IADSA NEWSFLASH

July 2019

Regulatory news

China

Actions to steer eCommerce rules

The China State Administration for Market Regulation (SAMR) together with seven other ministries has recently issued a notice strengthening measures on cross border e-commerce.

An inspection campaign will run from June until November of 2019 with 7 key goals:

- Standardize the qualification of e-commerce entities. Regulatory departments will investigate and punish violations of information disclosure obligations as specified in the E-commerce Law. It is also required to supervise whether e-commerce operators have complied with the requirements of market entity registration;
- Crack down on sales of counterfeit and sub-standard products including food, health food and medicines
- Crack down on unfair competitive behaviour and create a fair competitive market environment
- Improve the accuracy of advertising and create a good advertising market environment
- Crack down on other types of online transaction violations and increase efforts to rectify the operation of imports and exports of cross-border e-commerce.
- Strengthen online transaction information monitoring and product quality spot checks.
- Supervise the implementation of e-commerce operators' responsibilities.

This campaign has come six months after the implementation of the eCommerce law aiming to oversee product safety and optimise the taxation of Cross-border eCommerce (CBEC) imports.

http://gkml.samr.gov.cn/nsjg/wjs/201906/t20190620_302494.html

Rethink Hygienic Physical and Chemical requirements

The China State Administration for Market Regulation (SAMR) is consulting on a draft Standard for Hygienic Physical and Chemical Examination of Health Food. The draft Standard covers in particular test methods for 25 active ingredients, the determination of solvents' residue. it also covers the determination of stimulants and prohibited ingredients.

17 more health food ingredients to come

China is proposing to expand the list of ingredients that can be used in health foods that are subject to filing (notification). 17 are considered for inclusion: Menthol, Galactooligosaccharide (GOS), Fructo-oligose (FOS), Isomaltooligosaccharide, Edible sweet potato starch, Magnesium carbonate, Citric acid, Anhydrous citric acid, Phospholipid,Concentrated soybean phospholipids, Powdered soybean phospholipids, Fractionated soybean phospholipids, Transparent soybean phospholipids, Soybean phospholipids, Octyl and decyl giycerate, Curcumin and Fruits and vegetables powders.

http://gkml.samr.gov.cn/nsjg/tssps/201906/t20190604_302078.html

Cleaning up

The China State Administration for Market Regulation (SAMR) is consulting on the cancellation of 104 regulatory support documents used by authorities to help regulate various sectors including health food, infant formula and food for special medical purposes.

Among these is the document verified by provincial food and drug administrations on the production and sales of health food when the registration license is valid, or proof of changing manufacturer name and/or address.

The danger of misleading claims

SAMR has released its first batch of fraudulent advertisements for 2019 (30 cases violating the Advertising Law). Non- compliance relates mainly to:
Direct statement on health food efficacy in treating disease (pharmaceutical or therapeutic efficacy in pathological process);
indication of epidemiological evidence related to treatment of a disease and/or the rate of success;
use of medical terminology or terminology used for pharmaceutical or medical devices

http://samr.saic.gov.cn/xw/zj/201905/t20190508_293472.html

India

FSSAI boosts market surveillance

FSSAI has requested the Food Safety Commissioners of all Indian states to undertake market surveillance of all products covered under the Food Safety and Standards for Health Supplements, Nutraceuticals. It has come to the notice of the FSSAI that some products covered under the Nutraceutical Regulations are being marketed with certain false or exaggerated health claims. The report of these inspections will reach the FSSAI during July.

Korea

Making life easier

The Ministry of Food and Drug Safety MFDS has submitted 13 new regulations to reduce the regulatory burden on emerging industries. This includes four schemes for health functional food, namely: Recognition of raw materials sold abroad; simplification of GMP procedure; safe pharmaceutical ingredients to be permitted for use in the manufacture of health functional food; and simplification of the amendment of previously registered functional food.

