

The Significance of GRAS and Nature-Identical for Worldwide Harmonization of Flavor Regulation

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The three main pillars on which food regulations of all developed countries are based are:

- Safety of food and the protection of public health;
- Information to the consumer; and
- Fair competition between manufacturers.

Food Safety and Public Health

The first issue, food safety and public health, which is usually of predominant importance for food additives, has hardly ever been a problem as far as flavoring substances are concerned. The main reasons for this exceptional position are:

- Flavoring substances are identical to or closely related to the flavorings occurring in traditional, commonly consumed food.
- They are widely consumed in very small dosages.
- The several hundred that are being used in the largest quantities have been evaluated for safety, and no major concerns have come up.
- The risk for incidental significant overdosage is eliminated by their overpowering flavor strength. Their sensory threshold is far below their threshold of toxicity.

For these reasons, the regulation of flavoring substances as part of the food regulations in all developed countries has taken the form of classification rather than that of specific approval of certain flavoring substances with the exclusion of all others.

The two major trends for the classification of most flavoring substances are: Generally Recognized as Safe (GRAS) in the USA, and Nature-identical in most European countries and many other parts of the world.

The basis of each classification is completely different.

GRAS is based on expert safety evaluation of individual substances. The Nature-identical is based on the identity to traditional and unavoidable low levels of ingredients in foods generally assumed to be safe. So far both classifications have led to systems of flavor regulation that have served well for the protection of

public health. Flavoring substances have not provoked any of the many concerns about the safety of foods.

This is the reason why consumers have been generally confident about the safety of the flavorings in their foods, with only a generally strong bias against "artificial" flavorings.

The US flavor industry, organized as FEMA, has taken on the task of giving substance to the GRAS concept of the Federal Regulations by publishing lists of substances reviewed by their eminent, scientifically qualified Expert Panel. In this way FEMA notifies the public and the FDA about the many flavoring substances in use. However, these lists are not all-inclusive, and other substances may be GRAS-based on the criteria of the Code of Federal Regulations. FDA has watched the situation closely, and even though they have specifically endorsed only a limited number of substances on the FEMA/GRAS lists, the agency has not shown concern about the safety of the food flavorings in use in the US. To the best of my knowledge, the agency has never created a program to police compliance with any published list of flavoring substances in domestically manufactured or imported foods. This is undoubtedly true because of the public confidence about the safety of flavoring substances.

The fact that GRAS lists exist, and that there are many additional publications on the safety of flavoring substances and on their quantities and dosages used, has allowed the FDA to concentrate its enforcement on areas of greater importance as far as food safety is concerned. If they were to have the opportunity to deal with the control of flavoring substances, both in domestic and imported products, they would certainly do this with a clear understanding for their priority in regard to their potential for health hazard based

on safety evaluation. It is not surprising that FDA has guided and supported the worldwide implementation of priority setting in this area, and that the only major database for this purpose is on the FDA computer.

In Europe, the newly formed European Community, (EC) has to deal with

GRAS	—	Generally Recognized as Safe
FEMA	—	Food Extract Manufacturer's Association
FDA	—	Food and Drug Administration
EC	—	European Community
FAO	—	Food and Agriculture Organization of the United Nations
WHO	—	World Health Organization

the harmonization of flavor regulations between its individual member countries, most of which allow the use of all nature-identical flavoring substances. The European flavor industry, which so far has not been required to specifically identify the flavoring substances they consider nature-identical, is now preparing inventories of such substances. They are also preparing an inventory of artificial flavoring substances, and a separate inventory of natural source materials. At the moment we are aware of almost 5,000 flavoring substances present in food or added to it.

It is obvious that the European legislators, not having dealt with such large numbers of individual substances before, look for support from the GRAS procedure and other existing reviews, such as the one used by the Council of Europe Working Group. This is probably in the belief, shared by consumers, that lists, just by their paper presence, provide protection against potentially unsafe food ingredients. In this respect, these lists remind me of Hans Christian Andersen's fairy tale about the emperor's new clothes. As long as everybody believes that the protection is there, things seem to be fine, and flavoring substances present no practical hazard in the first place. But they overlook that the lists are not being enforced, and could in actual practice not be enforced even by the largest food-regulatory agency in the world.

The analytical identification of flavoring substances, in particular after they have been incorporated in food at very

low levels, is an extremely expensive research project. Moreover, even if the analysis could identify the presence of a flavoring substance that does not occur on an inclusive list, it is quite likely that this would be a substance known to occur naturally in traditional foods or spices. It would be virtually impossible to prove whether such a material has been added as a chemically defined substance, or as an ingredient of a food or an extractive thereof. In a tightly regulated and controlled area, factory inspection might provide such proof. However, in view of the extensive international trade in manufactured foods, this does not provide a practical solution either.

Requiring the publication of inclusive lists has a detrimental effect on flavor research. Such research, of great importance for the development of better and more affordable consumer foods, will only be carried out by industry if it might result in an advantage in quality or market share. This is not the case if the findings have to be shared with all domestic and foreign competitors in the form of a published list. This explains the minimal growth of the GRAS lists, compared to the new flavor developments in Europe.

Consumer Information and Competition

So far we have looked at the GRAS and nature-identical concepts only from the point of view of safety and public health. But how do they affect the other main principles of food regulation: consumer information and fair competition and trade?

