accord
hygiene, cosmetic & specialty products industry

ATTACHMENT 1

Members

Consumer, Cosmetic and Personal Care

Advanced Skin Technology Pty Ltd
Amway of Australia Pty Ltd
Apisant Pty Ltd
AVON Products Pty Limited
Beautiworx Australia Pty Ltd
Beautopia Hair & Beauty Pty Ltd
Beiersdorf Australia Ltd
BrandPoint Pty Ltd
Chanel Australia
Clorox Australia Pty Ltd
Colgate-Palmolive Pty Ltd
Combe Asia-Pacific Pty Ltd
Conair Australia Pty Ltd
Cosmax Prestige Brands Australia Pty Ltd
Coty Australia Pty Limited
De Lorenzo Hair & Cosmetic Research Pty Ltd
Elizabeth Arden Australia
Emeis Cosmetics Pty Ltd
Energizer Australia Pty Ltd
Estée Lauder Australia
Evolve Hair Concepts Pty Ltd
Frostbland Pty Ltd
GlaxoSmithKline Consumer Healthcare
Helios Health & Beauty Pty Ltd
iNova Pharmaceuticals – A Valeant Company
Integria Healthcare (Aus) Pty Ltd
International Beauty Supplies Pty Ltd
Johnson & Johnson Pacific
KAO Australia Pty Ltd
KAO Brands Australia Pty Ltd
Keune Australia
Kimberly-Clark Australia
La Biosthetique Australia
La Prairie Group
L'OCCITANE Australia Pty Ltd
L'Oréal Australia Pty Ltd
LVMH Perfumes and Cosmetics
Mary Kay Cosmetics Pty Ltd
Natural Australian Kulture Pty Ltd
Nutrimetics Australia
NYX Pty Ltd
Panamex Group
Procter & Gamble Australia Pty Ltd
PZ Cussons Australia Pty Ltd
Reckitt Benckiser
Revlon Australia
SC Johnson & Son Pty Ltd
Scental Pacific Pty Ltd
Shiseido (Australia) Pty Ltd
Syndet Works Pty Ltd
The Heat Group Pty Ltd
The Purist Company Pty Ltd
Three Six Five Pty Ltd
Trimex Pty Ltd
True Solutions International Pty Limited
Ultraceuticals
Unilever Australasia
Vitafive
Weleda Australia Pty Ltd

Hygiene and Specialty Products

Albright & Wilson (Aust) Ltd
Antaria Limited
BP Castrol Australia Pty Ltd
Brenntag Australia Pty Ltd
Castle Chemicals Pty Ltd
Chemetall (Australasia) Pty Ltd
Clariant (Australia) Pty Ltd
Deb Australia Pty Ltd
Dominant (Australia) Pty Ltd
Ecolab Pty Limited
Huntsman Corporation Australia Pty Ltd
Jalco Group Pty Limited
Jet Technologies Australia Pty Ltd
Lab 6 Pty Ltd
Novozymes Australia Pty Ltd
Nowra Chemical Manufacturers Pty Ltd
Peerless JAL Pty Ltd
Recochem Inc
Rohm and Haas Australia Pty Ltd
Solvay Interox Pty Ltd
Sopura Australia Pty Ltd
Tasman Chemicals Pty Ltd
Thor Specialties Pty Limited
True Blue Chemicals Pty Ltd

Univar Australia Pty Ltd

Whiteley Corporation Pty Ltd

Associate Members

Corporate Travel Services

Unique Group Travel

Graphic Design and Creative

Ident Pty Ltd

Legal and Business Management

FCB Lawyers

K&L Gates

KPMG

TressCox Lawyers

Regulatory and Technical Consultants

Clare Martin & Associates Pty Ltd

Competitive Advantage

Engel, Hellyer & Partners Pty Ltd

Robert Forbes & Associates

Seren Consulting Pty Ltd

Sue Akeroyd & Associates

Toxikos Pty Ltd

Specialist Laboratories and Testing

ams Laboratories

Dermatest Pty Ltd

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ATTACHMENT 2

A Simplified System for Registration of Dairy Cleansers and Sanitisers

THE ISSUES

Users of dairy sanitisers and cleansers (dairy farmers) and manufacturers of dairy sanitisers and cleansers require products that satisfy certain requirements. Key requirements are listed in the table below:

Users (On-Farm)	Manufacturers
Products used comply with requirements of AgVet Code	Products supplied comply with requirements of AgVet Code
Products used are effective	Products supplied are effective
Milk will not be rejected	Milk will not be rejected due to contamination by the supplied product
	Cost-effective process for commercialising products – Know the cost of bringing product to market
	Able to justify why any additional studies required for registration in Australia should be conducted

The list of requirements is not exhaustive. Matters such as cost are important but are outside the scope of this proposal.

The above table shows there are common requirements for users and manufacturers. Satisfying the user requirements for effective and compliant products that will not result in milk be rejected due to use of the product requires manufacturers/suppliers to register their products.

