Hazardous Substances and New Organisms Amendment Bill (No 2)

Government Bill

As reported from the Local Government and Environment Committee

Commentary

Recommendation

The Local Government and Environment Committee has examined the Hazardous Substances and New Organisms Amendment Bill (No 2) and recommends that it be passed with the amendments shown.

Introduction

The Hazardous Substances and New Organisms Act 1996 (the Act) restated and reformed the law relating to the management of hazardous substances and new organisms. The Act established the Environmental Risk Management Authority (the Authority), which carries the main responsibility for implementing the Act.

This bill amends the Act to reflect Government policy in respect of hazardous substances. Where possible, the bill aims to streamline and reduce the costs of procedures under the Act, but not at the expense of allowing informed public participation in processes designed to protect the environment and the health and safety of people and communities.

The Act is already in force for new (including genetically modified) organisms; but for hazardous substances, entry into force was delayed on account of difficulty finalising the text of relevant regulations. In the meantime, hazardous substances have continued to be controlled under several older statutes. The transitional arrangements under the Act, which would have expired on 1 January 2001, are adjusted in the bill to allow orderly transfer of hazardous substances once the Act enters into force for those substances. Were the transitional period not extended, hazardous substances—including everyday items such as motor fuels, most paints and printing ink—would become illegal at the end of this year.

Delegation by the Authority

The Authority has a number of functions relating to approving people and methods, to ensure compliance with the Act. Under section 19(2) of the Act, the Authority has the power to delegate, to any person, decision-making on:

- rapid assessment of an application to import new organisms which meet certain criteria
- rapid assessment of an application to develop, in containment, genetically modified organisms defined by regulation as low-risk.

It may also delegate the power to hear and decide any application involving the assessment of hazardous substances or new organisms to a committee appointed by the Authority.

Clause 5 of the bill extends the Authority's power to delegate decision-making on decisions made under the transitional provisions of the Act. On the basis of evidence received, we recommend provision for further delegations of the Authority's executive functions as set out below.

Delegation of hazardous substance containment approvals

We recommend, in clause 5, a new section 19(2)(e) which provides that the power to hear and decide on any application under section 31 to import into containment, or manufacture in containment, any hazardous substance may be delegated to the chief executive of the Authority (see below, under *Product development*, subheading *Field tests in containment*).

Delegation of functions related to ensuring compliance

The Authority, under section 83 of the Act, approves test certifiers. This allows the test certifiers to issue certification for handlers of hazardous substances, sites, and equipment, among other things, as required by the regulations. We consider that the power to approve test certifiers should be extended to any person whom the Authority considers has the necessary competence. We recommend this in clause 5, new section 19(2)(f). Among other things, this would allow continuation of the present arrangements for gas cylinder inspection where two certification agencies approve (under authority from the Chief Inspector of Dangerous Goods) cylinder testing stations. Cylinder testing stations are an example of test certification in current use.

Delegation of these powers would avoid an increase in the cost of the approval process. Systems that already exist could continue to be used. This would avoid creating additional administrative costs by requiring the Authority to approve test certifiers. The Authority is already required to keep records of test certifiers and monitor performance, and retains the ability both to revoke any delegation and to cancel a test certifier's approval. This situation should not be changed. The system as it stands is robust because the Authority is expected to keep tight control on the people doing the certification.

Test certificates are issued by test certifiers under section 82 of the Act. Section 140(1)(c) of the Act enables regulations to be made covering gas cylinders, but the Act does not provide for regulation-making powers in relation to test certificates in general. This omission appears to be an oversight, and we recommend, in new clause 29(2), the power to amend regulations to cover this.

The Authority has suggested that it might delegate to its chief executive the power to appoint enforcement officers under section 99 of the Act. Given that other agencies' chief executives are empowered under that section to appoint enforcement officers, this seems a reasonable suggestion, and it would decrease costs for the Authority. We therefore propose that the existing delegation machinery under section 19 of the Act be extended further, as set out in clause 5, new section 19(2)(g). The safeguards under section 85, which requires the Authority to keep records of test certifiers, and section 86, which provides for the ability to cancel a test certifier's approval, would continue to apply.

The new section 19(2)(d) in clause 5 has been lifted from clause 8(6), to place it with other delegations.

We consider that information about delegated power to assess risks related to hazardous substances and new organisms should be publicly accessible, and we recommend this in new subclause (2) of clause 5.

Approval for substance, not applicant

A key amendment to the Act is contained in clause 7. Section 28 of the Act requires every person intending to import or manufacture a hazardous substance, otherwise than in containment, to apply to the Authority for approval to do so. (The Act deals elsewhere with containment approvals.) Clause 7 clarifies that, except in certain specified circumstances, it is the substance that receives the approval, not the applicant. This approach is fundamental to the Act, in that the Act provides for managing the hazard of the substance, not for protecting intellectual property associated with the substance. If the applicant obtained a personal approval there would be, particularly for relatively widespread substances, multiple approvals based on the same information for the same substance dealing with the same risks. This would lead to large administrative costs for no environmental gain.

