Legislation Notes

The Hazardous Substances and New Organisms Act 1996

This note provides an overview of the scheme of the Hazardous Substances and New Organism Act 1996 ("the Act"). The Act focuses on the effects on the environment of hazardous substances and new organisms. These effects will also form the basis of controls set by regulations which will apply to any hazardous substance which is approved under the Act. How evidence on effects will be assessed is therefore of considerable importance in such an approval. That is particularly so when assessing risks and considering novel scientific theories about such effects.

The second part of the note examines the approach taken by the Courts to conflicts of scientific and/or technical evidence and sets out the manner in which the Courts assess the reliability of such evidence. The aim is to give guidance as to the standard of proof which is likely to be required to be met if parties to approvals under the Act wish to substantiate their opinions or claims.

Scheme Of The Act

Overview

The Act was enacted on 10 June 1996 and will come into force at a date to be determined by Order in Council, probably in April 1998. The Act prohibits the importation and manufacture of any hazardous substance and the importation, development, field testing or release of any new organism without an approval issued by the Environmental Risk Management Authority ("ERMA"). The Act will also establish a

comprehensive new set of controls for hazardous substances and for the containment of new organisms.

The Act will apply to all substances which fall within the definition of "hazardous substance" and to "new organisms" as defined by the Act. However, regulations can be made prescribing substances as not being hazardous for the purposes of the Act. Given the wide definition of hazardous substances in the Act,[1] such regulations will provide an essential threshold of effects, below which a substance falls outside the ambit of the Act.

Purpose and Principles

The purpose of the Act is set out in s 4 which states that:

> 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.

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1 Hazardous Substance means unless expressly provided otherwise by regulations, any substance -

(a) With one or more of the following intrinsic properties:

(i) Explosiveness;

(ii) Flammability;

(iii) A capacity to oxidise;

(iv) Corrosiveness;

(v) Toxicity (including chronic toxicity);

(vi) Ecotoxicity, with or without bioaccumulation; or

(b) Which on contact with air or water (other than air or water where the temperature or pressure has been artificially increased or decreased) generates a substance with any one or more of the properties specified in paragraph (a) of this definition.

Section 5 of the Act requires all persons exercising functions, powers, and duties under the Act to "recognise and provide for" the following principles to achieve the purpose of the Act:

(a) The safeguarding of the life supporting capacity of air, water, soil and ecosystems;
(b) The maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural well being and for the reasonably foreseeable needs of future generations.

Section 6 of the Act requires all persons exercising functions and powers and duties under the Act to "take into account" the following matters to achieve the purpose of the Act:

(a) The sustainability of all native and valued introduced flora and fauna;
(b) The intrinsic value of ecosystems;
(c) Public health;
(d) The relationship of Maori and their culture and traditions with their ancestral land, water, sites, waahi tapu, valued flora and fauna, and other taonga;
(e) The economic and related benefits to be derived from the use of a particular hazardous substance or new organism;
(f) New Zealand's international obligations.

A number of these matters reflect the "matters of national importance" or "other matters" in the Resource Management Act 1991 ("RMA").[2] The interpretations of those provisions under the RMA are likely to provide some guidance in interpreting these provisions of the Act.

Another significant section of the Act is the requirement in s 7 that:

All persons exercising functions, powers, and duties under this Act ... shall take

2 RMA, ss 6 and 7.

into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.

This may represent the first direct incorporation into New Zealand domestic legislation of the so-called "precautionary principle" of international environmental law.[3]

Finally, all persons exercising powers and functions under the Act are required by s 8 to take into account the principles of the Treaty of Waitangi.

Environmental Risk Management Authority

ERMA has a range of functions, including monitoring the effectiveness of the Act at reducing the adverse effects of hazardous substances and new organisms on the environment or people, and overseeing the enforcement of the Act.

ERMA's most important responsibility will be the assessment of hazardous substances and new organisms, and the setting of suitable controls on hazardous substances and new organisms approved for use.

