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SCF Guidance on NF - Areas for Updates

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Karl-Heinz Engel, ANS Panel member, Member of the Novel Food Working Group

SCF Guidance Document Novel Foods

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DIRECTORATE-GENERAL III
INDUSTRY
Industrial affairs III: Consumer goods industries
Foodstuffs - Legislation and scientific and technical aspects

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Scientific Committee for Food

OPINIONS ON THE ASSESSMENT OF NOVEL FOODS

Recommendations concerning the scientific aspects of

I. **information necessary to support** applications for placing on the market of Novel Foods and Novel Food ingredients	Opinion expressed on 7 June 1996
II. **the presentation of information necessary to support** applications for placing on the market of Novel Foods and Novel Food ingredients	Opinion expressed on 12/13 December 1996
III. **the preparation of the initial assessment reports on** applications for placing on the market of Novel Foods and Novel Food ingredients	Opinion expressed on 12/13 December 1996

Association between the categorization in the Novel Foods Regulation and the SCF recommendations

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EU Regulation Art. 1(2)

		a	b	c	d	e	f
Class 1	Pure chemicals or simple mixtures from non-GM sources			X	X	X	
Class 2	Complex NF from non-GM sources				X	X	
Class 3	GM plants and their products	X	X				
Class 4	GM animals and their products	X	X				
Class 5	GM microorganisms and their products	X	X				
Class 6	Food produced using a novel process						X

SCF Classes of Novel Foods

Class 1: Pure chemicals or simple mixtures from non-GM sources

1.1 the source of the NF has a history of food use in the EU

1.2 the source of the NF has no history of food use in the EU

Class 2: Complex NF from non-GM sources

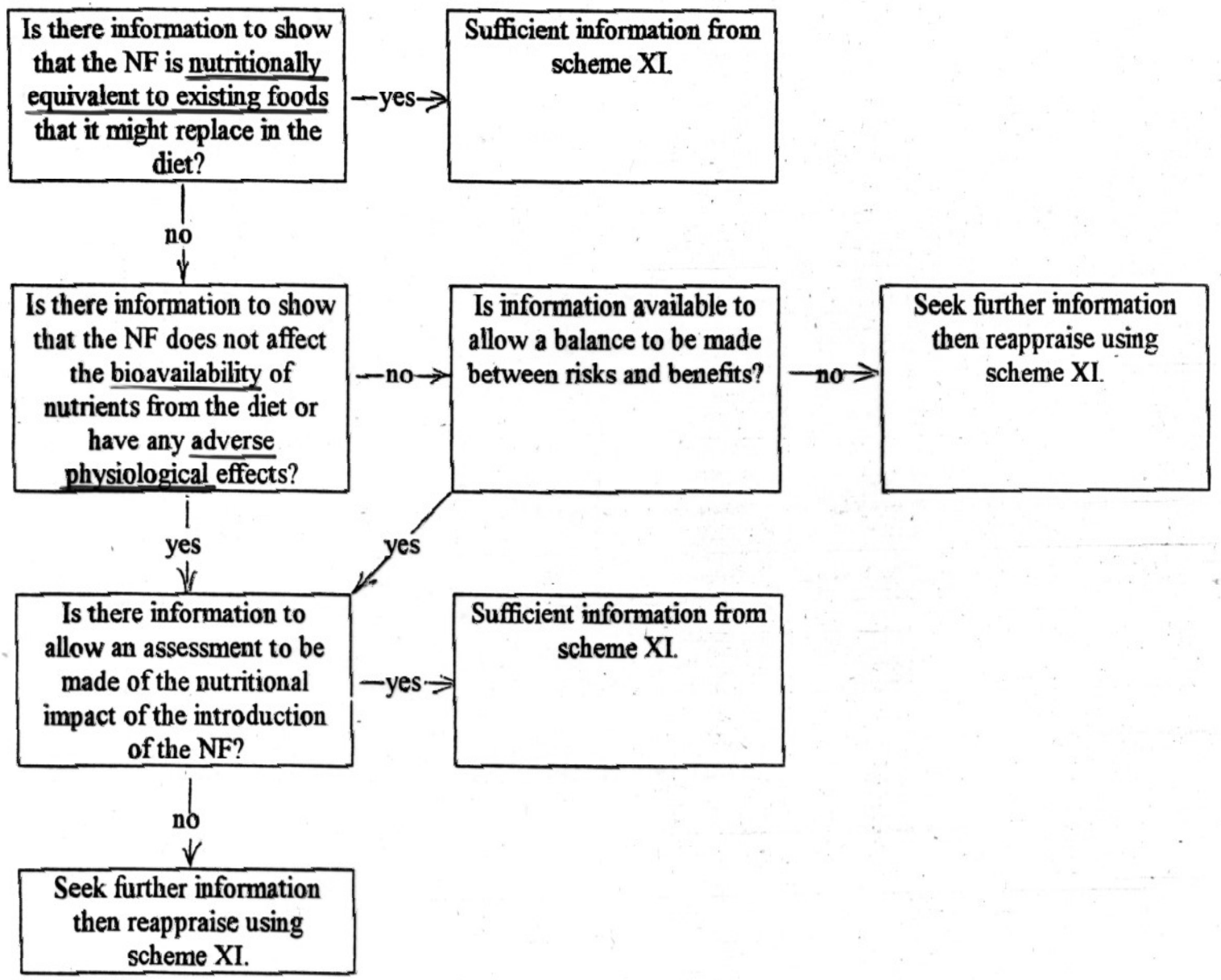
2.1 the source of the NF has a history of food use in the EU

