



International Organization
of the Flavor Industry



Safety and Uses of Food Flavourings

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Outline of the Presentation

- IOFI Mission & Responsibilities
- Challenges for Regulating Flavourings
- Codex Alimentarius Guideline for the Use of Flavourings (CAC/GL 66-2008)
- IOFI Code of Practice (2010)
- JECFA Evaluations of Flavourings
- The IOFI Global Reference List



IOFI

- Established in 1969 to be the global voice of the flavor industry
- Not-for-profit Association of Associations and Companies
- Headquarters in Geneva (Switzerland) and operations in Brussels (Belgium) and in Washington DC (USA)
- IOFI is a “Non-Governmental Organization with Observer Status” at the WHO/FAO Codex Alimentarius Commission and its subsidiary bodies



Membership Associations

•Ordinary Association Members

- Regional or national trade associations of companies active in the manufacture and sales of flavor ingredients
- EFFA (Europe)*; FEMA (USA); JFFMA (Japan); ABIFRA (Brazil); ANFPA (Mexico); ANDI (Colombia)

*EFFA is a regional association grouping the associations of A, BE, CH, D, DK, F, I, NL, SE, S, T, UK

•Corresponding Association Members (Non Voting)

- Regional or national trade associations that are early in their development
- AFFI (Indonesia); CAFEPa (Argentina), FAANZ (Australia/New Zealand); FFAS (Singapore); KFFA (Korea); FMAC (Canada); SAAFFI (South-Africa); (CAFFCI (China) is in the process of joining)



Membership Companies

- **Ordinary Company Members**
 - Flavor companies that are a member of national associations in at least three different regions*
 - Firmenich, Givaudan, Hasegawa, IFF, Mane, Robertet, Sensient, Symrise, Takasago, Wild

* Identified regions are North America, Latin America, Europe and Far East



IOFI Mission

- The International Organization of the Flavor Industry represents the interests of the global flavor industry and its partners by providing leadership in safety, scientific and regulatory matters.



IOFI Roles and Responsibilities

- The safe use of flavorings is the flavor industry's first priority, in order to prevent risk to the health of consumers, employees and the environment.
- Acting in partnership with its members, IOFI provides sound scientific information to the industry, its customers, and government agencies in order to promote the benefits and safe use of flavors.

More Info on IOFI: www.iofi.org



REGULATING FLAVOURINGS: A CHALLENGE!

- The public must have confidence that their food supply is safe.
- Food legislation and regulations are designed to ensure that consumer's food is safe and free of deception.
- Flavourings are an essential component of foods – All food ultimately contains flavourings, whether naturally present or added
- The complexity of added flavourings constitutes a major challenge for the regulator



Flavouring Substances

- Most occur naturally in Food
- Single substances must be used with many others. Single substances can be used to contribute to many different flavour tonalities (effects).
- Flavouring substances are used at low levels – self limiting = consumer can usually detect overdose.
- Consumers expect flavourings to taste like those of recognizable foods – so flavouring substances must be at similar concentration as found in Nature.
- > 3000+ single flavouring substances listed

