

4.9

Rapid Assessment for Importation or Manufacture of Hazardous Substances for Release - Criteria for Determining Eligibility

Introduction

Rapid assessment provides a streamlined application process for those situations where the hazardous properties of a new substance are low, or where the proposed substance has similar composition and similar hazardous properties to an approved substance or where the proposed substance has been formulated to have a lesser hazard than an approved substance. The Agency advises that an applicant should submit a Status of Substance request (form HS-6) in the first instance for advice from ERMA New Zealand on whether rapid assessment is applicable.

This policy applies to applications under the rapid assessment provisions allowed for by section 28A of the HSNO Act. The power to determine such applications has been delegated to the Chief Executive of ERMA New Zealand. The Chief Executive is expected to exercise his/her delegation in the context of this policy. Where the Chief Executive is unable to determine an application in accordance with this policy, the matter must then be referred to the relevant committee of the Authority for consideration.

Overall Legislative Criteria

Section 28A(1) specifies the criteria for applications to be accepted for rapid assessment. It states that:

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.

Substances that meet these criteria and are accepted for rapid assessment under section 28A are not required to be publicly notified.

The rapid assessment route available under section 28A is discretionary. In other words, the guidelines set out in this policy do not preclude the exercise of the discretion afforded to the Authority (or delegated decision-maker) under section 28A to decline to approve a hazardous substance under the rapid route in any particular case. In such circumstances the applicant may choose to submit an application for full assessment under section 28 of the Act.

Section 28A(2) specifies the three routes for considering rapid assessment.

- (2) *The Authority may approve a hazardous substance under this section if the Authority is satisfied that: -*
- a substance having a similar composition and similar hazardous properties has been approved; or*
 - the substance has one or more hazardous properties and each hazardous property has the least degree of hazard for that property; or*

the substance has been formulated so that 1 or more of its hazardous properties has a lesser degree of hazard than any substance that has been approved under this Act.

These are discussed separately below.

Dealing with Applications on the Grounds of Similarity

Section 28A(2)(a) allows rapid assessment of a proposed substance if the Authority is satisfied that a substance having a similar composition and similar hazardous properties has been approved under the HSNO Act. For this application route to be used there must be: a reference substance with a HSNO approval; and a proposed substance with similar composition **and** similar hazardous properties to the reference substance.

The Reference Substance

Rapid assessments on the grounds of similarity require comparison with a reference substance that has already been approved. More than one reference substance may be applicable.

In section 28A(2)(a), **‘approved’** means approved under the HSNO Act, by the Authority. This means the reference substance has either been approved in an earlier Part V HSNO approval or it has obtained a ‘deemed approval’ through the process for the transfer of existing substances under (now expired) Parts XI to XV of the Act. The Authority (or the Chief Executive) must be satisfied that one of these criteria has been met.

The reference substance should have a similar life cycle and use to that of the proposed substance. For example, if the proposed substance is a veterinary medicine, then the reference substance should also be a veterinary medicine

A reference substance may be legally adequate as the basis for an application, but may be technically deficient, ie. may not be considered by the decision maker to be a robust reference. This may on occasion lead to a ‘decline’, even if the similarity criteria are met.

Legally, reference substances can include substances which have been approved by ‘similar’ substance rapid assessment. In practice, however, there may be difficulties in using such references and there will generally be a requirement to ‘look behind’ the proposed reference to the original reference substance. There is otherwise the risk of ‘creep’ occurring in the degree of similarity required. If a satisfactory match with the original reference substance cannot be obtained, the application may be declined.

General Interpretation of ‘Similar’

The key issue in relation to section 28A(2)(a) is the interpretation of ‘similar’. ‘Similar’ is not defined in the Act and it therefore must take its ordinary, everyday meaning for which ERMA New Zealand has accepted the Shorter Oxford English Dictionary definition - “of the same nature or kind”.

The issue of “same nature or kind” has to be addressed in respect of both the composition and the hazardous properties of the substance under section 28A(2)(a). There is a natural

correlation between the composition of a substance and its properties and these two aspects cannot be considered entirely in isolation of each other. Composition includes the chemical components making up the substance and also its physical form. The properties of the substance include any hazardous properties and also other properties such as boiling point and physical state.

For substances coming under similar substances criteria, the new substance should lead to similar effects to the reference substance or, more importantly, should not lead to any adverse effects not found with the reference substance¹. There is very little scope for flexibility, when the decision maker is making judgements about similarity, in the direction of increased adverse effects. There is more scope for flexibility where adverse effects are reduced.