2.2 the source of the NF has no history of food use in the EU

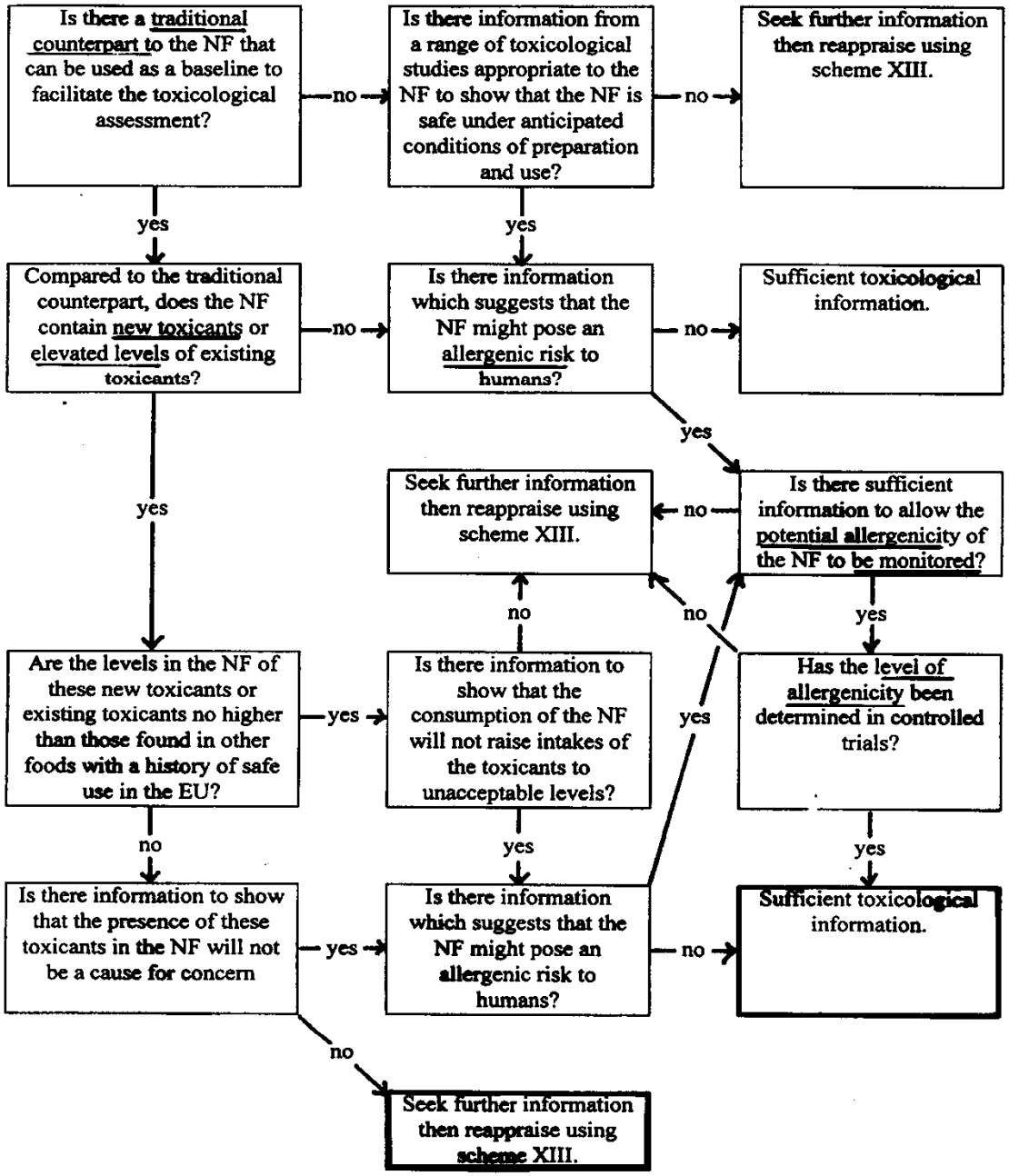
Index to structured schemes to be followed for each class of NF

