

IADSA Newsflash

October 2016

Supporting Great Ideas

As you look across the world at the range and variety of regulatory change, it becomes perfectly clear that to be effective in shaping regulation, an engaged national association that understands the local issues and dynamics is key to success.

However, it is often forgotten how challenging it can be for many who run associations. While the larger ones have paid staff to carry out the work and a team of experts to call on for specific tasks, many are run by one or two people who fit in the association work during or after their day-jobs in companies and who have very small budgets to work with. Amazing results have been achieved by many small associations over the years but it is clear that there is so much potential to achieve more.

The power of a global network such as IADSA lies in linking people together, sharing ideas, experience and resource. But there is also another significant element that it can bring. And that is to help associations to do great things that would be unachievable without support.

It is with this goal that the IADSA Project Grant is being launched. The Grant has been established to provide support to member associations to achieve ideas that help further build the credibility of the sector and could potentially be replicated as best

practice in other parts of the world. To be awarded the Grant, associations must demonstrate that their project has the engagement of their members, and it is replicable, ambitious and achievable.

The project proposals will be reviewed by IADSA's Executive Council and the award will be announced at the 2017 Annual Meeting in Seoul.

The launch of this Grant is a small but important step forward. Supporting member associations in their work with governments and other decision makers and continuing to support the development of new associations to engage in their markets is vital work for all of us.

IADSA

International Alliance of Dietary/
Food Supplement Associations

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Supplement Associations

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IADSA at ICN2017

The 21st IUNS-ICN Congress of Nutrition has accepted a proposal by IADSA to hold a session on the role of supplements in nutrition and health at the Congress that will take place in Buenos Aires on 15th - 20th October 2017.

The International Congress of Nutrition (ICN), organized every four years by the International Union of Nutritional Sciences, brings together several thousand people from across the world's nutrition science community. It is a well-recognized forum for the international scientific community, which aims to address the key aspects of nutrition in a multicultural environment, from state-of-the-art reviews to cutting edge nutritional science.

The IADSA session will be chaired by Johanna Dwyer, PhD, Tufts University who will invite, among others, Jeff Blumberg (Tufts University), Ligia Martini of Sao Paulo University and Andrew Shao (IADSA Chair of the IADSA Scientific Council) to examine how the field of nutrition has evolved and discuss the potential role of dietary/food supplements in health promotion. The session will also review how the category is regulated in key markets around the world and discuss the scientific, regulatory and industry challenges that hamper our understanding of the role of supplements.

Regulatory news



Thailand

Thailand consults on its draft list of botanicals

The Thai FDA has issued a new draft notification "Botanicals, animals or parts of botanicals or animals prohibited when used in food" for consultation. The new regulation is expected to come into force from 2017 onwards and is based on the "ASEAN Guiding Principles for Inclusion into or Exclusion from the Negative List of Substances for Health Supplements". It will apply to all food products, including Food Supplements.

Japan

New provision for naphthalate

Japan MHLW published a new regulation Notification No.245 on the use of polyethylene naphthalate (PEN) in food contact materials and articles. Food contact materials and articles made from PEN must comply with the requirements stated in the regulation, in relation to cadmium content, lead content, migration of heavy metals expressed as lead, and consumption of potassium permanganate. The new regulation will take effect from 8 December 2016.

India

FSSAI's risk assessment cell

FSSAI has established a National Risk Assessment Cell at its headquarters to ascertain risk areas of concern. Pawan Agarwal, CEO, FSSAI, has stated that this would eventually develop into a National Food Safety Risk Assessment Centre. The work of this cell is expected to have an influence on the future implementation of the new food supplement regulations, which are expected to be agreed by year-end.



Australia

Australian TGA announces new labelling

New labelling changes will be implemented over 4 years from 31 August 2016, split into two new labelling Orders:
TGO 91 - Standard for labels of prescription and related medicines (link is external) (TGO91)
TGO 92 - Standard for labels of non-prescription medicines (link is external) (TGO92)
This split was applied to better consider the different risk levels for prescription and non-prescription medicines and also to improve overall readability. Food supplements will be required to comply with the requirements stated in TGO 92.

