SNE Specialised Nutrition Europe

November 2018

A point of view from interested parties

Specialised Nutrition Europe (SNE)

EFSA Workshop on foods for infants below 16 weeks of age

30 November 2018

Outline

- Introduction
- Use of additives in early life
- SNE contribution to EFSA guidance consultation
- SNE Special additives interest group – ways of working
- Main challenges and considerations

SNE Specialised Nutrition Europe

Who we are

Trade association representing the interests of the specialised nutrition industry across the European Union.
SNE members are the national associations of 19 Member States

Members provide tailor made dietary solutions for populations with very specific nutritional needs including infants and young children, patients under medical supervision, sportspeople, overweight and obese consumers, and those suffering from coeliac disease

Dedicated and committed to developing and delivering specific requirements to guarantee high level standards and tailor made nutrition for population with specific nutritional needs

5% of turnover is invested in research

SNE - Membership in Europe

SNE members are the national associations of 18 Member States

Member States with SNE National associations

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The different sectors SNE is representing…

Infants and young children nutrition

Foods for Special Medical Purposes

Gluten-free foods

Foods intended for weight control

Foods intended for sportspeople

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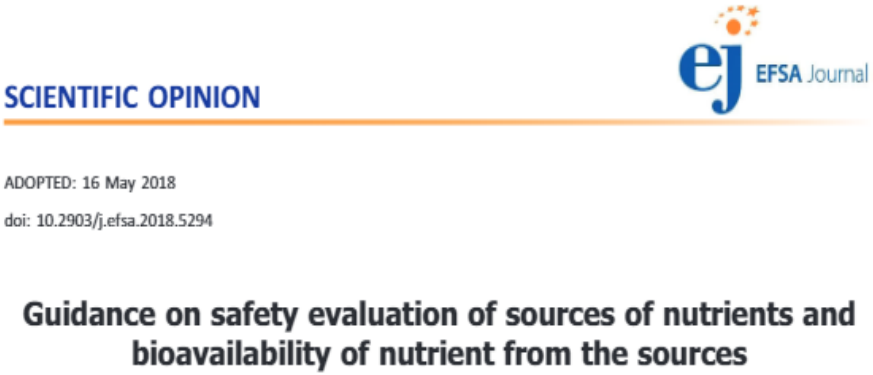
Use of Additives in Early Life

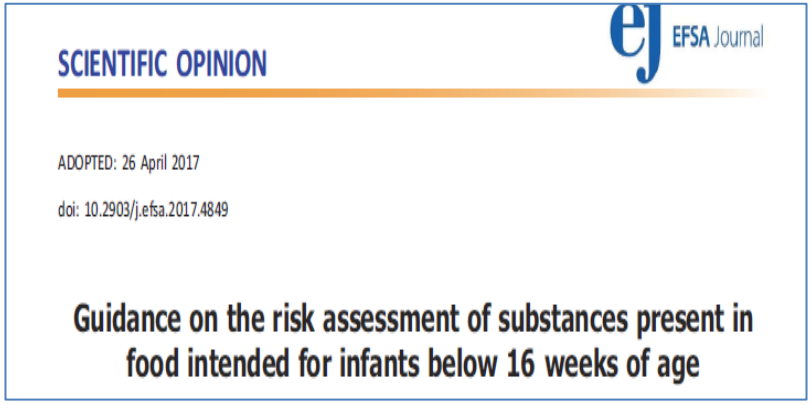
- Food additives in formulas for infants should only be used as necessary
- The use of certain additives for specific technological purposes is necessary to produce infant formula
- Manufacturers use only the amount of additives absolutely necessary to achieve the desired technical effect:
  - Inherent properties of food additives limit the amount that can be used in IYC products
  - For infant foods, nutrition *and* ingredient safety are equally essential; product must support normal growth and development
  - Additional ingredients add to the cost of manufacturing
- Due to differences in manufacturing process (e.g. spray dried vs. dry blend), ingredients (e.g. intact vs. hydrolyzed protein), and product format (e.g. powder vs. liquid), a variety of additives is needed to allow for the most appropriate food additive use for each product.
- Prioritization should be to ensure additives are used at lowest level possible, rather than limiting the total number of authorized additives

SNE contribution to EFSA Public consultations

- Guidance on safety evaluation of sources of nutrients and bioavailability of nutrient from the sources
  - Ability to reference existing regulations for nutrient mix/ max values
  - Consideration of all possible sources of a nutrient for intake estimates



- Guidance for the risk assessment of substances present in foods for infants <16weeks – April 2017
  - History of safe use and clinical data could substitute for animal studies on a case-by-case basis
  - Different considerations for dual function substances (additives and nutrient substances)
  - Comments on the criteria around requiring studies such as physiochemical properties



