Brexit: The journey begins!

In general, political change has only a limited impact on what we do in the supplement industry globally. Yes, changes of government or a Minister can make a difference but in general the margins for change are relatively small in most countries. However, there is probably no major political change that we have been asked more about by the members than the UK decision of June to leave the European Union.

What is clear is that the EU was little understood in the UK Parliament and hardly understood at all in the general population. The past few weeks since the Referendum have been a bigger education about the EU for most people than the previous 30 years. And the education is just starting.

What the UK has taken on now is simply staggering in its enormity. After a decade of government ministries being reduced in size, they now need to take on the biggest task they have faced since 1945. New trade agreements need to worked out worldwide, hugely complex and challenging negotiations with the 27 EU Member States need to be started on issues ranging from access to the EU's Single Market to R&D programmes to exchange programmes for students. Somewhere in UK government there must by now be a list and it must be extremely long and every day it is certainly getting longer.

It is very difficult to predict what will be the result of this process. For a start, many of the key promises made by the Leave Campaign during the Referendum are, to put it politely, unachievable. How will it play out when this becomes clear? Second, there simply are not enough UK officials or officials with the right skills to do the work that is required. This means that many hundreds of millions will be spent on bringing in external legal and trade experts at a time when the clients of these external law and trade companies are needing them to advice them. Third, the UK media has seen a surge in circulation during the Referendum. The anti-EU papers in particular will be longing to engage in some big-time Brussels bashing over the next few years to keep their sales up. The British tabloid media has never played out well on continental Europe and it promises to be the same again. And of course, while all this is happening, the UK could be losing Scotland.

What this means for the supplement sector is far from clear. However, what we can say is that for many years UK government influence in the EU has been, in broad terms, a positive influence. With a generally pro-business approach, the UK input has helped move a number of important initiatives towards a positive conclusion.

With the UK leaving the EU, the UK influence will not disappear entirely but it will be dramatically reduced. If the UK goes in the same direction as Norway in its relations with the EU, it will keep an observer role in meetings of the Member States but no decision-making role. The UK will also of course lose its Members of the powerful European Parliament. On the other hand, the UK has the largest percentage involvement of scientists in the European Food Safety Agency of any EU Member State. EFSA will not be keen to lose these scientists, at least in the short to medium term. So, a solution will inevitably be found for that.

These are huge and challenging changes for the UK, for UK business and for Europe as a whole.

IADSA

International Alliance of Dietary/
Food Supplement Associations

International Alliance of Dietary/Food Supplement Associations
Gridiron Building
One Pancras Square
London N1C 4AG
United Kingdom

Regulatory news

ASEAN

25th Meeting of the Traditional Medicines and Health Supplements Product Working Group

The TMHS PWG held its 25th Meeting from 31 May to 3 June 2016 in Singapore. The key objective of for the meeting was to finalise and endorse the ASEAN traditional medicines and health supplements agreements and their annexes. However, Indonesia had raised concerna on the legally binding agreement, and had therefore requested further changes to the title and the content of the agreement. As the Member States will need to conduct another national consultation on the proposed change, the timeline for signing of the agreement is now delayed to August 2017.

The TMHS PWG also discussed the technical capacity building activities for ASEAN Member States, which include good manufacturing practice (GMP), claims requirements, safety data requirements, and stability studies. The TMHS PWG will continue discussion on the project proposals for each task and also the source of funding in the next meeting.

Korea

Registration of Foreign Facilities Producing Food sold in South Korea

All foreign food and food packaging manufacturing facilities, including Health Functional Food companies that manufacture products intended for South Korea must register with the Ministry of Food and Drug Safety (MFDS) by 3 August 2016. The registration system is intended to provide the necessary information on foreign manufacturers marketing within Korea. The registration can be done online via the MFDS website. The information required includes company name, contact information and address, manufacturing facility name and person in charge and manufacturing facility address. Besides the basic information, documents such as HACCAP, ISO and GMP certificates should also be uploaded into the system.

