COURTESY TRANSLATION

Twenty-First Ordinance

amending the Consumer Goods Ordinance (*Bedarfsgegenständeverordnung))**

of … 2016

The Federal Ministry of Food and Agriculture hereby issues on the following basis:

- Article 31(2) Clause 1 Item 2, Food and Feed Act (LFGB), in the version stated in the Notice of 3 June 2013 (Federal Law Gazette I, p. 1426) and

- Article 32(1) Items 1, 2, 4 b) and Item 5, also in connection with Article 4(2) Item 2 of the Food and Feed Act (LFGB), in the version stated in the Notice of 3 June 2013 (Federal Law Gazette I, p. 1426), last amended by means of Article 67 of the Ordinance of 31 August 2015 (Federal Law Gazette I, p. 1474), in agreement with the Federal Ministry for Economic Affairs and Energy:

*) Notification given in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (Official Journal of the European Union, L 241, 17.9.2015, p.1)

Article 1

The Consumer Goods Ordinance in the version stated in the Notice of 23 December 1997 (Federal Law Gazette 1998 I, p. 5), last amended by means of the Ordinance of 24 June 2013 (Federal Law Gazette I, p. 1682), shall be amended as follows:

1. Article 2 shall be amended as follows:

a) The wording hitherto in use shall be amended as follows:

aa) In Item 6, the full stop shall be replaced by a semi-colon.

bb) The following Items, 7 to 12, shall be added:

"7. Printing inks: Printing inks or printing varnishes, applied onto food contact materials and articles in a printing process or varnishing process;

8. printed food contact materials and articles: food contact materials and articles produced by means of use of printing inks;

9. Nanomaterials: Materials in printing inks,

a) which are of natural origin and either emerge in manufacturing processes or are manufactured in a targeted way,

b) which contain the particles in an unbound state, as an aggregate, or as an agglomerate, and

c) with regard to which at least 50 per cent of the particles, in relation to the number size distribution, have one or more external dimension in the range from 1 to 100 nanometres;

10. Particle: a very small piece of a substance, with defined physical boundaries;

11. Agglomerate: a collection of weakly bound particles or aggregates in which the resulting surface area is similar to the sum of the surface areas of the individual components;

12. Aggregate: a particle comprising of strongly bound or fused particles."

b) The following sentences shall be added:

"Preparations used to dye food contact materials and articles and also decorative inks for ceramic food contact materials and articles, applied in a combustion process, shall not constitute printing inks as defined by Clause 1 Item 7. Fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm shall also constitute nanomaterials as defined by Clause 1 Item 9."

2. The following Paragraphs, 5 to 10, shall be added to Article 4:

"(5) With regard to the commercial manufacture of printed food contact materials and articles, subject to Paragraphs 7 to 9, it is solely

1. Polymers obtained from monomers or other starting substances stated in Annex 14 Table 1 and
2. the substances stated in Annex 14 Table 1, as monomers or other starting substances, or as colourants, solvents, photoinitiators or other additives

that shall be permitted to be used.

The substances shall be permitted to be used only if they correspond to the other restrictions, specifications and purity requirements established in Annex 14 Table 1 Column 8. If no purity requirements are stipulated, the substances shall be of good technical quality with regard to the purity requirements. Substances in the form of nanomaterials shall not be permitted to be used unless explicit provision is made for this in Annex 14 Table 1 Column 8. Apart from the acids, phenols and alcohols named in Annex 14 Table 1, it shall also be permitted for their salts to be used, including the double salts and acid salts, of aluminium, ammonium, barium, calcium, iron, potassium, cobalt, copper, lithium, magnesium, manganese, sodium and zinc. If Annex 14 Table 1 names salts of acids, phenols or alcohols, it shall solely be these salts that it is permissible to use, and also the salts, including the double salts and acid salts, of aluminium, ammonium, barium, calcium, iron, potassium, cobalt, copper, lithium, magnesium, manganese, sodium and zinc of these acids, phenols or alcohols.

(6) Subject to Paragraphs 7, 8 and 10, it shall solely be permitted to use as additives those monomers or other starting substances stated in Annex 14 Table 1, and to use as monomers or other starting substances those additives stated in Annex 14 Table 1, provided that they correspond to the other restrictions, specifications and purity requirements stipulated in Annex 14 Table 1 Column 8.

(7) Provided that the printing inks are not intended to come into contact with the food directly, by derogation from Paragraphs 5 and 6 the following shall be permitted to be used in printing inks for the commercial manufacture of printed food contact materials and articles:

1. Polymers obtained from monomers or other starting substances other than those stated in Annex 14 Table 1, and
2. Substances other than those stated in Annex 14 Table 1, used as monomers or other starting substances, or as colourants, solvents, photoinitiators or other additives.

In addition, the substances as defined in Clause 1 shall solely be permitted to be used if they are not classified as "mutagenic", "carcinogenic" or "toxic for reproduction", as defined in the requirements in Annex I, Sections 3.5, 3.6 and 3.7 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directive 67/548/EEC and Directive 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Official Journal (OJ) of the European Union, L 353 of 31.12.2008, p. 1). Substances as defined in Clause 1 shall also be those in the form of nanomaterials. Clause 1 shall not apply to printed food contact materials and articles for which it is foreseeable that the printing inks directly come into contact with foods although they are not intended to do so.

(8) In addition, in the commercial manufacture of printed food contact materials and articles it shall be permitted to use monomers or other starting substances or additives in the printing inks, provided that they:

1. are listed in the respective valid version of Annex I of Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ of the European Union, L 12, 15.01.2011, p. 1) without group restrictions according to the corresponding Table 1 Column 9 of that document, or without restrictions and specifications according to the corresponding Table 1 Column 10 of that document,

2. correspond to the general requirements according to Article 8 of Regulation (EU) No 10/2011 in the version valid on [*to be inserted: date of the latest Regulation amending (EU) No 10/2011*] and

3. , in relation to the printed food contact material and article, comply with the limits for the transfer onto food stated in Annex I Table 1 Column 8 of Regulation (EU) No 10/2011, in its respective valid version, or Article 11(2) of Regulation (EU) No 10/2011 in the version valid on [*to be inserted: date of the latest Regulation amending Regulation (EU) No 10/2011*].

Paragraph 5 Clause 5 shall apply accordingly.

(9) By derogation from Paragraph 5 Clause 1, in printing on food contact materials and articles referred to in Article 4(7) Clause 4, it shall also be permitted to use the pigments named in Annex 14 Table 2, according to the conditions, specifications and purity requirements stipulated there. Paragraph 5 Clause 3 shall apply accordingly.

(10) The Paragraphs 5 to 9 shall not apply for any printed food contact materials and articles with regard to which it is ruled out that there will be a transfer of substances from the printing ink to the food, including such substances in the form of nanomaterials."

3. The following Paragraphs, 5 to 7, shall be added to Article 8:

"(5) With regard to printed food contact materials and articles, the substances listed in Annex 14 Tables 1 and 2 shall not be permitted to exceed the respective limits for the transfer onto foods, stated for them in Column 6 or 7 in connection with Annex 14 Table 3. Transfers of barium, iron, cobalt, copper, lithium, manganese and zinc and also of primary aromatic amines shall not be permitted to exceed the respective limits stipulated in Annex 14 Table 4.

(6) For substances stated in Annex 14 Table 1, for which Annex 14 Table 1 or 3 does not specify a specific migration limit, group restriction or any other restrictions, it shall solely be permitted for a maximum limit of 60 milligrams per kilogram respectively to be transferred onto food from printed food contact materials and articles.

(7) With regard to printed food contact materials and articles, a detectable transfer of substances from printing inks, used according to Article 4(7), shall not be permitted. For substances other than those in the form of nanomaterials, a transfer of up to 0,01 milligrams per kilogram of food shall be deemed to be non-detectable."

4. In Article 12 (2) Item 3 the word "a" is replaced by the words "or (5) Clause 1, 2 or 4 a in that context mentioned".

5. The following Paragraphs, namely 15, 16, 17 and 18, shall be added to Article 16:

"(15) Printed food contact materials or articles placed on the market according to the rules valid until the [*to be inserted: the last day of the twenty-fourth calendar month that follows the announcement of this Ordinance*] shall also still be permitted to be placed on the market after this date, according to these rules, until the stocks have been sold.

(16) Article 2 Clause 1 Items 7 to 12, Clauses 2 and 3; Article 4(5) to (9); Article 8(5) to (7); and Article 12(2) Item 3: these shall be applied starting on the [*to be inserted: first day of the twenty-fifth calendar month following the announcement of this Ordinance]*."

(17) Food contact materials as specified in Article 4(7) Clause 4, printed by using pigments listed in Annex 14 Table 2, and placed on the market market according to the rules valid until the [*to be inserted: last day of the forty-eight calendar month following the announcement of this Ordinance]* shall also still be permitted to be placed on the market after this date, according to these rules, until the stocks have been sold.

(18) Article 4(9), in connection with Annex 14 Table 2, shall no longer be applied from the [*to be inserted: the last day of the forty-eighth calendar month following the announcement of this Ordinance*]."

6. After Annex 13, the following shall be added - Annex 14:

"**Annex 14**

The subsequent Tables, 1 and 2, shall contain the following information:

Column 1 (substance name): Chemical name

Column 2 (CAS No.): Chemical Abstract Service number

Column 3 (REF No.): EEC packaging material reference number

Column 4 (substance No.): Substance number

Column 5 (purpose of use): Use as

- I: Monomers or other starting substances (substances that are polymerised to manufacture macromolecules (polymers) or that are used to modify natural or artificially-manufactured macromolecules (polymers);
- II: Colourants (colouring substances (pigments and colourings));
- III: Solvents (fluids capable of dissolving other substances without chemically changing either themselves or the dissolved substance in the process);
- IV: Additives (substances used in order to attain a technical effect during the process of printing or varnishing or in the end-product. This does not include additives used for pigments);

V: Photoinitiators (additives which, by being exposed to irradiation, are transferred into free radicals or ions and which start a chemical reaction).

Column 6 (SML [mg/kg]): Specific migration limit, stated in milligrams of the substance affected per kilogram of food. If "ND" is indicated, a detectable transfer of the substance onto foods shall not be permitted. A transfer of up to 0,01 milligrams per kilogram of food shall be deemed to be a non-detectable transfer.

Column 7 (group limit no.): Number of the substance group for which a group restriction is stipulated in Table 3.

Column 8 (other restrictions, specifications and purity requirements): Restrictions other than those stated in Columns 6 and 7 in connection with Table 3, and also specifications and purity requirements.

Table 1: List of monomers or other starting substances, colourants, solvents, photoinitiators or other additives

(related to Article 4 (5), (6) and (7), Article 8 (5) clause 1 and (6))

1	2	3	4	5					6	7	8
Substance name	**CAS-No**	**REF-No**	**Substance-No**	**intended use**					**SML [mg/kg]**	**Group restriction No**	**Restrictions, specifications and purity requirements**
				I	**II**	**III**	**IV**	**V**			
acetaldehyde	0000075-07-0	10060	1	x					6		
acrylic acid, ester with tri-methylethanolammonium chloride	0044992-01-0		2	x					0,05		
acrylic acid	0000079-10-7	10690	3	x			x			(20)	
acrylic acid, dicyclopentadienyl ester	0050976-02-8	11000	4	x					0,05		
adipic acid, dimethyl ester	0000627-93-0		5			x			3		
polyester of adipic acid with 1,3-butanediol	0024937-93-7	76780	6				x			(28) (29)	
α-alkenes(C20-C24) copol-ymer with maleic anhydride, reaction product with 4-amino-2,2,6,6-tetramethylpiperidine	0152261-33-1	33535	7				x				Not to be used for articles in con-tact with fatty foods for which simulant D is laid down. Not to be used in contact with alcoholic foods.