Assessment of hazardous substances and new organisms

The Act contains detailed provisions relating to the procedures, information requirements, criteria and decision-making power of ERMA

3 For a discussion of the role of the precautionary principle under RMA, see Nolan, D., and Williams, M., "Electromagnetic reduction emissions and the 'precautionary principle'", (1996) 1 *Butterworths Resource Management Bulletin* 213. Arguably however, there is a valid distinction between being cautious, and the precautionary principle discussed in the article, as applied in the context of international environmental law.

in relation to each type of application provided for in the Act[4]. It is clear, however, that the Act contemplates that the assessment will focus on the effects of a hazardous substance or new organism which is the subject of an application. Notably, "effect" is widely defined in a manner similar to, but not the same as, the definition of "effect" in the RMA.[5] The differences between these definitions is to some extent applicable by reference to the specific subject-matter which each Act is dealing with.

An applicant for an approval to import or manufacture a hazardous substance or new organism is required to lodge an application including a wide range of information, including information on all the possible adverse effects of the substance or organism on the environment. ERMA may, in its discretion, approve an application if the positive effects of the substance or organism outweigh the adverse effects or, conversely, decline it if it considers that the adverse effects of the substance or organism outweigh

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4 The Act requires approval to:

(a) import or manufacture hazardous substances for release;

(b) import for release or release from containment any new organism;

(c) import any new organism into containment, field test any new organism in containment, or development of any new organism in containment;

(d) import any hazardous substance into containment, or manufacture any new hazardous substances in containment;

(e) import or manufacture any hazardous substance for release in an emergency, import any new organism for release in an emergency, or release any new organism from containment in an emergency.

5 "Effect" is defined to include:

(a) Any potential or probable effect.

(b) Any temporary or permanent effect.

(c) Any past, present or future effect.

(d) Any acute or chronic effect.

(e) Any cumulative effect which arises over time or in combination with other effects.

the positive effects. Once approved, the controls which apply to that substance, based on the hazardous properties (effects) of that substance, will bind all subsequent manufacturers, importers and users of the substance. Overall therefore, it is the effects of a substance or organism that are all important in terms of assessing applications, and in determining the type of regulations and controls which will ultimately apply to the substance.

Procedure for assessment - public participation

The Act requires public notification of most applications. Any person may make a written submission on a publicly notified application. ERMA is not required to hold a hearing unless it considers that a hearing is necessary or the applicant or a submitter requests to be heard. All hearings must be held in public. ERMA has the powers of a Commission of Inquiry and may establish its own procedure. Cross-examination is permitted.

ERMA's decision must be released in writing, including reasons. Any party to an application for approval and any person who made submissions to ERMA on such an application may appeal ERMA's decision to the High Court on a question of law. There is no general right of appeal against a decision on whether to grant or decline approval to a substance or organism.

Control of hazardous substances

The Act requires that a hazard classification system be established. The system will comprise a number of hazard classifications each consisting of a prescribed intrinsic hazardous substance property, and a prescribed hazard level or type of hazard for that property. This system is to be implemented by regulations describing controls reflecting the intrinsic characteristics of the substances in question.

The Act requires ERMA, when issuing an approval, to give the substance one or more hazard classifications. The controls prescribed for each of the relevant hazard classifications will then attach to the substance unless varied by ERMA.

The controls imposed on hazardous substances will be performance based. Such controls may differ from most of the controls imposed by regulations under the previous legislation in that they are intended to define what is to be achieved, not how the requirement is to be met. The specific performance requirements will be derived from an overall objective and may be achieved using methods set out in approved codes of practice.

Enforcement

While ERMA is responsible for overseeing enforcement of the Act, other agencies also have responsibilities for enforcing the provisions of the Act in specified situations. For example, the Director of Land Transport Safety is responsible for enforcing the provisions of the Act in any motor vehicle, road, or rail service vehicle. Territorial authorities are responsible for enforcement in any premises in their district.

