Some Aspects of Flavourings Legislation

By Francois-Claude Guglielmina, Federation Francaise des Syndicats de L'Aromatiques, Paris, France

Flavourings legislation is a difficult subject and could, indeed, be the subject of a whole book. Therefore, my goal here is to present the main lines leading to the different flavourings legislation in the world.

Every human activity is submitted to legislation. Everyone experiences this daily and flavourings manufacture and sale are no exception. The main objectives of a flavourings legislation are:

- To protect consumer's health
- To prevent frauds and introduce equivalent conditions of competition for all manufacturers

Let us try to put ourselves in the legislators' place. First, they have to become familiar with the different flavouring ingredients—the flavouring substances. The accepted *Codex Alimentarius* terminology classifies the flavouring substances in the following categories:

- *Natural flavouring substances:* Isolated from a natural aromatic raw material by physical methods (distillation, extraction by means of a solvent, expression)
- *Nature-identical flavouring substances:* Obtained by synthesis or isolated through chemical processes from a natural aromatic raw material and chemically identical to a substance present in natural products intended for human consumption, either processed or not
- *Artificial flavouring substances:* Not yet identified in a natural product intended for human consumption, either processed or not

Table I shows how the natural raw materials are used in flavourings. The infusions, "alcoolats," concentrated juices, concretes, absolutes, and essential oils are mixtures of natural flavouring substances which can be isolated by means of physical processes. An example is natural menthol precipitated for mint oil.

Infusions are obtained through maceration of plants, parts of plants or fruits in alcohol, "alcoolats" by distilling the materials together with alcohol.

By extracting the plants or parts of plants by means of a volatile solvent, and subsequent elimination of the solvent, one gets the concrete. Absolutes are obtained by dissolution of the concrete in alcohol and subsequent elimination of the waxes. Essential oils are obtained through steam distillation or by expression.

Table II shows the synthetic materials used in flavourings. From natural aromatic raw materials, well-defined chemical substances are isolated through a chemical process. An example is the isolation of citral by means of its bisulfitic

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Table I. Natural Raw Materials

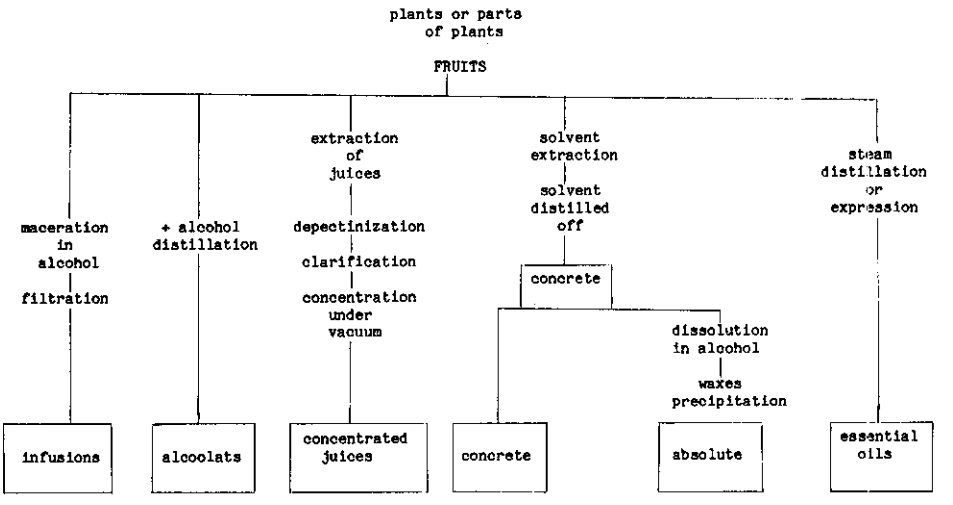
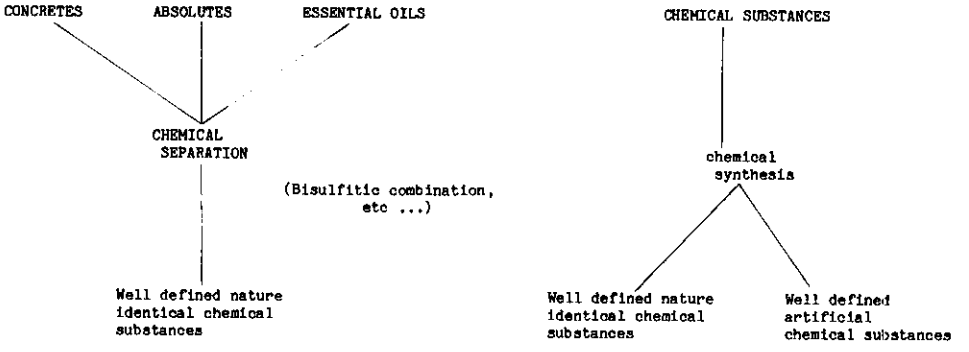


