

## Office of the Minister for the Environment

The Chair

CABINET BUSINESS COMMITTEE

### **DISCUSSION PAPER CONTAINING PROPOSALS TO IMPROVE THE WORKABILITY OF THE HAZARDOUS SUBSTANCES SECTIONS OF THE HSNO ACT 1996**

#### **Proposal**

1. I seek Cabinet's agreement to the release of a public discussion paper containing proposals to improve the workability of the hazardous substances sections of the Hazardous Substances and New Organisms (HSNO) Act 1996. Subject to Cabinet agreement, these proposals will lead to an amendment bill late this year.

#### **Executive summary**

2. The short term actions under the hazardous substances strategy that I announced in June 2003 are now complete. Significant improvements in how the HSNO Act works have already been achieved as a result.
3. To progress the longer term actions under the strategy, Cabinet is asked to release a two-volume HSNO discussion paper. Volume 1 covers the longer term actions identified in the hazardous substances strategy approved by Cabinet in June 2003 [CAB Min (03) 21/10 refers]. Volume 2 covers matters that have arisen since Cabinet's consideration of the strategy and is intended for a more specialised audience.

#### **Background**

4. The purpose of the HSNO Act in respect of hazardous substances is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances. The Act does this by placing controls on the substance, such as labelling, packaging and storage requirements.
5. The hazardous substances strategy proposed a set of short term and longer term actions to improve the workability of the hazardous substances part of the HSNO Act.
6. Short term actions included:
  - Completion of the full set of Hazardous Substances Regulations;
  - Passing of an amendment bill to simplify and speed up the process of transferring substances from old controls to Hazardous Substances and New Organisms Act 1996 (HSNO) controls,

- Implementation of funding to maintain local government involvement in hazardous substance enforcement, and
  - Implementation of funding to make application fees under HSNO more predictable for businesses.
7. These actions are now complete with the HSNO (Transitional Provisions and Controls) Amendment Act coming into effect on 24 March and the necessary regulations gazetted in time for the transfer of single component dangerous goods and scheduled toxic substances to HSNO controls on 1 April 2004.
  8. The changes contained in the amendment bill provide the Environmental Risk Management Authority with significantly more flexibility in the ways they manage hazardous substances.
  9. The longer term actions identified by the hazardous substances strategy were those that required more time to consider and consult on before the policy could be brought forward for approval. Issues identified in the strategy include:
    - a) Increasing the flexibility of application pathways for new and transferred substances, to reduce costs and reflect the risks;
    - b) Providing alternatives to codes of practice and regulations that make controls easier to understand;
    - c) Strengthening hazardous substances enforcement arrangements including clarifying the roles of Environmental Risk Management Authority (ERMA), territorial authorities and regional councils; and
    - d) Closing gaps and correcting overlaps with other legislation, particularly the Resource Management Act 1991 (RMA) and the Agricultural Compounds and Veterinary Medicines Act 1996 (ACVM).
  10. Since the strategy was endorsed by Cabinet, a number of other technical areas of HSNO (the Act and regulations) have been identified (through ERMA's and other departments' experiences with the Act) as in need of improvement and where policy decisions will be required. Proposals have been developed to:
    - a) Improve the workability of exposure limit controls for protecting people and the environment from the effects of toxic and ecotoxic substances;
    - b) Facilitate the movement of specialty substances between research institutions;
    - c) Provide for substances imported for export only to be covered by the existing containment approvals mechanism in HSNO;
    - d) Improve compliance, monitoring and enforcement by:
      - (i) requiring HSNO approval numbers on labels
      - (ii) providing for a register of test certificates
      - (iii) giving ERMA the power to revoke an approved handler test certificate
      - (iv) ensuring that if an unapproved substance is imported, it must be re-exported
      - (v) providing for enforcement agencies, when doing HSNO work, to use powers of entry and inspection that they have under other legislation
      - (vi) taking a fresh look at HSNO systems to report hazardous substance related injuries;

- e) Review data protection provisions for agrichemicals;
  - f) Provide new pathways to:
    - (i) Enable “rapid approval” for substances needed in an environmental emergency
    - (ii) Enable “rapid reassessment” if the approval pathway was rapid assessment.
11. A two-volume public discussion paper (attached) has been prepared that canvasses these matters and seeks submissions. The first volume addresses the longer term matters identified in the strategy and is intended for the general audience. The second volume addresses the technical issues identified since the strategy was endorsed by Cabinet and is intended for a more specialist audience. The main proposals in each volume are outlined below.

