

Medlemmerne af Folketingets Europaudvalg

og deres stedfortrædere

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KOMITÉSAG

Til underretning for Folketingets Europaudvalg vedlægges Fødevareministeriets notat om forslag til Kommissionens direktiv om ændring af direktiv 90/128/EØF om plastmaterialer og –genstande bestemt til at komme i berøring med levnedsmidler, dokument SANCO/2001/2779-Rev.1.

Forslaget er sat til afstemning på mødet i Den Stående Levnedsmiddelkomité den 17.-18. december 2001.

om forslag til Kommissionens direktiv om ændring af direktiv 90/128/EØF om plastmaterialer og -genstande bestemt til at komme i berøring med levnedsmidler

Dokument SANCO/2001/2779-rev 1

Forslaget kan blive sat til afstemning på mødet i Den Stående Levnedsmiddelkomité den 17. – 18. december 2001.

Forslaget behandles i en III a-procedure i Den Stående Komité for Levnedsmidler. Hvis der er kvalificeret flertal, udsteder Kommissionen direktivet. Opnås der ikke kvalificeret flertal, forlægger Kommissionen sagen for Rådet, der kan vedtage forslaget uændret med kvalificeret flertal eller ændre det med enstemmighed. Handler Rådet ikke inden en frist på højest tre måneder, kan Kommissionen udstede direktivet.

Formålet med forslaget er at regulere anvendelsen af materialer og genstande bestemt til at komme i berøring med fødevarer på fællesskabsplan med henblik på at undgå risici for menneskers sundhed.

Forslaget til ændring af plastdirektivet, direktiv 90/128/EØF, indeholder følgende hovedpunkter:

1. Indførelse af restriktion for divinylbenzen i form af forbud mod fremstilling og import i Fællesskabet af materialer og genstande, der indeholder divinylbenzen, fra den 1. december 2002.
2. Justering af restriktioner for isocyanater (af redaktionel karakter).
3. Udvidelse af listen over additiver (tilsætningsstoffer), der må anvendes i plast, i bilag III i direktiv 90/128/EØF samt optagelse af visse monomerer (bestanddele i plaststoffer) på fællesskabslisten over tilladte stoffer.

De foreslæde ændringer i punkt 3 berører stoffer, der tillades anvendt i plastmaterialer til opbygning af materialet. Ændringerne følger anbefalingerne fra Den videnskabelige Komité for Levnedsmidler, der har vurderet de sundhedsmæssige aspekter ved en evt. migration (afsmitning) af stofferne fra materialet til fødevaren.

Forslaget skønnes at ville øge beskyttelsesniveauet i Danmark, idet det medfører en præcisering af reglerne. Virksomhederne har i dag selv ansvaret for at regulere de stoffer, der ikke er på positivlisten og da forslaget indebærer, at flere stoffer kommer på positivlisten, vurderes forslaget at ville øge beskyttelsesniveauet.

Regeringen agter på den baggrund at stemme for forslaget.

Ministeriet for Fødevarer, Landbrug og Fiskeri

1. afdeling, 2. kontor

J.nr.: 1997-4133-0001

Den 11. december 2001

Initialer TAJ/BFA/JHC/MKR

LFM 0579

Aktuelt Notat Folketingets Europaudvalg

om forslag til Kommissionens direktiv om ændring af direktiv 90/128/EØF om plastmaterialer og -genstande bestemt til at komme i berøring med levnedsmidler

Dokument SANCO/2001/2779-rev 1

Resumé

Kommissionens forslag til ændring af plastdirektivet 90/128/EØF har til formål at regulere anvendelsen af materialer og genstande bestemt til at komme i berøring med fødevarer.

Forslaget indeholder tre følgende hovedpunkter:

1. En indførsel af restriktion for divinylbenzyn i form af forbud mod fremstilling og import i Fællesskabet af materialer og genstande, der indeholder divinylbenzan.
2. Forslaget vil indebære en justering af restriktioner for isocyanater.
3. Udvidelse af listen over tilsætningsstoffer i bilag III i direktiv 90/128/EØF, der må anvendes i plast.

De foreslæde ændringeri punkt 3 berører stoffer, der tillades anvendt i plastmaterialer til opbygning af materialet. Ændringerne følger anbefalingerne fra Den videnskabelige Komité for Levnedsmidler, der har vurderet de sundhedsmæssige aspekter ved en evt. afsmitning af stofferne fra materialet til fødevaren.