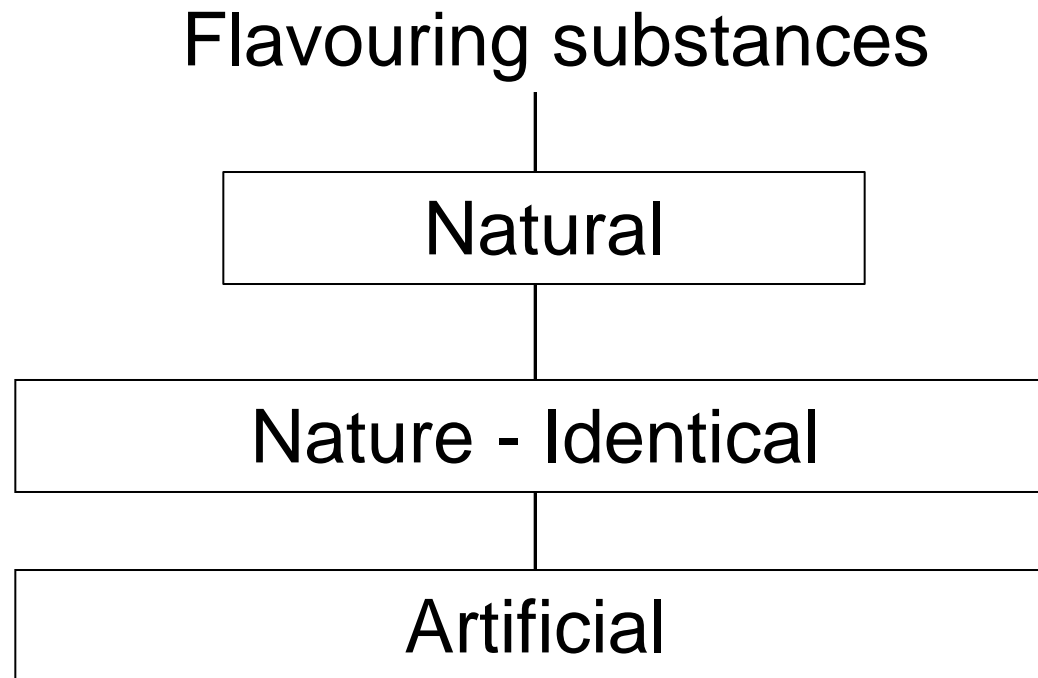
Food Additives

- Majority are not naturally occurring in Food
- Usually only one technological effect (e.g. Antioxidant, Preservative, Emulsifier ...) with an optimum addition level
- Usually not self-limiting = consumer will not be able to detect overdose
- Limited number – 10-20 per technological effect

Flavourings: single substances and complex materials

Single, chemically defined, substances	Preparations, complexes, complex materials
Substances that are natural or synthetic	Essential oils, extracts and oleoresins from botanical/natural origin
Usually compounded (mixed) to form 'formulated' flavourings	Compounded or used as is
e.g. Citral, benzaldehyde,..	e.g. Lemongrass, Bitter almond oil

Traditional definitions for flavouring*



* Codex Food Additives and Contaminants (CCFAC) – 1972 / Codex Food Labelling (CCFL) - 1985



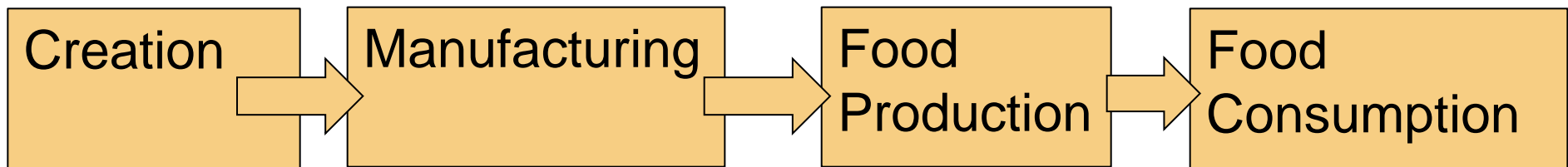
Formulation of “Compounded” Flavourings

- Single, chemically-defined substances (from a few to over 50 or more substances that are natural or synthetic) and/or a natural flavouring complex (e.g. essential oil, oleoresin, extracts) are mixed.
- + Food additives (stabilizers, emulsifiers, antioxidants, preservatives,.....)
- + Carrier(s) (food additive, food ingredient, solvent.....) added
 - Example*: Formula of a Confectionery (Vanilla) Flavouring designed to be used at the rate of 0.1 to 0.2% in the finished product.

• Maltol	0.250
• Dihydrocoumarin	0.500
• Vanillin	8.000
• Ethylvanillin	2.000
• Heliotropin	0.020
• Cinnamon bark oil	0.005
• Water	20.000
• Propylene glycol	ad 100.00

*Food Flavourings (Ed. P. R. Ashurst) Blackie - 1991

Supply Chain for Flavourings....



Formula developed containing approved flavouring substances, extracts, essential oils, etc... + food additives and carriers/solvents

Flavouring is manufactured and shipped to the food producer as a concentrated mixture of ingredients

Food product is manufactured containing 0.1 – 0.5 % of the flavouring in the final product

Consumer purchases the food product and consumes it



Codex Alimentarius Food Additives Definition

- Food additive means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods.

