In Confidence

Office of the Minister for the Environment

Chair

Cabinet Economic Growth and Infrastructure Committee

Consultation on amendments to regulations prescribing organisms as not genetically modified for the purposes of the HSNO Act

Proposal

1. The purpose of this paper is to seek approval for the Environmental Protection Authority (EPA) to consult on minor amendments to the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998 (the Regulations).

Executive summary

2. The Hazardous Substances and New Organisms Act 1996 (the HSNO Act) contains a definition of what is considered to be a genetically modified organism (GMO) in New Zealand. The Regulations expressly provide for certain organisms that meet the definition of a GMO but are *not* to be regarded as genetically modified for the purposes of the HSNO Act. Therefore these organisms do not require HSNO Act approval as GMOs.
3. A High Court decision in 2014 identified problems with the wording of the Regulations and clarified that a strict interpretation of the wording as drafted is correct. As a result, widely-used chemical and radiation treatments commonly thought to be included in the Regulations may not be captured, which means that some organisms may unintentionally be regulated as GMOs.
4. The proposed solution to these issues is to update the Regulations by Order in Council, and in doing so:
    - correct the drafting errors identified by the High Court; and
    - confirm that all organisms developed through conventional and longstanding chemical and radiation treatments do not require HSNO Act approval as GMOs.
5. Subject to Cabinet's agreement, the EPA, which has the statutory role to consult, will release a consultation document to seek public feedback on these proposed amendments.
6. Organisms developed from techniques other than those captured in the Regulations would continue to be regulated as GMOs.
7. The boundary between unregulated organisms and those regulated as GMOs is being increasingly challenged by the development of new and more precise biotechnology techniques. Some of these new techniques produce organisms that cannot be distinguished from organisms developed through conventional breeding, natural mutation, or by techniques currently captured in the

Regulations. It will become progressively more difficult to enforce the HSNO Act requirements for imports and exports of organisms when there is no way of distinguishing regulated organisms from unregulated organisms with a satisfactory degree of certainty.

8. The challenges facing New Zealand's regulation of GMOs are also being faced by other countries. In some countries new techniques or their products are unregulated, and others are reviewing their regulatory systems in light of these new techniques.

9. If New Zealand were to be an early mover in regards to deregulating any new techniques, there may be risks to trade relationships. Although there are no known health or environmental risks associated specifically with the new techniques, there remains some negative consumer perception about biotechnology in general in some markets.

10. Due to this risk, I propose taking a cautious approach and limiting regulatory amendments to fixing the drafting issues identified by the High Court and clarifying the status of chemical and radiation treatments.

Background

The HSNO Act

11. The purpose of the HSNO 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. The HSNO Act achieves this by requiring an approval from the EPA for the import, development, field testing or release of new organisms. New organisms include GMOs.

12. The definition of GMO in the HSNO Act is very broad – any organism containing or derived from *in vitro* altered genetic material is a GMO (see Appendix 1 for full definition and regulatory steps). This was originally seen as an appropriate trigger so that, once an organism was captured under the legislation, the effects of a particular modification could be assessed. However, section 140(1)(b) of the HSNO Act also provides for the making of regulations exempting specific organisms from the scope of the Act.

13. The 1998 Regulations were made for this purpose. They provide that certain organisms under the broad *in vitro*-based definition are not GMOs for the purposes of the HSNO Act.

14. This means that to develop, import, field test, or release these organisms (plants, animals, microbes) in New Zealand, an approval from the EPA under the HSNO Act is not required.

The Regulations

15. The Regulations have not been reviewed since they were introduced in 1998. Consequently, organisms currently not regulated as GMOs are derived using techniques that were widely in use and generally considered routine and low risk when the Regulations were made.

16. The HSNO Act does not provide express criteria for the making of regulations prescribing organisms that are not GMOs for the purposes of the HSNO Act. Such regulations must be consistent with the purpose of the Act. The organisms

currently captured under the 1998 Regulations are grouped by the class of technique used to make the organism.

