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IPA Europe comments on the EFSA Strategy 2020

Trusted science for safe food

The International Probiotics Association (IPA) Europe is the European voice for probiotic products, advocating for a well-defined status for probiotics in Europe.

As such, we welcome this public consultation on EFSA's strategy for 2020 because it provides us with an opportunity to feedback on EFSA's plans. Engagement and interaction with EFSA is a key goal for our organisation.

EFSA's policy document confirms the mission and values of EFSA as well as identifying the main drivers to prepare EFSA to execute its mission within the next five years. We see the strategic objectives of EFSA for 2020 as extremely important for its ability to adjust to a constantly evolving environment.

We would like to contribute to the development of EFSA's strategy 2020 with the following comments:

I. EFSA and its environment

i. Our vision: Trusted science for safe food//ii. Who we are (p4)

It is important to emphasise that EFSA does not deal solely with food safety: EFSA's remit also covers nutrition. IPA Europe is striving to obtain approval for probiotic health claims in Europe because we believe probiotics could be used to help maintain health.

iv. EFSA's values (p4)

It is good to see that, as well as scientific excellence, two of the five EFSA values are openness and co-operation. We welcome the intention of EFSA to communicate openly and promptly on its scientific work, to be transparent, and to work together. These values will help achieve a solution to the current deadlock on use of the term 'probiotic' in the EU, therefore we advocate a focus on increased cooperation with health claim applicants.

vi. Who we work with (p5)

Whilst EFSA currently works with a broad range of partners within Europe, the probiotic sector believes that a two-way interaction between health claim applicants and the EFSA NDA panel is essential because this would provide meaningful input that would assist in the proper evaluation of health claim dossiers. Such direct scientific dialogue would facilitate an efficient and effective exchange of information; this would be of benefit to both the EFSA assessors and industry scientists.

As stipulated in EU Regulation 178/2002 Article 30, EFSA shall exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.

Mutual recognition of scientific assessments, both at EU level (there are strict procedures in case of divergences in 178/2002 which do not guarantee EFSA's pre-eminence over national agencies) and at the international level (so benefit can be gained from different but recognised and credible international approaches).

It would therefore be helpful for IPA Europe to understand how EFSA is considering opinions that have been given by other scientific authorities in Europe and other countries involved in the scientific assessment and approval of health claims. This is important as authorities in several countries have approved health claims for probiotics; examples include Switzerland and Canada.

The outcome of a scientific opinion on a health claim should be the same irrespective of the evaluation procedure, particularly if a valid scientific rationale (based on written opinions from recognised scientific experts) is the basis for the claim approval.

We would also welcome clarification on how EFSA envisage its cooperation with Member States of the EU so as to enable them to become more closely involved in scientific procedures.

III. Challenges and opportunities – drivers for change

iii. Evolving scientific knowledge, creating a need for innovative and collaborative approaches (p7)

EFSA acknowledges the rapid evolution of scientific knowledge. One example of this is how newly developed microbiological methods have dramatically improved our understanding of how the gut microbiota influences health. The strategy document states that the partnership of EFSA with research bodies, risk managers and funding bodies will identify and prioritise research funding for the generation of data for its work. In the area of gut and immune claims, there is a lack of validated biomarkers for health (as opposed to biomarkers for disease).

As EFSA's remit is food, not drugs, a priority for funding could be the identification of new, relevant and validated biomarkers to asses short or long term health or disease risk in healthy people or people with sub-optimal health. For example, a panel of biomarkers could be developed for the assessment of food or food ingredients on the development of prevalent metabolic diseases such as type 2 diabetes.

The strategy document also states that EFSA will have to monitor and take stock of new scientific developments generated by these partners. It is important that this includes scientific evidence relating to the impact of the gut microbiota on health, in particular how particular microorganisms or their metabolites influence health.

While we understand that EFSA's mandate is to conduct evaluations of the highest possible standard, we believe that in the case of probiotics, the requirements applied so far have been unrealistic for certain claimed effects and that the 'generally accepted scientific evidence' is not being taken into account. Based on the outcome of many dossiers evaluated thus far, we believe that EFSA has interpreted and placed the 'evaluation of the highest possible standard' on the *scientific evidence* rather than holding the evaluation process itself to the highest possible standard. In the case of probiotics, there is a wealth of accepted scientific information and an accumulated body of knowledge on such microorganisms.

