IADSA NEWSFLASH

December 2021

Regulatory news

China

Rules for food importation and facility registration

Decree 248 requires overseas manufacturers of specific foods and ingredients that are imported to China (from all countries) to obtain registration with the General Administration of Customs China (GACC).

Under Decree 248, there are two methods to apply for registration with GACC. The registration depends on which category the food/ ingredient that the operator manufactures for export to China comes under.

Group 1 requires a recommendation from a competent authority of the home country as a condition for the registration. This Group includes 18 food categories including health foods (supplements) and foods for special dietary purposes.

Group 2 that permits self registration as of 1 November 2021 without the recommendation from a competent authority.

The Decree will take effect on 1 January 2022 with, at present, no transitional period foreseen.

However, details related to the implementation of the Decree are still lacking.

IADSA has submitted comments to the General Administration of Customs in China (GACC) to address challenges faced many members.

Korea

Warning statements

The Ministry of Food and Drug Safety (MFDS) has recently revised the warming statements for seven functional ingredients as below. The new provisions came into effect on 24 November.

Ginseng
Current : People who are taking medicines related to diabetes and anticoagulants should be cautious to take this product.
Revised
(a) People who are taking medicines related to diabetes and anticoagulants should be cautious to take this product;
(b) Allergy may be triggered for people with an allergic constitution;
(c) If any adverse reactions occur, stop eating and consult an expert immediately.

Red ginseng
Current: People who are taking medicines related to diabetes and anticoagulants should be cautious to take this product.

Revised
(a) People who are taking medicines related to diabetes and anticoagulants should be cautious to take this product;

(b) Allergy may be triggered for people with an allergic constitution;
(c) If any adverse reactions occur, stop eating and consult an expert immediately.

Chlorella
Newly added: If any adverse reactions occur, stop eating and consult an expert immediately.
The level of lead is also reduced from 3 to 1 ppm.

Milk Thistle *(Cardus marianus)* extract
Current: Stop eating if an allergic reaction occurs. Be cautious to take the product when gastrointestinal disease occurs, such as diarrhea, stomachache, abdominal distension, etc.

Revised
(a) Children, pregnant and lactating women should avoid this product;
(b) Stop eating if an allergic reaction occurs;
(c) Be cautious to take the product when gastrointestinal disease occurs, such as diarrhea, stomachache, and abdominal distension, etc.;
(d) If any adverse reactions occur, stop eating and consult an expert immediately.

Marigold Extract
Current: Excessive intake may turn the skin yellow temporarily.

Revised
(a) Children, pregnant and lactating women should avoid this product;

(b) Smokers should consult experts before taking this product;
(c) Excessive intake may turn the skin yellow temporarily;
(d) If any adverse reactions occur, stop eating and consult an expert immediately.

Indigestible Maltodextrin
Current: Drink sufficient water when taking the product (except for liquid type product)

Revised
(a) Drink sufficient water when taking the product (except for liquid type product)

(b) If any adverse reactions occur, stop eating and consult an expert immediately.
The conditions of use for claims made on indigestible Maltodextrin have also been amended.

MSM (Methyl sulfonylmethane/dimethyl sulfone)

Newly added:
(a) People with kidney disease should consult an expert before taking this product;

(b) If any adverse reactions occur, stop eating and consult an expert immediately.

EU

TiO2: one step closer

EU countries have backed the European Commission's proposal to ban the use of titanium dioxide from all food products including supplements. The draft measure will now be sent to the European Parliament and Council for scrutiny for a period of three months. Unless an objection is raised by the end of the year by either the Council or the European Parliament, the draft law will enter into force in early 2022. This will be followed by a six-month transition period after which a full ban will apply in all food products.

Green light for 3 novel ingredients

The EU has recently authorised the following novel ingredients for use in food supplements.
Dried fruits of *Synsepalum dulcificum* at a maximum level of 0.7g/day in supplements. The food supplement should be consumed by adults only, excluding pregnant and lactating women.

Vitamin D2 mushroom powder at a level up to 15 µg of vitamin D2/ day in supplements. The labelling of food supplements containing vitamin D2 mushroom powder shall bear a statement that the product "should not be consumed by infants and children under 3 years of age."

3-Fucosyllactose (3-FL) as a novel food for use in food supplements at a maximum level of 5g/day. The labelling of food supplements containing 3-Fucosyllactose (3-FL) shall bear a statement that these should not be consumed "if foods containing added 3-Fucosyllactose are consumed on the same day, and by infants and children under 3 years of age".

For each ingredient, data protection of 5 years applies.

Import to the EU: change of rules

The EU is proposing changes to requirements for the entry of some products to the EU.

These includes:
Vitamin D: The importation of vitamin D3 derived from lanolin of sheep wool has been allowed based on transitional measures. Rules are foreseen to change as following:
1) Vitamin D3 can only originate from a third country or region included in the list for those animals and goods laid down in Regulation (EU) 2021/405. 2) Imports of vitamin D3 should be accompanied by a health certificate. 3) Composite products containing vitamin D3 can only come from third countries listed in the Annex to Decision 2011/163/EU as having an approved residues monitoring plan in accordance with Directive 96/23/EC for sheep.