New Zealand

MOH Update: Extension to Deadline for Permitted Substances List

Considering that the implementation of the Natural Health Products Bill is not expected before November 2016, the Ministry of Health has announced that requests of ingredients for inclusion on the Permitted substances list and the draft list of conditions can be submitted until 31 October 2016.



European Union

Commission addresses health claims on food supplements for under 3s

The European Commission consults on the use of health claims made on foods and referring to children's development and health. The consultation primarily focusses on whether health claims should be banned or permitted on follow-on formula, processed cereal-based food and baby food. Some concerns were previously raised by Member States regarding the use of the claims,

highlighting that those claims could discourage breastfeeding or mislead consumers where made on some products and not all knowing that all these products have very similar compositions set by law. The consultation also focus on health claims on food supplements for infants and children, asking whether claims on these products should be banned, and, if so, to provide a justification in line with the health claims law.

Thumbs up for trans-resveratrol in capsule and tablet

European Commission has recently published a Decision authorising the placing on the market of a novel ingredient - trans-resveratrol - to be used in food supplements in capsule or tablet form. The substance is intended for the adult population only with a maximum dose of 150 mg per day. from EFSA published earlier this year.

EFSA requested to assess green tea catechins safety

Following concerns raised by Sweden, Denmark and Norway, The European Commission has recently requested EFSA to provide a scientific opinion on the safety of green tea catechins under the Article 8 of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods. A negotiated deadline of 4 October 2017 is proposed.

Commission initiates Article 8 procedure for hydroxyanthracene derivatives

The European Commission has recently initiated the Article 8 procedure for the intake of hydroxyanthracene derivatives in order to address the safety concerns raised during the discussions on the authorisation of a health claim on the improvement of bowel function for which a positive opinion was delivered by EFSA. (EFSA Journal 2013;11(10):3412 [12 pp.]). The Commission has now requested the Authority to proceed with the risk assessment of the substance. The EFSA opinion is expected by June next year.

EFSA consults on Adequate Intakes for Potassium

The European Food Safety Authority's experts have recommended adequate intakes (AI) for potassium: 3500 mg/day are proposed for men and women, young adults (15-17 y.o) and pregnant women. An additional 500 mg per day - to reach an AI of 4000 mg - is suggested for lactating women to

compensate the losses of potassium through breast milk.

EFSA publishes advice on choline

EFSA has set dietary reference values for choline as part of its review of scientific advice on nutrient intakes. The Panel on Dietetic Products, Nutrition and Allergies (NDA) defines daily adequate intakes (AIs) for choline as follows: 400 mg for adults and adolescents aged 15-17 years, 140 to 340 mg for children aged 1-14 years., 160 mg for infants aged 7-11 months., 480 mg for pregnant women and 520 mg for lactating women. The findings of the NDA Panel are based on consumption data from national surveys conducted on healthy people in the European Union.

Titanium dioxide (E 171) does not pose health concerns for consumers

EFSA has completed its re-evaluation of all food colours permitted for use in the European Union before 2009. For the final re-evaluation, EFSA's experts concluded that available data on titanium dioxide (E 171) in food do not indicate health concerns for consumers. But they recommended new studies be carried out to fill data gaps on possible effects on the reproductive system, which could enable them to set an Acceptable Daily Intake (ADI).

Possible revision of the Mutual Recognition Regulation (EC) No 764/2008

The Commission is currently exploring the way in which the Mutual Recognition Regulation 764/2008 is working in practice under its REFIT programme (making EU law lighter, simpler and less costly). A consultation has recently been launched. With this consultation the Commission seeks views on the mutual recognition principle and its possible shortcomings, the functioning of the Mutual Recognition Regulation, and potential options to be explored for its revision. Mutual recognition aims at guaranteeing the free movement of goods where legislation has not been harmonised at EU level. Essentially, it states that where a product is lawfully marketed in one Member State, it should be allowed to be sold in other Member States.

Belgium

Communication to Healthcare Professionals: Belgium revises its position

Following the publication this summer of the conclusions of the EU Court of Justice on B2B communication and communication to Healthcare Professionals, (Case C-19/15), the Belgian Authorities have recently informed the Industry of their new position by acknowledging the opinion of the Court that communications of a commercial nature relating to products intended to be sold to the final consumer, although exclusively addressed to Healthcare Professionals, should fall within the scope of application of the Claims Regulation. The 2013 interpretative letter clarifies that communications made by Healthcare Professionals to Consumers would not fall within the scope of the legislation has now been withdrawn from the Authority's website.