17. It is not possible to generalise about an array of techniques as diverse as those currently captured in the Regulations (see Appendix 2), except that they were all in common use in 1998 when the Regulations were made. Collectively these techniques have been used to generate a large variety of organisms with genetic changes ranging from small point mutations (a mutation in which one or a few base pairs of DNA are altered), to larger chromosome rearrangements, and the introduction of new genetic material from other species (i.e. cell fusion and embryo rescue).

High Court Decision – May 2014

18. In 2012, Scion applied to the EPA to determine whether organisms resulting from the use of two new biotechnology techniques, Zinc Finger Nuclease Type 1 (ZFN-1) and Transcription Activator-Like Effector Nucleases (TALENs) would be GMO under the Act. Scion proposed to use the techniques in relation to conifer research and developments (e.g., *Pinus radiata*). The EPA determined that the two techniques were within the scope of the Regulations and organisms produced using these techniques would therefore not need to be regulated as GMOs. This was based on an interpretation that treated the list of techniques captured in the Regulations as not exhaustive and that scientifically similar techniques should also be captured.

19. Applications for determinations of new organisms (including GMOs) are made under section 26 of the HSNO Act and do not require public notification. However, the EPA sought input from the Sustainability Council.

20. The Sustainability Council appealed the determination, claiming that the EPA acted beyond the scope of its powers and incorrectly interpreted the Regulations. The Sustainability Council took the view that the list in the Regulations is exhaustive. It argued that the precautionary approach adopted by the HSNO Act should apply given that there is scientific uncertainty surrounding new biotechnology techniques and that the two techniques are not expressly listed in the Regulations.

21. In May 2014, the High Court released its decision on the appeal by the Sustainability Council against the determination by the EPA. The case considered whether or not organisms resulting from the use of ZFN-1 and TALENs were captured by cl 3(1)(b) of the Regulations.

22. The Judge upheld the appeal and overturned the EPA's determination. The High Court's decision views the list in cl 3(1)(b) as exhaustive.

23. The High Court decision affects organisms produced by both traditional techniques and new techniques. As a result, only organisms produced by chemical and radiation treatments that result in changes to chromosome numbers or chromosome rearrangements are captured in the Regulations, rather than all chemical and radiation treatments including those that make point mutations, as has been the interpretation to date. The High Court judgment also identified drafting errors in the Regulations which will need to be corrected.

24. The Court's interpretation is also relevant for the EPA's assessment and the Ministry for Primary Industries' (MPI) enforcement of organisms developed using

new biotechnologies. The High Court decision means that organisms produced by new techniques (such as ZFN-1 and TALENs at issue in the case) developed since 1998 are not captured by the Regulations, and are therefore subject to HSNO approval. Officials are not aware of any organisms developed using new techniques that have been released in New Zealand.

25. The High Court judgment did not make an assessment whether the organisms produced by the two techniques at issue should or should not be considered GMOs, just that they were not captured by the Regulations.

26. The only way to prescribe such an organism as not being a GMO for the purposes of the HSNO Act is through amendment to the Regulations.

Comment

27. In light of the High Court judgment there is uncertainty about the legal status of organisms produced by chemical and radiation treatments, which are in common use in the New Zealand primary production sector and internationally, and have been used to develop some widely used crop varieties. Certainty for stakeholders and realignment with international regulatory practice is required.

28. I seek your approval to direct the Board of the EPA to consult on:

    - correcting drafting errors to clarify interpretation of cl 3(1)(b) of the Regulations, and
    - removing uncertainty arising from the High Court decision about the regulatory status of organisms developed through chemical and radiation treatments.

29. The regulation of GMOs in New Zealand needs to be consistent with New Zealand's obligations under the Cartagena Protocol on Biosafety, which New Zealand ratified in 2005. The Protocol regulates the movement of "living modified organisms" (LMOs) produced by modern biotechnology from one country to another, including through an advance informed consent procedure. LMOs produced using traditional breeding and selection techniques are excluded from the scope of the Protocol. The exemption under the Regulations of GMOs produced by chemical and radiation treatments is therefore consistent with the coverage of the Protocol.