Standards and specifications of health functional ingredients: Revision notice

As part of the amendment of its "Standards and Specifications for Health Functional Foods", MFDS is consulting on the following proposals:

- Inclusion of 5-MTHF-glucosamine ((6S)-5-Methyltetrahydrofolic Acid, Glucosamine Salt) as a source of folic acid.
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- Newly functional claims for ginseng and hyaluronic acid: Ginseng can help improve bone healt; and hyaluronic acid can help maintain skin health and help protect skin against ultraviolet radiation (daily intake 240 mg).
- Revision of the conditions of use for bilberry extract
- Revision of the specification of green tea extract.
- Revision of the testing method of 8 functional ingredients, namely: vitamin A, vitamin E, vitamin B1, chondroitin sulfate, batyl alcohol, anthraquinones, total flavonoid and phosphatidylserine.

https://www.mfds.go.kr/brd/m_209/view.do?seq=43115&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1

Taiwan

Taiwan FDA to curb fake claims

Only 27 claims are now permitted to be used on food labels, promotions and advertising content together with specific wordings for a number of nutrients.

The compliance of label will be identified from evaluation of product name, product description, and any promotional information available.

False, exaggerated or misleading claims will be attributed to those claims where no scientific consensus is established, when evidence is insufficient or where claims promote functionality in maintaining or changing human organs, tissue, physiology or appearance.

https://www.fda.gov.tw/tc/includes/GetFile.ashx?id=f636958587968474611

Vietnam

Alignment with Codex

Vietnam is expected to soon adopt the Codex Fish oil standards. This standard was the first Codex Alimentarius standard for fish oil. While Codex Alimentarius standards are not mandatory, many countries adopt them as their own standards.

European Union

EU unveils the back-room details on Ti02 discussion

The European Commission has published official minutes of the Standing Committee meeting held in Brussels on 13 May 2019, regarding in particular: "Exchange of views on the emergency measure regarding titanium dioxide when used as a food additive (E171). The report highlights that the Commission is still reflecting on appropriate action and will follow up after the EFSA opinion on the characterisation of the TiO2 specifications.

The EFSA opinion released mid-July clarifies that the characterisation of E171 does not provide a reason to revise the conclusion on genotoxicity of titanium dioxide previously developed by EFSA (EFSA ANS Panel, 2016, 2018). It reiterates the need for further research to decrease the level of uncertainty regarding the safety of the additive.

https://ec.europa.eu/food/sites/food/files/safety/docs/reg-com_toxic_20190513_sum.pdf

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Safety of chlorides confirmed

EFSA publishes its opinion on the re-evaluation of hydrochloric acid (E 507), potassium chloride (E 508), calcium chloride (E 509) and magnesium chloride (E 511) as food additives. On the basis of the assessment, EFSA identified a dose of 40 mg chloride/kg bw per day as a reference value and concluded that mean levels of exposure in all age groups were below or at this reference value, which indicates no safety concern. While the 95th percentile exposure estimates were slightly above this reference value EFSA considers that this does not raise a safety concern at the reported use levels.

http://www.efsa.europa.eu/en/efsajournal/pub/5751

What will be the limit?

EFSA has recently published its scientific opinion on the re-evaluation of phosphates as food additives. Currently phosphates as additives in food supplements can be used at quantum satis (i.e. as much as is technologically needed). EFSA's experts found that for those above the age of 3 years who take such supplements regularly, estimated dietary exposure may exceed the ADI at levels associated with risks for kidney function. Dr Younes, Chair of EFSA's expert Panel on Food Additives and Flavouring, said: "Based on the exposure assessment, the panel recommends the introduction of numerical maximum permitted levels of phosphates used as additives in food supplements in place of quantum satis."

https://www.efsa.europa.eu/en/press/news/190612

Green light for Yarrowia lipolytica yeast biomass

A Regulation authorising Yarrowia lipolytica yeast biomass as a novel food ingredient for use in food supplements has recently been published. The novel ingredient is allowed at the levels of 6 g/day for children from 10 years of age, adolescents and general adult population and 3 g/day for children from 3 to 9 years of age. The ingredient should be declared as: "Yarrowia lipolytica yeast heat-killed biomass".

