Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to

a 10th list of substances for food contact materials

Question N°EFSA-Q-2005-053, EFSA-Q-2005-052, EFSA-Q-2004-038, EFSA-Q-2004-153, EFSA-Q-2005-155, EFSA-Q-2004-039, EFSA-Q-2004-042, EFSA-Q-2004-046, EFSA-Q-2003-228, EFSA-Q-2003-185

Adopted on 5 October 2005

SUMMARY

Within the general task of evaluating substances intended for use in materials in contact with food according to the Regulation (EC) No.1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with foodstuffs, the AFC Panel evaluated the following substances:

Ref. No.:	12786
Name of the substance:	3-Aminopropyltriethoxysilane
CAS number:	000919-30-2
Classified in list:	3
Restriction:	0.05 mg/kg food when used for the surface treatment of materials and articles
Ref. No.:	13618
Name of the substance:	1,2-Bis(triethoxysilyl)ethane
CAS number:	016068-37-4
Classified in list:	3
Restriction:	0.05 mg/kg food when used for the surface treatment of materials and articles
Ref. No.:	16450
Name of the substance:	1,3-Dioxolane
CAS number:	00646-06-0
Classified in list:	3
Restriction:	5 mg/kg food
Ref. No.:	19112
Name of the substance:	1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane homopolymer, methyl ethyl ketone oxime-blocked
CAS number:	103170-26-9
Classified in list:	3

Restriction:	0.05 mg/kg food for the blocked trimer Only to be used for thermoset can coatings
Ref. No.:	24886
Name of the substance:	5-Sulphoisophthalic acid, monolithium salt
CAS number:	46728-75-0
Classified in list:	3
Restriction:	5 mg/kg food
Ref. No.:	25900
Name of the substance:	1,3,5-Trioxane
CAS number:	110-88-3
Classified in list:	3
Restriction:	5 mg/kg food
Ref. No.:	38885
Name of the substance:	2,4-Bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine
CAS number:	002725-22-6
Classified in list:	3
Restriction:	0.05 mg/kg food
Ref. No.:	80480
Name of the substance:	Poly(6-morpholino-1,3,5-triazine-2,4-diyl)-(2,2,6,6-tetramethyl-4-piperidyl)imino)hexa-methylene-(2,2,6,6-tetramethyl-4-piperidyl)imino)
CAS number:	90751-07-8
Classified in list:	5
Restriction:	
Ref. No.:	93760
Name of the substance:	Tri-n-butyl acetyl citrate
CAS number:	000077-90-7
Classified in list:	2
Restriction:	TDI: 1.0 mg/kg bw
Ref. No.:	93970
Name of the substance:	Tricyclodecane dimethanol-bis(hexahydrophthalate)
CAS number:	-
Classified in list:	3
Restriction:	0.05 mg/kg food

KEY WORDS
Food Contact Materials, Plastics, Monomers, Additives, 3-aminopropyltriethoxysilane, REF. No 12786, CAS No 000919-30-2, 1,2-Bis(triethoxysilyl)ethane, REF. No 13618, CAS No 016068-37-4, 1,3-Dioxolane, REF. No 16450, CAS No 00646-06-0, 1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane homopolymer, methyl ethyl ketone oxime-blocked, REF. No 19112, CAS No 103170-26-9, 5-Sulphoisophthalic acid, monolithium salt, REF. No 24886, CAS No 46728-75-0, 1,3,5-Trioxane, REF. No 25900, CAS No 110-88-3, 2,4-Bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine, REF. No 38885, CAS No 002725-22-6, Poly(6-morpholino-1,3,5-triazine-2,4-diyl)-(2,2,6,6-tetramethyl-4-piperidyl)imino)hexa-methylene-(2,2,6,6-tetramethyl-4-piperidyl)imino), REF. No 80480, CAS No 90751-07-8, Tri-n-butyl acetyl citrate, REF. No 93760, CAS No 000077-90-7, Tricyclodecane dimethanol-bis(hexahydrophthalate), REF. No 93970

BACKGROUND
Before a substance is authorised to be used in food contact materials and is included in a positive list EFSA´s opinion on its safety is required. This procedure has been established in Articles 8 and 9 of the Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food[1].

TERMS OF REFERENCE
The EFSA is required by Article 10 of Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food to carry out risk assessments on the risks originating from the migration of substances from food contact materials into food and deliver a scientific opinion on:

1. new substances intended to be used in food contact materials before their authorisation and inclusion in a positive list;
2. substances which are already authorised in the framework of Regulation (EC) No. 1935/2004 but need to be re-evaluated.

ASSESSMENT
Within this general task the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) evaluated the following substances used in food contact materials. The substances examined are listed in ascending order of their Reference Number (REF No.), with their chemical name, Chemical Abstract Number (CAS No.) and classification according to the “SCF list”. (Since in the past the evaluation of substances used in food contact materials was undertaken by the Scientific Committee on Food (SCF), the same system of classification into a “SCF list” is retained for uniformity purposes). The definitions of the various SCF lists and the abbreviations used are given in the appendix.

[1] This Regulation replaces Directive 89/109/EEC of 21 December 1988, OJ L 40, 11.2.1989, P.38

Ref. No.:	12786
Name of the substance:	3-Aminopropyltriethoxysilane

CAS number: 000919-30-2

Document reference: EFSA/AFC/FCM/408-Rev.IIA/12786 of September 2005

General information: According to the petitioner in this application 3-aminopropyl-triethoxysilane is used as a co-monomer in a polysiloxane layer applied on metal substrates which subsequently are coated by polymer coatings.

Previous evaluations (by SCF or AFC): The substance was evaluated by the AFC Panel in 2005 (EFSA, 2005) for its use as a coupling agent on inorganic materials that are blended into polymers in order to render the inorganic materials more compatible with the polymers. On the basis of migration and negative genotoxicity tests the substance was classified in SCF List 3 with a restriction of residual extractable content of 3-aminopropyltriethoxysilane less than 3 mg/kg filler.