Table II. Synthetic Raw Materials



combination from lemongrass oil. The citral obtained is chemically identical to the natural citral obtained by distillation of lemongrass oil and is, therefore, classified as a nature-identical substance.

The same molecule, citral, can also be obtained by chemical synthesis (from isoprene, for instance). This citral will also be classified as nature-identical. The only important difference between natural citral and the two types of nature-identical citral obtained above are found in the by-products and manufacturing residues.

Through chemical synthesis, artificial substances are obtained, e.g., allyl hexanoate.

In a second step, legislators will have to recognize that up to this date about 12,000 flavouring substances are known, of which several thousands are used daily.

Safety Aspect of Flavourings

Flavourings are used with great safety. One cannot find a single mention in the scientific literature of a toxicological adverse reaction due to the use of flavourings manufactured according to Good Manufacturing Practice (GMP). (Dr. Grundschober, Scientific Advisor of the International Organization of the Flavor Industry, has clearly explained why in a conference held in Grenoble, France in October 1981.[1])

In addition, the taste and olfactory thresholds of the substances are very low: an overdosage makes the flavouring and, therefore, the foodstuff unpalatable. This explains why the concentrations used are well below those giving an undesirable biological effect. Furthermore, most of the nature-identical substances are consumed in far greater quantities as natural ingredients of food than as food additives added intentionally to food by the flavouring industry.

Stofberg and Stoffelsma calculated for some flavouring substances the quantities present naturally in foodstuffs and the quantities synthesized by industry.[2] For example (these calculations are based on figures obtained in the U.S.)

5-Methylfurfural
consumed in roasted coffee ....40,932 kg/year
produced by industry ..... 18 kg/year
2-Nonenal
consumed in cucumbers ..... 3,090 kg/year
produced by industry ..... 34 kg/year

All this summarizes what the legislators should keep in mind when writing flavorings legislation.

Basic Systems for Legislation

Table III shows the systems. The first two systems are independent; the third one is a combination of the previous two.

The first system is composed of positive lists (exclusive and closed lists) for every category of flavouring substances. Only those substances having been cleared toxicologically and inscribed on the lists would be authorized.

In my opinion, such a system would be highly desirable for those substances which lack historical records of use in foodstuffs—the artificial flavouring substances. Such substances should be submitted to toxicological evaluation, and only those having "passed the exam" should be authorized. They would then be inscribed on the list and would be cleared for use to the exclusion of all others.

As far as natural and nature-identical flavouring substances are concerned, such a system presents the disadvantage of not being enforceable: each peak of the control chromatogram would have to be identified and compared to about 10 to 12,000 substances. Just keep in mind that 300 flavouring substances have been identified in the strawberry flavour, 250 in apple and 600 in coffee.

Furthermore, such a system leads to the need to differentiate in a practical way the nature-identical flavouring substances from their natural counterparts. This differentiation is possible at the present time in restricted conditions for a small number of substances at a tremendous cost.

If such a system was applied, it would be very difficult to introduce new flavouring substances and if the number of authorized substances was too small, all flavourings would tend to have the same flavour.

