

**A.L. 57 ta' l-2005**

**ATT DWAR IS-SIGURTÀ FL-IKEL  
(KAP. 449)**

**Regolamenti ta' l-2005 li jemendaw ir-Regolamenti dwar  
Materjali li jiġu f'Kuntatt ma' Ogġetti ta' l-Ikel**

BIS-SAHHA tas-setgħat mogħtija bl-artikolu 10 ta' l-Att dwar is-Sigurtà fl-Ikel, il-Ministru tas-Saħħa, l-Anzjani u Kura fil-Komunità għamel ir-regolamenti li ġejjin:-

**1.** (1) It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2005 li jemendaw ir-Regolamenti dwar Materjali li jiġu f'Kuntatt ma' Ogġetti ta' l-Ikel, u għandhom jinqraw u jiftiehm bħala haġa wahda mar-Regolamenti ta' l-2003 dwar Materjali li jiġu f'Kuntatt ma' Ogġetti ta' l-Ikel, hawn iktar 'il quddiem imsejhin "ir-regolamenti prinċipali".

Titolu u skop.

A.L. 138 ta' l-2003.

(2) Dawn ir-regolamenti jimplementaw il-provvedimenti tad-Direttiva tal-Kummissjoni 2004/13/KE ta' 29 ta' Jannar, 2004.

**2.** Minflok l-Għaxar Skeda li tinsab mar-regolamenti prinċipali għandha tidhol din l-Iskeda li ġejja:-

Jemenda l-Għaxar Skeda li tinsab mar-regolamenti prinċipali.

“L-GHAXAR SKEDA

*Derivattivi epossidii f' materjali u oġġetti maħsubin biex jiġu f'kuntatt ma' oġġetti ta' l-ikel*

1. Din l-Iskeda hija dispożizzjoni speċifika fis-sens tat-tifsira tar-regolament 4.
2. Din l-Iskeda għandha tapplika għal materjali u oġġetti li, fl-istat tal-prodott lest, huma maħsubin biex jiġu f'kuntatt ma' oġġetti ta' l-ikel, jew li jingiebu f'kuntatt ma' oġġetti ta' l-ikel u huma maħsubin għal dak l-iskop, u li huma manifatturati b'wahda jew aktar mis-sustanzi li ġejjin jew li fihom wahda jew aktar mis-sustanzi li ġejjin:
  - (a) *2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether* (minn issa 'l quddiem 'BADGE'), u xi whud mid-derivattivi tiegħu;
  - (b) *bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ethers* (minn issa 'l quddiem 'BFDGE'), u xi whud mid-derivattivi tagħhom;
  - (c) eteri glicidil novolak ohra (minn issa 'l quddiem 'NOGE'), u xi whud mid-derivattivi tagħhom.

Għall-finijiet ta' din l-Iskeda, “materjali u oġġetti” huma:

- (a) materjali u oġġetti magħmulin minn kull tip ta' plastik;
  - (b) materjali u oġġetti koperti b'kisjiet fuq is-superfiċje;
  - (c) adeżivi.
3. Din l-Iskeda m'għandhiex tapplika għal kontenituri jew tankijiet ta' hżin li jesgħu aktar minn 10,000 litru jew għal kanen li jkun magħhom jew konnessi magħhom, koperti mill-kisjiet speċjali msejhin '*heavy-duty coatings*'.
  4. Il-materjali u oġġetti msemmija fil-paragrafu 2 m'għandhomx jitfgħu 'l barra s-sustanzi elenkati fil-Parti I ta' din l-Iskeda fi kwantitajiet li jaqbzu l-limitu preskritt f'dik il-Parti. L-użu u/jew il-preżenza ta' BADGE fil-manifattura ta' dawk il-materjali u oġġetti tista' tibqa' ssir biss sal-31 ta' Diembru 2005.
  5. Il-materjali u oġġetti msemmija fil-paragrafu 2 m'għandhomx jitfgħu 'l barra s-sustanzi elenkati fil-Parti II ta' din l-Iskeda fi kwantità li, meta tingħadd, it-total ta' BADGE u d-derivattivi tagħha elenkati fil-Parti I jaqbzu i-limitu preskritt fil-Parti II.
  6. Il-kwantità ta' komponenti NOGE b'aktar minn żewġ ċrieki aromatiċi u mill-inqas grupp epossidiku wiehed u wkoll id-derivattivi tagħhom li fihom il-funzjonijiet kloridrin u għandhom massa molekulari inqas minn 1 000 daltons m'għandhomx ikunu jstgħu jingħarfu fil-materjali u oġġetti msemmija fil-paragrafu 2 fil-limitu ta'