Some submitters pointed out that this approach has the disadvantage that the original applicant may incur all the costs of seeking an approval under the Act. However, the original applicant has the advantage of being able to secure the market by being first to use the approval. In addition, the Act provides mechanisms to reduce the cost disadvantage. These mechanisms include the ability to approve a large number of products as a single substance and, by not restricting it, the ability for applicants to share in approval costs. [1]

Exception to approval of the substance

Clause 9 modifies this treatment with respect to certain agricultural and medical compounds. Two submitters considered that the proposed change in clause 9 was anti-competitive and created an effective monopoly for these products. Both submitters proposed that the clause be deleted. However, most submitters were concerned that

[1] For example, paint. Section 2(1) of the Act defines a "substance" to include, *inter alia*, any compound, or defined mixture of compounds... produced synthetically..., and section 2(2) states that, for the purposes of the definition of "substance", the definition... may include a range of percentages of the... compounds making up the substance.

the proposed changes would not be sufficient to protect commercially sensitive data and prevent others from piggybacking on their approvals. While these submitters supported the clarification in clause 7, they did not feel that the proposed change would provide sufficient protection with respect to innovative agricultural compounds and veterinary medicines.

Clause 9 is drafted to ensure that the Act complies with New Zealand's international commitments under the Agreement on Trade-Related Aspects of Intellectual Property Rights. The agreement requires that the intellectual property contained in certain compounds that utilise new chemical entities receive protection. Several statutes were amended in 1994 to give effect to this requirement, and we are not recommending any change in this area.

At a practical level, this type of data protection means that the information provided with an application cannot be used by the Authority to evaluate any subsequent approval. Therefore, any other party wishing to use the substance during the protected period must have an application assessed from scratch.

Transitional arrangements

There is a potential problem in the transition of notified toxic substances to the new regime created by the Act. This is due to differences in the nature of a notification under the Toxic Substances Act 1979. The result is that only those persons that have notified a toxic substance will be able to continue to import and manufacture it. This situation will continue until such time as the substance is transferred to the new regime. This has the effect of making the ability to import or manufacture that toxic substance the personal property of the notifier during this interim period, contrary to the intent of the Act. We consider that the Act should be amended to allow anyone who complies with the current controls to be able to use any notified toxic substance during the interim period. This can be achieved by providing that the approval for any substance notified under section 32 of the Toxic Substances Act relates to the substance, not solely to the notifier. We recommend the inclusion of a new clause 31B amending section 184 of the Act to provide for this.

In addition, new clauses 31A and 31C continue the protection of certain information provided by Part IIIA of the Pesticides Act 1979 and Part IIA of the Animal Remedies Act 1967.

Rapid assessment of hazardous substances

Clause 8 sets out circumstances in which the Authority might make a rapid assessment of the adverse effects of importing or manufacturing a hazardous substance. This provision, which would reduce costs for applicants, relates only to low-risk substances, or substances with properties similar to substances already approved. It parallels a provision already in the Act for new organisms.

The use criterion

New section 28A(2)(c) in clause 8 provided for rapid assessment based on the likelihood that the risks from the specific uses declared at the time approval was sought for the substance were low. A subsequent use of the substance, not visualised by the original applicant, could have increased the risk substantially. For example, a chemical to be used to control algae in closed-circuit cooling applications might subsequently have been used as spray-applied pesticide.

To ensure that the substance would not subsequently have been used in a more risky context, new section 28A(4), would have allowed for the Authority to require anyone to notify it if they intended to use that substance for a different purpose.

For this provision to work effectively, the Authority would have had to ensure that it was always informed of any change in use. This would have implied a level and type of enforcement that is well outside the current scope of its activities. We consider that adding sections 28A(2)(c) and 28A(4) to the Act would have presented risks, and could have weakened the purpose of the Act. Accordingly we recommend deletion of both those provisions and, consequentially, the definition of the term "risk" in clause 2.

"Similar" composition and "similar" properties

The meaning of "similar" in the context of rapid assessment is important. The intention of the bill is to give the Authority scope to streamline process, without compromising the health and safety of people, or risking damage to the environment. Difficulty arises because substances with quite similar composition may not have similarly hazardous properties. The technical categories applying to intrinsically hazardous properties are not sufficiently finely graded, in all cases, for them to be able to be used as a basis for a statutory definition of "similar" hazardous properties.

We considered whether something could be gained by qualifying the term "similar" in this context. Possibilities included essentially similar, essentially the same, and substantially the same. In proposing "essentially similar", we emphasise that there should be very little flexibility, when the Authority is making judgements about similarity, in the direction of increased hazard. Moreover, we see no scope for trade-off between different intrinsically hazardous properties, for example weighing flammability against toxicity, when substances are being compared for similarity in terms of clause 8.

Ensuring accuracy of information supplied

The Act, in four specific cases, gives the Authority the discretion to require a statutory declaration to attest to the accuracy and completeness of information provided. The sanction for providing false information in a statutory declaration is set out in the Crimes Act 1961. It is a term of imprisonment not exceeding three years.

Accuracy of information supplied by an applicant for rapid assessment is crucial, particularly taking into account the absence of a countervailing public input into the rapid assessment process. The provision in the bill with regard to verification of information supplied in terms of this clause, which flows from section 28 of the Act, is discretionary. Taking the nature of the rapid assessment procedure into account, we consider that this provision should be strengthened. We propose that a statutory declaration should be mandatory in relation to applications for rapid assessment for the importation or manufacture of hazardous substances, and recommend that section 28A(1) in clause 8 of the bill be changed accordingly.

Product development

Submitters recognised two contrasting perspectives on product development. On one hand, the environmental risks associated with innovative activities had to be carefully assessed to prevent activities that were likely to be environmentally damaging. On the other hand, it was of no less importance that this assessment should be as cost-effective as possible and prompt, so that innovation would not be inhibited by the costs of process and delay.

