

Regulation of the State Secretary of Health, Welfare and Sport of 2025,-WJZ, amending the Commodities Act Regulation on packaging and consumer articles in relation to adding substances to Part A of the Annex and several technical amendments

The State Secretary of Health, Welfare and Sport,

Having regard to articles 3 (1) (a) and (4) (1) of the Commodities Act Regulation on packaging and consumer articles;

Decision:

ARTICLE I

Part A of the annexe to the Commodities Act Regulation on packaging and consumer articles is amended as follows:

A

In Chapter 0, Section 0.5.1(e) reads as follows:

e) The release of primary aromatic amines from materials or articles manufactured using aromatic isocyanates or dyes prepared by diazo-coupling must comply with the requirements set out in Section 2 of Annex II to Regulation (EU) No 10/2011.

B

In Chapter I, Table I-1 is amended as follows:

1. The substance 'di-isobutyl phthalate' with associated data is replaced by:

-	84-69-5	di-isobutyl phthalate	0.6	(9)
---	---------	-----------------------	-----	-----

2. A note is added at the bottom of the table, reading as follows:

(9) The SML applies to the sum of dibutyl phthalate (DBP), di-isobutyl phthalate

Regulation of the State Secretary of Health, Welfare and Sport of 2025,-WJZ, amending the Commodities Act Regulation on packaging and consumer articles in relation to adding substances to Part A of the Annex and several technical amendments

(DIBP), benzyl butyl phthalate (BBP) and di(2-ethylhexyl) phthalate (DEHP), expressed as DEHP equivalents using the following formula: $DBP*5 + DIBP*4 + BBP*0.1 + DEHP*1$.

C

Chapter II shall be amended as follows:

1. In Section 1.2.2(o), 'butyl benzyl phthalate, containing not more than 1 % dibenzyl phthalate;' is replaced by 'benzyl butyl phthalate, containing not more than 1 % dibenzyl phthalate;'.
2. In Section 1.3.3, the table is amended as follows:

a. The substance '2,2-bis(4-hydroxyphenyl) propane' with associated data is replaced by:

2,2-bis(4-hydroxyphenyl) propane:	0.05
-----------------------------------	------

b. After the substance '1,2-benzisothiazoline-3-one', the following substance and associated data are inserted:

benzyl butyl phthalate:	0.6 ²
-------------------------	------------------

c. The substance 'dibutyl phthalate' with associated data is replaced by:

dibutyl phthalate:	0.6 ²
--------------------	------------------

d. The substance 'di(2-ethylhexyl) phthalate' with associated data is replaced by:

di(2-ethylhexyl) phthalate:	0.6 ²
-----------------------------	------------------

Regulation of the State Secretary of Health, Welfare and Sport of 2025,-WJZ, amending the Commodities Act Regulation on packaging and consumer articles in relation to adding substances to Part A of the Annex and several technical amendments

- e. The substance 'di-isobutyl phthalate' with associated data is replaced by:

di-isobutyl phthalate:	0.6 ²
------------------------	------------------

- f. A note is added at the bottom of the table, reading as follows:
² The SML applies to the sum of dibutyl phthalate (DBP), di-isobutyl phthalate (DIBP), benzyl butyl phthalate (BBP) and di(2-ethylhexyl) phthalate (DEHP), expressed as DEHP equivalents using the following formula: $DBP*5 + DIBP*4 + BBP*0.1 + DEHP*1$.
3. The subsection 1.3.5 shall read:
1.3.5 The release of primary aromatic amines from materials or articles manufactured using aromatic isocyanates or dyes prepared by diazo-coupling must comply with the requirements set out in Section 2 of Annex II to Regulation (EU) No 10/2011.
4. In Section 2.3.2, the table is amended as follows:
a. 'aromatic amines: NA' is replaced by 'primary aromatic amines: NA¹'.
b. A note is added at the bottom of the table, reading as follows:
¹ Expressed as aniline. The limit of detection is 0.002 mg/kg of food or food simulant.
5. Paragraph 2.3.4 shall read as follows:
2.3.4. The release of primary aromatic amines from materials or articles manufactured using aromatic isocyanates or dyes prepared by diazo-coupling must comply with the requirements set out in Section 2 of Annex II to Regulation (EU) No 10/2011.

