Inside “Natural” Flavor Law

Among the major changes that the new EU Regulation on flavorings introduces, is a revision to no longer make a distinction between “nature-identical” and “artificial” flavoring substances.

by Maud Perrudin

The EU Regulation on Flavorings (Regulation (EC) No 1334/2008) came into effect from January 20, 2011 onwards and repeals the current Directive 88/388/EEC. As a matter of principle, this Regulation is directly applicable in all the Member States and must be given an autonomous and uniform interpretation throughout the Community. This is assured under the control of the European Commission and the ultimate jurisdiction of the Court of Justice of the European Union.

That being said, the practical implementation of some provisions of this text is more than likely going to raise difficulties of interpretation. Indeed, despite the two-year period allowed for a smoother transition to the new harmonized regulatory framework, no official position has yet been adopted and made public at EU level for clarifying the way flavorings can be used and labeled in compliance with the Regulation.

Regulation Background

The Regulation applies to flavorings which are used or intended to be used in or on foods (without prejudice to the specific provisions on smoke flavorings set in Regulation (EC) 2065/2003) and to source materials used for the production of flavorings, but also to (i) food ingredients with flavoring properties, (ii) food containing flavorings and food ingredients with flavoring properties, as well as (iii) to source materials for food ingredients with flavoring properties.

Among the major changes it introduces, the Regulation revises certain of the current definitions and in particular that of “flavoring substance” to no longer make a distinction between “nature-identical” and “artificial” flavoring substances. Also, the remaining definition of “natural flavoring substance” now includes reference to the processes allowed in their production (i.e. a definition of “appropriate physical process” and a list of the traditional food preparation processes).

Identified Flavorings

With respect to the conditions for use of flavorings, the Regulation identifies the flavorings for which no evaluation and approval is required and subjects the other flavorings and source materials to approval and inclusion in the Union list [the term “Community list” used in the Regulation will no longer be used in line with the Lisbon Treaty in accordance with the Common Authorization Procedure established in Regulation 1331/2008 [see “Harmonizing the Law” by Jean Savigny, TWFJ, Feb 2009].

The most important interpretation issues come from the labeling requirements. Indeed, the Regulation makes considerable changes to the rules governing the use in the description of flavorings of the term “natural” which apply to flavorings, whether sold as such to the food industry or to the final consumer.

I) Permitted Flavorings

The flavorings and source materials for which a pre-marketing authorization is required may only be marketed in the EU and used in or on foods if they have undergone the EU Common Authorization Procedure and are included in the Union list annexed to the Regulation (Annex I). This is the case of (i) “flavoring substances,” (ii) “flavoring preparations” obtained from source material other than food, (iii) “thermal process flavoring” obtained partially or totally from source material other than food, and (iv) “other flavorings” obtained from source material other than food. The other flavorings, for which no evaluation and approval is required, can be used in or on foods provided they meet the following conditions: (i) they do not, on the basis of the scientific evidence available,
pose a safety risk to the health of the consumer and (ii) their use does not mislead the consumer.

**Listed Substances**

The principle of a positive list that should be set up after the completion of the evaluation program foreseen by Regulation (EC) 2232/96 is maintained. Accordingly, starting from the EU Register of flavoring substances (Commission Decision 1999/217 as amended) some 2,000 substances from about 2,600 have been subject to evaluation by the EU Scientific Committee on Food (till 2001) and then the European Food Safety Agency (EFSA).

In early November 2010, EFSA announced its completion of the first stage of that safety review. While "the majority of flavoring substances (1667) do not give rise to safety concerns," according to the EFSA panel, further data on around 400 substances have been asked to manufacturers of the flavoring substances concerned to allow the completion of the evaluation. EFSA should finalize its assessment of those latter substances on the basis of the additional data received [probably by the end of 2014].

**Little Risk**

Based on EFSA's work, the list of flavoring substances should have been adopted by the Commission by December 31, 2010 at the latest and introduced into the Union list annexed to the Regulation. However, due to some difficulties, notably in reflecting the specific situation of substances for which additional data have been asked, the list has not yet been adopted.