Section 33 of the Act currently exempts (with certain safeguards) from its provisions "small-scale uses of hazardous substances in scientific investigations or teaching". Clause 12 of the bill proposes to replace the words "scientific investigations" with the words

"research and development". Clause 2 defines a laboratory in a way that would include a building or structure set aside and equipped for product development.

Currently, section 30 of the Act allows research on hazardous substances which receive approval for manufacture or importation in containment, specifically for the purpose of acquiring information for an application under Part V of the Act. We recommend in new clause 9A, as a clarification, an addition to section 30 of the Act, which would allow the Authority to approve applications to manufacture or import hazardous substances for the purpose of research and development in containment. Such applications would be approved subject to controls. (See also under the heading *Field tests in containment* below.)

Small-scale research

The purpose of these changes, which enlarge the scope of the section 33 exemption, is to facilitate product development by industry. Submitters pointed out that industrial research and development may in some cases involve only a few kilograms of material, but in other cases it could be hundreds of kilograms, or even tonnes. Partly because larger quantities of material might now be involved, clause 12 introduces additional conditions for the exemption, related to importing, storing and transporting the hazardous substances being used for research and development, in containment. Clause 29 allows the relevant provisions to be introduced in regulations. Clause 12 also precludes sale of the hazardous substance, or any substance created or derived from the hazardous substance.

Small-scale is not synonymous with small quantities. The bill intentionally does not define small-scale use, which implies a range of quantities depending on the context. We endorse this approach, but we would expect administrative guidance to be developed by the Authority in this area.

Field tests in containment

In response to submissions from industry, we considered a proposal to extend the small-scale research exemption to include field-testing, for example, of agricultural chemicals and animal remedies. The small-scale research and development exemption takes into account regulations to provide a standard set of predetermined controls that will ensure there will be no escape of material from the site. This can

be achieved where the site is physically contained and this physical containment is then augmented with additional controls, such as in a laboratory. A field trial, however, is done in the open and has direct contact with the atmosphere, the soil, and possibly even the water table.

The solution as we see it is to treat this type of work as a matter to be addressed by specific containment controls, to be dealt with under sections 30 to 32 of the Act. This would include the provision mentioned above to extend the purposes in section 30 to enable research and development in containment. This option is reasonable because containment approvals will be considered case by case, using the matters set out in the Third Schedule of the Act.

We consider that the assessment of such applications under delegated authority (proposed in clause 5) is also reasonable, because these types of field trials, when each instance is controlled addressing the matters set out in Schedule 3, present a low risk to the environment.

Public notification of applications

Clause 17 exempts applications for rapid assessment under proposed new section 28A from the public notification requirements of the Act.

A related matter that the Authority brought to our attention concerns importing a new organism into containment. Although the Authority has the discretion to give public notice of applications to develop genetically modified organisms in containment, there is no parallel discretion for new organisms. An example could be importing and holding high-risk disease organisms in containment for diagnostic purposes. We recommend, in new clause 17(2), amending section 53(2) of the Act to make such provision.

The Authority reported that surveys it had conducted indicated that very little of the public participation in its consideration of applications had stemmed from participants having read about the applications in the Public Notices section of the main metropolitan areas' newspapers. Our concern is to minimise costs to applicants, but to retain effective public participation. The Authority suggested that it might develop a form of public notification more relevant and effective than the form that has been used until now.

We consider that a process similar to that set out in the Act for public consultation on fees and charges would be suitable for seeking public comment on any alternative form of public notification.

Accordingly, we recommend that the definition of public notice be changed, as set out in our amended definition of "public notice" in clause 2, to enable the Authority to proceed along the line set out in new clause 17A.

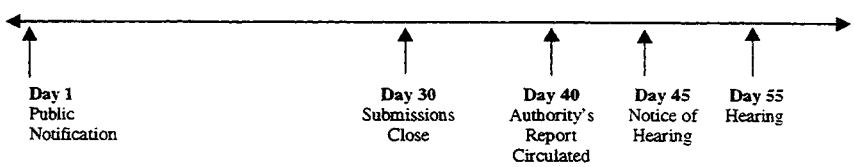
All applications received are viewable on the Authority's web site. In addition, the Authority uses a mailing list to inform people who wish to be informed about particular types of application. We suggest that routinely informing rūnanga and iwi publications about new applications would assist Māori in keeping up with new applications.

Application timelines

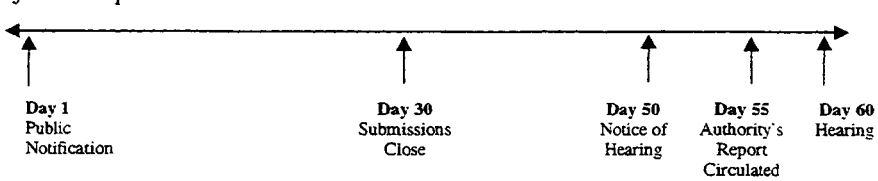
Clauses 18 and 19 of the bill change the timeline for applications to the Authority. This is because the Act allows only ten working days for the preparation of the evaluation report under section 58(1) after the closing date for submissions. The Authority has found that it takes longer to prepare these reports, and in almost every case so far, it has had to use section 59(5) to waive the time limit.

