IADSA Newsflash

June 2014

Ten Years of China FDA-IADSA Cooperation

China is in the process of considering some of the most substantial changes to its regulatory system for many years. In China health foods/food supplements need to be registered to be placed on the market. This process can take a considerable amount of time and be costly.

It has been recognised in the Chinese government that changes are necessary. A proposal for the introduction of a notification system for some health foods has therefore been proposed and will shortly be reviewed by the People's Congress.

At this point the proposal establishes a framework for change and does not define the detail of how it would work. The IADSA Board recently met in Beijing and used this opportunity to discuss with the regulatory bodies further cooperation on both the concept of the introduction of a notification system and the practical detail. This included meetings with the Vice Minister in the China FDA and with senior officials across the various divisions. CFDA requests for information and advice have been confirmed and a programme of workshops and other activities is currently being discussed.

It does not need to be stated how significant China is in the global market, both as a major supplier of raw material and finished products and as a global market. Therefore, it continues to be a top priority for IADSA work.

Below photo of the Director General of the CFDA Evaluation Center for Health Food, with his deputy director-general and divisional directors meeting the IADSA Board.

2004-2014 Highlights

2004	First workshop with FDA in Beijing Visit of delegation of senior FDA officials to IADSA offices for fact finding mission.
2005	Joint Expert Workshop between FDA and IADSA, Beijing involving international experts and the EU.
2010	IADSA Scientific Conference on botanical supplements, Beijing International joint FDA-IADSA Conference, Beijing, bringing together senior regulators from the world's major markets. FDA-IADSA Expert Roundtable, Beijing
2011	FDA Training, Switzerland: Three week training for 20 senior officials from central and regional FDA in three centres in Switzerland.
2012	Expert workshop on notification systems, Beijing. Agreement on Cooperation with the FDA Institute for Executive Training: Translation of IADSA GMP for the FDA for distribution in China.
2013	Facilitation of FDA visit for fact finding to the EU. Expert workshop on notification systems for health foods, Beijing
2014	IADSA Board meeting and high level meetings with China FDA, Beijing, June 2014.

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Regulatory news

ASEAN

ACCSQ TMHS PWG meeting to be held 23-27 June

The next meeting for the Scientific Committee, Framework Task Force and GMP Task force, will be held from 23- 27 June 2014, back to back with the 22nd ACCSQ TMHS PWG meeting, in Siem Reap, Cambodia. The Scientific Committee is expected to conclude their discussion on limits of microbial contamination and safety data requirement.

China

State Council adopts draft of the revised Food Safety Law

The State Council Standing Committee meeting held 14 May in-principle approved the Draft Food Safety Law. The revised Law will focus on more comprehensive food safety management through the entire food chain, higher penalties on violations to regulations, better mechanisms for food safety risk monitoring and evaluation, and will give incentives and power to consumers, industry associations, and media to establish food safety awareness from the entire society. The draft revision will be reviewed in first reading by the Standing Committee of the National People's Congress on 23-27 June.

China to regulate Internet selling of food and drugs

China Food & Drug Administration (CFDA) on 28 May published Draft Regulation on Internet Selling of Food and Drugs for public consultation until 27 June. The draft regulation is based on the Regulation on Internet Selling of Drugs and expanded to food, health food, cosmetics, and medical devices. It is therefore the first regulation that regulates online selling practice for food and health food. It requires that "the online published information for food and health food products shall not contain claims on disease prevention and treatment" and "products not registered or not notified shall not claim health benefits".

Tawain

FDA refreshes Nutrition Claim and Labelling regulations

Taiwan FDA is revising a series of regulations on nutrition claim (Reg. No. 1031300988) and labelling of foods including foods in tablet and capsule forms (Reg. No. 1031301120), both under public consultation.

The first will allow nutrient content claims while the Labelling Regulation will introduce tolerance levels and reference values for toddlers and pregnant and breastfeeding women.

Japan

New DRI Standard to become effective on 1 April 2015

In Japan, Dietary Reference Intakes (DRI) are revised every five years giving consideration to factors such as nutritional status, changes of dietary habits and the progress of science. In the new edition that will become effective on 1 April 2015, recommended intakes for the prevention of insufficiency are set for macro nutrients, n-6 unsaturated fatty acids, n-3 unsaturated fatty acids, carbohydrates, dietary fibers, micro nutrients (Vitamins A, D, E, K, B1, B2, B6, B12, C, Niacin, Folic acid, Pantothenic acid, Biotin, Potassium, Calcium, Magnesium, Phosphorus, Iron, Zinc, Copper, Manganese, Iodine, Selenium, Chromium and Molybdenum). The new standard also establishes ULs for the prevention of excessive intakes of fats, saturated fatty acids, cholesterol, sugars (mono- and di-saccharide (excluding sugar alcohol) and Sodium.