Shelf-stable composite products containing colostrum-based products: Such products should originate from countries authorised by the EU. These products will no longer benefit from the possibility of being accompanied by a private attestation instead of an official certificate.
Empty gelatine capsules: The obligation to list establishments for entry in the EU, applicable to gelatine, should also now apply to empty gelatine capsules.

Mutual recognition applies to vitamin limits

The European Commission has recently confirmed that mutual recognition is to be applied to a food supplement containing vitamin D lawfully marketed in Greece (at 100 µg/ day) that was refused by the Bulgarian authorities as non-compliant with the maximum levels established in Bulgarian law.

The maximum permitted daily amount of vitamin D stipulated in the Bulgarian Regulation is 10 µg.

The mutual recognition principle ensures market access for goods that are not, or are only partly subject to EU harmonised legislation. It guarantees that any good lawfully sold in one EU country can be sold in another.

Reduce exposure to 3-MCPD and GE

The European Commission is considering establishing maximum levels for glycidyl esters (GE) and 3-monochloropropane diol (3-MCPD) in foods that are today not yet covered by legislation. For food supplements containing special fatty acids (e.g. omega-3, fish oils) the newly proposed levels are:

- Glycidyl esters (GE): 400 µg/kg
- Sum of 3-MCPD and 3-MCPD esters (expressed as 3-MCPD): 750 µg/kg

3-monochloropropane diol (3-MCPD) and glycidyl esters (GE) are food processing contaminants found in some processed foods and oils, mainly palm oil. Given the potential health concerns associated with 3-MCPDE and GE, many countries are working on proposals to help reduce the exposure to both 3-MCPDE and GE.

Nutrient inadequacy in the EU

A new EFSA report has revealed a number of nutrient gaps in the European population. Key findings show inadequate status , in particular for:

Vitamin D in a large proportion of children and adults living in the EU. In elderly people calcium intake may not be sufficient to reduce the risk of osteoporotic fractures and risk of falling, especially if associated with suboptimal vitamin D status, even if the intake is sufficient in comparison with the recommended amount.

Periconceptual folate intake in women of childbearing age

Iron in population groups that are commonly considered to have a higher risk of inadequate iron status, including woman of childbearing age, pregnant women and children.

Czech Republic

Moving to online notification

From 11 November, an electronic system (SOP) for the notification of food supplements and fortified foods in the Czech Republic is required. The establishment of the electronic system aims to simplify the notification process for Food Business Operators.

Before placing a food supplement or fortified food on the market, the Food Business Operator must login to the new system and provide information, such as the composition and a copy of label.

The food notification system can be found at this link: https://eagri.cz/public/web/mze/potraviny/doplnky-stravy/

France

Vitamin D classified as endocrine disruptor

Cholecalciferol (vitamin D3), has been identified as a potential Endocrine Disruptor by the French authorities.

According to the draft law notified by France to the European Commission, any person who places on the market products which contain substances that have been determined by ANSES (French Agency for Food, Environmental and Occupational Health & Safety) as having verified, presumed or suspected endocrine disrupting properties must provide information to the public.

It is understood that all food products containing vitamin D (from infant formula to fortified foods and food supplements) are covered by the draft law. It however remains unclear whether the scope also includes foodstuffs naturally containing the listed substances.

The law is causing deep concern in the EU, noting that vitamin D is an essential nutrient and there are high levels of deficiencies across Europe. The law is scheduled to enter into force in January 2022.

Norway

Safety of Omega 3 for children

VKM, the Norwegian Scientific Committee for Food and Environment, cannot conclude on the safety of daily intake of 1100 mg DHA, 1550 mg EPA, or both 1550 mg EPA and 1100 mg DHA, for 3- to 18-year-olds.

The Norwegian Food Safety Authority (NFSA) requested VKM to assess daily intake of a food supplement containing the above ingredients.

Based on the data reviewed, a health-based guidance value or a point of departure for DHA, EPA, or DHA and EPA combined for 3-18-year-olds cannot be established or identified. VKM considered that bleeding, glucose/insulin homeostasis, inflammation, lipid homeostasis, and liver effects were the most important outcomes addressed in the randomised controlled trials on children and adolescents.

South Africa

Addressing cases of detained products

SAHPRA recently published a notice informing all stakeholders of the process that needs to be followed in cases of products being held up at customs by Port Health. A form has been set up on the SAHPRA website which importers must complete in order for SAHPRA to evaluate the products for import.

