SUBMISSION ON

Improving our GMO regulations for laboratory and biomedical research: Consultation document

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To: Ministry for Environment
Name of Submitter: Horticulture New Zealand
Supported By: Tomatoes NZ, Summerfruit NZ, Pukekohe Vegetable Growers Association.

Michelle Sands
General Manager Strategy and Policy
Horticulture New Zealand
PO Box 10-232 WELLINGTON
Ph: 021 610 653
Email: michelle.sands@hortnz.co.nz

Horticulture™ New Zealand
Ahumāra Kai Aotearoa

OVERVIEW

Submission structure

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Our submission

Horticulture New Zealand (HortNZ) thanks Ministry for Environment for the opportunity to submit on the *Improving our GMO regulations for laboratory and biomedical research* consultation document and welcomes any opportunity to continue to work with Ministry for Environment and to discuss our submission.

The details of HortNZ's submission and the decisions we seek are set out in our submission below.

PART 1

HortNZ's Role

Background to HortNZ

HortNZ represents the interests of approximately 4,200 commercial fruit and vegetable growers in New Zealand who grow around 100 different fruits, and vegetables. The horticultural sector provides over 40,000 jobs.

There is approximately, 80,000 hectares of land in New Zealand producing fruit and vegetables for domestic consumers and supplying our global trading partners with high quality food.

It is not just the direct economic benefits associated with horticultural production that are important. Horticulture production provides a platform for long-term prosperity for communities, supports the growth of knowledge-intensive agri-tech and suppliers along the supply chain; and plays a key role in helping to achieve New Zealand's climate change objectives.

The horticulture sector plays an important role in food security for New Zealanders. Over 80% of vegetables grown are for the domestic market and many varieties of fruits are grown to serve the domestic market.

HortNZ's purpose is to create an enduring environment where growers prosper. This is done through enabling, promoting and advocating for growers in New Zealand.

Export

Fruit $4.04bn

Vegetables $0.64bn

Domestic

Fruit $0.93bn

Vegetables $1.34bn

Industry value $6.95bn

Total exports $4.68bn

Total domestic $2.27bn

PART 2

Executive Summary

The consultation is on proposed changes to the legislation and regulations concerning laboratory research, and biomedical research and development, for genetically modified organisms by removing barriers to laboratory research.

The consultation includes ten policy proposals related to the regulations and controls for laboratory research, the assessment and approval of medicines that are, or contain, new organisms (which includes GMOs), and updating and future-proofing the legislation and regulations more generally. These proposed policy changes would require amendments to the HSNO Act, its regulations, and related standards.

The assessment in the consultation document is that the current regulatory compliance setting associated with laboratory research for GMOs is adding costs but is not reducing risks for low-risk and very-low-risk technologies and that if the regulatory system was simplified, greater benefits could be achieved for a lesser cost, with a similar level of risk.

HortNZ recommendations

- The objectives of the review would be better aligned with the purpose of the HSNO Act, which is focused on the protection of the environment, and the health and safety of people and communities.
- Support a risk tier approach aligned with the Australian system for GMOs.
- Ensuring the risk tiers require minimal interpretation by the biosafety committees, by creating prescriptive risk tiers, including listing those organisms that are considered unsuitable for a certain risk tier under a higher risk tier or explicitly excluding it from the risk-tiering framework.
- In determining the content of the risk tiers, undertake a risk assessment that considers both the magnitude of an adverse effect and the probability of its occurrence, and align the assessment of adverse effect against those matters the HSNO Act seeks to protect.
- In considering activities suitable for risk tier 1, the chance of illegitimate research should be considered and managed.
- GMO somatic cells that can be induced to form a whole plant should not be included in risk tier 1.
- Retain controls over the importation of new organisms, including GMOs.
- Require very clear and robust assurance processes are developed, including accreditation, audit, certification, and enforcement.
- Require annual EPA audits of assessments by internal biosafety committees and promote consistency.
- In a future review, analyse and discuss the changes to the GMO definition that have been adopted in the United Kingdom and the definition proposed in Europe.
- As the definitions are relevant to all categories, undertake a review of the definitions prior to changing the legislation to implement a risk tier framework.