The combined effect of clauses 18 and 19 would be to increase the time between the closing date for submissions and the hearing date from 25 to 30 days, and to increase from 10 to 25 days the time allowed for the Authority to obtain additional information and circulate its report. This is illustrated by the following timelines:

Current situation (as set out in sections 58 and 59 of the Act)

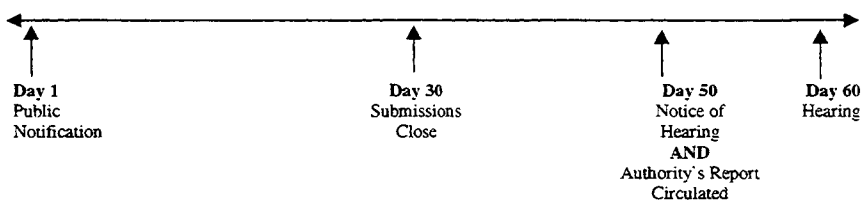


If bill is passed as it stands



We consider that the change in clause 18 would mean that submitters and applicants would not have adequate time (only five days) to consider the Authority's evaluation report or any other additional information supplied to the Authority under section 58(1). We consider that ten days' notice is more reasonable. Our proposed change is illustrated below.

Proposed change to the bill



Codes of practice

Section 78 of the Act, as amended by clause 25, empowers the Authority to issue, amend, approve or revoke any code of practice for hazardous substances for the purpose of implementing any requirements included in controls or in regulations in force under the Act. The amendment makes it clear that notification, consultation and consideration in terms of section 79(2) of the Act must precede approval by the Authority of any code of practice. Because such codes give effect to current technology, it is our view that the procedure for improving them in the light of new technology should not be cumbersome.

Compliance with these codes of practice is at present voluntary. However, compliance with approved codes of practice may be a defence to prosecution for failing to comply with controls specified in regulations. We consider, therefore, that these codes must be developed in a robust way, and be clear, concisely drafted, and reviewable by Parliament. Accordingly we recommend, by majority, the insertion of a new clause 25A, which widens the obligation of the Authority to consult with the public before approving, amending or revoking codes of practice, ensures accessibility to these codes, and provides that codes of practice should be deemed to be regulations for the purposes of the Regulations (Disallowance) Act 1989.

The minority expressed concern that this recommendation runs counter to departmental advice to the effect that deeming codes of practice to be regulations could transform what was intended as a low-cost method of meeting the obligations and principles of the legislation into a costly and administratively cumbersome mechanism.

Minor amendments to approvals and controls

Clause 23 creates a new section 67A of the Act that authorises the Authority to make minor amendments to the controls that it sets on substances that it has approved. This is to allow adjustments to controls if there has been a mistake or a technical error, or a minor change to the control to decrease costs, without having to resort to a full reassessment of the substance.

We consider that a slightly broader authorisation would be in order, allowing elements of an "approval" (which includes "controls") to be amended, provided this is minor in effect, or corrects a minor or technical defect. This could include adjustments that corrected the identity of the substance, without changing the identity. We have discussed the sorts of limitations that there could be on any adjustment, and consider that these would be provided by the provision as stated.

Accordingly, we recommend in new clause 23 the insertion of a new section 67A into the Act to allow correction of minor or technical errors in an approval (which includes any controls attached to the approval).

Powers of entry for inspection

Clause 2 changes the definition of "premises" to include dwellings. This allows premises to be understood more broadly in the Act. For example, the scope of local authority enforcement in section 97(h) of the Act refers to premises, and recognises that currently, council dangerous goods officers check dwellings for problems such as barbecue gas cylinders with dangerous connections.

Consequentially, clause 28 of the bill modifies the general power of entry into premises for inspection, in section 103(1)(a) of the Act, to exclude dwellings. The power of entry into dwellings is specified separately in section 103(1)(b), and requires the agreement of the occupier, or a search warrant under section 119.

Enforcement officers are empowered, for the purposes of their inspection, to "take measurements and sketches". To reflect modern practice, we consider that this provision should include the ability to use still and moving image recording. We therefore recommend a new clause 28(2), which amends section 103(2)(c) accordingly.

The experience of enforcement officers in the Department of Labour's Occupational Safety and Health Service, and in the health sector, suggests that a power to require a particular place to be left undisturbed would be useful in some circumstances. The Act being silent on this matter suggests that at present, an enforcement officer could not exercise such a power. To enable information to be collected as part of an inspection, we recommend in new clause 28(3) the addition of a new section 103(2)(ea) to provide for this.

Practical considerations also indicate that enforcement officers, who are empowered to take copies of documents relevant to their inspection, should have the ability to take statements as well. This would be in line with a similar provision in the Health and Safety in Employment Act 1992. We recommend provision for this, also in clause 28(3), adding a new section 103(2)(eb). In giving enforcement officers this additional power, we note that it is balanced by the provision in section 103(7) of the Act relating to the privilege against self-incrimination.

Section 103(6) of the Act provides for enforcement officers "if authorised" to take another person on to premises to assist with the inspection of the premises. The intention was to allow relevant specialists to assist. A recent Crown Law opinion, however, says that the wording of this section means that the authorisation must be given separately for each occasion. A more general authorisation would be useful, but we consider that this should be carefully circumscribed, by limiting the authorisation to persons with relevant experience or expertise. We recommend accordingly in new clause 28(4).