Regulation of the State Secretary of Health, Welfare and Sport of 2025,-WJZ, amending the Commodities Act Regulation on packaging and consumer articles in relation to adding substances to Part A of the Annex and several technical amendments

D

Chapter III shall be amended as follows:

1. In Section 4.2, the table is amended as follows:

a. The substance 'dibutyl phthalate' with associated data is replaced by:

	dibutyl phthalate		+	+		0.6 ⁹
--	-------------------	--	---	---	--	------------------

b. The substance 'di(2-ethylhexyl) phthalate' with associated data is replaced by:

	di(2-ethylhexyl) phthalate		+	+		0.6 ⁹
--	----------------------------	--	---	---	--	------------------

c. A note is added at the bottom of the table, reading as follows:

⁹ SML for the sum of dibutyl phthalate (DBP), di-isobutyl phthalate (DIBP), benzyl butyl phthalate (BBP) and di(2-ethylhexyl) phthalate (DEHP), expressed as DEHP equivalents using the following formula: $DBP*5 + DIBP*4 + BBP*0.1 + DEHP*1$

2. In Section 5.7, the table with footnotes is replaced by:

	SML (mg/kg)
	Product category referred to in section 3.3

Regulation of the State Secretary of Health, Welfare and Sport of 2025,-WJZ, amending the Commodities Act Regulation on packaging and consumer articles in relation to adding substances to Part A of the Annex and several technical amendments

substance/group of substances	I	II
aluminium	1	1
6-aminohexane lactam	1.5 ¹	15
Primary aromatic amines	NA ^{1,2}	NA ²
benzothiazole	0.05 ¹	0.5
dibenzyl amine	0.05 ¹	0.5
mercaptans	NA ^{1,3}	NA ³
zinc	5	5

¹ For practical purposes, it is assumed that five disposable teats per day are used for a child. The specific migration limit per teat is therefore one-fifth part of the value given in the table. Reusable teats and pacifiers are subject to the provisions in part B, chapter I, subsection 4.2.1 (5), and subsection 4.2.2 (1), for the examination of articles intended to come into repeated contact with foodstuffs.

² The content is expressed as aniline. The limit of detection is 0.002 mg/kg of food or food simulant.

³ The limit of detection is 0.05 mg/kg of food or food simulant.

3. Paragraph 5.9 shall read as follows:

5.9 The release of primary aromatic amines from materials or articles

Regulation of the State Secretary of Health, Welfare and Sport of 2025,-WJZ, amending the Commodities Act Regulation on packaging and consumer articles in relation to adding substances to Part A of the Annex and several technical amendments

manufactured using aromatic isocyanates or dyes prepared by diazo-coupling must comply with the requirements set out in Section 2 of Annex II to Regulation (EU) No 10/2011.

E

Chapter IV shall be amended as follows:

1. Section 2.2(g)(4^o) is amended as follows:

- a. 'butyl benzyl phthalate, containing not more than 1 % dibenzyl phthalate;' is replaced by 'benzyl butyl phthalate, containing not more than 1 % dibenzyl phthalate;';
- b. 'diisodecyl phthalate' is deleted;
- c. the following is inserted in alphabetical order:
phthalic acid, diesters with primary saturated C₉-C₁₁ alcohols containing more than 90 % C₁₀ (CAS Nos 0068515-49-1 and 0026761-40-0);

2. In Section 4.3, the table with footnotes is replaced by:

substance/group of substances	SML (mg/kg)
prim. aliphatic amines, total:	3
sec. aliphatic amines:	NA ¹
alkyl(C ₈ -C ₁₈) benzene sulphonates, total:	30

Regulation of the State Secretary of Health, Welfare and Sport of 2025,-WJZ, amending the Commodities Act Regulation on packaging and consumer articles in relation to adding substances to Part A of the Annex and several technical amendments

aluminium:	5
antimony:	0.04
Primary aromatic amines:	NA ²
arsenic:	0.002
barium:	1.2
1,2-benzisothiazoline-3-one:	30
benzyl butyl phthalate:	0.6 ³
beryllium:	0.01
bis(2-hydroxyethyl) ether and ethanediol, total:	30
2,2-bis(4-hydroxyphenyl) propane:	0.05
bismuth:	1
p-tert.butyl benzoic acid:	0.1
cadmium:	0.005
chromium:	0.25