The manufacturers that register with MFDS will be subjected to on-site inspection by the MFDS. Refusal of the on-site inspection may result in suspension of the importation of products into South Korea.

China

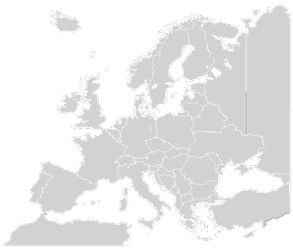
China approves 6 new probiotic strains

China National Health and Family Planning Commission (NFPC) announced the approval of the following probiotic ingredients for the use in general food: *Staphylococcus vitulinus,Staphylococcus xylosus Staphylococcus carnosus, Bacillus coagulans*. Beside the above probiotics ingredients approved for use in general food, Lactobacillus fermentum and Bifidobacterium breve were also added to the list of permitted probiotic ingredients for food targeted at infants.

A new chapter opens for health supplements

Since 1 July 16 companies have now the choice between the notification or registration procedure to place their products on the market.

While it is true that there is still room for improvement, this development is an important positive step for the supplement sector, which is the result of more than 10 years of our cooperation programmes with CFDA.



European Union

EC roadmap relating to a possible change of the Mutual Recognition Regulation

The European Commission has published its plans for a possible revision of the Mutual Recognition Regulation 764/2008. The aim is to achieve more and better mutual recognition for the single market for goods. The mutual recognition procedure permits the free movement of goods within the European Union except where a potential serious risk to public health has been identified by the authorities where the products will be marketed. This procedure is widely used for the placing on the market of food supplements in the European Union.

Nutrition and Health Claims Regulation applies B2B communications

The EU Court of Justice answered this July the burning question on whether the requirements under the Nutrition and Health Claims Regulation apply to nutrition and health claims made in commercial communications to final consumers, where such communications are addressed not to those consumers but exclusively to healthcare professionals.
While the principle to preclude non commercial communication from the scope of the regulation was not put into question, the Court decided to follow the conclusions of the Advocate General made early this year and acknowledged that commercial communications does not exclude commercial communications addressed exclusively to healthcare professionals. This verdict is likely to have a considerable impact on the way in which companies will be able to communicate on the health benefits to healthcare professionals, in particular when such claims relate to a product that is intended to be delivered to the final consumer. The context in which the information is dispatched will play a key role in the assessment that will now need to be made of each B2B commercial communication.

EFSA to revise its guidance on submissions for evaluation of nutrient sources

EFSA is considering revising its guidance on submissions for evaluation of nutrient sources or other nutrients proposed for use in the manufacture of food, including food supplements. The main scope of the new publication will be to provide guidance with respect to the data requirements for the assessment of the bioavailability of the nutrient from the source. The finalisation of this guidance document is foreseen by 30 June 2017.

Re-evaluation programme for food additives whose safety assessment was hindered by limited data availability

Food additives permitted before 20 January 2009 must go through a new risk assessment by the European Food Safety Authority (EFSA). For additives

whose safety re-evaluation is hindered by limited data availability, a specific call for data will be launched through a dedicated web site to permit EFSA to complete its assessment.

Companies will be requested to communicate to the Commission within 6 weeks whether they are interested that the additive remains permitted and whether they are interested in providing the new data. A decision to remove or not the additions from the Union list of permitted additives, will be taken based on the outcome of EFSA's final opinion.
More information at the following link: http://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation/index_en.htm

European Parliament vetoes claims on caffeine

The European Parliament has voted to veto the authorisation of four caffeine-related health claims in a resolution adopted at the Strasbourg plenary session on 7 July, saying it was unacceptable to put them on energy drinks. "From statistics we know that many young people and even children are drinking a lot of these energy drinks", said lead MEP Christel Schaldemose (S&D, DK). "It's not just the caffeine, it's also that energy drinks contain a lot of sugar too. And we don't think that these sorts of drinks should have any kind of health claims put on them", she added.
The caffeine claims, which had been on the on-hold could still continue to be used but it is more likely foreseen that the Commission will be press to propose banning these claims.