Expiry of transitional provisions

Clause 30 extends the expiry date on the period for completing the transition for hazardous substances from 1 January 2001 to a period three years from start-up, with the option to extend for an additional two years if necessary. Much of the infrastructure for managing hazardous substances is winding down in anticipation of the commencement of the hazardous substances aspects of the Act. For example, although the machinery under the Dangerous Goods Act

1974 remains in place, the number of Inspectors of Dangerous Goods has been allowed to fall. However, the new, less labour-intensive regime envisaged under the Hazardous Substances and New Organisms Act (based on a requirement for test certificates) is not yet in place.

A larger task is the transfer of some 130,000 notifications under the Toxic Substances Act 1979 (a number which includes, we are advised, significant duplication) to the regime created by the Hazardous Substances and New Organisms Act. The Authority, taking other priorities into account, is planning to deal with the transfer between 2003 and 2006. We would not want to see the transfer delayed beyond that timeframe.

Minority report

The Act Party expressed concern that the amendments do not diminish adequately the complexity and cost of processes under the Hazardous Substances and New Organisms Act 1996 involving the Environmental Risk Management Authority. Evidence from submitters representing industry claimed that the reporting and public participation processes were unnecessarily cumbersome and the added compliance costs since 1996 would effectively curtail commercial research and development in New Zealand to the detriment of growth and jobs and the competitive advantage of New Zealand business. The Act Party agrees.

Appendix

Committee process

The Hazardous Substances and New Organisms Amendment Bill (No 2) was referred to the committee on 5 October 1999. The closing date for submissions was 8 May 2000. We received and considered 16 submissions from interested groups and individuals. We heard nine submissions, eight of which (all from industry) were in a joint session. The hearing of evidence took 1 hour and 28 minutes. Consideration, including time spent in discussion with advisers from the Ministry for the Environment, and deliberation took a further 11 hours and 15 minutes.

Committee membership

Jeanette Fitzsimons (Chairperson)
Martin Gallagher (Deputy Chairperson)
David Benson-Pope
Georgina Beyer
Ann Hartley
Joe Hawke
Owen Jennings
Hon Murray McCully
Eric Roy
Richard Worth

Key to symbols used in reprinted bill

As reported from a select committee

Struck out (unanimous)

Subject to this Act,	Text struck out unanimously

New (unanimous)

Subject to this Act,	Text inserted unanimously

New (majority)

Subject to this Act,	Text inserted by a majority

(*Subject to this Act,*)	Words struck out unanimously
Subject to this Act,	Words inserted unanimously

Note: This bill has been reformatted in accordance with the resolution of the House of 22 December 1999.

Hon Marian Hobbs

Hazardous Substances and New Organisms Amendment Bill (No 2)

Government Bill

Contents

The Parliament of New Zealand enacts as follows:

1 Title

(1) This Act is the Hazardous Substances and New Organisms Amendment Act **(No 2) 1999**.

(2) In this Act, the Hazardous Substances and New Organisms Act 1996[1] is called "the principal Act".

[1] 1996 No 30

1A Commencement

This Act comes into force on a date to be fixed by the Governor-General by Order in Council; and 1 or more Orders in Council may be made fixing different dates for different provisions and for different purposes.

2 Interpretation

(1) Section 2(1) of the principal Act is amended by inserting, in their appropriate alphabetical order, the following definitions:

"**approved form** means a form approved by the Authority under **section 11(fa)**

"**laboratory** means a vehicle, room, building, or any other structure set aside and equipped for scientific experiments or research, for teaching science, or for the development of chemical or medicinal products

"**research and development**, in relation to a hazardous substance, means systematic investigation or experimentation activities that involve innovation or technology transfer for the purpose of gaining knowledge about the properties or uses of that substance.

Struck out (unanimous)

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

(2) Section 2(1) of the principal Act is amended by repealing the definition of **premises**, and substituting the following definition:

"**premises** includes a dwelling, building, aircraft, ship, carriage, vehicle, box, receptacle, and place".

New (unanimous)

(3) Section 2(1) of the principal Act is amended by repealing the definition of *public notice*, and substituting the following definition:

"**public notice** means—

"(a) a method determined by the Authority under section 53A; or

"(b) if section 53A does not apply or no method has been determined under that section, a notice published in 1 or more daily newspapers circulating in the main metropolitan areas together with such other public notice (if any) as the Authority or Minister thinks fit".

3 Precautionary approach

Section 7 of the principal Act is amended by inserting, after the word "sections", the expression "28A,".

4 Powers, functions, and duties of Authority

Section 11 of the principal Act is amended by inserting, after paragraph (f), the following paragraph:

"(fa) approve forms for applications under Part V:".

5 Delegation by Authority

(1) Section 19(2) of the principal Act is amended by adding the following (*paragraph*) paragraphs:

"(c) the power to decide any application for permission or other matter under Parts XI to XVI to—

"(i) any employee of the Ministry of Agriculture and Forestry, or of any person specified in section 97, with relevant experience in the subject matter of the application; or

"(ii) if there is no employee with that relevant experience, any other person with that relevant experience whether or not that person is a member of the Authority:

New (unanimous)

"(d) the power to conduct a rapid assessment under section 28A to its chief executive:

"(e) the power to hear and decide any application made under section 31 to its chief executive:

"(f) the power to hear and decide an application made under section 83 for approval as a test certifier to any person, whether or not that person is a member of the Authority:

"(g) the power to appoint an enforcement officer under section 99(3)(a) to its chief executive."

(2) Section 19 of the principal Act is amended by adding the following subsection:

"(6) Every delegation under **subsection (2)** must be available for public inspection at the office of the Authority during ordinary office hours."

