EU REGULATION

Time for New Novel Food Definitions?

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by Nigel Baldwin

The much anticipated new Novel Food Regulation is back on the table again in the EU, and Parliamentarians are in the process of debating it. Now, as ever before, it is the definition of what is, and what is not, a “novel food” that is of most importance to all.

If your product of interest happens to meet the controversial definition of “novel food,” then you are likely going to be looking at 1-3 years before you can take your product to market; whereas, if your product does not meet this definition, then off you go to market (once you have completed your health claims submissions!).

So perhaps now is the time to take a bit of a closer look at what is now, and what will be, as far as the current proposal states, and whether or not the proposed definitions will clarify or confuse food and food ingredient producers, regulators and enforcers further.

Defining Novel Foods

The original Novel Food Regulation (Regulation (EC) No 258/97) laid down the definition of a novel food under article 1, point 2, as foods and food ingredients which have not been used for human consumption to a significant degree within the Community before May 15, 1997, and which fall under the following categories:

• Foods and food ingredients with a new, or intentionally modified, primary molecular structure;
• Foods and food ingredients consisting of, or isolated from, microorganisms, fungi or algae;
• Foods and food ingredients consisting of, or isolated from, plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use;
• Foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

Selective Confusion

With this 1997 definition, there were a number of cases where confusion, and in some cases “selective confusion,” arose related to the interaction between this definition and other legislation with positive lists. Sources of this confusion included the food supplements directive (2002/46); the addition of vitamins and minerals and certain other substances to foods regulation (1925/2006); foods for particular nutritional purposes (Directive 2009/39) including foods for special medical purposes (1999/21) and infant and follow-on formula directive (2005/41).

For foods and food ingredients that carry approved health claims, it has taken a few years for the dust to settle on applicable definitions, but the following rules can be assigned:

1. If it has only been used in supplements before May 15th 1997, then food uses are novel, supplements are not novel;
2. If not consumed before May 1997, the product is novel and so you must apply for pre-market approval under Regulation 258/97;
3. Novel foods and food ingredients must then also go through the approval procedures for inclusion onto the Annexes of the above Regulations and Directives.

Generic Disadvantage

The complexity and confusion with the following example of vitamin K2 from natto, gaining novel food approval under Commission Decision 2009/345/EC:

“Vitamin K2 (menaquinone) as a source of Vitamin K as specified in the Annex may be placed on the market in the Community as a novel food ingredient to be used in compliance with Directive 2001/15/EC and/or Regulation (EC) No 1925/2006.”

“This Decision is addressed to NattoParma, Dammensveien 40, PO Box 2896 Solli, N-0230 Oslo, Norway.”

Yet when this product was subsequently incorporated into the various annexes...
via Commission regulation 1170/2009, this vitally important company specific approval as a novel food ingredient was nowhere to be seen, the approval appeared to be generic: 4. Vitamin K: (a) Phylloquinone (phytomenadione)  (b) Menaquinone (**)  (**) Menaquinone occurring principally as menaquinone-7 and, to a minor extent, menaquinone-6.

Reading the 1170/2009 rule alone suggests that you could get this material from any source and freely use it, yet you would have been breaking the law.

False Assumptions
This circumstance is likewise true in a number of additional examples from the world of health claims. While applying for a health claim and a novel food approval in parallel, there is a reasonable assumption that if the health claim has been granted then the product should likewise be considered safe and approved to be used. However, this is a false assumption, as illustrated in table 1, with the example of betaine, which has a positive health claim under Commission Regulation of betaine, which has a positive health as illustrated in table 1, with the example used. However, this is a false assumption, be considered safe and approved to be as menaquinone-7 and, to a minor extent, menaquinone-6.

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Complex Procedure
These examples illustrate that the legislation and related regulations are complicated and one should not assume the ability to automatically cross-reference by the reader. In fact, it is not uncommon for multiple regulatory approval processes run in series for new forms of vitamins and minerals. If you wanted to Annex 2 of the supplements directive a new form of a vitamin or mineral that had been consumed before May 1997, you would have to prepare a dossier compliant with the Scientific Committee of Foods guidance document related to the addition of nutrients to food, and EFSA would have to review this dossier.

Table 1: Approved EU Health Claim on Betaine

| Betaine | Betaine contributes to normal homocysteine metabolism | The claim may be used only for food which contains at least 500mg of betaine per quantified portion. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 1.5g of betaine. | In order to bear the claim information shall be given to the consumer that a daily intake in excess of 4g may significantly increase blood cholesterol levels. |

4. Vitamin K:
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(b) Menaquinone (***)

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Despite this approved health claim, there is a specific Commission Decision (2005/580/EC) stating: “Betaine may not be placed on the Community market as food or food ingredient.”

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If this new form of vitamin or mineral is also classified as “novel,” then a “novel foods” dossier is reviewed by one member state followed by the other 27, followed by review by EFSA. The process is a mess, it doesn’t make sense and it adds months and months to the approval process unless you are able to get agreement of “practical measures” that are granted on a case-by-case basis to speed things up. New legislation should surely take the opportunity to formalize such practical measures? So, you would think that the new proposed regulation might say: “if you have a new form of vitamin or mineral, since there is already an EFSA assessment required, it should logically now be excluded from novel foods rules in order to avoid double assessment and inefficiency.”

Time for New Definitions?
Well taking this hypothesis into consideration, let us look at the proposed new definitions which are as follows:

“Novel food” means all food that was not used for human consumption to a significant degree within the Union before May 15, 1997 irrespective of the date of accession of the various Member States to the Union and includes in particular:

(i) Food to which a new production process has been applied as referred to in point (i) of this paragraph; or

(ii) Food containing or consisting of “engineered nanomaterials,” as defined in Article 2(2)t of Regulation (EU) No 1169/2011;

(iii) Vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where:

a. A new production process has been applied as referred to in point (i) of this paragraph; or

b. Such substances contain or consist of “engineered nanomaterials” as defined in Article 2(2)t of Regulation (EU) No 1169/2011;

(iv) Food used exclusively in food supplements within the Union before May 15, 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC.”

“Traditional food from a third country” means novel food, other than the novel food as referred to in point (a)(i) to (iii), which is derived from primary production, with a history of safe food use in a third country;

“History of safe food use in a third country,” means that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a large part of the population of a third country.

OK, so looking at these details, we can see that:

- The cut-off date is unchanged;
- Engineered nanomaterials are added;
- The situation regarding prior use in supplements only is clarified;
- Vitamins and minerals are specifically now in scope rather than removed to avoid duplication of regulatory procedures. So this confirms that two reviews, two regulatory procedures, and two pieces of legislation remain in effect; and;
- Traditional foods from third countries opens the door to a different type of assessment for some minimally processed foods.

Meeting the Criteria
So it seems the new rules are solving some problems but not others. Certainly in the case of vitamins and minerals, one could argue that the concept of “REFIT” (the European Commission’s “Regulatory Fitness and Performance program) does not seem to quite fit yet? Or maybe the fitness and performance criteria will be met when the authorities look to modify and streamline the other related regulations and directives. We are just not quite there yet with this new novel food regulation. Until such time, those with less regulatory expertise and in particular small and medium sized businesses will probably continue to struggle when attempting to interpret their compliance obligations.

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