PART 3

Submission

1. Proposal

The consultation is on proposed changes to the legislation and regulations concerning laboratory research, and biomedical research and development, for genetically modified organisms.

The consultation document includes ten policy proposals related to the regulations and controls for laboratory research, the assessment and approval of medicines that are, or contain, new organisms (which includes GMOs), and updating and future-proofing the legislation and regulations more generally. These proposed policy changes would require amendments to the HSNO Act, its regulations and related standards.

The ten policy proposals are:

1. Introduce a risk-tiering framework for laboratory research.
2. Reduce the assessment and approval requirements for medicines that are, or contain, new organisms.
3. Replace current record-keeping requirements.
4. Adjust internal audit frequency to be proportionate to risk.
5. Adjust the requirements for the movement of new organisms to be proportionate to risk.
6. Reduce regulatory requirements for the use of eukaryotic somatic cells.
7. Clarify the regulatory status of certain biotechnologies.
8. Reduce assessment requirements for low-risk fermentation.
9. Maintain or adjust the approach to standards for containment facilities.
10. Require regular reviews of regulatory setting.

These policy proposals are intended to provide benefits to researchers, the research community and New Zealanders by:

- making more time and funding available for research by reducing the time and resources required for applications, approvals and day-to-day administrative tasks.
- fostering new research efforts, innovation, educational opportunities and collaboration.
- delivering better health outcomes for New Zealanders by streamlining assessment and approval processes for biomedical therapies.
- providing greater certainty to researchers, organisations and biotechnology companies.
- ensuring the regulatory framework for GMOs remains appropriately set and up to date.

2. GMOs, New Breeding Technology and Horticulture

The focus of HortNZ's submission is on matters that are directly relevant to the horticulture sector. HortNZ has not commented on the elements of the consultation that relate to biomedical research.

2.1. Plant breeding

For centuries, growers have been using breeding to influence the genetics of plants, searching for ways to improve traits that include yield, disease resistance, flavour and resilience. Some of those breeding techniques, including methods such as wide cross-breeding, breeding using natural mutations, and mutagenesis of seeds using radiation or chemicals, can involve years of laboratory and fieldwork.

Advancements in biotechnology in recent decades have given breeders the ability to exert greater, timely, and more precise control over the breeding process.

There are a diverse collection of new genetic techniques, many of which have emerged over the last decade and are still evolving. Te Puna Whakaaronui report[1] on modern genetic technology described and defined these terms, summarised below.

New Breeding Techniques encapsulate New Genomic Techniques, Precision Breeding, Genome Editing, Gene Editing, New Precision Breeding Techniques, Precision Breeding Techniques, and New Plant Engineering Techniques.

Cisgenesis describes a process where DNA from the same, or a closely related species, is inserted into the organism's genetic information without changing the inserted DNA sequence or arrangement. cisgenesis may lead to a new organism that is indistinguishable from its wild relative and could feasibly be produced via selective breeding.

Intragenesis is similar to cisgenesis, except the DNA to be inserted is changed from its original form, often to include additional pieces of DNA from the same or a closely related species, and/or rearranged in some way before being inserted in the genome. may produce an organism that is not obtainable by selective breeding alone.

Transgenesis describes the process of introducing a transgene, or foreign gene, from a different species with the aim of the resulting organism exhibiting some new characteristic that could not be achieved through selective breeding due to reproductive barriers.

2.2. Risks, Cost and Benefits

The interim regulatory impact statement explains that New Zealand's regulatory framework is regarded as one of the strictest in the OECD and, having not been updated since 2003, its settings have not kept pace with developments in biotechnology and our additional understanding of its risks over the last 20 years.[2]

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[1] https://fitforabetterworld.org.nz/assets/Te-Puna-Whakaaronui-publications/WELL-NZ-Modern-genetic-technology-2023.pdf

[2] Library of Congress: Law Library (2014). *Restrictions on Genetically Modified Organisms: New Zealand*. Available at: https://web.archive.org/web/20210206072656/https://www.loc.gov/law/help/restrictions-on-gmos/new-zealand.php and Library of Congress: Law Library (2014). *Restrictions on Genetically Modified Organisms: European Union*. Available at:

The assessment in the consultation document is that the current regulatory settings associated with laboratory research for GMOs is adding costs but is not reducing risks for low and very low risk technologies and that if the regulatory system was simplified, greater benefits could be achieved for a lesser cost, with a similar level of risk.