6 Determination of new organism or hazardous substance

(1) Section 26(1) of the principal Act is amended by adding the words ", or (without limiting any regulations made under section 74(b)) whether or not any substance is a hazardous substance".

(2) The heading of section 26 of the principal Act is amended by adding the words "**or hazardous substance**".

7 Application for approval to import or manufacture hazardous substances

(1) Section 28(1) of the principal Act is amended by omitting the words "Every person", and substituting the words "Unless an approval under **section 28A** or section 29 applies to the importation or manufacture of the substance, every person".

(2) Section 28(2) of the principal Act is amended by omitting the words "the prescribed form", and substituting the words "an approved form".

8 (*Rapid assessment for importation or manufacture of hazardous substances*) New section 28A inserted

The principal Act is amended by inserting, after section 28, the following section:

"28A **Rapid assessment for importation or manufacture of hazardous substances**

"(1) When the Authority receives an application under section 28 in respect of a hazardous substance, and the applicant has verified the information contained in the application by statutory declaration, the Authority may make a rapid assessment of the adverse effects of importing or manufacturing the substance.

"(2) The Authority may approve a hazardous substance under this section if the Authority is satisfied that—

Struck out (unanimous)

"(a) a substance with a similar composition and hazardous properties has been approved; or

New (unanimous)

"(a) a substance having a similar composition and essentially similar hazardous properties has been approved; or

"(b) the substance has one or more hazardous properties and each hazardous property has the least degree of hazard for that (*property; or*) property.

Struck out (unanimous)

"(c) the information provided in accordance with section 28(2) indicates that the uses of the substance are likely to be low risk.

"(3) Section 77 applies to a hazardous substance approved by the Authority under this section as if the approval had been given under section 29.

Struck out (unanimous)

"(4) If the Authority is satisfied that **subsection (2)(c)** applies to a hazardous substance, the Authority may, in addition to the

Struck out (unanimous)

controls applied in accordance with section 77, require, as a control upon the substance, notification to it before any person manufactures or imports the substance.

"(5) If the Authority does not approve a hazardous substance under this section the application under section 28 may be determined under section 29."

Struck out (unanimous)

"(6) The Authority may, in writing and on such terms and conditions as it thinks fit, delegate to its chief executive any of its functions, powers, or duties under this section, and—

"(a) section 19(3) to (5) apply to every such delegation as if it were made under section 19(2); and

"(b) every such delegation must be available for public inspection at the office of the Authority during ordinary office hours."

9 ***(Approvals for innovative agricultural compounds and medicines)*** **New section 29A inserted**

The principal Act is amended by inserting, after section 29, the following section:

"29A **Approvals for innovative agricultural compounds and medicines**

"(1) Despite sections 28(1) and **28A**, no person may import or manufacture a hazardous substance that is the subject of—

"(a) an innovative agricultural compound application; or

"(b) an innovative medicine application—

unless that person has made an application for approval to import or manufacture that substance and that application has been approved under **section 28A** or section 29.

"(2) **Subsection (1)** ceases to apply in respect of a hazardous substance on the date that section 55(3) to (6) ceases to apply either to the Authority or to any information held by the Authority in relation to the hazardous substance concerned.

"(3) In this section,—

"(a) **innovative agricultural compound application** has the same meaning as in section 72 of the Agricultural Compounds and Veterinary Medicines Act 1997:

"(b) **innovative medicine application** has the same meaning as in section 23A of the Medicines Act 1981."

New (unanimous)

9A Importing hazardous substances in containment

Section 30 of the principal Act is amended by inserting, after paragraph (b), the following paragraph:

"(ba) research and development on any hazardous substance; or".

10 Application for hazardous substance containment approval

Section 31(2) of the principal Act is amended by omitting the words "the prescribed form", and substituting the words "an approved form".

11 Decision on application

Section 32 of the principal Act is amended by repealing subsection (2), and substituting the following subsection:

"(2) An approval under this section—

"(a) must include controls that provide for each of the applicable matters specified in the Third Schedule; and

"(b) may include controls that provide for any other matters in order to give effect to the purpose of this Act."

12 (*Exemptions from Act for small-scale research on hazardous substances*) New section 33 substituted

The principal Act is amended by repealing section 33, and substituting the following section:

"33 **Exemptions from Act for small-scale research on hazardous substances**

Nothing in this Act applies to any small-scale use of hazardous substances in research and development or teaching if—

"(a) the use occurs in a laboratory that meets the prescribed requirements; and

"(b) the use does not create or involve a hazardous substance for which any application for approval has been declined under this Act; and

"(c) the importation, storage, and transportation of the hazardous substances each meets the prescribed requirements; and

"(d) no such hazardous substance, nor any substance created from that use, is sold as a substance or in a product containing or derived from that substance."

13 Application for approval to import or release

Section 34(2) of the principal Act is amended by omitting the words "the prescribed form", and substituting the words "an approved form".

14 Application for containment approval for new organisms

Section 40(2) of the principal Act is amended by omitting the words "the prescribed form", and substituting the words "an approved form".

15 Determination of application

Section 45 of the principal Act is amended by repealing subsection (2), and substituting the following subsection:

"(2) An approval under this section—

"(a) must include controls that provide for each of the applicable matters specified in the Third Schedule; and

"(b) may include controls that provide for any other matters in order to give effect to the purpose of this Act."

16 Application for approval to use a hazardous substance or new organism in an emergency

Section 47(2) of the principal Act is amended by omitting the words "the prescribed form", and substituting the words "an approved form".

