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International Flavour Legislation—A Review

by J. J. JENKINS

(Food Industries Limited, Bromborough Port, Wirral, Cheshire)

This paper was read on 7 May 1974 at an International Seminar entitled 'Basic Aspects of Flavouring', held at the Central College of German Confectionery Trade, Solingen, Germany.

United Kingdom

There are no specific regulations for the control of flavourings in the United Kingdom. The Food and Drugs Act 1955 prohibits the use in food of substances injurious to health and also makes it an offence to sell to the prejudice of the purchaser any food which is not of the nature, substance or quality demanded by him. The Labelling of Food Regulations, however, require that a picture of a food, e.g., strawberry, must not appear on a label unless the flavour derives wholly or mainly from that food. If the flavour is not wholly or mainly derived from the named food then the word 'flavour' must appear in the title, e.g. 'strawberry flavour jelly' instead of 'strawberry jelly'.

The Food Standards Committee, in its report in 1965, recommended that certain flavouring agents should be prohibited. These were:

Coumarin	Dihydrosafrole	Dulcamara	Birch Tar Oil
Tonka Bean	Iso-Safrole	Pennyroyal Oil	Cade Oil
Safrole	Agaric Acid	Oil of Tansy	Volatile Bitter
Sassafras Oil	Nitrobenzene	Rue Oil	Almond Oil
			Male Fern

In 1966, however, the Ministry of Agriculture, Fisheries and Food, the Ministry of Health and the Home Office issued a joint statement that the recommendation of the F.S.C. would not be adopted and that the most effective way of controlling the use of flavouring agents was by means of a permitted list. The Food Additives and Contaminants Committee was asked to consider the matter with a view to producing recommendations for a permitted list of flavourings for use in food. The F.S.C. report, in the meantime, would act as a guide to manufacturers and others, pending the introduction of more specific control. As yet no list has been published but it is understood that one is being compiled, based on the deliberations of the Council of Europe working party.

West Germany

The use of flavourings is specifically controlled by the 'Essenzen-Verordnung' which defines the products regulated, e.g. 'Essenzen', 'Aromen', 'Grundstoffe', and lists materials which are prohibited or restricted. Food flavours are, of course, subject to the basic food law, 'Lebensmittelgesetz', which prohibits the use of substances hazardous to human health and forbids falsification and mislabelling. Although artificial substances are defined as 'Fremdstoffe' and may only be used if on a positive permitted list, synthetic flavouring substances which have a chemical structure identical to those which occur naturally are not regarded as 'Fremdstoffe' and therefore may be used without declaration.

The 'Essenzen-Verordnung' permits natural and nature-identical flavours with the exception of:

Agaric acid, Bittersweet, Coumarin, Tonka Bean, Vanilla Leaf, Melilot, Woodruff, Pennyroyal, Quillaia, Tansy, Rue, Safrole, Sassafras wood, leaf, bark and oil, Camphor wood and oil, Polypody, Birch Tar Oil, Bitter Almond Oil containing HCN, Cade Oil, Thujone, Calamus Oil containing more than 10 per cent. of Asarone.

The use of the following is restricted:

Peruvian Bark, Cinchona, Quinine and its salts

Quassia wood

Calamus Oil, containing less than 10 per cent. of Asarone.

There is also a short permitted list of artificial flavours:

Ethyl vanillin

Propenyl guaethol

Hydroxy citronellal

Dimethyl resorcinol

These may only be used in the following foodstuffs and their presence must be declared as 'mit Aromastoff'.

1. Artificial drinks
2. Cream desserts, puddings, jellies, syrups
3. Artificial ice-cream
4. Flour confectionery
5. Sugar confectionery
6. Chocolate fillings
7. Chewing gum
8. Tobacco

Ethyl vanillin may also be used in chocolate and declaration is not needed as long as it does not produce a predominant flavour. The use of flavours may be further restricted by the regulations controlling individual classes of foodstuffs. Nature-identical substances may not be referred to as natural flavours and hence may not be used in certain categories of ice cream and soft drinks.

France

No regulations concerning flavourings have as yet been published. The basic food law, which is concerned mainly with the repression of fraud, prohibits the adulteration of food and demands severe penalties in the case of harmful and toxic substances. Natural flavours are permitted and the Administration has let it be known that artificial flavours (including nature-identical synthetic flavourings) may be used provided that they are deemed to be safe by virtue of their long usage or by safety testing. There is a Code of Practice agreed by the flavour industry which defines the various types of flavour.