#### **VOLUME 1**

#### **Streamlining the hazardous substance application process when use is lower risk**

12. The HSNO application process is seen as overly complicated, particularly for substances used in a low risk manner. The key proposition put forward for discussion is the development of “a group standard pathway”. This would enable ERMA to set up groups of substances and apply a single set of controls to all the substances in that group. Substances could be grouped according to compositional and/or hazard classification bands; and/or exposure characteristics such as use type, or volume considerations.
13. The controls to be assigned to the group would include labelling, packaging and safety data sheet requirements. As well as controls, ERMA would be able to apply conditions to the group. These might be requirements to provide information on how much of the substance would be used on an annual basis, or, if a group standard approval is limited to certain uses, it might stipulate how approval for other uses can be obtained. It might, for instance, stipulate that such an application would be considered by means of rapid assessment.
14. Once a group standard is set up, the pathway will be cheaper for business than existing application pathways because it will be largely automatic, involving minimal interaction with ERMA and minimal collation of information to prepare an ‘application’.
15. The benefits of having a pathway that business consider cheaper and easier is that HSNO will not be seen as a barrier to the introduction of newer more environmentally friendly or more innovative substances into New Zealand.

#### **Improving how controls are communicated**

16. The purpose of the HSNO Act (protecting the environment and the health and safety of people and communities) is achieved by the application of ‘controls’. It is these controls on packaging, labelling, storage, for example, that reduce the likelihood of any adverse event and, should one occur, reduce the potential damage.

17. Industry has indicated the controls would be more “user friendly” if the controls were organised by the means by which they may be implemented (for example, all requirements for labels in one place), or the site where they are to be implemented (for example, dangerous goods workrooms). At present controls are organised by the function they perform (for example, identification, containment, managing emergencies). Industry has also indicated that the controls could be simplified and more prescriptive, rather than being performance based.
18. To address these issues, the discussion paper proposes that ERMA create standard sets of controls. This not only allows the better resourced industry sectors to take advantage of the performance based nature of the regulations, but would also interpret the regulations’ requirements for those industries that are not so well-resourced. The proposal should also reduce the number of sets of controls being used, potentially making it easier for enforcement agencies to enforce the HSNO requirements and help people to comply.

### **Compliance and enforcement**

19. The Hazardous Substances Strategy identified compliance monitoring and enforcement as a high priority. Section 97 of the HSNO Act lists enforcement agencies together with the places or subject areas each is responsible for. Under HSNO, the Department of Labour has prime responsibility for all hazardous substance enforcement in the workplace.
20. At a meeting held with some representatives of local government in October 2003, territorial authority (TA) staff raised concerns regarding the decreased role for TAs under HSNO; the role has decreased from about 1 full time equivalent per TA under the old Dangerous Goods Act regime to about 0.1 of a full time equivalent per TA under the HSNO regime. Notwithstanding that section 97 of HSNO names TAs as an enforcement agency and lists their responsibilities, many TAs have chosen to opt out of hazardous substance compliance and enforcement altogether rather than pick up a reduced role.
21. TAs present at the October meeting wished ministers to know that without greatly increasing the role for TAs under HSNO, it is extremely difficult for them to retain a skilled hazardous substance officer on staff.
22. As part of the hazardous substances strategy, short term funding was provided to ERMA to maintain local involvement in HSNO compliance and enforcement. Department of Labour and ERMA are working on contracts with TAs to ensure where possible they do keep skilled people on staff. The contracts give TAs greater involvement, by funding them to carry out work on behalf of the Department of Labour in addition to their direct responsibilities under HSNO. The discussion paper discusses ways TAs’ concerns could be addressed in the longer term.
23. The discussion paper also puts forward a proposal to give regional councils a HSNO enforcement role (regional councils currently have no role at all in the HSNO regime). Such a role would overlap and extend their current function of

managing discharges and hazardous facilities under the RMA. Some regional councils have indicated that are very supportive of this proposal.

