

Riding Out the Storm

If this year can promise anything, it will be higher levels of stress for anyone working in the functional food and nutraceuticals sector. The spectre of major regulatory change has been with us for some time, and although some progress is being made to better regulate the industry, it feels like the blind are leading the partially sighted through an ever-more complex maze. As soon as the European Commission published the Article 13 claims list on EFSA's website, the constructive criticism began to flow in. The European Responsible Nutrition Alliance (ERNA) said that although it welcomed the chance to finally assess the list, it had noted that some aspects of the jointly compiled EHPM, ERNA, CIAA and EBF industry list of Article 13 claims had been modified without clear explanation. ERNA noted that the aspects modified from the industry list include conditions of use and examples of wording, adding that in other cases, entries from the industry list have been omitted completely from the published document. "We are pleased that the list has finally been published, so that everybody at last can have a clear view on what EFSA will assess, after almost one year of guessing," said Gert Krabichler, Chairman of ERNA. "However, our assessment shows that many entries from our industry list have been modified, some are missing and EFSA comments are included quite inconsistently. In a way, it is inevitable that, given the number of claims in the list, inconsistencies and errors creep in, but we hope that there will be an opportunity to clarify and rectify this situation."

Another concern that ERNA has voiced in the past is that EFSA does not intend to do a different type of assessment for Article 13 claims (as it believes the law prescribes) to that of Article 14 claims. "This may result in many



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claims being rejected, not because they are not true, but because they will not meet the criteria that EFSA has defined," said Patrick Coppens, Secretary General of ERNA. "The EFSA scientists are looking for proof from intervention trials to show cause-effect relationships with measurable effects. This is and should be possible for submissions under the authorization procedure, but is not necessarily appropriate for many claims submitted in the Article 13 list." Under the EU's Nutrition and Health Claims Regulation, Article 13 covers health claims that describe or refer to the role of a nutrient or other substance in growth, development and the functions of the body. "Many of the nutrients and substances that we eat have a certain function, and their intake is intended to contribute to the maintenance of that function, not necessarily to constitute a measurable improvement of it," Mr Coppens continued. "If EFSA does not appreciate this in its opinions, the list will be decimated."

Joining the fray, EHPM also reiterated its concern that EFSA intends to follow an identical process of assessment for Article 13 claims (claims based on generally accepted scientific evidence) as the one used for

assessing individual dossiers submitted under Article 14 claims (disease risk reduction claims and children's claims), which it says was not the original intention of the law. The trade organization said that the intention of the regulation — when it had been initially discussed and adopted — was for claims that had been accepted on a national level, based on generally accepted scientific evidence (Article 13.1 claims), to undergo a quicker assessment process than the full authorization procedure for Article 14 claims, and be allowed to continue to be used. "We believe that the task of EFSA, as originally intended by the regulation, should be to check and confirm that the evidence supporting Article 13.1 claims is considered as generally accepted, by taking into account and weighing all of the existing evidence," said Lorene Courrege, EHPM's Director of Regulatory Affairs. "However, EFSA would have great difficulties in applying the same assessment process as that used for Article 14 claims, as the regulation has not requested Member States to provide the same detailed information, as the claims were deemed to be supported by long-established and non-controversial science. We believe the insistence of EFSA to apply the same process of assessment simply does not make sense and could potentially decimate the final Article 13.1 list. We hope to clarify this in further talks with EFSA." EFSA will now begin its assessment of the list, after which the European Commission and EU Member States will make the final decision on the Article 13.1 claims that will be allowed for use in the final Community List.

