or chromosome rearrangements and that this is not the aim of the process. Dr Dijkwel says that the two sets of chromosomes which a cell has from this process can give rise to unstable genomes. He says that several generations of growth and propagation may stabilise the genomes with the end result being genetically altered plants with increased chromosome numbers and/or exchange of chromosome fragments.

Chemical or radiation treatments that cause changes in chromosome number or cause chromosome rearrangements

[43] Professor Heinemann explains that certain chemicals and radiation are capable of penetrating a cell to gain access to the genetic material and to interact with and alter the chemical constituents of DNA or RNA. The chemicals and radiation are consumed by the reaction process. The process commonly causes changes in chromosome number or chromosome rearrangements. The use of chemicals in this way is known as chemical mutagenesis. Chemical or radiation treatments of this kind are not types of cell fusion. Nor are they types of somaclonal variants or embryo rescue. Dr Dijkwel agrees with this.

[44] However Dr Dijkwel also explains that chemicals can indirectly cause DNA damage. One example is cell fusion which occurs in the presence of certain chemicals. This results in the fused cell having the genetic content of the two parent cells. Another example is chemical treatments that induce plant cell regeneration. In each of these examples there is DNA alteration indirectly caused by the chemicals which induce the process. In these indirect examples Dr Dijkwel says that some

chemical treatments could be considered a subset of cell fusion and others could be considered a subset of somaclonal variation.

The list of the specified techniques

[45] From the above descriptions it is clear that the experts are agreed that the words in reg 3(1)(b) that follow "organisms that are regenerated from organs, tissues, or cell culture" are (or can be)[36] in vitro techniques by which organisms are regenerated from organs, tissues or cell culture. Both experts agree that those remaining words describe the following scientific techniques:

(a) selection and propagation of somaclonal variants;

(b) embryo rescue;

(c) cell fusion;

(d) protoplast fusion;

(e) chemical treatments that cause changes in chromosome number or cause chromosome rearrangement (commonly called chemical mutagenesis); and

(f) radiation treatments that cause changes in chromosome number or cause chromosome rearrangement.

[46] The expert evidence is also that:

(a) protoplast fusion is a subset of cell fusion.

---

[36] A difference between the experts is the extent to which each of the techniques will be "in vitro" techniques. Dr Dijkwel would regard all the techniques as within the subset of in vitro techniques, with only radiation treatments sometimes falling outside in vitro techniques. Professor Heinemann would regard embryo rescue and protoplast fusion as always being in vitro techniques (as would Dr Dijkwel), but he would regard all the other techniques as sometimes not being in vitro techniques.

(b) protoplast fusion does not usually cause changes in chromosome number or cause chromosome rearrangement, although after several generations of growth and propagation it may do so;

(c) chemical treatments that cause changes in chromosome number or chromosome rearrangement are not a subset of cell fusion;[37]

(d) radiation treatments that cause changes in chromosome number or chromosome rearrangement are not a subset of cell fusion.

(e) protoplast fusion, and chemical and radiation treatments that cause changes in chromosome number or cause chromosome rearrangements, are not subsets of selection and propagation of somaclonal variants[38] and embryo rescue.

[47] On this basis the closing bracket of reg 3(1)(b) is in the wrong place. The words only make sense if the regulation is read as "cell fusion (including protoplast fusion), or chemical or radiation treatments …". It also means that the "and" in "and cell fusion" is unnecessary. The regulation would therefore be better expressed as "including those produced through selection and propagation of somaclonal variants, embryo rescue, cell fusion (including protoplast fusion), and chemical or radiation treatments that cause changes in chromosome number or cause chromosome rearrangement."

Do the words describe a broader class of things that share common characteristics?

[48] In general terms the experts agree that the opening words of reg 3(1)(b) ("organisms that are regenerated from organs, tissues, or cell culture") are not a meaningful description of a class of organisms that should be exempted from the definition of genetically modified organisms. As Professor Heinemann puts it,

---

37 Except, as Dr Dijkwel says, if this term refers to chemicals that are used to promote cell fusion rather than chemical mutagenesis, but in this case it is the cell fusion where the genetic alteration occurs.