17 Applications required to be publicly notified

(1) Section 53(1)(a) of the principal Act is amended by adding the words ", if the application has not been approved under **section 28A**".

New (unanimous)

(2) Section 53 of the principal Act is amended by repealing subsection (2), and substituting the following subsection:

"(2) The Authority may, if it considers that there is likely to be significant public interest, publicly notify any application under section 40 to—

"(a) import into containment any new organism or develop any new organism in containment; or

"(b) develop any genetically modified organism in containment, if that application has not been approved in accordance with section 42."

17A New section 53A inserted

The principal Act is amended by inserting, after section 53, the following section:

"53A **Method of public notification**

"(1) The Authority may, if it thinks fit, determine a method of public notification of the applications referred to in section 53(1).

"(2) The method must, in the Authority's opinion, be a means of providing effective public notification at reasonable cost.

"(3) Before determining a method of public notification under **subsection (1)**, the Authority must—

"(a) publicly notify the method it proposes to determine; and

"(b) allow the period of time that the Authority thinks fit for any person who may be affected by the proposed method to comment in writing to the Authority on whether the proposed method is reasonable; and

"(c) consider any comments made in accordance with **paragraph (b)**.

"(4) The Authority must, as soon as practicable after determining a method of public notification in accordance with this section,

New (unanimous)

publicly notify the method in accordance with **paragraph (b)** of the definition of **public notice** in section 2(1)."

18 Further information

(1) Section 58 of the principal Act is amended by inserting, after subsection (1), the following subsection:

"(1A) Any report, advice, or other information obtained under subsection (1) may be considered at any hearing conducted by the Authority."

(2) Section 58(2) of the principal Act is amended by omitting the expression "15", and substituting the expression (*"5"*) "10".

19 Time limits and waivers

(1) Section 59(1)(b) of the principal Act is amended by inserting, before the expression "35" in each place where it occurs, the words "**28A** or section".

(2) Section 59(1)(d) of the principal Act is amended by omitting the expression "25", and substituting the expression "30".

(3) Section 59(4) of the principal Act is amended by inserting, after the word "extend", the words "or reduce".

(4) Section 59(5) of the principal Act is amended by inserting, after the word "extend", the words "or reduce".

20 Provisions relating to hearings

Section 61(5) of the principal Act is amended by omitting the words "the prescribed form", and substituting the words "an approved form".

21 Grounds for reassessment of a substance or organism

Section 62(4) of the principal Act is amended by inserting, after the words "any of sections", the expression "**28A**,".

22 Reassessment

Section 63(2) (a) of the principal Act is amended by inserting, after the word "under", the words "**section 28A** or".

Struck out (unanimous)

23 Minor amendments to controls

The principal Act is amended by inserting, after section 67, the following section:

"67A **Minor amendments to controls**

The Authority may amend the controls on an existing approval if the amendment is minor in effect, or corrects a minor error."

New (unanimous)

23 New section 67A inserted

The principal Act is amended by inserting, after section 67, the following section:

"67A **Minor or technical amendments to approvals**

The Authority may, of its own motion, amend any approval given by it under this Part if it considers that the alteration is minor in effect or corrects a minor or technical error."

24 Controls on hazardous substances

Section 77(1) of the principal Act is amended by inserting, before the expression "29", the words "**28A** or section".

25 Codes of practice

Section 78 of the principal Act is amended by repealing subsection (1), and substituting the following subsection:

"(1) The Authority may from time to time issue, amend, approve, or revoke any code of practice for hazardous substances for the purpose of implementing any requirement included in controls or in regulations in force under this Act."

New (majority)

25A Codes may be approved by Authority

(1) Section 79(2)(b) of the principal Act is amended by inserting, after the word "revocation", the words "or who have advised the Authority in writing that they wish to be consulted".

(2) Section 79 of the principal Act is amended by omitting subsection (4) and substituting the following subsection:

"(4) Where the Authority approves a code of practice, the Authority must ensure that, so long as the code of practice remains in force, copies of that code of practice, and all amendments to that code, are available—

"(a) for inspection by members of the public free of charge; and

"(b) for purchase by members of the public at a reasonable price."

(3) Section 79 of the principal Act is amended by adding the following subsection:

"(6) A code of practice that has been approved by the Authority is to be treated for the purposes of the Regulations (Disallowance) Act 1989 (but not for the purposes of the Acts and Regulations Publication Act 1989) as if it were a regulation within the meaning of that Act."

26 Processing applications for approval as test certifier

Section 84 of the principal Act is amended by repealing subsection (7), and substituting the following subsection:

"(7) An approval expires on the earlier of the following dates:

"(a) 5 years after the date on which it is given:

"(b) the date of expiry (if any) specified by the Authority in the approval."

27 Co-ordination of inspection

Section 98 of the principal Act is amended by repealing subsection (4).

28 Powers of entry for inspection

(1) Section 103(1)(a) of the principal Act is amended by inserting, after the word "premises", the words "(excluding dwellings)".

New (unanimous)

(2) Section 103(2) of the principal Act is amended by repealing paragraph (c), and substituting the following paragraph:

"(c) take photographs and measurements and make sketches and recordings; and".

(3) Section 103(2) of the principal Act is amended by inserting, after paragraph (e), the following paragraphs:

"(ea) require that any place or thing specified by the enforcement officer is not disturbed for a reasonable time pending any examination, test, inquiry, demonstration, or inspection; and

"(eb) require the making of statements by the person in charge of the premises, in any form or manner specified by the enforcement officer, about conditions, material, or equipment relevant to the purpose of the inspection; and".

