

MAF Food Assurance Authority

**Agricultural Compounds and
Veterinary Medicines Group
Operational Policy**

**CLASSIFICATION OF SUBSTANCES AS
GENERALLY RECOGNISED AS SAFE
(GRAS)**

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Approval

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ACVM GROUP OPERATIONAL POLICY - CLASSIFICATION OF SUBSTANCES AS GENERALLY RECOGNISED AS SAFE (GRAS)

1 BACKGROUND

Many common substances known to present negligible hazards to human or animal health or the environment are used in agricultural compound trade name products both in New Zealand and around the world. The Ministry of Agriculture and Forestry (MAF) considers that repeated assessment of such substances when they are incorporated into new trade name products is not necessary.

MAF has adopted a mechanism used in North America and Europe to provide for substances to be assessed by experts, considered by the public and placed on public registers if they are proven to be generally recognised as safe (GRAS).

The registers provide a practical means of ensuring that regulatory interest focuses on substances that should be of concern either because they do pose hazards or because there is insufficient experience to determine whether or not the substance should be recognised as safe when incorporated into a range of products.

The purpose of this policy is:

- To clarify the ACVM Group operational policy on applications for substances to be generally recognised as safe; and
- To ensure consistency in communication with applicants.

2 POLICY

- 2.1 A GRAS register will list **substances** that are generally recognised as safe, not trade name products.
- 2.2 Substances are considered on a case by case basis, but not in regard to their inclusion in a particular trade name product.
- 2.3 The criteria for inclusion on GRAS registers are conservative so that only very safe substances will ever be classified as GRAS.
- 2.4 The applicant must provide a satisfactory case showing that a substance proposed to be GRAS is well-known and has a history of safety in the context of use. This may include a reference to another regulatory authority's GRAS register if that reference is relevant to what is being proposed.
- 2.5 The substance must be safe across a wide range of trade name products before it could be considered as GRAS. The classification of some substances may be

qualified where required. Those qualifications will be stated on the GRAS register with the associated substance.

- 2.6 A substance is considered safe only when it is manufactured according to good manufacturing practices and used according to good feeding practices or applied/administered according to good agricultural or good clinical practices. This means that a substance can be considered safe only when it is manufactured and used in accordance with common practice.
- 2.7 Three registers will be established. Each will list substances considered to be GRAS for inclusion in one of the following categories:
- oral nutritional compounds;
 - veterinary medicines other than oral nutritional compounds;
 - plant compounds.
- 2.8 Applications will not be initiated by the Agricultural Compounds and Veterinary Medicines (ACVM) Group unless there is a compelling public interest reason.
- 2.9 Applications must be assessed by a network of technical experts, notified for public comment and approved by MAF before being placed on the GRAS register.
- 2.10 Existing entries on registers can be reassessed in light of new information that shows that a substance should no longer be considered safe.
- 2.11 No fee will be charged for applications to classify substances as GRAS.
- 2.12 Listing a substance as GRAS will bring no automatic consequences in regard to registration of trade name products containing that substance. A product in which all ingredients are GRAS may still require assessment depending upon other characteristics of that product, e.g. application/administration method, claims, interactions.