# SCHEMATIC VIEW OF EU FOOD CONTACT MATERIALS LEGISLATION

**Regulation (EC) No. 1935/2004**

Lays down the main principle that food contact materials and articles must be manufactured using good manufacturing practice so as not to allow their constituents to migrate into food in quantities that could harm human health or affect the nature or quality of the

General requirements for all food contact materials:

**Regulation (EC) No. 2023/2006 on good manufacturing practice**

**Specific Measures for Particular Food Contact Materials**

**Food Contact Plastics 2002/72/EC (as amended by 2004/1/EC; 2004/19/EC; 2005/79/EC, 2007/19/EC, 2008/39/EC and Regulation (EC) No. --)**

Overall migration limit for all substances.
Mandatory EU positive list of monomers[31] with some restrictions on use
Specific migration limits for monomers & additives ingredient.
Community and provisional EU lists of additives. assessment

**Directives 82/711/EEC & 85/572/EEC**

Basic rules for migration testing and simulant use

**Regenerated Cellulose Film Directive 2007/42/EC**

Mandatory EU positive list of authorised components with restrictions expressed as maximum quantity in the finished. material

**Ceramics 84/500/EEC (as amended by 2005/31/EC)**

Migration limits for cadmium and lead.
Basic rules for the enforcement of limits.
Method of analysis for determining the migration of cadmium and lead.

**Recycled plastic Regulation (EC) No. 282/2008 and amending Regulation (EC) No. 2023/2006**

Lays down the quality standard for the recycled material. Specifies the process for process authorisation.

**Active and Intelligent Materials regulation (EC) No. 450/2009**

Designates the migrant as an

Requires

and approval of material

**Measures on Individual Substances**

**Directive 78/142/EEC on vinyl chloride monomer (VCM) and 2 application Directives on Methods for VCM determination.**

**Directive 93/11/EEC on Nitrosamines from elastomers or rubber teats and soothers**

**Regulation (EC) No.1895/2005 on certain Epoxy Derivatives (BADGE, BFDGE & NOGE)**

**Materials not yet covered by specific directives**

Varnishes & coatings; paper & board; metals & alloys; textile products; elastomers & rubber; glass; wood (inc cork); paraffin waxes & microcrystaline waxes.

[31] Substances used to synthesise polymers for the manufacture of plastics

Rev July 09.

ENFCM1

# Stainless Steels and Metal Migration into Foodstuffs

## A statement by CATRA 2009

Within UK and European legislation there are 2 pieces of relative legislation which are key to this subject.

European Regulation (EC) No 1935/2004 concerning articles intended to come into contact with food and UK Statutory Instrument 2007/2790 which makes the 1935/ 2004 a legal requirement in the UK and makes it an offence not to comply. (Note 1935/2004 repeals both earlier directive 89/109/EEC)

The general requirements of 1935/2004 is that articles that come into contact with food shall be manufactured by good manufacturing practice and that under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could

- Endanger human health
- Bring about unacceptable change in the composition of the food
- bring about a deterioration in the organoleptic characteristics i.e. affect the taste

In respect of stainless steels this legislation makes no further references or provides any levels of compliance.

The analysis of the Food Standards Agency in the UK made in an explanatory note 2009 states there are currently no specific directives regarding metals and alloys.

However in 2002 the Council of Europe issued a policy statement technical document concerning metals and alloys which does gives guidelines in respect of stainless steels and to the best of CATRA's knowledge no further such document has been produced.

This guideline implies that standard grades of stainless steel (of which there are over 100) are not likely to cause any problems in respect of the above requirements. Indeed it specifically quotes the grades of stainless steel listed in the EN ISO 8442 series of standards.

It also states that "studies on the migration of chromium and nickel using cooking utensils made of ferritic and austenitic stainless steels have shown that the migration of nickel and chromium into an average daily diet is negligible compared with the natural contents of these elements in foodstuffs". CATRA comments that cooking with stainless steels is likely to have higher levels of migration than low contact time items such as cutlery, flatware, knives etc.

The guideline makes the following safety aspect statements:-

"There has been no formal evaluation of stainless steel products used in food contact applications in relation to their potential to give rise to concern for health"

"Numerous studies of corrosion in various media and of uptake of metals by foods cooked on stainless steel pans give rise to no concern for health due to excessive intakes of nickel for chromium from stainless steels"

The guideline gives no indication therefore as to any levels of metal migration that may or may not be acceptable, presumably on the grounds that it doesn't see a problem.

