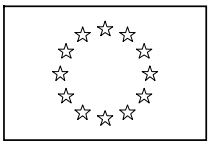

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 01.10.2001
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REPORT FROM THE COMMISSION

on Dietary Food Additive Intake in the European Union

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EXECUTIVE SUMMARY

European Parliament and Council Directives 94/35/EC, 94/36/EC and 95/2/EC require each Member State to monitor the consumption and usage of food additives. The Commission is required to submit a report on this monitoring exercise to the European Parliament and Council.

Ten Member States and Norway, acting under EU Scientific Co-operation, have been working together to develop a tiered approach to evaluate dietary intake of food additives. The 'tiers' described are essentially additive intake estimation methods that progress in complexity and data requirements, intended to produce gradually a more accurate estimate of the additive intake. Where results of the estimates in a tier indicate that an ADI is unlikely ever to be exceeded, the additives in question are eliminated from further consideration. Resources can then be focused on the remaining additives for a more refined intake estimate. It must be emphasised that these tiers are essentially tools for establishing priorities for further monitoring.

This report represents a first attempt to obtain an overview of the dietary food additive intake in the European Union. Even if the results must be regarded as a very preliminary indication on the dietary intake of food additives, they indicate that the intake of the majority of food additives permitted today in the European Union is below the acceptable daily intake (ADI) set by the Scientific Committee on Food.

This report has many limitations. Food consumption data used was insufficient to estimate accurately food additive intake leading to worst case assumptions and consequent over-estimations of intake. Also several Member States did not use the agreed methodology for estimation of additive intake, leading to lack of comparability of the collected data. This highlights the need for Member States to apply the agreed, harmonised methodology to ensure consistency of approach and to allocate adequate resources for all future intake estimations. The current study should then be repeated and a new report should be drawn up within three years from now.

Introduction

The authorisation and use of food additives in the European Union are based on the framework Directive 89/107/EEC[1] on food additives. On the basis of the framework Directive, three specific directives were adopted by the Council and European Parliament: on sweeteners (Directive 94/35/EC[2]), colours (Directive 94/36/EC[3]) and on additives other than colours and sweeteners (Directive 95/2/EC[4]). Since the adoption of the last directive in 1995, legislation on food additives has been fully harmonised in the European Union.

According to European Parliament and Council Directives 94/35/EC (Article 8), 94/36/EC (Article 6) and 95/2/EC (Article 7) on food additives, the Member States shall establish a monitoring system for the consumption of food additives. The objective is to monitor food additive consumption and to ensure that their use does not exceed the acceptable daily intake (ADI) set for additives by the Scientific Committee on Food (SCF).

For this purpose, the Member States discussed, through scientific co-operation (SCOOP), a method to gather data that would be comparable among the Member States. The SCOOP task was finalised in January 1998.

In August 1999 the Commission sent to the Member States guidelines on how to report their findings to the Commission. Information was received from the following Member States: Austria, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Spain, Sweden and the United Kingdom. The other Member States had not been able to carry out the exercise due to lack of resources. From the EFTA countries, Norway submitted information to the Commission.

The report describes the monitoring task, how the results were reported and what kind of information was received. The food consumption data used for the intake calculations are described. Intake results are listed in tables for adults and children separately. The report also draws conclusions with regard to future work.

The report represents a first attempt to obtain an overview of the food additive intake in the European Union. It must be regarded as a very preliminary indication of the dietary intake of food additives.

The Commission would like to thank Dr Wendy Matthews from the United Kingdom Food Standards Agency, Dr Inge Meyland from the Danish Veterinary and Food Administration, Dr Pirjo-Liisa Penttilä from the Finnish National Food Administration and Dr Philippe Verger from the Institut National de la Recherche Agronomique (INRA), for assisting the Commission in drafting this report.

1 O.J. n° L 40, 11.2.1989, p. 27
2 O.J. n° L 237, 10.09.1994, p.1
3 O.J. n° L 237, 10.09.1994, p. 13
4 O.J. n° L 61, 18.03.1995, p. 1

2. BACKGROUND

In 1996, under Council Directive 93/5/EEC on assistance to the Commission and co-operation by the Member States in the scientific examination of questions relating to food[5], a task was set up on "Methodologies for monitoring of food additive intakes" (SCOOP Task 4.2). The objectives of the task were:

- to identify data that can be used to assess likely additive intakes,
- to review methodologies currently used for monitoring additive usage and estimating intakes,
- to consider the need for different approaches to different types of additives,
- to establish systematic procedures for the identification of additives for which potential dietary intake gives most cause for concern
- and to develop a strategy that matches the complexity and cost of intake estimation to the level of concern posed by the potential intake of an additive.

The following Member States participated in the scientific co-operation task: Austria, Denmark, Greece, Finland, France, Ireland, the Netherlands, Spain, Sweden and the United Kingdom. In addition, Norway participated in the task. The report was produced in January 1998[6].

The participants of the SCOOP task reviewed the relevant methods for estimating the intake of food additives and proposed a tiered approach, which could be used by the Member States to meet the monitoring requirements set out in EC directives. According to the report, "*monitoring of additive intake should concentrate on discovering whether the exposure of consumers to any food additives regularly exceeds the acceptable daily intake (ADI)"*. This information can then be used by the Community regulator to determine what action (if any) is required to ensure that safety advice is being followed.

The definition of a number of key terms used throughout the report is given in box 1.

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5 O.J. n° L 052, 04.03.1993, p. 18

6 The scientific co-operation report on development of methodologies for the monitoring of food additive intake across the European Union (SCOOP/INT/REPORT/2)

Box 1:

Scientific Committee on Food (SCF) = A scientific advisory body to the European Commission on any problem relating to the protection of the health and safety of persons arising or likely to arise from the consumption of food.

Scientific co-operation (SCOOP) = Assistance to the European Commission and co-operation by the Member States in the scientific examination of questions relating to food.

Intake = The amount of food additive ingested in the diet (calculated as food consumption x food additive concentration).

Acceptable daily intake (ADI) = The amount of a food additive, expressed as mg/kg body weight, that can be ingested daily over a lifetime without incurring any appreciable health risk. The ADI is based on an evaluation of available toxicological data and established by identifying the No-Observed-Adverse-Effect-Level (NOAEL) in the most sensitive experiment among a battery of studies in test animals performed with the test compound and extrapolating to man by dividing the NOAEL with a safety factor of usually 100.

ADI "not specified" = A term used when, on the basis of the available toxicological, biochemical and clinical data, the total intake of the substance, arising from its natural occurrence and/or its present use or uses in food at the levels necessary to achieve the desired technological effect, will not represent a hazard to health. For this reason, the establishment of a numerical limit for the ADI is not considered necessary for the substance.

Maximum usage level = Highest level of a food additive permitted in foodstuff to achieve an intended technological effect. The levels are set in the specific directives: for sweeteners in Directive 94/35/EC, for colours in Directive 94/36/EC and for additives other than colours and sweeteners in Directive 95/2/EC.