Only natural flavours may be added to dairy products and beverages and although artificial flavouring may be added to other food commodities the declaration 'Arôme artificiel' must be made. Reinforced flavours, consisting of specific natural flavouring substances to which a small quantity of nature-identical flavouring substances have been added, may be used in certain foods providing the reinforcement does not exceed a stated limit as follows:

Sugar and flour confectionery, chocolates, pastries, fillings, decorations, instant dessert preparations, powders for beverages:—all vegetable flavours except citrus fruit and vanilla,—maximum 4 g of nature-identical flavouring per kilo of natural flavour which has been concentrated at least 4 times (or 3 times in the case of coffee).

Yoghurt, curdled or gelled milk, flavoured milk:—apricot, pineapple, banana, strawberry, raspberry, pear, plum, cherry,—2 g per kilo, concentrated at least 4 times.

Preparations with fruit and sugar for yoghurt and fresh cheese with fruit:—apricot, pineapple, cherry, strawberry, banana, raspberry, pear, plum,—4 g per kilo concentrated at least 4 times—total reinforcement must not exceed 200 mg per kilo of preparation at time of use.

Italy

Only the additives stipulated in the Ministerial Decree of 31.3.65, and as subsequently amended, may be used in food. Natural flavouring constituents of plants which are edible are generally permitted together with the following:

1. alcoholised, concentrated or dehydrated juices;
2. essential oils, simple, rectified or terpeneless;
3. essences, concentrates and extracts of flavouring substances;
4. tinctures and infusions;
5. distilled flavours;
6. constituents of natural flavours, extracted or isolated, or reproduced by chemical synthesis;
7. constituents of natural substances even if not flavourings, extracted or isolated or reproduced by chemical synthesis, and which enhance the flavour or odour of food.

Foods containing the above must declare them as 'natural flavours' on the label.

Artificial flavours are restricted to a permitted list which is further limited as to types of food and levels of use:

Ethyl acetoacetate	}	Hard boiled sweets, 2 p.p.m.
<i>p</i> -Tolualdehyde		Fondants and the like, 2 p.p.m.
Allyl hexanoate		Hard boiled sweets, 2 p.p.m.
Dimethyl resorcinol	}	Hard boiled sweets, 1 p.p.m.
Amyl methyl ketone		
Methyl cyclopentenolone		
Ethyl <i>beta</i> -naphthol	}	Hard boiled sweets, 1 p.p.m.
		Liqueurs, 1 p.p.m.
Allyl cyclohexyl propionate	}	Hard boiled sweets, 2 p.p.m.
Methyl heptin carbonate		Liqueurs, 1 p.p.m.
Ethyl methyl phenyl glycidate	{	Hard boiled sweets, 10 p.p.m.
		Liqueurs, 5 p.p.m.
		Biscuits, 10 p.p.m.
		Pudding preparations, 100 p.p.m. (of the finished product)
Ethyl vanillin	{	Hard boiled sweets, 200 p.p.m.
		Baking powder, 200 p.p.m. (of the finished product)
		Chocolate, chestnut preserves, quince jam, candied fruits, 100 p.p.m.
		Liqueurs, spiced wines, 50 p.p.m.
		Biscuits, 200 p.p.m.
		Pudding preparations, 200 p.p.m.
		Icing sugar, 900 p.p.m.
γ -Nonalactone	{	Ice cream, 5 p.p.m.
		Hard boiled sweets, 1 p.p.m.
		Biscuits, 0.5 p.p.m.
Hydroxy citronellal	{	Margarine, 0.5 p.p.m.
		Hard boiled sweets, 0.5 p.p.m.
		Liqueurs, 0.25 p.p.m.
Methyl ionones	{	Margarine, 0.5 p.p.m.
		Hard boiled sweets, 0.25 p.p.m.
		Fondants and the like, 0.25 p.p.m.
		Biscuits, 0.25 p.p.m.
Naphthyl methyl ketone	{	Liqueurs, 0.25 p.p.m.
		Hard boiled sweets, 0.1 p.p.m.

