

IDACE

ASSOCIATION DES INDUSTRIES DES ALIMENTS DIÉTÉTIQUES DE L'UNION EUROPÉENNE
ASSOCIATION OF THE FOOD INDUSTRIES FOR PARTICULAR NUTRITIONAL USES OF THE EUROPEAN UNION

TO:
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IDACE comments on EFSA Scientific Opinion on the substantiation of a health claim related to thiamin and maintenance of normal neurological development and function pursuant to Article 14 of Regulation (EC) No 1924/2006 (EFSA Journal 2011;9(2):1980)

Dear Mr Griffin,

On 10 February 2011, EFSA has published its opinion on the following claim: “*Thiamin contributes to the maintenance of normal neurological development and function.*” (EFSA Q-2009-00455). The Panel concluded that a cause and effect relationship has been established between the dietary intake of thiamin and *maintenance of normal neurological development and function*. The target population is infants and young children from birth to 3 years of age as defined in Directive 2009/39/EC on foodstuffs intended for particular nutritional uses.

While IDACE welcomes EFSA positive opinion, we would like to share our concerns with regard to the conditions and restrictions of use for the claim, in line with Article 16.6 of the Nutrition and Health Claims Regulation 1924/2006/EC.

As indicated in our comment on IDACE dossier “*thiamine and carbohydrate and energy-yielding metabolism*”, IDACE reiterates that as regards to the conditions of use, the target population of infants and young children up to the age of 3 years old should be only covered by this opinion.

As this EFSA opinion may have an implication for other IDACE dossiers, we would like to highlight the following issues:

- A clarification on the category “*Other foodstuffs intended for*” is needed. IDACE understands, that as EFSA has linked the conditions of use for “other foodstuffs” in its opinion on Hipp dossier, to directive 2006/125/EC, that “baby foods” would fall under this definition. The same appears in EFSA opinion on IDACE dossier “*thiamine and carbohydrate and energy-yielding metabolism*” published in July 2010.

In IDACE thiamin dossier, as in all IDACE dossiers covering this sub-category of products, “*Other foodstuffs intended for*” cover products such as *Toddlers milk, formulae for low-birth weight infants, formulae for premature infants* but not “baby foods” as defined in directive 2006/125/EC.

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Condition of use as proposed by IDACE in its dossiers, for IDACE category “*Other foodstuffs*”, are linked to directive 2006/141/EC (15% NRV per 100ml as per directive 2006/141/EC) and not to directive 2006/125/EC.

As a consequence, in the view of both EFSA opinions on thiamine, products such as *Toddlers milk or formulae for low-birth weight infants* are not covered and “other foods” represents “baby foods” which is not the case in IDACE dossiers.

- For processed Cereal-based Foods, the condition of use is linked to “criteria of composition” set in directive 2006/125/EC. In EFSA opinion on IDACE thiamin dossier, the condition of 15% of thiamin NRV laid down in directive 2006/125/EC is proposed (as in IDACE thiamine dossier). IDACE would recommend aligning the two conditions of use.

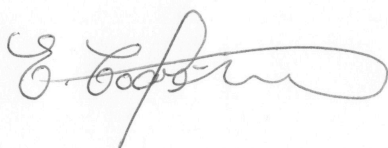
- For FSMPs, EFSA conditions of use is restricted to “complete” FSMPs (as in EFSA opinion on IDACE thiamin dossier), and as a consequence, there are no condition of use of for “incomplete FSPMs” (see annex).

In order to allow products such as *Toddlers milk, formulae for low-birth weight infants* to benefit of EFSA opinion, IDACE would welcome if our comments could be considered.

A detailed rationale is attached.

We remain at your disposal for any further question.

Kind regards,



Elena Cogalniceanu
IDACE Executive Director

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Annex

Rational for IDACE comments

on Scientific Opinion on the substantiation of a health claim related to thiamin and maintenance of normal neurological development and function pursuant to Article 14 of Regulation (EC) No 1924/2006 (EFSA Journal 2011;9(2):1980)

1) IDACE comments on the EFSA category “other foods than”

EFSA proposes conditions and restrictions of use for 4 categories of foods intended for infant and young children: 1. *follow-on formulae*; 2. *nutritionally complete foods for special medical purposes* intended for use by infants and FSMPs other than those intended for infants; 3. *processed cereal-based foods* for infants and young children; 4. *other foodstuffs intended for infants and young children*.