Offence provisions

The Act sets out a range of offences. The penalty for committing most offences is a maximum fine of $500,000, and if the offence is a continuing one, a further fine not exceeding $50,000 may be imposed for every day or part of a day during which the offence has continued. There is also the possibility of imprisonment for a maximum term of three months.

The Act makes employers liable for the acts of their employees, and principals liable for the acts of their agents, subject to certain defences.

Directors can also be held ultimately responsible where any body corporate is convicted of an offence, under provisions which closely follow similar provisions contained in the RMA.[6]

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6 See Hazardous Substances and New Organisms Act 1996, s 116; cf RMA, s 340(3).

The defences in the Act are also similar to those in the RMA.[7] An additional defence involves the situation where the action to which the prosecution related was within the defendant's control, but the defendant had taken all reasonable steps to prevent the action, and taken all reasonable mitigation measures to remedy the effects of the action or event after it occurred. There is also a defence of compliance with any code of practice where it is alleged that a control has not been complied with.

Transitional provisions

The key substantive provisions of previous legislation dealing with pesticides, toxic substances, dangerous goods and explosives are carried forward into the Act as transitional provisions. These provisions will probably expire on 1 January 2000. It is an offence under the transitional provisions to breach any requirements of regulations, orders or notices issued under the previous legislation.

Assessing the Reliability of Scientific Evidence

As noted, the overall effects of a substance or new organism will be all important. Only if the positive effects outweigh the negative effects, can a substance be approved. For new organisms, a range of additional matters must also be considered, including the ability of the organism to establish "an undesirable self-sustaining population" and the ease with which the organism could be eradicated if it established an undesirable self-sustaining population.

When faced with, for example, an application to release a new herbicide or pesticide into the environment (and therefore potentially into the food-chain) or, for example, an application to import and release a

7 Hazardous Substances and New Organisms Act 1996, ss 115(3), 117(2)-(3). Cf RMA, ss 340(2), 341(2)-(3).

biological control agent, this type of assessment may involve a significant amount of complicated scientific data, coupled with complex and conflicting theories describing the biological, chemical or physical interaction of the substance or organism with the environment.

Due to the wide definition of effects, when considering applications for approvals, ERMA is required to have regard to the actual and potential effects on the environment of the substance concerned. How reliable must evidence be before ERMA should consider it in determining whether a potential effect exists? Will a mere allegation that there is a potential adverse effect suffice? Or must reliable scientific evidence be produced? How is the reliability of technical evidence to be assessed by ERMA?

A related issue to consider is how ERMA should deal with differences of opinion and competing scientific theories over adverse or potentially adverse effects? In such an event it is likely to be argued by a party that s 7 should require that the approvals be declined in light of scientific uncertainty. In addition to s 7, it may be argued that the more general "precautionary principle" of environmental law is also relevant.[8]

These issues arose in *McIntyre v Christchurch City Council*[9] which considered the relevance of the precautionary principle under the RMA. This case provides a useful illustration of the approach that the Court takes to competing expert evidence and novel scientific theories.

In the *McIntyre* case, the potential effect at issue concerned the alleged harmful health effects from a mobile telephone transmitter. The opponents' case was that there was scientific opinion which suggested that exposure to the amounts of radiation which would be emitted by the transmitter is potentially harmful to health. The opponents argued that it would involve

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8 A discussion of the role of the precautionary principle in a HSNO assessment is beyond the scope of this note. For an introduction to the issues see the article by Nolan & Williams, supra, note 3.

9 [1996] NZRMA 289.

an error of law to require this effect to be demonstrated on the state of present scientific knowledge. Instead the opponents submitted that sustainable management of resources requires acknowledging that scientific hypotheses take time to be proven but warrant attention, and if need be precaution, in the meantime.

The applicant for the telephone transmitter submitted that a threshold needed to be crossed before a scientific hypothesis reached a confidence level where any notice should be taken of it, and that a theory advanced by an expert should be assessed in light of the present state of scientific knowledge.