alkyl(C10-C21)sulphonic acid, esters with phenol	0091082-17-6	34240	8				x		0,05		
Food Red 17 (E 129)	0025956-17-6		9		x						
amines, bis(hydrogenated tallow alkyl) oxidised	0143925-92-2	34850	10				x				Not to be used for articles in contact with fatty foods for which simulant D is laid down. Only to be used in: (a) polyolefins at 0,1 % (w/w) concentration and in (b) PET at 0,25 % (w/w) concentration.
2-aminobenzamide	0000088-68-6	34895	11				x		0,05		
2-aminoethanol	0000141-43-5	12763 35170	12	x			x		0,05		
N-(2-aminoethyl)ethanolamine	0000111-41-1	35284	13	x			x		0,05		
1-propanol, 2-amino-2-methyl-	0000124-68-5		14	x		x	x		5		
3-aminopropyltriethoxysilane	0000919-30-2	12786	15	x			x		0,05		
antimony trioxide	0001309-64-4	35760	16				x		0,04		SML expressed as antimony

malic acid	0006915-15-7	19965 65020	17	x			x				
azelaic acid, bis(2-ethylhexyl) ester	0000103-24-2		18				x		0,05		
barium tetraborate	0012007-55-5	36840	19				x			(14)	
1,2-benzisothiazolin-3-one	0002634-33-5	37520	20				x		0,5		
pyromellitic acid	0000089-05-4	24055	21	x					0,05		For the sum of pyromellitic acid und pyromellitic acid anhydride (CAS-No. 0000089-32-7) the transfer into food shall not exceed 0.05 mg/kg.
1,2,4-benzenetricarboxylic acid, tris(decyl) ester	0004130-35-2		22				x		0,05		
1,2,4-benzenetricarboxylic acid, tris(2-ethylhexyl) ester	0003319-31-1		23			x			0,05		
phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-, branched and linear	0125304-04-3		24				x		5		
acrylic acid, benzyl ester	0002495-35-4	10750	25	x						(20)	
methacrylic acid, benzyl ester	0002495-37-6	20080	26	x						(21)	

cis-endo-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, salts		38507	27				x		5		Not to be used in direct contact with acidic foods. Purity ≥ 96 %.
phosphorous acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester	0145650-60-8	74010	28				x		5		expressed as sum of phosphite and phosphate
bis(2,6-di-tert-butyl-4-methylphenyl)pentaerythritol diphosphite	0080693-00-1	38810	29				x		5		expressed as sum of phosphite and phosphate
bis(2,4-dicumylphenyl)pentaerythritol-diphosphite	0154862-43-8	38840	30				x		5		expressed as sum of the substance itself, its oxidised form bis(2,4-dicumylphenyl)pentaerythritol-phosphate and its hydrolysis product (2,4-dicumylphenol)
bis(2,6-diisopropylphenyl) carbodiimide	0002162-74-5	13303	31				x		0,05		Expressed as the sum of bis(2,6-diisopropylphenyl)carbodiimide and its hydrolysis product 2,6-diisopropylaniline
2,4-bis(dodecylthiomethyl)-6-methylphenol	0110675-26-8	38940	33				x			(22)	
adipic acid, bis(2-ethylhexyl) ester	0000103-23-1	31920	34	x			x		18	(29)	
terephthalic acid, bis(2-ethylhexyl)ester	0006422-86-2	92200	35				x		60	(29)	

N,N-bis(2-hydroxyethyl)alkyl(C8-C18)amine		39090	36				x			(5)	
N,N-bis(2-hydroxyethyl)alkyl(C8-C18)amine hydrochlorides		39120	37				x			(5)	expressed excluding HCl
hydantoin, 1,3-bis(hydroxymethyl)-5,5-dimethyl-	0006440-58-0		39				x		0,05		
bis(2-hydroxyphenyl)methane bis(2,3-epoxypropyl) ether	0054208-63-8	12974	40	x							according to Regulation (EC) No 1895/2005
2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether	0001675-54-3	13510 13610	41	x			x				In compliance with Commission Regulation (EC) No 1895/2005 (1)
2,2-bis(4-hydroxyphenyl)propane bis(2-hydroxypropyl) ether	0000116-37-0	13520	42	x					0,05		
2,4-bis(octylthiomethyl)-6-methylphenol	0110553-27-0	40020	43				x			(22)	
1-piperidinyloxy, 4,4'-[1,10-dioxo-1,10-dec-anediyl)bis(oxy)]bis[2,2,6,6-	0002516-92-9		44				x		0,05		

tetramethyl]-											
boron nitride	0010043-11-5	40400	45				x			(14)	
boric acid	0010043-35-3	13620 40320	46	x			x			(14)	
Food Brown 3 (E 155)	0004553-89-3		47		x						
Food Black 1 (E 151)	0002519-30-4		48		x						
1,3-propanediol, 2-bromo-2-nitro-	0000052-51-7		49				x		0,05		
butadiene	0000106-99-0	13630	50	x					NN		1 mg/kg in final product
1,4-butanediol	0000110-63-4	13720 40580	51			x	x			(27)	
1,4-butanediol bis(2,3-epoxypropyl)ether	0002425-79-8	13780	52	x					NN		1 mg/kg in final product (expressed as epoxygroup, Molecular weight = 43 Da)
2-butanol	0000078-92-2		53			x			1		
tert-butanol	0000075-65-0	13845 40594	54			x			10		
2-butanone	0000078-93-3	21827 66655	55			x			5		

1,2-propylene glycol 1-monobutyl ether	0005131-66-8		56			x			0,05		
propanol, 1(or 2)-butoxy-	0029387-86-8		57			x			0,05		
acrylic acid, n-butyl ester	0000141-32-2	10780	58	x						(20)	
acrylic acid, sec-butyl ester	0002998-08-5	10810	59	x						(20)	
acrylic acid, tert-butyl ester	0001663-39-4	10840	60	x						(20)	
tert-butyl-hydroquinone (TBHQ)	0001948-33-0		61	x			x		42		
methacrylic acid, butyl ester	0000097-88-1	20110	62	x						(21)	
methacrylic acid, tert-butyl ester	0000585-07-9	20170	63	x						(21)	
phenol, m-tert-butyl-	0000585-34-2		64	x					0,05		
caprolactam	0000105-60-2	14200 41840	65	x			x		15		
caprolactone	0000502-44-3	14260	66	x						(26)	
carbonyl chloride	0000075-44-5	14380 23155	67	x					NN		1 mg/kg in final product

cellulose acetate propionate	0009004-39-1	14512	68	x							
p-chloro-m-cresol	0000059-50-7		69				x		5		
5-chloro-2-methyl-2H-isothiazol-3-one, mixture with 2-methyl-2H-isothiazol-3-one (3:1)	0055965-84-9	43730	70				x		0,15		
coumarin	0000091-64-5		71	x					0,6		
1,4-cyclohexanedicarboxylic acid	0001076-97-7	14876	72	x					5		
1,2-cyclohexanedicarboxylic acid, diisononyl ester	0166412-78-8	45705	73				x			(29)	
1-decene, homopolymer, hydrogenated	0068037-01-4		74				x				
dextrin	0009004-53-9		75				x				
ammonium, diallyldimethyl-, chloride	0007398-69-8		76	x					5		
pentanedinitrile, 2-bromo-2-(bromomethyl)-	0035691-65-7		77				x		1		
sebacic acid, dibutyl ester	0000109-43-3	85360	78				x			(29)	

dibutylthiostannoic acid polymer	0026427-07-6	47210	79				x				Molecular unit = (C8H18S3Sn2)n (n = 1,5-2)
3(2H)-isothiazolone, 4,5-dichloro-2-octyl-	0064359-81-5		80				x		5		
dicyclohexylmethane-4,4′-diisocyanate	0005124-30-1	13560 15700	81	x						(15)	1 mg/kg in final product ex-pressed as isocyanate moiety
phthalic acid, dicyclohexyl ester	0000084-61-7		82				x		6		
dicyclopentadiene	0000077-73-6		83	x					5		
didecyldimethylammonium chloride	0007173-51-5		84				x		5		
thiodipropionic acid, didodecyl ester	0000123-28-4	93120	85				x			(12)	
di-n-dodecyltin bis(isooctyl mercaptoacetate)	0084030-61-5	47600	86				x			(23)	
diethanolamine	0000111-42-2		87	x					0,3		
methacrylic acid, 2-(diethylamino)ethyl ester	0000105-16-8		88	x					0,05		
diethyleneglycol	0000111-46-6	13326 15760 47680	89	x		x	x			(1)	
ethanamine, N-ethyl-N-	0003710-		90	x			x		0,05		

hydroxy-	84-7										
ethanol, 2-(diethylamino)-	0000100-37-8		91				x		0,05		
2,4-dihydroxybenzophenone	0000131-56-6	48640	92				x			(6)	
4,4′-dihydroxybenzophenone	0000611-99-4	15970 48720	93				x			(6)	
2,2′-dihydroxy-4-methoxybenzophenone	0000131-53-3	48880	94				x			(6)	
N-(2,6-diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3(2H)-dione	0852282-89-4	49080	95				x		0,05		
acids, fatty, unsaturated (C18), dimers, non hydrogenated, distilled and non-distilled	0061788-89-4	10599/90A 10599/91	96	x			x			(16)	
acids, fatty, unsaturated (C18), dimers, hydrogenated, distilled and non-distilled	0068783-41-5	10599/92A 10599/93	97	x			x			(16)	
dimethylamine	0000124-40-3		98	x					0,05		

acrylic acid, 2-(dimethylamino)ethyl ester	0002439-35-2		99	x					0,05		
3,3′-dimethyl-4,4′-diaminodicyclohexylmethane	0006864-37-5	16210	100	x					0,05		
3,3′-dimethyl-4,4′-diisocyanatobiphenyl	0000091-97-4	16240	101	x						(15)	1 mg/kg in final product expressed as isocyanate moiety
2,6-dimethyl-4-heptanone	0000108-83-8		102			x			0,05		
hydantoin, 5,5-dimethyl-	0000077-71-4		103				x		5		
benzenemethanaminium, N,N-dimethyl-N-[2-[(1-oxo-2-propenyl)oxy]ethyl]-, chloride	0046830-22-2		104				x		0,05		
phthalic acid, dimethyl ester	0000131-11-3		105				x		0,05		
polydimethylsiloxane (Mw > 6 800 Da)	0063148-62-9	23547 76721	106	x							Viscosity at 25 °C not less than 100 cSt (100 × 10-6 m2/s)
dimethyltin bis(ethylhexyl mercaptoacetate)	0057583-35-4	49595	107				x			(7)	
dimethyltin bis(isooctyl mercaptoacetate)	0026636-01-1	49600	108				x			(7)	
stannane, dimethylbis[(1-oxoneodecyl)oxy]-	0068928-76-7		109				x		0,05		

thiodipropionic acid, dioctadecyl ester	0000693-36-7	93280	110				x			(12)	
di-n-octyltin bis(n-alkyl(C10-C16) mercaptoacetate)		50160	111				x			(8)	
di-n-octyltin bis(2-ethylhexyl maleate)	0010039-33-5	50240	112				x			(8)	
di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	0015571-58-1	50320	113				x			(8)	
di-n-octyltin bis(ethyl maleate)		50360	114				x			(8)	
di-n-octyltin bis(isooctyl maleate)	0033568-99-9	50400	115				x			(8)	
di-n-octyltin bis(isooctyl mercaptoacetate)	0026401-97-8	50480	116				x			(8)	
di-n-octyltin 1,4-butanediol bis(mercaptoacetate)		50560	117				x			(8)	
di-n-octyltin dilaurate	0003648-18-8	50640	118				x			(8)	
di-n-octyltin dimaleate	0015571-60-5	50720	119				x			(8)	
di-n-octyltin dimaleate, polymers (n = 2-4)		50880	120				x			(8)	
di-n-octyltin dimaleate, esterified		50800	121				x			(8)	

di-n-octyltin ethyleneglycol bis(mercaptoacetate)	0069226-44-4	50960	122				x			(8)	
di-n-octyltin thiobenzoate 2-ethylhexyl mercaptoacetate		51120	123				x			(8)	
di-n-octyltin mercaptoacetate	0015535-79-2	51040	124				x			(8)	
diphenylmethane-2,4′-diisocyanate	0005873-54-1	16600	125	x						(15)	1 mg/kg in final product expressed as isocyanate moiety
diphenylmethane-4,4′-diisocyanate	0000101-68-8	16630	126	x						(15)	1 mg/kg in final product expressed as isocyanate moiety
dipropyleneglycol methyl ether acetate	0088917-22-0		127			x			0,05		
dipropyleneglycol monomethyl ether	0034590-94-8		128			x	x		0,05		
dipropyleneglycol n-butyl ether	0029911-28-2		129			x			0,05		
divinylbenzene	0001321-74-0	16690	130	x					NN		expressed as the sum of divinylbenzene and ethylvinylbenzene. It may contain up to 45 % (m/m) of ethylvinylbenzene.
1-dodecanol	0000112-53-8	16701 51975	131	x							
gallic acid, dodecyl ester	0001166-	55200	132				x			(18)	

	52-5										
Natural Red 4 (E 120)	0001260-17-9		133		x						
iron phosphide	0012751-22-3	62245	134				x		0,05		
elaidic acid	0000112-79-8		135				x				
epichlorohydrin	0000106-89-8	14570 16750	136	x					NN		1 mg/kg in final product
trialkyl(C5-C15)acetic acid, 2,3-epoxypropyl ester		25360	137	x					NN		1 mg/kg in final product expressed as epoxygroup. Molecular weight is 43 Da.
petroleum hydrocarbon resins (hydrogenated)		72081/10	138				x				Petroleum hydrocarbon resins, hydrogenated are produced by the catalytic or thermalpolymerisation of dienes and olefins of the aliphatic, alicyclic and/or monobenzenoidarylalkene types from distillates of cracked petroleum stocks with a boiling range not greater than 220 °C, as well as the pure monomers found in these distillation streams, subsequently followed by distillation, hydro-

											genation and additional processing. Properties: — Viscosity at 120 °C: > 3 Pa.s, — Softening point: > 95 °C as determined by ASTM Method E 28-67, — Bromine number: < 40 (ASTM D1159), — The colour of a 50 % solution in toluene < 11 on the Gardner scale, — Residual aromatic monomer ≤ 50 ppm,
acetic acid, isobutyl ester	0000110-19-0		139			x			1		
acetic acid, isopropyl ester	0000108-21-4		140			x			0,05		
glycerides, castor-oil mono-, hydrogenated, acetates	0736150-63-3	55910	141				x			(29)	
stearic acid, esters with ethyleneglycol		89440	142				x			(1)	
acrylic acid, ethyl ester	0000140-88-5	11470	143	x						(20)	