Criteria for Similar Composition

The guidelines provided below on limits to variation of composition only apply when the overall hazardous nature of the substance is not increased, ie. there is no increase in any hazard classification and no introduction of a hazard classification that was not previously triggered.

In considering similarity of composition, aspects to consider will include: number of components; concentration of components; type (elemental composition, chemical class, molecular weight) of components; and physical form, although arguably the latter is a property.

The Major Hazardous Components

The major hazardous components are those that determine the hazardous properties of the substance and are important to the intended use of the substance. For the composition to be similar, the major hazardous components of the substance should desirably be the same as the major hazardous components in the existing substance.

However, there may be variations in the proportions of the major hazardous components, and one or more of the components may be excluded, provided in each case that the general nature and character of the substance are not changed in a material way. For example, similarity would be considered to be maintained in the following cases:

- (a) The proportion of all major hazardous components making up the substance is not increased by more than 10% above the proportion in the reference substance; for example, if the major hazardous components make up 30% of the substance then they may not increase to more than 33%. This tolerance may generally be increased when the total percentage of major hazardous components is low, for example, less than 10%.
- (b) The proportion of major hazardous components may decrease without limit, provided that there is evidence that decreasing proportion does not lead to an increase in hazardous properties, ie. dilution is acceptable.
- (c) Provided that (a) is also met, the proportion of any one major hazardous component does not increase by more than 25%; for example, an increase from 20% to 25% for any one such component is acceptable. This tolerance may generally be increased when the proportion of the component is low, for example, less than 5%.

¹ See section at end 'Circumstances under which a substance which meets the criteria for similar or reduced hazard may nevertheless be declined'

In addition, new major hazardous components may be introduced as substitutions for or additions to existing components provided:

- the hazard classification of the substance is not increased; and
- the new major hazardous component does not produce adverse effects different in character to those already presented by the reference substance²;
- the new major hazardous component is listed on the ERMA New Zealand Inventory of Chemicals; and
- the guidelines (a)-(c) continue to be met.

The Minor Hazardous or Non-hazardous Components

It is permissible to introduce new minor components if they are hazardous but are introduced only at a level that does not increase the overall hazard. There is no quantity limit on the concentration of non-hazardous components that may be introduced.

An example would be a change from a 5% pesticide active in 95% kaolin (inert mineral) to a 5% pesticide active in 95% talc. This could be considered for rapid assessment approval as it meets the 'same nature and kind' test. For example, kaolin and talc are of the same general type of component, of the same form, have a similar lack of hazardous properties, and perform the same function in the substance.

Changes in Physical Form

Generally a change in physical form will derive from a significant change in composition and the new substance will fail the 'same nature and kind' test. Some discretion can be allowed where there is clearly a reduction in adverse effects as a result of the physical change; for example, the reference substance is liquid and the proposed substance is granular and adverse effects are reduced through reduced exposure.

Similar Hazardous Properties

A substance may be regarded as having similar hazardous properties to a previously approved substance if it:

- does not exceed a hazardous property threshold for any hazardous property not triggered by the reference substance, ie. a new hazard class or subclass may not be introduced in the proposed substance; and
- does not have a higher hazard classification to the reference substance in respect of any hazardous property, ie. there cannot be an increase of hazard category within a hazard subclass. However exceptions to this may be allowed where it is considered that an increase in hazard classification would not result in any significant increase in adverse effects; for example, an increase from 6.3B to 6.3A.

The reduced hazard route (section 28A(2)(c)) may be the more appropriate route if the proposed substance is less hazardous than the reference substance.

Variation of Controls

In general the controls for the new substance should be the same as those for the reference substance and this is a good "cross check" on similarity. There may, however, be circumstances in which a change of controls could be acceptable. This would be applicable for minor changes, and would not apply to any major change or variation to controls as this

would not be consistent with the intent of sections 77 and 77A. Reasons for allowing changes could include:

- Reductions in controls resulting from reduced hazardous properties. For example, an acceptable variation could be changes in the requirements for label statements resulting from a drop from severe skin irritant to minor skin irritant.
- A situation where the controls on the reference substance require revision due to changes; for example, changes in the application of classification criteria since the approval of the reference substance.