Regulation of the State Secretary of Health, Welfare and Sport of 2025,-WJZ, amending the Commodities Act Regulation on packaging and consumer articles in relation to adding substances to Part A of the Annex and several technical amendments

cyanate groups or isocyanate groups:	NA ¹
dibutyl phthalate:	0.6 ³
dicyclohexyl phthalate:	30
diethylene glycol monoethyl ether and triethylene-	
di(2-ethylhexyl) phthalate:	0.6 ³
epichlorohydrin:	QM = 1 mg/kg EP
Epoxy-containing substances, other than epoxidised linseed and soybean oils, in total:	5 mg/kg in EP (as epoxy group, MG = 43)
phenolic compounds, total:	15 (as phenol)
o-phenyl phenol, sodium salt:	0.1
formaldehyde and hexamethylene tetramine, total:	15
phosphoric esters of epoxidised polybutadiene with terminal hydroxyl groups:	0.05
phthalic acid, diesters with primary saturated C ₉ -C ₁₁ alcohols containing more than 90 % C ₁₀	1.8

Regulation of the State Secretary of Health, Welfare and Sport of 2025,-WJZ, amending the Commodities Act Regulation on packaging and consumer articles in relation to adding substances to Part A of the Annex and several technical amendments

glycol monoethyl ether, total:	30
iron:	40
cobalt:	0.02
copper:	4
mercury:	0.003
lithium compounds, total:	0.048 (as lithium)
lead:	0.01 ⁴
manganese:	1.8
melamine:	2.5
molybdenum:	0.12
nickel:	0.14
peroxides:	NA ¹
2,4,7,9-tetramethyl-5-decyn-4,7-diol, ethylene oxide adduct:	0.05
thallium:	0.0001

Regulation of the State Secretary of Health, Welfare and Sport of 2025,-WJZ, amending the Commodities Act Regulation on packaging and consumer articles in relation to adding substances to Part A of the Annex and several technical amendments

tin:	100 (unless otherwise provided in Regulation (EU) 2023/915) ²⁰
toluene sulphonyl chloride:	NA ¹
vanadium:	0.01
silver:	0.08
zinc:	5
zirconium:	2 ⁵

¹ The term 'NA' means undetectable ['niet aantoonbaar'] and is equated for practical purposes with a value of no more than 0.05.

² The content is expressed as aniline. The limit of detection is 0.002 mg/kg of food or food simulant.

³ The SML applies to the sum of dibutyl phthalate (DBP), di-isobutyl phthalate (DIBP), benzyl butyl phthalate (BBP) and di(2-ethylhexyl) phthalate (DEHP), expressed as DEHP equivalents using the following formula: $DBP*5 + DIBP*4 + BBP*0.1 + DEHP*1$.

⁴ Not applicable to tinplate used as packaging of foodstuffs

⁵ For passivated metals that (may) come into contact with acidic food, compliance with the SML for zirconium must be demonstrated in the food itself, or alternatively in 1.5 % citric acid.

Regulation of the State Secretary of Health, Welfare and Sport of 2025,-WJZ, amending the Commodities Act Regulation on packaging and consumer articles in relation to adding substances to Part A of the Annex and several technical amendments

Chapter IX shall be amended as follows:

1. In Section 3.2, the table is amended as follows:

a. The substance "aromatic amines" with associated data is deleted.

b. The substance 'dibutyl phthalate' with associated data is replaced by:

dibutyl phthalate:	0.6 ²
--------------------	------------------

c. The substance 'di(2-ethylhexyl) phthalate' with associated data is replaced by:

di(2-ethylhexyl) phthalate:	0.6 ²
-----------------------------	------------------

d. After the substance 'melamine', the following substance and associated data are inserted:

Primary aromatic amines:	NA ³
--------------------------	-----------------

e. Two notes are added at the bottom of the table, reading as follows:

² The SML applies to the sum of dibutyl phthalate (DBP), di-isobutyl phthalate (DIBP), benzyl butyl phthalate (BBP) and di(2-ethylhexyl) phthalate (DEHP), expressed as DEHP equivalents using the following formula: $DBP*5 + DIBP*4 + BBP*0.1 + DEHP*1$.