The term "probiotic" might be allowed as a "voluntary statement"

The European Commission is considering whether to allow the term "probiotic" to be used as a "voluntary statement" under the Food Information to Consumer Regulation.
Probiotics claims are currently not permitted in the EU because a 2007-guidance from the European Commission concluded that "probiotic" in itself was a health claim. No favourable opinions on health claims for probiotics has been delivered so far.

Czech Republic

Czech republic notifies new draft decree on food supplements

The Czech Republic has notified the European Commission and Member States of its draft decree on food supplements, which contains specific conditions of use for 16 plants and for 7 substances (e.g. 10 mg Monacolin K from fermented red yeast rice) and a list with 108 forbidden plants and 8 other substances (including melatonin,N-acetylcysteine and lactulose).

The Draft decree is currently under the review of the European Member States who have until mid September to submit their comments on the possible impact of the proposed provisions on the EU internal market.

Italy

Italy updates its food supplement guidelines

The Italian Ministry of Health has recently updated its guidelines regarding the ingredients allowed in food supplements. The main changes includes an increase of maximum levels from 48 to 54 mg for Niacin and 12.5 to 15 mg for Zinc (adults). A limit of 7.5 mg is also set for children from 3 years of age , and 5 mg for the under 3's.The daily maximum level for inositol is raised from 2 g to 4 g. A daily limit 600 mg has also now been established for N-acetyl-cysteine.

EFSA publishes first version of its botanicals compendium database

EFSA has published its first version of the botanicals compendium in a searchable database. This version of the compendium does not yet include all new (mainly non-European) botanicals that are currently being assessed. The complete database will be released early next year.

The content of the current database should be the same as the content of the paper version of the compendium already available. It is of course more user friendly as it allows searches on the basis of the plant, but also of substances of concern.

The Netherlands

Melatonin not necessarily classified as a medicine

Supplements containing a dose of 0.3 mg or higher should not necessarily be regarded as medicinal products: This is the conclusion of the Hague Court of Justice which was asked to clarify early June the status of melatonin supplements classified as medicines by the IZG (Health inspection).

The Court highlighted that such products must not unconditionally be qualified as medicinal product by function. The assessment should take into account all characteristics of the product, in particular its composition, its pharmacological, immunological and metabolic properties.

The approaches towards the regulatory status of melatonin are today divergent across Europe. Levels permitted in Food Supplements have recently been reduced to 1 mg /day in a number of Member States including France or Italy.

United Kingdom

MHRA to re-examine glucosamine status

Since the release of the UK Royal Courts of Justice verdict 2 years ago, the UK Court of Appeal has now Issued its conclusions: The UK Medicines and Healthcare products Regulatory Agency (MHRA) should reconsider the dual status of supplements containing glucosamine. Regardless of the classification of glucosamine supplements, the MHRA should have investigated whether consumers were perceiving or using them as medicines said the Court, which was ruling on an appeal by a Chinese manufacturer of prescription-only glucosamine products. In 2014, the High Court dismissed the company's attempt to have glucosamine products at dosages over 1 500mg classified as medicines.

While the UK Court of Appeal confirmed the earlier ruling that glucosamine above 1500 mg could not *de facto* be classified as food supplements, MHRA has now been urged to revisit the issue. Just as melatonin in the Netherlands, It is not clear yet what will be the future legal status of the products.

Norway

Risk Assessment of other substances: Norway releases its second batch

Norway has now published its second batch of scientific opinions related to the safety assessment of other substances. This batch includes: CLA, L-tryptophan, inulin, L-phenylalanine and DL-phenylalanine, L-arginine and Arginine alpha ketoglutarate. The risk assessments have been performed on specific levels found on the market.

South Africa

MCC consults on Health Supplements Safety and Efficacy

The Medicines Control council has recently published for consultation its guidelines setting out the quality, safety and efficacy requirements to register a health supplement in South Africa. This guideline is published in anticipation of the publication of Regulations contemplating the inclusion of Health Supplements as a sub-category of Complementary Medicines. The new approach proposed by MCC has raised major concerns among the sector.