Quantum satis = no maximum level is specified for the additive in question. However, the additive shall be used in accordance with good manufacturing practice, at a level not higher than necessary to achieve the intended purpose and provided that it does not mislead the consumer (Article 2(8) of Directive 95/2/EC).

In the tiered approach (see box 2), tier 1 is based on theoretical food consumption data[7] and maximum usage levels for additives as permitted by relevant Community legislation. The second and third tiers refer to assessment at the level of individual Member States, combining national data on food consumption with the maximum permitted usage levels for the additive (tier 2) and with its actual usage patterns (tier 3).

[7] Hansen, S. (1979). Conditions for Use of Food Additives Based on a Budget for an Acceptable Daily Intake. Journal of Food Protection 42 5, 429-434.

The SCF has recommended that special attention should be given to intake by children, since there is evidence suggesting that their dietary behaviour means that their intake of some additives, expressed on a bodyweight basis, may be markedly higher than that of adults. Therefore, in the SCOOP task, it was concluded that adults and children should be covered by a separate assessment.

Box 2:

TIER 1 = **theoretical food consumption data** combined with the **maximum permitted usage levels** for the additive

TIER 2 = **actual national food consumption data** combined with the **maximum permitted usage levels** for the additive

TIER 3 = **actual national food consumption data** combined with **the actual usage levels** of the additive

3. THE MONITORING TASK

The monitoring task was carried out in a stepwise manner. An overview of the method used is given in Annex I.

3.1. Additives excluded from the monitoring task:

Because priorities had to be set, it was decided to exclude from the monitoring exercise a series of additives on the basis of the following criteria:

- Additives with an ADI "not specified" allocated by the SCF; since an additive is only allocated an ADI "not specified" when, on the basis of the available scientific data, the total intake of the substance will not represent a hazard to health (see box 1).

- Additives that, based on the safety-in-use evaluation by the SCF, are only authorised in one or few specific food categories since their intake is limited to these food categories.

- New additives that have only been permitted for a short period of time since they were not in full use at the time information was collected.

These additives are listed in Annex II.

3.2. Additives subject to tier-1 screening

In tier 1, all additives with a numerical ADI were examined, with the exception of:

- those falling under 3.1, second and third bullet point and

- those authorised at *quantum satis*; they could not be examined in tier 1 or 2 since no maximum-permitted-use levels exist and were therefore moved to tier 3. These additives are listed in Annex IV.

The additives of tier 1 were screened using **theoretical food consumption data** combined with **maximum permitted use levels** of the additive. Food additives, for which the calculated intake exceeded the ADI, were moved to tier 2.

Up to this stage the exercise was carried out as part of the SCOOP task.

3.3. Additives subject to tier-2 screening

In tier 2 the additives from tier 1 that exceeded the calculated intake were examined. Their theoretical intake was calculated by combining the **mean national food consumption data** of the whole population with the **maximum permitted use levels** of the additive. This information was requested for both adults and young children, where available. The basis of the national consumption data was requested. Food additives, for which the calculated intake exceeded the ADI, were moved to tier 3.

3.4. Additives subject to tier-3 screening

At tier 3, two groups of additives were to be examined:

- additives moved to tier 3 from tier 2
- additives with numerical ADIs that are permitted for use at *quantum satis*

Member States were requested to examine these additives by calculating the **actual intake** from the **national food consumption data** combined with **actual use levels** of the additive.

4. THE MONITORING DATA

4.1. Instructions for reporting the monitoring data

A table containing information on additives and the permitted use levels was provided to the Member States. By adding the information from the national consumption data, the theoretical intake could be calculated (tier 2). The actual intake could be evaluated (tier 3) if both the national consumption data and the additive usage levels were available. It could be calculated by adding the usage level to the table.

For the purpose of the intake report:

- Young children means children under 3 years[8], referring to a bodyweight of 15 kg
- Adult refers to a bodyweight of 60 kg

Values were requested in:

- mg of additive/day

[8] Information submitted from the United Kingdom was for children of age range 1½ - 4½ years old referring to bodyweight of 15 kg.

- % of ADI based on 60 kg bodyweight for an adult or 15 kg for a young child, or on actual bodyweight, which had to be specified.

4.2. The type of monitoring data obtained

The following 6 Member States submitted information to the Commission as requested: Denmark, France, Italy, The Netherlands, Spain[9], the United Kingdom and in addition Norway. Austria, Finland, Germany[10], Ireland, Spain and Sweden submitted information obtained on a basis other than the intake estimation methods defined under the SCOOP task.

The data were submitted in the form of additive intake tables from the 7 countries in the requested format and 12 reports or notes on national studies.

Intake estimate was reported on average consumption of the population as a whole and in some cases also for high level consumers or special groups of the population.

Box 3:

Mean population intake = total food additive intake divided by the whole population

Mean intake for consumers only = total food additive intake divided by the number of actual consumers of the additive

High level consumer = a consumer with a high intake of the additive based on the distribution of individual intake values for actual consumers

The data present the following characteristics:

4.2.1. Age of data

- Collected between 1995 and 1999 for France, Spain (other additives than cyclamate), Austria (adults), Italy, Finland, Sweden, Denmark (nitrates and nitrites in meat and meat products), Ireland (second study) and the Netherlands.

- Collected between 1990 and 1994 for Ireland (first study), Spain (cyclamate), Austria (children over 6 years old, pregnant women, lactating women, elderly, diabetics), Norway and the United Kingdom (children).

- Collected between 1987 and 1989 for Denmark and the United Kingdom (adults).

For the purpose of monitoring the food additive intake in the European Union after the full harmonisation in 1995, the information gathered should have described the situation

[9] Information submitted from Spain was for the whole population. The division between adults and children was made on the basis of the assumption that children represent a percentage of the whole population. As data for children did not come from an actual survey, it was considered appropriate to report only the information for the whole population.

[10] Information for Germany was local data from Bavaria and consisted only of food consumption figures. The information on food additive intake was not provided.

after the entry into force of the Community legislation. However, some Member States were collecting data between 1987 and 1999. Because collecting food consumption data is very costly, it was considered useful for the purposes of this report to include any data submitted by the Member States, even if it dated from before 1995.

4.2.2. Representativity

Two surveys were performed locally and are, therefore, not considered to be representative of the whole population: In Spain, the intake study of cyclamate in Catalonia, and in Finland, the STRIP (Children's Coronary Heart Disease Risk Factor Intervention) project conducted on children in Turku.

4.2.3. Type of survey

- Recall for Austria (adults), Finland (adults) and Spain (cyclamate).
- Record for Austria (children over 6 years old, pregnant women, lactating women, elderly, diabetics), Denmark, Finland (children), Ireland, Italy, The Netherlands, France, Spain (other additives), and the United Kingdom.
- Food Frequency Questionnaire for Norway and Sweden (diabetics).