Available data used for this evaluation:

Non-toxicity data:
- Measurement of the residual content of treated metal sheets
- Evidence for lack of significant residues of oligomers or breakdown products extractable from the treated metal sheets.

Toxicity data:
- This aspect was evaluated by the AFC Panel in 2005 (EFSA, 2005)

Evaluation:

The residual content of the substance has been determined by solvent extraction of a metal sheet coated with polysiloxanes and without any second, top, coating. There was no detectable 3-aminopropyltriethoxy-silane in the extracts and from this the petitioner has calculated the worst case migration to be less than 5.7 µg/kg food. The analytical method for the determination of the residual content of detectable 3-aminopropyltriethoxysilane in the polysiloxane layer was properly described and validated for precision and recovery.
The petitioner has also demonstrated by extraction tests that there are no significant oligomers or other detectable reaction products.

Conclusion: Based on the above-mentioned data the substance is classified*:*

SCF_List: 3

Ref. No.:	**12786**
Name of the substance:	**3-Aminopropyltriethoxysilane**

Restriction: 0.05 mg/kg food when used for the surface treatment of materials and articles

Remark for Commission: Only method of analysis for the determination of the residual monomer on the treated surface (QMA) is provided.
Used as a surface treatment agent.

Needed data or information: None

References: Unpublished data submitted by the petitioner on March 2005

EFSA, Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC)
on a request from the Commission related to a 7th list of substances for food contact materials, adopted on 29 March 2005
http://www.efsa.eu.int/science/afc/afc_opinions/890_en.html

Ref. No.:	**13618**
Name of the substance:	**1,2-Bis(triethoxysilyl)ethane**
CAS number:	016068-37-4
Document reference:	EFSA/AFC/FCM447-Rev.0A/13618 of May 2005

General information: According to the petitioner substance 1,2-bis(triethoxysilyl)ethane is used as co-monomer in a polysiloxane layer which is applied on metal substrates which subsequently are coated by polymer coatings.

Previous evaluations (by SCF or AFC): None

Available data used for this evaluation:

Non-toxicity data:
- Identity, physical/chemical properties, use, authorisation
- Data on residual content in a polymer coating and calculation of migration assuming the complete transfer
- Evidence for lack of oligomers in a polymer coating

Toxicity data
- Gene mutation assay in bacteria
- *In vitro* mammalian cell gene mutation test

Ref. No.:	13618
Name of the substance:	1,2-Bis(triethoxysilyl)ethane

- *In vitro* mammalian cell chromosome aberration test

Evaluation:

The residual content of 1,2-bis(triethoxysilyl)ethane of a polysiloxane layer on a metal substrate has been determined by solvent extraction to be < 15 µg/6 dm². In the finished state the polysiloxane layer is separated from food by a polymer coating.
The analytical method for the determination of the residual content of 1,2-bis(triethoxysilyl)ethane in the polysilane layer was properly described and validated for precision and recovery.
The petitioner has demonstrated by extraction tests that there are no oligomers or other detectable reaction products.

1,2-Bis(triethoxysilyl)ethane did not induce mutations in the gene mutation assay in bacteria either with or without metabolic activation. Negative results were also obtained in an *in vitro* assay for chromosomal aberrations in Chinese hamster ovary cells both with and without metabolic activation. In the mouse lymphoma $tk^{+/-}$ assay no significant dose-related increase of the mutant frequency was observed at those dose levels in the presence and in the absence of metabolic activation.
The submitted genotoxicity data indicate that 1,2-bis(triethoxysilyl)ethane is not genotoxic *in vitro*.

Conclusion: Based on the above-mentioned data the substance is classified:

SCF_List: **3**

Restriction: **0.05 mg/kg food when used for the surface treatment of materials and articles**

Remark for Commission: Only method of analysis for the determination of the residual monomer in the polymer (QMA) is provided
Used as a surface treatment agent.

Needed data or information: None

References: Unpublished data submitted by the petitioner on 21/03/2005

Ref. No.:	16450
Name of the substance:	1,3-Dioxolane
CAS number:	00646-06-0
Document reference:	EFSA/AFC/FCM/418-Rev.IIA/16450 of May 2005

General information: According to the petitioner 1,3-dioxolane is used as a co-monomer

Ref. No.:	16450
Name of the substance:	1,3-Dioxolane

in the catalytic polymerization of trioxane to polyacetals, resulting in polyoxymethylene (POM) copolymers. POM is used for a variety of parts in kitchen machines and utensils. So it is intended to come into repeated contact with all types of food. POM is also used in drinking water applications.

Previous evaluations (by SCF): Based on migration and usage data showing exposure to be below 0.05 mg/kg, adequate 14-day, inadequate 28-day and 7-month oral toxicity studies, 3 inadequate reproduction studies, adequate teratogenicity study, several *in vitro* and *in vivo* mutagenicity studies, the substance was classified in SCF_List 3 with a restriction of 0.05 mg/kg of food (reported in SCF, 1999)

Available data used for this evaluation:

Non-toxicity data:
- Data on identity
- Data on physical/chemical properties
- Data on use
- Data on authorisation
- LogPo/w (new)
- Data on specific migration from POM into water, 3% acetic acid, 10 % ethanol, 95% ethanol and olive oil

Toxicity data:
- Gene mutation assay in bacteria
- *In vitro* mammalian cell gene mutation test
- *In vitro* mammalian cell chromosome aberration test
- *In vivo* mouse micronucleus test
- 14-day repeated dose oral study (new)
- 90-day inhalation study (new)

Evaluation: Due to a foreseen upscale of the production process, higher residual levels of 1,3-dioxolane in final articles and consequently higher migration levels of 1,3-dioxolane are expected. Therefore, additional migration and toxicity data were provided to support an increase from the current SML of 0.05 mg/kg to 5 mg/kg.