³ The content is expressed as aniline. The limit of detection is 0.002 mg/kg of food or food simulant.

2. Paragraph 3.4 shall read as follows:

3.4. The release of primary aromatic amines from materials or articles manufactured using aromatic isocyanates or dyes prepared by diazo-

Regulation of the State Secretary of Health, Welfare and Sport of 2025,-WJZ, amending the Commodities Act Regulation on packaging and consumer articles in relation to adding substances to Part A of the Annex and several technical amendments

coupling must comply with the requirements set out in Section 2 of Annex II to Regulation (EU) No 10/2011.

G

Chapter X is amended as follows:

1. Section 3(a) is amended as follows:
 - a. After the substance '1,2-bis(triethoxysilyl)ethane', the following substance is inserted:
2-butyl-2-ethyl-1,3-propanediol;
 - b. 'N-(1,1-dimethyl-3-oxobutyl)acrylamide, CAS 2873-97-4, to be used only as a comonomer in acrylic copolymers, to induce keto side groups cross-linked with adipic acid dihydrazide, in coatings on plastics and not in direct contact with food;' is replaced by 'N-(1,1-dimethyl-3-oxobutyl)acrylamide, CAS 2873-97-4;'
2. In Section 3(k), 'butyl benzyl phthalate, containing not more than 1 % dibenzyl phthalate;' is replaced by 'benzyl butyl phthalate, containing not more than 1 % dibenzyl phthalate;'
3. In Section 9(a), 'according to Section 7(c) of this Chapter' is replaced by 'chromium nitride (CAS No 24094-93-7 or 12053-27-0), in chromium nitride-based coatings obtained by Physical Vapour Deposition (PVD); other substances: according to Section 7(c) of this Chapter.'
4. Section 12.3 is amended as follows:
 - a. After the substance 'tert-butylbenzoic acid', the following substances and associated data are inserted:

Regulation of the State Secretary of Health, Welfare and Sport of 2025,-WJZ, amending the Commodities Act Regulation on packaging and consumer articles in relation to adding substances to Part A of the Annex and several technical amendments

benzyl butyl phthalate:	0.6 ⁵
2-butyl-2-ethyl-1,3-propanediol:	5

- b. After the substance '5-chloro-2-methyl-4-isothiazolin-3-one', the following substance and associated data are inserted:

Chromium compounds	0.1 (as chromium)
--------------------	-------------------

- c. The substance 'dibutyl phthalate' with associated data is replaced by:

dibutyl phthalate:	0.6 ⁵
--------------------	------------------

- d. After the substance 'dibutyl phthalate', the following substance and associated data are inserted:

di(2-ethylhexyl) phthalate:	0.6 ⁵
-----------------------------	------------------

- e. The substance 'di-isobutyl phthalate' with associated data is replaced by:

di-isobutyl phthalate:	0.6 ⁵
------------------------	------------------

- f. A note is added at the bottom of the table, reading as follows:

⁵ The SML of 0.6 mg/kg applies to the sum of dibutyl phthalate (DBP), di-isobutyl phthalate (DIBP), benzyl butyl phthalate (BBP) and di(2-ethylhexyl) phthalate (DEHP), expressed as DEHP equivalents using the following formula: $DBP*5 + DIBP*4 + BBP*0.1 + DEHP*1$.

5. Paragraph 12.6 shall read as follows:

12.6. The release of primary aromatic amines from materials or articles

Regulation of the State Secretary of Health, Welfare and Sport of 2025,-WJZ, amending the Commodities Act Regulation on packaging and consumer articles in relation to adding substances to Part A of the Annex and several technical amendments

manufactured using aromatic isocyanates or dyes prepared by diazo-coupling must comply with the requirements set out in Section 2 of Annex II to Regulation (EU) No 10/2011.