The issue which this type of argument raises is not unique to the environmental context. In overseas jurisdictions, where legal actions for personal injury to gain compensatory damages may be brought, courts are often faced with novel or new scientific theories, for example, that a particular form of injury or illness had been caused by a certain defendant's actions or product. This is especially the case in the United States in the area of pharmaceuticals where hopeful plaintiffs attempt to convince a jury or a court that a drug product has produced some form of adverse health impact.

The courts in the United States and elsewhere have evolved various tests for screening reliable scientific theories about such causes and their effects from the less reliable.[10] These tests include tests assessing whether a theory has been generally accepted by the relevant scientific community.[11] Such a test may be said to be similar to that relied on by the applicant in

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10 See for example, Black, B., "Science and the Law in the Wake of Daubert: A New Search for Scientific Knowledge" (1994) 72 *Tex.L.Rev* 715.

11 *Frye v United States* 498 F.2d 741, 744 CD.C.Cir. 1974, rejected in the criminal context by the High Court in New Zealand in *R v Calder* (Unreported, High Court, Christchurch. April 12 1995 CT 154-94. Tipping J) due to criticisms of it in the United States Courts.

McIntyre. The other type of test used in the United States attempts to focus directly on the evidence in question and assess its reliability.

There is a spectrum of reliability in science between an untested idea which explains an occurrence (such as an illness) and a proven scientific theory which is generally accepted in the scientific community as demonstrating this type of causal link. The issue in a legal forum is to determine the point at which an idea warrants sufficient attention to be considered by the Court in establishing liability, or proving a point in issue.

The Court in *McIntyre* referred to the United States decision *Daubert v Merrill Dow Pharmaceuticals Incorporated*[12] in considering the reliability of the contested scientific evidence. This American decision involved the allegation that ingestion of an anti nausea drug produced birth defects. Prior to *Daubert* the American courts had often applied the requirement that a scientific theory be "generally accepted" in the scientific community before it could be considered as being reliable. Variations to this approach have been applied in the civil and criminal courts in Australia and New Zealand.[13] The US Supreme Court in *Daubert* considered that this test was too strict and that scientific theories which did warrant attention, but which had not yet been generally accepted, should still be considered.

The US Supreme Court replaced the "general acceptance" test with a requirement that the allegation involved be based on "scientific knowledge". Knowledge was taken to imply a grounding in fact, rather than speculation or belief. The adjective "scientific" applies the use of the scientific method

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12 113 S. Ct 2786 (1993). Notably, this decision of the Supreme Court of the United States has itself been criticised and sometimes not followed by State Courts.

13 See Odgers S.J. and Richardson J.T., "Keeping Bad Science out of the Courtroom -Changes in American and Australian Expert Evidence Law (1995) 18 *UNSW Law Journal* 108. See also the decision of the New Zealand Court of Appeal in *R v B* [1987] 1 NZLR 362.

whereby a new hypothesis explaining events is subjected to repeated testing to determining its validity. The *Daubert* decision therefore replaced the "general acceptance" test with a requirement that the hypothesis concerned had been subject to testing. In science, this usually involves a process of falsification, or attempting to prove the hypothesis wrong. An hypothesis which has survived a number of attempts at falsification, can be said to be fairly reliable.[14]

In addition, the Court in *Daubert* held that whether an hypothesis had been subjected to peer view amongst other scientists was relevant. Finally, it held that "general acceptance" could be indicative of reliability but not necessarily decisive. Certainly, if the appellants in the *McIntyre* decision had been required to show that their hypothesis had been "generally accepted" by the scientific community they would have failed that test and the Environment Court would not have considered the hypothesis at all.