(Codex Alimentarius Commission Procedural Manual, page 22, 21th Ed., 2013)



Flavourings in the Codex Alimentarius

- Hence, flavourings are considered as “food additives” in the Codex standards,
- However, the General Standard on Food Additives (GSFA) (CODEX STAN 192-1995) does not specifically deal with flavouring substances.
- Moreover, flavourings have no “INS” – additive number! See Introduction of CAC/GL 36-1989 (Class Names and the International Numbering System for Food Additives): “The INS does not include flavourings, which have a JECFA number as identifier”
- JECFA has completed the safety evaluation of many chemically- defined flavouring substances- so far more than 2186 substances were evaluated. At the next JECFA meeting (June 2014) an additional 28 substances will be evaluated.
- A clear need to clarify the Codex status of flavourings!



Development of a “Codex Guideline on the Use of Flavourings”

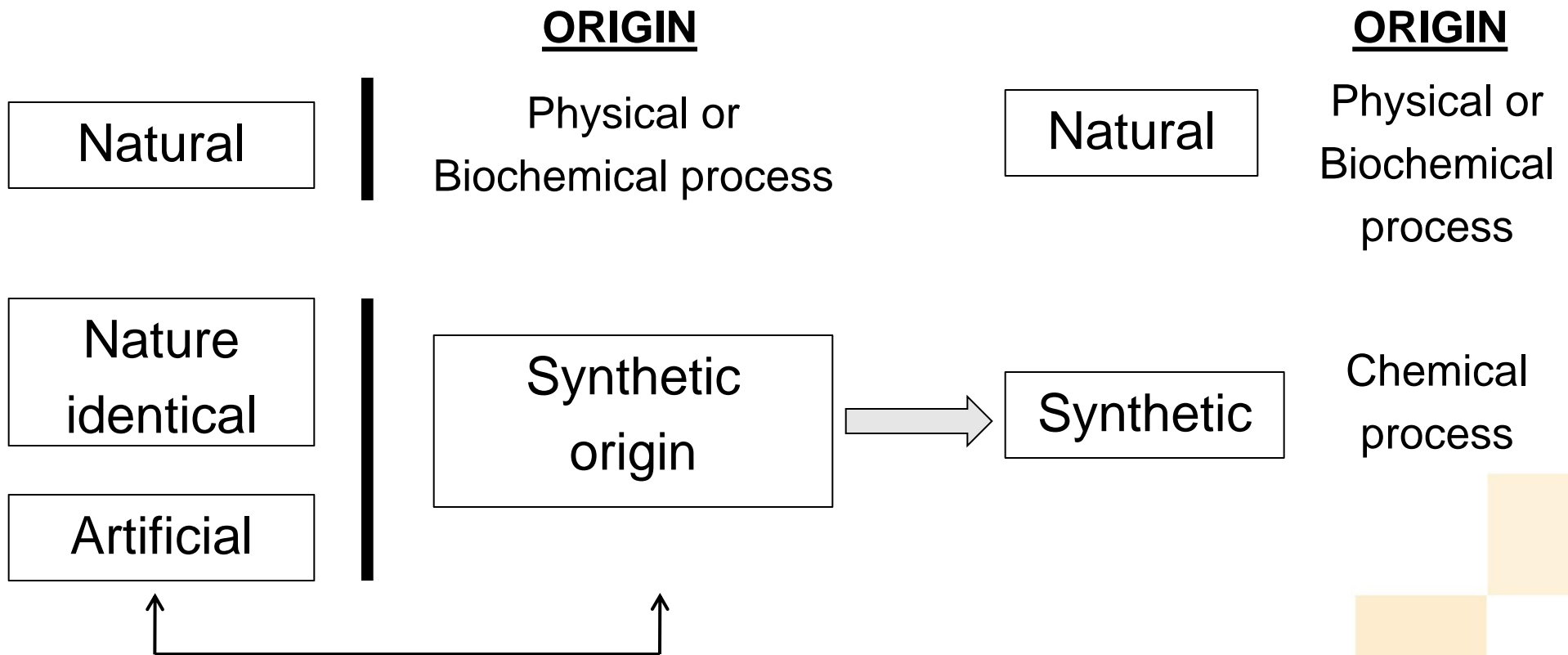
- At the 37th meeting (2005) of the Codex Committee on Food Additives (CCFA) it was decided to develop a Codex Guideline for the Use of Flavourings, that establishes safe conditions of use for flavourings in food similar to the principles for the safe use of food additives contained in the GSFA, and with a reference to the evaluations completed by JECFA.
- The 38th meeting (2006) of the CCFA: start of drafting work.
- At the 40th meeting (2008) the CCFA completed the work and proposed adoption by the Codex Alimentarius Commission.
- Published in Codex Alimentarius as Codex Guideline for the Use of Flavourings (CAC/GL 66-2008).