New migration experiments were carried out with a representative sample. The sample was tested by total immersion in 3% acetic acid, 10% ethanol and olive oil, for 2 h at 70˚C, 2 h at 100˚C and 10 days at 40˚C. The level of 1,3-dioxolane in the food simulants was determined by GC/MS. The specific migration of 1,3-dioxolane was found to be maximum 0.72 mg/kg in 10% ethanol. Residual content of 1,3-dioxolane in the sample tested was found to be 12.73 mg/kg polymer.

Ref. No.:	**16450**
Name of the substance:	**1,3-Dioxolane**

Dioxolane was consistently negative in the 3 *in vitro* genotoxicity studies (gene mutation assays in bacteria and in mammalian cells, chromosome aberration) perfomed under appropriate quality control. While dioxolane was reported as weakly positive in an *in vitro* cell transformation assay, it was negative in a second study and overall no significance is attributed to this finding. Additionally, it did not result in increased incidences of micronuclei in bone marrow of mice after *in vivo* administration. The substance is considered as non genotoxic.

Dioxolane shows low acute toxicity after oral and inhalation exposures. The major toxic effects seen after repeated inhalation exposure were functional reductions of myeloid activity with a No-Observed-Adverse-Effect-Level (NOAEL) of 300 ppm (equivalent to 1 mg/L air). Using generally accepted values for alveolar ventilation rates in the rat, the concentrations used in the 90-day inhalation study can be transformed to a systemic dose to give a systemic NOAEL of approximately 100 – 250 mg/kg bw/day.

The submitted inhalation and the oral 14-day gavage study both showed mild effects on the same target tissue (reduced white blood cell count without morphologic alterations in bone marrow or lymphatic tissue). A systemic NOAEL of 100 mg/kg bw/day can be derived from the inhalation study. The NOAEL from the 14-day gavage study was 75 mg/kg bw/day.

Due to the volatility of the compound accumulation in man is not expected.

Based on the above analysis, a restriction of 5 mg/kg food, is considered appropriate taking into account the NOAELs from the oral and inhalation studies.

Conclusion: Based on the above-mentioned data the substance is classified:

SCF_List: **3**

Restriction: **5 mg/kg food**

Remark for Commission: None

Needed data or information: None

References:

Unpublished data submitted by the petitioner on 16-01-2004 and 18-03-2005.

SCF (Scientific Committee on Food), 1999. In "Compilation of the evaluations on the Scientific Committee for Food on certain monomers and additives used in the manufacture of plastic materials intended to come into contact with foodstuffs until the 21 March 1997". 42nd Series of Reports of the Scientific Committee for Food.

Ref. No.:	**16450**
Name of the substance:	**1,3-Dioxolane**

Office of Official Publications of the European Communities, Luxembourg, 1999.
http://europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_42.pdf

Ref. No.:	**19112**
Name of the substance:	**1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane homopolymer, methyl ethyl ketone oxime-blocked**
CAS number:	103170-26-9
Document reference:	EFSA/AFC/FCM/357-Rev.0A of June 2005

General information: According to the petitioner, 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane (Isophorone diisocyanate, IPDI) homopolymer, methyl ethyl ketone oxime-(MEKO) blocked, is used as a starting substance in coating formulations, to cross-link polyester/urethane resins to make polymeric coatings for metal food cans.

Previous evaluations (by SCF or AFC): None

Available data used for this evaluation:

Non-toxicity data:
- Determination of residual content of blocked trimer, the MEKO blocking agent and unblocked IPDI trimer
- Worst-case estimation of migration potential
- Overall migration
- Chemical analysis of the <1000 Dalton fraction of the overall migrate

Toxicity data:
- Gene mutation assay in bacteria
- *In vitro* mammalian cell gene mutation test
- *In vitro* mammalian cell chromosome aberration test

Evaluation: The test substance is a defined mixture of mainly MEKO-blocked IPDI trimer along with smaller amounts of higher molecular weight blocked pentamer, heptamer and nonamer. The blocking reagent is released and evaporates during the high temperature stoving conditions used, leaving the reactive isocyanate molecules to cross-link with hydroxyl groups on the polyester chain. The blocked trimer, the free blocking agent, and the unblocked trimer, were not detectable in a worst-case cured coating with detection limits of 1.2,

Ref. No.:	19112
Name of the substance:	1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane homopolymer, methyl ethyl ketone oxime-blocked

3.2 and 5.8 µg/6 dm^2 respectively. Using the conventional 6:1 surface area:mass ratio and assuming total migration, the worst-case migration potential is calculated to be less than 1.2, 3.2 and 5.8 µg/kg of food or food stimulant.
The overall migration from coatings was low at up to 3 mg/dm^2 using different aggressive solvents and test conditions. Comprehensive tests were conducted to characterise and identify this overall migrate. The fraction of migrate below 1000 Daltons was in the range 0.1 to 0.8 mg/dm^2. The chemical tests conducted concluded that this comprised largely polyester oligomers, oleic acid and aliphatic hydrocarbons, and so derived from the polyester resin and additives used in the coating. No reaction or decomposition products derived from the test substance itself were observed.

1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane homopolymer, methyl ethyl ketone oxime-blocked was consistently negative in the three genotoxicity tests: gene mutation in bacteria, gene mutation in mammalian cells, chromosome aberration in mammalian cells. Consequently it was considered as non-genotoxic.

Conclusion: Based on the above-mentioned data the substance is classified*:*

SCF_List: **3**

Restriction: **0.05 mg/kg food for the blocked trimer**
Only to be used for thermoset can coatings

Remark for Commission: Only method of analysis for the determination of the residual monomer in the polymer (QMA) is provided

Needed data or information: None

References: Unpublished data provided by petitioner on 4/11/2004

Ref. No.:	24886
Name of the substance:	5-Sulphoisophthalic acid, monolithium salt

CAS number: 46728-75-0
Document reference: SDS EFSA/AFC/FCM518-Rev.0A/24886 of September 2005

General information: According to the petitioner 5-sulphoisophthalic acid, monolithium salt is intended for use as a monomer in polyester polymers for food packaging. Specific polymers in which it is intended to be used include polyethylene terephthalate (PET) polymers and copolymers

Ref. No.:	24886
Name of the substance:	5-Sulphoisophthalic acid, monolithium salt

fabricated into containers for aqueous, acidic and alcoholic foods (up to 10 % alcohol).