After reviewing decisions such as *Daubert,* the Environment Court in *McIntyre* noted that it is not bound by the formal rules of evidence that apply to the ordinary courts. Even so, it noted that such principles of evidence developed by the general courts can provide a valuable guide for fact finding by the Environment Court. The Court then went on to say that the existence of a "serious scientific hypothesis" or even one that can be regarded as "deserving priority for testing" is not necessarily sufficient by itself to establish a potential effect. On the other hand the Court held that it would not be appropriate to impose a threshold based on current scientific knowledge as requested by the applicant, before paying attention to a scientific hypothesis. Such a test would be similar to that rejected in the United States by *Daubert.* Following *Daubert,* it held that grounds for the hypothesis in question would have to be exposed to testing, and scrutinised to determine whether it met a basic threshold of reliability to assist the Court in weighing the evidence and to make a finding one way or the other.

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14 See for example, Popper, K., *The Logic of Scientific Discovery* (1959).

What the Court was effectively saying is that mere allegations of harm or of adverse environmental effects will not be considered when determining whether a potential environmental effect may occur. On the other hand a scientific theory which has been the subject of testing and debate in the scientific community will often deserve consideration. The particular scientific hypothesis involved need not be proved to a point of certainty before it is **considered** by the Court, in making a finding as to the existence of a potential effect on the environment. The issue which then arises is how to treat such evidence where it is in conflict with the expert opinion of an opposing party.

Where there are conflicts of evidence between experts on facts about which there can be no certainty, courts are nevertheless obliged to make a finding on the issue. The Environment Court has held (for example, in *McIntyre*) that to do so in this type of situation it needs to be satisfied on the balance of probabilities, having regard to the gravity of the matter in question, whether the existence of the alleged effect has been demonstrated. Therefore, where an effect is alleged by a party to Environment Court proceedings to be likely to occur, reliable evidence (in the sense described above) must be given in support of that allegation. The onus will then be on the other party to prove to the balance of probabilities that the alleged effect would not occur. In some cases, where the alleged effect is particularly serious, a higher standard of proof may be required.

In the *McIntyre* case, the Environment Court was not satisfied, on the evidence before it, that exposure to radio frequency radiation of the type produced by cellphone transmitters would have an effect on people's health. The Court noted that although there are some scientists who maintain that there is a serious hypothesis that this radiation could be harmful, this had not been generally accepted in the scientific community, a factor cited as being relevant, although no longer decisive, in *Daubert*. On the totality of the evidence the Court found that there would not be an actual or potential effect on the environment from the radio frequency radiation.

In an earlier decision of the Environment Court in *Trans Power New Zealand v Rodney District Council*[15] the Court made the following observation:

> [A]lthough we can accept that scientific knowledge about the potential health effects of the field may be incomplete, it is our duty to make a decision now, on the present state of knowledge. It would be an abdication of that duty if we were to allow opponents of proposals to prevent them from proceeding on the basis that science might in the future discover effects that not had yet been established. It is not to reject the precautionary approach, but there needs to be some plausible basis, not mere suspicion or innuendo for adopting that approach.

This passage summarises the Court's view of the issue as discussed here. Some type of threshold of reliability is required before scientific theories will be considered by the Environment Court. The scientific theory or hypothesis forming the basis of the evidence linking cause and effects needs to have been exposed to testing and peer review, and the status of that hypothesis in the scientific community generally, will also be relevant.

It is suggested that the approach adopted by the Environment Court is the appropriate approach which ERMA should take in considering applications for approval. The following questions will be relevant in assessing the reliability of that evidence, although formal cross-examination is unlikely to be available at an ERMA hearing despite being permissible under the Act. Has the theory in question been tested? Have the findings of any study or theory been published? What view does the rest of the scientific community make of these findings?

If ERMA were to admit or consider evidence in a way which substantially departed from the approach taken by the Environment Court

15 Unreported, Planning Tribunal A 85/94, 14/11/94, Judge Sheppard, noted (1995) 1 *Butterworths Resource Management Bulletin* 114.

under RMA, it could be argued that this would constitute an error of law, appealable to the High Court, or provide grounds for judicial review. While the formal requirements of the law of evidence would not appear to bind ERMA, the fact that appeals on questions of law can be made, must indicate that there is some limit to which ERMA could depart from accepted legal principles regarding admissibility of evidence.

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