Box 4:

Recall = based on memory of food consumption prior to the interview

Record = food consumption recorded systematically by the consumer over a set period of time

Food frequency questionnaire (quantitative) = the consumer reports the frequency and amount of food consumed

4.2.4. Types of population

- Individuals for Austria, Italy, Finland, Spain (cyclamate), Denmark (nitrates and nitrites in meat and meat products), Ireland, Italy, The Netherlands, France (11 additives - tier 2), Sweden, Norway and the United Kingdom.
- Household for Denmark, France (17 additives - tier 2) and Spain (additives other than cyclamate).

4.2.5. Duration of the survey

- One-day survey in Austria, Finland (adults) and Spain.
- Two-day survey in the Netherlands.
- 4-day survey in Finland (children) and the United Kingdom (children).

- 7-day survey in Austria, Denmark (nitrates and nitrites in meat and meat products), Italy, France (11 additives - tier 2), Spain and the United Kingdom (adults).

- One month collection of typical consumption in Denmark

- One-year record in France (17 additives - tier 2).

5. INTAKE RESULTS

For the purposes of this report, only the data obtained on the basis of the estimation methods defined under the SCOOP task could be used. Data submitted that were obtained on a different basis could not be used because of their incomparability. Nevertheless, it was considered interesting to summarise the information received in Annex VI.

5.1. Tier 1

On the basis of tier 1, it is already possible to exclude a number of food additives from further examination, since the theoretical intake based on conservative assumptions on food consumption and additive usage did not exceed the ADI. For adults, there were 21 additives or additive groups* that were excluded from further examination. For children, 9 additives or additive groups were excluded. These additives are listed in Annex III.

5.2. Tier 2

The outcome of the tier 2 of this first monitoring of dietary food additive intake in the European Union shows relatively consistent results. Using the mean exposure of the population in six Member States and Norway, it is possible to exclude most additives from the list for tier-3 evaluation since the theoretical intake based on actual food consumption data combined with the maximum permitted usage levels for the additive did not exceed the ADI.

For adults and the whole population, the following food additives and food additive groups were excluded from further examination:

- E 210-213 benzoates, E 297 fumaric acid, E 310-312 gallates, E 315-316 erythorbates, E 320 BHA, E 321 BHT, E 355- 357 adipates, E 416 karaya gum, E 442 ammonium phosphatides, E 475 polyglycerol esters, E 476 polyglycerol polyricinoleate, E 479b TOSOM, E 483 stearyl tartrate, E 491/492/495 sorbitan esters, E 535-538 ferrocyanides, E 950 acesulfame K, and E 952 cyclamates.

- All the colours

For children, the following food additives and food additive groups were excluded from further examination:

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* Additive group = closely related substances that have been allocated a group ADI (e.g. phosphoric acid and phosphates, saccharin and its salts etc.)

- E 200-203 sorbates, E 297 fumaric acid, E 310-312 gallates, E 315-316 erythorbates, E 320 BHA, E 355- 357 adipates, E 416 karaya gum, E 442 ammonium phosphatides, E 444 sucrose acetate isobutyrate, E 476 polyglycerol polyricinoleate, E 479b TOSOM, E 951 aspartame, E 952 cyclamates, E 954 saccharin, E 959 neohesperedine DC and E 999 quillaia extract.

- All the colours (except E 160b annatto).

Additives were moved to tier 3 for further detailed intake estimation on the basis that the theoretical intake at tier-2 level approached or exceeded the ADI at least in one Member State or if there was further information suggesting that some groups of consumers may have unusually high intake levels.

For adults and the whole population, the following food additives and food additive groups were moved to tier 3:

- E 220-228 sulphites, E 249-250 nitrites, E 432-436 polysorbates, E 473-474 sucrose esters and sucroglycerides, E 481-482 stearoyl-2-lactylates, E 493-494 sorbitan monolaureate and sorbitan monooleate, E 520-523 aluminium sulphates, E 541 sodium aluminium phosphate and E 554-556/559 aluminium silicates.

For children, the following food additives and food additive groups were moved to tier 3:

- E 160b annatto, E 220-228 sulphites, E 210-213 benzoates, E 249-250 nitrites, E 321 BHT, E 338-341/343/450-452 phosphoric acid and phosphates, E 432-436 polysorbates, E 473-474 sucrose esters and sucroglycerides, E 475 polyglycerol esters, E 481-482 stearoyl-2-lactylates, E 483 stearyl tartrate, E 491-495 sorbitan esters, 535-538 ferrocyanides, E 520-523 aluminium sulphates, E 541 sodium aluminium phosphate, E 554-556/559 aluminium silicates and E 950 acesulfame-K.

In addition, E 558 bentonite (both for adults and children) was moved to tier 3 due to lack of information on the intake of this additive at tier-2 level.

Furthermore, nine additives with numerical ADIs that are permitted for use at *quantum satis* were moved directly to tier 3 (see Annex IV) because actual use levels are necessary for intake estimations.

Results obtained for the intake of food additives at tier 2 are listed in Annex V for adults and the whole population (Table 1) and for young children (Table 2). The following information is given in the tables: E-number, the specific name and the ADI of the additive, the Member State that provided the information, the range of the intake of the additive expressed as a percentage of the ADI, consequence for tier-estimation.

5.3. Tier 3

No Member State submitted complete information on tier 3 results according to the method agreed.

Discussion

This report is the first attempt to obtain an overview of the dietary food additive intake in the European Union. The results reported must be regarded as a very preliminary indication on the dietary intake of food additives due to the many limitations the current exercise had.

In its request for information on food additive intake, the objective of the Commission was to obtain information from as many Member States as possible. Therefore, a pragmatic approach to use information calculated on the food consumption of the population mean was chosen. However, the use of the population mean does not take into account intake by high-level consumers. On the other hand, the estimates reported here are extremely conservative, since they assume that each additive is used in the widest possible range of foods at the maximum permitted levels, which in many cases leads to over-estimation of the additive intake. Therefore, more precise studies are needed in the future. In several Member States, work is already in progress for gathering information to enable more refined intake estimations to be carried out.

Today, 171 additives and additive groups are permitted for use in the EU. On the basis of the limited data available, it can be concluded that for the majority of these additives, intake is below the ADI set by the Scientific Committee on Food. As a result of tier-2 intake estimations, eight additives or additive groups were prioritised for tier-3 estimations for adults and seventeen additives or additive groups were prioritised for tier-3 estimations for children. The tier-2 values for these additives theoretically exceeded the ADI at least in one Member State or no information was provided on the substance. It should be noted that the range of intake of the same additive could vary considerably between different countries. In addition, nine additives allocated a numerical ADI, but permitted for use in certain foods according to *quantum satis*, were prioritised for tier-3 examination.

To carry out the tier-3 estimation for these additives, more detailed information should be collected on the real use of additives and on the real food consumption (actual intake, special groups of consumers, high-level consumers). This work should be carried out without delay.