Previous evaluations (by SCF or AFC):

The analogous sodium salt, 5-sulphoisophthalic acid, monosodium salt (REF No 24887) has been evaluated by the SCF (SCF, reports, 42nd series, 1999) and a restriction of 5 mg/kg food has been allocated on the basis of a 90-day oral rat study, three negative mutagenicity studies, bioaccumulation data and migration data.

Available data used for this evaluation:

Non-toxicity data:

- Identity of the substance
- Chemical and physical properties
- Intended use
- Authorisation of the substance
- Determination of the specific migration
- Determination of the overall migration

Toxicity data

- Gene mutation assays in bacteria
- *In vitro* mammalian cell gene mutation tests
- *In vitro* mammalian cell chromosome aberration tests

Evaluation:

A PET sample with 0.6% w/w of the test substance has been tested for migration into food simulants. The overall migration was 0.6 mg/kg. There was no detectable migration of the test substance (< 24 µg/kg) or of lithium (<1 µg/kg) or of oligomers and possible breakdown or transformation products derived from the test substance (< 24 µg/kg).

5-Sulphoisophthalic acid, monolithium salt did not induce mutations in the gene mutation assay in bacteria either with or without metabolic activation. Negative results were also obtained in an *in vitro* assay for chromosomal aberrations in Chinese hamster ovary cells both with and without metabolic activation. In the mouse lymphoma tk+/- assay no significant increase of the mutant frequency was observed at any dose level either in the absence or in the presence of S9-mix .The submitted genotoxicity data indicate that 5-sulphoisophthalic acid, monolithium salt is not genotoxic *in vitro*.

The analogous sodium salt is listed in the Directive 2002/72/EEC with an SML of 5 mg/kg based on three negative mutagenicity tests, 90 days study and a study demonstrating the absence of potential for accumulation in man. Lithium is also listed in the Directive

Ref. No.:	24886
Name of the substance:	5-Sulphoisophthalic acid, monolithium salt

2002/72/EEC with a group restriction of 0.6 mg/kg food. According to these previous evaluations and three negative mutagenicity tests on 5-sulphoisophthalic acid, monolithium salt a restriction of 5 mg/kg food can be applied for 5-sulphoisophthalic acid, monolithium salt. This restriction is consistent with the group restriction for lithium.

Conclusion: Based on the above-mentioned data the substance is classified:

SCF_List: **3**

Restriction: **5 mg/kg food**

Remark for Commission: None

Needed data or information: None

References:

Unpublished data submitted by the petitioner on 5/7/2005

Commission Directive 2002/72/EC, relating to plastic materials and articles intended to come into contact with foodstuffs http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72_en.pdf

SCF (Scientific Committee for Food), 1999. In "Compilation of the evaluations of the Scientific Committee for Food on certain monomers and additives used in the manufacture of plastic materials intended to come into contact with foodstuffs until the 21 March 1997". 42nd Series of Reports of the Scientific Committee for Food. Office of Official Publications of the European Communities, Luxembourg, 1999. http://europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_42.pdf

Ref. No.:	25900
Name of the substance:	1,3,5-Trioxane

CAS number: 110-83-3

Document reference: EFSA/AFC/FCM/180-Rev.III/25900 of July 2005

General information: According to the petitioner trioxane is used as a monomer in the manufacturing of polyoxymethylene (POM) copolymers. The maximum percentage in the formulation can be up to 100%. POM is used for a variety of parts in kitchen machines and utensils intended for repeated use with all types of food.

Previous evaluations (by The substance was evaluated by SCF in 1999 (SCF, 1999) and

Ref. No.:	**25900**
Name of the substance:	**1,3,5-Trioxane**

SCF or AFC): classified in list 3 with a restriction of 0.05 mg/kg based on migration data and three gene mutation assays in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); two gene mutation assays in cultured mammalian cells (TK+/- study is positive at very high doses and HPRT-study is not accepted); *in vivo* micronucleus assay (negative); *in vivo* UDS assay (negative); induction of DNA single-strand breaks *in vivo* (positive); *in vitro* cell transformation assay (negative); acute toxicity data; 28-day oral rat study; 2-week inhalation rat study; 2 metabolism studies; skin/eye irritation studies; sensitisation studies. (RIVM/TNO SDS, September 1998 = CS/PM/2577 REV. I/25900). (Adopted at 117th SCF meeting) (17 June 1999)

Available data used for this evaluation:

Non-toxicity data:
- Data on identity
- Data on physical/chemical properties
- Data on use
- Data on authorisation
- Data on specific migration from POM into water, 3% acetic acid, 15 % ethanol, 95% ethanol and olive oil
- Data on specific migration of formaldehyde from POM
- Data on specific migration of acetaldehyde

Microbiological data:
- Absence of antimicrobial activity from POM samples

Toxicity data:
- 90-day oral study in rat

Evaluation: Due to a foreseen upscale of the production process, higher residual levels of 1,3-dioxolane in final articles and consequently higher migration levels of 1,3-dioxolane are expected. Therefore, additional migration and toxicity data were provided to support an increase from the current SML of 0.05 mg/kg to 5 mg/kg.

New migration experiments were carried out with a representative sample. The sample was tested by total immersion in 3% acetic acid, 10% ethanol and olive oil, for 2 hr at 70˚C, 2 hr at 100˚C and 10 days at 40˚C. The level of 1,3,5-trioxane in the food simulants was determined by GC/MS. The specific migration of 1,3,5-trioxane was found to be maximum 1.45 mg/kg in 10% ethanol. The residual content in the sample tested was found to be 26.39 mg/kg polymer.

