

Consumer Exposure to Chemically Defined Flavoring Substances

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The following observations should put into perspective the exposure of consumers to flavoring substances. This may help us to establish a reasonable priority for the safety evaluation of the unmanageably large number of flavoring substances occurring in food and used by the flavor industry.

Flavoring substances in the U.S. are exempt from the food additives regulations if they are Generally Recognized as Safe (21 CFR 170.30). In addition to having been used in food prior to 1958, through experience based on common use in food, a substance may be considered GRAS based on safety evaluation by experts qualified by scientific training and experience, using scientific procedures. Even though, strictly speaking, the resulting FEMA GRAS lists are not limitative in the sense that they exclude all other flavoring materials, they at least establish an inventory of ingredients proposed for use in flavorings by the U.S. flavor manufacturers and evaluated for safety by experts.

In addition to information about their toxicological and pharmacological properties, and their metabolic pathway in humans, a very important factor in the safety evaluation of flavoring substances is the quantity to which the consumer is exposed.

The existence of GRAS lists makes it much easier to conduct surveys on the quantity ("poundage") of flavoring substances in the U.S. as opposed to other countries where the individual manufacturers prefer not to share infor-

mation on what flavoring substances are being used. Several such surveys have been conducted in which the Flavoring and Extracts Manufacturer's Association (FEMA) closely cooperated with the National Academy of Sciences/National Research Council as part of a much wider survey of the quantity of food additives reported to be used in the U.S.A. The results of the last survey, on the quantities used in 1982 have been published by the National Academy Press, as PB84 162148.

At the time of the 1982 survey, FEMA GRAS lists 3 through 12 had been published. The 1982 survey covered 1175 chemically defined flavoring substances occurring on these GRAS lists, on the list of synthetic flavoring substances in 21 CFR 172.515, as well as a few additional substances (1,4-cineole, linalool oxide and 2-ethyl furan). This number of 1175 was established by eliminating from the survey those materials that are non-flavoring materials, natural flavorings or flavoring substances, and amino acids. For the purpose of this review I have ranked these 1175 substances in descending order of the quantity reported.

It will not come as a surprise to anyone experienced in formulating flavors that the volume of use in total kg per year, as reported, is not evenly distributed over all flavoring substances that occur on the GRAS lists. Still, it is amazing how lop-sided the distribution is. In Table I, the number of substances occurring in the volume category, expressed in kilograms per year, is shown, as reported in the last survey over 1982.

Table I. Volume of Use of All Flavoring Substances

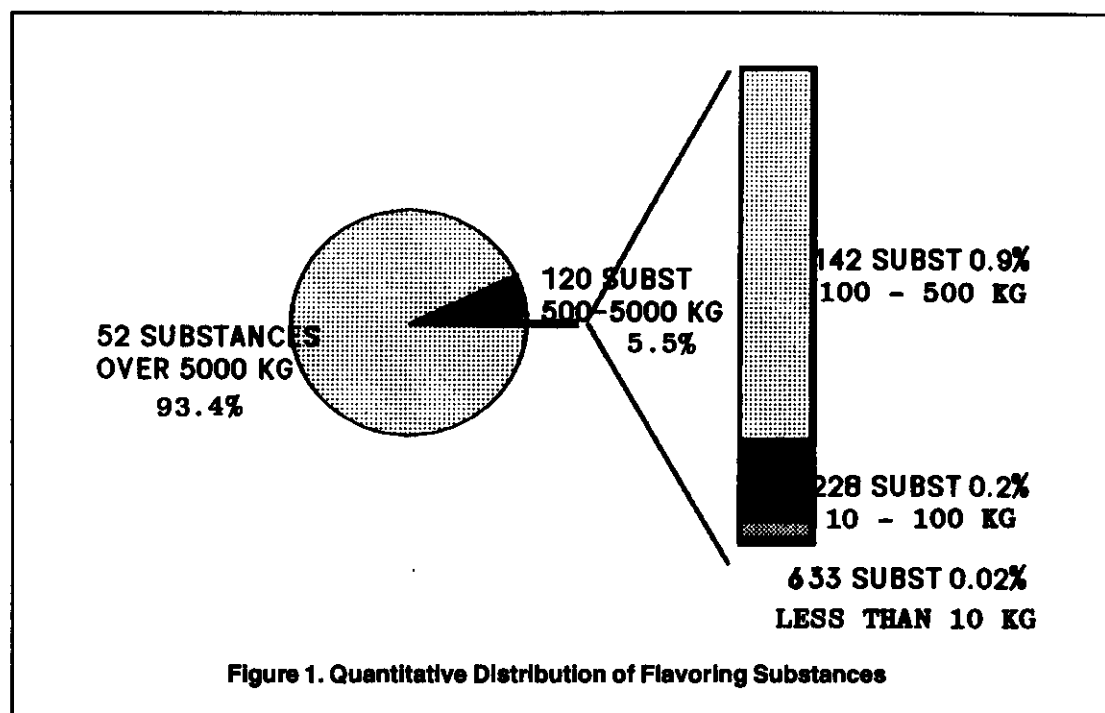
Number of Flavoring Substances In This Category	Usage Per Year In kg.
>100,000	8
50,000 - 100,000	6
20,000 - 50,000	9
10,000 - 20,000	13
5,000 - 10,000	16
2,000 - 5,000	42
1,000 - 2,000	36
500 - 1,000	42
200 - 500	82
100 - 200	60
50 - 100	65
20 - 50	92
10 - 20	71
<10	<u>633</u>
	1175

Table I shows that of the 1175 chemically defined flavoring substances, on the FEMA and/or FDA GRAS lists valid at the time of the survey, only 130 were used in a quantity of more than 1000 kg per year in the U.S. Moreover it shows that 633 of these 1175 substances (more than half of them) were used in a quantity of less than 10 kg per year.