## VOLUME 2

### Technical issues

24. Twelve proposals are covered in the second volume of the discussion paper (see para 10 above). Five key topics are discussed below:
- The workability of exposure limit controls for toxic and ecotoxic substances
  - The movement of specialty substances between research institutions
  - HSNO approval numbers on labels
  - Enforcement agency powers of entry and inspection
  - Data protection provisions for agrichemicals

#### *The workability of exposure limit controls for toxic and ecotoxic substances*

25. Exposure limit controls are set for ecotoxic and toxic substances. There are concerns that these controls could conflict with established methods for setting environmental concentration limits and that they will be very difficult to enforce.
26. Exposure limits have long been conceived to be the regulatory backstop to deal with agrichemical spraydrift. In drafting the HSNO regulations, the concept became widened so as to apply to all ecotoxic and toxic substances, and for use situations other than agriculture. It is timely to take a fresh look at what exposure limits were intended to achieve, how they would interface with similar RMA mechanisms, and how they could be enforced. It is proposed that exposure limit controls only be set when risks are not already being managed under other legislation.

#### *The movement of specialty substances between research institutions*

27. Concerns have been raised regarding the operation of provisions governing laboratory research, particularly barriers to the movement of specialty substances between laboratories. The discussion paper examines these concerns and concludes by suggesting that there is a need for minor amendments to the Act.

#### *HSNO approval numbers on labels*

28. HSNO Regulations do not at present require HSNO approval numbers to be on labels. There are costs to be considered but it is suggested there should be such a requirement. This issue is linked to the difficulty in searching ERMA's hazardous substance register for information on a particular substance. A unique identifying number would make such a search more efficient.

#### *Enforcement agency powers of entry and inspection*

29. The discussion paper proposes to amend HSNO to provide that section 97 enforcement agencies can exercise the powers of entry and inspection under their own legislation when carrying out their responsibilities as an enforcement agency under HSNO. This is consistent with the objective on which the HSNO enforcement functions were predicated; that is, to maximize overlap with enforcement agencies' existing functions.

### *Data protection provisions for agrichemicals*

30. Data protection is the term for protecting the data lodged with ERMA in support of an application for a new substance. There are significant costs in generating this information and data supporting an application is not covered by intellectual property or patent protection law. HSNO provides data protection by referencing the relevant provisions in the Agricultural Compounds and Veterinary Medicines Act, and the Medicines Act. These provisions reflect our obligations under the World Trade Organisation Agreement on Trade Related Intellectual Property Rights (TRIPS) applying to "new chemical entities". Although legal opinion is that New Zealand meets its obligations under TRIPS, a review is proposed for 3 reasons. Firstly, the scope of our legislation does not align completely with TRIPS. There are some data packages that receive TRIPS-based protection in overseas jurisdictions that would not be similarly protected here.
31. Secondly, TRIPS does not specify the period of data protection. We offer 5 years, where Australia and the US offer 10. It has been suggested some multinational companies have decided against applying for regulatory approvals to market new agrichemicals in New Zealand for this reason.
32. Lastly, if an agrichemical is reassessed by ERMA, data protection provisions are unlikely to apply. This is because the agrichemical will typically not be "new". Patent periods may have expired and there may be "generic" versions of the original on the market. A multinational may, however, have new data relevant to the reassessment. Without data protection, it may be unwilling to take the risk of inadvertent disclosure of this data to competitors, even if it means loss of the HSNO approval.
33. The paper suggests an overhaul of agrichemical data protection policy (to be scoped as agricultural compounds, including turf products) is warranted and proposes a process for this to occur. A review is likely to be welcomed by stakeholders. Data protection may also be an important aspect of future trade negotiations.

### **Next Steps**

34. If Cabinet agrees to the release of this discussion paper, it will be distributed immediately. Six weeks has been allowed for submissions, and a further two months to develop policy for the bill. I will report back to Cabinet Policy Committee with proposals to amend the HSNO Act on (or before) 1 October 2004.