Ethylbenzene	0000100-41-4	53255	144			x	x		0,6		
ethylene carbonate	0000096-49-1	16955	145	x					30		expressed as ethyleneglycol
ethyleneglycol	0000107-21-1	16990 53650	146	x		x	x			(1)	
ethyleneglycol butyl ether acetate	0000112-07-2		147			x				(35)	
acrylic acid, monoester with ethyleneglycol	0000818-61-1	11510 11830	148	x						(20)	
ethyleneglycol monobutyl ether	0000111-76-2	16993	149			x				(35)	Only for use on the non food-contact side.
methacrylic acid, monoester with ethyleneglycol	0000868-77-9	21190	150	x						(21)	
ethyleneglycol monopropyl ether	0002807-30-9		152			x			0,05		
ethylene oxide	0000075-21-8	17020	153	x					NN		1 mg/kg in final product
2-ethylhexanoic acid	0000149-57-5		154	x			x		0,05		
acrylic acid, acrylic acid, 2-ethylhexyl ester, copolymer	0025134-51-4	31500	155				x		0,05	(20)	SMG expressed as acrylic acid, 2-ethylhexyl ester
benzoic acid, p-(dimethylamino)-, 2-	0021245-02-3		156				x	x	0,05		

ethylhexyl ester											
methacrylic acid, ethyl ester	0000097-63-2	20890	157	x						(21)	
N-ethyl-toluenesulphonamide (NETSA)	0008047-99-2		158				x		5		
ethylvanillin	0000121-32-4	54420	159				x				
acids, fatty (C8-C22), esters with pentaerythritol	0085116-93-4	31348	161			x	x				
fatty acids, montan-wax, 1-methyl-1,3-propanediyl esters	0073138-44-0		162				x				
fatty acids, tallow, hydrogenated	0061790-38-3	54760	163				x				
formaldehyde	0000050-00-0	17260 54880	164	x			x			(13)	
tannic acids	0001401-55-4	92150	165				x				According to the JECFA specifications
glass	0065997-17-3		166				x				
gluconic acid lactone	0000090-80-2		167				x				
gluconic acid	0000526-		168				x				

	95-4										
glycerides, montan-wax	0068476-38-0		169				x				
glycerol monolaurate diacetate	0030899-62-8	56800	170				x			(29)	
glycerol monoricinolate	0001323-38-2	57440	171				x				
glycerol monostearate	0031566-31-1	18115 57520	172	x							
glycerol tris(12-hydroxystearate)	0000139-44-6	58160	173				x				
glycerol diacetate	0025395-31-7	56000	174				x				
glycerol dioleate	0025637-84-7	56080	175				x				
glycerol distearate	0001323-83-7	56320	176				x				
glycerol monolaurate	0027215-38-9	56780	177				x				
glycerol monomyristate	0027214-38-6	56840	178				x				
glycerol monooleate	0025496-72-4	56960	179				x				
glycerol tributyrate	0000060-	57840	180				x				

	01-5										
glycerol trilaurate	0000538-24-9	57960	181				x				
glycolic acid	0000079-14-1	18117	182	x			x		0,05		
glyoxal	0000107-22-2		183	x					0,05		
1-heptanol	0000111-70-6	18150	184	x							
silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-	0000999-97-3		185				x			(30)	
disiloxane, hexamethyl-	0000107-46-0		186	x						(30)	
hexamethylene diisocyanate	0000822-06-0	18640	187	x						(15)	1 mg/kg in final product expressed as isocyanate moiety
hexamethylenetetramine	0000100-97-0	18670 59280	188	x			x			(13)	
hexanol	0000111-27-3	18780	189			x					
hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-		60027	190				x				Average molecular weight not less than 440 Da. Viscosity at 100 °C not less than 3,8 cSt (3,8 × 10-6 m2/s).

tetradecene (Mw: 440–12 000)											
3-hydroxybutanoic acid-3-hydroxypentanoic acid, co-polymer	0080181-31-3	18888	191	x							The substance is used as product obtained by bacterial fermentation. In compliance with the specifications mentioned in the Table 4 of Annex I of Commission Regulation (EU) No 10/2011 of 14 January 2011.
2-(2′-hydroxy-3′-tert-butyl-5′-methylphenyl)-5-chlorobenzotriazole	0003896-11-5	60400	192				x			(10)	
2-(2′-hydroxy-3,5′-di-tert-butylphenyl)-5-chlorobenzotriazole	0003864-99-1	60480	193				x			(10)	
2-hydroxy-4-n-hexyloxybenzophenone	0003293-97-8	61280	194				x			(6)	
2-hydroxy-4-methoxybenzophenone	0000131-57-7	61360	195				x			(6)	
2-(2′-hydroxy-5′-methylphenyl)benzotriazole	0002440-22-4	61440	196				x			(10)	
2-hydroxy-4-n-octyloxybenzophenone	0001843-05-6	61600	197				x			(6)	
acrylic acid, 2-hydroxypropyl	0000999-	11530	198	x					0,05		expressed as the sum of acrylic

ester	61-1										acid, 2-hydroxypropyl ester and acrylic acid, 2-hydroxyisopropyl ester. It may contain up to 25 % (m/m) of acrylic acid, 2-hydroxyisopropyl ester (CAS No 0002918-23-2).
1-piperidinyloxy, 4-hydroxy-2,2,6,6-tetramethyl-	0002226-96-2		199				x		0,05		
aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt	0144538-83-0		200				x		5		
3-iodo-2-propynyl butyl carbamate	0055406-53-6		201				x		9		
propane, 2-methyl-	0000075-28-5		202	x					1		
acrylic acid, isobutyl ester	0000106-63-8	11590	203	x						(20)	
isobutanol	0000078-83-1		204	x		x			1		
methacrylic acid, isobutyl ester	0000097-86-9	21010	205	x						(21)	
1-isocyanato-3-isocyanatomethyl-3,5,5-	0004098-71-9	19110	206	x						(15)	1 mg/kg in final product ex-pressed as isocyanate moiety

trimethylcyclohexane											
1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane homo-polymer, methyl ethyl ketone oxime-blocked	0103170-26-9	19112	207	x					0,05		expressed as blocked trimer
isophthalic acid	0000121-91-5	19150	208	x						(25)	
isophthalic acid dichloride	0000099-63-8	19180	209	x						(25)	
2-methyl-1,3-butadiene	0000078-79-5	19243 21640	210	x					NN		1 mg/kg in final product
acrylic acid, isopropyl ester	0000689-12-3	11680	211	x						(20)	
2-isopropyl thioxanthone	0005495-84-1		212					x		(32)	
4-isopropyl thioxanthone	0083846-86-0		213					x		(32)	
potassium iodide	0007681-11-0	81680	214				x			(4)	
naphthenic acids, cobalt salts	0061789-51-3		215				x		0,05		
fatty acids, coco, diesters with polyethylene glycol	0068139-91-3		216				x				

fatty acids, coco, hydrogenated	0068938-15-8	17175	217	x							
copper iodide	0001335-23-5	45200	218				x			(4)	
N,N-bis(2-hydroxyethyl)dodecanamide	0000120-40-1	39150	219				x		5		The residual amount of diethanolamine in plastics, as an impurity and decomposition product of the substance, should not result in a migration of diethanolamine higher than 0,3 mg/kg food.
Food Blue 2	0003844-45-9		220		x						
Food Red 3	0003567-69-9		221		x						
Food Red 7	0002611-82-7		222		x						
Food Red 9	0000915-67-3		223		x				30		
lignosulphonic acid	0008062-15-5	63940	224				x		0,24		
lithium iodide	0010377-51-2	64320	225				x			(4)	
silicic acid, magnesium-sodium-fluoride salt	0037296-97-2	85950	226				x		0,15		SMG expressed as fluoride. Only to be used in layers not

											coming into direct contact with food.
maleic acid	0000110-16-7	19540 64800	227	x			x			(2)	
maleic anhydride	0000108-31-6	19960	228	x						(2)	
maleic anhydride-styrene, copolymer, sodium salt	0025736-61-2	64990	229				x				The fraction with molecular weight below 1 000 Da should not exceed 0,05 % (w/w)
maltodextrine	0009050-36-6		230				x				
[3-(methacryloxy)propyl]trimethoxysilane	0002530-85-0	21498	231	x			x		0,05		
methacrylic acid, ester with trimethylethanolammonium chloride	0005039-78-1		232	x					0,05		
methacrylic acid	0000079-41-4	20020	233	x						(21)	
methacrylic anhydride	0000760-93-0	21460	234	x						(21)	
1-(2-Methoxy-1-methylethoxy)-2-propanol	0020324-32-7		235			x			0,05		
2-propanol, 1-methoxy-	0000107-		236			x				(38)	Only for use on the non food-

	98-2										contact side.
2-propanol, 1-methoxy-, 2-acetate	0000108-65-6		237			x				(38)	Only for use on the non food-contact side.
3-methyl-1,5-pentanediol	0004457-71-0	22074	238	x					0,05		
2-methyl-2,4-pentanediol	0000107-41-5		239			x			0,05		
acrylic acid, methyl ester	0000096-33-3	11710	240	x						(20)	
acrylic acid, methyl ester, telomer with 1-dodecanethiol, C16-C18 alkyl esters	0174254-23-0	31542	241				x				0,5 % in final product
benzophenone, 4-methyl-	0000134-84-9		242					x	0,05		For the sum of 4-methylbenzophenon und benzo-phenon (CAS-No. 0000119-61-9) the transfer into food shall not exceed 0.05 mg/kg.
acrylamide, N,N'-methylenebis-	0000110-26-9		243	x					0,05		
2,2′-methylene bis(4-ethyl-6-tert-butylphenol)	0000088-24-4	66400	244				x			(11)	
2,2′-methylene bis(4-methyl-6-tert-butylphenol)	0000119-47-1	66480	245				x			(11)	

2,2′-methylenebis(4-methyl-6-cyclohexylphenol)	0004066-02-8	66560	246				x			(3)	
2,2′-methylenebis(4-methyl-6-(1-methylcyclohexyl)phenol)	0000077-62-3	66580	247				x			(3)	
2-methyl-4-isothiazolin-3-one	0002682-20-4	66755	248				x		0,5		
methacrylic acid, methyl ester	0000080-62-6	21130	249	x						(21)	
propanoic acid, 2-methyl-, 2-methylpropyl ester	0000097-85-8		250			x			0,05		
2-methyl-4-pentanone	0000108-10-1	66725	251			x			5		
2-methyl-1,3-propanediol	0002163-42-0	22190	252	x					5		
methylsilsesquioxane	0068554-70-1	66930	253				x				Residual monomer in methylsilsesquioxane: < 1 mg methyltrimethoxysilane/kg of methylsilsesquioxane
paraffin wax and hydrocarbon waxes, microcristalline	0063231-60-7		254				x				Average molecular weight not less than 500 Da. Viscosity not less than 1,1 × 10 – 5 m 2 s – 1 at 100 °C or: not less than 0,8 × 10 – 5 m 2 s – 1 at

											120 °C, if solid at 100 °C. Carbon number at 5 % distillation point: not more than 5 % of the molecules with Carbon number less than 25
mixture of (40% w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60% w/w) 2,4,4-trimethylhexane-1,6-diisocyanate		22332	255	x			x			(15)	1 mg/kg in final product expressed as isocyanate moiety
mixture of (50 % w/w) phthalic acid n-decyl n-octyl ester, (25 % w/w) phthalic acid di-n-decyl ester, (25 % w/w) phthalic acid di-n- octyl ester.		67180	256				x		5		
mixture of 4-(2-benzoxazolyl)-4′-(5-methyl-2-benzoxazolyl)stilbene, 4,4′-bis(2-benzoxazolyl) stilbene and 4,4′-bis(5-methyl-2-benzoxazolyl)stilbene		67155	258				x				Not more than 0,05 % (w/w) (quantity of substance used/quantity of the formulation). Mixture obtained from the manufacturing process in the typical ratio of (58-62 %):(23-27 %):(13-17 %).
acetylated mono- and diglycerides of fatty acids		30401	259				x			(29)	

benzene, chloro-	0000108-90-7	67280	260	x					10		
monochloroacetic acid	0000079-11-8	22333	261	x					0,05		
mono-n-dodecyltin tris(isooctyl mercaptoacetate)	0067649-65-4	67360	262				x			(23)	
monomethyltin tris(ethylhexyl mercaptoacetate)	0057583-34-3	67515	264				x			(7)	
monomethyltin tris(isooctyl mercaptoacetate)	0054849-38-6	67520	265				x			(7)	
mono-n-octyltin tris(alkyl(C10-C16) mercap-toacetate)		67600	266				x			(9)	
mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)	0027107-89-7	67680	267				x			(9)	
mono-n-octyltin tris(isooctyl mercaptoacetate)	0026401-86-5	67760	268				x			(9)	
starch, phosphate	0011120-02-8		269	x							
1,5-naphthalene diisocyanate	0003173-72-6	22420	271	x						(15)	1 mg/kg in final product ex-pressed as isocyanate moiety
sodium aluminate	0001302-42-7	86440	272				x		0,9		

sodium bisulphite	0007631-90-5	86480	273				x			(17)	
pyrosulfurous acid, disodium salt	0007681-57-4		274	x						(17)	
gluconic acid, monosodium salt, D-	0000527-07-1		275	x							
sodium iodide	0007681-82-5	86800	276				x			(4)	
stearic acid, ester with lactic acid bimol. ester, sodium salt	0025383-99-7		277				x				
sodium sulphite	0007757-83-7	86960	278				x			(17)	
sodium tetraborate	0001330-43-4	87040	279				x			(14)	
sodium thiosulphate	0007772-98-7	87120	280				x			(17)	
neodecanoic acid, salts		68110	281				x		0,05		expressed as neodecanoic acid
2,2′,2′-nitrilo(triethyl tris(3,3′,5,5′-tetra-tert-butyl-1,1′-bi-phenyl-2,2′-diyl)phosphite)	0080410-33-9	68145	282				x		5		expressed as sum of phosphite and phosphate
1-octadecanol	0000112-92-5	22555 68225	283	x							
octadecyl isocyanate	0000112-	22570	284	x						(15)	1 mg/kg in final product ex-