Registration adds additional requirements on manufacturers:

- The cost of registration must be justified by the potential returns. Commonly, manufacturers/suppliers will examine where to invest limited resources by looking at:
  - The cost of competing projects;
  - The time to when different projects will be finished and products commercialised; and
  - Market potential.

- While local affiliates of overseas companies may consider an opportunity worthy of investment, their parent company will generally require justification as to why any additional data not required by other regulators needs to be generated to obtain APVMA registration.

This proposal looks at a way of:

1. Allowing potential registrants to determine what will be required to obtain registration of specific products.
   a. Self-assessment against a 'Standard' defines whether a product conforms with the relevant Standard or not.
   b. Having determined conformance, relevant data are provided to APVMA to allow APVMA to confirm the product conforms with the

Standard.

2. Minimises data requirements by recognising eligible products are already used in comparable situations for comparable purposes.
    a. The history of use (documented with the application) enables APVMA to be satisfied the product will not pose an undue hazard and will be effective when used according to directions.

3. Minimises the need for assessment by allowing APVMA to check information against a standard rather than requiring APVMA to conduct a comprehensive evaluation of a proposed product.

AgVet Code Requirements

AgVet Code requires APVMA to be satisfied that:

- Substances approved/registered by APVMA will not pose undue hazard to people, animals, things, or the environment.
- Approved/registered substances will not adversely affect trade between Australia and Australia's trading partners.
- Registered products when used in accordance with directions on the approved label will be effective.

AgVet Code lists a number of things that APVMA 'may have regard to' in determining whether a product will pose undue hazard, be likely to adversely impact trade or will be effective. The AgVet Code does not require these things to be assessed but does require certain particulars to be recorded.

What are Dairy Sanitisers and Cleaners?

Products used on-farm to clean and/or sanitise dairy equipment including lines, tanks and other equipment.

Dairy sanitisers are NOT intended for use in controlling specific animal diseases, e.g. mastitis.

Dairy sanitisers and cleaners:

- Are frequently used in situations related to production of milk products, e.g. cleaning tanks, cleaning/sanitising equipment in dairy processing plants.
- May be the same products as used for other uses on-farm that are not APVMA regulated.
- Often are products with a long history of use in other situations. Where formulated products do not have a long history of use, the active constituents used to formulate the products generally have a long history of use.
- Generally have been developed overseas and are used in similar situations overseas.

Eligible Products

The scheme would restrict those products that are eligible for participation in the scheme. Eligible products would have the following characteristics:

1. Active constituents known to APVMA:
    a. Restrict the actives used in eligible products to:
        i. Actives that are already approved; or

ii. Actives that are excluded from the requirements for approval.

2. Products that do not have health effects of concern:
    a. Products must NOT be classified as:
        i. Carcinogens;
        ii. Having adverse effects on sexual function and fertility; and/or
        iii. Having adverse effects on development of offspring.

3. Products must not have unintended effects harmful to things:
    a. The products must be supplied and used in comparable situations:
        i. In Australia or overseas.
        ii. Have not caused unexpected harm to things when used in situations and ways comparable with those proposed.

4. Products must be effective when used according to directions:
    a. The eligible products must be supplied and used in comparable situations for similar purposes:
        i. They continue to be used.
        ii. There are no restrictions imposed in other comparable situations due to concerns about efficacy.

5. Residues will not remain to cause harm to people or trade:
    a. The eligible products must be washed off treated surfaces with potable water before coming into contact with foods (milk/milk products).

SATISFYING APVMA'S DATA REQUIREMENTS

1. Category 10 application:
    a. Category 10 application form.
    b. No assessable data.

2. Declaration product is identical to that used in similar situations:
    a. Provide to APVMA details of uses of the product in other comparable situations including:
        i. How product is used.
        ii. Situations in which product is used.
        iii. How product is used.
        iv. Targets/purpose for using product.
    b. Provide to APVMA comparison of proposed product with product used in comparable situations.
        i. Proposed product should be the same.
        ii. Explain why the current use situations should be considered similar to on-farm dairy use.
    c. Provide copy of label for currently used product plus copy of draft label for proposed product.

3. Draft label:
    a. Label standard to be developed.
        i. Will provide guidance rather than be prescriptive, e.g. the types of permitted claims.

    b. First Aid Instructions and Safety Directions:

i. For products containing Scheduled substances, use First Aid instructions and Safety Directions from FAISD.
ii. If not Scheduled, recognise diary cleansers and sanitisers are workplace chemicals. Use relevant GHS Prevention and Response statements.

c. Formulation composition.

d. Details of the formulation process.

e. Basic chemistry information:
   i. Same information that would normally appear on an SDS.
   ii. Storage stability not required if product has a history of use in similar situations elsewhere.

f. Product specifications:
   i. As used in manufacture (formulation) of the product.
   ii. No need to list 'specifications' not actually used in production of the product.
   iii. Specifications should be sufficient to demonstrate to APVMA the product being supplied is the same as the product submitted for registration.
   iv. Container specifications.

