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20 December 2012

Committee Secretary
Senate Standing Committees on Rural and Regional Affairs and Transport
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

Dear Committee Secretary,

Syngenta welcomes the opportunity to provide input into the Senate Standing Committee on Rural and Regional Affairs and Transport's inquiry into the ***Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012***

Syngenta is a world-leading agribusiness committed to sustainable agriculture and dedicated to our purpose: Bringing plant potential to life. In Australia, Syngenta is strongly focused on leveraging the best of our R&D and agricultural technologies from around the world to deliver Australian growers integrated solutions which allow them to realise new levels of productivity and performance on Australian farms.

As a leading member of Croplife Australia, Syngenta has contributed to Croplife's detailed submission in response to the Bill.

Syngenta fully supports the recommendations outlined in Croplife's submission. As one of the few Croplife members focused on discovering, developing and delivering new active ingredients into the Australian market, we have a unique perspective on a number of aspects of the Bill.

In seeking to reform Australia's agricultural and veterinary chemical regulatory framework, the Government has consistently outlined a goal to create *"more flexible and streamlined regulatory processes with high levels of transparency and predictability for business seeking approval for agvet chemicals to enter the market"* with a view to encouraging *"the development of newer and safer chemicals"* (Explanatory Memorandum, p.1)

There are a number of elements of the proposed Bill which will make a positive contribution towards achieving this goal. Syngenta is supportive of proposed changes in Schedule 3 of the Bill relating to the APVMA's compliance and enforcement powers and in Schedule 4 relating to improved data protection (subject to their proper implementation in line with the government's stated intent[1])

Syngenta retains concerns over the potential impact of a number of the proposed amendments in Schedule 1, on the ability of innovative companies to introduce new chemistry, in particular new active ingredients, into the Australian market.

The Explanatory Memorandum claims the Bill and associated measures will deliver increased transparency and predictability for applicants, primarily through the APVMA developing "*an overarching risk-based compendium*" that will "*improve transparency by detailing all relevant guidelines, standards and methods which would guide regulatory decisions*".

On the basis of the Government's belief that the risk-based compendium will deliver applicants with predictability as to the exact data and information the APVMA will require to assess an application, the proposed Bill substantially constrains the manner with which, and the timeframes within which, applicants can engage with the APVMA to provide additional information in support of

[1] refer to Croplife Australia's submission

their application (under a Section 159 request). The Bill and associated regulations will require the APVMA to refuse an application if an applicant is unable to provide this additional information within the short timeframe specified in the regulations (Section 14 (2)).

While the Government's goal of preparing a comprehensive risk compendium that provides clarity on the exact requirements facing an applicant wanting to register a new active ingredient and/or product in Australia is laudable, Syngenta questions whether the proposed compendium will be able to offer applicants with full predictability in the case of every application.

Syngenta has extensive international experience applying to register innovative agricultural chemicals in regulatory systems underpinned by risk compendiums and manuals including the United States and Canada. Despite the immense detail contained in the US and Canadian risk compendiums, it is not possible to predict the exact data or information requirements the US EPA or Canadian PMRA may require in assessing an application. For this reason both the US and Canadian systems provide scope for applicants to address technical questions during the assessment process.

In reality, the specific risks associated with a new active ingredient or other complex application are not always fully apparent at the time the application is lodged. The current Australian regulatory framework provide registrants with the opportunity to interact with the APVMA and its regulatory partners over the duration of a complex assessment to clarify any areas of uncertainty and to provide supplementary information/data to address specific questions identified by an assessor. In certain cases, questions from evaluators require the generation of additional data (the need for which could not have been foreseen at the time of lodgment).

The rigid processes and constraints proposed in Schedule 1 of the Bill will largely remove any opportunity for an applicant to engage with the APVMA over the duration of an assessment and to provide clarifying information/data to address evaluator's questions as they arise. Similarly, the short extension periods proposed under the "*maximum extended assessment periods*" in the draft regulations are likely to prohibit the generation of additional data to address unforeseen information requests. These provisions are likely to condemn applications with minor data deficiencies to rejection, or alternately require applicants to pay considerable additional fees in cases where the APVMA elects to vary the application under Section 28(4).

Although the explanatory memorandum suggests these measures will increase predictability and certainty, in reality the changes will increase the business risk facing an applicant considering introducing new chemistry into the Australian market; specifically the risk that, in cases where the risk compendium is not definitive as to the information required by the APVMA, an applicant may not have sufficient time to generate additional data required to address the APVMA's s.159 request and therefore have their application rejected (or face considerable additional regulatory costs).

Given the costs and reputational consequences of having an application for a brand new active ingredient rejected in a developed market such as Australia, this proposed aspect of the Bill has the potential to reduce the relative attractiveness of Australia as a market to introduce new world-leading agricultural innovations. This will ultimately be to the detriment of Australian agriculture, potentially constraining future productivity improvement and international competitiveness.

To ensure the proposed reforms do not have a perverse effect on the introduction of "*newer and safer chemicals*" into Australia, Syngenta believes that the draft legislation must be amended to provide applicants (submitting complex applications) with greater flexibility to provide additional information/data in response to requests from the APVMA or evaluators, the need for which could not have been reasonably foreseen at the time of application.

Syngenta is also concerned about the proposed preliminary assessment process outlined in Schedule 1 of the Bill (Section 11). Given the non-binding nature of the APVMA's pre-registration

advice, the rigid process proposed for preliminary assessment, the requirement that the APVMA refuse applications not meeting the application criteria (Section 11(3)), and the inability of the APVMA to alter an application during a preliminary assessment (Section 11(4)), Syngenta can foresee a situation where applicants will effectively face a guessing game as to which category their application falls, where an incorrect guess will result in a refusal.

Under the APVMA's current application category framework it is not always clear or possible to predict the correct application category. For example, a product may be considered to be similar to a registered product based on the information the applicant can obtain in public records, and so on that basis, an application may be reasonably submitted with supporting data under requirements for a category 5 application. On examination an APVMA evaluator may judge that the product is not sufficiently similar, and therefore trigger some further assessment modules that would re-categorise the application as category 10, even though no additional data is required. Similarly a category 12 application may be re-categorised by the APVMA evaluator as category 14, or a category 14 application as category 11. In Syngenta's reading of the Bill (and associated regulations), applications judged by the APVMA to fall in a different category to that specified by the applicant (on the basis of their good faith judgment), would need to be refused during preliminary assessment.

This lack of predictability for applicants at the preliminary assessment stage has the potential to delay the introduction of new agricultural innovations into the Australian market and impose additional costs on technology developers. To address this potential issue, it is important that the legislative package be amended to remove any penalty against a registrant for submitting their application in a different category to the one the APVMA ultimately decides. This should just be a simple rectification of the category and not a complete refusal of the application.

Syngenta welcomes the opportunity to provide input into the Committee's inquiry into this important piece of legislation. If you have any questions in relation to this submission please do not hesitate to make contact with either of us.

Yours Sincerely,

PETER ARKLE
Head of Corporate Affairs

KEVIN PATTERSON
Regulatory Affairs Manager