kif jingharfu ta' 0,2 mg/6 dm<sup>2</sup>, inkluża t-tolleranza analitika. Għall-finijiet ta' din l-Iskeda, il-limitu ta' kif jingharfu speċifikat f'dan il-paragrafu għandu jkun verifikat minn metodu ta' analiżi validat. Jekk dan il-metodu ma jeżistix, jista' jintuża metodu analitiku b'karatteristiċi li jahdmu kif addattat, sakemm ikun żviluppat metodu validat.

7. Il-paragrafi 4, 5 u 6 ma' għandhomx japplikaw għall-materjali u artikoli li hemm referenza għalihom f'punti (b) u (ċ) ta' paragrafu 1 li nġiebu f'kuntatt ma' oġġetti ta' l-ikel qabel l-1 ta' Marzu 2003. Dawk il-materjali u artikoli jistgħu jitpoġġew fuq is-suq sakemm id-data tal-mili tidher fuq il-materjali u artikoli. Madanakollu, id-data tal-mili tista' tinbidel b'indikazzjoni oħra, sakemm din l-indikazzjoni tippermetti l-identifikazzjoni tad-data tal-mili. Meta ssir talba, id-data tal-mili għandha tiġi mgħarrfa lill-awtorità kompetenti u lil kull persuna li tkun qegħda tenforza l-htigiet ta' dawn ir-regolamenti.

8. Paragrafu 7 għandu japplika mingħajr hsara għall-htigiet tar-Regolamenti ta' l-2004 dwar Ittikettjar, Prezentazzjoni u Reklamar ta' Oġġetti ta' l-Ikel (A.L. 483 ta' l-2004).

## PARTI I

### *Limitu ta' migrazzjoni speċifika għal BADGE u xi wħud mid-derivati tagħha*

1. It-total tal-livelli ta' migrazzjoni tas-sustanzi li ġejjin:

- (a) BADGE (= 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether);
- (b) BADGE.H<sub>2</sub>O;
- (c) BADGE.HCl;
- (d) BADGE.2HCl;
- (e) BADGE.H<sub>2</sub>O.HCl

m'għandux jaqbeż il-limiti li ġejjin:

- 1 mg/kg f'oġġetti ta' l-ikel jew f'simulanti ta' l-ikel (tolleranza analitika hija eskluża), jew
- 1 mg/6 dm<sup>2</sup> skond il-kazijiet imsemmija fil-paragrafu 13 tal-Hames Skeda.

2. L-ittestjar ta' migrazzjoni għandu jsir skond ir-regoli stabbiliti fis-Sitt Skeda u wkoll fil-Hames Skeda. Izda f'simulanti ta' l-ikel milwiema dan il-valur għandu jinkludi wkoll BADGE.2H<sub>2</sub>O sakemm il-materjal jew oġġett ma jgibx it-tikketta biex jintuża f'kuntatt biss ma' dak l-ikel u/jew xarbiel li fil-kaz tagħhom intwera li t-total ta' livelli ta' migrazzjoni tal-hames sustanzi elenkati fil-paragrafu 1(a), (b), (ċ), (d) u (e) ma jistax jaqbeż il-limiti preskritti fil-paragrafu 1.

3. Għall-finijiet ta' din l-Iskeda, il-migrazzjoni speċifika tas-sustanzi mniżżlin fil-paragrafu 1(a), (b), (ċ), (d) u (e) għandhom ikunu determinati b'metodu ta' analiżi validat. Jekk dan il-metodu ma jeżistix, jista' jintuża metodu analitiku b'karatteristiċi li jahdmu kif addattat, sakemm ikun żviluppat metodu validat.