	96-9										pressed as isocyanate moiety
acrylic acid, n-octyl ester	0002499-59-4	11890	285			x				(20)	
gallic acid, octyl ester	0001034-01-1	55280	286				x			(18)	
oils, orange, sweet	0008008-57-9		287	x							
oils, lemon	0008008-56-8		288	x							
Acid Blue 3 (E 131)	0003536-49-0		289		x						
pentaerythritol dioleate	0025151-96-6	71635	290				x		0,05		
fluoropolyether dicarboxy derivative ammonium salt	0069991-62-4		291				x		0,05		
2,2′-(1,4-phenylene)bis[4H-3,1-benzoxazin-4-one]	0018600-59-4	72141	292				x		0,05		SMG including the sum of its hydrolysis products
methacrylic acid, phenyl ester	0002177-70-0	21280	293	x						(21)	
2-phenylphenol	0000090-43-7		294				x		12		
1,2,4-butanetricarboxylic acid, 2-phosphono-	0037971-36-1		295				x		5		
phosphoric anhydride	0001314-	23173	296	x							

	56-3										
fluoropolyethers ammonium phosphate salt	0200013-65-6		297				x		0,05		
phosphoric acid, octadecyl esters	0039471-52-8		298				x		0,05		
phthalic acid, benzyl butyl ester	0000085-68-7	74560	299				x		30	(29)	
phthalic acid, bis(2-ethylhexyl) ester	0000117-81-7	74640	300				x		1,5	(29)	Not to be used in direct contact with fatty foods.
phthalic acid, dibutyl ester	0000084-74-2	74880	301				x		0,3	(29)	
phthalic acid, diesters with primary, saturated C8-C10 branched alcohols, more than 60 % C9	0068515-48-0 0028553-12-0	75100	302				x			(24) (29)	
phthalic acid, diesters with primary, saturated C9-C11 alcohols more than 90 % C10	0068515-49-1 0026761-40-0	75105	303				x			(24) (29)	
Pigment Metal 1	0007429-90-5		304		x		x				
Pigment White 5	0001345-05-7	64400	305		x						
poly(ethylene propyl-	0061725-		306				x		0,05		

ene)glycol tridecyl ether	89-1										
polyacrylic acid	0009003-01-4		307				x			(20)	
polyacrylic acid, salts		76463	308				x			(20)	
polydimethylsiloxane, 3-aminopropyl terminated, polymer with 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	0661476-41-1	76725	309				x				The fraction with molecular weight below 1 000 Da should not exceed 1 % (w/w)
polydimethylsiloxane, 3-aminopropyl terminated, polymer with dicyclohexyl-methane-4,4′-diisocyanate	0167883-16-1	76723	310				x				The fraction with molecular weight below 1 000 Da should not exceed 1,5 % (w/w)
polyester of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol	0073018-26-5	76807	311				x			(28) (29)	
polyester of adipic acid with glycerol or pentaerythritol, esters with even numbered, unbranched C12-C22 fatty acids		76815	312				x			(29)	The fraction with molecular weight below 1 000 Da should not exceed 5 % (w/w)
polyester of 1,4-butanediol with caprolactone	0031831-53-5	76845	313				x			(26) (27)	The fraction with molecular weight below 1 000 Da should not

											exceed 0,5 % (w/w)
polyesters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropyleneglycol with adipic acid, which may be end-capped with acetic acid or fatty acids C12-C18 or n-octanol and/or n-decanol		76866	314				x			(28) (29)	
polyethylene glycol (EO = 1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate		77732	315				x		0,05		
polyethyleneglycol (EO = 1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate		77733	316				x		0,05		
polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C8-C22) alcohols		77708	317				x		1,8		In compliance with the purity criteria for ethylene oxide as laid down in Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners (OJ L 253, 20.9.2008, p. 1)
polyethyleneglycol (EO = 2-	0068439-	77895	318			x	x		0,05		The composition of this mixture is

6) monoalkyl (C16-C18) ether	49-6										as follows: — polyethyleneglycol (EO = 2-6)monoalkyl (C16-C18) ether (approximately 28 %), — fatty alcohols (C16-C18) (approximately 48 %), — ethyleneglycol monoalkyl (C16-C18) ether (approximately 24 %),
polyethyleneglycol dilaurate	0009005-02-1	77280	319				x				
polyethyleneglycol dimyristate		77320	320				x				
polyethyleneglycol dioleate	0009005-07-6	77360	321				x				
polyethyleneglycol esters of natural fatty acids		77660	322				x				
polyethyleneglycol monolaurate	0009004-81-3	78080	323				x				
polyethyleneglycol monomyristate		78120	324				x				
polyethyleneglycol monooleate	0009004-96-0	78160	325				x				
polyethyleneglycol	0009004-	78240	326				x				

monopalmitate	94-8										
polyethyleneglycol stearate		79520	327				x				
polyethyleneglycol tridecyl ether phosphate	0009046-01-9	79600	328				x		5		Polyethyleneglycol (EO ≤ 11) tridecyl ether phosphate (mono- and dialkyl ester) with a maximum 10 % content of polyethyleneglycol (EO ≤ 11) tridecylether.
polyethyleneimine, butylated		79760	329				x		6		
poly(3-nonyl-1,1-dioxo-1-thiopropane-1,3-diyl)-block-poly(x-oleyl-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x = 1 and/or 5, neutralised with dodecylbenzenesulfonic acid	1010121-89-7	80510	330				x				Only to be used as polymer production aid in polyethylene (PE), polypropylene (PP) and polystyrene (PS)
ethenol, homopolymer	0009002-89-5		331				x				
polyvinylpyrrolidone	0009003-39-8	81500	332				x				The substance shall meet the purity criteria as laid down in Commission Directive 2008/84/EC (OJ L 253, 20.9.2008, p. 1.)
1,3-bis(3-	0035674-	81870	333				x		0,05		

octadecylureido)propane	65-8										
acrylic acid, propyl ester	0000925-60-0	11980	334	x						(20)	
carbonic acid, cyclic propylene ester	0000108-32-7		335			x			0,05		
propylene oxide	0000075-56-9	24010	336	x					NN		1 mg/kg in final product
gallic acid, propyl ester	0000121-79-9	55360	337				x			(18)	
methacrylic acid, propyl ester	0002210-28-8	21340	338	x						(21)	
proteins, soy	0009010-10-0		339	x							
waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, high viscosity		95859	340				x				Average molecular weight not less than 500 Da. Viscosity at 100 °C not less than 11 cSt (11 × 10-6 m2/s). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).
reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-	0119345-01-6	83595	341				x		18		Composition: — 4,4′-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS

butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl											No 0038613-77-3) (36-46 % w/w (*)), — 4,3′-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0118421-00-4) (17-23 % w/w (*)), — 3,3′-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0118421-01-5) (1-5 % w/w (*)), — 4-biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 0091362-37-7) (11-19 % w/w (*)), — tris(2,4-di-tert-butylphenyl)phosphite (CAS No 0031570-04-4) (9-18 % w/w (*)), — 4,4′-biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonate-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 0112949-97-0) (< 5 % w/w (*))

											(*) Quantity of substance used/quantity of formulation Other specifications: — Phosphor content of min. 5,4 % to max. 5,9 %, — Acid value of max. 10 mg KOH per gram, — Melt range of 85– 110 °C,
reaction products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and tri-chloromethyltin	0068442-12-6	83599	342				x			(7)	
resorcinol diglycidyl ether	0000101-90-6	24073	343	x					NN		
castor oil, hydrogenated	0008001-78-3	14470 43120	344	x			x				
castor oil fatty acids, hydro-genated	0061790-39-4	14453	345	x							
carbon black	0001333-86-4	42080	346		x		x				Primary particles of 10 – 300 nm which are aggregated to a size of 100 – 1 200 nm which may form agglomerates within the size dis-tribution of 300 nm – mm. Toluene extractables: maximum

											0,1 %, determined according to ISO method 6209. UV absorption of cyclohexane extract at 386 nm: < 0,02 AU for a 1 cm cell or < 0,1 AU for a 5 cm cell, determined according to a generally recognised method of analysis. Benzo(a)pyrene content: max 0,25 mg/kg carbon black.
nitric acid	0007697-37-2	68140	347				x				
Acid Yellow 3 (Quinoline Yellow)	0008004-92-0 0095193-83-2		348		x				30		
Acid Yellow 23	0001934-21-0		349		x						
Acid Red 51	0012227-78-0 0016423-68-0		350		x				6		
Shellac	0009000-59-3	24440 85550	351	x							

silicon dioxide	0007631-86-9 ~~0112945-52-5~~	86240	352		x		x				For synthetic amorphous silicon dioxide: primary particles of 1 – 100 nm which are aggregated to a size of 0,1 – 1 µm which may form agglomerates within the size distribution of 0,3 µm to the mm size.
syrups, hydrolysed starch, hydrogenated	0068425-17-2	24903	353	x							In compliance with the purity criteria for maltitol syrup E 965(ii) as laid down in Commission Directive 2008/60/EC (5)
soybean oil, epoxidised	0008013-07-8	88640	354	x			x		60	(29)	Oxirane < 8 %, iodine number < 6.
starch, oxidised	0065996-62-5		355				x				
tallow	0061789-97-7	92100	356				x				
tall oil	0008002-26-4	24905	357	x			x				
terephthalic acid	0000100-21-0	24910	358	x					7,5		
terpinolene	0000586-62-9		359				x		0,05		
glycoluril, 1,3,4,6-	0005395-		360				x		0,05		

tetrakis(hydroxymethyl)-	50-6										
4-(1,1,3,3-tetramethylbutyl)phenol	0000140-66-9		361	x					NN		
2,4,7,9-tetramethyl-5-decyne-4,7-diol	0000126-86-3		362	x			x			(33)	
polyethyleneglycol- 2,4,7,9-tetramethyl-5-decyn-4,7-diol ether	0009014-85-1	79550	363				x			(34)	
thiodipropionic acid, ditetradecyl ester	0016545-54-3	93360	364				x			(12)	
titanium dioxide, coated with a copolymer of n-octyltrichlorosilane and [aminotris(methylenephosphonic acid), penta sodium salt]		93450	365				x				The content of the surface treatment copolymer of the coated titanium dioxide is less than 1 % w/w
toluene	0000108-88-3	93540	366			x			1,2		
benzene, 1,3-diisocyanatomethyl-	0026471-62-5	25208	367	x						(15)	1 mg/kg in final product expressed as isocyanate moiety
2,4-toluene diisocyanate	0000584-84-9	25210	368	x						(15)	1 mg/kg in final product expressed as isocyanate moiety
2,4-toluene diisocyanate dimer	0026747-90-0	25270	369	x						(15)	1 mg/kg in final product expressed as isocyanate moiety

2,6-toluene diisocyanate	0000091-08-7	25240	370	x						(15)	1 mg/kg in final product expressed as isocyanate moiety
tri-n-butyl acetyl citrate	0000077-90-7	93760	371				x			(29)	
triethanolamine	0000102-71-6	94000	372	x			x		0,05		SMG expressed as the sum of triethanolamine and the hydrochloride adduct expressed as triethanolamine
citric acid, triethyl ester	0000077-93-0	44640	373				x			(29)	
methacrylic acid, diester with triethylene glycol	0000109-16-0		374	x					0,05		
phosphoric acid, tris(2-ethylhexyl) ester	0000078-42-2		375				x		0,05		
phosphorous acid, triethyl ester	0000122-52-1	23175	376	x					NN		1 mg/kg in final product
phosphoric acid, triisobutyl ester	0000126-71-6		377				x		0,05		
trimellitic acid	0000528-44-9	13050 25540	378	x						(19)	
trimellitic anhydride	0000552-30-7	25550	379	x						(19)	
2,2,4-trimethylhexane-1,6-diisocyanate	0016938-22-0	25573	380	x						(15)	1 mg/kg in final product expressed as isocyanate moiety