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0760&from=EN

Citrinin: Lowering the bar

The European Commission has agreed the new maximum level for citrinin in food supplements at 100 µg/kg lowered from the current ML of 2000 µg/kg. Citrinin is a nephrotoxic mycotoxin that can be produced by some strains of *Monascus purpureus*. This decision is based on analyses from an EU Member State showing that levels in such products are generally low.

Split views on folic acid

The Belgian Superior Health Council (SHC) has recently issued an opinion on recommendations regarding folic acid supplementation for women attempting to conceive and during early pregnancy. The SHC re-confirms the daily recommended dose of 400 µg to avoid malformations of the future newborn. The current Belgian Royal Decree on nutrients amended in 2017 allows a maximum level of folic acid in food supplements at 500 µg per recommended daily dose. The SHC is of the view that "higher doses than current recommendations have not been shown to be more effective for the general prevention".

https://www.health.belgium.be/en/node/35511

Green light for 2 new novel supplement ingredients

The European Commission has recently adopted two novel food ingredients for use in food supplements that have been judged safe by EFSA.

- 2'-Fucosyllactose / difucosyllactose mixture as a novel food (NF2018/0401) at a maximum daily intake in food supplements at 4 g/day for individuals above 1 year of age

- Xia Powder: including Xia Powder 125, a partially defatted chia seed powder as a novel food (NF2018/0381) and Xia Powder 435 as a novel food (NF2018/0522) proposed for use in supplements at a maximum daily intake of 7.5 g for Xia 125, and 12 g for Xia 435

No relaxation in EU discussion on Cannabiol

Extensive discussions on CBD and other cannabidiols have recently taken place at the EU working group on Novel Foods. The EU decision to list these ingredients as Novel Food has received much criticism from affected businesses and led to activities by CBD producers to try and revert this decisions, so far without success.

Although it was understood that all Member States supported and agreed with the listing of CBD and products enriched in cannabidiols as Novel Food in the novel food catalogue, there are some differences approaches being taken by the Member States. It was therefore decided that the Commission would collect information on the exact situation from the Member States (as EFSA already did in relation to tetrathydracannabidiol (THC) containing products). Within the Commission a cross-service discussion has now been initiated, involving units responsible for novel foods, agricultural aspects and medicinal applications. These discussions are not likely to be finalised by the end of the year and it is not certain concrete decisions will follow.

To date, only one request for novel food approval of purified CBD has been submitted and this application is still at the validation stage at EFSA, while some other requests are still at Commission level. An authorisation by Bulgaria, that was recently reported in the press, appeared to be a mistake and has been withdrawn.

Corrections to two items in the Novel food Union list

The European Commission has discussed two corrections to be made in the Union list of Novel Foods.

- Echinacea purpurea extract from cell cultures where an incorrect name of the cell line used as a source is mentioned in the current list.
- beta-glucans from yeast where the specification states an incorrect unit of the heavy metal content.

Both ingredients are authorised for use in food supplements.

Italy

Tumeric contamination

A warning statement for supplement products containing turmeric is currently being considered by the Ministry of Health in Italy. This decision is linked to reported cases of hepatitis that have been associated with the consumption of various food supplements containing curcumin.

While the exact source of contamination has not yet been clearly identified, it is suspected that the incident occurred at the level of cultivation or supply of the raw material.

Supplements based on turmeric, updates on withdrawn products: http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=3738

The non governmental order on nano additives

The Italian consumer organisation Altroconsumo calls for ban on titanium dioxide and other additives in nano form. The consumer organisation is highlighting the lack of labelling of the nano form of several food additives, including Titanium Dioxide E 171, Silicon Dioxide E 551 and Silver E 174.

Poland

Maximum levels to come into play

The Polish Chief Sanitary Inspectorate has recently published maximum levels for a number of vitamins and minerals in food supplements for adults. These were recommended by an advisory body established within the framework of the Sanitary and Epidemiological Council, Council whose members are nominated by the Ministry of Health.