38 Except, as Dr Dijkwel says, if chemical treatment refers to chemicals that induce plant cell regeneration rather than chemical mutagenesis. In this case the genetic alteration occurs in the somaclonal variant selection and propagation process rather than directly by the chemicals which induce the process.

regeneration/generation is not a technique for introducing genetic change, but rather is used for cloning or for constructing an organism after a treatment that does introduce genetic change.[39] It is by reference to the techniques that follow that the type of regenerated organisms that are exempt are defined. Each of those techniques effect genetic change in some way.[40]

[49] Professor Heinemann says that it is difficult to usefully describe particular features that these processes have in common or to describe them as members of a broader genus. He notes that none of the techniques in reg 3(1)(b) disrupt the integrity of the cell,[41]a point that Dr Dijkwel disagrees with. Professor Heinemann also says that all of the processes in reg 3(1)(a) to (e) maintain the physiological integrity of the cells or use natural physiological processes and that many of the processes can occur in some form without human intervention. However, as I understand it, Professor Heinemann does not regard these features as helpful in terms of identifying a broader genus to which the specified techniques in reg 3(1)(b) belong.[42]

[50] Professor Heinemann says that all the techniques in reg 3(1)(b) have in common that they are internationally recognised as having a history of use in traditional breeding. That is also the case with the processes referred to in reg 3(1)(a) and (c). The processes in reg 3(1)(d) and (e) do not always relate to breeding because some apply specifically to microorganisms which reproduce asexually, and others can apply to both breeding and to asexual microorganisms. However these processes are all also internationally recognised as having a long

---

39 Dr Dijkwel takes issue with this only in that he says that regeneration in plants is a method to introduce genetic alterations (in that the process causes DNA alterations from which somaclonal variants are selected and propagated). However in this description, as I understand it, he is linking that to the "propagation and selection of somaclonal variants" which is one of the techniques specifically referred to in the regulation.

40 Professor Heinemann says that selection of somaclonal variants is a means of identifying, isolating and amplifying genetic change; fusion techniques and chemical and radiation treatments are means of introducing genetic change; and, although embryo rescue does not by itself effect genetic change, it can enable some recombinations of genomes and could thereby be seen as enabling genetic change. Dr Dijkwel disagrees with that last description, saying that embryo rescue does introduce genetic alterations and that this is its purpose.

41 Although the rigid cell wall is often removed, the process occurs without disrupting the cell membrane.

42 I take this from his evidence that it is difficult to describe particular features that these processes have in common or to describe them as members of a broader genus, and because he considered it was of no benefit to the Court to explain why he did not agree with Dr Dijkwel about whether cellular integrity is maintained during the process of cell fusion.

history of use prior to the development of genetic engineering. If Dr Dijkwel disagrees with this, he does not say so.[43] This is also consistent with the staff view referred to above that the role of the regulations was to exclude certain commonly used techniques.[44]

[51] Professor Heinemann says that traditional breeding techniques (that is those in referred to in reg 3(1)(a),(b) and (c)) obtain desired changes in organisms through random change across multiple generations. He says that those processes similarly involve random changes selected through multiple generations. He says that such techniques can be contrasted with some modern in vitro techniques which seek to institute a specific change in an organism in one, or a small number of, generations. He says that the ZFN-1 technique produces specific and rapid changes in the genome of an organism.[45] They are specific because they are able to target a particular part of the genome, and performing it on a number of samples would be expected to produce the full range of possible changes and therefore presumably the desired change. They are rapid because the process would typically be performed on many cells at one time and will produce changes in the genome of the cells during the short treatment time (as little as one hour).