Consequences of CAC/GL 66-2008

- **Flavourings are products** that are added to food to impart, modify, or enhance the flavour of food (with the exception of flavour enhancers considered as food additives under the Codex Class Names and the International Numbering System for Food Additives-CAC/GL 36-1989). Flavourings do not include substances that have an exclusively sweet, sour, or salty taste (e.g. sugar, vinegar, and table salt). **Flavourings may consist of flavouring substances, natural flavouring complexes, thermal process flavourings or smoke flavourings and mixtures of them and may contain non-flavouring food ingredients.** They are not intended to be consumed as such. (Definition 2.2 of CAC/GL 66-2008)
- Flavour is the sum of those characteristics of any material taken in the mouth, perceived principally by the senses of taste and smell, and also the general pain and tactile receptors in the mouth, as received and interpreted by the brain. **The perception of flavour is a property of flavourings** (Definition 2.1)
- **“Non-flavouring food ingredients are food ingredients, such as food additives and foodstuffs that can be added to flavourings** and are necessary for dissolving, dispersing, or diluting flavourings, or are necessary for the production, storage, handling and use of flavourings”. (Definition 2.3)

Codex Guidelines: a Paradigm Shift





Conclusions- Codex Guideline CAC/GL 66-2008

- Expands and clarifies the definition(s) of flavourings.
- Provides principles for the safe use of components of flavourings evaluated by JECFA and determined to present no safety concern at estimated levels of intake.
- In addition the guideline provides principles for the establishment of practices that do not mislead the consumer.
- Makes reference to the JECFA evaluations and the database of specifications that were endorsed by the Codex Committee on Food Additives.



Consequences for the IOFI Code of Practice

- The IOFI Code of Practice, first published in 1978, and its amendments needed a major upgrade to account for the developments at Codex.
- Question: Do we still need an IOFI Code of Practice? YES!
- CAC/GL 66-2008 requires additions and clarifications. E.g. the Codex Guideline does mention the use of “thermal process flavourings”, but does not provide a definition.
- CAC/GL 66-2008 refers to the JECFA evaluations of flavourings and their specifications. This is a “reference list”, not a positive list as implied in footnote 1 of the guideline : “This guideline does not imply that the uses of flavouring components that have not yet been evaluated by JECFA are unsafe or otherwise unacceptable for use in food”.

Hence, what other flavouring substances are acceptable?



IOFI Code of Practice - 2010

The IOFI Code of Practice 2010 addresses open questions such as:

- what are acceptable flavouring substances other than those evaluated by JECFA?
- what are acceptable non-flavouring food ingredients (additives to flavourings)?
- how to deal with intellectual property issues?
- a definition for thermal process flavouring,

The new Code of Practice was approved at the 22 April 2010 meeting of the IOFI Board and it is regularly updated (Latest Update Feb 2012).

The Code of Practice can be downloaded from the IOFI website at:

<http://www.iofi.org/Home/Teaser-Code-of-Practice/IOFI-Code-of-Practice/page.aspx/103>



Conclusions- IOFI Code of Practice

- The IOFI Code of Practice has adopted all Codex definitions for flavourings from the Codex Guideline CAC/GL 66-2008 and provides additional information whenever relevant.
- The Codex Guideline was developed in order to describe practices that do not mislead the consumer and to establish safe conditions of use for flavourings whilst making a reference to the safety evaluations completed by JECFA.
- Similarly, the IOFI Code of Practice provides the basis for the IOFI Global Reference List of flavourings that are safe for the intended use.