Argentina

Public consultation for food allergens labeling

On 8 June the National Commission of Foods opened for public consultation the modification of the Argentinean Food Code to introduce the mandatory declaration of food allergens. The proposal includes the list of allergenic substances from Codex and proposes the following statement for the declaration of food allergens next to the list of ingredients: “Contains…”. Comments can be sent until 8 July 2016.

Brazil

Food allergens labelling comes into force

On 3 July 2016 the new regulation for the declaration of food allergens came into force. Due to the lack of consensus at Mercosur level where the issue is being discussed since 2011, and due to the pressure from consumers, Brazil approved its own regulation in 2015. ANVISA gave a 1-year period to adapt labels, despite the request of the food industry to extend the period. Products manufactured prior to this date will be allowed to be marketed.

GMO labelling for any GMO content again in force

On 19 May following a ruling from the Supreme Court of Brazil, the legal provision from 2012 which made GMO labelling mandatory only for products containing more than 1% of GMO had been changed. Any food product containing any amount of GMO would now need to be labelled with the yellow triangle with a “T” inside.

Electronic registration for imported food products

From 2 May 2016 the electronic system for requesting the authorisation for importing products of sanitary surveillance (which includes foods and food supplements) has started to operate. This process used to be done as a paper submission (not electronically). This electronic process, called Electronic Request for Imports (in Portuguese "Peticionamento Eletrônico para Importação” or its acronym PEI), shall be made through the VICOMEX system. ANVISA has highlighted that this new system will work 24 hours a day everyday, including weekends, to improve the dynamic of the process.

Bolivia

Modification on the GMO labelling symbol

The red triangle with the acronym “OGM” (in Spanish) has been switched to a yellow triangle. The new GMO labelling rules came into force on 1 June 2016.

Chile

Public consultation food additives

The Ministry of Health opened for public consultation the modification of the regulation on food additives, which applies to food supplements. Several food additives are proposed to be added to the positive list and some others to be removed. Maximum limits for sweeteners are proposed (actually only the ADI is foreseen) and maximum limits for a number of food additives were modified, including for many colorants.

Ecuador

Regulation for food supplements opened for public consultation

The sanitary authorities from ARCSA opened for public consultation the draft regulation for food supplements and nutraceutical products. The definition of food supplements foresees the use of vitamins, minerals, proteins, carbohydrates, amino acids, plants (concentrated or extracts), and other nutrients and derivatives where all should demonstrate a nutritional or physiological effect. It is proposed that such products follow a notification system at ARCSA, instead of a registration process. The public consultation closed on 17 June 2016.

Chile

Public consultation on Mercury in food

On 25 June the Ministry of Health from Chile opened for public consultation the modification of Article 160 of the Sanitary Regulation of Foods in relation to the maximum limit accepted for mercury in foods.
The proposal includes a specification for food supplements and foods for athletes containing DHA and EPA, being the maximum limit permitted for mercury 0.10 mg/kg. This is very new since the current regulation does not specify anything for food supplements in particular.

USA

Massachusetts Bill Prohibiting Weight loss and muscle building Dietary Supplements to minors Stopped

Massachusetts House Bill 3471, which would have prohibited the sale of dietary supplements for weight loss and muscle building to minors, has failed to pass in the Massachusetts Legislature.
The bill, introduced in 2015, would have also required weight loss and muscle building supplements to only be accessed by “managers, assistant managers, acting managers and supervisory personnel or in the case of

a pharmacy, an employee of the pharmacy located behind the pharmacy counter".

FDA Issues Final Rule Amending Food Facility Registration Regulations

The U.S. Food and Drug Administration (FDA) has finalized a rule as part of the implementation of the Food Safety Modernization Act (FSMA) to improve the accuracy of the food facility registration database. Food facilities that manufacture /process, pack or hold food for consumption in the United States are required to register with the FDA, and this final rule adds new provisions to the current regulations to codify certain provisions of FSMA that were self-implementing and effective upon enactment of FSMA. Those provisions include the requirement of an email address for registration, required renewal of registration every two years, and that all food facility registrations must contain an assurance that the FDA will be permitted to inspect the facility at the times and in the manner permitted by the Federal Food, Drug and Cosmetic Act.