[52] Dr Dijkwel disagrees with this. He considers that traditional plant breeding by natural crosses seeks plant improvement through specific and rapid changes. He gives an example of the breeding of resistance into a specific commercial variety. If such a resistant trait is dominant, then the offspring between a non-resistant and resistant variety will be resistant as well. He says that this is a rapid and specific change in a plant characteristic due to genetic alteration. Dr Dijkwel also considers that genetic alteration caused by chemical mutagenesis, radiation mutagenesis, cell fusion, somaclonal variants and embryo rescue can cause rapid and specific changes in the nature of an organism, as does the ZFN-1 technique.

---

43 He does specifically comment that he agrees that generation of DNA alterations using chemical mutagenesis could be regarded as a common and traditional plant breeding technique.

44 Above at [23](a).

45 The experts have discussed their views on the meaning of "rapid and specific" changes because of information before the Cabinet Economic Committee which refers to the purpose of the regulations. I discuss this further at footnote 49.

[53] Dr Dijkwel considers that the in vitro techniques in reg 3(1)(b) can be divided into two classes:

(a) those that cause genetic alterations that are indistinguishable from those caused by natural processes: radiation treatment (mutagenesis), chemical treatment (mutagenesis) and plant regeneration from somaclonal variants;

(b) those genetic alterations that cannot be caused by natural processes: embryo rescue and cell or protoplast fusion (because these processes allow the addition of extra chromosomes and chromosome segments from species that do not cross in nature).

[54] Dr Dijkwel considers that organisms from the ZFN-1 and TALEs techniques fall into the first category. Professor Heinemann says that this classification is novel. He also says that the two classes are not mutually exclusive, they are categories made on static knowledge, and the ability to distinguish between two things is itself largely a function of existing technology. He says that the Act avoids the issues around what is or is not indistinguishable from natural processes by using the process rather than the outcome as the criteria for determining whether an organism is a genetically modified organism. He says that using the outcome, rather than the processes, as the point of distinction assumes there is equal information and experience with the processes creating these outcomes and therefore the risks when that is not the case.

[55] In summary:

(a) some common features in the techniques that can be identified do not help to define a broader genus against which a new technique can be considered to determine if it belongs to that genus.

(b) all of the techniques in reg 3(1)(b), as well as the other techniques in reg 3(1)(a),(c),(d) and (e), were techniques in common use at the time of the regulation.

(c) Professor Heinemann says that all of the techniques also have in common that they do not introduce rapid and specific change, but Dr Dijkwel has a different view about what is a rapid and specific change.

(d) Professor Heinemann considers that there are problems with defining the techniques into the two groups which Dr Dijkwel suggests.

Assessment of the competing interpretations

[56] The broadest interpretation (that is, the one that would exempt the most organisms) is to read everything after "organisms that are regenerated from organs, tissues, or cell culture" as examples of the techniques by which organisms can be regenerated from organs, tissues, or cell culture. On this interpretation all organisms that are regenerated from organs, tissues or cell culture would be exempted. As discussed above, that would exempt all (or many)[46] genetically modified organisms because ultimately all genetic modification processes involve a step of generation from organs, tissues or cell culture. I agree with the parties that this cannot have been the intention.

[57] This leaves the second and third possible interpretations. The difference between them is whether the specified techniques are a closed list of techniques that are exempted, or whether they 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). That depends on what is meant by the first "including" in the context of reg 3(1)(b).

[58] The Sustainability Council submits that in this context "including" does not mean that the list of techniques that follow are a non-exclusive list. On the Sustainability Council's interpretation, "including" must be read as "by the following processes". That is not the usual meaning of "including" although in some contexts that word is sometimes used to refer to an exhaustive list that follows.[47]

---

[46] Whether "all" or "many" applies depends on Dr Dijkwel's point that there is a difference between generation and regeneration.

[47] John Burrows and Ross I Carter *Statute Law in New Zealand* (4th ed, LexisNexis, Wellington, 2009) at 417-421.