30. The advances in technique raise the question about whether the 1998 Regulations need further modification. The direction to the EPA means the consultation document does not contain proposals to update the Regulations reflecting technological developments since 1998. Reasons for this decision are based mainly on New Zealand's dependence on trade. Some of our major trading partners have highly conservative views on biotechnology and it is unclear how those markets might react to New Zealand choosing not to regulate some new techniques. Some jurisdictions have been making decisions by interpreting their existing legislation in a way that accounts for new techniques, but New Zealand would be the first to make regulatory amendments to account for the new techniques.

31. As a result of this uncertainty, I consider that it may be more appropriate for New Zealand to wait until other jurisdictions have further considered the place of such

new technologies in their legislative frameworks and whether better international alignment can be achieved.

Clarifying chemical and radiation treatments

32. This section briefly describes the issues associated with clarifying chemical and radiation treatments and recognises that this is not considered a long term solution. I have therefore also set out some of the regulatory issues that will arise from increased use globally of the new techniques, particularly in relation to indistinguishable organisms.

33. The objective of the proposal to clarify the status of chemical and radiation treatments is to address the issue identified by the High Court decision. The High Court's interpretation that only chemical and radiation treatments resulting in changes to chromosome numbers or chromosome rearrangements are captured by the Regulations, poses a significant compliance and regulatory challenge to MPI and the EPA respectively.

34. Globally, more than 3,000 crop varieties have been developed using chemical and radiation treatments, and the mutations generated cannot be distinguished from those arising naturally without the use of such treatments; many are sold or in use in New Zealand.

35. Stricter regulation of chemical and radiation treatments (which is the effect of the High Court's decision) puts New Zealand at odds with our major trading partners. Assessing the use of the types of chemical and radiation treatments now not captured is very difficult because:

    - There has never been a burden of proof (nationally and internationally) on industry to know what genetic changes have occurred, only that their product is safe for use and is not a biosecurity risk.
    - Many of the potentially affected crops were developed decades ago, which makes it difficult to trace their origin and information on development.
    - Drawing a line between what genetic changes are captured or not captured in the Regulations is difficult and the Regulations do not provide a definition.

36. Therefore, the consultation document, following my direction, will propose to amend the Regulations to clarify that chemical and radiation treatments are not restricted to chromosome level changes, in order to align with the common understanding internationally.

37. Some new techniques use other means to produce organisms that are indistinguishable from organisms produced using chemical and radiation treatments. However, the proposed clarification of chemical and radiation treatments does not include these new techniques, or chemical and radiation treatments developed since the Regulations came into effect in 1998. This is consistent with the High Court reasoning that those treatments included in the Regulations are those with a history of safe use.

38. The proposed amendment, which is in the nature of a technical fix, is not expected to be contentious as the purpose is to clarify current practice and recognise the history of low risk and safe use. Failure to address the uncertainties generated by the High Court decision would mean that organisms

developed from commonly used techniques, and of longstanding use, would need to be regulated retrospectively, creating an unworkable and difficult to enforce situation.

39. While the technical fix may not be controversial among those who view the current, conservative, regulatory settings as appropriate, it is possible that there will be substantial feedback from the scientific and research community seeking a review of the Regulations to ensure they are up to date. It is also likely that such feedback will include further calls to review the HSNO Act to ensure that its provisions are effective in meeting its purpose in the context of a rapidly changing biotechnological environment.

40. Addressing only drafting issues in the Regulations and clarifying the meaning of chemical and radiation treatments rather than also considering updating the Regulations is considered appropriate as it will allow New Zealand to wait until other jurisdictions make regulatory decisions about the new techniques.

Future developments

41. I recognise that since the Regulations were introduced in 1998, there have been major developments in genetic techniques that have advanced industrial, medical and agricultural biotechnology. The new techniques mimic genetic changes that could be achieved through many generations of conventional breeding, and could also arise through natural changes or changes made using the techniques listed in the Regulations. As a consequence, it will become increasingly difficult to distinguish organisms based on the technique that was used to develop them.