The levels published are as follows:

- Vitamin D: up to 2 000 IU (50 µg)/ day (for adults). Recommended labelling statements: "Before use, it is advisable to perform a 25- (0H) D blood test and consult the result of the examination with a doctor or pharmacist."
- Vitamin C: up to 1000 mg/ day (for adults). Recommended warning statement on products containing high doses of vitamin C: "Not for use by people who

have a predisposition to form kidney stones or those suffering from kidney stones."
- Vitamin A: up to 800 µg Retinol Equivalent (RE)/ day (for adults), Beta-carotene: up to 7 mg/day.
- Folic acid: up to 600 µg/ day (for adults), up to 800 µg for pregnant women. Recommended warning statement for food supplements containing 800 µg: "Pregnant women should consult their doctor before taking this food supplement."
- Niacin: Nicotinic acid amines: up to 830 mg/ day (for adults), Nicotinic acid: up to 16 mg/day (for adults).
- Manganese: up to 1,8 mg/ per day (for adults).
- Zinc: up to 15 mg/ per day (for adults).

Earlier this year, maximum levels and conditions of use were also established for Isoflavones (soy and others), aloe vera preparations and beta alanine, also available from: https://gis.gov.pl/zywnosc-i-woda/zespol-do-spraw-suplementow-diety/.

https://gis.gov.pl/aktualnosci/zespol-ds-suplementow-diety-okreslil-maksymalna-ilosc-witamin-i-skladnikow-mineralnych-w-suplementach-diety/

Switzerland

Balancing the risk for VMs supplements (Corrigendum)

Switzerland aims to lower in food supplements nutrients that they consider may have health consequences in cases of over-dosages (vitamin A, magnesium and zinc). Conversely, maximum amounts will be removed for 'non-problematic' substances such as vitamin B1. The foundations for the new approach was the publication by the German Federal Institute for Risk Assessment (BfR) "Maximum levels of vitamins and minerals in food supplements" (2018).

Netherlands

Amendment of botanical list

The Dutch authorities have notified the European Commission of an amendment to their Commodities Act Decree on herbal preparations and their Commodities Act Decree on administrative penalties regarding the addition of certain harmful (substances in) herbal preparations and applying certain technical amendments. The Annex to the Commodities Act Decree lists plants that are to be deemed toxic in all cases. Several plants are now added to this annex due to some risk assessments by the Dutch National Institute for Public Health and the Environment (RIVM) and the Office for Risk Assessment & Research of the Netherlands Food and Consumer Product Safety Authority (NVWA).

http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2019&num=331

United Kingdom

Balancing the risk

In order to provide appropriate advice on CBD products, The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) in the UK is being asked to review a scoping paper on the toxicity risks of CBD. This scoping paper will discuss the findings of a CBD literature survey and review of the available toxicological data as well as an overview of cannabis strains, methodologies of manufacturing CBD oil and summarise the current legal status.

USA

US FDA approves qualified health claims for EPA and DHA Omega-3 consumption and the risk of hypertension and coronary heart disease

The US Food and Drug Administration has approved a list of qualified health claims for omega-3 fatty acids and their effect on blood pressure. However, the FDA found that the overall evidence did not meet the 'significant scientific agreement' standard required for an authorised health claim but did meet the 'credible evidence' standard for a qualified health claim. To prevent consumer deception, the qualified health claims have to be accompanied by the disclaimer "FDA has concluded that the evidence is inconsistent and inconclusive"

https://www.fda.gov/food/cfsan-constituent-updates/fda-announces-new-qualified-health-claims-epa-and-dha-omega-3-consumption-and-risk-hypertension-and

Tracking down military habits

An amendment to the National Defense Authorization Act (NDAA) introduced to Congress calls for the creation of a reporting system for adverse events that may be associated with dietary supplements use in the military.

The amendment notably requires the "*reporting of adverse event report data regarding dietary supplement use by members of the Armed Forces to the Food and Drug Administration*".

Brazil

Brazil updates its regulation for food additives for use in food supplements

In May, the National Health Surveillance Agency (ANVISA) launched Resolution RDC Nº 281 that introduces changes to the list of the food additives and processing aids to be used in food supplements. Some highlights from the text:

- Advantame (INS 969) has been included as a sweetener permitted in liquid and chewable food supplements.