En vedtagelse af forslaget skønnes at ville øge beskyttelsesniveauet i Danmark, idet det vil medføre en præcisering af reglerne. Forslaget indebærer, at flere stoffer vil komme på positivlisten. Da virksomhederne hidtil har haft ansvaret for at regulere de stoffer, som ikke var på positivlisten, vurderes forslaget at ville øge beskyttelsesniveauet.

Baggrund

Kommissionen har ved dokument SANCO/2001/2779-rev 1 den 26. november 2001 fremsendt forslag til Kommissionens direktiv om ændring af Kommissionens direktiv 90/128/EØF af 23. februar 1990 om plastmaterialer og -genstande bestemt til at komme i berøring med levnedsmidler. Forslaget kan blive sat til afstemning på mødet i Den Stående Levnedsmiddelkomité den 17. – 18. december 2001.

Forslaget er fremsat med hjemmel i artikel 3 i Rådets direktiv 89/109/EØF af 21. december 1988 om indbyrdes tilnærmelse af medlemslandenes lovgivning om materialer og genstande bestemt til at komme i berøring med levnedsmidler.

Forslaget behandles i en III a-procedure i Den Stående Komité for Levnedsmidler. Hvis der er kvalificeret flertal, udsteder Kommissionen direktivet. Opnås der ikke kvalificeret flertal, forelægger Kommissionen sagen for Rådet, der kan vedtage forslaget uændret med kvalificeret flertal eller ændre det med enstemmighed. Handler Rådet ikke inden en frist på højst tre måneder, kan Kommissionen udstede direktivet.

Nærheds- og proportionalitetsprincippet

Ved at fastlægge harmoniserede grænseværdier og samtidigt at sikre et reduceret indtag af migration (afsmitning) af stoffer fra plast og genstande til fødevarer, styrkes det indre marked under opretholdelse at et højt beskyttelsesniveau. Forslaget anses derfor for at være i overensstemmelse med nærheds- og proportionalitetsprincipippet.

Formål og indhold

Formålet med forslaget er at regulere anvendelsen af materialer og genstande bestemt til at komme i berøring med fødevarer på fællesskabsplan med henblik på at undgå risici for menneskers sundhed.

Forslaget til ændring af plastdirektivet, direktiv 90/128/EØF, indeholder følgende hovedpunkter:

1. Indførelse af restriktion for divinylbenzen i form af forbud mod fremstilling og import i Fællesskabet af materialer og genstande, der indeholder divinylbenzen, fra den 1. december 2002.
1. Justering af restriktioner for isocyanater (af redaktionel karakter).
1. Udvidelse af listen over additiver (tilsætningsstoffer), der må anvendes i plast, i bilag III i direktiv 90/128/EØF samt optagelse af visse monomerer (bestanddele i plaststoffer) på fællesskabslisten over tilladte stoffer.

De forslæde ændringer i punkt 3 berører stoffer, der tillades anvendt i plastmaterialer til opbygning af materialet. Ændringerne følger anbefalingerne fra Den Videnskabelige Komité for Levnedsmidler, der har vurderet de sundhedsmæssige aspekter ved en evt. migration (afsmidning) af stofferne fra materialet til fødevaren.

Udtalelser

Europa-Parlamentet skal ikke udtales sig om forslaget.

Gældende dansk ret

Stofferne er reguleret i Bekendtgørelse nr. 1215 af 18. december 2000 om materialer og genstande bestemt til at komme i berøring med fødevarer.

Konsekvenser

Vedtagelse af forslaget implementeres ved ændring af bekendtgørelse om materialer og genstande.

Forslaget skønnes ikke at få statsfinansielle eller samfundsøkonomiske konsekvenser for Danmark.

En vedtagelse af forslaget skønnes at ville øge beskyttelsesniveauet i Danmark, idet det medfører en præcisering af reglerne. Virksomhederne har i dag selv ansvaret for at regulere de stoffer, der ikke er på positivlisten og da forslaget indebærer, at flere stoffer kommer på positivlisten, vurderes forslaget at ville øge beskyttelsesniveauet.

Høring

Et udkast til forslaget har været sendt til høring i erhvervs og forbrugerorganisationer.

Forbrugerrådet støtter de foreslæde ændringer.

Plastindustrien i Danmark og **Mejeriforeningen** har ikke haft bemærkninger til forslaget.

Forslaget er desuden sendt i høring i Det Rådgivende Fødevareudvalg. **Danske Slagterier** har meddelt, at de ikke ser sig i stand til at fremsende et kvalificeret høringssvar inden for den meget korte tidsfrist.