### **Consultation**

35. The following government departments have been consulted on this paper: Ministry of Health, Department of Labour (OSH), New Zealand Defence Force, Ministry of Economic Development, New Zealand Food Safety Authority, Department of Prime Minister and Cabinet, Treasury, Ministry of Consumer Affairs (Energy Safety Service), and the Ministry of Foreign Affairs and Trade.

36. The Environmental Risk Management Authority, Local Government New Zealand and the New Zealand Fire Service have also been consulted.

### **Financial Implications**

37. There are no fiscal implications for the government arising from the release of this paper.

### **Human rights, NZ Bill of Rights and Treaty of Waitangi implications**

38. No potential inconsistencies with the Human Rights Act 1993, the New Zealand Bill of Rights Act 1990 or the Treaty of Waitangi have been identified in the preparation of this paper.

### **Legislative implications**

39. There are no immediate legislative implications, but the proposals in this paper may eventually give rise to a bill to amend the HSNO Act. I expect to bring policy proposals for consideration by POL later this year with view to submitting an amendment bill [The HSNO (Approvals and Enforcement) Amendment Bill] in late 2004 for passage through the House by July 2005. The bill has Category 4 priority on the 2004 legislative programme (to proceed to a select committee in 2004).

### **Regulatory impact and compliance cost statement**

37. A Regulatory Impact and Business Compliance Cost Statement is not required.

### **Publicity**

38. I propose to make a media release when the discussion paper is ready for distribution. Both volumes will be available on the Ministry's website. Volume 1 will be mailed to a list people and organisations who have previously signalled an interest in HSNO Act matters. Volume 2 is more technical and will be circulated to a smaller number of people.

### **Recommendations**

39. I recommend that the Cabinet Policy Committee:

#### *Hazardous substances strategy*

1. **Note** the achievement of the short term actions of Hazardous Substances Strategy [CAB Min (03) 21/10 refers] and that release of this discussion paper initiates the longer term actions;

#### *Discussion paper content*

2. **Note** that Volume 1 of the attached discussion paper contains proposals to address the longer term actions noted in the strategy;

- 2.1 Increasing the flexibility of application pathways for new and transferred substances, to reduce costs and reflect the risks,
  - 2.2 Providing alternatives to codes of practice and regulations that make controls easier to understand,
  - 2.3 Strengthening hazardous substances enforcement arrangements including clarifying the roles of Environmental Risk Management Authority (ERMA), territorial authorities and regional councils, and
  - 2.4 Closing some of the gaps and correcting some overlaps with other pieces of legislation, particularly the Resource Management Act and the Agricultural Compounds and Veterinary Medicines Act;
3. **Note** that Volume 2 of the discussion paper contains proposals to address technical issues identified since Cabinet's consideration of the strategy. These are to:
- 3.1 Improve the workability of exposure limit controls for toxic and ecotoxic substances,
  - 3.2 Facilitate the movement of specialty substances between research institutions,
  - 3.3 Provide for substances imported for export only to be covered by the existing containment approvals mechanism in the Hazardous Substances and New Organisms (HSNO) Act,
  - 3.4 Improve compliance, monitoring and enforcement by:
    - (i) requiring HSNO approval numbers on labels
    - (ii) providing for a register of test certificates
    - (iii) giving ERMA the power to revoke an approved handler test certificate
    - (iv) ensuring that if an unapproved substance is imported, it must be re-exported
    - (v) providing for enforcement agencies, when doing HSNO work, to use powers of entry and inspection that they have under other legislation
    - (vi) taking a fresh look at HSNO systems to report hazardous substance related injuries,
  - 3.5 Review data protection provisions for agrichemicals,
  - 3.6 Develop new pathways to:
    - (i) Enable "rapid approval" for substances needed in an environmental emergency
    - (ii) Provide for "rapid reassessment" if the approval pathway used was "rapid assessment";
4. **Agree** to the release of the discussion paper, subject to minor editorial change;
5. **Direct** the Ministry for the Environment to report back to Cabinet Policy Committee with proposals to amend the HSNO Act as a result of the consultation on the discussion paper by 1 October 2004; and

6. **Note** that the Minister for the Environment will publicly release this cabinet paper and associated cabinet minute after the cabinet minute is released.

*Marian L Hobbs*

Hon Marian L Hobbs  
**MINISTER FOR THE ENVIRONMENT**