IOFI Global Reference List

- A global, open list of flavourings that were evaluated for intended use based on a common safety evaluation process.
- All substances have to be reviewed for safety by a methodology that is consistent with the Joint FAO/WHO Expert Committee on Food Additives (JECFA) methodology for the safety evaluation of flavouring substances.

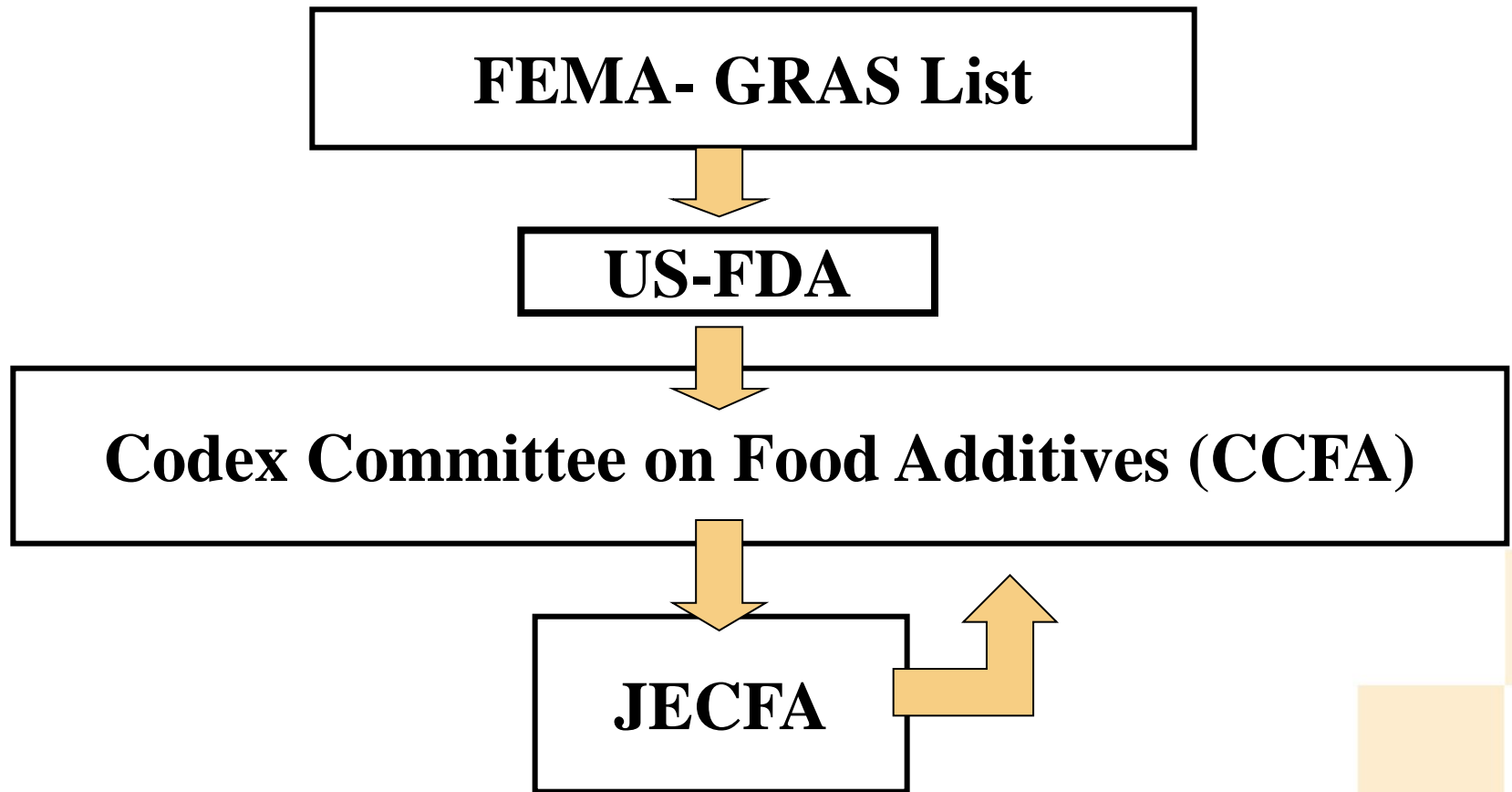
Joint FAO/WHO Expert Committee on Food Additives (JECFA)