## PARTI II

### *Limitu ta' migrazzjoni speċifika għal BFDGE u xi wħud mid-derivati tagħha*

1. It-total tal-livelli ta' migrazzjoni tas-sustanzi li ġejjin:

- (a) BFDGE (= *bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers*);
- (b) BFDGE.H<sub>2</sub>O;
- (c) BFDGE.HCl;
- (d) BFDGE.2HCl;
- (e) BFDGE.H<sub>2</sub>O.HCl

miżjud mat-total ta' dawk elenkati fil-Parti I, m'għandhiex taqbeż il-limiti li ġejjin:

- 1 mg/kg f'ogġetti ta' l-ikel jew f'simulanti ta' l-ikel (tolleranza analitika hija eskluża), jew
- 1 mg/6 dm<sup>2</sup> skond il-każijiet imsemmija fil-paragrafu 13 tal-Hames Skeda.

2. L-ittejtjar ta' migrazzjoni għandu jsir skond ir-regoli stabbiliti fis-Sitt Skeda u wkoll fil-Hames Skeda. Izda f'simulanti ta' l-ikel milwiema dan il-valur għandu jinkludi wkoll BFDGE.2H<sub>2</sub>O sakemm il-materjal jew ogġett ma jgħibx it-tikketta biex jintuża f'kontatt biss ma' dak l-ikel u/jew xarbiet li fil-każ tagħhom intwera li t-total ta' livelli ta' migrazzjoni tal-hames sustanzi elenkati fil-paragrafu 1(a), (b), (ċ), (d) u (e), miżjudin ma' dawk elenkati fil-Parti I, ma jistax jaqbeż il-limiti preskritti fil-paragrafu 1.

3. Għall-finijiet ta' din l-Iskeda, il-migrazzjoni speċifika tas-sustanzi mniżżlin fil-paragrafu 1(a), (b), (ċ), (d) u (e) għandhom ikunu determinati b'metodu ta' analiżi validat. Jekk dan il-metodu ma jeżistix, jista' jintuża metodu analitiku b'karatteristiċi li jahdmu kif adattat, sakemm ikun żviluppat metodu validat.”.

**L.N. 57 of 2005**

**FOOD SAFETY ACT  
(CAP. 449)**

**Materials in Contact with Foodstuffs (Amendment) Regulations,  
2005**

IN exercise of the powers conferred by article 10 of the Food Safety Act, the Minister of Health, the Elderly and Community Care has made the following regulations:

**1.** (1) The title of these regulations is the **Materials in Contact with Foodstuffs (Amendment) Regulations, 2005**, and they shall be read and construed as one with the **Materials in Contact with Foodstuffs Regulations, 2003**, hereinafter referred to as **the principal regulations**.  
Citation and scope.  
L.N. 138 of 2003.

(2) These regulations implement the provisions of Commission Directive 2004/13/EC of the 29th January, 2004.

**2.** For the Tenth Schedule to the principal regulations there shall be substituted the following:-  
Amends the Tenth Schedule to the principal regulations.

“TENTH SCHEDULE

*Epoxy derivatives in materials and articles intended to come into contact with foodstuffs*

1. This Schedule constitutes specific provisions within the meaning of regulation 4.

2. This Schedule shall apply to materials and articles which, in the finished product state, are intended to come into contact or are brought into contact with foodstuffs and are intended for that purpose and which are manufactured with or contain one or more of the following substances:

(a) 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (hereinafter ‘BADGE’), and some of its derivatives;

(b) bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers (hereinafter ‘BFDGE’), and some of their derivatives;

(c) other novolac glycidyl ethers (hereinafter ‘NOGE’), and some of their derivatives.

For the purposes of this Schedule, ‘materials and articles’ are:

(a) materials and articles made of any type of plastics;

(b) materials and articles covered by surface coatings;

(c) adhesives.

(3) This Schedule shall not apply to containers or storage tanks having a capacity greater than 10,000 litres or to pipelines belonging to or connected with them, covered by special coatings called ‘heavy-duty coatings’.

4. The materials and articles referred to in paragraph 2 shall not release the substances listed in Part I of this Schedule in a quantity exceeding the limit laid down in that Part. The use and/or presence of BADGE in the manufacture of those materials and articles may only be continued until 31 December 2005.