In addition, the final rule adds certain new requirements that will improve the food facility registration system. All food facility registrations are required to be submitted to the FDA electronically, although this requirement does not take effect until January 4, 2020.

FDA Announces New Nutrition Facts Label

The U.S. Food and Drug Administration (FDA) announced in May a new Nutrition Facts Label for most packaged foods that reflects the latest in nutrition science and includes additional nutrient information.
The new label features a new design, reflects updated information about nutrition science and updates serving sizes and labeling requirements for certain package sizes.
Most food manufacturers will be required to use the new label by July 26, 2018. Manufacturers with less than $10 million in annual food sales will have an additional year to comply with the new rules.

Congress Clears Federal Mandatory GMO Labeling Bill

President Obama is expected to sign legislation in July to require food packages to display text, a symbol or electronic code that indicates if the food includes genetically modified ingredients. The law, which is intended to inform consumers and not to be considered as a food safety measure. It will apply to both conventional foods and to dietary supplements.

Russia

FAS proposes strict measures as applied to dietary supplement market

Russia's Federal Antimonopoly Service (FAS) has drafted a government resolution on adopting a roadmap entitled "Stimulating competition in the health care sector". One of the roadmap sections contains proposals related to improving the Russian legislation as applied to the circulation of dietary supplements.
The document proposes drafting a federal law that would ban medicines or products containing medicines from being registered as dietary supplements; the draft law would also ban registering dietary supplements as medicines, as well as banning registration of dietary supplements whose names are identical or confusingly similar to those of medicines. The law is expected to help in preventing illegal marketing of dietary supplements and in avoiding consumer confusion as to the composition and properties of dietary supplements. The law Is to be adopted in December 2017. Beyond that, the document calls for cancelling the state registration certificates for all those previously registered dietary supplements whose names are identical or confusingly similar to the names of medicines, and withdrawing such products from the market. This is just another attempt at banning the use of umbrella brands for both dietary supplements and medicines.

In accordance with the roadmap, this process is to be completed by December 2020. The agencies responsible for implementing the measures will be the consumer rights watchdog Rospotrebnadzor, the Health Ministry, and the FAS.

Uzbekistan

Uzbekistan moves to regulate production, importation of dietary supplements

At the end of April the national Government adopted a resolution introducing requirements for the manufacture and importation of dietary supplements in Uzbekistan. The document describes the procedures covering the issuance of dietary supplement importation and manufacture permits; in particular, dietary supplement will only be cleared for importation after passing a toxicological and hygienic assessment procedure. Until now, dietary supplements have not been regulated by a separate piece of legislation.
The resolution states that permits for the manufacture of dietary supplements are to be issued to legal entities and individuals for a period of five years.