POM may release constantly a small amount of formaldehyde and

Ref. No.:	25900
Name of the substance:	**1,3,5-Trioxane**

thus may in theory have antimicrobial activity on the surface of the polymer. No antimicrobial activity at the surface of POM samples could be detected.
Specific migration of formaldehyde into food simulants was found to be 0.12 – 0.95 mg/kg food.
A rat 90-day oral toxicity study with doses of 30, 100 and 300 mg/kg was provided. The highest dose used did not induce gross pathology. It reduced male body weight gain and some small effects on erythropoiesis were observed in male rats only. A NOAEL of 100 mg/kg bw/day is derived for 1,3,5-trioxane.
Given the low log Po/w value no further data on accumulation are requested.

Conclusion: Based on the above-mentioned data the substance is classified in:
SCF_List: **3**
Restriction: **5 mg/kg food**
Remark for Commission: None
Needed data or information: None

References:

- Unpublished data submitted by the petitioner on 16-01-04 and 24-05-2005.
- Opinion of the Scientific Committee on Food of the 117th meeting (adopted on 17-6-1999) http://europa.eu.int/comm/food/fs/sc/scf/out37_en.pdf

Ref. No.:	38885
Name of the substance:	**2,4-Bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine**

CAS number: 002725-22-6
Document reference: EFSA/AFC/FCM/203-Rev.IA/38885 of June 2005

General information: According to the petitioner 2,4-bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine is used as a UV light stabiliser in polyolefins. Maximum percentage in the formulation is 0.1% in polypropylene and 0.04% in polyethylene.

Previous evaluations (by SCF or AFC): None

Available data

Ref. No.:	**38885**
Name of the substance:	**2,4-Bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine**

used for this evaluation:

Non-toxicity data:
- Identity of the substance, purity and impurities, chemical and physical properties, intended use, authorisation of the substance
- Specific migration
- Actual content in the polymer

Toxicity data:
- Gene mutation in bacteria
- *In vitro* mammalian cell gene mutation test
- *In vitro* mammalian chromosome aberration test

Evaluation:

The purity of the additive is stated to be 96-100%; details on the establishment of the purity and impurities including supporting documents are provided.

Solubility of the substance in olive oil is 5 - 10 g/l, in 95% ethanol <0.01 g/l and in isooctane 3 - 5 g/l.

Migration test were performed using 95% ethanol and iso-octane as substitute fatty food simulants because the use of olive oil is not feasible as a fatty food simulant at a migration level ≤ 0.05 mg/kg food.

Specific migration of the substance was determined in 3% acetic acid, 10% ethanol and 95% ethanol using polypropylene (PP), high-density polyethylene (HDPE), low-density polyethylene (LDPE) and linear low density polyethylene (LLDPE) tested for 2 h at 121ºC and/or 0.5h at 66ºC (depending on the type of polymer) followed by 10 d at 40ºC. In isooctane specific migration from PP, LDPE and LLDPE was determined after 10 d at 40ºC as well as after 0.5 h at 70 ºC. In 3% acetic acid and 10% ethanol the specific migration of the substance was found to be not detectable or < 0.05 mg/kg into food. In 95% ethanol, migration values for samples containing the UV light stabiliser at the intended level of use ranged from 1.1 – 7.6 mg/kg into food, depending on the type of polymer. In isooctane, migration values for samples containing the substance at the intended level of use ranged from 1.7 to 15.1 mg/kg of food, depending on the type of polymer.

Based on the fact that 2,4-bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octylphenyl)-1,3,5-triazine is very lipophilic and showed relatively high migration in fatty food simulants, polymers containing this UV light stabilizer shall not be used in contact with fatty food.

2,4-Bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octylphenyl)-1,3,5-triazine was consistently negative in *in vitro* genotoxicity studies

Ref. No.:	38885
Name of the substance:	2,4-Bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine

performed under appropriate quality control. Consequently, the substance is considered as non-genotoxic.

Conclusion: Based on the above-mentioned data, the substance is classified:
SCF_List: **3**
Restriction: **0.05 mg/kg food**
Remark for Commission: Not to be used in contact with fatty foods
Needed data or information: None

References: Unpublished data submitted by the petitioner on 20-02-2004 and 10-02-2005.

Ref. No.:	80480
Name of the substance:	Poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino]

CAS number: 90751-07-8
Document reference: EFSA/AFC/FCM/294-Rev.IA/80480 of September 2005

General information: According to the petitioner, poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino] is used as a UV light stabiliser in polyolefins. Maximum use level is 0.3%.

Previous evaluations (by SCF or AFC): None

Available data used for this evaluation:

Non-toxicity data:
- Data on identity, physical/chemical properties, use, authorisation;
- Migration data into food simulants;
- Data on the actual content.
- Data on log Po/w
- Analytical method for the determination of the specific migration into food simulants, suitable for enforcement purposes

Toxicity data:
- Three *in vitro* mutagenicity assays on the poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino];

Ref. No.:	80480
Name of the substance:	Poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino]

- Three *in vitro* mutagenicity assays on the monomer N,N'-bis[(2,2,6,6-tetramethyl)-4-piperidinyl]-1,6-hexanediamine (BPIP);
- 90 days oral toxicity study in rats
- 90 days oral toxicity study in dogs

Evaluation:

The UV light stabiliser is a mixture of oligomers with a molecular mass range of 286 – 16100 Dalton (D) and a fraction with MW < 1000 D of 19 – 21%.

Residual level of morpholine is $\leq$ 0.01% w/w, of N,N'-bis(2,2,6,6-tetramethylpiperidin-4-yl)hexane-1,6-diamine (BPIP) $\leq$ 14000 mg/kg and of 2,4-dichloro-6-morpholino-1,3,5-triazine (DCMT) $\leq$150 mg/kg in the stabiliser.