Circumstances under which a substance which does not meet the criteria may nevertheless be considered

A substance that does not meet the similarity of composition criteria because the increase in the proportion of all the major hazardous components, or the increase in concentration of any one major hazardous component, exceeds the limits described above in the criteria for major hazardous substances may still be considered if the variation is relatively minor and generally applies to one of the criteria, e.g. a new component makes up 30% rather than 25% of the total major hazardous components, but all other guidelines are met. Marginal cases like this are more likely to be considered favourably if there is a clear reduction in risk of the new substance compared with the reference substance. Such situations will be evaluated on a case-by-case basis.

Dealing with Applications on the Grounds of Least Degree of Hazard

Section 28A(2)(b) allows rapid assessment of a proposed substance if ERMA New Zealand is satisfied that the substance has one or more hazardous properties and each hazardous property has the least degree of hazard for that property.

Least Degree of Hazard

In the first instance, eligibility for this assessment route is determined by direct evaluation against the criteria for the lowest classification levels contained in the Hazardous Substances (Classification) Regulations.

ERMA New Zealand has, however, further determined that only certain of the classification classes and sub-classes are automatically appropriate for consideration by this rapid assessment route. This is because not all of the least degrees of hazard can be considered as representing equivalent degrees of severity of the hazardous property concerned. For instance, classification 6.7B, suspected human carcinogen, represents rather more of a level of concern than does classification 6.3B, mild skin irritant. Also, some classification subclasses are composed of only one degree of hazard – thus the least degree of hazard is also the greatest degree of hazard.

This discretion by the Authority is allowed by the wording of the Act, which provides (section 28A(2)):

“The Authority may approve a hazardous substance under this section if the Authority is satisfied that –

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

The least degrees of hazard considered appropriate for rapid assessment under this policy are as follows:

Explosive articles	classification 1.4S	
Flammable gases	classification 2.1.1B	
Flammable aerosols	classification 2.1.2A	
Flammable liquid	classification 3.1D	
Readily combustible solid	classification 4.1.1B	
Self-reactive substances	classification 4.1.2G	
Dangerous when wet substances	classification 4.3C	
Organic peroxides	classification 5.2G	
Acute toxicity	classification 6.1E	
Skin irritant	classification 6.3B	
Eye irritant	classification 6.4A	(Note 1)
Sensitisation	classifications 6.5A, 6.5B	(Note 2)
Mutagenicity	classification 6.6B	
Target organ/system toxicity	classification 6.9B	
Metallic corrosives	classification 8.1A	
Ecotoxic	classifications 9.1D, 9.2D, 9.3C, 9.4C	

Note 1: There is only one degree of hazard for the toxic subclass of eye irritancy. This essentially represents the lowest degree of hazard for the property of adverse effects to the eye as the classification criteria for this level relate to reversible effects. More severe irreversible effects are covered by classification 8.3A, eye corrosive.

Note 2: ERMA New Zealand has adopted the Globally Harmonised System for Classification and Labelling of Chemicals (GHS) cut-off levels of 0.1% for both respiratory and contact sensitisers.

There is only 1 degree of hazard for respiratory and dermal sensitisers. Substances that contain respiratory and/or dermal sensitisers require a consideration of the severity of the allergic manifestations in humans or animals, as well as frequency in exposed populations. ERMA New Zealand will consider for rapid assessment under the least degrees of hazard criteria substances containing respiratory and/or dermal sensitisers provided the following conditions are met:

- (1) (a) there is a low or moderate frequency or severity of occurrence within an exposed population; or
- (b) there is a probability of occurrence of a low to moderate sensitisation rate in humans based on animal or other tests; and
- (2) the sensitiser is not “released” from the substance during use.

The caveat in (1) is to differentiate between substances that are strong sensitisers, and substances that are low to moderate sensitisers. Substances that meet the criteria in 1(a) and (b) may be considered to be low to moderate sensitisers.

The caveat in (2) is to prevent increased exposure through certain uses, such as aerial spraying. The idea of “release” of the sensitiser relates to the substance being used in a wide dispersive manner where there is potential for increased risk of an effect to non-target people or the environment.

It is sufficient to show that only classifications from the above list have been triggered in order for rapid assessment to be applicable. All of the least degree of hazard properties triggered will be considered in making a decision on an application.

Dealing with Applications on the Grounds of Reduced Hazard

Section 28A(2)(c) allows rapid assessment of a substance if the Authority is satisfied that it has been formulated so that one or more of its hazardous properties has a lesser degree of hazard than a substance which has been approved under the HSNO Act. For this application route to be used there must be:

- a reference substance with a HSNO approval; and
- a proposed substance with a lesser degree of hazard in at least one of the hazardous properties compared with the reference substance.