42. These techniques have in common the ability to create mutations in an extremely precise and directed way. This improved accuracy will make processes more cost competitive. The specificity of the new techniques means a shorter development period and therefore a shorter time to market. The precision of these new techniques reduces the likelihood of unwanted effects. The use of these techniques is expected to become rapidly more prevalent internationally.

Indistinguishable organisms

43. Compliance with the Regulations, for which MPI is responsible, will become increasingly problematic with the international uptake of new techniques. Indistinguishable organisms will need to be regulated differently depending on which technique was used to develop them. Although a mutation, or other genetic change, may be detected (if there is prior knowledge of its occurrence) it will often be impossible to attribute it to the use of a specific technique with certainty.

44. Where the use of a particular technique is detectable, regulatory bodies could add more tests to those currently conducted on importation of the organisms or product(s) derived from it. However, each additional test increases the cost of importation. With organisms and products where the technique used to produce the changes cannot be detected, compliance agencies cannot reliably test for the use of that technique.

International context

45. Internationally, there is a range of approaches to GM regulation and the international regulatory environment is not harmonised. The novelty of the recently developed techniques and their apparent bridging of the gap between what has traditionally been seen as a clearer dichotomy between GM and non-GM techniques places them in a grey zone when considered under regulations designed to regulate older GM techniques.

46. In most jurisdictions, it is unclear whether some new techniques fall within legislation regarding GM; for example whether the meaning of chemical treatments can extend to include some of the new techniques. Already some recently commercialised products derived from organisms developed using new techniques are not regulated, or were regulated and subsequently approved for commercialisation in other countries.

47. At present, other jurisdictions are making case-by-case decisions on organisms and products developed using the new techniques. The international uncertainty can be demonstrated as follows:

    - The Australian regulator has stated that they do not intend to regulate ZFN-1, or cisgenesis where the sequence of the relocated DNA is unchanged from its source and all foreign DNA has been removed from the final product. Australian legislation does not capture any organisms without a new trait derived from gene technology, or any organism that does not contain foreign DNA. The decisions of the regulator to date reflect their interpretation of those provisions.
    - Australia and New Zealand share a common regulatory body for food standards, Food Standards Australia New Zealand (FSANZ). FSANZ is currently considering which new plant breeding techniques require pre-approval.
    - Japan has decided not to regulate maize produced using a new technique because there is no foreign DNA in the final product. However, South Africa chose to regulate that maize as a GMO.
    - Germany has decided that canola developed using a new technique is not a GMO.
    - The European Commission has indicated that it will release guidance on which new techniques are in scope of their legislation by the end of 2015.
    - Products, including canola, apples and potatoes, developed using a number of the new techniques are being commercialised in the USA and Canada which have much more permissive biotechnology regimes.
    - Switzerland has indicated that all new techniques are to be regulated as GM.
    - Argentina has recently issued guidance that it will not regulate products of the new techniques where there is no “new combination of genetic material”. Researchers can ask the regulatory agency to determine if their product is regulated or not (this can happen before the product is developed).

48. The undetectable new techniques pose new issues for trade and heighten the issue of regulatory discrepancies between jurisdictions. A regime that cannot be

enforced lacks credibility. This is not an issue unique to New Zealand and it is appropriate for New Zealand to take a cautious approach while other jurisdictions, in particular our more conservative trading partners, are considering what to do.

Should we review the HSNO Act?

49. In light of the High Court decision, unless a technique/class of technique is listed in the Regulations, any use of the new techniques (irrespective of likeness to organisms currently not regulated as GMOs) will require HSNO approval. This means that industry is reluctant to proceed with research which is likely to be unable to progress to or beyond field trial stage.

50. I receive ongoing feedback, mainly from industries using biotechnology, that there are wider issues with the way the Act regulates GMOs, e.g. that the regulatory burden is not proportionate to risk. The Act's requirements are considered by these stakeholders to reduce New Zealand's ability to innovate and keep pace with emerging techniques.