The octanol/water partition coefficient of the UV light stabiliser was measured as 2.88 ± 0.05. In addition, a mixture of exclusively low molecular weight (MW < 1000 D) components of the polymeric additive was prepared and its log P o/w was measured as 2.51 ± 0.07.

Potential for formation of N-nitrosomorpholine was calculated based on literature data on reaction rate constants. Assuming 100% migration of residual morpholine, i.e. 0.004 mg morpholine per kg food, the maximum possible formation of N-nitrosomorpholine from 4 µg morpholine/kg nitrite containing foodstuffs (e.g. cured bacon) could result in a concentration of 0.36 µg/kg foodstuff. In addition, formation of N-nitroso compounds in nitrite containing foodstuffs from other morpholine containing compounds in the UV light stabiliser was calculated to be maximum 0.54 µg nitroso compounds per kg foodstuff. Specific migration tests were performed. LDPE, HDPE and PP sheets containing 0.2% and 0.3% of the UV light stabiliser were tested by total immersion in water, 3% acetic acid, 10% ethanol and in HB307. The tests were performed for 10 d at 40°C and 2hr at 70°C/ 2hr at 100°C. Migration into HB307 after 10 days 40°C was found to be maximum 6.78 mg/kg into food, from an LDPE sample containing 0.3% of the stabiliser. Because also in aqueous simulants considerable amounts of the light stabiliser migrates (2.9 mg/kg) the Fat Reduction Factor (FRF) is not applicable. A method for the determination of the specific migration of the UV light stabilizer into food simulants has been provided based on HPLC with UV detection. Also a method for the determination of the content of light stabiliser in polyolefins

Ref. No.:	80480
Name of the substance:	Poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino]

is provided.

Both the poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)-imino] and the monomer N,N'-bis(2,2,6,6-tetramethylpiperidin-4-yl)hexane-1,6-diamine (BPIP), were tested with negative results in three *in vitro* mutagenicity assays (reversion in bacteria, forward mutation and chromosomal aberrations in cultured mammalian cells). No genotoxicity data are available on the other starting substance 2,4-dichloro-6-morpholino-1,3,5-triazine (DCMT).

Two subchronic dietary toxicity studies, in rats and dogs, with the UV stabiliser were performed. The NOAEL derived from these studies is 100 mg/kg bw/day.

Based on the $\log P_{o/w}$ value of the oligomeric fraction with MW < 1000 D, no potential for accumulation in man is expected.

From the data available it is concluded that even though experimental results do not highlight a genotoxic potential for the UV stabilizer, the formation of genotoxic and carcinogenic N-nitroso derivatives from morpholine, BIBP and DCMT cannot be ruled out. In this respect it is noted that morpholine is currently classified in the SCF List 5. On this basis poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino] containing morpholine as residue, should not be used in food contact materials.

Conclusion: Based on the above-mentioned data, the substance is classified:

SCF_List: **5**

Restriction:

Remark for Commission: None

Needed data or information: None

References: Unpublished data submitted by the petitioner on 05-03-2004, 15-04-2004 and 03-06-2005.

Ref. No.:	**93760**
Name of the substance:	**Tri-n-butyl acetyl citrate**
CAS number:	000077-90-7
Document reference:	EFSA/AFC/FCM/227-REV. IVA/93760 of September 2005

General information:

According to the petitioner, tri-n-butyl acetyl citrate, synonym acetyl tributyl citrate (ATBC), is a plasticizer used in polyvinylidenechloride (PVDC) films, in polyvinylchloride/polyvinylidenechloride (PVC/PVDC) polymer blend food films, in nitrocellulose barrier films and in PVC sealing gaskets for food containers. ATBC is also widely used in cling films at household and industrial levels. Maximum percentage of use is 4.8%.

Food contact conditions vary from refrigerating and frozen storage to reheating in a microwave or steam sterilisation. All types of foods can be in contact.

Previous evaluations (by SCF or AFC):

The substance was first considered by the SCF in 1998 (SCF, 1998) and classified in SCF List 7. Available: specific migration values in 3% acetic acid and olive oil ranging from 9.0-28.2 mg/6 dm^2; 14-day range-finding rat study; 90-day rat study; 2-generation reproduction study using rats; gene mutation assay in bacteria (negative); two chromosomal aberration assays in cultured mammalian cells (both negative); two gene mutation assays in cultured mammalian cells (one negative and one positive); *in vivo* UDS assay (negative); metabolism study (rat); skin and eye irritation studies (only summaries available); sensitisation study.
RIVM/ISS/TNO SDS, June 1997 = CS/PM/2966 REV.I/93760.

Available data used for this evaluation:

Non-toxicity data:

- Data on identity, physical/chemical properties, use, authorisation;
- IR spectrum and impurities;
- Specific migration in 3% acetic acid and olive oil;
- Data on the actual content
- Log Po/w;
- Literature data about ATBC migration in simulants and in foods

Toxicity data:

- Ames assay (3 studies, negative)
- two chromosomal aberration assays (negative)
- HPRT assay (negative)

Ref. No.:	93760
Name of the substance:	Tri-n-butyl acetyl citrate

- mouse lymphoma assay (two studies, one positive and one negative)
- *in vivo* rat liver UDS (negative)
- 90-d oral rat study
- 90-d oral rat study with *in utero* exposure
- chronic toxicity/oncogenicity study in the rat
- 2-generation reproduction study using rats
- studies on metabolism *in vitro* and *in vivo*.

