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Dugald MacLachlan
Director, Residues and Microbiology Policy
Export Reform and Traceability Branch
Trade Reform Division
Department of Agriculture, Water and the Environment

Submitted via Export Control Rules 2021 – Proposed amendments | Have Your Say - Agriculture, Water and the Environment (awe.gov.au)

Dear Mr MacLachlan,

**Re: Export Control Rules 2021 – Proposed amendments**

Thank you for the opportunity to provide comment on the proposed amendments to the Export Control Rules 2021.

Animal Medicines Australia (AMA) is the peak industry body representing the leaders of the animal medicines industry in Australia. Our members companies are the innovators, manufacturers, formulators and registrants of a broad range of veterinary medicine products to protect and treat animal illness, disease and injury, and support animal welfare across the livestock, equine and companion animal sectors. AMA members range from local businesses to the local divisions of global companies and includes companies who manufacture in Australia for global export markets. AMA members represent more than 90% of Australian sales of registered veterinary products.

Animal Medicines Australia wishes to note our concern with proposed changes to the definition of Hormonal Growth Promotants (HGPs) and bovine meat products treated with HGPs. The proposed amendment includes additional wording in the HGP definition, as highlighted in paragraph b in the screenshot below.

## Schedule 2—Amendment of the Export Control (Meat and Meat Products) Rules 2021

***Export Control (Meat and Meat Products) Rules 2021***

**1 Section 1-5 (definition of *HGP*)**

Repeal the definition, substitute:

***HGP*** (short for hormonal growth promotant) means:

(a) a veterinary chemical product that:

(i) contains a substance that is, or a mixture of substances that are, responsible for oestrogenic, androgenic, gestagenic or thyrostatic activity to enhance growth or production in cattle; and

(ii) is registered for use for this purpose in Australia under section 14 of the Agvet Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*; or

(b) a veterinary chemical product that contains oestradiol-17β or an ester-like derivative of oestradiol-17β.

The proposed changes will capture some reproductive hormone products that have not previously been considered to be HGPs, do not act as growth promotants and are not registered for use as growth promotants. The words 'ester-like derivatives of oestradiol-17b' will also capture oestradiol benzoate or cypionate products, as the proposed definition adds the oestradiol wording after paragraph (a)(ii), and not before. These products are used for reproductive manipulation in cattle; they are not used, nor registered, as HGPs.

If oestradiol products are to be considered HGPs, then AMA is concerned that they may be controlled in the same way as existing HGPs. This would include licensing of all wholesalers, retailers, registrant warehouses and any other locations where these products are held or supplied, licensing of all farms that use them, and reporting of the disposition of every dose.

This would represent a significant change from current policy and practice that has not been discussed with key stakeholders and that will impose a significant administrative burden on the APVMA as well as every manufacturer, supplier and user of oestradiol products. Licensing and reporting requirements would also be extended to production sectors that have previously never been involved in HGP reporting, such as dairy cattle. Further, the consultation documents provide no indication of responsibilities or cost implications for establishing and maintaining such a scheme for these products.

AMA seeks confirmation that this change to the definition of HGPs will not impact licensing and control requirements for products not currently defined as HGPs.

Correspondence from the Export Reform and Traceability Branch, Department of Agriculture, Water and the Environment, notes that the intention of this change is to support the existing European Union Cattle Accreditation Scheme (EUCAS) arrangements for export to EU markets. The prohibition on the use of HGP products, including products containing oestradiol-17β and ester-like derivatives, *will only be applicable to livestock kept on accredited properties that export meat and meat products to EU markets*. Compliance with the new scope of products defined as HGPs under the EUCAS scheme will continue to be managed through the existing regulatory mechanisms.

Animal Medicines Australia considers that having a different definition for HGPs in legislation controlling exports compared to the legislation responsible for controlling supply of such products may lead to confusion and misinterpretation. In particular, the APVMA defines HGPs as substances that 'enhance growth or production in bovines' (https://apvma.gov.au/node/4136) – this definition clearly excludes oestradiol products that are used for reproductive purposes. There will, therefore, be a need to clearly and consistently exclude oestradiol products used on non-EUCAS-accredited properties from the HGP notification scheme.

However, if the proposed amendments reflect an intention to change the scope of current policy and practice in relation to HGPs used on non-EUCAS-accredited properties, AMA notes that any such proposals should be preceded by appropriate consultation with affected stakeholders, in accordance with the Australian Government Guide to Regulatory Impact Analysis (2nd Ed., 2020)[1], prior to amendments being made to the Export Control Rules. We would be pleased to participate in further consultation.

If we can provide any further information at this time, please do not hesitate to contact me.

Yours Sincerely,

Dr Charmian Bennett

Director Science and Policy

*(unsigned for electronic submission)*

[1] www.pmc.gov.au/regulation