Commission Regulation (EC) No 372/2007 of 2 April 2007 laying down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with foods (Text with EEA relevance)

COMMISSION REGULATION (EC) No 372/2007

of 2 April 2007

laying down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with foods

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC[(1)], and in particular Article 5(1) thereof,

After consulting the European Food Safety Authority (the Authority),

Whereas:

(1) In 1999 the Scientific Committee for food has assigned to epoxidised soybean oil (ESBO) a tolerable daily intake (TDI) of 1 mg/kg body weight per day. This TDI is translated into a specific migration limit (SML) of 60 mg/kg food for plastic materials and articles in Commission Directive 2002/72/EC[(2)].

[[X1](2) Commission Directive 2007/19/EC of 2 April 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food[(3)]clarifies that gaskets in lids fall under the scope of Directive 2002/72/EC. It stipulates that Member States have to adopt measures by 1 May 2008 that allow free circulation of gaskets in lids if they comply with SML. Non-compliant gaskets in lids will be prohibited as from 1 July 2008.**]**

(3) It appears necessary to regulate the placing on the market of those products pending the implementation of Directive 2007/19/EC.

(4) Indeed, recent data from Member States and Switzerland showed concentrations of ESBO in fatty food, such as sauces and vegetables or fish in oil, reaching up to 1 150 mg/kg. With such high values, the TDI may be exceeded for consumers.

(5) Recently business operators have shown an interest in using other plasticisers as substitutes for ESBO which either have a higher TDI or migrate to lesser extent. Therefore specific rules for these substitutes are also necessary.

(6) Moreover, the legal situation of these products is currently uncertain. Directive 2002/72/EC applies to materials and articles, and parts thereof, which consist exclusively of plastics or are composed of two or more layers consisting exclusively of plastics.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 372/2007. (See end of Document for details)*

Gaskets in metal lids could alternatively be regarded as a plastic part of a material or article and thus covered by Directive 2002/72/EC or as a plastic coating on a metal substrate, and thus not covered by Directive 2002/72/EC.

(7) As a consequence, Member States currently apply diverging rules that may pose a barrier to trade.

(8) It therefore appears proportionate to fix transitional SML for the sum of certain plasticisers used in gaskets in lids contacting fatty foods, so that the free circulation of those products is not endangered, the lids and foods that pose a significant risk are immediately excluded form the market and, at the same time, industry has sufficient time to finalise the development of gaskets that are compliant with the SML laid down in Directive 2002/72/EC as amended by Directive 2007/19/EC.

(9) The transitional SML should be set at a level ensuring that normally the TDI will not be exceeded, taking into account the average consumption of the foods concerned and the opinion issued by EFSA on 16 March 2006, which indicated that the level of plasticisers present in 90 % of the fatty food in glass jars is below 300 mg/kg food.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Editorial Information

X1 Substituted by Corrigendum to Commission Regulation (EC) No 372/2007 of 2 April 2007 laying down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with foods (Official Journal of the European Union L 92 of 3 April 2007).

[F1 Article 1

By way of derogation from point (b) of the third subparagraph of Article 3(1) of Directive 2007/19/EC, lids containing plastic layers or plastic coatings, forming gaskets in these lids, that together are composed of two or more layers of different types of materials, may be placed on the market in the Community if they comply with the restrictions and specifications indicated in the Annex to this Regulation.**]**

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 597/2008 of 24 June 2008 amending Regulation (EC) No 372/2007 laying down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with foods (Text with EEA relevance).

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall apply until **[**F1 30 April 2009**]**.

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 597/2008 of 24 June 2008 amending Regulation (EC) No 372/2007 laying down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with foods (Text with EEA relevance).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 372/2007. (See end of Document for details)*

ANNEX

RESTRICTIONS AND SPECIFICATIONS RELATED TO PLASTICISERS USED IN GASKETS IN LIDS

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
88640	008013-07-8	Soybean oil, epoxidised (ESBO)	For materials and articles intended for or brought into contact with foods for which simulant D testing is required by Directive 85/572/EEC SML(T)[ab] = 300 mg/kg of food or food simulants or 50 mg/dm^2 of the total food contact surface of lid and sealed container. For materials and articles intended for or brought into contact with infant formulae and follow-on formulae as defined by Commission Directive 91/321/EEC on infant formulae and follow-on formulae and products according to Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children SML = 30 mg/kg of food or food simulant. For materials and articles intended for or brought into contact with all other types of foods

a 'SML' means specific migration limit.

b SML(T) in this specific case means that the specific migration limit shall not be exceeded by the sum of the migration levels of the substances mentioned with reference numbers 88640, 30401, 76815, 93760, 56800 and 30340.

			SML(T)[b] = 60 mg/kg of food or food simulants or 10 mg/dm^2 of the total food contact surface of lid and sealed container.
30401	—	Acetylated mono- and diglycerides of fatty acids	For materials and articles intended for or brought into contact with foods for which simulant D testing is required by Directive 85/572/EEC SML(T)[b] = 300 mg/kg of food or food simulants or 50 mg/dm^2 of the total food contact surface of lid and sealed container. For materials and articles intended for or brought into contact with all other types of foods SML(T)[b] = 60 mg/kg of food or food simulants or 10 mg/dm^2 of the total food contact surface of lid and sealed container.
76815	—	Polyester of adipic acid with glycerol or pentaerythritol, esters with even numbered, unbranched C_{12}-C_{22} fatty acids	For materials and articles intended for or brought into contact with foods for which simulant D testing is required by Directive 85/572/EEC SML(T)[b] = 300 mg/kg of food or food simulants or 50 mg/dm^2 of the total food contact surface of lid and sealed container. For materials and articles intended

a 'SML' means specific migration limit.

b SML(T) in this specific case means that the specific migration limit shall not be exceeded by the sum of the migration levels of the substances mentioned with reference numbers 88640, 30401, 76815, 93760, 56800 and 30340.