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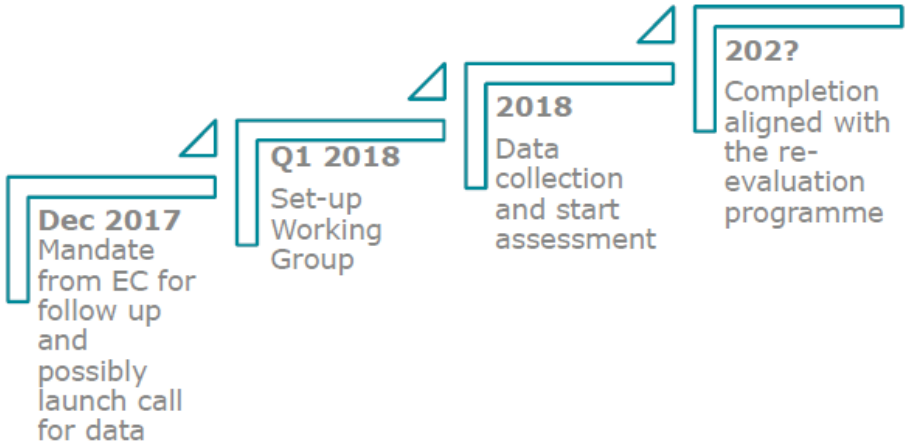
SNE Additives Special Interest Group (ASIG)

- Consisting of 13 companies aiming to coordinate the IYC industry contribution to the EFSA calls for data on additives for use in infants <16weeks
- Operates under the SNE umbrella and follows the SNE antitrust rules.

E-number	Name of the food additive
E 170	Calcium carbonate
E 304i-ii	Fatty acid esters of ascorbic acid: Ascorbyl palmitate; Fatty acid esters of ascorbic acid: Ascorbyl stearate
E 306	Tocopherol-rich extract
E 307	α-Tocopherol
E 308	γ-Tocopherol
E 309	δ-Tocopherol
E 322	Lecithins
E 407	Carrageenan
E 410	Locust bean gum
E 412	Guar gum
E 415	Xanthan gum
E 440	Pectins
E 466	Carboxy methyl cellulose, Sodium carboxy methyl cellulose, cellulose gum (changed to "Sodium carboxy methyl cellulose, Cellulose gum" on 12/2013)
E 471	Mono-and diglycerides of fatty acids
E 472c	Citric acid esters of mono- and diglycerides of fatty acids
E 473	Sucrose esters of fatty acids
E 1450	Starch sodium octenyl succinate



- The responsibility for the writing of the dossiers and the generation of new data rests with the companies
- Preparation of dossiers brings considerable additional cost and effort to industry members
- Competitively sensitive information or confidential information will not be shared amongst companies but directly to EFSA either via the companies themselves or via the SNE

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SNE is working in close collaboration with suppliers to ensure the delivery of all relevant information to EFSA

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List of 17 food additives for which EFSA will provide complementary Opinions regarding safety for very young infants

Additives with an active call for data → SNE plans to respond

ADDITIVE		SNE support
E 170	Calcium carbonates	✓
E 304	Fatty acid esters of ascorbic acid	✓
E 306	Tocopherol-rich extract	✓
E 307	Alpha-tocopherol	✓
E 308	Gamma-tocopherol	✓
E 309	Delta-tocopherol	✓
E 322	Lecithins	✓
E 407	Carrageenan	✓
E 410	Locust bean gum	✓
E 412	Guar gum	Orphan
E 415	Xanthan gum	✓
E 440	Pectins	✓
E 466	Sodium carboxy methyl cellulose, Cellulose gum	Orphan
E 471	Mono- and diglycerides of fatty acids	✓
E 472c	Citric acid esters of Mono- and diglycerides of fatty acids	✓
E 473	Sucrose esters of fatty acids	Orphan
E 1450	Starch sodium octenyl succinate	✓

Orphans:
Additives SNE is not planning to respond to the call for data

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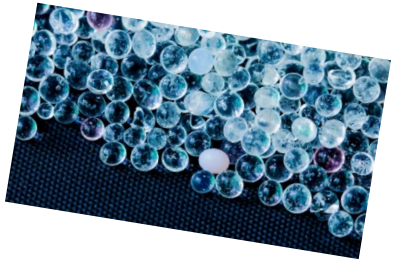
Overview of SNE response to EFSA calls for data