The second system is based on restrictive and negative lists only. In such a system all substances are authorized except those specifically limited or forbidden. This system is entirely suitable for natural and nature-identical

Table III. Different Basic Legislation Systems

System	Description	Remarks
Positive lists system	Exclusives and Closed Lists - natural - nature-identical - artifical flavouring substances Only inscribed substances can be used.	suitable for artificial flavouring substances unenforceable for natural and nature-identical flavouring substances does not resolve "residues" problem
Restrictive and negative lists system	Restrictive and Negative Lists - natural - nature-identical - artificial flavouring substances All substances can be used except those specifically limited or forbidden.	unsuitable for artificial flavouring substances suitable for natural and nature-identical flavouring substances does resolve "residues" problem for natural and nature-identical flavouring substances
Mixed system	Restrictive and Negative Lists - natural - nature-identical flavouring substances Positive List - artificial flavouring substances	combination of the two previous systems well suited for modern legislation correctly solves "residues" problem protect public health efficiently

flavouring substances, because it limits or forbids the biologically active principles but is unsuitable for artificial flavouring substances for which only the positive list is acceptable based on health protection requirements.

The third system, known as "mixed" system, is based on a positive list for artificial flavouring substances and restrictive lists for natural and nature-identical flavouring substances. Certainly the best suited for a modern flavourings legislation, this system is enforceable because it allows an efficient analytical control.

Legislation for Labeling

Let us say one word about labeling. It is legitimate for consumers to know what they are buying. An adequate label concerning flavouring should be attached to the final product. Precise and exact information should be given. One could envisage labels stating:

- "natural flavourings"—when only natural flavouring substances are used
- "flavourings"—when one or several nature-identical flavouring substances are used
- "artificial flavourings"—when one or several artificial substances are used

This represents minimum basic information which could be completed by a mention concerning the type of substances used, for instance: "mixture of natural and nature-identical flavouring substances."

Supranational Legislation

Let us now examine legislation around the world. The existing supranational legislation is presented in Table IV.

The world authority is a joint venture between the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) called the Codex Alimentarius Commission.

The Codex Committee on Food Additives (CCFA), an intergovernmental subsidiary body, endorsed on a provisional basis the natural and nature-identical flavouring substances, and those artificial flavouring substances subjected to toxicological assessment by the Joint Expert Committee on Food Additives (JECFA).[3] The JECFA is composed of experts who serve in their professional capacity.

For practical purposes food additives and flavouring substances have been grouped in three toxicological categories—Categories A, B, and C. (These lists should not be regarded as complete or final.)

Category A has been subdivided in two parts, A1 and A2. Category A1 flavouring substances are those which have been fully cleared by the JECFA. Category A2 are those with incomplete evaluation but which have been accepted for use on a provisional basis. The interesting point is that the Codex Alimentarius Commission does not regard substances not inscribed in Category A as unsafe or suspect from a point of view of

health (unless they also appear in Category C). This clearly indicates that Category A is not a positive list.

Category B is a working list of substances on which evaluation is pending but in which technological interest has been confirmed.

Category C has also been subdivided in two parts, C1 and C2. Category C1 are those substances which have been considered by the JECFA unsafe for use in food. Category C2 are those substances which have been restricted for reasons of safety to health.

At the present time, JECFA is setting up criteria for the evaluation of priorities for safety assessment of flavouring materials.

One of the factors taken into account for a given flavouring substance is the quantity consumed per capita. For such a substance, the ratio between the quantity consumed as an ingredient of traditional foods and the quantity consumed as flavouring intentionally added to food, called "consumption ratio," allows such a classification to be set up.[4] The International Organization of the Flavor Industry (IOFI) has offered to help for the calculations of the consumption figures.

The Council of Europe (CE) has approached the problem in a more restrictive way. The working party on Flavouring Materials of the Council of Europe up to now has recognized only two categories of flavouring substances:

- *Natural flavouring substances* obtained from vegetable and sometimes animal sources exclusively through the appropriate physical processes
- *Artificial flavouring substances* obtained by a chemical process including substances which exist in natural products (nature-identical flavouring substances) and substances not present or as yet undiscovered in natural