Indeed, noting that the majority of these substances have been positively evaluated by other scientific bodies such as JECFA (FAO/WHO Joint Expert Committee on Food Additives), FEXPAN (FEMA Expert Panel) and the Council of Europe, they are unlikely to pose a risk to health and, hence, it would arguably be inappropriate to exclude them at this stage from the Union List. Accordingly, the substances subject to re-assessment will most probably be included in the Union list accompanied by specific transitional measures. Once adopted by the Commission, published and entered into application [date still unknown], the Union list will only be legally binding 18 months later. In other words, after that 18-month period starting from date of application of the Union list, it will not be permitted to place on the EU market and use in or on foods any flavoring substance not on the list. That being said, as certain substances are expected to be granted transition periods, the binding application of the list may be further delayed.

**Subject to Approval**

The other flavorings subject to approval may be placed on the market and used in or on foods provided they have undergone the Common Authorization Procedure. This procedure applies in theory from the date of application of the implementing measures foreseen by Regulation 1331/2008 (i.e. the content, drafting and presentation of the application, the arrangements for checking the validity of applications, and the type of information that must be included in the opinion of the Authority) to be adopted by the Commission based on scientific advice from EFSA.

The late adoption by EFSA [in May 2010] of its guidance on the data required for risk
assessment of flavorings [with the exception of the “other flavorings” the nature of which remaining unclear it is more appropriate to go into a process of inter- and pro-active exchange of information between Commission, Applicant and EFSA before the actual submission of data] has postponed the adoption by the Commission of its implementing measures.

Though initially foreseen by December 16, 2010, the adoption of those measures is now expected for the first semester of 2011. As a result, taking into account also the delay of EFSA in evaluating the flavoring substances (those included in the Register and some new substances), the initial Union list will only include flavoring substances and, hence, only apply to them and not to the other flavorings and source materials for which an evaluation and approval is also required.

I) New Requirements:

The major interpretation issues come from the changes introduced by the Regulation to the labeling rules governing the use in the description of flavorings of the term “natural,” applying to both the sales designation of flavorings sold as such to the food industry or to the final consumer and the designation of flavorings in the list of ingredients of final flavored foodstuffs.

The Regulation still reserves the term “natural” to the description of flavorings the flavoring component of which comprises only the following categories: flavoring preparations and/or natural flavoring substances. However, depending on the composition of their flavoring component and flavor/taste perception, natural flavorings may be designated by four different terms:

• “natural flavoring substances” provided the flavoring component comprises only flavoring substances.
• “natural ‘x’ flavoring” (e.g. “natural lemon flavoring”) provided the flavoring component has been obtained exclusively or by at least 95% by w/w from the source material referred to (e.g. lemon) provided the said source can be easily recognized. The other maximum 5% by w/w from other sources should only be used for standardization or to give a, for example, more fresh, pungent, ripe or green note to the flavoring.
• “natural ‘x’ flavoring with other natural flavorings” (e.g. “natural raspberry flavoring with other natural flavorings”) provided the flavoring component is partially (less than 95%) derived from the source material referred to (e.g. raspberry), the flavor of which can easily be recognized.
• “natural flavoring” provided the flavoring component is derived from different source materials and where a reference to the source materials would not reflect their flavor or taste.

While the terms “natural flavoring substances” and “natural ‘x’ flavoring with other natural flavorings” are new possible designations introduced by the Regulation, the existing terms “natural ‘x’ flavoring” and “natural flavoring” are now subject to different conditions of use. These changes impact both the labeling of flavorings sold as such to the food industry and their declaration in the list of ingredients of the final flavored foods, raising a large number of interpretation issues common and specific to the two situations.

In view of these difficulties, it will be necessary to develop a harmonized EU approach. The food industry and the flavor industry at national and EU levels have already been working together with this aim in view. Now that the Member States will be enforcing the Regulation, confronting hence with practical interpretation issues, the Member States and the Commission might wish to develop official EU guidance.

Using “Natural”

Unlike the current situation, the Regulation requires a numerical minimum percentage of 95% of the flavoring component, which must come from the source referred to (also called the “95/5 rule”) to qualify for the designation “natural ‘x’ flavoring.” Under Directive 88/388, in the absence of a legally binding numerical minimum percentage, the majority of the flavor industry agreed on a minimum of 90%. As a consequence of this numerical change, some existing “natural ‘x’ flavorings” may need to be reformulated in order to remain in compliance with the applicable legislation.