The Netherlands

The Netherlands Journal of Medicine warns on red yeast rice

The Dutch Journal of Medicine (NTvG) has recently released an article warning about the safety of red yeast rice supplements. In this publication, the authors urge the Netherlands Food and Consumer Product Safety Authority to test the red yeast rice supplements available on the Dutch market. The authors also call for a registration of monacolin K products as herbal medicines to better control the quality and the safety of these products. They also specifically warn about the potential drug interactions and serious risks associated with the use of the substance during pregnancy.



Israel

Israel increases its vitamin D limits for supplements

Israel has recently updated its food supplement Regulation by increasing the ULs for Vitamin D from 400 to 1,000 IU and the RDA from 200 to 600IU.



Pacific Alliance

ASEAN/ Pacific Alliance cooperation

The Pacific Alliance and the Association of Southeast Asian Nations (ASEAN) adopted on 26 September in New York a document that sets out a broad framework for cooperation between the two bodies with emphasis on the economic, educational, science and technology and sustainable development. The framework was adopted at the Ministerial Meeting between ASEAN and the Pacific Alliance, a body which met for the third consecutive year in New York on the occasion of the United Nations General Meeting .

Brazil

Food Labels shall inform the presence of lactose

Brazil approved Law N°13.305 that obliges the food industry to indicate on food labels the presence of lactose. According to the approved text, the Law establishes that those products where the original content of lactose was reduced shall also inform the residual content. ANVISA is working on the regulation of this act.

Development of a regulation for food supplements continues

ANVISA has clarified that that they still intend to continue with the development of a specific regulation for the category of food supplements and aim for this to be finalized in 2017. ANVISA has clarified that this new regulation aims to bring more clarity to the categorization of food supplements.

Dominican Republic

Online Free Sales Certificate

The General Directorate of Medicines, Foods and Sanitary Products (DIGEMAPS), from the Ministry of Health, has presented a new application that allows companies to obtain Free Sales Certificate online. It aims to make it easier for users and to

accelerate the process. The time to expedite the Free Sales Certificate would be 7 days.

Ecuador

Draft Sanitary Technical Regulation related to sanitary certificates and control of food supplements

The Sanitary Technical Regulation which has been notified to WTO establish the requirements governing sanitary certificates for food supplements.

It also establishes the requirements for the production, processing, formulation, labelling, quality, safety, advertising, control and monitoring of food supplements in establishments that manufacture, store, distribute, import or market such products.

This Sanitary Technical Regulation is binding on natural and legal persons, whether Ecuadorean or foreign, who are responsible for manufacturing, importing, exporting, storing, distributing or marketing food supplements throughout Ecuador.

Puerto Rico

Puerto Rico Administrative Order on Dietary Supplements Delayed

The Puerto Rico Secretary of Health, Ana Rius Armendáriz, M.D., has recently announced that the Department of Health will not enforce Administrative Order (AO) 346 at this time, advising she will now go through proper channels of notice, including a hearing, followed by a comment and rule making period later this year. The Department of Health order would have imposed a regulatory scheme for distributors of dietary supplements in Puerto Rico and ultimately limited consumer access to products.

Venezuela

Gluten Free Declaration

The Ministry of Health opened for public consultation the proposal to regulate and control gluten free products. The proposal stresses, among other measures, that for food products to be labelled as "gluten free" they shall not contain more than 20ppm of gluten, and that all food products, including food supplements, shall carry the declaration "contains gluten", "can contain gluten" or "gluten free". SACS would register all food companies manufacturing or importing gluten free products. The public consultation closed on 31 July.



Canada

Health Canada to change standards for natural health products

Health Canada is planning to review the regulation of natural health products to address concerns over what they refer to as the multiplication of misleading and unproven claims on product labels. Under the proposed new system Health Canada would bring natural health products, over-the-counter drugs and cosmetics under one set of rules and regulate them based on the potential health risks they pose.

The new system would also classify many vitamins, minerals and homeopathic products, as well as cosmetics as "low risk." These products would no longer be licensed by Health Canada.