In addition to action being taken on additives prioritised for tier 3, examination should also continue on additives that passed tier 2 and were not prioritised for tier 3. Firstly not all the Member States have studied these additives and, as stated above, the results can vary considerably depending on the country. Secondly, estimation of the intake of these additives should be done also on high-level consumers, not only on the population mean.

7. CONCLUSIONS

- The Member States should follow up the SCOOP task on methodologies for the monitoring of food additives in order to achieve harmonisation of intake studies of additives in the European Union. In addition, better food consumption data should be gathered in order to estimate dietary food additive intake more accurately.

- The preliminary results with limited data available indicate that for the majority of food additives the dietary intake is below the acceptable daily intake.

- For the additives that were moved to tier 3 (see Annex V) and certain additives that are permitted at *quantum satis* (see Annex IV), intake estimations should be carried out using actual food consumption data combined with the actual usage levels of the additive. The examination should be carried out by all the Member States without delay and the results should be reported to the Commission with a view to initiating necessary action, if any.

- Intake of additives that did not exceed the ADI in tier 2 should, nevertheless, be re-examined in the light of the more detailed food consumption data (see Annex V).

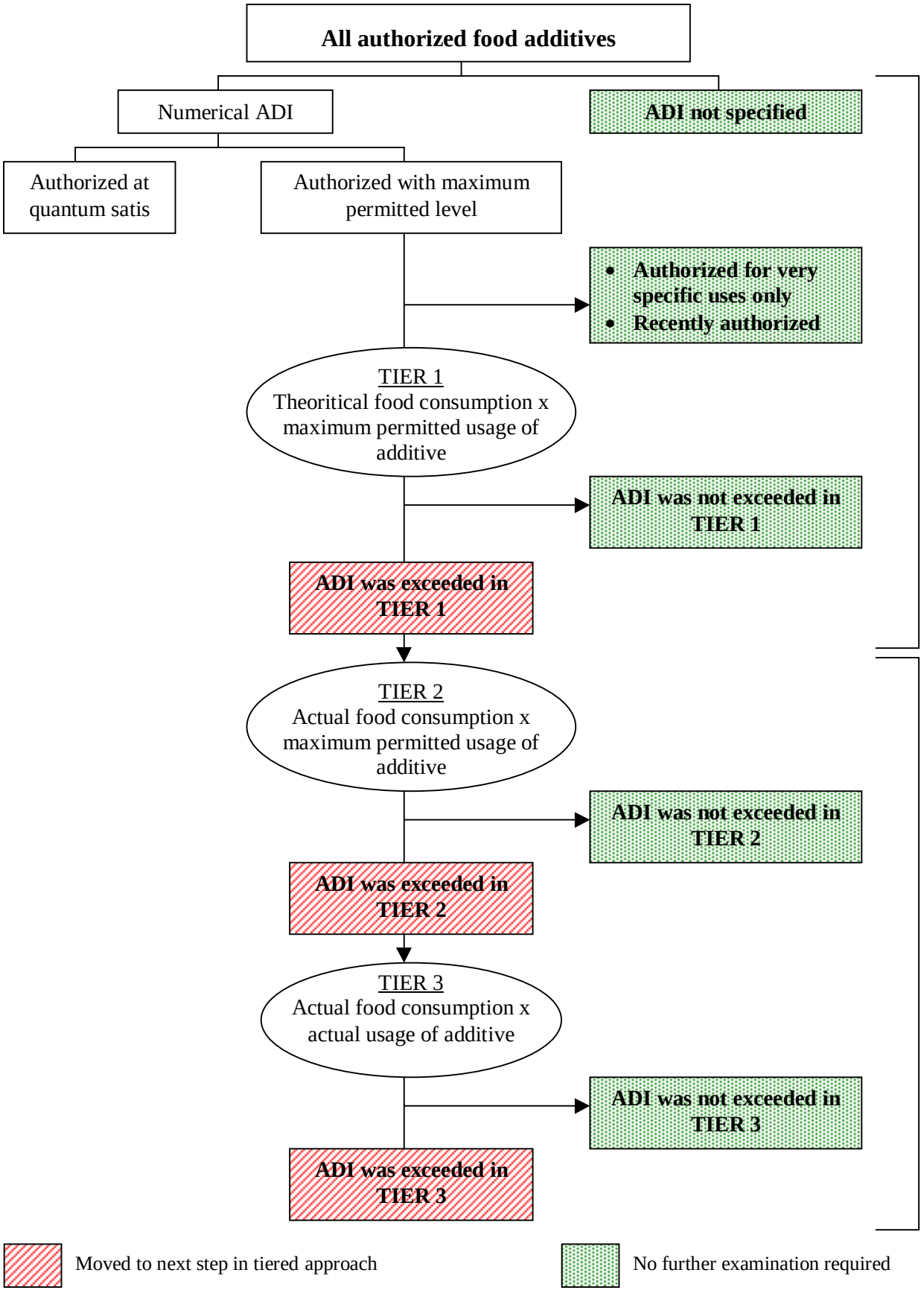
- Intake studies should be carried out in respect of the additives which, at the time of this exercise, had only recently been approved.

- Co-operation with the food industry should be developed with a view to obtaining better information on food additive usage.

- A new report on the overall situation on food additive intake in the European Union should be compiled in three years time. It is essential that efforts are made by all the Member States to participate fully in the next monitoring task on dietary intake of food additives.

Annex I

Outline of the tiered approach



Annex II

List of food additives with ADI "not specified", found acceptable for specified use as recommended by the SCF or new additives. These additives were excluded from the examination