New Zealand

Parliament has passed the New Food Act 2014

The Food Act 2014 has passed its third and final reading in the Parliament during late May, four years after it was introduced. The new Act provides a risk-based food safety approach to ensure that the food including food supplements produced is safe and suitable for sale. The law will come fully into force on 1 March 2016 and will replace the Food Act 1981. In the next 21 months, further public consultations will be conducted and detailed implementing regulations and guidance will be developed. According to the new Act, food businesses with a higher food safety risk will operate under more stringent food safety requirements and checks than those with lower risks.

Europe

EFSA publishes more health claims opinions

Scientific Opinions on the substantiation of health claims published by EFSA on 5 May 2014, gave rise to two positive opinions with a 'cause effect relationship established'. These are for:
Article 14 'children' claim: zinc and normal function of the immune system
Article 13.5 claim: cocoa flavanols and maintenance of endothelium-dependent vasolidation

Several other health claims applications received unfavourable opinions since they were deemed 'general and non-specific' or had 'insufficient evidence'.

Europe authorises sweetener Advantame

The European Commission has recently published a Regulation authorising the use of advantame a non-caloric high-intensity sweetener in various foods. Since 5 June, the new additive which has been assigned the E number E 969 can be used in supplements under the following conditions: a) Supplements supplied in a solid form including capsules and tablets and similar forms 20 mg/kg ; b) Food supplements supplied in a liquid form 6 mg/l ; c) Food supplements supplied in a syrup-type or chewable form 55 mg/l or kg. The regulation can be found here:

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.143.01.0006.01.ENG

PVA-PEG graft co-polymer added to the EU list of additives

The European Commission has authorised the glazing agent polyvinyl alcohol- polyethylene glycol-graft-co-polymer (PVA-PEG graft co-polymer), giving it the 'E-number' 1209. The new additive is intended for use in aqueous instant-release film coatings for food supplements at a maximum level of 100 000 mg/kg. 'It protects against unpleasant tastes or odours, improves appearance, makes tablets easier to swallow, gives a distinctive appearance, and protects sensitive active ingredient' says the Regulation.

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_182_R_0008&from=EN

Italy adopts the BELFRIT list

Italy has published a new plant Decree revising its Decree of 9 July 2012 on "Regulation of the use of substances in food supplements and herbal preparations". The new decree adopts the BELFRIT list, a joint effort with Belgium and France to harmonise the use of 1,041 botanicals in supplements.

ANSES publishes its recommendations on supplements containing p-synephrine

On 5 May 2014, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) published its recommendations on the use of P-synephrine, a substance present in bitter orange peel and used as an ingredient in numerous "weight-loss" food supplements:

Food supplements containing a dose above 20 mg should not be made available to the consumer;

Synephrine and caffeine or any substance possessing cardiovascular effects similar to those of caffeine should not be combined into a single food supplement;

Individuals with heightened risks of adverse effects (people under treatment for high blood pressure, heart disease or depression in particular), pregnant or breastfeeding women, children and adolescents should be discouraged to consume p-synephrin ;

The use of p-synephrine should also be avoided during physical exercise.

Since the creation of its nutrivigilance system in 2009,ANSES has received 18 reports of adverse reactions likely to be linked to consumption of food supplements containing p-synephrine.

New labelling requirements for Honey with GMOs

Following the European Court of Justice (ECJ) decision regarding the affair Bablock vs Freistaat Bayern in which the honey produced on a Bavarian farm was reportedly found to contain genetically modified (GM) pollen from a nearby experimental plot growing EU-authorised crops, the Honey Directive has now been amended.

The directive explains that pollen is a natural constituent, and not an ingredient, of honey but recalls that any presence of traces of pollen derived from GMOs triggers the application of Regulation 1829/2003 on genetically modified food and feed. Therefore, honey or food supplements containing honey from GM source cannot be marketed without prior authorisation. The revised Directive also defines new labeling requirements for the cases where honey originates in more than one Member States and third county. 'Blend of EU honeys', 'Blend of non-EU honeys' and 'Blend of EU and non EU honeys 'should replace the indication of the countries of origin.