2,4,4-trimethylhexane-1,6-diisocyanate	0015646-96-5	25574	381	x						(15)	1 mg/kg in final product expressed as isocyanate moiety
2,2,4-trimethyl-1,3-pentanediol diisobutyrate	0006846-50-0	95020	382			x	x		5		
tripropyleneglycol monomethyl ether	0025498-49-1		383			x			0,05		
2,4,6-tris(tert-butyl)phenyl-2-butyl-2-ethyl-1,3-propanediol phosphite	0161717-32-4	95270	384				x		2		expressed as sum of phosphite, phosphate and the hydrolysis product TTBP
vanillin	0000121-33-5	95680	385				x				
vinyl acetate-vinylpyrrolidone, copolymer	0025086-89-9		386				x				
vinyl chloride	0000075-01-4	26050	387	x					NN		1 mg/kg in final product
methyl vinyl ether	0000107-25-5		388	x					0,05		
vinylpyrrolidone	0000088-12-0	26230 95810	389	x					NN		
vinyltriethoxysilane	0000078-08-0	26305	390	x					0,05		
waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocar-		95858	391				x		0,05		Not to be used in direct contact with fatty foods. - Average molecular weight not

bon feedstocks, low viscosity											less than 350 Da. - Viscosity at 100 °C not less than 2,5 cSt (2,5 × 10-6 m2/s). - Content of hydrocarbons with Carbon number less than 25, not more than 40 % (w/w).
water	0007732-18-5	26360 95855	392			x	x				In compliance with Directive 98/83/EC (2)
hydrogen peroxide	0007722-84-1		393				x				
white mineral oils, paraffinic, derived from petroleum based hydrocarbon feed-stocks		95883	394				x				Average molecular weight not less than 480 Da. Viscosity at 100 °C not less than 8,5 cSt (8,5 × 10-6 m2/s). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).
xylene	0001330-20-7	26370 95945	395			x			1		
tin chloride	0007772-99-8		396				x		12		
silver chloride (20% w/w) coated onto titanium dioxide (80% w/w)		86430	397				x			(36)	

curcumin	0000458-37-7		398		x						
riboflavin	0000083-88-5		399		x						
riboflavin-5'-phosphate	0000130-40-5		400		x						
Orange Yellow S	0002783-94-0 0015790-07-5		401		x						
cochineal, carminic acid, carmine (Natural Red 4)	0001390-65-4		402		x						
Patent Blue V	0020262-76-4		403		x						
indigo carmine (indigotine, FD&C Blue 2)	0000860-22-0 0016521-38-3		404		x						
chlorophylls and chlorophyllins: (i) Chlorophylls (ii) Chlorophyllins	0001406-65-1		405		x						
copper complexes of chlorophylls and chlorophyllins (i) Copper complexes of chloro-	0012262-74-7		406		x						

phylls (ii) Copper complexes of chlorophyllins											
Green S	0003087-16-9		407		x						
plain caramel	0008028-89-5		408		x						
caustic sulphite caramel	0008028-89-5		409		x						
ammonia caramel	0008028-89-5		410		x						
sulphite ammonia caramel	0008028-89-5		411		x						
carotenes i) mixed carotenes ii) Beta-carotene	0000036-88-4		412		x						
annatto	0001393-63-1		413		x						
bixin	0006983-79-5		414		x						
norbixin	0000542-40-5		415		x						
paprika extract			416		x						
capsanthin	0000465-42-9		417		x						

capsorubin	0000470-38-2		418		x						
lycopene	0000502-65-8		419		x						
Beta-apo-8'-carotenal (C 30)	0001107-26-2		420		x						
ethyl ester of beta-apo-8'-carotenic acid (C 30)	0001109-11-1		421		x						
lutein	0000127-40-2		422		x						
canthaxanthin	0000514-78-3		423		x						
Beetroot Red	0007659-95-2		424		x						
anthocyanins	0011029-12-2		425		x						
silver	0007440-22-4		426		x					(36)	
gold	0007440-57-5		427		x						
Lithol Rubine BK	0005281-04-9		428		x						
tocopherols (natural)			430		x						
gamma-tocopherol	0007616-		431		x						

	22-0										
delta-tocopherol	0000119-13-1		432		x						
agar	0009002-18-0		434				x				
carrageenan	0009000-07-1		435				x				
processed eucheuma seaweed			436				x				
karaya gum	0009000-36-6		437				x				
konjac gum	0037220-17-0		438				x				
glycerol esters of wood rosins	0068475-37-6		439			x					
sucrose esters of fatty acids	0025339-99-5		440				x				
thermally oxidized soya bean oil interacted with mono- and diglycerides of fatty acids			441			x					
xylitol	0000087-99-0		442				x				
isoascorbic acid	0000089-65-6		443				x				
cyclohexane	0000110-		444			x			1		benzene content < 0.1% (mass)

	82-7										
maltitol	0000585-88-6		445				x				
acetic acid, propyl ester	0000109-60-4		446			x					
2,2-bis(4-hydroxyphenyl) propane, oligomeric reaction product with epichlorohydrin and acrylic acid	0055818-57-0		447	x					0,05		Only for use on the non food-contact side.
glycerol propoxylated, triacrylate	0052408-84-1		448	x					0,05		Only for use on the non food-contact side.
2,5,8,11-tetramethyl-6-dodecyne-5,8-diol	0068227-33-8		449				x			(33)	
2,4,7,9-tetramethyl-5-decyne-4,7-dioldi(polyoxyethylen-polyoxypropylene)ether	0182211-02-5		450				x			(34)	
1,1,1-trimethylolpropane, ethoxylated, triacrylate	0028961-43-5		451	x			x		0,05		Only for use on the non food-contact side.
(methylamino)diethane-2,1-diylbis(4-dimethylamino amino benzoate)	0925246-00-0		452					x	0,05		Only for use on the non food-contact side.
tris{4-[(4-acetylphenyl)sulfanyl]phenyl	0953084-13-4		453					x	0,05		SMG expressed as sum of Tris{4-[(4-

}sulfonium hexafluorophos-phate											acetylphenyl)sulfanyl]phenyl}sulfonium hexafluorophosphate (CAS-No.: 953084-13-4) und 1-(4-Phenylsulfanyl-phenyl)-ethanone (CAS-No.: 10169-55-8). A transfer of 1-(4-{4-[4-(4-acetyl-phenylsulfanyl)-phenylsulfanyl]-phenylsulfanyl}phenyl)-ethanon into food shall not be detectable. Only for use on the non food-contact side.
acetic acid esters of mono- and diglycerides of fatty acids			454			x					
lactic acid esters of mono- and diglycerides of fatty acids			455			x					
citric acid esters of mono- and diglycerides of fatty acids			456			x					
mono- and diacetyl tartaric acid esters of mono- and diglycerides of fatty acids			457			x					
mixed acetic and tartaric acid esters of mono- and diglycer-			458			x					

ides of fatty acids											
2-octanol	0000123-96-6		459			x			0,05		
1,10-decanediamine	0000646-25-3	15260	460	x					0,05		
Pigment Blue 60	0000081-77-6		462		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Blue 15	0000147-14-8		463		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Blue 15:3	0000147-14-8		464		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Blue 15:4	0000147-14-8		465		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Blue 15:6	0000147-14-8		466		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of

											nanoparticles to food occurs.
Pigment Blue 15:1	0000147-14-8 0012239-87-1		467		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Blue 15:2	0000147-14-8 0012239-87-1		468		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment White 18	0000471-34-1		469		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Natural Blue 1	0000482-89-3		470		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Blue 16	0000574-93-6		471		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Violet 19	0001047-16-1		472		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of

											nanoparticles to food occurs.
Pigment Red 49:2	0001103-39-5		473		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 101	0001309-37-1		474		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Green 7	0001328-53-6		476		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Green 37	0001330-37-6		477		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment White 24	0001332-73-6		478		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 4	0001657-16-5		479		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of

											nanoparticles to food occurs.
Pigment Red 3	0002425-85-6		480		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 1	0002512-29-0		481		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 170	0002786-76-7		482		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 4	0002814-77-9		483		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 202	0003089-17-6		484		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Orange 13	0003520-72-7		486		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of

											nanoparticles to food occurs.
Pigment Red 166	0003905-19-9		487		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Orange 43	0004424-06-0		488		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 17	0004531-49-1		489		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 149	0004948-15-6		490		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 13	0005102-83-0		491		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 146	0005280-68-2		492		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of

											nanoparticles to food occurs.
Pigment Red 144	0005280-78-4		493		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 95	0005280-80-8		494		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 14	0005468-75-7		496		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 83	0005567-15-7		497		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 93	0005580-57-4		498		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 110	0005590-18-1 0106276-		499		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of

	80-6										nanoparticles to food occurs.
Pigment Yellow 16	0005979-28-2		500		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 2	0006041-94-7		501		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Violet 23	0006358-30-1 0215247-95-3		502		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 12	0006410-32-8		503		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 3	0006486-23-3		504		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Orange 16	0006505-28-8		505		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of

											nanoparticles to food occurs.
Pigment Red 112	0006535-46-2		506		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 48:2	0007023-61-2		507		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Metal 2	0007440-50-8		508		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 53	0008007-18-9		509		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment White 25	0010101-41-4		510		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Violet 32	0012225-08-0		511		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of

											nanoparticles to food occurs.
Pigment Black 11	0012227-89-3		512		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Orange 36	0012236-62-3		513		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 62	0012286-66-7		514		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Blue 27	0014038-43-8 0012240-15-2		515		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 48:3	0015782-05-5		516		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 122	0016043-40-6 0000980-		517		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of

	26-7										nanoparticles to food occurs.
Pigment Violet 37	0017741-63-8		518		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 52:1	0017852-99-2		519		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 138	0030125-47-4		520		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 208	0031778-10-6		521		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Brown 23	0035869-64-8		522		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 139	0036888-99-0		523		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of

											nanoparticles to food occurs.
Pigment Red 214	0040618-31-3		524		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Orange 61	0040716-47-0		525		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 42	0051274-00-1		526		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 242	0052238-92-3		527		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Blue 29	0057455-37-5		528		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 220	0068259-05-2		529		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of

											nanoparticles to food occurs.
Pigment Yellow 155	0068516-73-4		530		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Orange 64	0072102-84-2		531		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 180	0077804-81-0		532		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 128	0079953-85-8		533		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Orange 71	0084632-50-8		534		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 264	0088949-33-1		535		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of

											nanoparticles to food occurs.
1,2,4-benzenetricarboxylic acid, mixed decyl and octyl triesters	0090218-76-1		606				x		0,05		Only for use on the non food-contact side.
diethyleneglycol butyl ether	0000112-34-5		607	x		x				(35)	Only for use on the non food-contact side.
diethyleneglycol monoethyl ether	0000111-90-0		608			x			5		Only for use on the non food-contact side.
trimethylolpropane, mixed triesters and diesters with n-octanoic and n-decanoic acids		94987	609			x			5		Only for use on the non food-contact side.
1-ethoxy-2-propanol	0001569-02-4		610			x				(37)	Only for use on the non food-contact side.
1-ethoxy-2-propylacetat	0054839-24-6		611			x				(37)	Only for use on the non food-contact side.
diethylene glycol butyl ether acetate	0000124-17-4		613			x				(35)	Only for use on the non food-contact side.
1,3-benzenedimethanamine	0001477-55-0	13000	614	x						(39)	
adipic acid, dibutyl ester	0000105-99-7	32240	615				x		0,05		
tris(2-ethylhexyl) acetylcitrate	0000144-15-0	95440	616				x		0,05		

citric acid, diethyl ester	0032074-56-9		617				x		0,05		
aluminium hydroxy chloride	0001327-41-9	34660	618				x		0,4		
1-propoxy-2-propanol	0001569-01-3		619			x			5		Content of 2-propoxy-1-propanol (CAS-No.: 10215-30-2) not more than 5%. Only for use on the non food-contact side.

Table 2 List of pigments permitted to be used additionally to table 1 for printing of food contact materials and articles described in Article 4 (7) clause 4

(related to Article 4 (9), Article 8 (5) clause 1)

1	2	3	4	5					6	7	8
Substance name	**CAS-No**	**REF-No**	**Substance-No**	**intended use**					**SML [mg/kg]**	**Group restriction No**	**Restrictions, specifications and purity requirements**
				I	**II**	**III**	**IV**	**V**			
Calcium-Aluminium-Borosilicate			538		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Calcium-Sodium-Borosilicate			539		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Iron oxide, (Fe3O4)	0001317-61-9		541		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs..
Iron hydroxide oxide (Fe(OH)O)	0020344-49-4		542		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.

Pigment Black 16	0007440-66-6		546		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Black 32	0083524-75-8		547		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Blue 27	0025869-00-5		548		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Blue 79	0014154-42-8		549		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Green 36	0014302-13-7		550		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs..
Pigment Orange 34	0015793-73-4		551		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.

Pigment Orange 38	0012236-64-5		552		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Orange 46	0067801-01-8		553		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Orange 72	0078245-94-0		554		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Orange 73	0084632-59-7		555		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 48:4	0005280-66-0		556		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 63:1	0006417-83-0		557		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.

Pigment Red 147	0068227-78-1		558		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 148	0094276-08-1		559		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 176	0012225-06-8		560		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 177	0004051-63-2		561		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 184	0099402-80-9		562		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs..
Pigment Red 185	0061951-98-2 0051920-12-8		563		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.

Pigment Red 200	0032041-58-0		564		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 200	0058067-05-3		565		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 210	0061932-63-6		566		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 238	0140114-63-2		567		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 254	0084632-65-5		568		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 254	0122390-98-1		569		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.

Pigment Red 266	0036968-27-1		570		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 268	0016403-84-2		571		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs..
Pigment Red 269	0067990-05-0		572		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 282	0938065-79-3		573		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 12	0006358-85-6		574		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 109	0005045-40-9		575		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.

Pigment Yellow 111	0015993-42-7		576		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 120	0029920-31-8		577		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 126	0090268-23-8		578		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs..
Pigment Yellow 127	0068610-86-6		579		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 138	0056731-19-2		580		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 151	0061036-28-0		582		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.