PROCESS

1. Similar to New Zealand Group Standards.
   a. An example of a NZ Group Standard is attached.
      i. While the NZ system allows for self-assessment for compliance, the Australian system will require information to be provided to APVMA and registration to be granted by APVMA.
      ii. The APVMA 'Standard' for diary cleansers and sanitisers will require evidence of conformance with the Standard.

2. Applicants would assess their product against the relevant standard.

3. Applicants would submit the relevant information to APVMA confirming the product conforms with the Standard.

4. APVMA would confirm the product conforms with the relevant Standard.

5. The product is registered unless APVMA concludes the product does not conform with the Standard.

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ATTACHMENT 3

International comparisons and trade issues, including effect on small companies

The New Zealand Environmental Protection Agency (EPA) manages low and medium risk products with similar hazard classifications through the adoption of a Group Standard. The Group Standard contains all the controls required for managing a class of products with a similar hazard profile and includes such matters as storage and handling, transportation, and labelling. Companies self-assess against the Group Standard hazard classification for their particular products. The NZ EPA has recently commenced developing Group Standards for agvet products. We believe that this is a good example of how products which represent a low regulatory concern could be managed in a pragmatic, low cost way and could be considered as a model to be adopted in Australia. In addition, the APVMA should mutually recognise products from NZ which are regulated under these controls rather than requiring registration. Two examples are provided for the PC's information:

- Agricultural Compounds Special Circumstances
  The Agricultural Compounds Special Circumstances group standard is for agricultural compounds (i.e. plant protection products or veterinary medicines) that are for use in specific, restricted situations, as detailed in the scope of the group standard. More information can be found on the NZ EPA's website at: http://www.epa.govt.nz/hazardous-substances/approvals/group-standards/Pages/Agricultural-compounds-special-circumstances.aspx.

- Animal nutritional and animal care products group standard
  The animal nutritional and animal care products group standard is for products intended for administration to an animal to achieve a nutritional benefit, and products used in the external care or grooming of an animal. More information this Group Standard can be found on the NZ EPA website at: http://www.epa.govt.nz/hazardous-substances/approvals/group-standards/Pages/animal-nutrition-care.aspx.

In general Accord believes that there should be greater recognition of approved ingredients by Australian chemical regulators as well as those overseas. For example the APVMA could recognise those ingredients and/or products which have been assessed by the Therapeutic Goods Administration (TGA), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and Food Standards Australia New Zealand (FSANZ). If ingredients appear on the approved lists or inventories of these agencies then they should be accepted by the APVMA, or as a minimum, not be regarded by the APVMA as new.

Furthermore, the APVMA should also accept the decisions of comparable advanced economy regulators such as the US EPA on ingredients and/or products deemed as low risk. This would allow for timelier introduction of low risk products and would lower costs and make registration processes simpler which would facilitate small business engagement in the agvet sector. Two examples of efforts by the US Government are as follows:

- Generally Recognized as Safe (GRAS)
  "GRAS" is an acronym for the phrase Generally Recognized As Safe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe

under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive. In addition to its mandate under FIFRA, EPA has authority to regulate pesticide products under the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 408 of FFDCA authorizes EPA to establish tolerances or safe levels of pesticide residues in raw agricultural commodities; section 409 similarly authorizes EPA to issue food additive regulations for pesticide residues in processed foods. Prior to the establishment of the EPA, the Food and Drug Administration (FDA) had the responsibility for establishing tolerances and food additive regulations for pesticide residues. More information can be found on the US FDA website at: http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/default.htm.

- Pesticides; Revisions to Minimum Risk Exemption
  In addition US EPA is proposing to more clearly describe the active and inert ingredients permitted in products eligible for the exemption from regulation for minimum risk pesticides. EPA is proposing to reorganize these lists with a focus on clarity and transparency by adding specific chemical identifiers. The identifiers would make it clearer to manufacturers; the public; and Federal, state, and tribal inspectors which ingredients are permitted in minimum risk pesticide products. EPA is also proposing to modify the label requirements in the exemption to require the use of specific common chemical names in lists of ingredients on minimum risk pesticide product labels, and to require producer contact information on the label. Once final, these proposed changes would maintain the availability of minimum risk pesticide products while providing more consistent information for consumers, clearer regulations for producers, and easier identification by states, tribes and EPA as to whether a product is in compliance with the exemption.

  More information on this reform activity can be found at https://s3.amazonaws.com/public-inspection.federalregister.gov/201231188.pdf?utm_source=BPIA+Government+Affairs+Committee+January+2nd%2C+2013&utm_campaign=Government+Affairs+Connections&utm_medium=email.

These are just a few examples of where similar jurisdictions recognise that low risk products require an alternative regulatory pathway which recognises their risk profile. This situation does not exist in Australia and while there is renewed emphasis on risk management we believe that this should be strengthened with specific statements regarding the treatment of low risk products.