- International scientific expert committee established in 1956 to evaluate the safety of food additives, including flavouring substances
- Because of the large number of flavouring substances JECFA developed a special methodology for the safety evaluation of flavouring substances. Methodology is in use at JECFA since 1995
- This approach is now also used by other expert authorities such as the FEMA Expert Panel (FEMA-GRAS) and the European Food Safety Authority (EFSA)

The JECFA Methodology for the Evaluation of Flavouring Substances

- Safety Evaluation of flavouring substances based on:
 - Exposure (“How much is eaten”)
 - Metabolism of flavouring substances (“How is the flavouring digested in the body”)
 - Evaluation in groups of substances (“Alcohols”, “Esters”, “Aldehydes”,... i.e. JECFA recognized > 50 groups of flavouring substances so far)
 - Structure activity relationships (“Similar molecular structures typically give the same level of potential toxicity”)
- Conclusions provided: “no safety concern under conditions of intended use”

Submission Process for JECFA Evaluation





IOFI Global Reference List

- IOFI Global Reference List: the flavour industry's global, open, positive list
 - “Global”; supported by the global flavour industry
 - “Open”; flavourings are added whenever the safety of a specific flavouring is scientifically established and documented
 - “Positive list”; linked to the IOFI Code of Practice; the flavour industry commits itself to only using chemically-defined substances present on the list.



IOFI Global Reference List

- IOFI considers as acceptable flavouring substances materials that meet one or more of the following requirements and these materials comprise the IOFI Global reference List of Flavourings:
 - Flavourings evaluated by JECFA to represent “no safety concern under conditions of intended use”
 - Flavourings that were evaluated by authoritative bodies such as the European Food Safety Authority (EFSA) and the Japanese Food Safety Commission (FSC) using the same or similar methodology as used by JECFA.
 - Flavourings that are generally Recognized As Safe (GRAS) by the US Food and Drug Administration (US FDA) including GRAS determinations published by the Expert panel of the Flavor and Extract Manufacturers Association of the United States (FEMA)

(IOFI Code of Practice- 2010)



IOFI Global Reference List

- The IOFI Global Reference List of Chemically Defined Substances is publically available at www.iofi.org and it is updated regularly to include new entries on the FEMA-GRAS, JECFA or European Union Lists



Global Reference List of Chemically Defined Substances

03 September 2012

Name	CAS	JECFA	FEMA	FL No
Allyl propionate	2408-20-0	0001	2040	09.233
Allyl butyrate	2051-78-7	0002	2021	09.054
Allyl hexanoate	123-68-2	0003	2032	09.244
Allyl heptanoate	142-19-8	0004	2031	09.097
Allyl octanoate	4230-97-1	0005	2037	09.119
Allyl nonanoate	7493-72-3	0006	2036	09.109
Allyl isovalerate	2835-39-4	0007	2045	09.489
Allyl sorbate	7493-75-6	0008	2041	09.312
Allyl undec-10-enoate	7493-76-7	0009	2044	09.146
Allyl 2-methylcrotonate	7493-71-2	0010	2043	09.493



Increasing Acceptance of Reference List Approach

- Historically direct reference was made to the FEMA-GRAS list and regular updates by many countries already: e.g. Australia/New Zealand, The Philippines, Mercosur (Argentina, Brazil, Paraguay, Uruguay, Venezuela (2012)), and more recently by Malaysia (Food Amendment (N°3) Regulations of 27 September 2012).
- With the establishment of the European Union List (2012) it is expected that additional countries will accept flavouring substances on the Union List by reference as well.
- Finally, the Codex Alimentarius secretariat has recently updated the list of food additives and flavouring substances which have established specification obtained from their evaluation by JECFA. This list is available on the Codex website (www.codexalimentarius.org) as CAC/MISC 6-2012. Malaysia has introduced it by reference in its food additives regulations. More Codex members are expected to follow.



QUESTIONS?