51. I recognise there is a wide range of views on biotechnology, from those who are concerned that the Act is unduly stringent, to those who have ethical, spiritual, and environmental concerns about "unnatural processes", e.g., material from one species being transplanted into a different species. However, the robust legislative framework in place to control new organisms provides for the full range of views to be taken into account in the decision-making process. The Government remains committed to this legislative framework, and committed to protecting exports, people, and the environment.

Consultation

Interagency consultation

52. The Department of Conservation, Environmental Protection Authority, Food Standards Australia New Zealand, Ministry of Business, Innovation and Employment, the Ministry of Foreign Affairs and Trade, the Ministry of Health, Ministry for Primary Industries, Te Puni Kokiri and Treasury were consulted on the content of this paper. Their feedback has been incorporated. The Department of Prime Minister and Cabinet were informed of the proposals contained in this paper.

Iwi consultation

53. Officials advise that Maori, and the New Zealand public in general, are unaffected by these amendments as these methods have been in use in New Zealand for decades. The proposed amendments normalise the use of traditional chemical and radiation treatments.

54. The Ministry and the EPA are conscious of the need to consult with Maori, and recognise that some concern may arise as Maori have not yet been advised that the amendments only normalise the situation as it has been for decades.

55. The EPA has discussed the proposed amendments with the Ngai Tahu HSNO Committee, who expressed concern about the lack of consultation with Maori to date. They noted that it had been some time since issues relating to GM had

been discussed and that a four week consultation was considered to be a short time for feedback.

56. The EPA has sought input from Ngā Kaihautū, the Māori advisory committee to the EPA, who have provided a position statement for the consultation document noting that the proposal is a narrow and technical change.

Public consultation

57. The EPA is required to lead the consultation process. The procedure for making an Order in Council to amend the Regulations is set out in section 141 of the Act. I must request the EPA to—

    (i) do everything reasonably practicable on its part to advise all persons, who or which in its opinion may be affected by any Order in Council made in accordance with the recommendation, of the proposed terms of the Order in Council; and

    (ii) give such persons a reasonable opportunity to make submissions on them to the EPA; and

    (iii) advise me of any submissions received, and any comments the EPA wishes to make on the submissions or the proposed Order in Council;

58. Under this same section, I will need to request the EPA to advise on the best international practices and standards for the safe management of hazardous substances and new organisms. Following the consultation process, I shall have regard to the submissions and EPA comments received.

59. Following cabinet approval I expect public consultation to be undertaken as soon as possible. Note the draft EPA consultation document is attached at Appendix 4.

Financial implications

60. I do not anticipate any immediate financial implications of making the proposed amendments as it is simply normalising industry practice to date. However, in the medium-long term, the new techniques mean that an increasing number of products that cannot be distinguished from unregulated ones will come onto the global market. This is likely to place an unnecessary (and unenforceable) compliance burden on industry and result in negative trade implications for New Zealand.

Human rights

61. There are no inconsistencies between the proposals in this paper and the Human Rights Act 1993.

Legislative implications

62. The proposals will result in amendments to regulations, which are disallowable instruments for the purposes of the Legislation Act 2012.

Regulatory impact analysis

63. The Regulatory Impact Analysis (RIA) requirements apply to the proposal and a Regulatory Impact Statement (RIS) has been prepared (see Appendix 3).

Quality of the Impact Analysis

64. Treasury's Regulatory Impact Analysis Team (RIAT) has reviewed the RIS prepared by the Ministry and associated supporting material, and has advised that:

> "The Regulatory Impact Analysis (RIA) requirements apply to the proposal in this paper and a Regulatory Impact Statement (RIS) has been prepared and is attached.
>
> The Regulatory Impact Analysis Team (RIAT) has reviewed the RIS prepared by Ministry for the Environment and associated supporting material, and considers that the information and analysis summarised in the RIS *partially meets* the quality assurance criteria.
>
> The RIS identifies significant limits in the understanding of the impacts of any changes beyond restoring the regulations as they were understood prior to the High Court decision. The options analysis considers the most plausible options for the scope of the consultation, and how those options could be enforced. However, due to the limited understanding of the impacts, the preferred options for amending the Regulations only partly address the defined problem. RIAT notes the RIS suggests a full review of the HSNO regime would be beneficial once this review of the Regulations is completed."