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0024&from=EN

EFSA publishes discussion paper on health claims guidance for public consultation

EFSA has published for public consultation a discussion paper on the revision of the guidance on the scientific requirements for health claims related to gut and immune function. This is not the guidance as such, but a paper setting out a plan for the revision, an outline of the scope and issues to be covered in the revised guidance document. The stepwise approach and the structure of the consultation shows a promising opening of the Panel towards better guidance, also embracing new scientific findings. The timetable for finalising the guidance indicates that the guidance document itself will also be subject to a public consultation in December this year with possible finalisation by June 2015.

Status of Glucosamine discussed in Court

The UK Courts were asked to reflect on the status of glucosamine following a litigation filed by a pharmaceutical company seeking to stop the recognition of glucosamine as a food supplement ingredient/ product. The company in question holds a prescription-only medicines registration throughout Europe for a glucosamine sulphate product. The Court finally decided to support the position of MHRA, the UK Medicines and Healthcare products Regulatory Agency, defending the supplement's dual status. This is a very significant development both in Europe and potentially worldwide with a number of countries currently restricting the use of glucosamine to pharmaceuticals.

Ecuador

New draft Regulation on Food Labeling

On May 2nd, Ecuador notified the WTO of a new Technical Regulation on “Labeling of processed and packed food” (INEN 022). Since there is no specific regulation on food supplements, these products are usually registered as food and they have to comply with the new provisions.

According to the proposal, all processed food for human consumption with transgenic ingredients must include on its label the phrase “CONTAINS GMOs”. Additionally, a horizontal bar must be added to the label regarding the concentrations of fats and sugars in the product. Taking into consideration the parameters mentioned in the proposal, the color of the bar will be Red (high), Yellow (medium) or Green (low).
Once approved, the Technical Regulation will apply to all food products imported into Ecuador. The period for compliance was set at November 29th, 2014.

Argentina

Update on new draft for food supplements regulation

The National Food Commission (CONAL) has defined a proposal for updating the regulation applicable to food supplements in Argentina which is currently being examined by CONAL’s Board of Advice (CONASE). The proposal includes a series of amendments to the regulation currently in force as, for example, related to the minimum values of vitamins and minerals required, maximum levels and the plants permitted in food supplements. After been approved by CONAL, the proposal will be in public consultation for 30 days.

Costa Rica

Ministry of Health bans irregular products

During the month of May, the Ministry of Health of Costa Rica conducted a series of operations to detect and remove targeted market products not complying with the national Technical Regulation on food supplements. This included the search for counterfeit and adulterated products, as well as those that do not have the corresponding authorization.
In this context several products marketed as dietary supplements were recalled from the market for apparent differences in the registration process with the Ministry of Health, causing the closure of some stores for not complying with current regulations.

Brazil

ANVISA approves public consultation on allergens labeling

On 29th May, the Directorate of ANVISA approved the document on food allergens labelling that will be presented at public consultation. The proposal includes a list of major food allergens and presents standards for the labelling of processed food containing these substances, such as font size, position and background color. Additionally, the proposal encourages industries to nominally mention the use of cereals with gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, sulfites or derived substances in food. Once published in Brazil´s Official Journal, the proposed draft will remain available for comments and suggestions for 60 days. The text also provides for a term of 12 month for companies to adapt their products to the new rules.

Morocco

Decree on labeling requirements delayed

In order to give more time to companies to adapt and change their labels, the National Office for Food Safety (ONSSA) has delayed the publication of the Draft Decree No. 2-12-389 establishing labelling requirements for food products to November 2015. This text which is based on the EU labelling regulation (FIC) introduces provisions on minimum font size, on allergen declaration, mandatory Arabic language and indication of country of origin labelling for primary ingredients.

South Africa

Phase 2 of the "Regulations relating to the Labelling and advertising of foods" (R429) Amendment published

The South Africa Department of Health has launched a consultation on Phase 2 of the "Regulations relating to the Labelling and advertising of foods" Amendment (R429). The regulation includes mandatory nutrition information declaration, a nutrient profiling model, and provisions for functional claims and health claims (positive lists). Front of Pack labelling is permitted in a voluntary manner. Companies will be given 36 months to comply after the promulgation of this regulation.
http://www.health.gov.za/docs/regulation/2013/DraftAmendment.pdf

United States

FDA extends comment period on Proposed Rules on the Nutrition and Supplement Facts Labels

The Food and Drug Administration (FDA) has announced the extension of the comment period by 60 days, to August 1, 2014, for the following two proposed rules:

- Food Labeling: Revision of the Nutrition and Supplement Facts Labels
- Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments.