As part of the process of evidence assessment and of 'weighing the evidence' for probiotics, we believe that the Panel should consider the probiotic research and publications over the last 30 years. Currently the practice is for EFSA to consider only new and high-level clinical studies as being relevant for health claim substantiation.

We therefore believe that EFSA should adapt their evaluation criteria for probiotics by considering the totality of evidence, without compromising in any way their mandate.

iv. The impact of globalisation (p8)

A key aim of the Nutrition and Health Claims Regulation (EC) No 1924/2006 was to regulate and harmonise health claims on foods in all EU countries. The increased globalisation of food trade shows there is an increasing need for the harmonisation of health claims to be worldwide. Probiotic claims have been approved in other countries of the world but not in the EU, thus it would be helpful for EFSA to look at the approval procedures of other countries and to see how they differ.

v. Efficient operation of the agency's activities (p8)

To ensure the efficient operation of the health claim approval procedure and to avoid wasting the time and resources of EFSA, it is important that health claim applications that are sub-standard are either not submitted or rejected at an early stage of the procedure. To address this, IPA Europe believes that allowing a pre-submission consultation will ultimately achieve a more efficient submission process for both applicants and EFSA (as appears to be the case for the European Medicines Agency).

IV. Strategic Objectives (p9)

i. Prioritise public engagement in the process of scientific assessment (p11)

We acknowledge and welcome EFSA's willingness to promote dialogue with the scientific community and society, and to strengthen its engagement with applicants for regulated products. We further acknowledge and appreciate the recently implemented EFSA measures enhancing openness and dialogue with applicants including the creation of the EFSA Application Desk in 2012, the workshops with stakeholders and the recent possibility of having a teleconference post-adoption after and EFSA opinion.

While these measures have been welcomed, it is our belief that in the case of the regulated products, they do not extend far enough. For some of the application processes, in particular the evaluation of health claims, it is clear that the EFSA case-by-case approach therefore requires a case-by-case dialogue between interested party (i.e. the applicant) and EFSA.

The probiotic sector welcomes EFSA's commitment to openness but the operational objectives in EFSA's strategy document focus on openness and do not address the need for dialogue. It is not possible to engage with the public without a dedicated channel or structure to invite responses from the public, and to respond accordingly. In this context, the principle of open discussions before the submission of applications would be extremely valuable for the majority of applicants of dossiers for regulated products.

This principle has not been addressed in any recent changes to the application process, despite the fact that pre-submission would not just help applicants but would also benefit EFSA (for example in ensuring the correct format, tools and methods included in dossiers) and improve the content of future guidance from EFSA.

We advocate the introduction of pre-submission meetings with applicants, subject to certain conditions. Enhanced scientific dialogue is necessary throughout the evaluation process – in the pre-

submission phase (during the preparation of dossier applications) and while applications are being evaluated, to ensure an adequate two-way interaction.

To manage this process properly, conditions should be set to govern such interactions and the scientific dialogue, and certain eligibility criteria introduced to limit the number of potential consultations. Scientific dialogue should be granted to applicants who are in real need of advice.

A two-way interaction between EFSA Panels and interested parties, in particular applicants, could be facilitated by the following changes:

- EFSA could allow for written submissions of applicants' draft dossiers in the pre-assessment stage. Feedback from panel members would help applicants to submit high quality dossiers more likely to satisfy EFSA's requirements for each particular case, in line with the case-by-case dossier evaluation.

- EFSA could compile and publish a FAQ document consisting of questions and answers asked during the stop-the-clock procedure. Such a document would provide applicants with additional information that would help claim submission preparation.

Such interaction would allow for the exchange of data in a more systematic and regular manner. We believe that such measures would significantly help EFSA in carrying out its mandate, and would lead to concrete gains.

Other authorities outside the EU dealing with foods (e.g. the FDA and Health Canada) as well as European agencies from other sectors (e.g. the European Chemicals Agency and the European Medicines Agency) have already successfully implemented pre-submission methods. Therefore it is evident that such processes are possible and also that they would not undermine the independence of the EFSA scientists.