The R Word

As the global financial meltdown continues and the omnipresent recession becomes more

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and more “official,” NBT surveyed a few key market players to assess the impact of the economic situation on their business. Anthony Hehir of DSM Nutritional Products Europe commented that, at present, the company’s current sales activities were not being affected; but, he felt that the industry seemed nervous regarding the outcome of the Article 13.1 health claims. “Despite this,” he added, “DSM is totally committed to innovation, believes in its ingredients and continues to invest in further strengthening their claims.” Antoine Dauby of Naturex supported this view and added that company sales had not been adversely affected by the crisis ... yet. In a similar vein, Lipid Nutrition’s John Kurstjens felt that, although it was a case of business as usual at the moment, he expected some projects to be delayed or postponed. Gunilla Traberg of EPAX AS noted that “we have not seen/ experienced any reductions in our deliveries; however, orders coming from the US, which are notoriously “last minute” by nature, are arriving even later than usual.” The over-riding theme was a lack of commitment from customers who are, not surprisingly, keeping their cards close to their chests and waiting to see how long and how deep this recession will run. Sarah Millns of Croda said that budget cuts regarding marketing and executive travel were inevitable, which is bound to affect the success of both trade shows and B2B publications! Several Big Nutra organizations have instigated no new hire policies and are taking a close look at conference attendance and international meetings. In the regular food sector, as well, manufacturing companies are cutting costs. As a result of reduced access to credit and finance, new product development is being put on the backburner until the market recovers.

REACH Ready?


The REACH (Registration, Evaluation and Authorization of Chemicals) regulation

came into force on 1 June 2007, and it’s important that all manufacturers, importers and downstream users of chemicals are prepared and fully aware of the impact that this new legislation has on their business. There are a number of differing and potentially confusing requirements for chemicals used in the nutra/pharma industry: in some cases, substances are exempt, but this applies only in certain situations and, overall, widespread misunderstanding remains about which substances are subject to REACH requirements — and when. However, companies must be prepared to act. Under the “No Data, No Market” mantra of REACH, firms must register substances that are imported or manufactured in quantities of more than one tonne per year, providing toxicological data on the substance and risk assessment on their uses to the European Chemical Agency (ECHA). Users of substances have to make sure that their use is included in the registration and that they comply with authorization and restriction requirements under REACH. Starting with the assumption that all substances used in the pharmaceutical industry are subject to some requirements under REACH, there is clearly going to be some far-reaching effects. The main, initial short-term consequence is a possible interruption of supply of some starting materials or reagents that have not been preregistered by EU suppliers, or from suppliers outside the EU who have not appointed an “Only Representative” — an independent third party that takes on the REACH obligations. The number of orphan substances — those that have not been preregistered by any supplier but have a user with more than one tonne/year — will be known by early 2009. However, substance withdrawal may also happen separately as a consequence of supplier portfolio rationalization.

Carole Garcia at SAFC advises companies to quickly assess what substances they produce

or import that are subject to REACH, and what steps must be taken to comply. The most difficult part is to assess the supply chain of purchased substances. It is important to list the substances bought within the EU and make sure that all the participants in the supply chain are ready to implement REACH. This should be done for all critical starting materials and reagents, whatever the volume purchased. However, it can be difficult to obtain proof from a supplier of REACH compliance. A supplier cannot prove REACH readiness until the full registration is done (between 2010 and 2018 for phase-in substances), and there is no certificate of compliance. Companies must work closely with their suppliers to ensure that the appropriate efforts are being made. It is important for suppliers and users to work very closely on REACH implementation to avoid any potential problems. Communication will be a key component of achieving that objective to proactively identify the registration/substitution need. If that is not done, companies may face serious problems if the supply of key raw materials dries up and there is no alternative plan in place.

Back to Health Claims

As the health claims debacle lumbers on, I asked our panel of experts for a pop quiz response to the situation. On the plus side, they felt that the legislation might help to weed out poor ingredients. On the negative side, the amount of time being taken and the final decision — whatever it turns out to be — could seriously affect the marketability of the products under examination. And, as the first of the four horsemen of the apocalypse appeared on the horizon, they conceded that the whole process could put the industry at risk. Indeed, adopting the policy of wait and see is about as much as we can do; innovation, quality control and staving off the competition will just have to wait ... for now. 

For more information

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