

20th January 2022

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First Assistant Secretary
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Re India's Draft Biotechnology Regulations

Dear Chris,

Grain Trade Australia (GTA) seeks to make comments to the Australian Government on proposed regulations notified on 15/11/21 to the World Trade Organisation (WTO) by the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI). The draft regulations are in regard to Genetically Modified Organisms or Genetically Engineered Organisms, or Living Modified Organisms intended for direct use as food or for processing.

1.0 About GTA

Grain Trade Australia (GTA) is the focal point for the commercial grains industry within Australia. It facilitates trade and works to provide an efficient, equitable and open trading environment by providing leadership, advocacy and commercial services to the Australian grain value chain.

GTA members are responsible for over 95% of all grain storage and freight movements made each year in Australia. Over 95% of the grain contracts executed in Australia each year refer to GTA grain standards and/or trade rules.

GTA members are drawn from all sectors of the grain value chain from production to domestic end users and exporters. GTA members are involved in grain trading activities, grain storage, grain for human consumption and stock feed milling.

GTA welcomes the opportunity to provide comments to help inform the Australian Government's response to India's draft biotechnology regulation. The Australian grain industry's profitability, competitiveness and sustainability has been based on continual innovation and adoption of new technologies. Biotechnology is one such technology that has significant potential to create productivity and market opportunity and growth. GTA is actively involved in industry discussions on this issue globally via its membership of the International Grain Trade Coalition (IGTC) and domestically via the GTA technical committee on Plant Breeding Innovation that brings together representatives from across the Australian grain value chain.

India is an important trading partner for Australia with significant growth potential. Alignment and regulatory coherence will assist to avoid unnecessarily eroding the value of the innovation and/or driving up costs and complexity in the global food system.

Thus, GTA provides the following comments in the draft regulations and encourages the Australian Government to engage with like-minded countries and Indian officials on this issue.

2.0 Comments on draft regulations

Whilst the move by India to adopt a regulatory approach to biotechnology products is positive, GTA has concerns there are a number of elements that could potentially be trade inhibiting. GTA's comments

primarily focus on the trade aspects of the regulations, however, we recognise the technology proponents may also have substantive comments on the process for approval of GM products which they may communicate directly to DAWE.

Some of the trade related issues that GTA would like raise are discussed following and include:

- *Scope includes plants developed using gene editing*

The definition of a genetically engineered organism in the draft regulations captures products that are developed using new plant breeding techniques such as gene editing. GTA has supported the position (in the Australian review of OGTR regulations) that products developed using gene editing that do not have foreign DNA should be regulated on a risk-based approach and in a similar manner to products from conventional plant breeding. GTA promotes the development of policies and regulatory approaches for gene edited plants that are trade-facilitative, and risk and evidence based. We note that globally, and in Australia, many countries have implemented regulations for gene-edited products outside their GMO regulations.

GTA recommends that the Australian Government request that plants developed using gene editing are removed from the proposed Regulation's scope.

- *India's non-GMO Order*

India introduced an Order in 2020 (effective from 1 January 2021) which requires non-GMO certifications for products listed in the Order – this included canola, wheat, safflower, soybeans and corn (although excluded processed products), and includes crops grown in Australia that do not have any GM varieties. At the time, GTA encouraged the Australian Government to oppose the Order on the basis that this was another example of India imposing measures that add unnecessary red tape and risk for exporters. It was also noted that compliance would be difficult given that it is not typical for the Australian Government to provide non-GMO certifications. GTA believes that these draft regulations provide a further opportunity to highlight that the Order is potentially contrary to WTO principles, and advocate for removal of the Order (noting that once India has clear regulations in place for the import of GM products, this Order becomes unnecessary).

GTA recommends that the Australian Government advocate for removal of the Non-GM Order.

- *Bulk commodities and processed products subject to the 1% labelling rule*

The regulations propose a 1% threshold for food labelling, including all food ingredients and processed products that do not contain DNA. In Australia, like many other countries, highly processed products are exempt from their GM labelling rules due to the products being physically identical, and challenges in administering and enforcing this requirement where products that do not contain DNA. Further, having a 1% threshold for both foods and individual ingredients is confusing. The USDA's bioengineered food labelling law provides an allowance for inadvertent or technically unavoidable bioengineered presence of up to 5% for each ingredient. This supports predictable trade in bulk commodities like grain, where technically unavoidable presence may occur.

GTA recommends that processed products with no DNA be removed from the food labelling requirement.

- *Aspects that support good regulation*

As indicated above there are a number of aspects of the regulations that technology developers and their industry bodies may wish to comment on including approval processes and safety assessments.

However, from a trade facilitative perspective, GTA believes there are a number of aspects that could be highlighted and provide an opportunity to encourage regulatory cooperation. These include:

- *Ensure that regulations are science and evidence based, and risk based.* For example, the draft regulations prohibit use of genetically engineered ingredients in baby/infant food (4(12)). There is no scientific rationale for banning the use of GM ingredients in baby/infant food products, and this may potentially influence consumers perception of safety. If a GMO is assessed as being safe by other global regulators, it's deemed to be safe for all types of foods. Consumers will ultimately choose if they wish purchase foods which contain GMO ingredients.
- *Incorporation of Low level Presence (LLP) and adventitious presence (AP) thresholds* – this could be aligned with the labelling threshold of 1%. While this is below the 5% threshold that the global grain industry supports, it would assist to remove an interpretation of zero tolerance.
- *Minimising testing of imports at destination for GMOs unless a legitimate health and safety concern is identified.*

GTA **recommends** that the Australian Government utilise the opportunity to promote regulatory coherence on trade related issues.

▪ *Form I and Form II:*

There are a number of specific requirements in the forms that are not practical for importers to complete.

Some specific issues raised by our members include (but not limited to):

- Form 1 section 4 Procedure for grant of prior approval – we **suggest the following edits** which will enable a parallel approach approval from GEAC FSSAI etc., thus saving time and enhancing aspects such as environmental safety trials.

(1) In case a Genetically Modified or Engineered Food contains any Living Modified Organisms (LMOs), ~~after taking prior approval from GEAC for Environmental safety,~~ the application may be submitted to both GEAC and Food Authority (in Form I) simultaneously for the approval ~~of the Food Authority may be submitted in Form I~~ along with the documents and fees as specified by the ~~Food~~ Authority from time to time. ~~However, the approval granted by Food authority, if any shall be subject to approval from GEAC for Environmental safety.~~

- Form I section 7 and Form II requires (3) three years data of the safe use of the GMOs derived food in the country of origin – A requirement of three years use in the country of origin will create an significant trade barrier of such a food in India as well as hamper any innovations and delay introduction of new products into the Indian market. Should this clause remain unchanged it will lead to asynchronous approvals for new GM events cultivated in the origin countries that will only be allowed to enter India after a minimum period of 3 years.

We thank you for the opportunity to provide these comments and trust they assist in developing the Governments response to FSSAI.

As noted above, we also encourage the Australian Government to work with like-minded Governments to assist to obtain a globally aligned regulatory approach. For your information, our counterpart organisation in Canada has reached out to us to work collaboratively around any advocacy in relation to India's draft regulations.

Please do not hesitate to contact GTA at any stage including if we can provide any additional information.

Yours faithfully,



Pat O'Shannassy
CEO, Grain Grade Australia