[59] The middle ground interpretation arguably gives a more usual meaning to the first "including". On this interpretation it describes the kinds of "organisms that are regenerated from organs, tissues, or cell culture" that are not to be regarded as genetically modified, by reference to a list of examples. Organisms that are regenerated from organisms, tissues, or cell culture from those examples and any other processes that are sufficiently similar to those examples are not to be regarded as genetically modified organisms.

[60] The Authority submits that there is some support for this middle ground interpretation by contrasting the use of "including" in reg 3(1)(b) with the use of "solely" in reg 3(1)(a), (c), and (d) and the more precise list (as compared with reg 3(1)(b)) in reg 3(1)(e). However, as I read the "solely" in those subparagraphs, it is used in the sense of exempting each of those techniques only if those techniques are not combined with other processes or techniques. Thus, in reg 3(1)(a) for example, the exemption covers organisms that result solely from selection or natural regeneration, or solely from hand pollination, or solely from other managed, controlled pollination.

[61] If "including" in reg 3(1)(b) is to be distinguished from this use of "solely" then it would mean reading the words as saying "organisms that are regenerated from organs, tissues, or cell culture, by a process that includes selection and propagation of somaclonal variants, or by a process that includes embryo rescue, or by a process that includes cell fusion (including protoplast fusion) or by process that includes chemical or radiation treatments that cause changes in chromosome number or cause chromosome rearrangement." In other words if any of those processes are involved, the use of that process will not of itself make the organisms genetically modified.[48]

[62] I therefore consider that the contrast between "solely" in the other subparagraphs and "including" in reg 3(1)(b) does not provide support for the interpretation put forward by the Authority as a middle ground.

---

[48] That would still allow for the possibility that the organism could be regarded as genetically modified if some other process is also involved in regenerating the organism, depending on what that other process is.

[63] The Authority submits that by using the word "including" reg 3(1)(b) the intention may have been to enable the regulation to be interpreted in light of developments in the future. In other words, as new techniques are developed which have the same outcomes as organisms produced from the listed processes then they are not to be regarded as genetically modified organisms. The Authority, as a specialist body, could be said to be properly placed to make this assessment.

[64] However, as the Authority acknowledges, there are a number of difficulties with this interpretation. As the Authority puts it, grouping the techniques listed in reg 3(1)(b) to find some commonality is problematic because the listed techniques are themselves quite disparate. As discussed above, on the scientific evidence before me, the techniques do not have the same characteristics unless Professor Heinemann's evidence, that the techniques do not result in rapid and specific changes, is preferred.[49] It seems unlikely that the intention was to exempt any technique (the specified ones and any new technique) which does not cause rapid and specific change if there can be reasonable debate between experts as to whether a particular technique has that outcome or not. As Professor Heinemann

---

[49] That finds some support in cabinet papers relating to the regulation. Specifically, a paper from the Office of the Minister for the Environment to the Chair of the Cabinet Economic Committee, which appears to have been provided in about May 1998, discusses the proposed regulations to be made under the Act. It says that "the advent of genetic manipulation has enabled a greatly increased rate and specificity of change". It notes the need for "clear definitions" as to what is or is not "genetic manipulation." It says that "[t]hrough the process of extensive consultation already described, a number of techniques have been identified which can be shown not to produce rapid or extensive change in the nature of the organism. These techniques have been identified, either on the basis of an extended record of use of the technique, or on the basis of scientific knowledge of the effect of the technique." Similarly, an 18 May 1998 Cabinet Economic Committee Paper notes that a "number of techniques have been identified which can be shown not to produce rapid or extensive change in the nature of the organism. It is proposed that these techniques be formally excluded from the scope of genetic manipulation through the regulation making powers in the HSNO Act." That paper further notes that the Minister for the Environment recommends that the Committee "agree to establish by regulation, under section 140(1)(b) of that Act, the proposed thresholds for genetic manipulation that exclude from consideration under the Act genetic techniques shown not to produce rapid or specific change in the nature of the organism". Cabinet papers are regarded as irrelevant when interpreting statutes: *Wellington International Airport Ltd v Air New Zealand* [1993] 1 NZLR 671 (CA) at 673; *Pfizer Inc v Commissioner of Patents* [2005] 1 NZLR 362 (CA). It has, however, been held that they are not irrelevant when interpreting regulations: *B v Chief Executive of the Ministry of Social Development* [2012] NZHC 3165, (2012) NZCC 55-041. That decision was upheld by the Court of Appeal, although it did not discuss the High Court finding on the relevance of Cabinet materials to interpreting regulations: *B v Chief Executive of the Ministry of Social Development* [2013] NZCA 410, [2013] NZAR 1309. However this issue has elsewhere been treated with greater caution: *Marlborough Lines Ltd v Cassels* [2012] NZHC 9. I do not need to resolve this issue because in my view, the regulation would have expressly said "or any other techniques that do not result in rapid or specific change."