United States

Obama signs bill requiring labelling of GMO foods

As reported in our last edition, the federal GMO labeling legislation passed in the House and Senate and was signed into law by President Obama on 29 July. The new legislation, setting provisions for the labelling of genetically modified ingredients for the first time, will require most food packages to carry a text label, a symbol or an electronic code readable by smartphone that indicates whether the food contains genetically modified ingredients, or GMOs.

FDA's questions legal status of vinpocetine

The Food and Drug Administration (FDA or we) is requesting comments related to the regulatory status of vinpocetine. Specifically, FDA requests comments on its tentative conclusion that vinpocetine is not a dietary ingredient and is excluded from the definition of dietary supplement in the Federal Food, Drug, and Cosmetic Act (FD&C Act). According to FDA's Federal Register notice, "vinpocetine is a synthetic compound, derived from vincamine, an

alkaloid found in the Vinca minor plant, or tabersonine, an alkaloid found in Voacanga seeds." FDA maintains that it is not found in botanicals, but is a synthetic derivative of vincamine or tabersonine.

Vinpocetine is not approved as a drug in the U.S., but is currently sold as a dietary supplement marketed for the improvement of memory and cerebral metabolism.

New Dietary Ingredient Draft Guidance

FDA issued in August its revised draft guidance for industry on dietary ingredient notifications and related issues. The revised draft guidance supersedes FDA's July 2011 draft guidance on the same topic. The draft guidance, subject to a 60-day comment period, is meant to help manufacturers and distributors of dietary ingredients and dietary supplements decide whether to submit a premarket safety notification to FDA for a product that is or contains an NDI.

Under the Dietary Supplement Health and Education Act (DSHEA), the manufacturer or distributor must notify the FDA at least 75 days before beginning to market a dietary supplement that contains a new dietary ingredient (one that was not marketed in the United States before Oct. 15, 1994), unless the NDI is used in the food supply without chemical alteration.

FDA estimates that more than 55,600 dietary supplements are on the market, and that 5,560 new dietary supplement products come on the market each year - in contrast to the approximately 4,000 products that were on the market in 1994 - but the agency says it has received fewer than 1,000 NDI notifications since the Dietary Supplement Health and Education Act (DSHEA) was passed in 1994.

FDA releases final rule on GRAS substances

The Food and Drug Administration (FDA) has issued a final rule that amends and clarifies the criteria in the regulations for when the use of a substance in food for humans or animals is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) because the substance is generally recognized as safe (GRAS) under the conditions of its intended use.

The clarified criteria for GRAS status should help stakeholders draw more informed conclusions about whether the intended conditions of use of a substance in food for humans or animals complies with the FD&C Act said the US FDA.



Russia

Rospotrebnadzor and Institute of Nutrition propose withdrawing approach related to dietary supplement from national legislation

The Russian consumer rights watchdog Rospotrebnadzor and the Institute of Nutrition have drafted the Federal Law 'On amending certain legislative acts of the Russian Federation as applied to food safety'. The law 'On quality and safety of food products' is to be amended. The bill is aimed at bringing the Russian legislation in line with Customs Union technical regulations and with the Treaty on the Eurasian Economic Union (EAEU).

The amendments proposed by the bill are primarily aimed at specifying certain definitions and clarifying certain aspects of the food compliance assessment/validation and state registration procedures, which are being brought in line with similar EAEU-wide requirements. The bill proposes replacing the current notion of (biologically active) food supplement with three new approaches - dietary supplement (nutraceutical), dietary supplement (phytonutraceutical) and parapharmaceutical. The bill at the same time proposes excluding nutraceuticals and phytonutraceuticals from the food product category. The bill is currently being considered by the executive branch.

Rosdravnadzor may be entrusted with oversight of dietary supplement quality

Oversight of the quality of dietary supplements may be moved from the Russian consumer rights watchdog Rospotrebnadzor to the Federal Service for Surveillance in Health Care (Rosdravnadzor). The idea has been recently proposed by the Social Policy and Health Care Committee of the

Young Legislators House under the Federation Council (higher house of the Russian parliament). The main argument is that Rospotrebnadzor is incapable of controlling the quality of dietary supplements, as it has neither professional laboratories that could detect different medicinal substances nor methods for determining the composition of medicines, including dietary substances. The authors of the idea believe that though Rospotrebnadzor might still retain part of its oversight powers, it is of utmost importance that oversight over the composition and quality of dietary supplements is handed over to Rosdravnadzor.

