Australian Government

Australian Pesticides and Veterinary Medicines Authority

Proposed establishment of a new standard undersection 6E of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) (Code)

Submissions received

July 2022

Director Chemistry and Manufacture
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001
Email: enquiries@apvma.gov.au

Dear Madam/Sir

Accord is pleased to provide this submission to the APVMA on the Proposed establishment of a new standard under section 6E of the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994.

Accord is the peak national industry association representing the manufacturers and marketers of formulated hygiene, personal care and specialty products, their raw material suppliers, and service providers. Accord member companies make and/or market broad range of consumer and commercial goods that play integral roles in safeguarding public health, promoting personal hygiene, boosting confidence and emotional wellbeing, maintaining comfortable homes, and enhancing quality of life, as well as keeping the wheels of commerce and industry turning. Member companies include large global manufacturers as well as small dynamic Australian and family-owned businesses. A list of Accord member companies is available on our website: http://accord.asn.au/about/members.

Headline statistics[1] for our industry's economic footprint include:

- Accord's membership is approximately 100 companies.
- Collectively, Accord member companies directly contribute more than 12,000 fulltime equivalent jobs.
- Nationally, more than 175 offices and more than 65 manufacturing sites are operated by Accord member companies.
- 80% of member companies export products overseas.

Accord's member companies support the establishment of the new Standard, the Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard.

Accord is appreciative that the APVMA has implemented alternate allowable variations from those within the 2(a) table for constituents such as solvents, fillers and pH adjusters.

Accord would like to thank the APVMA for the opportunity to provide comments on the Allowable Variation in Concentrations of Constituents in Agricultural Products Standard. We appreciate the APVMA's continued open engagement with us. If you have any queries regarding our submission, please do not hesitate to contact me at tdolahenty@accord.asn.au.

Yours sincerely

Authorised for electronic submission

Thomas Dolahenty
Science and Technical Associate

30 May 2022

[1] Results from Accord Industry Size and Scale Survey 2018

The Director
Chemistries and Manufacture
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
SYDNEY NSW 2001

Via Email: enquiries@apvma.gov.au

31 May 2022

Re: APVMA Consultation for Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products.

As the peak industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia, CropLife represents the manufacturers, innovators, developers and formulators of crop protection and agricultural biotechnology products. CropLife's membership is made up of both large and small, patent holding and generic, Australian and international companies and accordingly CropLife advocates for policy positions that deliver whole of industry benefit. As such, CropLife provides the following comments on the Australian Pesticides and Veterinary Medicines Authority (APVMA) Consultation for the proposed establishment of a new standard under section 6E of the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (Cth) (Code).

CropLife acknowledges and recognises that there has been no defined allowable variation in the concentrations of non-active constituents. This has created undue burden on both the Regulator and registrants, as variation applications were required to compensate for the results of manufacturing processes that do not compromise either the safety, efficacy or trade criteria. We thank the APVMA for recognising the importance of the issue and proceeding to consultation with such haste.

CropLife supports the intent of the inclusion as a 6E standard and recognises this will reduce administrative burden on both registrants and the Regulator.

CropLife notes, however, that in countries such as the US and Canada where similar limits exist, generally much wider allowable ranges for non-active constituents are requested as part of the formulation declaration. In practice, the default ranges are considered too tight to meet manufacturing needs. Furthermore, broader limits (twofold FAO limits[1]) for non-active constituents are used in practice by the German authorities[2]. In an Australian context, this could be satisfactorily solved by aligning with FAO guidance, whereby allowable variations for active constituents specified in 1(a) of the draft legislative instrument are repeated in 2(a) as the allowable ranges for the non-active constituents.