The purpose of the Hazardous Substances and New Organisms Act 1996 **(HSNO),** is outlined in Section 4 of the HSNO Act, quoted below.

> *The purpose of this 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.*

When assessing a new organism against the purpose of the HSNO Act, the risks are defined as adverse effects. These risks are assessed and managed separately from assessing the potential benefits and costs of the GMO.

The proposals within the consultation document are focused on laboratory research. The direct benefits of these proposals sit with the research sector. With the proposed changes, the research sector will potentially be able to undertake more research at a lesser cost. The pre-consultation for these proposals targeted the research sector.

If a future consultation looks more broadly at this topic, including reviewing definitions and the settings for field trials, we will welcome a broader conversation with the wider public.

To support a meaningful conversation with the wider public, science communication will be required, so all the people who are potentially affected can meaningfully engage with this topic.

2.2.1. POTENTIAL RISKS AND BENEFITS ASSOCIATED WITH GMOS AND NEW BREEDING TECHNOLOGY FOR HORTICULTURE

There is horticulture research that makes use of GMOs and new breeding technologies. These technologies potentially have commercial and climate change benefits.

Fruit and vegetables are already the lowest emissions food, and so unlike other farming activities, there is not the same incentive to use GMOs to breed fruits and vegetables that can be grown, producing lesser greenhouse gas emissions.

However, a key aspect of transitioning to a low-emissions economy is increasing plant-based diets. Plant breeding has a role in developing new varieties that are more desirable and nutritious and may support greater consumption of fruit and vegetables. Plant breeding for desirable traits may rely on new breeding techniques that produce plants that could be found in nature.

There are potential adverse environmental and human health impacts of some of the agrichemicals that are used to protect plants from pests and disease. Plant breeding, including a full range of breeding techniques, may be able to develop plants that are more resilient and less reliant on the use of agrichemicals.

In the future, with a changing climate, there is likely to be increased droughts and pests. Plant breeding may be able to produce plants that are more resilient to future growing conditions The technology that supports plants that grow in conditions different from our existing environment may rely on a full range of breeding techniques.

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https://web.archive.org/web/20210111062552/https://www.loc.gov/law/help/restrictions-on-gmos/eu.php

One of the adverse effects that the horticulture sector is concerned about is related to the potential for GMO plants to contaminate non-GMO plants and create an economic impact on fruit and vegetables that are organic or sold into markets that value GMO foods less.

3. Consultation Questions

The consultation document poses a number of questions. The HortNZ submission does not comment on those questions relevant specifically to biomedical research and is only focused on those questions we considered most relevant to horticulture.

Objectives

Q. 1	In your view, are these objectives the most effective for developing policy changes to improve the regulatory settings for genetically modified organisms? If not, what should the objectives be, and why?

Proposed approach

The consultation document identifies three objectives:

1. proportionately manages the risks that laboratory research poses to the environment, and the health and safety of people and communities[3]
2. contributes to better health outcomes for New Zealanders through better biomedical research outcomes and innovation, and through greater access to therapies and medicines.
3. It is not only up to date but also future proof to anticipate and flexibly accommodate future technological developments to the best extent possible.

Discussion of the proposed approach

The premise in the consultation document is that administrative constraints within the existing regulations for GMO research within laboratories are adding cost and are inefficient. But that these administrative requirements do not reduce the risk associated with very-low-risk and low-risk GMO research in laboratories because the risks associated with these activities are inherently very-low or low.

It is proposed that a less onerous and more efficient system would deliver the equivalent risk to the environment, and the health and safety of people and communities, at a lesser cost. It is envisaged that those cost savings would result in benefits for the economy and society due to a predicted increase in GMO research as a result of reduced administrative costs and a more future-proofed and flexible regulatory system.