Evaluation:

Specific migration of ATBC was determined from PVDC films representative of the different applications. The films investigated contained 2.6 - 4.9% ATBC. Tests were performed for 10 days at 40°C and 2 hours at 70°C. Migration values in 3% acetic acid and olive/sunflower oil ranged from 9.0 to 28.2 mg/kg were found.
In further studies, specific migration of ATBC was determined from PVDC cling films (three different thicknesses, from 10 to 19 µm), containing 4.4 - 4.8% ATBC. Tests were performed in olive oil for 10 days at 22°C, 10 days at 6°C and 2 hours at 70°C. Migration values at 6 °C ranged from 4.1 to 6.7 mg/kg, at 22°C ranged from 10.3 to 11.5 mg/kg and after 2 hours at 70 °C were from 19.5 to 22.7 mg/kg
Log Po/w is 4.92. However, considering the migration into aqueous food simulants the Fat (consumption) Reduction Factor (FRF) is not applicable

Tri-n-butyl acetyl citrate was not mutagenic in bacteria and not clastogenic in mammalian cells; gene mutations assays in mammalian cells gave negative results at the HPRT locus; contradictory results were detected at the tk locus. Therefore an UDS study was requested. The adequately performed *in vivo* assay (UDS in rat liver) gave negative results, indicating lack of genotoxicity *in vivo*.
Tri-n-butyl acetyl citrate was tested in 90-day oral toxicity studies in rats, also including an *in utero* exposure phase, and in a 2-generation reproduction study using rats: the NOAEL from these studies, which only showed mild effects on body weight and some biochemical parameters, was 100 mg/kg bw/day. There was no evidence of any carcinogenic potential of ATBC when administered orally in the diet for 2 years to rats.
ATBC was shown to be extensively metabolised in human serum and rat liver homogenate. In a metabolism study in rats, ^{14}C-ATBC was rapidly absorbed and completely metabolised and excreted, mainly in urine. Monobutyl citrate was the major urinary metabolite. Based on the ADME characteristics of the compound,

Ref. No.:	93760
Name of the substance:	Tri-n-butyl acetyl citrate

there is no indication for possible accumulation in man.
Taking into account the lack of genotoxicity, the overall low toxicity, the nature of the toxic effects elicited in chronic and subchronic animal studies, the lack of carcinogenicity and the extensive metabolic transformation into compounds of low toxicity, a full Tolerable Daily Intake (TDI) can be established for tri-n-butyl acetyl citrate. Applying the default uncertainty factor of 100 to the NOAEL of 100 mg/kg bw/day for general toxicity derived from oral toxicity studies in rats, a TDI of 1.0 mg/kg bw is derived.

Conclusion: Based on the above-mentioned data the substance is classified:

SCF_List: **2**

Restriction: **TDI: 1.0 mg/kg bw**

Remark for Commission: None

Needed data or information: None

References:

- Opinion of the Scientific Committee on Food on an additional list of monomers and additives for food contact materials (19 March 1998) http://europa.eu.int/comm/food/fs/sc/scf/out10_en.pdf
- Castle, L., et al, 1988 a, Migration from plasticized films into foods 3. Migration of phthalate,sebacate, citrate and phosphate esters from films used for retail food. Food additives and contaminants., VOL. 5, No.1, 9-20
- Castle et al. (1988b), Migration of the Plasticizer Acetyltributyl Citrate from Plastic Film into Foods during Microwave Cooking and Other Domestic Use. Journal of Food Protection. Vol. 5, No, 12, Pages 916-919
- Finkelstein M., Gold H. Toxicology of the Citric Acid Esters: Tributyl Citrate, Acetyl Tributyl Citrate, Triethyl Citrate and Acetyl Triethyl Citrate. Toxicology and Applied Pharmacology 1, 283-298 (1959).
- Goulas et Al, 1995, Effect of gamma-radiation on migration behaviour of dioctyladipate and acetyltributylcitrate plasticizers from food-grade PVC and PVDC/PVC films into olive oil, Z Lebensm Unters Forsch 201: 74
- Goulas et Al, 1998,Effect of High-Dose Electron Beam Irradiation on the Migration of DOA and ATBC Plasticizers from Food-Grade PVC and PVDC/PVC Films, Respectively, into Olive Oil, Journal of Food Protection. Vol. 61. No.6.. Pages 720-724

Ref. No.:	93760
Name of the substance:	Tri-n-butyl acetyl citrate

- Heath, J.L. and M. Reilly (1982) Mutagenesis testing of acetyl-tributylcitrate and epoxidized soybean oil. Poultry Science, 61, 2517-2519.
- Unpublished data submitted by the petitioner, November 2003 and July 2005.

Ref. No.:	93970
Name of the substance:	Tricyclodecane dimethanol-bis-(hexahydrophthalate)

CAS number: -

Document reference: EFSA/AFC/FCM/414-Rev.1B/93970 of May 2005

General information: According to the petitioner tricyclodecane dimethanol-bis-(hexahydrophthalate) (TCD-emulsifier) is used as an emulsifier in concentrations up to 0.79 % in the emulsion polymerisation of vinyl monomers, especially butadiene, in the manufacture of acrylonitrile-butadiene-styrene (ABS) copolymers and acrylonitrile-butadiene-styrene/polycarbonate (ABS/PC) blends which are mainly used for the production of typical household appliances like kitchen blenders and coffee machines.

Previous evaluations (by SCF or AFC): The substance was previously evaluated by the Scientific Committee on Food in 2001 (SCF, 2001) and it was classified in the List 7 with the requirement for the following data to be provided: Information on the proportion of the main isomers that comprise the 97.5% of the named substance, along with the impurities.

Available data used for this evaluation:

Non-toxicity data:
- Data on identity, chemical and physical properties, intended use, authorisation
- Specific migration from ABS, into 3% acetic acid, 15 % and 50 % ethanol
- Data on solubility, impurities

Toxicity data
- Gene mutation test in bacteria,
- *In vitro* mammalian cell gene mutation test,
- *In vitro* mammalian chromosome aberration test,
- Micronucleus assay,
- Subacute toxicity (30-day study)

Ref. No.:	**93970**
Name of the substance:	**Tricyclodecane dimethanol-bis-(hexahydrophthalate)**

Evaluation:

TCD emulsifier is considered as a defined mixture, consisting of four structural isomers amounting, in average, at 95,7% of the substance. Information concerning the proportions of the structural isomers in the mixture of the tricyclodecane alcohol is provided.