Kazakhstan

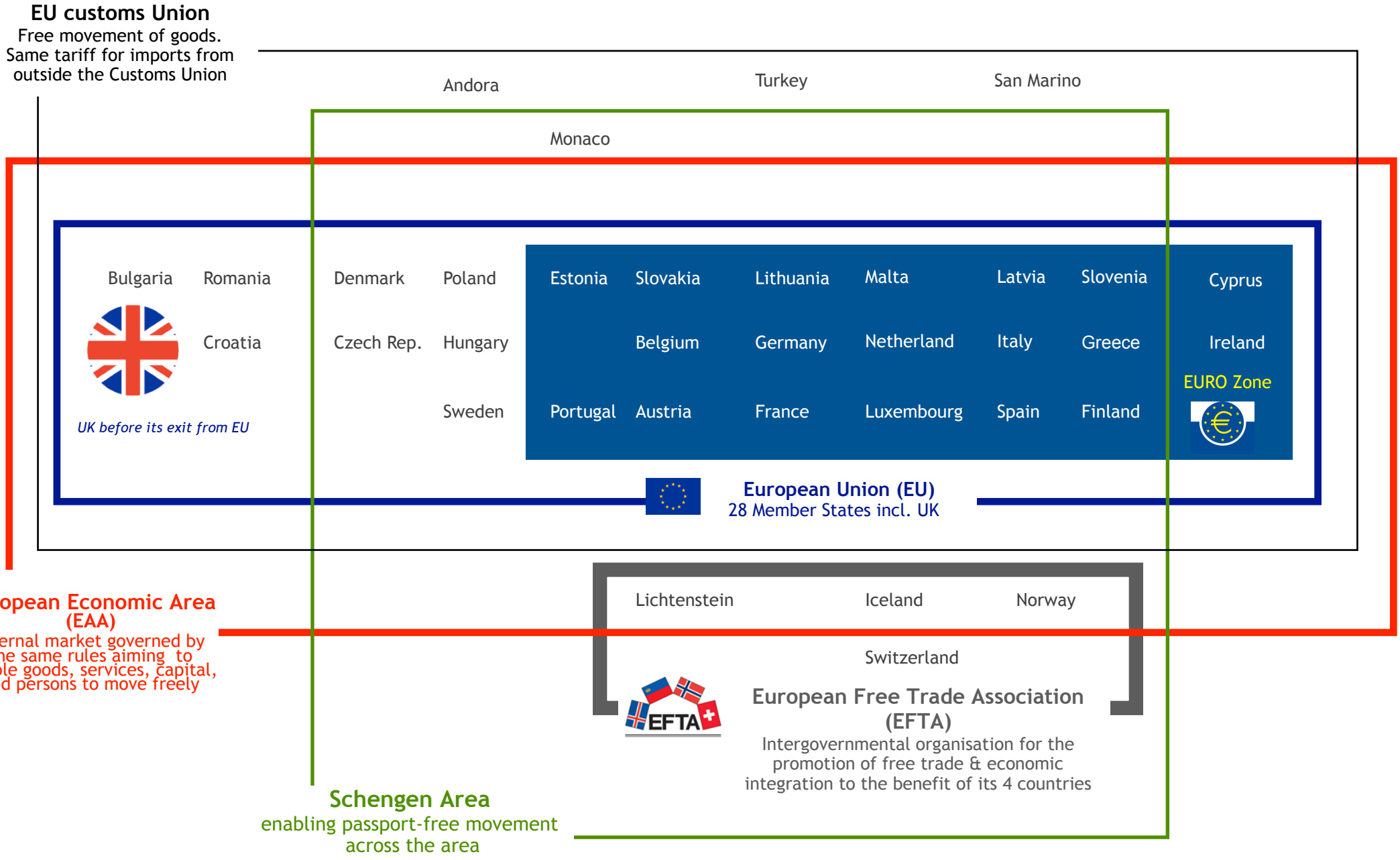
New requirements for circulation, advertising of dietary supplements drafted in Kazakhstan

The National Economics Ministry has proposed for public discussion three draft documents directly related to the circulation of dietary supplements in the country.

Rules governing the circulation of dietary supplements; which introduce requirements for the development, production and circulation of dietary supplements. In particular, the document reads that dietary supplements may be retailed through pharmacies, specialised stores and the retail network. They may not be sold via the Internet, by way of multi-level marketing, and through convenience stores.

Rules governing the advertising of dietary supplements, the provisions of which partially coincide with the requirements contained in the Russian law on advertising. The draft rules ban dietary supplement advertisements from public transport and organisations not related to the use and sales of such products.
Rules governing the organisation of evidence-based safety assessments as applied to dietary supplements, introducing the mandatory requirement that the documents to be submitted for the purpose of state registration of a dietary supplement include a scientific report and an expert report.
Observance of all the three documents will be mandatory for legal entities and individual traders involved in the circulation of dietary supplements (production, storing, sales, etc). The rules cover all dietary supplements introduced into and sold in Kazakhstan. The rules are to be adopted by the national economic minister's decree.

Focus: UK in the European Union



Focus: European Union, from 6 to 28 to 27!