	SNE commitment to submit data	EFSA Deadline	Source of Nutrient	New data generation requested	Clarification requested	Extension of deadline
Pectins (E440i & E440ii)	Yes	31/12/2019	No	No	No	Not necessary, provided no additional data is needed
Lecithin (E322)	Yes	31/12/2019	No	Yes. Toxicological study	Yes	Necessary
Locust Bean Gum (E440)	Yes	31/12/2019	No	Yes. Neonatal animal study	No	Necessary for new data generation
Xanthan Gum (E415)	Yes	31/12/2018	No	Possible	No	Necessary for new data generation
OSA modified starch (E1450)	Yes	31/12/2018	No	No	No	Not necessary
Calcium carbonates (E170)	Yes	31/05/2019	No	No	No	Necessary
Carrageenan (E407)	Yes	30/09/2020	No	Yes. Toxicological study	No	Not necessary
Ascorbyl palmitate (E304(i))	Yes	28/02/2019	Yes	No	No	Necessary
Tocopherols (E306-E309)	Yes	30/05/2020	Yes	Yes. Toxicological study	No	Not necessary

Additional EFSA Calls for data in foods for infants below 16 weeks of age

- The list of the 17 additives has been updated with two additional food additives, silicon dioxide (E 551) and acacia gum (E 414), permitted in foods for infants below 16 weeks of age through their inclusion in the Annex III part 5, section B of Regulation (EC) No 1333/2008
- Acacia gum and Silicon dioxide do not have any technological function in foods for infants below 16 weeks
- SNE expects suppliers to respond to the data requirements and SNE remains available for any further support in the submission of all the relevant information to EFSA



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Main challenges and considerations

General remarks

- Additional data generation:
  - Dual use, additive/ nutrient substances (e.g. tocopherols) should rely on the EFSA guidance on safety evaluation of nutrient sources to reduce the need for additional animal data
  - Study design
  - Extension of deadline
  - Animal studies are not perfect and should be minimized → historical and clinical data, alternative methods
- Close collaboration with EFSA is key to achieve successful submissions

Locust bean gum (E 410)

SNE welcomes EFSA Call for data on locust bean gum (E 410) for uses as a food additive in foods for all population groups including infants below 16 weeks of age, but additional time may be needed for the dossier submission

- **New data generation is mandatory to fulfill the requirements of the call for data:**
  - Considerable additional cost
  - Complex tests to perform and interpret (study design, methodology and interpretation of results)
  - Significant animal use
  - Time restrictions
    - Limited capacity of Contract Research Laboratories/clinical research institutes/ hospitals
    - Time necessary to conduct in-life portions of the studies as well as analysis/ reporting
- **Necessary for SNE to fulfill the requirements of the call for data**:
  - Extension of the deadline to Q2 of 2022 for the completion of the dossier including the data generated by the new preclinical and possible clinical studies requested
  - Proactive close cooperation between SNE - EFSA is needed during the design of studies

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Lecithins (E 322)

SNE welcomes EFSA Call for data on lecithins (E 322) for uses as a food additive in foods for all population groups including infants below 16 weeks of age, but additional time may be needed for the dossier submission

- Deadline of 31 December 2019
- SNE confirms that we are able to provide together with the European Lecithin Manufacturers Association (ELMA) the majority of the required data by the deadline
- Exceptional: additional toxicological study, which, after the first contacts with Contract Research Laboratories (CROs), are rather complex to perform and interpret.
- Points to be clarified by EFSA – e.g. Necessity and rationale of DART study for infant formula applications?
- Request an extension to the deadline

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Xanthan gum (E 415)

SNE welcomes EFSA Call for data, but additional time may be needed for the dossier submission

- The EFSA call for data does not request additional data to support the review of xanthan gum at concentrations in infant formula up to 750 mg/L (as-consumed)
- Xanthan gum is currently authorized up to 1200 mg/L in infant formula FSMP, and some manufacturers use it at concentrations between 750 and 1200 mg/L
- If additional data is necessary to support review up to 1200 mg/L, SNE requests more information to estimate the time to allow for generation of that data

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Ascorbyl palmitate (E 304(i))

- Particular specification requirements for identity and purity of ascorbyl palmitate (E 304(i)) used in foods for infants below 16 weeks of age should be proposed
- For this purpose, in a first step the relevant data/information requested in part A. of the call for data must be gathered by the responsible suppliers
- SNE as all manufacturers of infant formulae using this food additive have to reach a consensus with the relevant suppliers concerning these proposals
- Discussion and alignment require a substantial amount of time among the involved parties

Tocopherols (E 306 – E 309)

- An extended One Generation Reproductive Toxicity Study is required

- Requirements for toxicological data generation
  - Considerable additional cost (ca. €500k)
  - Complex tests to perform and interpret
  - Significant animal use

Thank you

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