H

In Chapter XII, Section 2, Table XII-1 is amended as follows:

1. The substance 'dibutyl phthalate' with associated data is replaced by:

157	74880	84-74-2	dibutyl phthalate	0.6	(1)(2)
-----	-------	---------	-------------------	-----	--------

2. The substance 'di(2-ethylhexyl) phthalate' with associated data is replaced by:

283	74640	117-81-7	di(2-ethylhexyl) phthalate	0.6	(1)(2)
-----	-------	----------	----------------------------	-----	--------

3. A note is added at the bottom of the table, reading as follows:
(2) The SML applies to the sum of dibutyl phthalate (DBP), di-isobutyl phthalate (DIBP), benzyl butyl phthalate (BBP) and di(2-ethylhexyl) phthalate (DEHP), expressed as DEHP equivalents using the following formula: $DBP*5 + DIBP*4 + BBP*0.1 + DEHP*1$.

ARTICLE II

Packaging and consumer articles complying with the Commodities Act regulation on packaging and consumer articles as it read on 30 June 2025 and placed on the market before 1 January 2026 may be marketed until stocks are exhausted.

Ministerie van Volksgezondheid,
Welzijn en Sport

Ministry for Public Health, Welfare
and Sport

Regulation of the State Secretary of Health, Welfare and
Sport of 2025,-WJZ,
amending the Commodities Act Regulation on packaging
and consumer articles in relation to adding substances to
Part A of the Annex and several technical amendments

ARTICLE III

This Regulation shall enter into force on 1 July 2025.

This regulation and the explanatory notes shall be published in the Official
Gazette.

The State Secretary for Health, Welfare and Sport,

Explanatory notes

I. General

1. Introduction

The purpose of this Regulation is to add new substances to Part A of the Annex to the Commodities Act Regulation on packaging and consumer articles that have been requested in recent months by interested parties and assessed by the Dutch Committee for Safety Assessment of Food Contact Materials (hereinafter: NCbvv). The NCbvv carries out the risk assessments for national authorisations under the Commodities Act Decree on packaging and consumer articles on behalf of the Minister of Health, Welfare and Sport.

Based on risk assessments carried out, the NCbvv advised that certain substances could be authorised and under what conditions this could happen. NCbvv assessments are made public by default. To this end, the relevant assessments on the website of the National Institute for Public Health and the Environment (www.rivm.nl) are published.

In addition, several technical amendments and corrections are made, and the Specific Migration Limit (hereinafter: SML) of a number of substances aligned with the SML applicable in Regulation (EU) No 10/2011¹. Several amendments were made to substances and footnotes in some tables. For the sake of readability, those tables have been replaced in their entirety.

2. Consultation

The draft of this Regulation was submitted to the participants in the Regular Consultation on the Commodities Act². This consultation resulted in an adaptation of the draft to align the SMLs of dibutyl phthalate (DBP), di-isobutyl phthalate (DIBP), benzyl butyl phthalate (BBP) and di(2-ethylhexyl) phthalate (DEHP) and the provisions for the absence of primary aromatic amines with the provisions laid down in Regulation (EU) No 10/2011.

3. Notification

The draft version of this regulation has been reported to the European Commission under article 5 (1) of Directive (EU) 2015/1535³. Notification to the European Commission is required, as article I of this regulation contains technical provisions as defined by Directive (EU) 2015/1535. In response to this notification **to be specified**

4. Consequences for regulatory burden and financial impact

This regulation does not impact the administrative burden on citizens and businesses. There is no information cost. There are limited compliance costs. In some cases, the Specific Migration Limit of substances is tightened for food safety

¹ Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ 2011, L 12).

² Representatives of industry and commerce, consumers, relevant ministries and the Dutch Food and Consumer Product Safety Authority (NVWA) participate in the ROW.

³ Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 concerning an information procedure on technical provisions and rules regarding the services of the information society (codification) (PbEU 2015, L 241).

reasons; in these cases, companies will have to check whether their products still comply with the legislation and, if necessary, adapt the products to the new requirements.