Table IV. Supranational Legislation

Codex Alimentarius	Council of Europe (CE)	European Commission - CEE (Proposal)
- natural - nature-idential - artificial flavouring substances	- natural - artificial flavouring substances	- natural - nature-identical - artificial flavouring substances
Lists A, B, C (no exclusive lists)	Positive Lists	Specific directives to be issued including positive lists for each category of flavouring substance
- A1 substances fully cleared - A2 substances accepted on a provisional basis - B waiting list - C1 negative list - C2 restrictive list	- natural flavouring substances based on their source materials - artificial flavouring substances	- artificial flavouring substances - nature-identical flavouring substances - source materials for preparation of natural flavouring substances - source materials for preparation artificial flavouring substances
Evaluation of priorities for safety assessment "Consumption Ratio"	Classification N1 serie 1 admitted natural flavouring substances N1 serie 2 natural flavouring substances for which - insuffiicient toxicological data or - limited for health protection requirements	Amended by European Parliament (18/19 Feb 82) mixed system instead of positive list system - positive list artificial flavouring substances - positive list source materials for production of artificial flavouring substances - negative list nature-identical flavouring substances - negative list source materials for production of natural flavouring substances

products (artificial flavouring substances)

The ad hoc working party, a subsidiary body of the Sub-Committee on the Health Control of Foodstuffs has drawn up a list of natural flavourings based on their sources and a list of the artificial flavourings which may be added to foodstuffs without hazard to public health.[5] In contrast to the Codex, the Council of Europe has set up positive lists of all flavouring substances. The natural flavouring substances are classified in different categories.

- N1 serie 1 for those admissible in foodstuffs: natural, nature-identical and artificial
- N2 serie 2 for plants, parts of plants and flavourings derived from them, the technological needs of which are lacking or those for which the toxicological evaluation is incomplete. Also included in this category are certain flavouring substances known to contain a biologically active component for which it is necessary to set a limit in the final food as consumed

The different lists have been published in what is now called the "Blue Book" of the Council of Europe. The third edition should be published very soon.

Based on the work of the Council of Europe experts, the Commission of the European Community has established a proposal for a Directive on the approximation of the laws of the member states relating to flavourings for use in foodstuffs and to source materials for their production.[6]

The Commission recognizes three categories of flavouring substances—natural, nature-identical and artificial. A vertical directive, it implies the adoption at a later stage of specific directives setting out positive lists for each category of flavouring substances. Pending the adoption of the latter directives, specific maximum limits have been laid down for a number of biologically active substances, for instance, safrole and β-asarone.

The Commission project has recently been submitted to the European Parliament for advice. In its plenary session held on February 18 and 19, 1982, the European Parliament has amended Article 5 of the Commission proposal, setting up the mixed system instead of the positive list system.

There will be a positive list of artificial flavouring substances, a positive list of source materials for the production of artificial flavouring substances, a negative list for nature-identical flavouring substances, and a negative list for source materials for the production of natural flavouring substances.

National Legislation

Let us look at the legal situation of flavourings in different countries of the world (Table V).

In Europe, the situation is far from being simple. Some countries have legislation and others do not. In France, for instance, there is no flavouring legislation as such. The law of August 1, 1905 and the deriving decrees still govern the manufacture and sale of foodstuffs and drinks. As far as flavourings are concerned, an agreement was signed in 1957 between the flavouring

Table V. National Legislation

France	Federal Republic of Germany	The Netherlands	U.S.A.
Law August 1, 1905	- natural - nature-identical - artificial flavouring substances	- natural - nature-identical - artificial flavouring substances	- natural - nature-identical - artificial flavouring substances
Agreement 1957	Restrictive Lists	Restrictive List	GRAS Lists
- natural flavourings	natural and nature-identical flavouring substances	natural and nature-identical flavouring	(no exclusive lists)
- flavouring compositions	(5 substances)	substances (9 substances)	lists 3 to 12
- artificial flavourings	- Calamus (in spirits) 1 mg Asarone/litre	- B-Asarone (in spirits) 5 mg/Kg	environ 1700 substances
- reinforced flavourings	- Chinin (in spirits) 300 mg/litre, (in sodas) 25 mg/litre. etc...	- Coumarin (in spirits) 10 mg/Kg	
Proposal for a decree (Feb 82)	Negative List, natural and nature identical flavouring substances (20 substances)	hypericin, chinin, pulegon, cassin, safrol, thujone	
(too recent - not treated here)	Ricin, Safrole, Thujone, etc...	Postive List artificial flavouring substances environ 200	
	Positive List artificial flavouring substances (18 substances)		

manufacturers. It reflected the good manufacturing practices of that time and was countersigned by the French Ministry of Agriculture in 1963. It is still in application although technics have considerably evolved since that time. This agreement is out of date with modern legislation. Beginning February 1982, a decree proposal on flavourings was being discussed at the Ministry of Consumption. However, it is too early to describe it at this time.