Propenyl guaethol	{ Hard boiled sweets, 0.2 p.p.m. Baking powder, 0.2 p.p.m. Chocolate, 0.2 p.p.m. Chestnut preserves and quince jam, 0.2 p.p.m. Liqueurs and spiced wines, 0.2 p.p.m. Biscuits, 0.2 p.p.m. Pudding preparations, 0.2 p.p.m.
Undecalactone	{ Hard boiled sweets, 10 p.p.m. Liqueurs, 5 p.p.m. Biscuits, 5 p.p.m.

The presence of the above must be declared as 'artificial flavours' on the label of the food.

Belgium

Harmless flavouring substances are generally permitted. There is a short list of non-permitted substances:—coumarin and its derivatives, chloral, chloroform and ether. In 1943 and 1945, a list of flavouring materials was compiled but it does not seem to have been adopted.

Glutamic acid and its sodium, potassium and calcium salts are permitted in seasoning mixtures to a level of 200 g/kg.

Netherlands

There are no specific flavouring regulations. The addition of natural and artificial flavours is permitted in the 'free sector', *i.e.* unstandardised foods, and in a large number of standardised foods, *e.g.* chocolate, processed cheese, soft drinks, liqueurs, etc. Margarine is allowed to contain natural flavourings, nature-identical synthetic flavourings and a short list of artificial flavouring substances which include ethyl vanillin, γ -nonalactone, γ -undecalactone, heptyl acetate, methyl heptin carbonate, methyl octin carbonate, methyl undecylate and dimethyl resorcinol.

Denmark

The Food Additives Order of June 1973 does not contain a list of flavouring substances. It is understood that the Danish authorities will require, in the future, that the composition of all flavours should be declared to them. In the meantime flavourings which appear on the FDA and FEMA GRAS lists may be used without having to seek official approval.

Norway

A list of permitted flavourings and aromatic substances is given in the List of Approved Additives 1972, amended in 1974. Essential oils, natural and artificial non-toxic essences, vanillin and ethyl vanillin are among the

additives listed. Foods are divided into ten groups and the additives permitted are listed for each group. The situation with regard to flavourings is as follows:

- | | |
|--|--|
| 1. Milk and milk products: | |
| ice cream | essential oils and essences |
| 2. Egg products | none |
| 3. Meat and meat products | none |
| 4. Fish and fish products: | |
| wholly preserved and semi-preserved | essential oils and essences |
| 5. Flour and bakers' goods: | |
| cake, pastries and biscuit creams | essential oils and essences |
| 6. Preserved fruit and vegetables: | |
| candied fruit and substitutes | essential oils and essences |
| 7. Fats, oils, margarine, bakery fats: | |
| margarine and shortening | essential oils and essences |
| 8. Carbonated beverages: | |
| fruit drinks and lemonade | natural flavouring |
| others | essential oils and essences: declare |
| 9. Cocoa, chocolate, confectionery | essential oils and essences |
| 10. Others | essential oils and essences: |
| | declare in soups, sauces, sandwich fillings, and desserts. |

Sweden

Food commodities are divided into 15 groups. Non-toxic essences and aromatic substances used for flavouring purposes do not require approval and may be used according to the following table:

- | | |
|--|---------------|
| 1. Baby foods | permitted |
| 2. Milk and milk products | not permitted |
| 3. Cheese | permitted |
| 4. Edible fats and oils: | |
| (a) Butter | not permitted |
| (b) Margarine and minarion | permitted |
| (c) Lard and edible tallow | not permitted |
| (d) Other products | permitted |
| 5. Edible ices | permitted |
| 6. Meat products: | |
| (a) Meat, minced meat, organs and meat by-products | not permitted |
| (b) Other meat products | permitted |

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|---|-----------------------|
| 7. Fish and fishery products: | |
| (a) Fully preserved canned products | spices and oleoresins |
| (b) Semi-preserved and chilled products | spices and oleoresins |
| (c) Alkali-cured products | not permitted |
| (d) Cooked crustaceans | not permitted |
| (e) Other fish products | not permitted |
| 8. Egg and egg products | not permitted |
| 9. Cereal products: | |
| (a) Flour, groats and flakes from cereals | not permitted |
| (b) Bread | permitted |
| (c) Other bakery products | permitted |
| (d) Macaroni and spaghetti | not permitted |
| 10. Fruit and vegetables | permitted |
| 11. Fruit, syrup, juices, jam, soft drinks: | |
| (a) Nectar and fruit syrup | not permitted |
| (b) Juice | not permitted |
| (c) Jam, marmalade, jelly | permitted |
| (d) Carbonated beverages | permitted |
| (e) Other beverages | permitted |
| 12. Sugar and honey | not permitted |
| 13. Coffee and tea | not permitted |
| 14. Salt and vinegar | not permitted |
| 15. Other foods | permitted |