The new “natural ‘x’ flavoring with other natural flavorings” designation allows the use of the term “natural” together with the name of the source, even though the 95/5 rule is not met, provided the source referred to is recognizable. That being said, this perception criterion, subjective by definition, is one the major issues occurring with the Regulation. According to the European Flavor Association (EFFA) “it is recognized that different flavoring materials have different sensorial thresholds and that flavor-perception cannot be quantified easily. The qualification for meeting the requirement ‘can easily be recognized’ will therefore be based on expert opinion, by e.g. a flavorist or a sensory panel evaluating the consumer product.”

From an enforcement standpoint, the following questions remain: who within the national control bodies will decide if the flavor perception condition is met? And how?

Practically also, when referring to the name of the source

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What's Up for Vanilla?

Nielsen-Massey Vanillas has been producing premium pure vanilla products since 1907. The company’s product offering ranges from its ever-popular Madagascar Bourbon Vanilla to custom blends and flavors created for specific customer needs. Craig Nielsen, CEO of Nielsen-Massey Vanillas offers his thoughts on the outlook of the market.

What are your predictions for the market outlook?
Looking at the vanilla market as a whole, we have seen increased demand again in 2010, and while it has not reached the levels of the disastrous 2003-2004, there is certainly an upward trend in worldwide consumption. At that same time, we have seen relatively stable pricing. The projections for vanilla to be released in 2011 are also in line with the previous two to three years.

How significant is the natural trend for the vanilla business and can these demands be met?
Vanilla is not innovative. It is pure and natural, and that in itself is where we see vanilla’s strength and future. Product developers want clean ingredient labels. They want to work with what is naturally available and a consumer can understand. If you want to make the world’s finest ice cream, you need four items: milk, cream, sugar and pure vanilla.

What is in your development pipeline?
We are always looking at ways to deliver pure vanilla in different flavor systems. That’s why we have a paste, a powder, and a sugar as carriers for our pure vanilla flavor.
in either the term “natural ‘x’ flavorings” or “natural ‘x’ flavoring with other natural flavorings,” it remains unclear from the reading of the Regulation, whether a flavoring the flavoring component of which contains natural flavoring substances and/or flavoring preparations derived. For example, from orange and lemon can be labeled with a generic term instead of mentioning each source in the descending order by weight so as to read, depending on the total percentage of this orange/lemon source (+/- 95%), e.g. “natural citrus flavoring” or “natural citrus flavoring with other natural flavorings.”

Ingredient Listing
The flavor-perception criterion is also an issue for the food industry, as that perception may vary from a final flavored foodstuff to another, depending on the food matrix. Its evaluation might therefore, as appropriate, need to be carried out by the food industry — based e.g. on sensory panel evaluations — for each final flavored food in order to determine the appropriate designation in the list of ingredients. While the food manufacturer may rely on the sales designations of the flavorings it purchases and may in theory declare them as such in the list of ingredients, the resulting list is in many cases very likely to be long and take much more space on the label than before. For that reason, the food manufacturer may wish to re-group the flavorings used under a global flavorings designation.

Potential Distortion
The generic term “flavorings” remains applicable to designate all kind of flavorings regardless of their composition and flavor-perception but does not allow informing the consumer on the “natural” character of the flavorings. The non-availability of the general term “natural flavorings” to cover multiple natural flavorings, e.g. used in the same product or in a multi-flavor products pack, is in that regard the major practical concern of the food industry. The designation “natural flavoring” without reference to the specific source material being reserved under the Regulation for flavorings from different source materials the flavor or taste of which is not easily recognizable. For example, which of the following possible designations is acceptable in the list of ingredient of a biscuit containing a “natural raspberry flavoring with other natural flavorings” and a “natural lemon flavoring”? Under which conditions?

• “natural raspberry flavoring with other natural flavorings, natural lemon flavoring” or “flavorings” or “raspberry and lemon flavorings” or “natural flavoring substances” or “natural raspberry and lemon flavoring with other natural flavorings” or “natural raspberry flavoring with other natural flavorings” or “natural lemon flavoring with other natural flavorings”?

Further, noting that the Regulation only regulates the designation of flavorings in the list of ingredients of final flavored foodstuffs without however covering their declaration in the overall label, the use on the front of pack of claims such as “with natural flavorings” or “no artificial flavoring” as well as pictorial depictions of flavoring sources remains uncovered by harmonized EU rules and, thus, subject to the discretion of the Member States, allowing hence potential distortion within the EU.

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