Impurities consist of low amounts of the tricyclodecane dimethanol, hexahydrophthalic acid and a mixture of isomeric forms of the semi-ester of hexahydrophthalic acid with tricyclodecane dimethanol and/or the dehydrated tricyclodecane dimethanol.

The TCD emulsifier percentage in the formulation is 0.24% typically and 0.79% maximum.

Migration studies have been performed in 50% ethanol, 3% acetic acid and 15% ethanol. Two ABS samples were investigated, which contained an initial TCD emulsifier content of 0.24% and 0.79% by weight, respectively.

Specific migration was found to be not detectable under all conditions applied, with the detection limit of the analytical method reported 50 μg/kg in food simulants.
TCD emulsifier was tested under *in vitro* conditions for the induction of gene mutations in bacteria and for the induction of gene mutations and chromosomal aberrations in cultured mammalian cells and under *in vivo* conditions in the micronucleus assay. A clastogenic effect was observed in the *in vitro* chromosomal aberration assay, at highly cytotoxic dose levels with and without metabolic activation. No activity was seen in the other 3 assays which included an *in vivo* micronucleus test with evidence of exposure of bone marrow.
In a 30-day oral toxicity study with rats, body weight and haematological changes, changes in liver and kidney weights and hypertrophy of hepatocytes of the liver were observed at 125 and 625 mg/kg bw.
Based on the three *in vitro* genotoxicity studies submitted and on an additional *in vivo* micronucleus assay, TCD emulsifier is considered non-genotoxic.

Conclusion: Based on the above-mentioned data the substance is classified:

SCF_List: **3**

Restriction: **0.05 mg/kg food**

Remark for Commission: None

Needed data or information: None

Ref. No.:	**93970**
Name of the substance:	**Tricyclodecane dimethanol-bis-(hexahydrophthalate)**

References:
- Unpublished data submitted by the petitioner
- SCF opinion on a 13th additional list of monomers and additives for food contact materials, adopted on 30 May 2001 http://europa.eu.int/comm/food/fs/sc/scf/out86_en.pdf

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List of abbreviations:

bw	Body weight
D	Dalton
FRF	Fat (Consumption) Reduction Factor, see Opinion of the SCF in 2002 http://europa.eu.int/comm/food/fs/sc/scf/out149_en.pdf
GC/MS	Gas Chromatography/Mass Spectrometry
HPRT	Hypoxanthine PhosphoRibosyl Transferase
IR	Infra Red
LOAEL	Lowest observed adverse effect level
MW	Molecular weight
NOAEL	No observed adverse effect level
QMA	maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm^2 of the surface in contact with foodstuffs
SML	Specific migration limit
TDI	Tolerable daily intake
UDS	unscheduled DNA synthesis

APPENDIX

DEFINITION OF THE SCF LISTS

List 0 Substances, e.g. foods, which may be used in the production of plastic materials and articles, e.g. food ingredients and certain substances known from the intermediate metabolism in man and for which an ADI need not be established for this purpose.

List 1 Substances, e.g. food additives, for which an ADI (=Acceptable Daily Intake), a t-ADI (=temporary ADI), a MTDI (=Maximum Tolerable Daily Intake), a PMTDI (=Provisional Maximum Tolerable Daily Intake), a PTWI (=Provisional Tolerable Weekly Intake) or the classification "acceptable" has been established by this Committee or by JECFA.

List 2 Substances for which this Committee has established a TDI or a t-TDI.

List 3 Substances for which an ADI or a TDI could not be established, but where the present use could be accepted.

Some of these substances are self-limiting because of their organoleptic properties or are volatile and therefore unlikely to be present in the finished product. For other substances with very low migration, a TDI has not been set but the maximum level to be used in any packaging material or a specific limit of migration is stated. This is because the available toxicological data would give a TDI, which allows that a specific limit of migration or a composition limit could be fixed at levels very much higher than the maximum likely intakes arising from present uses of the additive.

Depending on the available toxicological studies a restriction of migration into food of 0.05 mg/kg of food (3 mutagenicity studies only) or 5 mg/kg of food (3 mutagenicity studies plus 90-day oral toxicity study and data to demonstrate the absence of potential for bio-accumulation in man) may be allocated.

List 4 **(for monomers)**

4A Substances for which an ADI or TDI could not be established, but which could be used if the substance migrating into foods or in food simulants is not detectable by an agreed sensitive method.

4B Substances for which an ADI or TDI could not be established, but which could be used if the levels of monomer residues in materials and articles intended to come into contact with foodstuffs are reduced as much as possible.

List 4 **(for additives)**

Substances for which an ADI or TDI could not be established, but which could be used if the substance migrating into foods or in food simulants is not detectable by an agreed sensitive method.

List 5 Substances that should not be used.

List 6 Substances for which there exist suspicions about their toxicity and for which data are lacking or are insufficient.

The allocation of substances to this list is mainly based upon similarity of structure with that of chemical substances already evaluated or known to have functional groups that indicate carcinogenic or other severe toxic properties.

6A Substances suspected to have carcinogenic properties. These substances should not be detectable in foods or in food simulants by an appropriate sensitive method for each substance.

6B Substances suspected to have toxic properties (other than carcinogenic). Restrictions may be indicated.

List 7 Substances for which some toxicological data exist, but for which an ADI or a TDI could not be established. The required additional information should be furnished.

List 8 Substances for which no or only scanty and inadequate data were available.

List 9 Substances and groups of substances which could not be evaluated due to lack of specifications (substances) or to lack of adequate description (groups of substances).

Groups of substances should be replaced, where possible, by individual substances actually in use. Polymers for which the data on identity specified in "SCF Guidelines" are not available.

List W "Waiting list". Substances not yet included in the Community lists, as they should be considered "new" substances, i.e. substances never approved at national level. These substances cannot be included in the Community lists, lacking the data requested by the Committee.