E No	Name
	Polyethyleneglycol 6000
E 100	Curcumin
E 101	(i) Riboflavin (ii) Riboflavin-5'phosphate
E 140	Chlorophyls and Chlorophyllins
E 150a	Plain caramel
E 153	Vegetable carbon
E 160d	Lycopene
E 161b	Lutein
E 162	Beetroot Red, betanin
E 163	Anthocyanins
E 170	Calcium carbonates
E 171	Titanium dioxide
E 172	Iron oxides and hydroxides
E 173	Aluminium
E 174	Silver
E 175	Gold
E 230	Biphenyl, diphenyl
E 231 E 232	Orthophenyl phenol Sodium orthophenyl phenol
E 235	Natamycin
E 239	Hexamethylene tetramine
E 242	Dimethyl dicarbonate
E 260 E 261 E 262 E 263	Acetic acid Potassium acetate Sodium acetates Calcium acetate
E 270 E 325 E 326 E 327	Lactic acid Sodium lactate Potassium lactate Calcium lactate
E 280 E 281 E 282 E 283	Propionic acid Sodium propionate Calcium propionate Potassium propionate
E 284 E 285	Boric acid Sodium tetraborate (Borax)
E 290	Carbon dioxide
E 296 E 350 E 351 E 352	Malic acid Sodium malates Potassium malate Calcium malates
E 300 E 301 E 302 E 304	Ascorbic acid Sodium ascorbate Calcium ascorbate Fatty acid esters of ascorbic acid
E 306 E 307 E 308 E 309	Tocopherol-rich extract Alpha-tocopherol Gamma-tocopherol Delta-tocopherol
E 322	Lecithins
E 330 E 331 E 332 E 333	Citric acid Sodium citrates Potassium citrates Calcium citrates
E 353	Metatartaric acid
E 363	Succinic acid
E 380	Triammonium citrate
E 400 E 401 E 402 E 403 E 404	Alginic acid Sodium alginate Potassium alginate Ammonium alginate Calcium alginate
E 406	Agar
E 407a	Processed eucheuma seeweed
E 410	Locust bean gum
E 412	Guar gum
E 413	Tragacanth
E 414	Acacia gum (gum arabic)
E 415	Xanthan gum
E 417	Tara gum
E 418	Gellan gum
E 420	(i) Sorbitol (ii) Sorbitol syrup
E 421	Mannitol
E 422	Glycerol
E 425	(i) Konjac gum (ii) Konjac glucomannane
E 431	Polyoxyethylene (40) stearate
E 440	Pectins
E 459	Beta-cyclodextrine
E 460	Cellulose
E 461 E 463 E 464 E 465 E 466 E 469	Methyl cellulose Hydroxypropyl cellulose Hydroxypropyl methyl cellulose Ethyl methyl cellulose Carboxy methyl cellulose Enzymatically hydrolysed carboxy methyl cellulose
E 468	Crosslinked sodium carboxy methyl cellulose
E 470a E 470b	Sodium, potassium and calcium salts of fatty acids Magnesium salts of fatty acids

E No	Name
E 471	Mono and diglycerides of fatty acids
E 472a	Acetic acid esters of mono and diglycerides of fatty acids
E 472b	Lactic acid esters of mono and diglycerides of fatty acids
E 472c	Citric acid esters of mono and diglycerides of fatty acids
E 472d	Tartaric acid esters of mono and diglycerides of fatty acids
E 472f	Mixed acetic and tartaric acid esters of mono and diglycerides of fatty acids
E 500	Sodium carbonates
E 501	Potassium carbonates
E 503	Ammonium carbonates
E 504	Magnesium carbonates
E 507	Hydrochloric acid
E 508	Potassium chloride
E 509	Calcium chloride
E 511	Magnesium chloride
E 512	Stannous chloride
E 513	Sulphuric acid
E 514	Sodium sulphates
E 515	Potassium sulphates
E 516	Calcium sulphate
E 517	Ammonium sulphate
E 524	Sodium hydroxide
E 525	Potassium hydroxide
E 526	Calcium hydroxide
E 527	Ammonium hydroxide
E 528	Magnesium hydroxide
E 529	Calcium oxide
E 530	Magnesium oxide
E 551	Silicon dioxide
E 552	Calcium silicate
E 553a	Magnesium silicates
E 553b	Talc
E 570	Fatty acids
E 574	Gluconic acid
E 575	Glucono-delta-lactone
E 576	Sodium gluconate
E 577	Potassium gluconate
E 578	Calcium gluconate
E 579	Ferrous gluconate
E 585	Ferrous lactate
E 620	Glutamic acid
E 621	Monosodium glutamate
E 622	Monopotassium glutamate
E 623	Calcium diglutamate
E 624	Monoammonium glutamate
E 625	Magnesium diglutamate

E No	Name
E 626	Guanylic acid
E 627	Disodium guanylate
E 628	Dipotassium guanylate
E 629	Calcium guanylate
E 630	Inosinic acid
E 631	Disodium inosinate
E 632	Dipotassium inosinate
E 633	Calcium inosinate
E 634	Calcium 5'-ribonucleotides
E 635	Disodium 5'-ribonucleotides
E 640	Glycine and its sodium salt
E 650	Zinc acetate
E 901	Beeswax, white and yellow
E 902	Candelilla wax
E 903	Carnauba wax
E 904	Shellac
E 905	Microcrystalline wax
E 912	Montan acid esters
E 914	Oxidised polyethylene wax
E 920	L-Cysteine
E 927b	Carbamide
E 938	Argon
E 939	Helium
E 941	Nitrogen
E 942	Nitrous oxide
E 943a	Butane
E 943b	Iso-butane
E 944	Propane
E 948	Oxygen
E 949	Hydrogen
E 953	Isomalt
E 957	Thaumatine
E 965	(i) Maltitol (ii) Maltitol syrup
E 966	Lactitol
E 967	Xylitol
E 1103	Invertase
E 1105	Lysozyme
E 1200	Polydextrose
E 1201	Polyvinylpyrrolidone
E 1202	Polyvinylpolypyrrolidone
E 1404	Oxidised starch
E 1410	Monostarch phosphate
E 1412	Distarch phosphate
E 1413	Phosphated distarch phosphate
E 1414	Acetylated distarch phosphate
E 1420	Acetylated starch
E 1422	Acetylated distarch adipate
E 1440	Hydroxy propyl starch
E 1442	Hydroxy propyl distarch phosphate
E 1450	Starch sodium octenyl succinate
E 1451	Acetylated oxidised starch
E 1518	Glyceryl triacetate (triacetine)
E 1520	Propan-1,2-diol

Annex III

Food additives for which the calculated intake in tier 1 did not exceed the ADI. These additives need no further examination at this stage

Table 1: Adults

E No	Name	ADI
E 102	Tartrazine	7.5 mg/kg
E 104	Quinoline Yellow	10 mg/kg
E 123	Amaranth	0.8 mg/kg
E 129	Allura Red AC	7 mg/kg
E 131	Patent Blue V	15 mg/kg
E 133	Brilliant Blue FCF	10 mg/kg
E 154	Brown FK	0.15 mg/kg
E 200 E 202 E 203	Sorbic acid Potassium sorbate Calcium sorbate	25 mg/kg
E 214 E 215 E 216 E 217 E 218 E 219	Ethyl p-hydroxybenzoate Sodium ethyl p-hydroxybenzoate Propyl p-hydroxybenzoate Sodium propyl p-hydroxybenzoate Methyl p-hydroxybenzoate Sodium methyl p-hydroxybenzoate	10 mg/kg
E 234	Nisin	0.13 mg/kg
E 251 E 252	Sodium nitrate Potassium nitrate	5 mg/kg
E 338 E 339 E 340 E 341 E 343 E 450 E 451 E 452	Phosphoric acid Sodium phosphates Potassium phosphates Calcium phosphates Magnesium phosphates Diphosphates Triphosphates Polyphosphates	70 mg/kg
E 385	Calcium disodium ethylene diamine tetra-acetate (EDTA)	2.5 mg/kg
E 405 E 477	Propane-1,2-diol alginate Propane-1,2-diol esters of fatty acids	25 mg/kg
E 444	Sucrose acetate isobutyrate	10 mg/kg
E 445	Glycerol esters of wood rosin	12.5 mg/kg
E 900	Dimethyl polysiloxane	1.5 mg/kg
E 951	Aspartame	40 mg/kg
E 954	Saccharin and its sodium, calcium and potassium salts	5 mg/kg
E 959	Neohesperidine dihydrochalcone (DC)	5 mg/kg
E 999	Quillaia extract	5 mg/kg