Ministry of Economic Development turns down proposal to liberalise printed ads for dietary supplements

The proposals turned down by the ministry include lifting the current restrictions on advertising of dietary supplements. The ministry only supported the proposal to increase advertising space in printed media up to 45% of the total volume of each issue, arguing that any amendments to the law on advertising introduced in the interest of entrepreneurs should not encroach on the interests of society.

The amendments to the law on advertising were drafted by the Federal Antimonopoly Service, and were submitted to the government in early August.

Kazakhstan

Kazakhstan's new rules for dietary supplements pose circulation risks for products registered in other EAEU states

On 12 August 2016, two directives related to dietary supplements issued by the National Economics Ministry came into force in Kazakhstan: Rules governing the marketing of dietary supplements (the marketing rules); and Rules governing research-backed safety validation for dietary supplements (the validation rules).

The newly introduced rules are mandatory for legal entities and individual entrepreneurs involved in any activities related to the circulation of dietary supplements (production, storage, sale, etc.) in Kazakhstan. They also apply to all dietary supplements imported to Kazakhstan.

The circulation rules contain requirements applied to the marketing and sale of dietary supplements, their

packaging and labelling, storage and transportation. In particular, the document states that dietary supplements may be retailed only via pharmacies, specialised outlets, and retail store chains. The validation rules make it mandatory for applicants to submit a scientific report and an expert report for state registration purposes. The scientific report is to substantiate the product's declared effectiveness. The marketing rules also contain a new definition of dietary supplements, which reads that these products may be used for diet enrichment or for preventing diseases whereas according to the EAEU regulations, dietary supplements are products intended exclusively for diet enrichment.

Ukraine

Amendments to requirements for dietary supplement advertisements adopted in Ukraine

Following two years of consideration, a bill on amending the law on advertising, initiated by the Ukrainian Health Ministry in 2014, has been recently approved by the State Registration Service. The bill is aimed at preventing sales of dietary supplements as medicines via call centres. The bill proposes two new paragraphs for inclusion:

"Advertisements of dietary supplements must not contain contact telephone numbers".

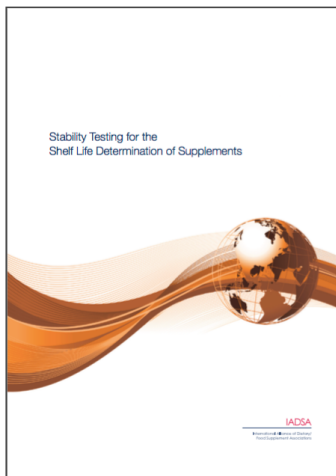
"It is prohibited to mention contact telephone numbers in printed publications, information and analytical broadcasts and programmes on medical topics, for the exception of advertisements for licensed health establishments."

The bill is yet to be approved by the government and submitted to the parliament of Ukraine.