'We believed that the 60- day extension should allow adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues 'says FDA.

These 2 proposed rules released last March foresee significant changes to nutrition Labelling requirements.

The FDA has therefore announced a public meeting on 26 June to discuss the proposed changes, to respond to questions about the proposed rules, and to hear oral comments.

Nutrient Content Claims for Omega-3s restricted

The Food and Drug Administration ("FDA") has issued a final rule prohibiting certain claims about omega-3 fatty acids on the labels of foods and dietary supplements. FDA says that certain nutrient content claims about omega-3 fatty acids at such nutrient content claims do not meet the requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).Nutrient content claims are labeling claims that characterize the level of a nutrient in a food or food supplants. The FDCA allows nutrient content claims, only when the claims are based on an authoritative statement that identifies a nutrient level to which the claims refer.The rule will impact affects a wide range of products

bearing omega-3 fatty acid claims.

FDA announces new head of supplement programs

FDA has announced that William Correll will serve as acting director of the agency's Division of Dietary Supplement Programs following the departure of Daniel Fabricant, Ph.D. for the Natural Products Association. Mr. Correll has been involved with FDA's food programs for 23 years. He has held several director positions within FDA's Center for Food Safety and Applied Nutrition, including serving as both acting director and deputy director of the Labeling and Dietary Supplements Compliance Team.

Russia

Roundtable on counterfeit drugs and dietary supplements held in the State Duma

15 May a roundtable on counterfeit drugs and dietary supplements was held in the State Duma.
Representatives of two Duma Committees, Russian Public Health Inspectorate, Russian Consumer Inspectorate, public organisations and business entities took part in the roundtable.Among other initiatives discussed at the roundtable was the vesting the Russian consumer rights watchdog (Rospotrebnadzor) with additional powers to conduct post-registration monitoring of dietary supplements for the purpose of detecting prohibited components, potent agents and pharmaceutical substances. Alternatively the Roszdravnadzor (Russian Public Health Inspectorate) should be vested with the powers, and provided with the technical capability, to validate the composition of dietary supplements in the process of their circulation in the market.The initiative is a consequence of random checks of marketed dietary supplements held in 2013-2014, which revealed, among other violations, the presence of synthetic pharmaceutical substances not listed in the composition of supplements and not disclosed during the registration.
Rospotrebnadzor head supported the initiative saying that the agency possessed the requisite technical capability.
Head of the State Duma Committee for Safety and Anti-corruption Measures suggested including the development of the proposed control and monitoring measures into the framework of a project law On introducing amendments to certain regulations on countermeasures against circulation of counterfeit drugs and dietary supplements. The law is intended to toughen the penalty for production and marketing of counterfeit medicines and supplements which ruin the reputation of diligent manufactures to say nothing about posing serious threat to the life and health of the population. The law project is also driven to bring the Russian legislation into conformity with the EU Medicrime convention.
Another great concern of parliamentarians in this fast-growing market is fraudulent health claims not proved clinically. The consumer is in no way protected from the promises of allegedly sound health.

"It is unacceptable to use the same name for a medicine and for a dietary supplement" said director of Department for medicine provision and medical products regulation of Ministry for Public Health

The need for the reinforcement of law on dietary supplements circulation has once again become a focal issue for market regulatory authorities and deputies of the State Duma of the Russian Federation initiating the parliamentary hearing on the issue. Elena Maksimkina, director of Department for medicine provision and medical products regulation of Russian Ministry for Public Health, believes that health care complexity by far exceeds the problem of medical aid provision or medicines supply.
"Hectic lifestyles make it difficult for a modern man to consume with food enough vitamins and microelements to feel healthy and fit. Dietary supplements are good facilitators," the expert says.
The course taken for regulation of dietary supplements circulation lies in the right direction, she highlights.
For instance, regulation of advertising of dietary supplements has already brought about some positive changes, meaning that customers are exposed to a well-balanced advertising.
"Our fundamental stance was to spare the Ministry for Public Health of procedures for registration and regulation of dietary supplements. It was done to make customers capable of telling medicines from dietary supplements," she notes.
As to the use of single name for both synthetic chemical agents serving as medicines and for particular dietary supplements that, being registered as bodies with lesser dose and thus qualified as the so called "light" substances, this is an ultimate deception of consumers, which is

unacceptable and should be corrected, she holds. Currently, a bill introducing amendments to the Law on Medicine Circulation is under preparation. A provision dealing with trade names of medicines has to be elaborated. The Ministry for Public Health proposed to forbid providing dietary supplements with names registered for medicines.