Tidlige forelæggelse for Folketingets Europaudvalg

Forslaget har ikke tidlige været forelagt Folketingets Europaudvalg

EN

SANCO/2001/2779-rev 1

COMMISSION OF THE EUROPEAN COMMUNITIES



Brussels, 24 16.11
NovemberSeptember 2001

SANCO/2001/2779-rev 1

Draft

COMMISSION DIRECTIVE..../.../EC

of [...]

CTIVE..../.../EC

amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs.

(Text with EEA relevance)

Draft

COMMISSION DIRECTIVE/.../EC

lastic materials and articles intended to come into contact with foodstuffs.

of [...]

CTIVE/.../EC

lastic materials and articles intended to come into contact with foodstuffs.

amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs.

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs, and in particular Article 3 thereof,

After consulting the Scientific Committee on Food,

Whereas:

(1) On the basis of the new information available to the Scientific Committee on Food, certain monomers provisionally admitted at national level as well as other monomers requested for use following the adoption of Commission Directive 90/128/EEC of 23 February 1990 relating to plastic materials and articles intended to come into contact with foodstuffs, as last amended by Directive 2001/62/EC, may be included in the Community list of admitted substances.

(2) Annex III to Directive 90/128/EEC includes a list of additives, which should be amended so as to include other additives evaluated by the Scientific Committee on Food.

(3) For certain substances, the restrictions already established at Community level should be amended on the basis of the information available.

(4) The current total list of additives is an incomplete list inasmuch as it does not contain all the substances, which are currently accepted in one or more Member States. Accordingly, these substances continue to be regulated by national laws only pending a decision on inclusion in the Community list.

(5) This Directive establishes specifications for only a few substances, and therefore the other substances, which may require specifications, remain regulated in this respect by national laws only pending a decision at Community level.

(6) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of ensuring the free movement of plastic materials and articles intended to come into contact with foodstuffs, to lay down rules on the definition of plastics and admitted substances. This Directive confines itself to what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 5 of the Treaty.

(7) Directive 90/128/EEC should therefore be amended accordingly.

(8) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article I

Annexes II, III, V and VI of Directive 90/128/EEC are amended as set out in Annexes I to IV to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 November 2002 at latest. They shall forthwith inform the Commission thereof.

Member States shall permit, as from 1 December 2002, the trade in and use of plastic materials and articles intended to come into contact with foodstuffs and complying with this Directive.

Member States shall prohibit, as from 1 December 2003, the manufacture and importation into the Community of plastic materials and articles intended to come into contact with foodstuffs and which do not comply with this Directive. However, for materials and articles which containing divinylbenzene and do not comply with the restriction set in this Directive, Member States they shall prohibit their manufacture and importation into the Community as from 1 December 2002

2. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission

Member of the Commission

ANNEX I

Annex II is amended as follows:

1. In point 8:

(a) The definition of QM (T) is replaced by the following:

QM (T) = maximum permitted quantity of the 'residual' substance in the material or article expressed as total of moiety or substance(s) indicated. For the purpose of this Directive "QM(T)" means that the quantity of the substance in the material or article should be determined by a validated method of analysis at the specified limit. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;

(b) the following text is inserted after QM(T):

QMA = Maximum permitted quantity of the "residual" substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs. For the purpose of this Directive "QMA" means that the quantity of the substance in the surface of the material or article should be determined by a validated method of analysis at the specified limit. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;

QMA(T) = Maximum permitted quantity of the "residual" substance in the material or article expressed as mg of total of moiety or substance(s) indicated per 6 dm² of the surface in contact with foodstuffs. For the purpose of this Directive "QMA(T)" means that the quantity of the substance in the surface of the material or article should be determined by a validated method of analysis at the specified limit. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;

(c) The definitions of SML and SML(T) are replaced by the following:

SML = specific migration limit in food or in food simulant, unless it is specified otherwise. For the purpose of this Directive the specific migration of the substance should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;

SML (T) = specific migration limit in food or in food simulant expressed as total of moiety or substance(s) indicated. For the purpose of this Directive the specific migration of the substances should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method.

2. Section A is amended as follows:

(a) The following monomers and other starting substances are inserted

REF_N	CAS_N	NAME	RESTRICTIONS AND/OR SPECIFICATIONS
13620	10043-35-3	BORIC ACID	SML(T) = 6 mg/kg (23) (expressed as boron). without prejudice to the provisions of Directive 98/83/EEC on water for human consumption . However in natural mineral water the limit of 0.3 mg/kg has to be fulfilled
16650	00127-63-9	DIPHENYL SULPHONE	SML(T) = 3 mg/kg (25)
18897	16712-64-4	6-HYDROXY-2-NAPHTHALENECARBOXYLIC ACID	SML = 0.05 mg/kg
18898	103-90-2	N-(4-HYDROXYPHENYL) ACETAMIDE	Only to be used in liquid crystals and behind a barrier layer in multilayered plastics.
22332	28679-16-5	MIXTURE OF (40% w/w) 2,2,4-TRIMETHYLHEXANE-1,6-DIISOCYANATE and (60% w/w) 2,4,4-TRIMETHYLHEXANE-1,6-DIISOCYANATE	QM(T) = 1 mg/Kg (expressed as NCO) (26).