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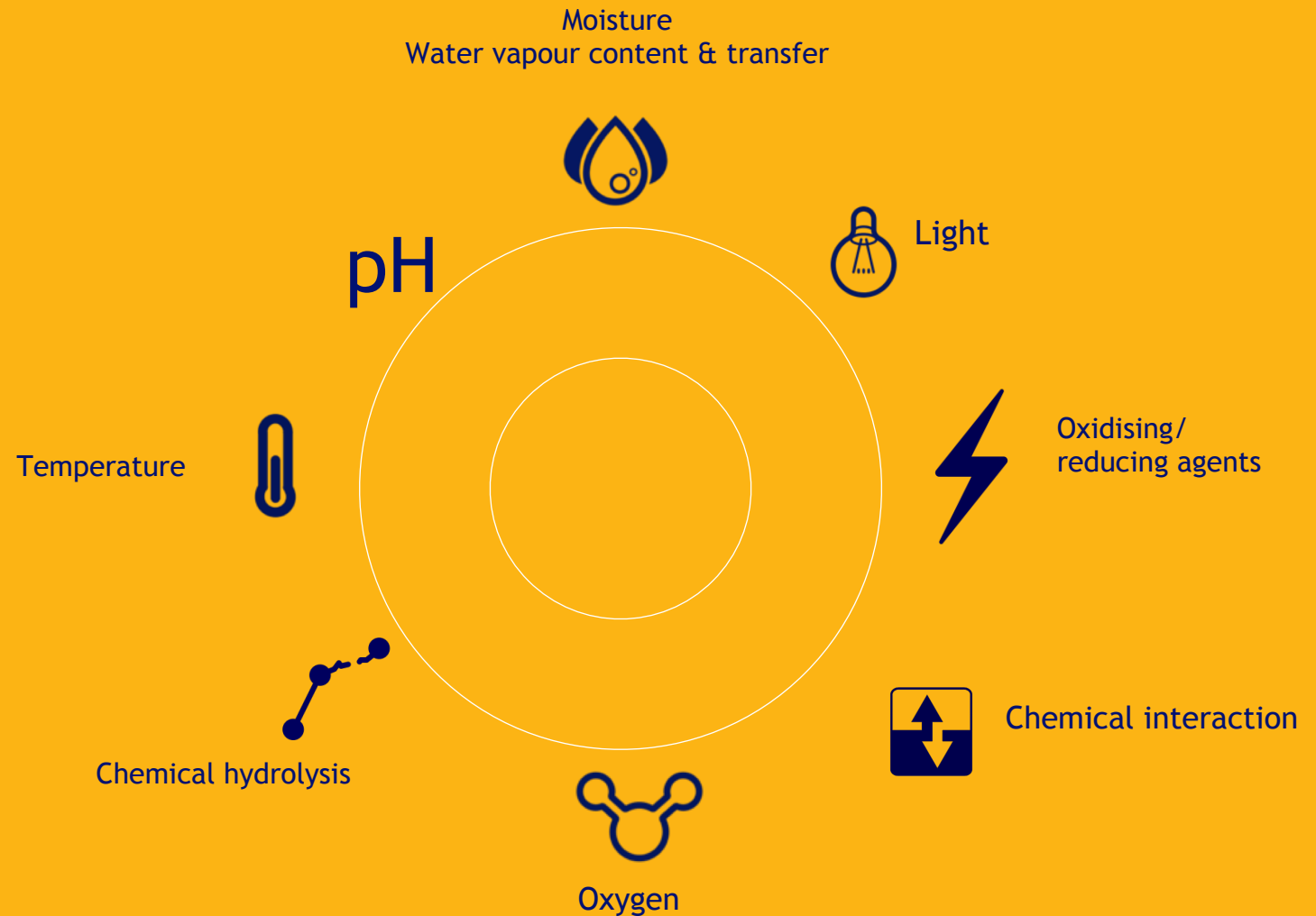
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Stability Testing for the Shelf-Life Determination of Supplements



Mechanism of product deterioration

Examples of chemical and physical effects that, singly and in combination, can affect the shelf life of a supplement





Stability testing can be costly, both in a monetary sense and time. It is important that consideration is given to the many factors that can affect stability and shelf life before stability studies are initiated.

A stability study should be the final confirmation that the product in a particular packaging will remain stable throughout the length of its intended shelf life. This requires that all possible sources of instability in terms of the formulation, processing and packaging have been evaluated and necessary action taken before any stability tests are undertaken.

This may require that smaller, selective studies are carried out before the formulation is finally agreed, to check for potential sources of instability, such as ingredient interactions. Similarly, small scale tests may be needed to ensure that the selected packing is suitable for the formulation in terms of oxygen, moisture and light barriers.

Shelf-life Studies

Shelf life studies for the purpose of setting an expiration date for a product should be carried out in the proposed retail packaging. Whenever possible, the processing and packaging of the test samples should simulate those proposed for the commercial production of the product.

Types of Stability Studies to Support Shelf-life determination

1. Stress Testing
2. Accelerated Testing
3. Long Term Testing
4. In-use Testing
5. Transit Testing

Analysis of appropriate stability data

The design of the stability protocol should be such as to provide the data from the study in a form and quantity that permits a realistic statistical analysis.

Extrapolation of stability data

The principle of extrapolation forms the basis of the accelerated study, in that the data obtained from a 3 or 6 month test is used to predict the behaviour of the product over two or three years.

Shelf-life Evaluation

