

**EUROPEAN COMMISSION**  
 DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

DEPUTY DIRECTOR GENERAL, IN CHARGE OF DIRECTORATES A AND B

Brussels,  
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[REDACTED]

First of all, I apologise for the delay in responding to your request of 19 August 2016 in which you seek clarification regarding fortification of organic food in general and baby food in particular within the permitted 5% limit. Your request being a delicate subject, it had to be thoroughly analysed by the Commission's Legal Service.

Let me clarify firstly that, regarding organic rules, Council Regulation (EC) No 834/2007<sup>1</sup> lays down the general rules on organic production and labelling of organic products and Commission Regulation (EC) No 889/2008<sup>2</sup> details production rules and requirements.

For replying to your question it is also necessary to refer to Directive 2009/39/EC<sup>3</sup> on foodstuffs intended for particular nutritional uses and in particular, to Commission Directive 2006/141/EC<sup>4</sup> on infant formulae and follow-on formulae and to Commission Directive 2006/125/EC<sup>5</sup> on processed cereal-based foods and baby foods for infants and young children, both partially repealed by Regulation (EU) No 609/2013<sup>6</sup>.

As regards "vitamins and minerals of non-agricultural origin within the permitted 5% limit where there is no organic replacement" mentioned in your email, two concepts are seemingly being mixed up: the use and authorisation of certain products and substances

<sup>1</sup> Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91. O.J. L 189, 20/07/2007, p. 1.

<sup>2</sup> Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control. O.J. L 250, 18.9.2008, p.1

<sup>3</sup> Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses. OJ L 124, 20.5.2009, p. 21

<sup>4</sup> Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC. OJ L 401, 30.12.2006, p. 1.

<sup>5</sup> Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children. OJ L 339, 6.12.2006, p. 16.

<sup>6</sup> Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009. OJ L 181, 29.6.2013, p. 35

in processing of food ("vitamins and minerals of non-agricultural origin") and certain conditions of labelling, where according to Article 23(4) of Regulation (EC) No 834/2007, the terms "organic", "bio" or equivalent, may be used in the sales description provided that the processed food complies with the provisions of Article 19 of the same Regulation and at least 95 % by weight, of its ingredients of agricultural origin are organic.

These are two issues that have to be considered independently. On one hand, the use of 95 % of organic ingredients in the processed food allows using in the label the term "organic"; yet, this does not allow using, in respect of the remaining 5 %, whatever ingredient the producer wants. Those remaining ingredients, such as vitamins and minerals need to be authorised too, in accordance with Article 21 of the same Regulation. Therefore, according to Article 23(2) thereof, the term "organic" could only be used when the whole product satisfies the requirements of the organic Regulation, not only 95%.

In your letter, you mentioned "baby food", which the Commission interpreted as referring to "processed cereal-based foods and baby foods for infants and young children and infant formulae and follow-on formulae".

According to Article 1(3) (c) of Directive 2009/39/EC<sup>7</sup> on foodstuffs intended for particular nutritional uses, "A particular nutritional use shall fulfil the particular nutritional requirements of infants or young children in good health". Annex I of the same Directive sets down the groups of foodstuffs for particular nutritional uses for which specific provisions are laid down by specific Directives. These groups include, among others, infant formulae and follow-on formulae, processed cereal-based foods and baby foods for infants and young children.

Article 27(1)(f) of Regulation (EC) No 889/2008 specifies that vitamins and minerals can be used in the processing of organic food, as far as their use is *legally required* in the foodstuff in which they are incorporated.

Whether the provision of Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children and Commission Directive 2006/141/EC on infant formulae and follow-on formulae would qualify as provisions that impose a legal requirement in the sense of Article 27(1)(f) of Regulation (EC) No 889/2008, should be interpreted in the light of the ECJ's judgment of 5 November 2015 (case C-137/13).

In this judgement the Court mentioned that "Article 27(1)(f) of Regulation No 889/2008 must be interpreted as follows: the use of one of the substances referred to is legally required only when a provision of EU law or a provision of national law compatible therewith directly requires that that substance be added to a foodstuff in order for that foodstuff to be placed on the market. The use of such a substance is not legally required within the meaning of that provision where a foodstuff is marketed as a food supplement, with a nutrition or health claim or as a foodstuff for a particular nutritional use, although that implies that, in order to comply with the provisions governing the incorporation of substances into foodstuffs, (...), that foodstuff must contain a determined quantity of the substance in question".

It should be noted that, in this case, the Court developed its reasoning as regards Directive 2002/46/EC of the European Parliament and of the Council, Regulation (EC) No 1924/2006 of the European Parliament and of the Council and Commission

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<sup>7</sup> Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses. OJ L 124, 20.5.2009, p. 21

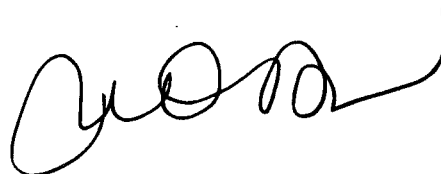
Regulation (EU) No 432/2012, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulation (EC) No 953/2009. In so far as the Court refers to food for particular nutritional purposes within the meaning of Directive 2009/39/EC, it does so only in conjunction with Regulation (EC) No 953/2009.

However, the Commission services are of the opinion that the reasoning of the Court in its judgment of 5 November 2015 (case C-137/13) could also apply to Commission Directives 2006/141/EC and 2006/125/EC, in the sense that even if a minimum amount of a substance (determined quantity) is set out in the annexes to both Directives, those rules do not prevent operators from marketing these products as food; rather they would just preclude them from marketing those products as "infant formulae" and "follow-on formulae" or "processed cereal-based foods" and "baby foods" (unless the minimum amount of substance is present) or to label these products as organic.

Therefore, as a reply to your request and for the reason above explained, the Commission services would consider that foodstuff intended for particular nutritional uses like processed cereal-based foods and baby foods for infants and young children and infant formulae and follow-on formulae supplemented "*with vitamins and minerals of non-agricultural origin*" as you mentioned in your email, cannot be labelled as organic as it does not comply with Article 27(1)(f) of Regulation (EC) No 889/2008.

The present information is provided on the basis of the facts as set out in your email of 19 August 2016 and in the understanding that, in the event of a dispute involving Union law, it is, under the Treaty on the Functioning of the European Union, ultimately for the Court of Justice of the European Union to provide a definitive interpretation of the applicable Union law.

Yours sincerely,



María Angeles BENITEZ SALAS