EFSA condition of use for the category “*Other foodstuffs intended for*” is related to directive 2006/125/CE. The same is done by EFSA in its opinion on IDACE dossier on “*thiamine and carbohydrate and energy-yielding metabolism*” published in July 2010. As directive 2006/125/EC¹ covers only two categories of complementary foods, IDACE understands that EFSA descriptor “corresponds to “*baby foods*” as define in directive 2006/125/EC.

In IDACE dossiers covering all IDACE sub-categories (such as IDACE thiamin dossier), IDACE gives separate conditions of use for the submitted health claim. The wording “*other foods*” used by IDACE in its list of proposed conditions of use (in paragraph 1.4.4) was chosen by IDACE in contrast to the other IDACE listed categories. It shows that it does not include “*baby foods*”

Example extracted from IDACE dossier on thiamin and carbohydrate and energy-yielding metabolism

- “Paragraph 1.4.1. - For being able to make the claim,
- **For follow-on formulae**, the content in vitamin B₁ should be within the range set in Dir. 2006/141/EC.
 - **For Foods for Special Medical Purpose**, the content in vitamin B₁ should be within the range set in Dir. 1999/21/EC, except if this is contrary to the intended use of the product.
 - **For processed cereal-based foods and baby foods**, the content in vitamin B₁ should reach at least 15% of the Nutrient Reference Values set in Dir. 2006/125/EC i.e. 15% of 500 µg (75 µg) per 100 g or 100 ml per serving, as reconstituted.
 - **For the other foods intended for infants and young children**, the content in vitamin B₁ should reach at least 15% of the Nutrient Reference Values set in Dir. 2006/141/EC i.e. 15% of 500 µg (75 µg) per 100 ml product ready for use.”

In addition, the IDACE proposed condition of use for “*other foods*”, is linked to directive 2006/141/EC². (15% of directive 2006/141/EC NRV per 100ml) as reflected in EFSA opinion on IDACE dossier thiamin (page 6) and not to directive 2006/125/EC as proposed by in both EFSA opinion on thiamin.

The reason is that this IDACE category “*other foodstuffs intended for*” represents the following products listed in the concerned IDACE dossiers (paragraph 2.2.1) as,

- Growing-up Milk/Toddlers milk (GUM): milk intended for young children
- Formulae for low-birth weight infants (LBW): Specific formulae for infants under 2500
- Formulae for very low-birth weight infants (VLBW): Specific formulae for infants under 1500 g
- Formulae for post hospital discharge infants (PHD): Specific formulae for low birth weight infants, very low birth weight infants, premature infants after having left the hospital
- Formulae for premature infants: Specific formulae for infants that are prematurely born
- Article 11 products (art. 9 in directive 89/398/CE) for infants and young children: fulfilling the specific nutritional requirements of infants and young children and not covered by directives 2006/141/EC and 2006/125/EC.

2) IDACE comments on conditions of use for “Foods for special medical purposes”

¹ on processed cereal-based foods and baby foods for infants and young children

² on infant formulae and follow-on formulae and amending Directive 1999/21/EC

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EFSA gives a condition of use for “nutritionally complete” FSMPs. No condition is provided for “*nutritionally incomplete FSMPs*”. The same is made by EFSA in its opinion on IDACE dossier “*thiamine and carbohydrate and energy-yielding metabolism (IDACE dossier)*”.

As define in directive 1999/21/EC, “*Nutritionally incomplete FSMPs*” are FSMPs with a standard formulation or a nutrient adapted formulation specific for a disease, disorder or medical condition which are not suitable to be used as the sole source of nourishment.”

This is why IDACE underline the importance that EFSA accepts to include “Nutritionally incomplete FSMPs” in its future opinions.