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The European Association for Bioindustries

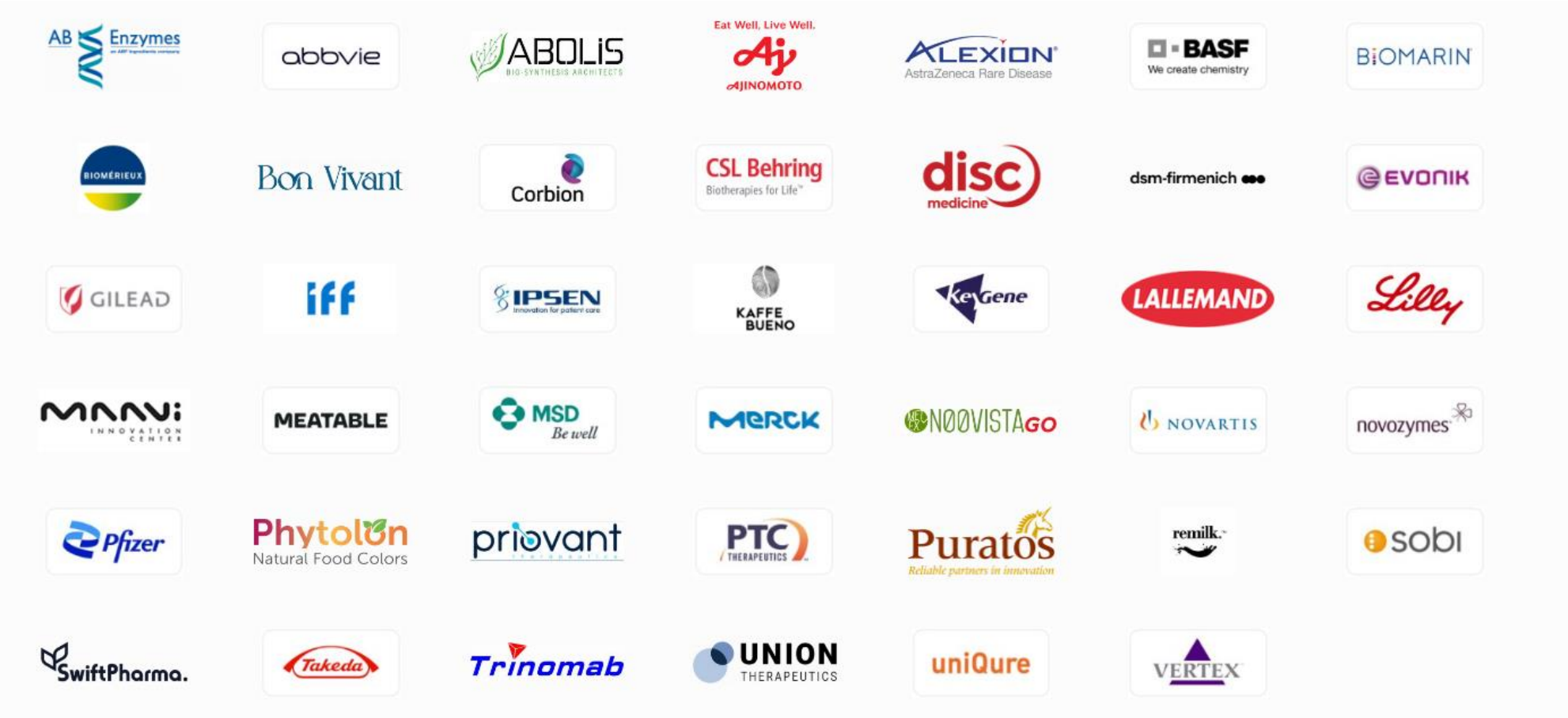
EFSA ad hoc meeting with industry on cell culture-derived foods and food ingredients