Finland

The food additives regulations do not cover natural spices nor products made from fruits or vegetables by pressing, extracting or distilling. Flavourings containing partly or fully artificial ingredients may be used in foods to improve their flavour or aroma only in accordance with the List of Food Additives as indicated below and in quantities not presenting a hazard to health.

- | | |
|---|---|
| 1. Milk and milk products: | |
| Dried milk products | 0.1 % permitted with declaration |
| Butter, chemically acidified and flavoured | diacetyl and butter acids 0.03 % with declaration |
| Milk jelly | permitted with declaration |
| 2. Oils and fats and products except margarine: | |
| Emulsions | 0.0006 % permitted |
| Mayonnaise | 0.0006 % permitted |
| 3. Edible ices | permitted with declaration |
| 4. Eggs and egg products | not permitted |
| 5. Meat and meat products: | |
| Broth products and concentrates | permitted with declaration |
| 6. Fish and fish products | not permitted |

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|--|--|
| 7. Cereal and cereal products: | |
| Processed flakes, breakfast foods etc. | permitted with declaration |
| Crisps, crackers, snacks etc. | permitted with declaration |
| Flour confectionery | permitted (vanillin and ethyl vanillin limited to 0.1 %) |
| Cake mixes | permitted |
| 8. Vegetables | not permitted |
| 9. Fruit and fruit products: | |
| Imitation fruit juices and jellies | permitted with declaration |
| 10. Salt, vinegar, spices, natural flavourings | not permitted |
| 11. Cocoa and cocoa products: | |
| Chocolate | permitted |
| Fillings of chocolate | permitted |
| 12. Sugar and honey products: | |
| Flavoured sugars | 2% vanillin and ethyl vanillin |
| Sugar confections | permitted |
| Chewing gum | permitted |
| Artificial sweetening products | permitted |
| 13. Soft drinks: | |
| Fruit, berry and vegetable beverages | permitted with declaration |
| Lemonade and artificial mead | permitted |
| Flavoured milk beverages | 0.1 % vanillin and ethyl vanillin |
| Imitation milk beverages | permitted with declaration (diacetyl to 0.01 %) |
| Mead and cider | permitted with declaration |
| 14. Coffee and tea | not permitted |
| 15. Other food | permitted (vanillin and ethyl vanillin limited to 0.1 %) |

Spain

The Food Code allows both natural and artificial flavourings. Certain flavouring ingredients are prohibited:

Hydrocyanic acid
Methyl and amyl alcohols
Coumarin and tonka beans
Diethylene and triethylene glycol
Nitrobenzene
Nux vomica
Safrole, saffrafrs
Saponins
Other toxic substances

Portugal

There are no regulations concerning flavouring substances and they are permitted without limit or declaration.

Switzerland

All flavours must be cleared with the Swiss Health Authorities before they can be used. The components must be covered by the Council of Europe lists. There are certain restrictions applying to the use of flavours for dairy products; no flavours may be used which lead to decrease in the use of commodities such as butter. For example, butter flavours may not be used in foods which would normally contain butter. However, butter flavours are permitted in certain products such as margarine, and low calorie biscuits. Artificial flavouring substances are permitted but their use is restricted to certain commodities, for example sugar confectionery, and the declaration 'mit aroma' is required. Natural flavours may be reinforced by a maximum of 5 per cent. of artificials without being considered artificial.

New Zealand

The Food and Drug Regulations 1973 permit the use of any wholesome substance that, when added or applied to food, is capable of imparting flavours to or enhancing flavours in that food. The addition of flavourings to the various food commodities is covered by the individual standards. There is a small list of prohibited substances:

Cade Oil, Coumarin, Nitrobenzene, Pyroligneous acid, Safrole, *iso*-Safrole, Sassafras oil.