Pigment Yellow 174	0078952-72-4		583		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 175	0035636-63-6		584		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 181	0074441-05-7		585		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 185	0076199-85-4		586		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 188	0023792-68-9		587		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs..
Pigment Yellow 55	0006358-37-8		588		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.

Pigment Yellow 74	0006358-31-2		589		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 97	0012225-18-2		590		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Tin oxide	0018282-10-5		593		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Zirconium dioxide	0001314-23-4		594		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 81:1	0080083-40-5		598		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Red 81:2	0075627-12-2		599		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.

Pigment Red 169	0012237-63-7		600		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 150	0068511-62-6 0025157-64-6 0086249-83-4		601		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Yellow 154	0068134-22-5		602		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Violet 27	0012237-62-6		603		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Blue 1	0001325-87-7		604		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.
Pigment Blue 61	0001324-76-1		605		x				NN		May also be used as nanomaterial according to Article 2 clause 1 No 9, provided that no transfer of nanoparticles to food occurs.

Table 3: Group restrictions
(related to Article 8 (5) clause 1)

Table 3 contains the following information:

Column 1 (Goup restriction No): number of the group of substances for which a group restriction according to Table 1 column 7 has been established.

Column 2 (Substance No): Substance number according to Table 1 column 4

Column 3 (SML (T) [mg/kg]): specific migration limit for the sum of the namend substance(s) of the respective substance group in milligram substance per kilogram food. If "ND" is indicated, a detectable transfer of the substance onto foods shall not be permitted. A transfer of up to 0.01 milligrams per kilogram of food shall be deemed to be a non-detectable transfer.

Column 4 (Group restriction specification): indication of the substance whose molecular weight forms the basis for expression of the result.

1	2	3	4
Group restriction No	**Substance-No**	**SML (T) [mg/kg]**	**Group restriction specification**
1	89 142 146	30	expressed as ethyleneglycol
2	227 228	30	expressed as maleic acid
3	246 247	3	expressed as the sum of the substances
4	214 218 225 276	1	expressed as iodine
5	36 37	1,2	expressed as tertiary amine
6	92 93 94 194	6	expressed as the sum of the substances

	195 197		
7	107 108 264 265 342	0,18	expressed as tin
8	111 112 113 114 115 116 117 118 119 120 121 122 123 124	0,006	expressed as tin
9	266 267 268	1,2	expressed as tin
10	192 193 196	30	expressed as the sum of the substances
11	244 245	1,5	expressed as the sum of the substances
12	85 110 364	5	expressed as the sum of the substances
13	164 188	15	expressed as formaldehyde
14	19 45 46 279	6	expressed as boron Without prejudice to the provisions of Directive 98/83/EC
15	81	NN	expressed as isocyanate moiety

	101 125 126 187 206 255 271 284 367 368 369 370 380 381 460* 476*		
16	96 97	0,05	expressed as the sum of the substances
17	273 274 278 280	10	expressed as SO_2
18	132 286 337	30	expressed as the sum of the substances
19	378 379	5	expressed as trimellitic acid
20	3 25 58 59 60 143 148 155 203 211 240 285	6	expressed as acrylic acid

	307 308 334		
21	26 62 63 150 157 205 233 234 249 293 338 457* 482*	6	expressed as methacrylic acid
22	33 43	5	expressed as the sum of the substances
23	86 262	0,05	sum of mono-n-dodecyltin tris(isooctylmercaptoacetate), di-n-dodecyltin bis(isooctyl mercaptoacetate), mono-dodecyltin trichloride and di-dodecyltin di-chloride) expressed as the sum of mono- and di-dodecyltin chloride
24	302 303	9	expressed as the sum of the substances
25	208 209	5	expressed as isophthalic acid
26	66 313	0,05	expressed as terephthalic acid
27	51 313	5	expressed as 1,4-butanediol
28	6 311 314	30	expressed as the sum of the substances
29	6 34 35 73	60	expressed as the sum of the substances

	78 141 170 259 299 300 301 302 303 311 312 314 354 371 373 810* 815*		
30	185 186	0,05	expressed as hexamethyldisiloxane
32	212 213	0,05	expressed as the sum of the substances
33	362 449	0,05	expressed as the sum of the substances
34	363 450	5	expressed as the sum of the substances
35	147 149 607 613	5	expressed as the sum of the substances
36	397 426	0,05	expressed as silver
37	610 611	5	expressed as the sum of the substances content of 2-Ethoxy-1-propanol (CAS-No.: 19089-47-5) and 2-Ethoxy-1-propylacetat (CAS-No.: 57350-24-0) not more than 3%, expressed as the sum of the substances .
38	236 237	5	expressed as the sum of the substances content of 2-Methoxy-1-propanol (CAS-No.: 1589-47-5) und 2-Methoxy-1-

			propylacetat (CAS-No.: 70657-70-4) not more than 0.3%, expressed as the sum of the substances .
39	614 988*	0,05	expressed as 1,3-benzenedimethanamine

* Substance No as in Annex I Table 1 Column 1 of Regulation (EU) No 10/2011

Table 4: Additional limit for specific substances

(related to Article 8 (5) clause 2)

Substance	**Limit expressed in milligram per kilogram food**
Barium	1
Iron	48
Cobalt	0,05
Copper	5
Lithium	0,6
Manganese	0,6
Zinc	25
Primary aromatic amines, except those listed in table 1	A transfer onto food shall not be detectable. A transfer up to 0,01 milligrams of the sum of primary aromatic amines per kilogram food shall be deemed to be a non-detectable transfer. Additionally, for primary aromatic amines listed in Annex 1 No 7 a detection limit of 0,002 milligrams per kilogram food applies per single substance.

Article 2

This Regulation shall enter into force on the day after its announcement.

The *Bundesrat* - Germany's Upper House of Parliament - has given its consent.

Bonn, (date) … 2016

The Federal Minister
of Food and Agriculture

Statement of Reasons

A. General Provisions

Situation at the outset

Food contact materials and articles, for instance food packaging, are printed on for the purposes of information and advertising. The printing inks used contain chemical substances which, unless precautions are taken, can be transferred to food and thereby be absorbed by consumers.

According to information from EuPIA (the European Printing Inks Association) the quantity of substances used in printing inks amounts to almost 6 000. Only a small part of these substances (around 15 %) has been sufficiently assessed in toxicological terms, in such a way that content limits can be deduced for the transfer of substances onto foods, below which no health disadvantages are to be feared. For the remaining substances, there are either no toxicological data or no sufficient toxicological data available which would permit a health assessment and thus the deduction of safe limits for the transfer of substances onto foods.

Constituent parts of printing inks can get into foods through set-off processes, through migration or through the gas phase. In instances of set-off, the transfer of substances takes place through food contact materials and articles being handled on rolls or in piles, with the printed outside coming into contact with the inside; consequently parts of the printing inks are passed over onto foods. In the case of migration, printing ink chemicals stray from the printed food contact material and article and into the food. In the gas phase, constituent parts of high volatility and of medium volatility respectively, e.g. mineral oils, can get into foods by means of vaporisation and subsequent absorption. In some instances, items of packaging are also printed upon on the inside; this can also result in a contamination of foods.

In 2005, the public food control authorities proved the presence of the printing ink chemical ITX (isoprophylthioxanthon) in foods; ITX was hitherto unknown with regard to migration from printed food contact materials and articles, and was detected in fruit juices, milk products and yoghurt products and also in baby foods, among other products. Only limited toxicological data are available for ITX. The Federal Institute for Risk Assessment (BfR) was in fact able to rule out that the substance has any toxic effect on reproduction; however, the release level that the BfR was able to categorise as being acceptable in health terms was no higher

than 50 micrograms per kilogram of food. In some instances, the content levels detected in the foods were significantly above this value, at up to 600 micrograms per kilogram.

The relevant business sector has given an assurance that it has converted its printing ink systems after the first findings in 2005 and that it no longer uses ITX since then. However, in checks by public authorities in 2009, 2010 and 2011, the presence of ITX was again detected in foods, even in quantities significantly above 50 micrograms per kilogram of food.

At the end of 2008, the *Laender* authorities competent for food control ascertained the presence of 4-methylbenzophenone, another constituent part of printing inks previously unknown with regard to its migration properties from printed food contact materials and articles; it was detected initially in breakfast cereals (muesli, cornflakes, etc.), then later in other foods, including foods frequently eaten by children. The highest level, measured in tacos, amounted to 50 milligrams per kilogram.
Taking as its basis a structurally-related compound, namely benzophenone, the European Food Safety Authority (EFSA) established that there is reason to presume that 4-methylbenzophenone is damaging to the kidneys and is carcinogenic in higher concentrations. Therefore the EFSA's view is that, in the case of long-term consumption of contaminated foods, health risks cannot be ruled out. A limit for the sum of benzophenone and 4-methylbenzophenone was set at 0.6 milligrams per kilogram of food, as recommended by the European Commission Standing Committee on the Food Chain and Animal Health, and taking into account the EFSA assessment; in 2009, many products exceeded this limit, as further studies conducted by the control authorities showed.
Likewise, in 2010 and 2011, public food control authorities ascertained benzophenone content-levels above the recommended limit, in vermicelli, biscuits, savoury snacks, couscous, wheat starch, rice paper and cinnamon powder, among other products. The highest content-level ascertained was 50.2 milligrams per kilogram of food.

In addition, in 2009, 2010 and 2011, the *Laender* food control institutions and also a project conducted as a decision-making aid on this topic, financially assisted by the Federal Ministry of Food and Agriculture, provided proof that a range of other printing ink chemicals were present in foods, in some cases in considerable amounts. In this context, please note the following overview:

Constituent part of printing ink	**Food**	**Content level**
1-Chloro-4-propoxy-9H-thioxanthen-9-one	Sausage	Up to 35 µg/kg[1)]

1-Hydroxycyclohexyl phenyl ketone	Breakfast cereals, wok noodles, biscuits, milk-drink powder, cinnamon powder, rice paper, marshmallow confectionery, marzipan confectionery	Up to 4300 µg/kg
1,6-Hexandiol diacrylate	Chocolate bars	Up to 37 µg/kg[2)]
2,2-Dimethoxy-2-phenylacetophenone	Breakfast cereals, flour, wok noodles	Up to 1455 µg/kg
2,4-Diethyl-9H-thioxanthen-9-one	Snack products, fresh cheese	Up to 130 µg/kg
2-Hydroxy-1-{4-[4-(2-hydroxy-2-methyl-propionyl)-benzyl]-phenyl}-2-methyl-propane-1-one	Sausage	Up to 160 µg/kg
2-Hydroxy-2-methylpropiophenone	Rice wafer snack, rice wafers	Up to 6100 µg/kg
2-Hydroxy-4-(octyloxy)benzophenone	Asian dried meat	Up to 12 µg/kg
2-Methyl-4-(methylthio)-2-morpholinopropiophenone	Snack products, fresh cheese	Up to 1568 µg/kg
3-Methyl-1,5-pentan diy diacrylate	Chocolate bars	Up to 37 µg/kg[2)]
4,4'-Bis(diethylamino)-benzophenone	Baked goods with long product-life (e.g. biscuits)	Up to 14 µg/kg
4-Benzoylbiphenyl	Snack products, yoghurt products, chocolate bars	Up to 630 µg/kg
Cyclohexanone	Chocolate eggs	Up to 800 µg/kg

Di-(ethylhexyl) sebacate	Whey bars, snack products, biscuits, puffed rice	Up to 1340 µg/kg
Diphenyl-(2,4,6-trimethylbenzoyl)-phosphine oxide	Rice wafer snack	Up to 40 µg/kg
Ethyl(2,4,6-trimethylbenzoyl)-phenylphosphinate	Snack products	Up to 64 µg/kg
Ethyl-4-dimethylaminobenzoate	Fresh cheese, chocolate bars	Up to 116 µg/kg
Mesitylene-2-carbaldehyde	Chocolate bars	Up to 45 µg/kg
Methyl-2-benzoylbenzoate	Breakfast cereals, poppadoms, marshmallow confectionery	Up to 10795 µg/kg
Phosphoric acid diphenyl 2-ethylhexyl ester	Snacks, ready-made meals, drink-powders	Up to 7000 µg/kg
α-Benzyl-α-(dimethylamino)-4-morpholinobutyrophenone	Fresh cheese, dairy products, sausage, snack products	Up to 55 µg/kg

[1)] µg/kg = micrograms per kilogram

[2)] Sum of 1,6-hexandioldiacrylate and 3-methyl-1,5-pentanediyl diacrylate

It transpires that for these substances there are no toxicological data available or no data of this type sufficient for a risk assessment. The BfR has given notification that corresponding constituent parts of printing inks must not be transferred into foods, because a health risk cannot be ruled out.

Furthermore, in April 2010, in the context of a further project financially supported by the Federal Ministry of Food and Agriculture and intended to provide decision-making assistance, mineral-oil hydrocarbons were ascertained as being present in foods packaged using printed folding box boards. Within this, the content-levels of saturated hydrocarbons found to be present were frequently far above a value that, according to the BfR's information, can still be categorised as being acceptable in health terms (in individual instances up to one hundred times that value). Hydrocarbons of this kind can be stored in the body and can damage the liver and the lymph glands, as reported by the BfR. Furthermore, the foods additionally examined to check for aromatic hydrocarbons were found to have them in relevant quantities. In the BfR's view, one should avoid consuming such foods because it cannot be ruled out that they include substances that, even in the smallest quantities, can give rise to health damage, such as cancer.