	Class of NF	1.1	1.2	2.1	2.2	3.1	3.2	4.1	4.2	5.1	5.2	6
	Structured scheme											
I.	Specification of the NF.	X	X	X	X	X	X	X	X	X	X	X
II.	Technical details of the production process undergone by the NF.	X	X	X	X	X	X	X	X	X	X	X
III.	History of the organism used as the source of the NF.	X	X	X	X	X	X	X	X	X	X	X
IV.	Effect of GM on the properties of the host organism.					X	X	X	X	X	X	
V.	Genetic stability of the GM organism used as NF source.					X	X	X	X	X	X	
VI.	Specificity of expression of any novel genetic material.					X	X	X	X	X	X	
VII.	Transfer of genetic material from GM microorganisms.					X	X	X	X	X	X	
VIII.	Ability to survive in and colonise the human gut.									X	X	
IX.	Anticipated intake/extent of use of the NF.	X	X	X	X	X	X	X	X	X	X	X
X.	Information from human exposure to the NF or its source.	X	X	X		X		X		X		X
XI.	Nutritional information on the NF.	X	X	X	X	X	X	X	X	X	X	X
XII.	Microbiological information on the NF.	X	X	X	X	X	X	X	X	X	X	X
XIII	Toxicological information on the NF.		X	X	X	X	X	X	X	X	X	X

XI. NUTRITIONAL INFORMATION ON THE NF



XIII. TOXICOLOGICAL INFORMATION ON THE NF



Data Requirements

I	Specification of the NF
II	Effect of the production process
III	History of the organism used as the source of the NF
IX	Anticipated intake/extent of use of the NF
X	Previous human exposure to the NF or its source
XI	Nutritional information
XII	Microbiological information
XIII	Toxicological information

I. Specification of the NF

- Origin & composition of NF
- Relevant parameters: species, taxonomy, chemical composition (nutritional properties), residuals & contaminations, anti-nutrients/naturally occurring toxicants