(4) Section 103 is amended by repealing subsection (6), and substituting the following subsection:

"(6) An enforcement officer may take any person with relevant experience or expertise on to the premises to assist the officer with the inspection."

29 Regulations

(1) Section 140(1) of the principal Act is amended by repealing paragraph (g), and substituting the following paragraph:

"(g) prescribing requirements to be met by a laboratory, and during the storage, importation, or transportation of any hazardous substance, for the purposes of section 33:".

New (unanimous)

(2) Section 140 of the principal Act is amended by adding the following subsection:

"(4) Any regulations made under subsection (1) may require any person to obtain a test certificate at any specified time certifying that a specified requirement has been met."

30 Expiry of transitional provisions

(1) Section 152 of the principal Act is amended by repealing subsection (1), and substituting the following subsections:

"(1) Parts XI to XVI and the Seventh Schedule expire on the later of the following dates:

"(a) the date that is 3 years after the commencement of those Parts:

"(b) the date specified in the most recent Order in Council (if any) made under subsection (2).

"(1A) The Governor-General may, by Order in Council made at any time or times before the date that Parts XI to XVI and the Seventh Schedule expire in accordance with subsection (1), specify a date on which those Parts and that Schedule expire, but that date must not be more than 5 years after the commencement of those Parts."

(2) Section 152 of the principal Act is amended by repealing subsection (4), and substituting the following subsection:

"(4) The regulations referred to in section 161 are revoked on the expiry of Parts XI to XVI and the Seventh Schedule."

31 Regulations relating to transitional provisions

(1) Section 160(1)(a)(iii) of the principal Act is amended by omitting the words "under section 77 of this Act".

(2) Section 160 of the principal Act is amended by repealing subsection (2), and substituting the following subsections:

"(2) A regulation made under subsection (1)(a) must provide 1 or more hazard classifications (as prescribed in regulations made under section 74) for the substance concerned in accordance with the intrinsic properties and degree of hazard of the substance; and, unless varied under **subsection (3)**, the controls

prescribed for each such hazard classification attach to the substance.

"(3) A regulation made under subsection (1)(a) may substitute, delete, or add controls for the purpose of continuing, to the extent and with such modifications as are appropriate, the requirements that applied to the substance under—

"(a) any enactment repealed by this Act; or

"(b) any regulations made under any enactment repealed by this Act; or

"(c) the Transport Act 1962, or the Transport Act 1998, or any regulations made under either of those Acts; or

"(d) the Animal Remedies Act 1967 or any regulations made under that Act."

New (unanimous)

31A Transitional provisions - pesticides

The principal Act is amended by inserting, after section 164, the following section:

"164A **Protection of information**

The protection given to information by Part IIIA of the Pesticides Act 1979 continues for the period specified in that Part as if that Act had not been repealed by this Act, and during that period, any information protected by that Part may not be used for the purposes of determining whether to grant an application under this Act."

31B Application of this Part

Section 184 of the principal Act is amended by inserting, after subsection (3), the following subsection:

"(3A) Any toxic substance which, before the date of commencement of this Act was the subject of a notification under section 32 of the Toxic Substances Act 1979, may continue to be imported or manufactured by any person under this Part until regulations made under section 160(1)(a)(i) apply to that substance."

New (unanimous)

31C Transitional provisions - toxic substances

The principal Act is amended by inserting, after section 184, the following section:

"184A **Protection of information**

The protection given to information by Part IIA of the Animal Remedies Act 1967 in respect of animal remedies that are toxic substances continues for the period specified in that Part as if that Act had not been repealed by the Agricultural Compounds and Veterinary Medicines Act 1997, and during that period any information protected by that Part may not be used for the purposes of determining whether to grant an application under this Act."

32 Third Schedule

The Third Schedule of the principal Act is amended by omitting from the heading to Part I the words "**Development and Field Testing of**", and substituting the words "**Importing, Developing, or Field Testing**".

33 Fourth Schedule

The Fourth Schedule of the principal Act is amended by repealing all items relating to the Building Act 1991.

34 Seventh Schedule

The Seventh Schedule of the principal Act is amended by omitting from class 6 of Part D the words "*Division 3*: Any ammunition which contains its own means of ignition and is not included in division 1", and substituting the following words:

"The term **safety cartridge** means a cartridge for small arms—

"(a) the case of which can be extracted from the small arm after firing; and

"(b) that is closed in order to prevent an explosion in 1 cartridge being communicated to other cartridges.

"The term **safety fuse** means a fuse for blasting which—

"(a) burns and does not explode; and

"(b) burns under all conditions of practical use at an approved even average rate; and

"(c) does not contain its own means of ignition; and

"(d) is of such strength and construction and contains an explosive in such quantity that the burning of the fuse will not communicate laterally to other like fuses.

"The term **containing its own means of ignition**, as applied to ammunition, means having an arrangement, whether attached to it or forming part of it, which is adapted to explode or fire it by friction or percussion.

"This class is in 3 divisions, namely—

"*Division 1:* This division consists of percussion caps, railway fog signals, safety cartridges, safety fuses, and other devices of a similar nature not capable of explosion en masse.

"*Division 2:* Any ammunition which does not contain its own means of ignition and is not included in division 1.

"*Division 3:* Any ammunition which contains its own means of ignition and is not included in division 1."

Legislative history

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