The probiotic industry continues to try and understand the exact requirements needed to achieve approval of a health claim dossier. We rely on information provided in EFSA's scientific opinions and as EFSA' guidance documents to design studies and prepare dossiers. We strongly believe the implementation of pre-submission meetings or consultations between EFSA and the applicants can be an effective way to improve the process of probiotic submission within the current legislative framework, and would be evidence of better cooperation with industry. Therefore we strongly recommend and request that EFSA look into the possibility of putting these meetings in place.

ii. Widen EFSA's evidence base and optimise access to its data (p12)

IPA Europe supports the open data approach in order to leverage existing data for data access. We are open to the concept of data sharing, and are evaluating a set of principles on sharing of clinical trial data that are appropriate and applicable to the food industry. The sharing of data (especially clinical trial data), however, poses very real risks. For example there is a potential of violation of data protection laws, as well as violation of ethical and/or regulatory principles.

Furthermore, data sharing could prove to be a disincentive for industry investment in biomedical research. Extreme caution should be exercised before taking any steps to increase the sharing of clinical trial data sharing. It would be very useful if EFSA could clarify its position on proprietary data, namely the basis for considering that the only way to retain exclusivity rights is conditional on non-published data.

To be clear, we acknowledge that the provision of raw clinical study data to EFSA panels within the scope of a regulatory dossier represents good practice, in particular with regard to the Data Transparency Initiative. But our concern is not just about making all data available, but about who will have access to the data and in what context. (For example, data access could be restricted to specified qualified professionals.)

iii. Build the EU's scientific assessment capacity and knowledge community (p14)

In the section related to the review and the development of EFSA's scientific assessment model, a critical point is how to sustain a body of experts on key scientific fields for EFSA. Most of the stakeholders who seek scientific advice already face the problem that there is a scarcity of available experts in given fields. This also increases the likelihood of conflicts of interest for the experts. It is important that EFSA identifies these scientific fields and formulates plans to encourage new scientists to work in these areas.

In addition, there are some emerging areas in biomedical research that are extremely relevant to health and that may directly affect the nature of EFSA's work: an important example is microbiota research, which has been the focus of recent multinational research programs. Learnings from the Human Microbiome Project and other initiatives will probably lead to refinements in regulations on health and diseases. We would like to ask how EFSA considers such large-scale scientific developments in the building of their collective European scientific assessment capacity.

On page 15, the document states that EFSA should review and further develop their scientific assessment model. It would help this objective if EFSA consults and engages with scientific experts, including those who work with industry, who have specific knowledge and research experience of the probiotic sector.

iv. Prepare for future risk assessment challenges (p15)

The probiotic sector believes that it is too late to wait until 2020 to introduce the changes that are necessary to improve two-way interactions between EFSA's panels and interested parties. Short term solutions are needed for certain food categories. We propose that EFSA implements pilot projects to assess the effectiveness of the option of pre-submission consultations with the probiotics industry.

We consider it essential for EFSA to identify at an early stage any potential divergence between any of its scientific opinions and those from other regulatory bodies, as mentioned in Article 30 of Regulation (EC) No 178/2002 on the establishment of EFSA. In particular, special attention must be paid where an EFSA opinion diverges from the opinions of other agencies relating to similar products.

There have been examples of such divergence, especially concerning probiotics, where EFSA has rejected a health claim but another national or foreign Agency had approved a similar claim. In such cases, we believe that EFSA should make public the fact that they are aware of the contradictory opinion(s) and, if possible, explain the reason(s) for the divergence.

v. Create an environment and culture that reflect EFSA's values (p17)

IPA Europe welcomes the aims of EFSA to foster a culture of openness, innovation, cooperation, independence and scientific excellence among its experts, partners and staff. Cooperation is a key word in this objective; the introduction of greater two-way dialogue would help achieve this objective. We would also like to repeat the points made earlier about the need to keep abreast of major scientific developments regarding the impact of the gut microbiota on health and the need to consult with experts who have current working knowledge of probiotic research.