5. The materials and articles referred to in paragraph 2 shall not release the substances listed in Part II of this Schedule in a quantity which, when added, to the sum of BADGE and its derivatives listed in Part I, exceeds the limit laid down in Part II.

6. The quantity of NOGE components with more than two aromatic rings and at least one epoxy group as well as their derivatives containing chlorohydrin functions

and having a molecular mass less than 1 000 daltons shall not be detectable in the materials and articles referred to in paragraph 2 at the detection limit of 0.2 mg/6 dm<sup>2</sup>, including analytical tolerance. For the purpose of this Schedule, the detection limit specified in this paragraph should be verified by a validated method of analysis. If such a method does not exist, an analytical method with appropriate performance characteristics may be used, pending the development of a validated method.

7. Paragraphs 4,5 and 6 shall not apply to the materials and articles referred to in points (b) and (c) of paragraph 1 which were brought into contact with foodstuffs before 1 March 2003. Those materials and articles may be placed on the market provided that the date of filling appears on the materials and articles. However, the date of filling may be replaced by another indication, provided that this indication permits the identification of the date of filling. Upon request, the date of filling shall be made available to the competent authority and any person enforcing the requirements of these regulations.

8. Paragraph 7 shall apply without prejudice to the requirements of the Labelling, Presentation and Advertising of Foodstuffs Regulations, 2004 (L.N. 483 of 2004).

## PART I

### *Specific migration limit for BADGE and certain of its derivatives*

(1) The sum of the migration levels of the following substances:

- (a) BADGE (= 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether;
- (b) BADGE.H<sub>2</sub>O;
- (c) BADGE.HCl;
- (d) BADGE.2HCl;
- (e) BADGE.H<sub>2</sub>O.HCl

shall not exceed the following limits:

- 1 mg/kg in foodstuffs or in food simulants (analytical tolerance excluded),  
or
- 1 mg/6 dm<sup>2</sup> in accordance with the cases provided by paragraph 13 of the Fifth Schedule.

(2) The migration testing shall be carried out in accordance to the rules established in the Sixth Schedule as well as in the Fifth Schedule. However in aqueous food simulants, this value should also include BADGE.2H<sub>2</sub>O unless the material or article is labelled for use in contact only with those foods and/or beverages for which it has been demonstrated that the sum of the migration levels of the five substances

listed in paragraph 1(a), (b), (c), (d) and (e) cannot exceed the limits provided in paragraph 1.

(3) For the purpose of this Schedule, the specific migration of the substances listed in paragraph 1(a), (b), (c), (d) and (e) should be determined by a validated method of analysis. If such a method does not exist, an analytical method with appropriate performance characteristics may be used, pending the development of a validated method.

## PART II

### *Specific migration limit for BFDGE and certain of its derivatives*

- (1) The sum of the migration levels of the following substances:
- (a) BFDGE (= bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers);
  - (b) BFDGE.H<sub>2</sub>O;
  - (c) BFDGE.HCl;
  - (d) BFDGE.2HCl;
  - (e) BFDGE.H<sub>2</sub>O.HCl

added to the sum of those listed in Part I, shall not exceed the following limits:

- 1 mg/kg in foodstuffs or in food simulants (analytical tolerance excluded),  
or
- 1 mg/6 dm<sup>2</sup> in accordance with the cases provided by paragraph 13 of the Fifth Schedule.

(2) The migration testing shall be carried out in accordance to the rules established in the Sixth Schedule as well as in the Fifth Schedule. However in aqueous food simulants, this value should also include BFDGE.2H<sub>2</sub>O unless the material or article is labelled for use in contact only with those foods and/or beverages for which it has been demonstrated that the sum of the migration levels of the five substances listed in paragraph 1(a), (b), (c), (d) and (e), added to those listed in Part I, cannot exceed the limits provided in paragraph 1.

(3) For the purpose of this Schedule, the specific migration of the substances listed in paragraph 1(a), (b), (c), (d) and (e) should be determined by a validated method of analysis. If such a method does not exist, an analytical method with appropriate performance characteristics may be used, pending the development of a validated method.”.