(b) For the following monomers and other starting substances the content of the column "Restrictions and/or specifications" is replaced by the following:

validated method of analysis If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method.

REF_N	CAS_N	NAME	
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**RESTRICTIONS
AND/OR
SPECIFICATIONS**

13510	01675-54-3	2,2-BIS(4-HYDROXYPHENYL)PROPANE (2,3-EPOXYPROPYL) ETHER (=Badge)	BIS	According to [Commission Directive .../.../EC of ... on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs]
13560	05124-30-1	BIS(4-ISOCYANATO CYCLOHEXYL)METHANE		See "DICYCLOHEXYLMETHANE-4,4'-DIISOCYANATE"
14650	00079-38-9	CHLOROTRIFLUOROETHYLENE		QMA = 0.5 mg/6 dm ²
14950	03173-53-3	CYCLOHEXYL ISOCYANATE		QM(T) = 1 mg/Kg (expressed as NCO) (26).
15700	05124-30-1	DICYCLOHEXYLMETHANE-4,4'-DIISOCYANATE		QM(T) = 1 mg/Kg (expressed as NCO) (26).
16240	00091-97-4	3,3'-DIMETHYL-4,4'-DIISOCYANATO BIPHENYL		QM(T) = 1 mg/Kg (expressed as NCO) (26).
16570	04128-73-8	DIPHENYLETHER-4,4'-DIISOCYANATE		QM(T) = 1 mg/Kg (expressed as NCO) (26).
16600	05873-54-1	DIPHENYLMETHANE-2,4'-DIISOCYANATE		QM(T) = 1 mg/Kg (expressed as NCO) (26).
16630	00101-68-8	DIPHENYLMETHANE-4,4'-DIISOCYANATE		QM(T) = 1 mg/Kg (expressed as NCO) (26).
18640	00822-06-0	HEXAMETHYLENE DIISOCYANATE		QM(T) = 1 mg/Kg (expressed as NCO) (26).
19110	04098-71-9	1-ISOCYANATO-3-ISOCYANATOMETHYL-3,5,5-TRIMETHYL CYCLOHEXANE		QM(T) = 1 mg/Kg (expressed as NCO) (26).
22420	03173-72-6	1,5-NAPHTHALENE DIISOCYANATE		QM(T) = 1 mg/Kg (expressed as NCO) (26).
22570	00112-96-9	OCTADECYL ISOCYANATE		QM(T) = 1 mg/Kg (expressed as NCO) (26).
25210	00584-84-9	2,4-TOLUENE DIISOCYANATE		QM(T) = 1 mg/Kg (expressed as NCO) (26).
25240	00091-08-7	2,6-TOLUENE DIISOCYANATE		QM(T) = 1 mg/Kg (expressed as NCO) (26).
25270	26747-90-0	2,4-TOLUENE DIISOCYANATE DIMER		QM(T) = 1 mg/Kg (expressed as NCO) (26).

(c) The following monomers and other starting substances are transferred from Section B to Section A

REF_N	CAS_N	NAME	RESTRICTIONS AND/OR SPECIFICATIONS
13075	00091-76-9	BENZOGUANAMINE	See "2,4-DIAMINO-6-PHENYL-1,3,5-TRIAZINE"
13720	00110-63-4	1,4-BUTANEDIOL	SML(T) = 0.05 mg/kg (24)
15310	00091-76-9	2,4-DIAMINO-6-PHENYL-1,3,5-TRIAZINE	SML = 5 mg/kg
15370	03236-53-1	1,6-DIAMINO-2,2,4-TRIMETHYLHEXANE	QMA = 5 mg/6 dm ² .
15400	03236-54-2	1,6-DIAMINO-2,4,4-TRIMETHYLHEXANE	QMA = 5 mg/6dm ²
16690	01321-74-0	DIVINYLBENZENE	QMA = 0.01 mg/6 dm ² or SML = ND (DL=0 .02 mg/kg, analytical tolerance included) for the sum of divinylbenzene and ethylvinylbenzene and in compliance with the specifications laid down in Annex V
16697	00693-23-2	n-DODECANEDIOIC ACID	
25840	03290-92-4		SML = 0.05 mg/kg

