



**MARKET ACCESS ADVICE**

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**Peoples Republic of China: Registration of Infant Formula Brands**

<b>Attention</b>	<b>Industries</b>	Industry bodies – Dairy Australia Export Dairy Establishments Licensed exporters
	<b>Department of Agriculture and Water Resources</b>	Central and Regional Offices ATMs and FOMs
<b>Affected Markets</b>		<b>Peoples Republic of China</b>
<b>Further Information</b>		Please contact <a href="mailto:exports@agriculture.gov.au">exports@agriculture.gov.au</a> if you have any queries.

This market access advice provides information on the new China Food and Drug Administration (CFDA) infant formula formulation registration requirements which will be enforced from **1 January 2018**.

In October 2015, CFDA implemented China’s revised Food Safety Law (FSL) which introduced a range of new food safety measures for domestically produced and imported foods in China. A key regulatory change under the FSL is the introduction of new registration requirements for infant formula manufacturers wishing to produce product for the Chinese market.

The *Administrative Measures for Registration of Infant and Young Children Milk Powder Formula Recipes* (Administrative Measures) outlines CFDA’s new registration requirements for domestic and foreign infant formula manufacturers. In accordance with these Administrative Measures, **all infant formula brands exported to China must be registered with CFDA prior to 1 January 2018**.

Please note, these new Administrative Measures are in addition to the existing Certification and Accreditation Administration of the People’s Republic of China (CNCA) infant formula establishment registration requirements.

**Registration Process**

Registration application

To register infant formula brands, manufacturing establishments must complete CFDA’s registration process, which includes submitting a formal registration application. The Department of Agriculture and Water Resources understands that the registration application must be submitted **in Mandarin** to CFDA directly in hard copy **AND** in soft copy through the CFDA website - <http://yp.zybh.gov.cn/yezwww/login/loginAction!login.dhtml> . A link to the application forms can be found at the above website.

CFDA have advised that the application process is now open. The department encourages manufacturers to submit registration applications as early as possible to allow CFDA enough time to assess and approve infant formula brands prior to 1 January 2018.

Guidance documents regarding the CFDA registration process and registration application have been provided by CFDA and are available at **Attachment 1**.

To assist applicants in answering part 5 of the application, "R&D Report", the department is developing a document that outlines the role of Food Standards Australia New Zealand (FSANZ) and provides links to information relating to the scientific research that underpins Australia's food safety standards for infant formula composition and production. This can be used to supplement information provided by each company. Please note, this document **will not** address questions relating to brand differentiation. This document will be available in both English and Mandarin on 1 February 2017.

Although the department has no formal role in the CFDA application process, we would be grateful if you could advise the departments [Dairy, Eggs and Fish Program](#) when your company has lodged their application, indicating the name of the individual brands submitted and the date the application was lodged. This process may assist in any follow-up questions or concerns expressed by CFDA.

#### On-site audits

The department understands that CFDA may request an on-site establishment audit prior to registering infant formula brands. The department is currently seeking further advice in relation to the coordination of these audits between the department, CFDA and CNCA.

The department will advise industry once further information becomes available.

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