Table 2: Young children

E No	Name	ADI
E 123	Amaranth	0.8 mg/kg
E 154	Brown FK	0.15 mg/kg
E 214 E 215 E 216 E 217 E 218 E 219	Ethyl p-hydroxybenzoate Sodium ethyl p-hydroxybenzoate Propyl p-hydroxybenzoate Sodium propyl p-hydroxybenzoate Methyl p-hydroxybenzoate Sodium methyl p-hydroxybenzoate	10 mg/kg
E 234	Nisin	0.13 mg/kg
E 251 E 252	Sodium nitrate Potassium nitrate	5 mg/kg
E 385	Calcium disodium ethylene diamine tetra-acetate (EDTA)	2.5 mg/kg
E 405 E 477	Propane-1,2-diol alginate Propane-1,2-diol esters of fatty acids	25 mg/kg
E 445	Glycerol esters of wood rosin	12.5 mg/kg
E 900	Dimethyl polysiloxane	1.5 mg/kg

Annex IV

Food additives with numerical ADIs that are permitted for use at *quantum satis* (moved to tier 3)

E No	Name	ADI
E 141	Copper complexes of Chlorophyls and Chlorophyllins	15 mg/kg
E 150b E 150d	Caustic sulphite caramel Sulphite ammonia caramel	200 mg/kg
E 150c	Ammonia caramel	200 mg/kg
E 160a(ii) E 160e E 160f	Beta-carotene Beta-apo-8-carotenal Ethyl ester of beta-apo-8-carotenoic acid	5 mg/kg[11]
E 180	Litholrubine BK	1.5 mg/kg
E 334 E 335 E 336 E 337 E 354	Tartaric acid Sodium tartrates Potassium tartrates Sodium potassium tartrate Calcium tartrate	30 mg/kg
E 407	Carrageenan	75 mg/kg
E 472e	Mono- and diacetyltartaric acid esters of mono- and diglycerides of fatty esters	25 mg/kg
E 1505	Triethyl citrate	20 mg/kg

[11] The Scientific Committee on Food withdrew the ADI for betacarotene (opinion adopted on 7 September 2000) and stated that its use is temporarily acceptable as a food colour with currently estimated intake.

Annex V

Results obtained for the intake of food additives at tier 2

Table 1: Adults and the whole population

E No	Name of the additive	ADI	Member States producing intake information	Range of estimated intake (% ADI)	Stays at tier 2 or moved to tier 3
E 110	Sunset Yellow FCF Orange Yellow 5	2.5 mg/kg	DK, ES, IT, UK, NO	2 – 26	Tier 2
E 120	Cochineal, Carminic acid, Carmines	5 mg/kg	DK, ES, IT, UK, NO	3 – 22	Tier 2
E 122	Azorubine, Carmoisine	4 mg/kg	DK, ES, IT, UK, NO	3 – 16	Tier 2
E 124	Ponceau 4R, Cochineal Red A	4 mg/kg	DK, ES, IT, UK, NO	3 –16	Tier 2
E 127	Erythrosine	0,1 mg/kg	DK, ES, IT, UK	0	Tier 2
E 128	Red 2G	0,1 mg/kg	DK, ES, IT, UK, NO	2 – 20	Tier 2
E 132	Indigotine, Indigo carmine	5 mg/kg	DK, ES, IT, UK. NO	2 – 13	Tier 2
E 142	Green S	5 mg/kg	DK, ES, IT, UK, NO	3 – 20	Tier 2
E 151	Brilliant Black BN, Black PN	5 mg/kg	DK, ES, IT, UK, NO	3 – 20	Tier 2
E 155	Brown HT	3 mg/kg	DK, ES, IT, UK, NO	3 – 22	Tier 2
E 160b	Annatto, bixin, norbixin	0.065 mg/kg	ES, FR, IT, UK, NO	0 - 62	Tier 2
E 161g	Canthaxanthin	0.03 mg/kg	ES, FR, IT, UK	0	Tier 2
E 210 E 211 E 212 E 213	Benzoic acid Sodium benzoate Potassium benzoate Calcium benzoate	5 mg/kg	DK, ES, FR, IT, NL, UK, NO	6 - 84	Tier 2
E 220 E 221 E 222 E 223 E 224 E 226 E 227 E 228	Sulphur dioxide Sodium sulphite Sodium hydrogen sulphite Sodium metabisulphite Potassium metabisulphite Calcium sulphite Calcium hydrogen sulphite Potassium hydrogen sulphite	0.7 mg/kg	DK, ES, FR, IT, NL, UK, NO	20 - 266[12]	Tier 3
E 249 E 250	Potassium nitrite Sodium nitrite	0.1 mg/kg	DK, ES, FR, IT, NL, UK, NO	40 - 230[12]	Tier 3
E 297	Fumaric acid	6 mg/kg	DK, ES, FR, NL, UK	1- 17	Tier 2
E 310 E 311 E 312	Propyl gallate Octyl gallate Dodecyl gallate	0.5 mg/kg	DK, ES, NL, UK	12 - 34	Tier 2
E 315 E 316	Erythorbic acid Sodium erythorbate	6 mg/kg	DK, ES, FR, IT, NL, UK	1- 24	Tier 2
E 320	Butylated hydroxyanisole (BHA)	0.5 mg/kg	DK, ES, FR, IT, NL, UK	12 - 37	Tier 2
E 321	Butylated hydroxytoluene (BHT)	0.05 mg/kg	DK, ES, FR, IT, NL, UK	23 - 80	Tier 2
E 355 E 356 E 357	Adipic acid Sodium adipate Potassium adipate	5 mg/kg	DK, FR, UK	2 – 20	Tier 2
E 416	Karaya gum	12.5 mg/kg	DK, ES, IT, NL, UK	0 – 65	Tier 2
E 442	Ammonium phosphatides	30 mg/kg	DK, ES, FR, IT, NL, UK	1 – 11	Tier 2

[12] Conservative intake estimate based on the assumption that the additive is used in the widest possible range of foods and at maximum permitted levels. Work is in progress to refine intake estimates using actual usage data, which will considerably reduce the degree of overestimation in the current figure