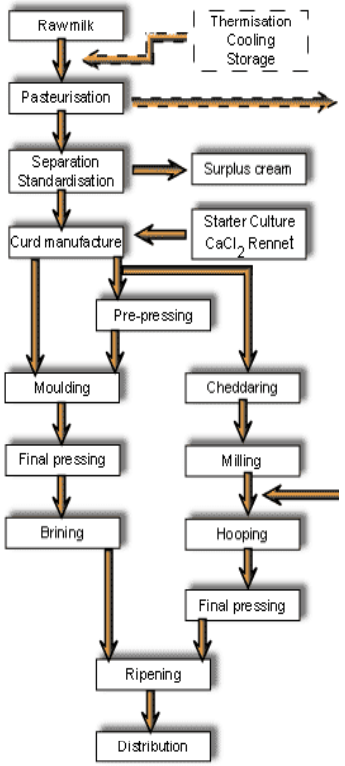
Chia (*Salvia hispanica*)

Issues for Update:

- representative number of batches
- representative type of constituents
- validation, certification

II. Effect of production process

- Description of the manufacturing process
- New technologies – address any organic/inorganic residues or contaminants derived from equipments or chemical, physical or biological aids used in the novel process
- Procedures for fermentation & preparation
- Description of transport & storage conditions
- Critical aspects – compliance of final product with specifications given under scheme I (batch testing)



Issues for Update:

- definition of „significant changes"

III. History of the organism used as source

- Information on past & present use of the plant, animal or microorganism and its products in countries outside the EU
- Past & present methods to obtain raw materials and food
- Its traditional role in the diet

IX. Anticipated intake

- Intake estimations to evaluate the dietary and nutritional significance of the NF
- Information on the nature of the NF and its anticipated uses based upon its properties, e.g. as a fat replacer, tea, supplements…
- Different population groups

Issues for Update:

- uniform approach for intake estimate by the applicant ?
- „reasonable worst case" intake estimate for high consumers
- reasonable estimate for average consumer
- margin of exposure (MOE) / margin of safety (MOS)
- EU food consumption data base

X. Previous human exposure

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to the NF or its source

- **Documentation on previous use of the NF source and/ or the NF in other parts of the world outside the EU**

Allanblackia species grow in the tropical forests along the Gulf of Guinea, Uganda and Tanzania. The oil obtained from the seed is used locally for food preparation & seeds are eaten by children as a high-energy snack.

Ice Structuring Proteins: USA marketing authorization in 2003, 470 million products and consumed)

Noni Juice/Noni Fruit: production and consumption figures from the USA

Issues for Update:

- criteria to define the term „history of (safe) food use"

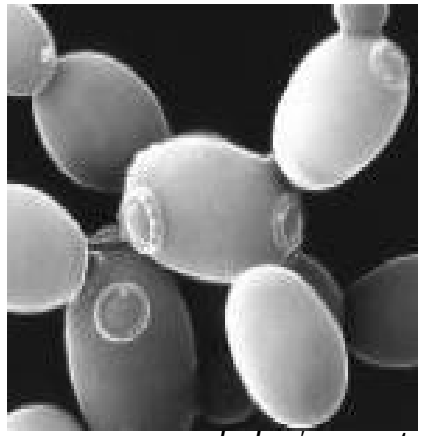
XI. Nutritional information

- Systematic review of the NF's composition, preparation and role expected in the diet
- Nutritional assessment (animal, human studies)
- Nutritional effects at normal & maximum levels of consumption
- Effect of anti-nutritional factors

(EC) No 258/97: <u>Should not be nutritionally disadvantageous</u> for the consumer when compared to foods or food ingredients which they are intended to replace

XII. Microbiological information

- Characterization of microorganisms present in the NF and analysis of their metabolites
- Organism (e.g. intentionally used source of the NF) has to be non-pathogenic, non-toxigenic and of known genetic stability



baker's yeast

XIII. Toxicological information

- comparison to traditional counterpart
- "substantial equivalence"

- animal feeding studies
  tests for genotoxicity (*in vitro* and *in vivo*)
  test for / prediction of potential allergenicity
  → no fixed testing regimes