- Neutral methacrylate copolymer (INS 1206) with glazing function has been included.

- The European Union has been added as an international reference to the list which included Codex, JECFA and EFSA.

These changes are now in force.

Call to collect data on the evaluation and proof of safety of Moringa

From 19 July 2019 to 19 July 2020, ANVISA will be collecting data on the evaluation and proof of safety of *Moringa olifeira* used in foods, including food supplements. The proposal seeks to obtain consistent information to assess whether or not to

maintain the ban on the use of this botanical species in all food products. On 4 June, ANVISA issued Resolution No. 1.478 which prohibits the use of *M. olifeira* in foods, since according to the authority, there has been no safety evaluation and there is insufficient proof that it has been used in food.

In Brazil, ingredients which are not included in the Brazilian regulation need a prior assessment by the authority to guarantee their safety for human consumption.

Colombia

INVIMA establishes the maximum number of claims to be assessed per product

The National Institute of Food and Drug Surveillance (INVIMA) has launched a resolution introducing changes to its service fees for food supplement modifications.

Although there is no change to the fees for modifying the food supplement label, the document establishes that modifications regarding claims is limited to a maximum number of three nutrition and health claims per product.

These claims are assessed by the Commission of Phytotherapeutic Products and Dietary Supplements (SEPFSD) from INVIMA.

https://www.invima.gov.co/images/pdf/tramites-y-servicios/tarifas/A_RES_2019012454_05_04_2019.pdf

Mexico

Mexico updates its Regulation on Food Additives

The Federal Commission for the Protection Against Sanitary Risks (COFEPRIS) has updated the regulation for food additives for use in food products, including food supplements.

Changes have been introduced to Annex I *"Food additives with diverse functional classes and with an*

established ADI" and *to Annex VI "Enzymes"*, of the Agreement to determine the permitted additives and processing aids in foods, beverages and food supplements.

https://www.gob.mx/cms/uploads/attachment/file/473783/ANEXO_I.pdf

Eurasian Economic Union (EAEU/EEC)

EEC initiates development of standards in support of CU TR 027/2012

The draft EEC resolution on developing interstate standards that would contain the testing and conformity assessment rules and methods associated with CU TR 027/2012 on the safety of certain types of foods for special use, including dietetic therapeutic and dietetic prophylactic foods, was published on the EAEU legal portal for public discussion in April. The public discussion closed on 10 May 2019. A total of 98 standards are to be developed; for most of these, the developing party has yet to be identified. All the standards are to be prepared by 2021.

EEC introduces electronic registration certificates

The EEC Board's Resolution of 18 June 2019 introduces electronic registration certificates.
The resolution specifies the validity periods of the certificates:

- the validity period of a registration certificate applies to products manufactured since the manufacturing date of the tested samples presented for the state registration;
- products released onto the EAEU market during the validity period of the relevant certificate may continue to be marketed until the expiry date set by the manufacturer (unless otherwise stated in the applicable technical regulation).

The document specifies the procedures and locations for the collection of samples as part of the certificate issuance procedure. For products manufactured within the EAEU, samples may be selected at the manufacturer's warehouse. For imported products, samples may be selected at the manufacturer's warehouse or at the applicant's warehouse.

The resolution comes into force on 20 July 2019.

Ukraine

New law mandates use of Ukrainian language in product labelling and marketing

Ukraine has published a law on ensuring the functioning of Ukrainian as the official language, which means that Ukrainian is the only official language in the country.

Article 30 of the law introduces the following requirements for the consumer market:

- consumers in Ukraine are to be served in the official language;
- enterprises, institutions and organisations of all forms of ownership which serve customers must provide services and information about goods/services, including online stores and online catalogues, in the official language; this information may also be provided in other languages;
- information about goods and services is to be provided in the official language and may only be supplemented by translations in any other languages.

The law comes into effect on 16 July 2019; Article 30 will come into effect on 16 January 2021.