1 https://www.fao.org/documents/card/en/c/cb8401en

2 Assessment of examinations made of plant protection products taken from the market, C. Vinke, Federal Office of Consumer Protection and Food Safety, Germany, 2014 https://www.bvl.bund.de/SharedDocs/Downloads/04_Pflanzenschutzmittel/Bewertung_v_Untersuchungen_an_PSM_a_%20d_Marktkontrolle_EN.html?nn=11010448

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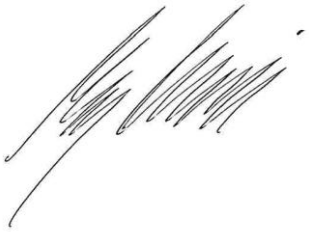
CropLife also requests clarity around Part 2 (d) for constituents such as pH adjusters or buffers, or viscosity modifiers, whose concentrations may be adjusted to bring a parameter such as pH or viscosity within a desired range, tolerances may be declared as, for example, q.s. pH 4.0-5.0, or q.s. 200-300 mPa.s.

This should include all titre constituents where the use is by necessity variable to achieve quality parameters, not limited to the above. At a minimum, this allowable list should be expanded include anti-foaming agents, dyes, neutralising bases and emulsifiers.

CropLife is pleased that the APVMA has committed to developing this instrument to give precedence to Australian standards in the cascading order of relevant publications. Please do not hesitate to contact me (gregory.sekulic@croplife.org.au | 02 6273 2733), should you require any additional information with regard to any aspect of this submission.

Yours sincerely,



Gregory Sekulic
Director, Agricultural Chemical Policy

24 May 2022

Director Chemistry and Manufacture
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Dear Director of Chemistry and Manufacture,

Proposed establishment of a new standard under section 6E of the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (Cth) (Code).

Nufarm welcomes the establishment of a new standard under section 6E of the Agricultural and Veterinary Chemicals Code to formalise the current guidance materials surrounding allowable variations for concentrations of active constituents of agricultural chemical products and to allow for variations for concentrations of non-active constituents. The purposed changes will harmonise with regulations of overseas authorities, including the US EPA and NZ Ministry of Primary Industries.

Nufarm is supportive of all the changes proposed but is seeking clarification on 2 sections of the standard. Firstly, the definition in the instrument for "Declared content, declared concentration, nominal content or nominal concentration". The definition is included here:

Declared content, declared concentration, nominal content or nominal concentration *all refer to the expected, mean, or target concentration of a constituent stated or referred to in the appropriate section of an application form for registration or variation of an agricultural chemical product by an applicant for a constituent in their product. In addition, for active constituents or constituents included in a Schedule of the Poisons Standard, declared content refers to the concentration listed in a constituent statement on a product label.*

In particular, we are seeking clarification on the use of the wording "mean or target concentration". Nufarm has always provided the target concentration for formulation details and is seeking clarification when the use of a mean would be appropriate.

Secondly, sections 2c & d make allowances for constituents such as solvents, pH adjusters and viscosity modifiers to be declared as q.s 1L or q.s pH 4.0-5.0 for example. There is no reference in these sections that these constituents are also expected to fall within the allowable variation percentages outlined in the table in part 2. Nufarm is seeking clarification that this assumption is correct.

Further to section 2d, Nufarm would like to enquire if the wording of this section is intended to be flexible. Currently section 2d states: "*For constituents **such as** pH adjusters or buffers, or viscosity modifiers, whose concentration may be adjusted to bring a parameter such as pH or visocosity within a desired range……*" The use of the wording "such as" suggests that several other types of constituents that are adjusted to bring a parameter in to a desired range may fall into this definition eg. the use of neutralising salts or antifoamer. Nufarm would like to clarify whether this is the case or whether a more prescriptive list should be included?

We have taken this opportunity to propose an example of how the formulation details table could be updated to incorporate these changes (attachment 1). We have spent time working with our Chemists, Regulatory Scientists and Quality Control teams and we believe that the attached example incorporates the proposed standard and provides clarity for the personnel filling in the information. In this case we have used an example where one of the neutralising salts is also used as the pH modifier, it is required to be listed as a neutralising salt for the label claim, but we also need the flexibility to adjust for pH. We would welcome the opportunity to discuss this further if required.

Yours sincerely

Katherine Lock
Senior Regulatory Scientist

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nufarm.com

Nufarm
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