The Federal Republic of Germany is one of the first countries in the world to have flavouring legislation.[8] It is based on the mixed system and contains:

- a restrictive list of five natural and nature-identical flavouring substances—Calamus, Quinine, Coumarin, Quassia Wood, Thujone
- a negative list of 20 natural and nature-identical flavouring substances (Ricin, Safrole, Thujone)
- a positive list of about 18 artificial flavouring substances

The Netherlands has legislation based on the same mixed system. It contains:

- a restrictive list of natural and nature-identical flavouring substances (β-Asarone, Coumarin, etc.)
- a positive list of about 200 artificial flavouring substances (all with maximum use levels)

The United Kingdom has a special status: as yet there is no flavourings legislation.

In the United States, the situation is based on a different concept: the Generally Recognized As Safe (GRAS) concept allows flavouring substances to be excluded from the legal definition of food additives.[10] The GRAS concept means a common consent on the innocuity of a substance by experts who are sufficiently trained and have enough experience to evaluate the innocuity.

The Expert's Committee of the Flavor & Extract Manufacturers Association (FEMA) has continuously collected information on characteristics of flavouring substances, amount produced, way of use, etc., and proceeded to a scientific evaluation. The main criteria are:

- chemical structure similarity with substances of known metabolism and toxicity
- way of use, concentration in final food, quantity produced
- possible metabolism pathway
- presence of the substance in natural food
- animal testing (for certain substances)

The results of these evaluations have been published in scientific literature under the name of GRAS lists. These lists should not be mistaken with positive lists. A manufacturer is entitled to use a substance not inscribed on the GRAS lists, but does it under its own responsibility. This would not be possible with a positive list system.

Conclusion

To conclude, I quote Dr. Grundschober, Scientific Adviser of the IOFI: "Consumers have the right to have the best products that science and flavouring art are able to deliver and also to be informed on the flavouring categories used in product. Research for new substances heavily depends on the type of horizontal legislation adopted. If positive listings of all categories of flavouring substances were to be imposed, the future would look dark."

It remains to hope that everywhere in the world realistic and enforceable legislation on flavourings will be adopted.

References

1. F. Grundschober, Perspectives et Evolution des Legislations, XIII eme journees de l'Aromatisation, Grenoble 9/10 October 1981
2. J. Stofberg and J. Stoffelsma, Perf. & Flav. **5** (7), 19-35, 1980
3. Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Guide to the Safe Use of Food Additives, CAC/FAL 5, 1979
4. J. Stofberg, Setting priorities for safety evaluation of flavouring material, Perf. & Flav. **6** (4), 69-72
5. Council of Europe, Natural flavouring substances, their sources, and added artificial flavouring substances, 3eme edition 1974—Editions Maisonneuve
6. Commission Des Communautes Europénnes (1980), "Proposition de directive du Conseil relative aux rapprochement des législations des Etats Membres, relative aux agents d'aromatisation destinés à être employés dans les denrées alimentaires et aux matériaux de base de leur production," Journal Officiel des Communautés Europénnes, Nr. C 144/9-15 13/6/80
7. "Le Commerce des Matières Aromatiques pour les Industries Alimentaires," Convention entre les fabricants, June 1957
8. Aromenverordnung, Bundesgesetzblatt 1981, No. 60, December 30, 1981, pp. 1677-1683
9. Geur-en Smaakstoffenbesluit (warenwet) June 28, 1979, Staatsblad 1979 No. 396
10. R. L. Hall and B. L. Oser (1965, 1970), B. L. Oser and R. L. Hall (1972), B. L. Oser and R. A. Ford (1973, 1974, 1975, 1977, 1978, 1979), "Recent progress in the consideration of flavouring ingredients under the Food Additives Amendment," GRAS substances 3-12, Food Technol. **19** (2, Part 2), 151 (1965); **24** (5), 25 (1970); **26** (I), 64 (1972); **27** (II), 56 (1973); **28** (9), 76 (1974); **29** (8), 70 (1975); **31** (I), 65 (1977); **32** (2), 60 (1978); **33** (7), 65 (1979)