

Submission

By



to the

**Ministry for the Environment
& Environmental Risk Management Authority**

on

Updating HSNO Regulations to Current GHS Criteria

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Introduction

Agcarm welcomes the opportunity to comment on the discussion paper “Updating HSNO Regulations to Current GHS Criteria” dated November 2009.

Agcarm is an industry association which represents crop protection, animal health, and rural supplies firms. Agcarm members distribute and sell the majority of animal remedies and crop protection products in New Zealand. For further information and a full list of members, see www.agcarm.co.nz.

We represent more than 30 manufacturers and distributors of crop protection and animal health products.

These products protect public health, improve animal welfare and help environmental management. They:

- Play a pivotal role in growing high yield, sustainable food and fibre products;
- Help supply healthy, nutritional and affordable food;
- Keep New Zealand’s agriculture, horticulture and forestry sectors internationally competitive.
- Our members are committed to safety, innovation and product stewardship.

The discussion document is available at: www.ermanz.govt.nz/hs/abouths/ghscriteria.html.

Agcarm’s specific comments on the questions raised in the discussion document follow. These should be read in conjunction with an accompanying paper “Why Veterinary Medicines Should Be Exempt From HSNO”, prepared jointly with Federated Farmers of New Zealand, the New Zealand Veterinary Association, and the Animal Remedy and Plant Protectant Association.

Q1: Do you consider any provisions contained in the HSNO regulations (other than matters addressed in section 3.3) to be unnecessary, ineffective and excessively costly?

Agcarm Response: Speaking in general, there certainly are areas in the HSNO regulations which are unnecessary, ineffective and excessively costly.

The most important example is the unnecessary inclusion of veterinary medicines under the HSNO Framework. The industry believes there is no basis for including veterinary medicines under HSNO. Veterinary medicines are regulated under the ACVM Act, which includes managing risks to public health. Veterinary medicines, with one notable exception, pose negligible risk to the environment and to people. Their inclusion under HSNO adds costs to industry, farmers and animal owners for no benefit. This will be explained more fully in the answer to question five.

Q2: Do you agree that the HSNO regulations should refer to sections of the GHS document rather than reproduce material from the GHS?

Agcarm Response: This would appear sensible. But industry would not support a situation where HSNO regulations were automatically updated without being properly thought through in the New Zealand context.

Industry would expect that any future changes to HSNO regulations to take account of GHS revisions would be scrutinised, and industry be given the chance to comment. Otherwise we could be inviting, without scrutiny or consultation, overly burdensome or inappropriate requirements that are automatically adopted into New Zealand regulations

Q3: Do you agree with the proposals to incorporate the GHS updates into the current classification framework and numbering system as far as possible and revise some of the classification category descriptors?

Agcarm Response: It would seem logical that, over time, New Zealand should adopt the finalised GHS classifications. That said, New Zealand should keep its numbering system. Changing the numbering system could require an enormous amount of change to those labels (mainly on pesticides) which list hazard classifications, and to Safety Data Sheets and Haznotes.

Q4: Should the HSNO regulations include the 'building block' approach?

Agcarm Response: Yes. The industry accepts that there are situations (such as transport accidents) where hazard labelling is appropriate. However, the hazard labelling should be limited to those building blocks that are really relevant for pesticide products. Beyond that, the industry would prefer the regulations to have a risk-based approach rather than a hazard-based approach, as risk-based labelling provides the user with advice appropriate to his or her situation.

For example, some companion animal products sold in 15 ml bottles are Dangerous Goods from an environmental perspective (9.1A). A risk-based approach would recognise that such a classification is ridiculously over the top.

Q5: Are there any other areas where you consider a full or partial exemption should apply?

Agcarm Response: Yes. An exemption should apply to veterinary medicines – excluding single ingredients for manufacturing veterinary medicines.

As background, it is important to state that the GHS was not intended to apply to veterinary medicines.