The business community has submitted applications for the authorisation of certain substances in packaging and consumer articles. This regulation provides for the addition of substances to various chapters of part A of the annexe to the Commodities Act Regulation on packaging and consumer articles. By adding these substances, the business community can make use of these substances. This will have a positive impact on business.

The costs for businesses are also moderate because there is a reasonable transitional period during which products which have already been placed on the market in the concerning form may still be placed on the market after their entry into force.

The Dutch Advisory Board on Regulatory Burden (ATR) did not select the dossier for a formal opinion, as it has no significant impact on regulatory burden.

5. Enforceability and feasibility

The draft of this Regulation was submitted to the Dutch Food and Consumer Product Safety Authority (hereinafter: NVWA) to assess the possible consequences for enforceability and feasibility. NVWA considers the proposed amendments to be enforceable, feasible and fraud-proof. In addition, the NVWA notes that Chapter I is missing the SML for dibutyl phthalate (DBP). It should, by analogy with the SML for di-isobutyl phthalate (DIBP), have a value of 0.6 for the weighted sum of DBP, DIBP, BBP and DEHP. The NVWA rightly points out that this SML also applies if only dibutyl phthalate is present, but the inclusion of the SML for dibutyl phthalate in Chapter I is superfluous, because in that case the SML for dibutyl phthalate in Regulation (EU) No 10/2011 applies. An adaptation of the text may therefore be omitted.

II. Explanatory Notes by Article

Article I

Substantive amendments based on dossier assessments by the NCbvv

Two substances are added to Chapter X (coatings) of Part A of the Annex to the Commodities Act Regulation on packaging and consumer articles (hereinafter: WVG). In addition, the conditions of use of one substance are amended. To this end, applicants who have applied for authorisation of these substances have submitted a dossier. The evaluation of the dossiers leads to the inclusion of these substances with corresponding restrictions, or to the adaptation of the listed restrictions.

In Chapter X (coatings), Section 3(a) (monomers) of Part A of the Annex to the WVG, the following adaptations are made on the basis of assessments by the NCbvv:

- One substance is added (2-butyl-2-ethyl-1,3-propanediol), to be used for polyester coatings on metal.
- The conditions of use of one substance (N-(1,1-dimethyl-3-oxobutyl)acrylamide) are extended.

In addition, Section 9 of the same chapter authorises a new substance (chromium nitride) used for coating metal utensils.

Corrections and clarifications

The WVG revealed different maximum migration values for the plasticisers dibutyl phthalate and di-isobutyl phthalate in different places. The European Plastics Regulation⁴, since the amendment of 11 July 2023⁵, applies a weighted sum SML of 0.6 mg/kg food for dibutyl phthalate (DBP), together with di-isobutyl phthalate (DIBP), benzyl butyl phthalate (BBP) and di(2-ethylhexyl) phthalate (DEHP). This limit has now been adopted in all places in the WVG where one of these substances is mentioned.

The substance '2,2-bis(4-hydroxyphenyl) propane' (better known as bisphenol A, BPA) has applications in plastics and coatings. In 2018, European legislation lowered the SML of BPA in plastics and coatings. This reduced SML should also apply to the materials regulated in the WVG. This Regulation ensures that the SML for this substance in the WVG is brought into line with that in European legislation. If the European legislation on the use and SML of BPA and similar substances is amended before the publication of this Regulation, this Amending Regulation shall be adapted so that the Commodities Act Regulation on packaging and consumer articles remains in line with European legislation.

Article II

A transitional period is provided for in Article II. The transitional period consists of two parts: a period of 6 months (until 1 December 2026) during which packaging and consumer articles complying with the WVG as it stood on 30 June 2025 may continue to be placed on the market, and an unrestricted period during which products already placed on the market may continue to be marketed. This transitional period is in line with the usual period in European Union legislation on food contact materials.

Article III

This article governs the entry into force of the regulation. The entry into force will be influenced by the fixed dates for changes.

The State Secretary for Health, Welfare and Sport,

⁴ Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ 2011, L 12).

⁵ Commission Regulation (EU) 2023/1442 of 11 July 2023 amending Annex I to Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, as regards changes to substance authorisations and addition of new substances (OJ 2023, L 177).