A wide range of foods is affected by this, e.g. flour, semolina, rice, bread, noodles, cornflakes, muesli, oat flakes, dumplings, sugar, chocolate, cakes or baking mixes, thereby also including many staple foods and foods frequently eaten by children. The source of the mineral oil is the printing inks used in printing the folding box boards, in addition to recycled paper fibres used as a raw material in the manufacture of recycled cartons or cardboard boxes.

Finally, in 2011 the BfR ascertained instances of transfer of primary aromatic amines (PAA) onto various foods, when examining napkins. This also included compounds categorised as being carcinogenic and mutagenic. The primary aromatic amines originate from the printed matter on the napkins. In some instances, the content-levels in the foods were found to be significantly above the limits sets for amines. The BfR's view is that, because of the presence of substances with carcinogenic and mutagenic characteristics, it shall be ensured that there is no detectable transfer of PAA from food contact materials and articles onto foods.

The ascertained instances of food contamination by constituent parts of printing inks show that Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food (the GMP Regulation), issued by the European Commission as a reaction to the ITX case in 2005, did not produce the desired effect. At all levels of the value chain (the manufacture of starting substances constitutes an exception), the GMP Regulation requires companies to establish quality-assurance systems and to implement quality checks which ensure conformity with Article 3(1) of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food and repealing Directive 80/590/EEC and Directive 89/109/EEC. The Regulation also includes requirements with regard to documentation and stipulates specific technical rules for good manufacturing practice with regard to printing inks. By means of this Regulation, following the ITX case, the Commission sought to address the matter of transfer of substances from printing inks, without issuing substance-specific rules such as setting obligatory maximum limits. However, despite the GMP Regulation, the presence of constituent parts of printing inks continues to be ascertained in foods, at levels beyond limits that are acceptable in health-protection terms: as a result, damage to health cannot be ruled out. Substances also emerge in foods which cannot be assessed because toxicological data are either unavailable or those that are available are insufficient. The consequences of this for consumers' health are not currently foreseeable. Against this background, it is necessary to establish specific rules.

Content of the Ordinance

The present Ordinance stipulates a list of substances that shall be permitted to be used in printing inks involved in the manufacture of food contact materials and articles (a positive list); this is done to protect consumers from possible health risk connected with the commerce

of printed food contact materials and articles; the positive list includes permissible maximum limits for the transfer of substances onto foods. The substances included in the positive list shall solely be those for which a risk assessment is available or toxicological data sufficient and suitable for that purpose are available; this is so that their effects on health can be checked and, on that basis, safe limits can be deduced regarding the transfer of substances onto food.

In addition, the Ordinance stipulates that also substances are permitted to be used for which either no documents, or no documents sufficient for a health assessment, are available. However, this shall apply solely to those food contact materials and articles for which no direct contact between the food and the printing ink or its constituent parts is intended or foreseeable. It shall also be a prerequisite for the use of substances not assessed or not sufficiently assessed that these substances are not transferred from the printing inks onto the food, i.e. that their presence is not detectable in the foods.

So-called CMR substances, with the characteristics of being carcinogenic, mutagenic or toxic for reproduction, shall not be permitted to be used unless a safety assessment is available that renders it possible both to justify their use and to derive limits regarding transfer onto food, thus enabling the substance to be taken up into the positive list.

The Ordinance takes into account the ResAP Resolution (2005)2 of the Council of Europe, on printing inks for food packaging materials, subject to adaptation to the latest knowledge on science and technology.

As far as documentation of compliance with the provisions of this Ordinance and the general rules applicable to food contact materials and articels, especially Article 3 of Regulation (EC) No 1935/2004 relating to the safety of food contact materials and articles, is concerned, reference is made to Article 7 of Regulation (EC) No 2023/2006. According to this provision, amongst others, appropriate documentation is required relating to specifications, manufacturing formulae and processing which are relevant to compliance and safety of the finished material or article. For instance, this documentation could relate to the compliance with specific migration limtis or the use of non-evaluated substances.

Resource commitment to fulfil Ordinance; other costs

The Ordinance will not impose a cost burden on the Federal Government. It is estimated that the BfR will be able to conduct the safety assessment for new substances, regarding inclusion in the positive list, without additional commitment of personnel resources and in the context of the BfR's customary assessment work.

The *Laender* have reported the following implementation costs on the basis of the Ordinance, with Berlin, Brandenburg and Bremen not submitting information on the subject:

Bavaria:
One-off personnel costs and costs of materials: approx. €110 000
Annual personnel costs and costs of materials: approx. €66 000

Baden-Württemberg:
Annual personnel costs and costs of materials: approx. €170 000

Baden-Württemberg attributes these costs to the provision both of analytical procedures, lending themselves to implementation on a routine basis, and also of suitable personnel with regard to analysis, and also to the checking of substances used and documentation available in the companies.

North German Cooperation (Hamburg, Schleswig-Holstein, Mecklenburg-West Pomerania):
One-off personnel costs and costs of materials: approx. €565 000
Annual personnel costs and costs of materials: approx. €130 000 €

Additionally, costs up to or over a million Euro were indicated regarding the rules on nanotechnology, for the acquisition of new measuring equipment or respectively the establishment of new facilities, among other cost factors (1/3 of these one-off personnel costs and costs of materials were taken into account in the above estimate: see below). However, rulings with regard to nanotechnology are not being introduced for the first time by this Ordnance, but rather they are already to be found in other rulings in the context of food contact materials and articles. In this regard, reference is also made to the specific details stated below.

Hesse:
One-off personnel costs and costs of materials: approx. €1 010 000
Annual personnel costs and costs of materials: approx. €310 000 or respectively, in the event that analyses regarding nanomaterials are commissioned, approx. €280 000

Hesse cites the acquisition of new analytical equipment (LC-MS/MS, GC-MS/MS, HPLC with FLD and DAD, equipment for processing of samples) as the reason for the additional costs. Additionally, extra expenditure (equipment for analysis and for preparation of samples) is indicated as being caused by the rulings on nanotechnology (see below).

Lower Saxony:
One-off personnel costs and costs of materials: approx. €490 000
Annual personnel costs and costs of materials: approx. €52 000

Lower Saxony's stated grounds for the additional costs of materials are the acquisition of a high-resolution LC-MS and also of standard substances.

North-Rhine Westphalia:
One-off personnel costs and costs of materials: approx. €570 000
Annual personnel costs and costs of materials: approx. €236 000

North-Rhine Westphalia attributes these costs to the development of methods relating to the substances used, among other cost factors.

Rhineland Palatinate:
One-off personnel costs and costs of materials: approx. €200 000
Annual personnel costs and costs of materials: approx. €64 000

Saarland:
One-off personnel costs and costs of materials: approx. €1 000 000
Annual personnel costs and costs of materials: approx. €150 000

According to Saarland's information, the costs arise due to the acquisition of a new item of analytical equipment (LC-MS/MS), standard substances, and chemicals. Moreover, Saarland states that additional personnel are necessary for method development and method validation and also for the GMP checks.

Saxony:
One-off personnel costs and costs of materials: approx. €600 000
Annual personnel costs and costs of materials: approx. €62 000

Saxony-Anhalt:
One-off personnel costs and costs of materials: approx. €400 000
Annual personnel costs and costs of materials: approx. €230 000

Saxony-Anhalt's stated grounds for the additional costs are the acquisition of measurement equipment (HPLC, HPLC/GC/MS), the lasting commitment of time resources by one scientist and by two technical members of staff, and also the purchase of such relevant consumable items as are required. Saxony-Anhalt continues to assert that the checks on transfer of constit

uent parts of printing inks, not yet implemented, would already be necessary in principle according to existing rules, independently of the passing of the planned ruling into law, yet even the checks currently required are not being implemented due to lack of capacity. Moreover, the general requirements of Regulation (EC) No 1935/2004 demanded a check on all transfers of substances.

Thuringia:

One-off personnel costs and costs of materials:	approx. €500 000
Annual personnel costs and costs of materials:	approx. €40 000

Thuringia attributes the costs to the acquisition of analytical technology (LC-MS/MS) and to analysis-related materials costs, among other factors.

Total costs for the *Laender*:

One-off personnel costs and costs of materials:	approx. €5 445 000
Annual personnel costs and costs of materials:	approx. €1 510 000

Some *Laender* indicated costs arising specifically due to the introduction of rules governing nanomaterials. However, only 1/3 of these costs were entered into the calculation; the reason is that requirements already emerge with regard to nanomaterials, as well as corresponding personnel costs and costs of materials, because of the rules stated in the following: Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, and also Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food. Thus, the national rulings on printing inks cannot be designated as the sole cost factor both for the acquisition of corresponding equipment and also for the provision of suitable personnel.

The business community and, in particular, small to medium-sized businesses are faced with additional costs because of the Ordinance. The printing inks industry quantified these costs at approx. EUR 18 million for the 20 companies based in Germany: stated reasons are expenditure on testing, work needed to meet the preconditions for being listed, rearrangement of product formulations, and specification of the printing inks in accordance with the Ordinance. The information from the business community states the following factors (among others): costs of approx. EUR 100 000 per substance in order to meet the preconditions for being listed, EUR 100 000 Euro company for obtaining information relating to raw materials and for its assessment, and also very substantial costs for adjustments of product formulations (where applicable), because of substances not being listed. The need to convert a product formulation arises if a listing of the relevant substances is not applied for, or respectively if this application would be declined because of negative effects being ascertained for human

health, or there is a failure to comply with the relevant maximum values for the transfer of substances from printed food contact materials and articles.

According to the information from the printing inks industry, at this stage in the value chain the estimated costs of EUR 18 million are comprised as follows:

Costs per company:

1. Communication with suppliers and assessment of suppliers' information
- Enquiries per raw material and per supplier: 1400
- Time expended per enquiry: one hour
- Total commitment: 1 400 hours, corresponding to full-time use of one worker: **€100 000**

2. Ongoing costs
- Customer care/communicating the compliance related work:
  equivalent to the full-time use of one worker **€ 100 000**

3. Resource commitment involved in reformulation
- 1 400 basic substances per company; a basic substance substitution rate of 5% is assumed (70 basic substances)
  Costs per basic substance substitution: 10 000 €
  Total costs – basic substance substitution: **€ 700 000**

Total expenditure – printing inks industry:
- Number of companies: 20
- Costs per company: € 900 000
- Total costs for the printing inks industry: **€18 000 000**

Likewise, a very substantial and lasting additional resource commitment was indicated for the downstream business operators.
The following exemplary scenario was presented: one single, small to medium-sized food company, packaging its own products and with 20 different packaging types in its product portfolio, faces costs of EUR 5 000 Euro to EUR 20 000 per packaging type in order to implement the Ordinance: these arise due to necessary chemical analyses, the additional compliance work, and the new qualification process (this depends on the composition of the printing inks, the technical changes, or the upstream work undertaken by suppliers). The ongoing costs (compliance work specific to the printing ink, and also chemical analyses) would amount to EUR 1 000 per packaging type annually. In total, what results for such a company, at this pac-

ticular stage in the value chain, is implementation costs of EUR 100 000 to EUR 500 000 and ongoing costs of EUR 20 000 per year.
Taking into account approximately 20 000 different articles on offer for the end-consumer in the national market, the costs for the business community as a whole were estimated to be around EUR 660 million (one-time implementing costs). However, it was also stated that a sound estimation of the real costs is quite difficult to provide.
It is not possible at present to fully estimate the annual consequential costs incurred by the entire value-added chain that result from new developments and production switches. The economic operators concerned cannot provide relevant data either. The above-mentioned example has been randomly selected to illustrate possible scenarios. However, the types of packaging used vary in their number and type from business to business. Any need for structural adjustment in individual companies also needs to be considered on a case-by-case basis and the frequency and scope cannot be reliably predicted or estimated.
The printing inks industry presumes that the listing of new substances will cause around EUR 2 million in annual costs. It can be assumed that this also contains costs that generally arise in the use of new substances if only because of the general legislation governing food contact materials, notably in order to prove the safety of corresponding products. For the use of new substances in the production of food contact materials, thus also for printing, generally presupposes a check of the suitability and safety of the use in order to be able to comply with the general requirements laid down in Regulation (EC) No 1935/2004. With regard to the communication with suppliers and assessment (see no 1 above), the annual consequential costs per business are estimated at around 20% of the amount stated for a one-off switchover (EUR 20 000), with the running costs (no 2) remaining steady at EUR 100 000. With respect to the expenditure involved in reformulation (no 3), the printing inks industry assumes that the cost level will remain stable possibly in the first five years after the entry into force of the Regulation (EUR 700 000), because they expect a gradual conversion of the printing ink formulations used until the printing companies and users of printed food contact materials have sufficient knowledge of the possible applications of specific printing ink formulations in terms of their migration procedures. The additional current compliance costs incurred by the printing inks industry was thus estimated at a total of EUR 16 million annually in the first five years after the entry into force of the Regulation (including any business-as-usual costs). Costs are expected to decrease substantially afterwards, however.
It can generally be assumed that the total costs indicated by the industry contain a significant proportion of so-called business-as-usual costs that either cannot or not exclusively be attributed to the new regime. The existing general legislation for food contact materials already involves different obligations imposed on the manufacturers or distributors of these products. Thus, producers or any other distributors have to ensure the safety of the food contact materials, in particular. This also comprises suitable migration or other tests with a view to the transfer of substances from food contact materials to foodstuffs. This can also be done by the food

packers depending on the case concerned. In light of the rules laid down in this Regulation, notably due to the stipulation of defined specific migration limits derived from pertinent risk assessments, such tests, also on the basis of model calculations, should become much easier. Thus, the case-by-case evaluation which the industry would otherwise be required to conduct in order to determine to what extent specific levels of a substance that migrated to foods pose a danger to human health or not can be dispensed with in the future because one can now draw on uniform officially derived limits. However, at present, it cannot be quantify to what extent this will ease the cost burden on the industry on the basis of the available data.
It is not to be ruled out that this additional burden placed on business has an effect on the development of end-consumer prices. However, in relation to specific products the scope of any price increases cannot be quantified exactly. Nevertheless, effects on the general price level and, in particular, the consumer price level are not to be expected.