The introduction to the GHS states: “at the point of intentional human intake or ingestion, or intentional application to animals, products such as human or veterinary pharmaceuticals are generally not subject to hazard labelling under existing systems. Such requirements would not normally be applied to these products as a result of the GHS”.

The GHS framework was always intended as a system for labelling of hazardous chemicals, including pesticides. Other substances such as human and animal medicines and food are typically not under the GHS umbrella.

In New Zealand, human medicines in final dose form obtained an exemption from HSNO in 2001. Veterinary medicines are in many cases very similar or identical to human medicines.

Other reasons for an exemption include:

- The ACVM Act has been amended and now covers the management of risks to public health. This should be sufficient oversight for the negligible risks that veterinary medicines pose to humans and the environment.
- The cost of the HSNO assessment process and application of controls is not justified when the risks of adverse effects are negligible;
- HSNO controls on veterinary medicines apply mainly to their toxic and ecotoxic properties. Under the ACVM Act, the ACVM Group already assesses toxic effects on animals so it would be a logical extension for ACVM Group to assess toxic risks to people as well;
- The actual and recognised adverse effects to people from veterinary medicines are not managed by HSNO controls (eg, antibiotic resistance, accidental injection with vaccine containing live infectious organisms, risks from needle-stick with oil-based vaccines, potential for interference with tuberculosis testing after self-injection with Johne’s disease vaccine);
- The only animal health products posing risks to the environment are those used in a bulk, dispersive manner (principally ecto-parasiticides for production animals);
- A one-step registration process for veterinary medicines would manage risks and save unnecessary costs;
- The animal health market in New Zealand is small and costs to registrants of dual regulatory process is hindering introduction of innovative products and technology which would benefit New Zealand agriculture and keep veterinary medicine abreast of international trends.
- An exemption would reduce the amount of superfluous information on veterinary medicine labels.
- An exemption would mean ERMA would have more resources to concentrate on important areas where hazardous substances pose higher risks to humans and the environment. eg light industrial/workshops.

Veterinary medicines should therefore also have an equivalent exemption. The industry would prefer a full exemption but if necessary would accept a partial exemption to take account of some veterinary medicines which, when used in a dispersive manner, may require continued

HSNO controls. These are mainly ecto-parasiticides for large animals. These products are bought in bulk and used for controlling insects on animals.

In seeking an exemption, there are a number of options, which are ranked from one to seven in order of their potential significance for regulatory improvement.

Agcarm believes that all options have merit, but option one and two are clearly the best because they are wide ranging and therefore remove the most unnecessary regulation.

Options for an exemption (in order of significance, with option one being the most desirable):

1. All veterinary medicines.
2. All veterinary medicines – excluding ecto-parasitidices for large animals.
3. All veterinary medicines – excluding parasiticides for large animals.
4. All veterinary medicines – excluding products which are classified as Dangerous Goods and in packages exceeding 200ml/200grams.
5. All Restricted Veterinary Medicines.
6. Unitised doses (ie, packed separately) of Restricted Veterinary Medicines.
7. Unitised doses of Restricted Veterinary Medicines for companion animals.

All the above options exclude single ingredients used in the manufacture of veterinary medicines.

The exact boundaries of an exemption could be worked through relatively easily. A one-day workshop of stakeholders and regulators could develop the draft boundaries for an exemption which would be acceptable to all parties.

An exemption would be in line with the Government's commitment to review the HSNO regulations and "remove requirements that are unnecessary, ineffective and excessively costly" both to industry and customers.

A more detailed explanation on the exemption is in the accompanying report "Why Animal Health Products Should Be Exempt From HSNO".

Q6: Should criteria for classification of mixtures, including concentration limits, be included in the regulations or should this be provided in guidance material?

Agcarm Response: Agcarm would prefer that the criteria for classification should continue to be provided in guidance material.

The current guidance document (the User Guide) is more than adequate, provides enough certainty, and is easier to read and understand than regulations.

Q7: Do you support an implementation period of five years to give effect to amendments to the regulations?

Agcarm Response: Yes.

Ends