Focus on CIS Harmonisation

Common code for three countries

The regional harmonisation in the Commonwealth of Independent States (CIS) has gathered pace as the customs union of Belarus, Kazakstan and the Russian Federation (the CU), launched in 2009, was taken a step closer to become a single market. On 29 May, presidents of the three countries signed an interstate treaty that marked the launch of the Eurasian economic union. The union is designed to facilitate a free flow of goods, services and labour between the member states and lay foundations of the single financial market and single currency

The treaty also declared the formation of the single market of pharmaceuticals and medical devices. Until now, the pre-market approval and circulation of medicinal products remained independent of the Eurasian commission under national regulations of the member states. With the new commitment to merge the three national pharma markets by 2016, some analysts point out at risks that could also affect the supplement industry. In particular, Russia's recentproposal to extend Kazakhstan's national legislation that divides supplements into parapharmaceuticals (supplements with para-therapeutic effect) and neutraceuticals (those designed to compensate alimentary deficiencies) to the whole CU, may be made part of the upcoming regulation of the single pharmaceutical market. One of the potential threats may take shape in mandatory licensing of the manufacturing and marketing of the parapharmaceuticals.

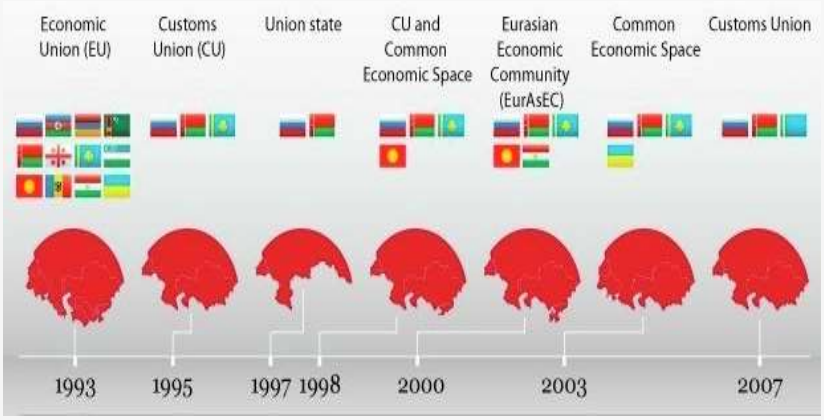
In view of those risks, companies in the IADSA working group continue consolidating their effort in drafting a CU technical regulation for supplements. The group has established a close partnership with Kazakhstan Academy of Nutrition which is expected to channel the industry proposal to the Eurasian Commission in the near future. At the recent meeting in DSM offices in Basel, Gerhard Gans, a IADSA board member, and the president of the Academy, Taregeldi Sharmanov, agreed that the academy needs to partner with responsible Kazakhstan authorities in submitting a formal proposal to the Eurasian Commission.

Meanwhile, a group of experts from Belarus, Kazakhstan and Russia held a WG-sponsored meeting in Moscow and agreed on the table of contents of the drafted regulation and key provisions that needed to be included in the text. It has been anticipated that the first draft of the regulation will be released for discussion in August this year.

The Russian Council of Dietary Supplement Producers has been registered as a self-regulatory body. The council which now unites 30 members has been granted a self-regulatory status that allows participation in drafting federal legislation and representing members in state offices.

Attempts at economic integration within the CIS

Source: RIA Novosti



Chronology of key ECU Developments

6 October 2007
Treaty setting up the Eurasian Customs Union (ECU) between Russia, Belarus and Kazakhstan signed

1 January 2010
Common customs tariff launched

1July 2010 (6 July for Belarus)
CU Commission starts work. Common customs territory becomes effective

1 July 2011
Internal physical border controls eliminated

1 July 2012
Eurasian Economic Commission becomes effective