acknowledges there is no universal scientific definition of "rapid" or "specific" and these terms are "at best, relative measures." Even if it was intended that they would be understood in the way Professor Heinemann explains, then the question would be why the regulation does not expressly say "and any other technique which does not result in rapid and specific changes."

[65] Dr Dijkwel suggests that the techniques could be divided into two groups. Professor Heinemann explains the difficulties with this. Apart from those difficulties, I also cannot see how this assists in determining the kind of processes that will be exempted. For example, Dr Dijkwel says that the ZFN-1 technique falls into the first group, but that alone cannot make it a technique that is exempted. What then of a new technique that falls into the second group? If the new technique cannot be caused by natural processes (so as to put it in the group with embryo rescue and cell or protoplast fusion) that alone cannot be sufficient to exempt organisms produced from that technique.

[66] A common feature of each of the techniques is that they were in common use at the time of the regulations. It makes sense that the regulations would exempt techniques that were well understood and established. There is less likely to be scientific and technical uncertainty about the effects of such techniques. It would therefore be consistent with the Act's purpose and the precautionary principle to exempt such common techniques rather than subjecting them to the approval regime in the Act. If that is the only common characteristic of the exempted techniques then it would follow that new techniques (that is, those techniques that are not well established and the effects of which may therefore be more uncertain) were not intended to be included in the exemption.

[67] The absence of any other common characteristic of the techniques leads the Authority to submit that the proper interpretation of the regulation is that it exempts the specified techniques and any other technique which is sufficiently similar to any of those specified techniques. However, as the Authority acknowledges, that is problematic in that it would require a judgment call to be made by the Authority and there is nothing in the legislation to indicate what factor or factors should be considered or given weight in such a determination. This is illustrated by the present

determination. The techniques shared some common characteristics with chemical treatments and some common characteristics with traditional genetic modification techniques. The initial staff view was that the ZFN-1 and TALEs techniques were not sufficiently similar to chemical treatments, giving weight to the techniques employed over the biological outcomes. The second staff advice noted that the techniques had similarities both with chemical mutagenesis and traditional genetic modification and a key issue for the decision making committee was which factors should be given more weight. In the event the decision making committee determined that the techniques were more similar to chemical mutagenesis than traditional genetic modification**.**

[68] The judgment call required does not sit well with the purpose of the Act or the precautionary approach adopted by the Act. The Authority says that the precautionary approach does not apply because it is concerned with scientific uncertainty. It says that here the uncertainty is as to statutory interpretation rather than scientific uncertainty. I do not agree. The technologies at issue are relatively new. They are expected to perform in a certain way. But the technology is intended to cause changes more specifically and rapidly than would be the case without the intervention of this technology. There is no evidence before me which says that the environmental effects of these changes in respect of any particular application are established and therefore certain.