For members of the public, no commitment of resources is required for the Ordinance to be fulfilled.

It is envisaged that the effects of this Regulation are to be evaluated no later than five years after the rules enter into force. In particular, this should also include the actual cost effects.

The ‘one in, one out-rule’ does not apply to the estimated one-time implementing costs resulting from this Ordinance. However, the additonal current compliance costs expected by industry are covered by the aforementioned rule. Compensation of these costs cannot be realised within this Ordinance. Therefore, it will have to be evaluated whether or not possibilities for compensation can be identified in an other context than within this regulatory project.

Gender-specific effects

The Ordinance includes no rulings that exert an effect specific to women's or men's respective life situations. Health protection is taken into account for women and for men in equal measure. Thus effects on equal opportunity for women and men are not to be expected.

Sustainable development

The Ordinance serves the protection of consumers against possible health dangers in their dealings with printed food contact materials and articles; it thereby contributes to sustainable development.

B. Particular provisions

Relating to Article 1

Relating to Item 1

Item 1 includes the definitions necessary in order to apply this Ordinance.

Items deemed to be printing inks shall be the following: printing inks or printing varnishes which are applied to food contact materials and articles in a printing process or varnishing process and which come or can come into contact with the food, directly or indirectly. An indirect contact takes place, in particular, if printing inks, even without being used on the food-contact side of the food contact material and article, release or can release their constituent parts onto the food. In this context, reference is also made to the ruling in Article 4(7), from which it is likewise clear that these rules cover direct as well as indirect food contact.
"Printing inks" and "printing varnishes" are fixed terms established in the supply chain. In accordance with this, these terms shall include printing inks and printing varnishes used, in particular, for inscription, for colouring, for imaging, or for attaining gloss effects, and also those used for adhesion or protection of the inks or varnishes.
Varnishes other than printing varnishes shall be outside the scope of the Ordinance, for instance those intended to exercise a protective function in relation to the food contact materials and article onto which they are applied (e.g. varnish for the interior of tins, as corrosion protection). In addition, decorative inks for ceramic food contact materials and articles, applied in a combustion process, shall not form part of this Ordinance's scope of application.
The definition used for nanomaterials takes as its point of reference the Commission Recommendation (2011/696/EU) of 18 October 2011 on the definition of nanomaterials. In the event of any future amendment of the Recommendation, a check would be made on whether to adapt the definition used for this Regulation.

Relating to Item 2

Item 2 determines which monomers or other starting substances for polymers, colourants, solvents, photoinitiators or other additives in printing inks shall be permitted to be used in the manufacture of printed food contact materials and articles.
Here, as is otherwise customary, the term "to use" shall be understood as meaning "planned using". Consequently, the following shall not constitute substances that are used, as defined in Item 2: "non-intentionally added substances" (NIAS), i.e. impurities in the substances used;

intermediate products from the reaction, which have formed in the manufacturing process; degradation products; reaction products.
To the extent that this Ordinance does not include any specific ruling for NIAS, the rules in Article 3(1) of Regulation (EC) No 1935/2004 shall apply. Whether the relevant NIAS correspond to Article 3(1)(a) of Regulation (EC) No 1935/2004 shall be checked in accordance with internationally recognised scientific principles of risk assessment.

Article 4(5) and (6) respectively of the Consumer Goods Ordinance make provision for authorisation of substances for which a risk assessment is available, or for which toxicological data suitable and sufficient for this are available; this is done so that such substances' effects on health can be checked by the BfR and, on this basis, limits can be deduced for the transfer onto foods, as can other restrictions, specifications and purity requirements (a positive list). If no purity requirements are stipulated, the substances shall be of good technical quality with regard to the purity requirements. This is the case if Article 3(1) of Regulation (EC) No 1935/2004 does not constitute an obstacle to the use.
A basis for the positive list is the ResAP (2005) 2 Resolution of the Council of Europe on printing inks for food packaging. Adaptations were made to the current level of knowledge of scientific and technology; in this context, among other things, the Ordinance by Switzerland's *Eidgenössische Departement des Innern* (EDI) of 7 March 2008 amending the EDI Ordinance of 23 November 2005 on utility articles (SR 817.023.21) was taken into account. By means of this Ordinance, Switzerland has issued specific rulings with regard to food contact materials and articles manufactured involving the use of printing inks. These rulings have been in force since 1 April 2010.

An amendment or an addition to the positive list can be applied for to the Federal Ministry of Food and Agriculture (BMEL). Together with the application, documents shall be submitted in accordance with the guideline published by the BfR, regarding the safety assessment for substances in printing inks used in the manufacture of food contact materials and articles. The BMEL shall decide regarding the amendment of or addition to the positive list, taking into account the opinion issued by the BfR. Furthermore, upon request and according to Articles 54 and 68 respectively of the Food and Feed Act (LFGB), general decrees can be issued or respectively exceptions to the rules stated in this Ordinance can be authorised.

Article 4(7) and (8) of the Consumer Goods Ordinance make provision for permitting the use of substances other than those stated in the positive list. In this context, on the one hand, reference is made to substances authorised according to Regulation (EU) No 10/2011 without group restrictions or without restrictions and specifications (so-called dynamic reference) (cf. Paragraph 8). On the other hand, substances are permitted for which no toxicological documents or no such documents sufficient for a health assessment are available; it is a prerequi-

site that the substances in question do not have carcinogenic, mutagenic or toxic-for-reproduction characteristics as defined in Categories 1 and 2, Annex I, Regulation (EC) No 1272/2008 (so-called CMR substances) (cf. Paragraph 7). CMR substances shall be excluded from use because otherwise, without a safety assessment, as stated in Article 8(7) of the Consumer Goods Ordinance, they can be expected to be transferred onto food in quantities of up to 0.01 milligrams per kilogram. This could adversely affect consumers in ways associated with an unacceptable health risk. This rule adopts the approach hitherto taken in EU law with regard to the use of substances not assessed in health terms in the realm of food contact materials and articles (cf. Regulation (EC) No 450/2009 and Regulation (EU) No 10/2011).
The possibility, provided for by Article 4(7) and (8), for use either of substances other than those stated in the positive list or of those encompassed by the reference to Regulation (EU) No 10/2011, shall apply solely to the manufacture of food contact materials and articles with regard to which the printing inks or what is printed on the articles are not intended to come into contact with the food directly; thus, for example, it relates to an item of food packaging with print on the outside. However, Article 4(7) Clause 4 additionally states that this ruling shall not apply to printed food contact materials and articles not intended to have direct food contact but with regard to which direct contact of the printing inks with the foods is foreseeable under normal conditions of use (cf. Article 1(2)(c) of Regulation (EC) No 1935/2004). For example, this can be the case with napkins or traymats. These may indeed not necessarily be intended to have food placed upon them, thereby causing direct contact. Yet without doubt it is foreseeable that napkins, for example, are also used for such purposes. Reference is made to Article 1(2)(c) of Regulation (EC) No 1935/2004.
Article 4(9) takes into account the fact that not enough of the relevant data are yet available for the assessment of some substances already used for printing on food contact materials and articles, such as napkins or traymats. On principle, for direct food contact, substances used in printing inks shall solely be those that have been health-assessed and are stated in the positive list in Annex 14 Table 1, or are authorised via the reference to Regulation (EU) No 10/2011. Provided that no transfer is provably taking place, and based on a detection limit of 0.01 milligrams per kilogram of food, substances not assessed in health terms shall be permitted solely on the printed part of the food contact material and article that is not intended to come into contact with the food directly, or with regard to which no direct contact is foreseeable. Napkins, traymats, etc. are food contact materials and articles with regard to which a direct contact with the food is foreseeable but the duration of contact is frequently short. Therefore, as an exception, for these cases the transitional period shall be prolonged by two years, thus amounting to four years in total. During this transitional period, the pigments stated in Annex 14 Table 2 shall be permitted to continue to be used. A transfer of these pigments onto foods shall not be detectable, i.e. a detection limit of 0.01 mg of pigment per kilogram of food applies. Within this period, the business sector affected should make sufficient toxicology

related documents available for a health assessment, so that the substances are able to be taken up into the positive list (Annex 14 Table 1), preferably before the transition deadline.

Article 4(10) excludes from the ruling those printed food contact materials and articles with regard to which a transfer of substances from the printing ink onto the food is ruled out. Examples for such food contact materials and articles include glass bottles or metal cans on which the printed labels or similar material are printed on the side that is turned away from the food. Based on their nature and their mode of handling, it can be assumed with regard to such food contact materials and articles that no transfer can take place from the constituent parts of the printing inks onto the food.

Relating to Item 3

Item 3 determines which limits shall not be permitted to be exceeded with regard to the transfer of substances from printed food contact materials articles and printing inks onto foods.

Article 8(5) of the Consumer Goods Ordinance establishes limits for substances stated in Annex 14 of the Consumer Goods Ordinance. For these substances, risk assessments or toxicological data suitable and sufficient for such assessments are available; this in order that their effects on health can be checked by the BfR and that, on this basis, maximum tolerable intake levels can be deduced. A limited-duration ruling on an exception exists for food contact materials and articles referred to in Article 4(7) Clause 4, with regard to which it is foreseeable that the printing inks come into direct contact with foods, although they are not intended to do so, such as napkins and traymats (see in this regard Art. 4(9) and Annex 14 Table 2). For primary aromatic amines categorised as Category 1A and Category 2B carcinogens respectively according to Regulation (EC) No 1272/2008, the detection limit provided for by Annex 14 Table 4 with regard to transfer onto foods (namely 0.01 milligrams of the sum of primary aromatic amines per kilogram of the food), shall be deemed to be insufficient as defined in consumer-protection terms: this is based on a risk assessment with that conclusion, made by the BfR. For these substances, listed in Annex 1 Item 7 of the Consumer Goods Ordinance, a detection limit of 0.002 milligrams per kilogram of food shall additionally apply per individual substance.

Article 8(6) of the Consumer Goods Ordinance sets at 60 milligrams per kilogram respectively the limit for the transfer of substances from food contact materials and articles listed in Annex 14 Table 1, for which no specific migration limit, no group restriction or no other restrictions are established.

The rules in Article 8(5) and (6) of the Consumer Goods Ordinance shall apply respectively, subject to the rulings for printed plastic food contact materials and articles: for the latter, rules are already stated in Article 11(1) and (2) of Regulation (EU) No 10/2011.

Article 8(7) of the Consumer Goods Ordinance stipulates that it shall not be permitted for transfer of printing inks onto food to take place in detectable quantities from substances permitted to be used, but for which either no documents are available or no documents sufficient for a health assessment are available. For substances other than those in the form of nanomaterials, the detection limit shall be set at 0.01 milligrams per kilogram of food respectively. For analytical reasons, it is not currently possible to establish a uniform detection limit for substances in the form of nanomaterials. It shall be for the competent authority to decide in the particular cases what is deemed to be non-detectable.
Likewise, these stipulations follow an established approach used at EU level. Regulation (EC) No 450/2009 and Regulation (EU) No 10/2011 contain rules comparable to Article 8(7) of the Consumer Goods Ordinance.

Relating to Item 4

Item 4 establishes rules for sanctioning of breaches of the rules in Article 4(5) of the Consumer Goods Ordinance.

It is not necessary to sanction a breach of Article 4(7) of the Consumer Goods Ordinance: this is because the use of CMR substances in a way that violates Article 4(7) would constitute a breach of Article 4(5).

The sanctioning of any breach of Article 8(5), (6) and (7) respectively of the Consumer Goods Ordinance is effected via Article 31(2) Clause 2 of the Food and Feed Act (LFGB).

Relating to Item 5

Item 5 includes the necessary rules for the transition.

Article 16(15) of the Consumer Goods Ordinance stipulates that printed food contact materials and articles that have been placed on the market in accordance with the rules that were in force until the Ordinance entered into force, shall also be permitted to be placed on the market after the Ordinance enters into force, until the stocks have been sold ("free right of sell-off").

Article 16(16) of the Consumer Goods Ordinance includes the necessary rules for the transition, with regard to application of the new rulings of Articles 2, 4, 8 and 12. Provision is made for a transition period of twenty-four months.

Article 16(18) includes an extended transitional period for printed food contact materials and articles with regard to which a direct contact of the printing inks with the food is foreseeable even if this is not the intention; see also the reasoning on Item 2 (Article 4(9)). For printed food contact materials and articles that have been placed on the market in accordance with the rules that were in force until the expire date of this transitional period, a free right of sell-off is regulated in Article 16(17).

Relating to Item 6

Reference is made to the reasoning given for Items 1, 2, 3 and 4.

Relating to Article 2

Article 2 establishes the ruling for the entry of the Ordinance into force.