This distribution of flavoring substances over the various quantitative categories is also clearly shown in figure 1. The narrow segment covering 1003 flavoring substances has been exploded into a bar which clearly shows the minute contribution the majority of flavoring substances makes to the total quantity used.

It is also interesting to review the annual volume (poundage) data as published in the 1982 survey for various classes in which chemically defined flavoring substances can be divided. One possible division is in nature identical flavoring substances versus artificial flavoring substances.

For this analysis we cannot use the definition of "artificial flavor" of the Code of Federal Reg-



ulations (21 CFR 101.22.a.1) since it covers both artificial (in the sense of not nature-identical) and nature-identical. We will use, therefore, the definitions of "artificial" and "nature-identical" adopted by the Codex Alimentarius (FAO/WHO):

Artificial flavoring substances are those substances which have not yet been identified in natural products intended for human consumption, either processed or not.

Nature-identical flavoring substances are substances chemically isolated from aromatic raw materials or obtained synthetically; they are chemically identical to substances present in natural products intended for human consumption, either processed or not.

Of the 1175 chemically defined flavoring substances reported in the 1982 survey, 336 were identified by Experts of the International Organization of the Flavor Industry as not yet found in traditional food, and they are therefore truly "artificial" as defined by the Codex Alimentarius.

For practical purposes I have subdivided these "artificial" flavoring substances into two classes, based on their usage data. It appears that a small number of artificial flavoring substances are

widely used in an annual quantity of more than 1000 kg. I call these "Major Artificial Flavoring Substances" in Table II. Several hundreds of other artificial flavoring substances are only used in relatively small quantities, less than 1000 kg per year in the U.S., and these I have grouped together in Table II as "Minor Artificial Flavoring Substances."

The quantitative aspects of "nature-identity" have been studied for many flavoring substances and the results have been expressed in the Consumption Ratio (CR). In the 1982 survey, usage data was reported on 839 nature-identical flavoring substances. Consumption Ratio data were calculated for 500 of these.* In order to review to what extent the consumer exposure to nature-identical flavoring substances has been covered by CR data, I have separated out the usage figures for those 500 substances in Table II.

Table II presents a review of the volume of the flavoring substances in the categories referred to above, in tons (1000 kg) reported for 1982.

From Table II it is apparent that, as far as significant consumer exposure is concerned, the main attention should be directed towards those

*The third cumulative series of Consumption Ratios on 499 nature identical flavoring substances was published in *Perfumer and Flavorist*, Vol. 12, No. 4, 27-86 (August/September 1987)

Table II. Distribution of the Usage of Flavoring Materials over Various Categories

Flavoring materials	Tons per Year
336 Artificial flavoring substances	
17 Major materials (over 1,000 kg each per year)	188.5
4 Materials(ethyl vanillin, ethyl maltol, butyl butylryllactate, EMPG)	165
Remaining 13 Materials	23.5
319 Minor materials	10.8
Total artificial flavoring substances	199.3
839 Nature Identical flavoring substances	
500 materials with Consumption Ratio data	3,654.6
339 materials without Consumption Ratio data	121.8
14 major materials (over 1,000 kg each)	109.1
Next 36 materials (over 100 kg each)	10.5
Remaining 289 materials	2.2
Total Nature Identical flavoring substances	3,776.4

nature-identical materials with a CR of less than 10 (191 of the 500), approximately 50 nature-identical materials on which the CR still has to be established, and a limited number of major artificial flavoring materials. The usage data also show that Consumption Ratios, even though incomplete, are already available on 97% by weight of all nature-identical flavoring materials in use in the U.S.

It is also interesting that the consumption, as unavoidable components of traditional food, of the 500 flavoring materials on which a CR has been established, is 283,105.8 tons per year, compared to a total quantity added in the form of flavoring of only 3654.6 tons. Consumers in the U.S. are therefore exposed to a total quantity of 286,777.5 tons of these nature-identical flavoring materials, 98.7% of which is unavoidably present in traditional foods. The number of nature-identical flavoring substances reviewed in this analysis form only the tip of the iceberg, if we consider how many potential flavoring substances occur in traditional food. At this time close to five thousand flavoring substances have been identified in traditional foods, and that number is growing fast because of improving analytical methods and lower detection limits.

I want to stress that there is no correlation between the quantity of a flavoring substance used and its importance for flavor creation. Low usage figures should not be interpreted to mean that such substances are not valuable or not needed

by the flavor industry. This is in particular the case if the target for the development of new flavors is to match the flavor quality of traditional foods. It is not possible to approach that goal without using a pattern of numerous individually minor quantities of flavoring materials similar to the natural flavorings present in such traditional foods. Their collective organoleptic effect determines the desirable flavor of the food.

Generally speaking, low and very low volume flavoring materials will not be used in high concentration in a very narrow area of application. The practice of flavor creation causes these minor components to be spread out over a large volume of flavorings, in very low concentration.

I hope that the above considerations will be useful to help put in perspective the real and assumed problems in setting priorities for the safety evaluation of the very large number of flavoring substances that has for so long baffled regulators in so many countries.

Another poundage survey, on the quantities of flavoring substances used during 1987, is being planned jointly by NAS/NRC and FEMA for 1988. It will be interesting to see if the trend shown in the 1982 usage, a relatively very low usage of many minor artificial and nature-identical flavoring substances, is maintained.

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