

Important Update

China's New Regulations for Manufacturer Registration and Import / Export Food Safety

On 12 April 2021, the GACC (General Administration of Customs of the People's Republic of China) issued new regulation for "Registration and Administration of Overseas Producers of Imported Food" and "Administrative Measures on Import and Export Food Safety", which will come into force from 1 January 2022. [Click here](#) for further information.

Under these new regulations, China requires that ALL manufacturers of food products be registered or exports will not be accepted into the country. This means overseas manufacturers of functional food* and food for special dietary purpose will also need to be registered with the GACC to export product to China.

**'Functional food' are foods that claim and have a specific health function or to supplement vitamins, minerals for the purpose of food. That is, suitable for consumption by a specific group of people, has the function of regulating the body, not for the purpose of treating disease, and does not produce any acute, subacute or chronic harm to the human body food.*

There will be two pathways for registration based on different food categories. Manufactures of 'functional food' and 'food for special dietary purpose' ([Description of food categories requiring registration](#)**) will be required to be endorsed by the competent government authority of the exporting country. Whereas, for all other products which are not listed on the description of food categories, businesses should be able to self-register through a GACC online system from 1 November.

***The Australian Government recommends where it is unclear whether your food is listed in [Article 7](#), it is advisable to proceed with your registration as an Article 7 food and comply with these requirements.*

In Australia, the Department of Agriculture Water and the Environment (DAWE) will first require assessment and approval for manufacturers of foods. While the requirements relate predominantly to foods, some of the product categories may be regulated as therapeutic goods (listed medicines) in Australia, including, for example: bee products; edible oils; foods for special dietary purposes (supplemental nutritional supplements, sports nutrition food); and functional foods (claiming specific health functions). As such, **the TGA (as the competent authority) will need to provide an endorsement to the GACC in relation to these goods to facilitate their continued export.**

This means CMA members who currently export to China may need to be endorsed by the TGA and/or the DAWE, depending on the category of their products, in order to be registered with the GACC.

Given the TGA/DAWE are requiring the submission of relevant information by very tight deadlines, CMA strongly advise CMA members to read the instruction below and take appropriate actions for each product category by the stipulated deadlines.

1. Therapeutic goods listed in the ARTG (via general trade)

- **Competent Authority: Therapeutic Goods Administration**
- The GACC is allowing a pre-registration process for companies who have exported to China since 1 January 2017 to the present. It appears this process will be much simpler and easier for sponsors to be registered to allow for the continuance of exports without further regulatory burden.
- The TGA will need to endorse all relevant “manufacturers” (sponsors) and their products by **26 October 2021** in order to take advantage of this pre-registration process. The GACC have indicated that pre-registration **must** occur before 31 October 2021.
- Sponsors are required to provide the following information to the TGA with the declaration form:
 - ARTG number
 - Sponsor name
 - Sponsor address
 - Product category
 - List of all relevant goods
 - HS Code
 - Latest date of trade to China
- Enquiries should be directed to complementary.medicines@health.gov.au
- Following 31 October 2021, the TGA understands that exporters will need to formally register to export their products to China. The TGA will provide further information on this process in due course.
- Please note, relevant products must have been exported since 1 January 2017 to the present. Products that have not been exported during this time must not be included in this list. As described above, further information on the registration of new products will be provided via separate correspondence from the TGA.

- The TGA will coordinate the provision of information to the GACC in consultation with the DAWE. Failure to pre-register your products with the TGA by COB Tuesday 26 October 2021 may result in export delays and disruption.

Action:

- **TGA to send an email to sponsors on 20 October 2021**
- **Sponsors to provide the required information to the TGA via email by COB 26 October 2021**

2. Any Other Food Products which are not listed in the ARTG (via general trade)

- **Competent Authority: Department of Agriculture Water and the Environment**
- DAWE issued [updated advice to Australian food businesses and exporters](#):
 - Refer [here](#) for plant products only
 - Refer [here](#) for all other products
- DAWE is seeking registration details from affected establishments by **22 October** via [an online tool](#).
 - Refer [here](#) for information required for online registration
- For all other products, businesses should be able to self-register through a GACC online system from 1 November.
- Australian food businesses and exporters are encouraged to review notices on the DAWE [website](#) and contact DAWE (exportlisting@awe.gov.au) to be kept informed of developments.
- The DAWE warns that **late submission may cause delays to registration and additional information may be required to support the registration process.**

Action:

- **Manufacturers of non-ARTG products to complete submission of relevant documentation via [DAWE's online tool](#) by 22 October 2021**

3. CBEC Products

- The TGA/DAWE currently understand these requirements do not apply to CBEC products, as Article 75 of Decree 249 (under 'Supplementary Provisions') states:

Article 75

*The safety oversight of import and export of food through mail, express delivery, **cross-border ecommerce** retail, or carried by travellers should be performed pursuant to the relevant GACC rules.*

(Reference: [Administrative Measures on Import and Export Food Safety – Decree 249](#))

- However, as these are not commercial pathways, the TGA/DAWE are not aware of what rules may or may not apply, thus, they recommend that **sponsors work with importers or agents to clarify these matters.**
- All this being said, if sponsors have exported the relevant products into China since 2017 (via e-commerce), it would be open for sponsors to include these products on their lists for TGA endorsement (noting of course that the products must be TGA approved).

Action:

- **Manufacturers of CBEC products to work with importers/agents to check if their products will be affected by these changes, or not.**

Resources:

1. The Department of Agriculture, Water and the Environment Website:
 - [2021-15: China: Update on new registration process for food processing and storage facilities handling product for export to China and product labelling requirements](#)
 - [Listing your business to export food to China](#)
2. A summary of Decree 248 and 249 from the United States Department of Agriculture, Global Agricultural Information Network reports:
 - [China: Regulations on the Registration and Administration of Overseas Producers of Imported Food - Decree 248](#)
 - [The Chinese version of Decree 248 is available to download as a pdf.](#)
 - [China: Administrative Measures on Import and Export Food Safety - Decree 249](#)
3. Austrade website:
 - [China Update: Market Opportunities and Challenges - Decrees 248 and 249](#)