This being the case, we think the framing of the review objectives would be improved to be more closely linked to the purpose of the Hazardous Substances and New Organisms Act 1996 **(HSNO),** outlined in Section 4 of the HSNO Act, quoted below.

> *The purpose of this 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.*

[3] Including the health and safety of laboratory staff.

HortNZ recommendations

We propose that the objectives of the review would be better framed as follows:

We want to ensure that the regulatory framework in Aotearoa New Zealand for GMOs:

1. Proportionately manages the risks ~~that~~ **of** laboratory research **in order** ~~poses~~ **to protect** the environment[4], and ~~to~~ the health and safety of people and communities[5]
2. Contributes to better health outcomes for New Zealanders through better biomedical research outcomes and innovation, and through greater access to therapies and medicines.
3. **Design a regulatory system that** is not only up-to-date but also future-proof to anticipate and flexibly accommodate future technological developments to the best extent possible.

Proposal 1: Introduce a risk-tiering framework for laboratory research

Q. 3	Do you agree with the proposed change: to establish a risk-tiering framework modelled on the risk-tiering framework under Australian regulations??

Proposed approach

The risk tier approach classifies the risk from GMOs from tier 1, where no containment is required, to tier 2, requiring PC1 containment, and tier 3, requiring PC 2 containment. tiers 1 – 3 do not require EPA assessment or approval. Above-risk tier 3 EPA approval is required.

The proposed approach is modelled on the Australian system with research cooperation benefits assumed related to greater regulatory alignment with Australia.

The Australian system is one where specific hosts and vectors, and risks are identified. An outline of the Australian risk-tiering framework is provided in the consultation for feedback.

The details of what will be included in any New Zealand risk-tiering framework will be consulted on later (that is, what organisms, modifications, vectors and exclusionary criteria should be included in the NZ risk tiers).

Discussion of the proposed approach

Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003, include a process for establishing regulations, and assessment of adverse effects of developing genetically modified organisms.

We anticipate that what is proposed is that the risk tier approach would be developed and replace the existing approach. The risk tier approach is more prescriptive than the existing approach because the risk tier approach removes the individual assessment by

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[4] HSNO defines Environment: environment *includes—(a) ecosystems and their constituent parts, including people and communities; and (b)all-natural and physical resources; and (c)amenity values; and(d) the social, economic, aesthetic, and cultural conditions which affect the matters stated in paragraphs (a) to (c) or which are affected by those matters.*

[5] Including the health and safety of laboratory staff.

the regulator for those matters within tiers 1 -3, relying on the assessment of the biosafety committee for assessments for risk tiers 2 – 3 and a trust-based system for tier 1.

We support the development of explicit criteria, given the role of the trust-based and biosafety committees in implementing the risk tier framework. We support an approach, where the risk from inappropriate classification is managed by listing those organisms that are considered unsuitable for a certain risk tier under a higher risk tier or explicitly excluding it from the risk-tiering framework. Research that does not fit neatly into the proposed risk tiers should be referred to EPA or a representative body for greater assessment.

The development of the content of the risk assessment would presumably be subject to meeting the purpose and principles of the Act. It would be useful to see a clear assessment of the Australian risk tiers, against the NZ legislation, and a clear framework for assessing risk for establishing the tiers.

We note the term risk – was defined in the Hazardous Substances and New Organisms (Methodology) Order 1998.

> **risk** *means the combination of the magnitude of an adverse effect and the probability of its occurrence.*

Using this definition, assessing whether the risk from a GMO is appropriately managed by the risk tiers is an assessment of both the likelihood and consequences of adverse effects. In this process, risk, cost and benefit are assessed separately.

In the context of low-risk GMOs and containment, risk management is focused on the probability of the release into the environment. As outlined in paragraph 13 of the interim regulatory statement, one of the reasons for the review is that very-low-risk GMOs have no ability to survive outside of their containers, and, therefore, essentially present no risk to the environment and the health and safety of people.