E No	Name of the additive	ADI	Member States producing intake information	Range of estimated intake (% ADI)	Stays at tier 2 or moved to tier 3
E 432 E 433 E 434 E 435 E 436	Polyoxyethylene sorbitan monolaurate (polysorbate 20) Polyoxyethylene sorbitan monooleate (polysorbate 80) Polyoxyethylene sorbitan monopalmitate (polysorbate 40) Polyoxyethylene sorbitan monostearate (polysorbate 60) Polyoxyethylene sorbitan tristearate (polysorbate 65)	10 mg/kg	DK, ES, FR, IT, NL, UK	2 – 78 (QS uses)	Tier 3[13]
E 475	Polyglycerol esters of fatty acids	25 mg/kg	DK, ES, FR, IT, NL, UK, NO	3 – 53	Tier 2
E 476	Polyglycerol polyricinoleate	7.5 mg/kg	DK, ES, FR, NL, UK, NO	4 – 33	Tier 2
E 479b	Thermally oxidised soya bean oil (TOSOM)	25 mg/kg	DK, NL, UK, NO	1 – 10	Tier 2
E 481 E 482	Sodium stearoyl-2-lactylate Calcium stearoyl-2-lactylate	20 mg/kg	DK, ES, FR, IT, NL, UK, NO	2 – 114[12]	Tier 3
E 483	Stearyl tartrate	20 mg/kg	DK, ES, FR, IT, NL, UK, NO	1 – 98	Tier 2
E 491 E 492 E 495	Sorbitan monostearate Sorbitan tristearate Sorbitan monopalmitate	25 mg/kg	DK, ES, FR, IT, NL, UK, NO	3 – 75	Tier 2
E 493 E 494	Sorbitan monolaurate Sorbitan monooleate	5 mg/kg	DK, ES, IT, NL, UK, NO	16 – 354[12]	Tier 3
E 520 E 521 E 522 E 523 E 541 . E 554 E 555 E 556 E 559	Aluminium sulphate Aluminium sodium sulphate Aluminium potassium sulphate Aluminium ammonium sulphate Sodium aluminium phosphate, acidic Sodium aluminium silicate Potassium aluminium silicate Calcium aluminium silicate Aluminium silicate	7 mg/kg[14]	DK, FR, IT, NL, UK, NO	6 – 624[12]	Tier 3
E 535 E 536 E 538	Sodium ferrocyanide Potassium ferrocyanide Calcium ferrocyanide	0.03 mg/kg	DK, IT, NL, NO	0	Tier 2
E 558	Bentonite	7 mg/kg[14]		No info	Tier 3
E 950	Acesulfame-K	9 mg/kg	DK, FR, IT, NL, UK, NO	2 –37	Tier 2
E 952	Cyclamic acid and its sodium and calcium salts	11 mg/kg[15]	DK, FR, IT, NL, UK, NO	0 – 10	Tier 2
E 1505	Triethyl citrate	20 mg/kg	DK	0 (QS uses)	Tier 3[13]

[13] Even if the intake of this additive did not exceed the ADI at tier-2 estimation, it has been prioritised for tier 3 as it has some uses that are permitted at *quantum satis*.

[14] Provisional tolerable weekly intake (PTWI)

[15] The SCF allocated a new ADI for cyclamic acid (7 mg/kg) on 13 March 2000.

Table 2: Young children

E No	Name of the additive	ADI	Member States producing intake information	Range of estimated intake (% ADI)	Stays at tier 2 or moved to tier 3
E 102	Tartrazine	7.5 mg/kg	UK	52	Tier 2
E 104	Quinoline yellow	10 mg/kg	UK	20	Tier 2
E 110	Sunset Yellow FCF Orange Yellow 5	2.5 mg/kg	UK	80	Tier 2
E 120	Cochineal, Carminic acid, Carmines	5 mg/kg	UK	80	Tier 2
E 122	Azorubine, Carmoisine	4 mg/kg	UK	50	Tier 2
E 124	Ponceau 4R, Cochineal Red A	4 mg/kg	UK	50	Tier 2
E 127	Erythrosine	0.1 mg/kg	UK	0	Tier 2
E 128	Red 2G	0.1 mg/kg	UK	40	Tier 2
E 129	Allura Red AC	7 mg/kg	UK	55	Tier 2
E 131	Patent Blue V	15 mg/kg	UK	13	Tier 2
E 132	Indigotine, Indigo carmine	5 mg/kg	UK	40	Tier 2
E 133	Brilliant Blue FCF	10 mg/kg	UK	38	Tier 2
E 142	Green S	5 mg/kg	UK	76	Tier 2
E 151	Brilliant Black BN, Black PN	5 mg/kg	UK	76	Tier 2
E 155	Brown HT	3 mg/kg	UK	67	Tier 2
E 160b	Annatto, bixin, norbixin	0.065 mg/kg	FR, UK	108 - 170[12]	Tier 3
E 161g	Canthaxanthin	0.03 mg/kg	UK	0	Tier 2
E 200 E 202 E 203	Sorbic acid Potassium sorbate Calcium sorbate	25 mg/kg	UK	76	Tier 2
E 210 E 211 E 212 E 213	Benzoic acid Sodium benzoate Potassium benzoate Calcium benzoate	5 mg/kg	FR, UK	17 – 96	Tier 3
E 220 E 221 E 222 E 223 E 224 E 226 E 227 E 228	Sulphur dioxide Sodium sulphite Sodium hydrogen sulphite Sodium metabisulphite Potassium metabisulphite Calcium sulphite Calcium hydrogen sulphite Potassium hydrogen sulphite	0.7 mg/kg	FR, UK	83 - 1227[12]	Tier 3
E 249 E 250	Potassium nitrite Sodium nitrite	0.1 mg/kg	FR, UK	50 – 360[12]	Tier 3
E 297	Fumaric acid	6 mg/kg	FR, NL, UK	6 – 66	Tier 2
E 310 E 311 E 312	Propyl gallate Octyl gallate Dodecyl gallate	0.5 mg/kg	NL, UK	17 – 70	Tier 2
E 315 E 316	Erythorbic acid Sodium erythorbate	6 mg/kg	NL, UK	1 – 80	Tier 2

E No	Name of the additive	ADI	Member States producing intake information	Range of estimated intake (% ADI)	Stays at tier 2 or moved to tier 3
E 338 E 339 E 340 E 341 E 343 E 450 E 451 E 452	Phosphoric acid Sodium phosphates Potassium phosphates Calcium phosphates Magnesium phosphates Diphosphates Triphosphates Polyphosphates	70 mg/kg	NL, UK	53 - 172[12]	Tier 3
E 355 E 356 E 357	Adipic acid Sodium adipate Potassium adipate	5 mg/kg	NL, UK	3 – 7	Tier 2
E 416	Karaya gum	12.5 mg/kg	NL, UK	17 – 48	Tier 2
E 432 E 433 E 434 E 435 E 436	Polyoxyethylene sorbitan monolaurate (polysorbate 20) Polyoxyethylene sorbitan monooleate (polysorbate 80) Polyoxyethylene sorbitan monopalmitate (polysorbate 40) Polyoxyethylene sorbitan monostearate (polysorbate 60) Polyoxyethylene sorbitan tristearate (polysorbate 65)	10 mg/kg	NL, UK	47 – 107[12] (QS uses)	Tier 3
E 442	Ammonium phosphatides	30 mg/kg	NL, UK	8 – 33	Tier 2
E 444	Sucrose acetate isobutyrate	10 mg/kg	UK	13	Tier 2
E 473 E 474	Sucrose ester of fatty acids Sucroglycerides	20 mg/kg	FR, NL, UK	226 – 375[12]	Tier 3
E 475	Polyglycerol esters of fatty acids	25 mg/kg	FR, NL, UK	114 – 160[12]	Tier 3
E 476	Polyglycerol polyricinoleate	7.5 mg/kg	FR, NL, UK	49 – 53	Tier 2
E 479b	Thermally oxidised soya bean oil (TOSOM)	25 mg/kg	NL, UK	5	Tier 2
E 481 E 482	Sodium stearoyl-2-lactylate Calcium stearoyl-2-lactylate	20 mg/kg	FR, NL, UK	136 – 268[12]	Tier 3
E 483	Stearyl tartrate	20 mg/kg	FR, NL, UK	49 – 112[12]	Tier 3
E 491 E 492 E 495	Sorbitan monostearate Sorbitan tristearate Sorbitan monopalmitate	25 mg/kg	FR, NL, UK	150 – 190[12]	Tier 3
E 493 E 494	Sorbitan monolaurate Sorbitan monooleate	5 mg/kg	NL, UK	657 – 802[12]	Tier 3