ANNEX II

Annex III is amended as follows:

1. The table of Section A is amended as follows:

(a) The following additives are inserted

REF_N	CAS_N	NAME	RESTRICTIONS AND/OR SPECIFICATIONS
36840	12007-55-5	BARIUM TETRABORATE	SML(T) = 1 mg/kg expressed as barium (12) and SML(T) = 6 mg/kg (23) (expressed as boron) without prejudice to the provisions of Directive 98/83/EEC on water for human consumption . SML(T)= 1 mg/kg (12) and SML(T) = 6 mg/kg (23) (expressed as boron). However in natural mineral water the limit of 0.3 mg/kg of boron has to be fulfilled.
40320	10043-35-3	BORIC ACID	SML(T) = 6 mg/kg (23) (expressed as boron)without prejudice to the provisions of Directive 98/83/EEC on water for human consumption . SML(T) = 6 mg/kg (23) (expressed as boron). However in natural mineral water the limit of 0.3 mg/kg has to be fulfilled
40580	00110-63-4	1,4-BUTANEDIOL	SML(T) = 0.05 mg/kg (24)
71670	178671-58-4	PENTAERYTHRITOL TETRAKIS (2-CYANO-3,3-DIPHENYLACRYLATE)	SML = 0.05 mg/kg
87040	01330-43-4	SODIUM TETRABORATE	SML(T) = 6 mg/kg (23) (expressed as boron)without prejudice to the provisions of Directive 98/83/EEC on water for human consumption . SML(T) = 6 mg/kg (23) (expressed as boron). However in natural mineral water the limit of 0.3 mg/kg has to be fulfilled

(b) For the following additives the content of column "Restriction and/or specifications" is replaced by the following

REF_N	CAS_N	NAME	RESTRICTIONS AND/OR SPECIFICATIONS
37360	000100-52-7	Benzaldehyde	In compliance with note 9 in Annex VI
40120	-68951-50-8	BIS(POLYETHYLENE GLYCOL)HYDROXY METHYLPHOSPHONATE	SML = 0.6 mg/kg
41680	000076-22-2	Camphor	In compliance with note 9 in Annex VI.

(c) The following additive is deleted

REF_N	CAS_N	NAME	

**RESTRICTIONS
AND/OR
SPECIFICATIONS**

40020	110553-27-0	2,4-BIS(OCTYLTHIOMETHYL)-6-METHYLPHENOL	SML = 6 mg/kg
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2. The table of Section B is amended as follows

(a) The following additives are inserted:

REF_N	CAS_N	NAME	RESTRICTIONS AND/OR SPECIFICATIONS
45650	6197-30-4	2-CYANO-3,3-DIPHENYLACRYLIC ACID, 2-ETHYLHEXYL ESTER	SML = 0.05 mg/kg
68860	04724-48-5	n-OCTYLPHOSPHONIC ACID	SML = 0.05 mg/kg
95000	28931-67-1	TRIMETHYLOLPROPANE TRIMETHACRYLATE-METHYL METHACRYLATE COPOLYMER	

(b) For the following additives the content of column "Restriction and/or specifications" is replaced by the following

REF_N	CAS_N	NAME	RESTRICTIONS AND/OR SPECIFICATIONS
39120	-	N,N-BIS(2-HYDROXYETHYL)ALKYL(C8-C18) AMINE HYDROCHLORIDES	SML(T) = 1.2 mg/kg (13) expressed as tertiary amine (expressed excluding HCl) (with REF_n. 39090).
51570	00127-63-9	DIPHENYL SULPHONE	SML(T) = 3 mg/kg (25)

ANNEX III

Annex V is amended as follows:

The following specifications are inserted in the table of Part B of Annex V

PM/REF No	OTHER SPECIFICATIONS
16690	DIVINYLBENZENE It may contain until 40% of ethylvinylbenzene.

ANNEX IV

Annex VI is amended as follows:

a) The notes (12) and (13) are replaced by the following:

"(12) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as PM/REF Nos.: 36720, 36800, 36840, 87040 and 92000.

(13) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as PM/REF Nos.: 39090 and 39120."

b) The following notes are added:

(23) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as PM/REF Nos.: 13620, 36840, 40320 and 87040.

(24) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as PM/REF Nos.: 13720 and 40580.

(25) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as PM/REF Nos.: 16650 and 51570.

(26) QMA(T) in this specific case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances mentioned as PM/REF Nos.: 13560, 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240, 25270.