[69] There are other factors that support the Sustainability Council's view. Parliament has decided that, if an organism is within the statutory definition of a "genetically modified organism" decisions about what will and will not be regarded as genetically modified organisms will be made in regulations. While the Authority may determine whether an organism is within the definition or the regulation, where there is doubt about that (and in particular where different experts could come to different views) a more cautious approach is for that decision to be made via a regulation. Consistent with that cautious approach, if an organism meets the criteria in sub paragraphs (a) and (b) of the definition of a genetically modified organism, it is a genetically modified organism unless a regulation "expressly" provides otherwise. Reading reg 3(1)(b) as referring to organisms regenerated by any of the

listed techniques "or any techniques that are sufficiently similar to those techniques" is inconsistent with the requirement that the exemption be express.[50]

[70] The Sustainability Council submits that interpreting reg 3(1)(b) as exempting only organisms regenerated using the specified techniques is consistent with New Zealand's international obligations. New Zealand has ratified the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the "Protocol"). The Protocol relates to the export of "Living Modified Organisms" from one Protocol country to another. New Zealand has given effect to the Protocol by enacting the Import and Export (Living Modified Organisms) Prohibition Order 2005 ("the Order"). Under the Order the export of a "living modified organism" from New Zealand is prohibited unless the consent of the Minister is obtained.[51] The definition of a genetically modified organism in the Act is similar but not identical to the definition of a living modified organism in the Order.[52]

[71] The Sustainability Council submits that applying a less restrictive definition of reg 3(1)(b) risks non-compliance with the Order and therefore the Protocol. It is not clear that this is so. The Act deals with organisms in the domestic environment. The Order deals with exports. Consent would still be required for the export of an organism that met the definition of "living modified organism" even if it was determined that it was not a "genetically modified organism" under the Act. The risk of non-compliance might arise if the genetically modified organism was unknowingly incorporated in food for export. However I do not have evidence about this risk. If that risk exists then there is the power to deal with this through new regulations. I therefore do not place weight on this point.

[72] The strongest argument against the Sustainability Council's submission is the unorthodox use of the first "including". However the regulation is not well drafted. It is clear that the brackets are in the wrong place. Further, given that the brackets are in the wrong place, the "and" before cell fusion is also poor grammar. There is

---

50 The submission would have to be that if, properly construed, the regulation means "and any other technique that is sufficiently similar" then there is an express exemption in respect of any sufficiently similar technique. That is a somewhat strained interpretation.

51 Clause 7.

52 Clause 3.

also a potential problem with referring only to "chemical or radiation treatments that cause changes in chromosome number or cause chromosome rearrangements" because, according to the Authority, some long-standing and accepted in vitro chemical treatments do not have these effects but will be caught by the definition of "genetically modified organisms".[53] Given these issues with the drafting, the fact that the Sustainability Council's interpretation requires an unusual reading of the first "including" is less problematic.

[73] For all these reasons I consider that the correct interpretation is that put forward by the Sustainability Council. That is, reg 3(1)(b) exempts organisms that are generated from organs, tissues or cell culture using any of the following techniques: selection and propagation of somaclonal variants, embryo rescue, cell fusion (including protoplast fusion), and chemical or radiation treatments that cause changes in chromosome number or cause chromosome rearrangements. It follows that the Authority erred in its interpretation of the regulation because it considered that the regulations did not set out an exhaustive list and that techniques that are comparable and sufficiently similar to those listed in the Regulations should also be excluded.

Relief

[74] The appeal is allowed. The Authority's determination is quashed. There is no need to refer the application back to the Authority for reconsideration because it is not contended that the ZFN-1 and TALEs techniques are in fact one of the specified techniques in reg 3(1)(b) (it was only contended that they were techniques sufficiently similar to those techniques). The Sustainability Council also sought an order requiring the Authority to publish that its determination was quashed. In my view any appropriate notification can be left to the Authority and no formal order about this is necessary. If there is any issue as to costs the parties may file brief memoranda (no more than five pages) confined to any specific matters in dispute.

Mallon J

---

[53] It may be that the words "that cause" should be interpreted as "including those that" because of that potential problem but this issue is better considered when it specifically arises and on specific evidence which is not before me.