For other GMOs, there is some chance, that they could exist in the environment – and could be released unintentionally, or potentially intentionally but illegally. The purpose of containment is to minimise that probability, so it is acceptably low. Given the potential consequences of the release, the discipline of assessing both the likelihood and consequences elements of risk is important to ensure appropriate containment design.

In the context of field trials – which are outside of the scope of this review – the consequences of adverse effects are more influential on the risk management design.

In the Australian risk-tiering framework, "a *dealing involving a genetically modified plant;*" is classified as needing at least containment level 2, or in other words, risk tier 3 or higher, with higher than risk tier 3 requiring EPA assessment.

In the context of laboratory research, we accept that research involving genetically modified plants does carry more risks than some other research related to the potential to establish if escape occurred, and in that respect, the classification of risk associated with research on GMO plants in the Australian system seems reasonable, given the existing definition of GMOs in the HSNO Act. (The existing definition of GMO in the HSNO Act is discussed further in this submission in response to proposal 7)

HortNZ recommendations

- Support a risk tier approach aligned in structure with the Australian system for GMOs.

- Ensuring the risk tiers require minimal interpretation by the biosafety committees, by creating prescriptive risk tiers, including listing those organisms that are considered unsuitable for a certain risk tier under a higher risk tier or explicitly excluding it from the risk-tiering framework.
- In determining the content of the risk tiers, undertake a transparent assessment of the magnitude of an adverse effect and the probability of its occurrence, and align the assessment of adverse effect against those matters the HSNO Act seeks to protect.
- Retain controls over the importation of new organisms, including GMOs.

Q.6.	Do you agree with the proposed establishment of accredited biosafety committees and an Environmental Protection Authority biosafety committee?

Proposed approach

At tiers 2 and 3, a biosafety committee is required to confirm that:

- the research meets the criteria for this risk tier,
- the committee is satisfied that the researcher can undertake the research, and
- the facility is appropriate for the research.

The biosafety committee would be accredited by the EPA and can be formed with staff from within the research organisation that is undertaking the research being assessed.

Discussion of the proposed approach

The proposed approach will likely be much more efficient than the current EPA process. It places a high degree of trust and expectations of ethical behaviour on these biosafety committees.

Given the importance of these committees, we consider the accreditation criteria and audit of the biosafety committees should be clear and robust and independent. The way this process is discussed in the consultation is not sufficiently clear to provide certainty that this would be a robust system. For example, the consultation document describes the process as follows.

> *The EPA would audit a proportion of assessment reports each year. For those ABSCs that require improvements to the quality of their assessments, the EPA would provide ongoing guidance or use other enforcement mechanisms, such as extra audits of future assessments.*

The consequences of incorrectly assessing and managing risks from GMO research in laboratories are potentially high, and so while we support an efficient system, the system also needs to provide high confidence that it is effective, and a method of ensuring that the system provides consistency between separate committees is important.

Our understanding is that in Australia, the biosafety committees are both responsible and accountable for decisions. It would be useful to understand how biosafety committees in the proposed NZ system would be held accountable.

HortNZ recommendation

- We recommend that very clear and robust assurance processes are developed, including accreditation, audit, certification, and enforcement for accountabilities.

- Require annual EPA audits of assessments by internal biosafety committees.
- Establish criteria or methods to ensure consistency between biosafety committees.

Proposal 6: Reduce regulatory requirements for the use of eukaryotic somatic cells

Q. 24	Do you agree with the proposed change: to include certain eukaryotic somatic cells under risk tier 1 of the risk-tiering framework outlined in Proposal 1?

Proposed approach

Eukaryotic cells are cells of eukaryotes, which as a category include animals, plants, fungi and many unicellular organisms, and which are distinct from bacteria and archaea. Risk tier 1 would likely include the somatic cells and tissues of animals, humans and plants.

This proposed change would mean the genetic modification of these cells would be exempt from EPA assessment and approval requirements and would not need to be undertaken in a containment facility approved by MPI. Specifically, these cells would be exempt from EPA assessment and approval for importation, development and use as or in medicine.