E No	Name of the additive	ADI	Member States producing intake information	Range of estimated intake (% ADI)	Stays at tier 2 or moved to tier 3
E 520 E 521 E 522 E 523 E 541 E 554 E 555 E 556 E 559	Aluminium sulphate Aluminium sodium sulphate Aluminium potassium sulphate Aluminium ammonium sulphate Sodium aluminium phosphate, acidic Sodium aluminium silicate Potassium aluminium silicate Calcium aluminium silicate Aluminium silicate	7 mg/kg[14]	FR, NL, UK	40 – 750[12]	Tier 3
E 535 E 536 E 538	Sodium ferrocyanide Potassium ferrocyanide Calcium ferrocyanide	0.03 mg/kg		No info	Tier 3
E 558	Bentonite	7 mg/kg[14]		No info	Tier 3
E 950	Acesulfame-K	9 mg/kg	FR, NL, UK	3 – 107[12]	Tier 3
E 951	Aspartame	40 mg/kg	NL, UK	1 – 40	Tier 2
E 952	Cyclamic acid and its sodium and calcium salts	11 mg/kg	FR, NL, UK	1 – 74	Tier 2
E 954	Saccharin and its sodium, calcium and potassium salts	5 mg/kg	FR, NL, UK	2 – 51	Tier 2
E 959	Neohesperidine dihydrochalcone (DC)	5 mg/kg	NL, UK	1 – 18	Tier 2
E 999	Quillaia extract	5 mg/kg	FR, NL, UK	1 – 71	Tier 2

Annex VI

Other information

All the Member States did not use the intake estimation methods defined under the SCOOP task. The reasons for selecting different methods was based on earlier intake work carried out in some Member States. Other information using non-SCOOP intake methodology was available mainly from Austria, Finland, Ireland, Spain and Sweden.

These countries have based their intake estimations on earlier selective studies, information from the food industry, marketing surveys or product databases. Quite often stepwise or hierarchical approaches have been used; moving from conservative, less refined to more refined exposure estimates.

Food additive occurrence data have been studied using preliminary surveys based on national food ingredient databases in Austria and Ireland. In Finland, similar data were collected using a market survey, based on labelling information. Information on the use of food additives was also provided from laboratories, the food industry or marketing associations. Only when additives were found in specific food categories, was that food category considered in the intake estimation or samples taken to the laboratory for analysis. Quite often these preliminary studies revealed that food additives were not widely used in the products even if they were permitted by legislation (Finland, Ireland).

Austria

Austria submitted a report on a detailed study based on the tiered approach described in the SCOOP report. However, as this study was not reported in accordance with the guidelines sent out by the Commission, it was not possible to include the results in chapter 5 of this report. The reported tier-2 calculation showed that, on the basis of intakes by high-level consumers, the ADI was likely to be exceeded for 15 additives or groups of additives. A tier-3 calculation has been carried out for several additives. Intake calculated for both 'whole population' and for 'consumers only' are reported. While intake by high-level consumers exceeding the ADI was only reported for a few additives based on 'whole population' estimates, intake by high-level consumers exceeding the ADI was reported for several additives based on 'consumers only' estimates.

Finland

Intake estimations (from 1999) submitted by Finland were done at tier-3 level and were targeted especially at children from 1-6 years. Estimations for children's intake were based on individual food consumption and analysed food additive levels in products consumed in Finland. The only food additives for which the ADI was exceeded were nitrites and benzoates.

For adults (consumers only, see box 3) nitrite intake was 93 % of the ADI; for children from 1-6 years (consumers only) 67% of ADI when the actual weight of each child was used. For high level consumers (95th percentile) the intake of children was 121-189 % of the ADI.

The average intake of benzoic acid for adults was 8.6 % of the ADI and with consumers only 113 % of the ADI. Average intake of children was 40 % of the ADI and with high-level consumers (95th percentile) 101-160 % of the ADI.

Ireland

The food additives in the Irish food supply were monitored using the Irish National Food Ingredient Database (INFID). This exercise showed the trend of individual additives' usage between two sampling periods 1995/97 and 1998/99. It also indicated which additives were most widely used in the foods chosen for the study. A number of additives were found not to be present in the foods included in the database.

Following the SCOOP tier-1 exercise, a variety of approaches such as portion size back calculations, food-intake data and nutrient-intake back calculations were used as a second stage screen. This identified 20 additives for further consideration.

Spain

Spain submitted information on cyclamate intake related to a published study conducted in 1992 in a region of Spain (Catalonia). For the cyclamate level in foodstuffs, the study was based on information from industry.

This study can be considered as a “tier 3” survey despite the fact that it is not designed to be representative of the whole population of Spain. The information provides clear indications of the major contribution made by soft drinks to cyclamate exposure and confirms that, even if it was unlikely to have caused any safety concerns at the time of the study, the margin of safety between the exposure and the ADI is small for high consumers of cyclamates.

Sweden

Information submitted by Sweden consists of a report of the Swedish Food Administration on intake of aspartame, acesulfame-K, saccharin and cyclamate among diabetics. This study was conducted in January 1999 on 1120 Swedish diabetic adults (16-90 years) and children (0-15 years).

Concerning sweetened foods, the maximum amount allowed was assumed to have been added. An estimated worst case calculation was performed assuming that all the foods consumed were sweetened by the same sweetener.

This study provides different scenarios for exposure assessment of diabetics, including children, who are a particularly exposed population for artificial sweeteners. The calculations are based on the measurement of intake of sweetened foods and on several assumptions concerning the type and the concentration of the substances in the food commodities. It shows that the intake of aspartame, acesulfame-K, saccharin and cyclamate, can be close to or exceed their respective ADI for the population of diabetics if they consume only one type of sweetener.