This allows for the rapid assessment of substances which have been formulated to be less hazardous than existing similar substances, with the overall aim of encouraging the use of lower hazard chemistry. In line with this, ERMA New Zealand would normally expect there to be a basis for comparison between the substances in terms of composition and use.

It is the responsibility of the applicant to provide evidence for these points in a clear and transparent manner so that a rapid assessment under s28A(2)(c) can proceed.

The Reference Substance

Rapid assessments on the grounds of reduced hazard require comparison with a reference substance that has already been approved. More than one reference substance may be applicable.

In section 28A(2)(c), '**approved**' means approved under the HSNO Act, by the Authority. This means the reference substance has either been approved in an earlier Part V HSNO approval, including those approved under the rapid route, or it has obtained a 'deemed approval' through the process for the transfer of existing substances under (now expired) Parts XI to XV of the Act. The Authority (or the Chief Executive) must be satisfied that one of these criteria has been met.

The reference substance should have a similar life cycle and use to that of the proposed substance. For example, if the proposed substance is a veterinary medicine, then the reference substance should also be a veterinary medicine.

Proposed Substance with a Lesser Degree of Hazard

A proposed substance may be regarded as having a lesser degree of hazard to a reference substance if it:

- does not exceed a hazardous property threshold for any hazardous property not triggered by the reference substance. For example, the proposed substance cannot be classified as a 9.1 aquatic ecotoxicant if the reference substance has no 9.1 classification; and
- does not have a higher hazard classification to the reference substance in respect of any hazardous property, ie. there cannot be an increase of hazard category within a hazard subclass; and

- does have a lesser degree of hazard compared to the reference substance in at least one hazardous property. This may include removal of a classification that was present in the reference substance, for example, the reference substance triggers a flammability classification and the proposed substance does not.

If the proposed substance meets the rapid (least degrees of hazard) criteria in accordance with section 28A(2)(b), the application should be processed by that route.

Basis for Comparison between the Substances

As part of the consideration of an application via this route, the decision maker must be satisfied that the overall risks posed by the proposed substance are the same as, or less than, those posed by the reference substance. This provides the context for the comparison between the two substances.

Composition

The same approach to composition as outlined above in the sections ‘Criteria for Similar Composition’ and ‘The Major Hazardous Components’ will also apply to the rapid/reduced hazard route. However, more variation in composition may be acceptable under this route than is acceptable under the rapid/similar route, provided there is a reduction in at least one hazardous property of the proposed substance relative to the reference substance.

Changes in Physical Form

A change in physical form may well occur as a result of the proposed substance being formulated to have a lesser hazard, and this is acceptable, provided it does not result in an increase in overall risk. For example, while a change from a powder to a granule may be acceptable; a change from a granule to a powder might not be acceptable because of possible additional risks associated with inhalation or solvency etc.

Variation of Controls

As the proposed substance has a lesser degree of hazard, the controls for the proposed substance are likely to be varied from those applied to the reference substance. Reasons for changes may include reductions in controls resulting from the reduced hazardous properties. For example, an acceptable variation could be removal of the flammability controls, as the proposed substance has been reformulated to be non-flammable.

Circumstances under which a substance which meets the criteria for similar or reduced hazard may nevertheless be declined

The proposed substance introduces additional adverse effects

Consideration of additional adverse effects will only come into play when the substance has not already been screened out from rapid assessment by higher-level differences in composition or hazardous properties.

The significance of the adverse effects will be considered in light of the uses of the proposed substance, and whether the residual risks are significant with the controls that apply to the reference substance in place. If the adverse effects of the new substance are significantly

different in kind or increased in level compared to the reference substance, then the application may be declined.

A situation where this might arise is when both reference and proposed substances are classified as 9.1A (very ecotoxic in the aquatic environment) but within this hazard category the proposed substance is ecotoxic to different taxonomic groups to the reference substance or the proposed substance is persistent whereas the reference substance is not. In this case, the hazardous properties would likely not be considered to be similar, and as such the substance should not be considered for rapid assessment except on a special case-by-case basis.

The proposed use is significantly different

Another circumstance is where the use of substance is significantly different, e.g. the reference substance was intended for contained use, while the new substance is intended for widely dispersive use. If the variation in use is essential to the application, ie. it cannot be dealt with by applying use related controls; again the application may be declined.