Australia

There is no list of approved flavouring substances, and both natural and artificial flavours are permitted. Their addition to the various food commodities is governed by the regulations of the individual states.

South Africa

There is no list of approved flavouring substances, and both natural and artificial flavours are permitted. Their incorporation into various foodstuffs is governed by standards applying to individual foods.

United States of America

A positive list of artificial and natural flavouring ingredients is provided by both the FDA and FEMA. The two lists are dissimilar at present but co-operation between the two bodies is increasing. Such flavourings may be used as restricted by additive regulations or by food standards, or in non-standardised foods. Other non-listed ingredients are sometimes used if declared GRAS by the users' advisers. The FEMA list is more fluid and expanding at present and will probably influence future developments. Substances which have been banned are Calamus Oil, Coumarin and Safrole.

Canada

No list of permitted flavouring substances is in existence. Both artificial and natural flavours may be used if they are permitted by the regulations governing the individual food commodities, *e.g.* bakery products, confectionery ice cream, milk ice, liqueurs, alcoholic beverages, sherbets, soft drinks, dairy drinks, malted milk, milk and skim milk, are allowed artificial flavour without label indication.

Japan

A list of additives permitted in foods is in existence, the additives being listed according to their application. Both nature-identical and artificial flavours are listed. Many of the headings are somewhat general (*e.g.* lactones) and no maximum levels of use are given.

A list of permitted chemical substances for import has also been drawn up (1974) which includes those which may be incorporated into flavouring preparations; if, however, the flavours are used in foods when imported this does not apply and they are controlled by the food additives list.

Natural flavours and natural substances in general are not controlled.

Poland

Natural and artificial flavouring substances are listed in the Decree of 4 June, 1971. Named oils, distillates and juices are permitted and there is a list of 42 permitted artificial flavourings. Ethyl alcohol is the only permitted solvent for flavouring substances. There are no maximum levels of use but flavours may not be incorporated into milk, butter, margarine, fats, oils, wine and honey drinks.

Bulgaria

The Bulgarian Health Regulations on Food Additives, 11 February 1972, permit the use of named essential oils, spice extracts and juices and list 32 permitted artificials, some of which have certain maximum dosage levels. Artificial flavourings may be used in soft drinks, milk beverages, margarine, bakery products, liqueurs and sugar confectionery. Chocolate products may be flavoured with vanillin only. The maximum level of all flavouring substances must not exceed 300 mg/kg.

It is necessary to obtain approval from the Ministry of Health to use any flavouring. The amount of permitted synthetic ingredient allowed is related to the established LD50 in rats for that material.

South America

The food legislation of the different countries is very similar, because of the influence of the Latin American Food Code and the Codex Alimentarius.

ARGENTINA: Standards are in existence for natural extracts of many types. Control is by commodity standards rather than additive lists.

BRAZIL: Flavourings are divided into natural and artificial. There is a small list of permitted artificial flavourings:

Propenyl guaethol; diacetyl; ethyl, amyl acetates, butyrates and valerates; acetaldehyde; benzaldehyde; cinnamic aldehyde; vanillin; coumarin; anethole; citral; glycerol.

CHILE: There is a prohibited list of flavour ingredients:

Alcohols except ethyl;

Acids except citric, lactic or tartaric;

Benzaldehyde and other harmful substances.

PERU: Importers of flavourings must register with the Inspector General of Pharmacy.

VENEZUELA: Flavours must be officially analysed and approved before use.

A prohibited list consists of:

Ethyl or amyl ethers;

Hydrocyanic acid;

Almond essence containing more than 4 per cent HCN;

Acetone, pyridine bases, alkyl halides, nitrobenzene;

Salicylic aldehyde, nitrates, nitrous derivatives;

Wormwood or rue.

European Economic Community

The recently published time-table of the food legislation harmonisation programme states that Proposals relating to 'Flavours and Essences' should be adopted by 1st January, 1978. The Association which represents the essence and flavour industry in the EEC is the 'Bureau de Liaison des Syndicats—Europeens (CEE) des Produits Aromatiques' and this body has been actively discussing the form and content of a fair and feasible directive on flavourings. As yet no proposals from either the Bureau or the Commission have been published.