XIII. Toxicological information

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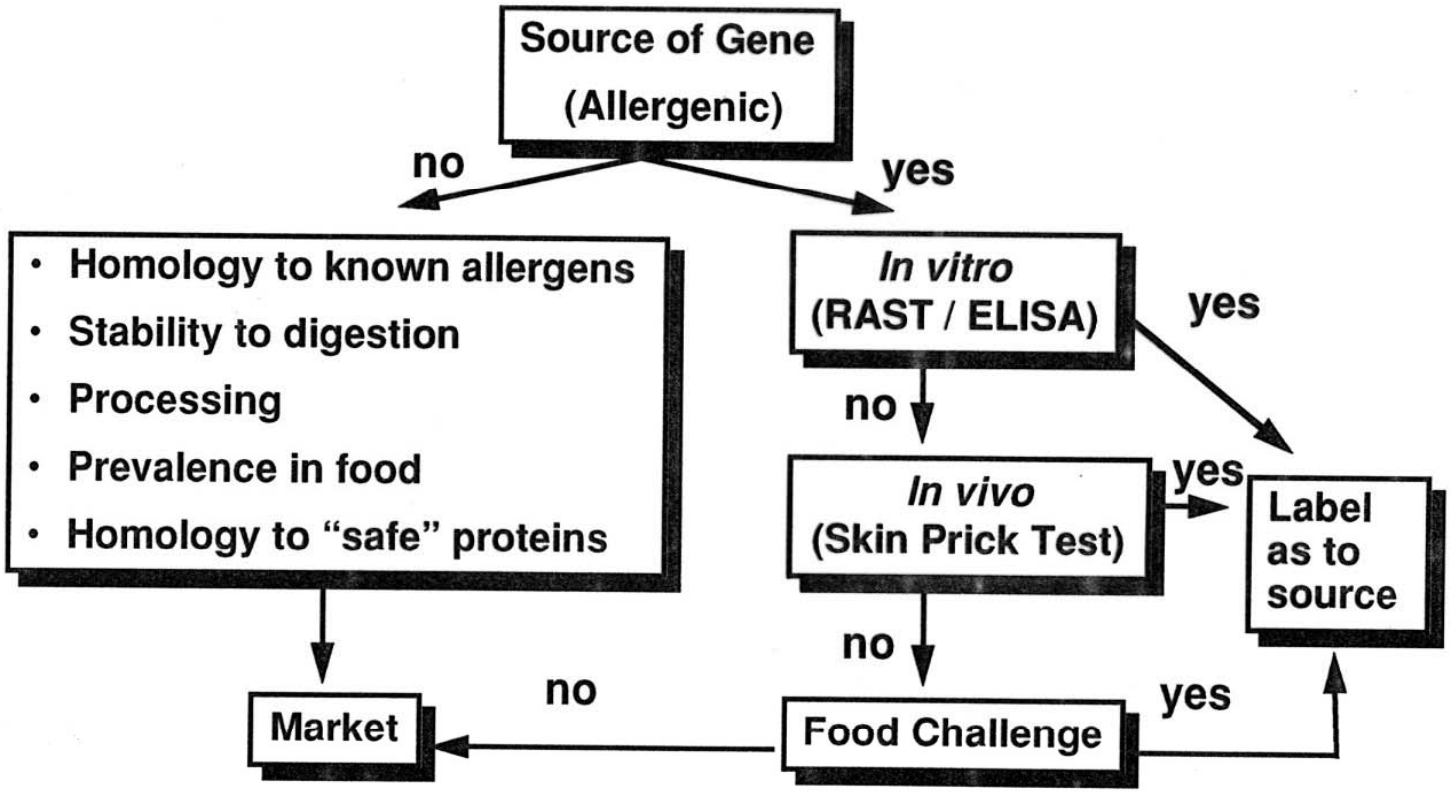
Issues for Update:

- recommendation of standard toxicological testing programmes for specific types of producs
  - ADME studies
  - 90-day feeding studies in rodents
  - genotoxicity studies
- testing of single substances vs. complex foods
- use of „compositional data" and „experience of continued use" to address concerns on potential allergenicity

Allergenicity

Assessing the allergenic potential of foods derived from genetically engineered crop plants should be based on a decision-tree approach . . .



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THANK YOU FOR YOUR KIND ATTENTION