Publicity

65. The EPA intends to issue a media release at the start of the consultation period, and will also supply contextual and process information on its website. The consultation will be supported by a communications plan.

Recommendations

66. The Minister for the Environment recommends that the Committee:

1. agree to consultation on proposed amendments to the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998 to address drafting problems identified by the High Court and to ensure that all chemical and radiation treatments in use in 1998 are captured without capturing any new techniques
2. invite the Minister for the Environment to request the Environmental Protection Authority to do everything reasonably practicable on its part to advise all persons, who or which in its opinion may be affected by any Order in Council, of the proposed terms of the Order in Council and give such persons a reasonable opportunity to make submissions to the Authority
3. invite the Minister for the Environment to request the Environmental Protection Authority to advise on any submissions received, and any comments the Authority wishes to make on the submissions or the proposed Order in Council
4. invite the Minister for the Environment to request the Environmental Protection Authority to advise on the best international practices and standards for the safe management of hazardous substances and new organisms
5. invite the Minister for the Environment to report back to the Committee early 2016

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Hon Dr Nick Smith
Minister for the Environment
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Appendix 1 Regulatory oversight of the use of GMOs in New Zealand

Definition of GMO (section 2 HSNO Act)

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.

HSNO (Organisms Not Genetically Modified) Regulations (1998)

(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—

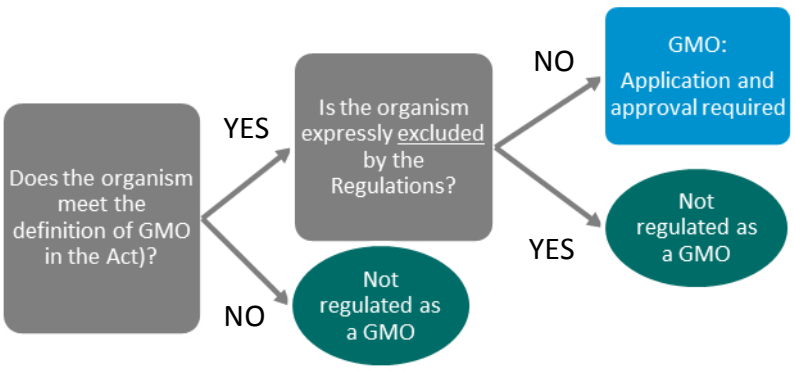
(i) the movement of nucleic acids using physiological processes, including conjugation, transduction, and transformation; and

(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.

Process for defining a GMO for the purposes of the HSNO Act



Appendix 2 Summary of Techniques

The following table describes the techniques currently captured in the Regulations:

Technique	Description
Conventional breeding (e.g. selection, hand pollination)	Selecting and cross-breeding to obtain organisms with desired traits/characteristics.
Somaclonal variation	Mutant organisms arising from natural changes in plant tissues are selected and propagated for desirable traits.
Cell fusion/embryo rescue	Cells from different species are fused. An organism may be generated or the hybrid cell used for research.
Chemical or radiation treatment (that cause changes in chromosome number or cause chromosome rearrangements)	Cells or whole organisms are exposed to radiation or mutagenic chemicals and mutant organisms generated and selected from them.
Artificial insemination, superovulation, embryo splitting and transfer	Selecting individuals with desirable traits and artificially increasing the number of offspring they can produce.
Movement of nucleic acids, plasmid loss	Natural genetic exchange mechanisms within and between species (usually bacteria or Archaea). Plasmid loss is the spontaneous loss of extrachromosomal genetic material.
Spontaneous rearrangement, amplification, deletion	Genomes can spontaneously mutate, sometimes extensively. If a beneficial mutation is noticed, the individual may be selected for breeding. Somaclonal variation is often a result of such phenomena.

Appendix 3 Regulatory Impact Statement

Appendix 4 Draft Consultation Document