18 October 2023

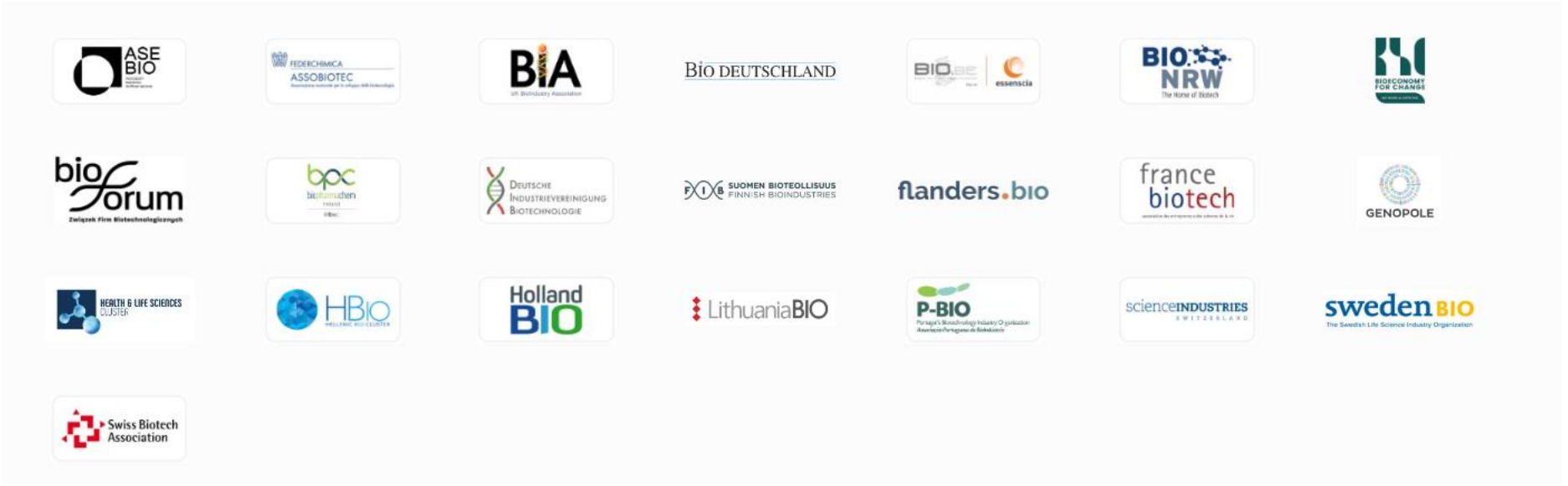
About EuropaBio

- EuropaBio represents the European biotechnology industry across sectors including healthcare and industrial biotechnology
- Delivering globally competitive biotechnology through science, regulation, accessibility, growth, infrastructure, competitiveness
- Driven by members, including biotech companies from start-up to multinational, as well as national associations across Europe
- Supported by the EuropaBio Biomanufacturing and SME Platforms

Corporate members



National Associations & Associate Members



EuropaBio scope

- Industrial biotechnology uses enzymes and microorganisms to make biobased products from renewable raw materials in sectors such as chemicals, food and feed, detergents, paper and pulp, textiles, and bioenergy.
- Industrial biotechnology plays a key role in sustainable food production. EuropaBio members' activities include food and feed applications: fermentation products (enzymes, vitamins, amino acids, oligosaccharides, aromas, proteins) and cell-cultivated products.

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General comments on dossier preparation and evaluation

Administrative challenges

- The intention of the revision of the Novel Food Regulation (EU) 2015/2283 was to reduce administrative burdens by implementing an EU-wide authorization and for the food safety assessment by EFSA to reduce the legal timeline from more than three years to an average of 18 months.
- However, it seems that the revised novel food regulation has not yet accelerated the time-to-market for novel foods to a significant degree.
- With regards to the expectation of the large numbers of dossiers that will be submitted to EFSA, will EFSA have enough staff/resources to be able to assess all the dossiers in a timely manner?
- How can industry support a smooth process in terms of dossier preparation?

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Dossier preparation and evaluation – Pre-submission advice

Product-specific pre-submission advice :

- Suggestion for scientific contact between applicant and EFSA, similar to pre-submission meetings currently offered by SFA or FDA
- Pre-submission advice should be more specific than the Q&As without being in the public domain.
- Focus should be on discussing the content of the dossier to avoid possible future clock-stops and advice on scientific rather than administrative aspects (e.g., on studies).
- On studies, guidance on scope and kinds of required studies would be welcomed.

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EFSA Guidance on Novel Foods

Technical and administrative questions

Novel Foods dossier preparation and evaluation – Technical Questions

Similarity

- With regards to the similarity of precision proteins to native proteins or already approved novel proteins: What type of testing will EFSA accept as proof of ‘similarity’?
- To which extent can data on native/already approved proteins be used as part of the totality of the evidence (if the precision fermentation protein is similar)?

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Update of the Novel Foods Guidance – possible administrative challenges?

- Many applicants are currently preparing dossiers with testing according to the current guidance.
- What will be the impact of the change in the guidance that is expected in 2024?
- How will EFSA deal with this transition period?

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Thank you for your attention!

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