The International Organisation of the Flavour Industry (IOFI) which comprises a number of national trade associations and is not confined to Europe, has, however, published a booklet entitled 'Basic Features of Modern Flavour Regulations'. This was prepared in order to provide an outline of the essential principles of legislation dealing with flavours, together with information about the particular characteristics of flavouring substances which necessitate special provisions for their regulation. In it IOFI advocates the adoption of a mixed or combined system by which any substance which occurs naturally in the diet may be used unless specifically prohibited or restricted, whilst a substance not yet found in the human diet may not be used without explicit permission. Definitions employed in this publication are as follows:

1. Flavourings are concentrated preparations, with or without solvents or carriers, used exclusively to impart flavour. They are not intended to be consumed as such.

2. Flavourings may contain the following flavouring ingredients:
 - a. Aromatic raw materials: vegetable or animal products used for their flavouring properties, either as such or processed for human consumption.
 - b. Natural flavours: concentrated preparations obtained exclusively by physical methods from aromatic raw materials.
 - c. Natural flavouring substances: substances isolated from aromatic raw materials exclusively by physical methods.
 - d. Nature-identical flavouring substances: substances obtained by synthesis or isolated through chemical processes from aromatic raw materials and chemically identical to substances present in natural products intended for human consumption, either processed or not.
 - e. Artificial flavouring substances: substances not yet identified in a natural product intended for human consumption, either processed or not.

For some years past, a working party under the aegis of the Council of Europe's Public Health Committee has been working on the preparation of lists of flavouring substances classified according to safety-in-use information available. A report entitled 'Natural and Artificial Flavouring Substances' was published in 1970, which listed the names of natural substances categorised according to whether they were admissible, temporarily admissible, or not admissible at present, and the names and the formulae of artificial substances categorised in a similar fashion. Since then, further work has been carried out on up-dating these lists and the publication of a second report is expected later this year. Although this body has no legislative authority itself, it may well be that the final version will provide a basis for EEC and other countries' legislation. Hence it will be imperative for all interested parties to examine closely the lists when they appear and make known their comments through the appropriate channels, nationally and internationally.

Finally, the Joint FAO/WHO Codex Alimentarius Commission, which was formed to implement the Joint FAO/WHO Food Standard Programme, influences attitudes towards flavouring substances by virtue of the procedure for the elaboration of Codex Standards. The individual Commodity Committees make the initial decisions about the use of flavours, but these have subsequently to be endorsed by the Codex Committee on Food Additives (CCFA) which examines not only safety aspects, but also the justification for their use and efficiency.

The terminology employed in the various standards differs somewhat and may lead to confusion as the following examples demonstrate: The Draft Standard for Flavoured Yoghurt includes as Flavours, 'Essences and extracts derived from fruit or parts of fruit and synthetic equivalents of essences'. The Draft Standard for Chocolate cites 'Natural flavours as defined in the Codex Alimentarius, and their synthetic equivalents, except those which would

imitate natural chocolate and milk flavours'. The Proposed Draft Standard for Baby Foods, under 'Flavour', lists:

1. Harmless natural flavouring materials and their identical synthetic equivalents.
2. Ethyl vanillin.

The Proposed Draft Standard for Canned Tropical Fruit Salad, on the other hand, lists:

1. Natural fruit essences.
2. Natural flavours as defined in the Codex Alimentarius and their synthetic equivalent.

The CCFA postponed endorsement of this section of the standard as it was considered that natural flavours also embraced natural fruit essences so that it was not clear why a distinction had been made between the two.

Therefore it is evident that, in spite of the fact that definitions similar to those proposed by IOFI have been adopted for Codex purposes, confusion still arises. As in the case of EEC legislation, it is incumbent upon members of the flavour industry to ensure that their colleagues in the food manufacturing industry are quite clear about flavour terminology.

With regard to individual flavouring substances, a small number have been evaluated by the FAO/WHO Joint Expert Committee on Food Additives, but it is expected that in the future much importance will be placed on the lists published by the Council of Europe Working Party.

Conclusion

The examples given in this paper are intended to indicate generally the methods of control adopted by a number of countries. It is to be stressed that errors in translation, differences in interpretation and the almost continual amendment of legislation now taking place, can result in some of the data being not strictly accurate.

Therefore, in answering specific questions, the original legislation or authoritative source should be consulted.