The discussion document includes likely conditions, and, for plants, only includes plant cells or tissues that cannot spontaneously generate a whole plant and cannot be regenerated into a whole plant.

Discussion of the proposed approach

GMO somatic cells that can be induced to form a whole plant should not be included in risk tier 1.

Inducing a somatic cell to form a whole plant is a specialist method, so could not be done accidentally, but there is a low probability of technically adept people removing genetically modified somatic cells from a laboratory for illegitimate research.

In our view, there is a need for some degree of oversight and containment to manage the risks of illegitimate activities that could result in GMOs being released into the environment, if they pose potential risks to the environment or the health and safety of people and communities.

HortNZ recommendation

- GMO somatic cells that can be induced to form a whole plant should not be included in risk tier 1.

Proposal 7: Clarify the regulatory status of certain biotechnologies

Q. 24	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?

Proposed approach

Biotechnologies exempt from regulation under the HSNO Act are listed under the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998 (Non-GMO Regulations). For example, under these regulations, technologies such as chemical mutagenesis or cell fusion are specified as technologies that would not result in a GMO.

The proposal recommends, under the Non-GMO Regulations, that the use of three biotechnologies, according to specific criteria, do not result in a GMO.

- The introduction of ribonucleic acid (RNA) into an organism
- The introduction of DNA into an organism
- Epigenetic modifications.

The proposal states that the conditions placed on the above three biotechnologies would prohibit modifications to the genetic makeup of an organism, including gene editing techniques in any form.

Discussion of the proposed approach

The approach is where the definition in the Act remains broad and specific biotechnologies are excluded by regulation. This approach is unambiguous.

In some countries, the definition of GMO has or are considering changing the definition of GMOs., for example, the United Kingdom and Europe described below:

New Zealand

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.

United Kingdom

The Genetic Technology (Precision Breeding) Act 6 was passed into law in 2023.

The term used in the UK law to be differentiated from GMO is precision-bred organism. The definition is:

Precision bred organism:

For the purposes of this Act an organism is "precision bred" if—

(a)any feature of its genome results from the application of modern biotechnology,

(b)every feature of its genome that results from the application of modern biotechnology is stable,

(c)every feature of its genome that results from the application of modern biotechnology could have resulted from traditional processes, whether or not in conjunction with selection techniques, alone, and

(d)its genome does not contain any feature that results from the application of any artificial modification technique other than modern biotechnology.

European Union

In July 2023, a proposal was put before the European Commissions called: REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625.[7]

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[6] https://bills.parliament.uk/bills/3167#:~:text=A%20Bill%20to%20make%20provision,animals%3B%20and%20for%20connected%20purposes.

[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0411

The term used in this paper is New genomic techniques (NGTs). Targeted mutagenesis and cisgenesis (including intragenesis) are considered NGTs. Targeted mutagenesis and cisgenesis do not introduce genetic material from noncrossable species -transgenesis. The proposal is for plants obtained by targeted mutagenesis or cisgenesis that could also occur naturally or be produced by conventional breeding would be treated similarly to conventional plants and would not require authorisation, risk assessment, traceability and labelling as GMOs, and for all other NGT plants and products would require (as today) an authorisation. The risk assessment would be adapted to cater for their diverse risk profiles and to address detection challenges.

The interim regulatory impact statement in paragraph 5 explained that because the scope of the review did not include the release of GMOs into the environment, changing the definition of the GMO to be risk-based was not considered, and as explained in paragraph 36, would likely require a full review of the HSNO Act.

HortNZ recommendation

- In a future review, analyse and discuss the changes to the GMO definition that have been adopted in the United Kingdom and the definition proposed in Europe, and assess the risks, benefits and costs in the context of the HSNO Act, if New Zealand was to adopt a similar change in definition.
- The definitions underpinning these regulations will have ramifications beyond lower-risk research. We recommend NZ review its current legislative definitions before designing any risk-tiering legislation. If our legislation uses outdated definitions, then the subsequent regulations themselves will be outdated quickly and there is a risk that they will not be easily understandable or implementable in a standardised and robust way.

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