Brazil

New rules for changes on the weight of final products

The Ministry of Justice has published new rules requiring the declaration of the alteration of weight in pre-packaged products, including food supplements. The main change is the adoption of rules to declare the information referring to products of a "NEW WEIGHT". The declaration must be in the main panel and must be in capital letters, bold, with contrast with the background, and a minimum height of 2 mm, except in containers with a main panel equal to or less than 100cm2, where the height must be 1mm. The minimum period for the labels to declare the weight alteration alert increases from 3 to 6 months. The rules - Portaria MJ 392/2921 - will enter into effect on 30 March 2022 and will replace Portaria MJ 81/2002.

Further ingredients authorised in supplements

Anvisa has recently approved the use of melatonin in food supplements intended exclusively for people aged 19 or over at a maximum level of 0.21 mg/day. Food supplements containing melatonin must warn that the product must not be consumed by pregnant and lactating women, children and individuals involved in activities that require constant attention. No claims have been approved for this substance.

This authorisation came in addition to a further 41 ingredients also authorised including colostrum, beta glucan, cranberry powder, DHA obtained from the oil of the algae Aurantiochytrium sp, DHA and EPA obtained from omega 3 lysinate.

Claims substantiation

ANVISA has published a Guide for the evaluation of functional and health

claims for bioactive substances in food and food supplements. This Guide expresses ANVISA's understanding of best practices regarding procedures, routines and methods considered adequate to meet technical requirements and/or administrative procedures required by the regulatory framework. It does not introduce new rules but rather aims to provide greater clarity and transparency when interpreting how the rules established in Resolutions 16/1999, 17/1999, 18/1999 and in Resolution RDC 243/2018 and Guide No. 23/2019 are applied.

Chile

Cadmium in supplements

The Ministry of Health is consulting on a proposal to align limits of heavy metals with the latest version of Codex Alimentarius General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995) and, for other categories not addressed in Codex (including food supplements), with the provisions of the European Union, Australia and New Zealand. The current ordinance sets a limit for mercury for food supplements, but not for cadmium. The proposal now provides a limit for cadmium of 3 mg/ kg for food supplements that consist exclusively or mainly of dry seaweed. For food supplements that specifically contain EPA and DHA, it is proposed to keep a limit of 0.10 mg/ kg.

Guatemala

Updating Regulation

The General Directorate for Health Regulation, Surveillance and Control notified to the WTO a new Regulation (002-2021) related to supplements for people over 3 years old. The provisions apply only to those food supplements classified under food regulation, considering that in Guatemala food supplements can be regarded as foods or medicines depending on the composition.
It is however unclear whether this new regulation will revoke the current Regulation in place (Regulation 002-2018).

Mexico

Bill that can improve the regulatory landscape for supplements

The United Commissions on Health and Legislative Studies of the Senate approved the bill that proposes to modify the General Health Law in order to modify the definition of a food supplement and additionally leave open the possibility for the Ministry of Health to issue a list of permitted claims for food supplements. The project was approved unanimously in the Committees and will next be discussed in the Senate's plenary.

Russia

Mandatory ID tagging to be introduced in September 2022

In October, the Center of Advanced Technology Development, operator of the government-led ID tagging of consumer goods, announced that the pilot ID tagging of dietary supplements will be followed by mandatory tagging introduced as early as 2022.

The Russian Government Decree No. 673 of last April approved the procedure for a pilot project in Russia to ID tag dietary supplements and also introduced the list of dietary supplements included in the pilot. The process is being coordinated by the Ministry of Industry and Trade.
The pilot project runs from 1 May 2021 to 31 August 2022 and participation is voluntary. As of October 2021, a total of 207 participants are taking part in the project, including manufacturers, importers, distributors, retailers, and systems integrators for manufacturing/retail trade.
The Decree specifies the list of dietary supplements subject to the pilot ID tagging. The list is based on customs harmonization codes. It should be noted that only state-registered supplements are allowed to be part of the pilot.

EAEU

Moving forward

On 4 October 2021, the working group responsible for developing draft amendments to technical regulations on food safety (amendments No. 4 to CU TR 021/2011) and on safety of specialised foods (amendments No. 1 to CU TR 027/2012) concluded its review of comments submitted during the public discussion. The amendments focus on dietary supplements but also include new provisions for baby foods and dietetic foods.

The WG version of the amendments reads as follows:

•The term "dietary supplement" is now defined as "specialized food that serves as an additional source of natural or identical to natural food and biologically active substances (proteins, carbohydrates, fats, dietary fiber and their components, vitamins and their active metabolites; macro and microelements, phytonutrients and other minor biologically active substances), isolated from sources that have a tradition of food use, or obtained by other methods, as well as probiotic microorganisms, intended for consumption as part of a diet to correct and optimize nutrition, sold to consumers in dosage forms (tablets, capsules, powders, lozenges, liquid and other forms)".

• Maximum levels have been increased for vitamins C, D, B6, B12, pantothenic acid, lutein and biotin contained in specialized foods, including dietary supplements.

• L-methylfolate calcium has been added to the forms of folic acid, and forms of vitamin K have been detailed further.

The updated draft amendments are to be submitted to the EAEU Commission for review by its Consultative Committee.

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