The GRAS concept only reviews the safety of materials, without any regard to their natural occurrence. Any flavoring substance in the US, not covered by the Code of Federal Regulations definition of "natural" (21 CFR 101.22 a 3) is an artificial flavoring substance, and has to be labeled as such on the food containing it. This should not present a problem for food industry professionals, for whom only the organoleptic quality and field of application of flavorings are relevant issues, not whether they originate from nature or from chemical synthesis.

However, the food industry has to deal with a consumer population which, in part because of misleading advertising over the years, has come to regard "artificial" as inferior, a low quality substitute for real "natural" flavorings that are thought to be so much more beneficial. The average, and even many above average consumers do not realize that nature is entirely chemical in composition and processes, and that both nature and kitchen cooking create all these beautiful natural flavoring substances by chemical processes just like the chemical syntheses in laboratory and factory!

Real consumer education is the only answer to this problem, but those who honestly tried this approach were not rewarded. So the only practical approach to avoid the derogatory word "artificial" has been to use only materials that do not have to be labeled as such. In the US that means that the flavoring materials have to be made "natural," since this is the only alternative to "artificial."

Only insiders can estimate how much research has gone into the creation of such "natural" flavoring substances, often at a high cost which eventually has to be paid by the

consumer. And even then the processes used are occasionally so questionable as to their compliance with the regulatory definition of natural flavor that the decision whether to use them or not is often up to an individual manufacturer. It is obvious that this approach will not provide flavorings that meet with the justified expectation a consumer may have when he sees the labeling "natural flavor." Can we blame an average consumer for expecting that a natural raspberry flavor has been made from raspberries? Does he expect a blend of chemical compounds, made by complicated and ineffective procedures so that they could be argued to meet the CFR definition of natural flavor? Moreover the fact that even flavor manufacturers cannot agree among themselves on what constitutes a natural process creates a clear potential for unfair competition.

The labeling aspect of natural versus artificial flavors is only a matter of consumer information and has no impact on the safety of the food to which they are added. It is understandable that this matter does not rank very high on the agenda of regulatory agencies whose major concerns deal with the safety of the food. However, it is clear that, in respect to both honest consumer information and fairness of competition, the regulation of natural versus artificial flavors as it presently exists in the US requires considerable clarification.

The approach taken by European and other countries, as well as the *Codex Alimentarius*¹ of FAO/WHO, to recognize

a category of flavoring substances as "nature-identical," has provided a solution for this labeling problem. The nature-identical concept is based on the idea that only those man-made substances that do not pre-exist in food as prepared for human consumption are truly "artificial." All flavoring substances identified in traditional food are classified as "nature-identical." However, if such nature-identical flavoring substances, prepared by deliberate chemical transformations by a flavor manufacturer, do not have to be considered "artificial," they certainly do not meet the consumer expectations for "natural" flavors either. The advantage of having the category "nature-identical" is that nature-identical flavoring substances added to food do not have to be declared on the food label as "artificial flavor," only as "flavor."

As long as vertical food regulations in many countries, as well as the monographs of the *Codex Alimentarius*, distinguish between the use and labeling of artificial and nature-identical flavoring substances, these categories should be kept separate. A correct designation as "nature-identical" is preferable over having a questionable "natural" as the only alternative to a mandatory labeling as "artificial."

The preferential treatment of nature-identical flavoring substances in Europe and elsewhere has led to the use of no more than about a dozen permitted artificial, i.e. not-nature-identical, flavoring substances. In the US, however, where the origin of the substances never was an issue,

hundreds of such artificial flavoring substances not identified in nature occur on the GRAS lists. This large block of not-nature-identical substances represents a major difference between the flavoring substances available to the industry in Europe and those available in the US. It will be one of the largest stumbling blocks in achieving harmonization between the flavor regulations on both sides of the Atlantic.

The best possible way to overcome this difference would be by not unnecessarily restricting the use of flavoring materials permitted and found useful at safe levels in any well regulated country. In addition, the requirements for labeling foods according to the origin of the flavorings present should be simplified in all countries, including the USA, since the distinction between natural and artificial flavor provides no meaningful information.

Forecast

Over the next several years, detailed regulations will be worked out for the harmonization of the flavor regulations between the European countries, hopefully in such a way that also a harmonization between Europe and the US is also possible. If this can be achieved, I expect that for flavorings both "nature-identical" (as a regulatory definition) and the GRAS lists will fade away into the cultural/historic background of the respective countries.

I truly hope that during the process of harmonization, particularly in Europe, good science and common sense will prevail. I hope that rote testing of thousands of substances, sacrificing tens of thousands of animals, will be avoided. A practical harmonization could be achieved by establishing a basic inventory of flavoring substances generally known to have been consumed without perceived hazard. All substances on such a basic inventory, irrespective of their origin, should in principle be subject to safety evaluation, according to a priority-setting procedure, ensuring that they will be reviewed in order of their potential hazard to human health based on chemical structure and consumption.

Moreover a mechanism should be established for the introduction of small quantities of additional materials under certain conditions. A procedure for the confidentiality of the use of such additional materials would provide the incentive for further research into the flavor of foods, in the interest of all consumers.

The harmonized regulations should also foresee in a labeling requirement for flavorings on foods that does not distinguish between flavorings from different origin. A simple reference to "Flavorings" on the list of ingredients on the food packaging would suffice. It would not lead to unjustified consumer expectations on a basically insignificant aspect of the food, and it avoids a waste of research and production costs on ways to manufacture so-called "natural" substances. It also allows flavor research and production to be geared towards the best consumer product in fair competition.

Reference

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1. *Codex Alimentarius* is published by World Health Organization, Geneva, Switzerland