1952
Belgique, France, Germany, Italy, Luxembourg, The Netherlands

6

1973
Denmark, Ireland, UK

9

1981
Greece

10

1986
Portugal, Spain

12

1990
Former East Germany (Germany unified)

1995
Austria, Finland, Sweden

15

2004
Central &Eastern countries, Cyprus, Malta

25

2007
Bulgaria, Romania

27

2013
Croatia

28

20XX
UK exit

27

Candidate countries
Still negotiating - or waiting to start

- Albania
- The former Yugoslav Republic of Macedonia
- Montenegro
- Serbia
- Turkey

Who can join the EU?

Membership Criteria

.

The Treaty on the European Union states that any European country may apply for membership if it respects the democratic values of the EU and is committed to promoting them. Countries wishing to join need:

- Stable institutions guaranteeing democracy, the rule of law, human rights and respect for and protection of minorities;
- A functioning market economy and the capacity to cope with competition and market forces in the EU;
- The ability to take on and implement effectively the obligations of membership, including adherence to the aims of political, economic and monetary union.

Brexit: Abbreviation of "British exit" that refers to the 23 June 2016 referendum to exit the European Union.

Article 50 of Lisbon Treaty

Any Member State may decide to withdraw from the EU in accordance with its own constitutional requirements

1 The Member State who decides to leave notifies the EU of intention invoking Article 50.
Remark: As of today (mid July 2016) the UK has not yet triggered Article 50

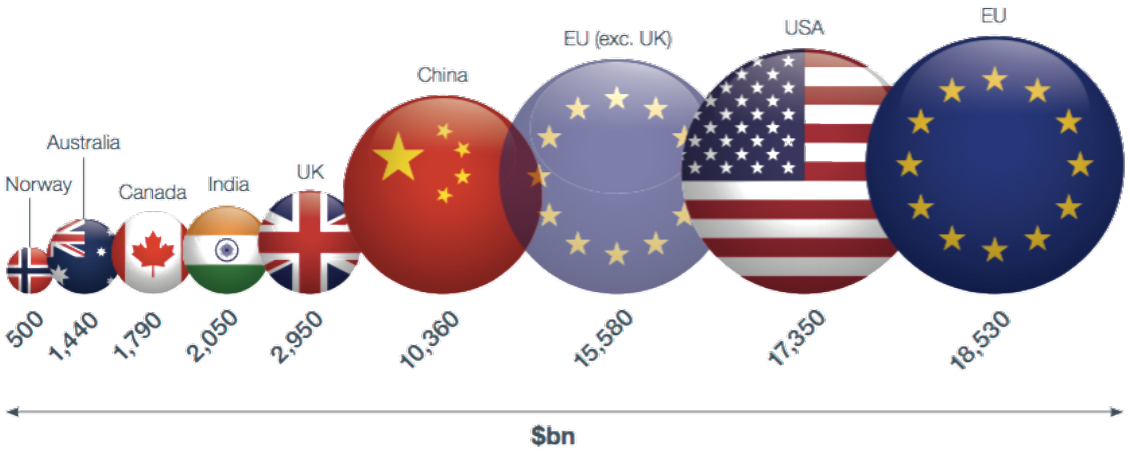
2 The Heads of States of EU Member States decide among themselves what agreement they want to offer. The Member State wishing to leave is not involved in the discussion.

3 Negotiation of the details of the agreement between the Member and the EU begin.

4 Approval of the agreement by the Heads of States of EU Member States and ratification by European Parliament. There is a two-year deadline to reach the withdrawal agreement. This deadline can be extended.

Size of economy (GDP, $bn)

With and without the UK in the European Union



Key political pressure points during the UK exit negotiation period

UK EU Referendum
June 2016

Dutch General Election
March 2017

French Presidential Election
April – May 2017

UK meant to hold rotating EU presidency!
July – December 2017

German Federal Election
August – October 2017

Italian General Election
Spring 2018

Swedish General Election
September 2018

Two-year deadline from Art. 50 being invoked
Extension possible
2018

Romania due to join the Euro
1 January 2019

European Parliament elections
Spring 2019

New European Commission enters office
1 November 2019