**Lead and Cadmium**

Lead should not be used in food contact materials. It is unlikely to be found in stainless steels other than free cutting grades where it is added to improve machining properties. Lead is commonly used in solder alloys and so may cause a risk if it is used for items such as hip flasks.

Cadmium plating is forbidden (EEC directive 91/338/EEC) and its use in stainless steels is unacceptable and is unlikely to be present, although as most stainless steels are manufactured from recycled steel there is a small risk of its presence. It may also be present in small quantities (up to 0.5%) in solder used to join stainless steel items.

**Testing**

There are a number of tests that can detect the levels of metal migration from stainless steels and other than for BS EN14372:2004 Cutlery and feeding utensils intended for use by children's under 36 months of age, there are no specific maximum levels of metal migration actually laid down in standard or legislation. However we at CATRA may pass an opinion on a particular items migration level taking into account its duty, design and type of use and whether such level is within the norm.

**Supplies of stainless steels and products made from stainless steel**

It is CATRA's experience that stainless steel comes from many well established manufacturers in Europe, USA, Japan, but also much are now comes from less experienced Chinese steel makers. The products made from stainless steels are coming from Chinese manufacturers in very significant quantities. It is our evaluation that many grades of stainless steel analysed by us do not conform to the recognised standards such as the EN ISO 8442 series. This means that a wide range of chemical analysis could be found in many different stainless steel products.

**So what does this mean?**

It is CATRA's opinion that stainless steels conforming to recognised grades within the EN ISO 8442 series of standards are not likely to cause problems in respect of health, taste or composition of food.

However it is the manufacturer/ distributor/ retailer's ultimate decision to decide as matter of due diligence within their company that when making a risk assessment to decide whether stainless steel items should be tested for metal migration, or simple metal analysis and type identification, or not tested at all. CATRA can advise, but ultimately it is not CATRA's decision whether to test and if so at what level.

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Issue Date: 11 DEC 2008

Subject: Regulatory Declaration and/or Product Stewardship Information Statement(s) - Request

Dear Sir/Madam:

In response to your request, please find enclosed the regulatory declaration and/or product stewardship information statement(s) for the following ExxonMobil Chemical product(s):

EXXONMOBIL PP7064L1

These statements are provided by or on behalf of the above referenced ExxonMobil selling affiliate.

If you have any questions or need additional information please contact your ExxonMobil sales representative.

Enclosure(s):

EXXONMOBIL PP7064L1 - EUROPEAN FOOD LAW
Reference Number: 0011933

**STATEMENT**

Issue Date: 11 DEC 2008
At request of: PLASTRIBUTION LTD .
Product Name(s): EXXONMOBIL PP7064L1
Material Code(s): 5074181

With regard to the compliance status of the ExxonMobil Chemical product referenced above with the regulation(s) identified below the following can be declared:

EC LEGISLATION

* The composition of the base polymeric component(s) in the above polymer grade complies with the positive lists for allowed monomers in Annex II of EC Directive 2002/72/EC - as amended up to EC Directive 2008/39/EC (relating to plastics materials and articles intended to come in contact with foodstuffs).

* The additives that may be present in the above polymer grade comply with the incomplete list of additives in Annex III of EC Directive 2002/72/EC- as amended up to EC Directive 2008/39/EC (relating to plastics materials and articles intended to come in contact with foodstuffs).

* The above polymer grade complies with the relevant requirements of Regulation (EC) No 1935/2004 in as far as:
- the grade is produced using Good Manufacturing Practice as required in article 3.1 of Regulation (EC) No 1935/2004 and meets the guidelines for Good Manufacturing Practice as specified in Regulation (EC) No 2023/2006 (on good manufacturing practice for materials and articles intended to come in contact with food).
- the production of the above grade ensures traceability as required in article 17.1 of Regulation (EC) No 1935/2004

EC MEMBER STATES LEGISLATIONS

- The composition of the base polymeric components in this polymer grade complies with the positive lists of allowed monomers in the legislations referenced below.

- The additives and/or polymerisation production aids (if applicable in the specific legislation) are permitted because they already figure on the EC "incomplete lists of allowed additives" and /or they already have been approved for food contact use in the specific countries.

AUSTRIA:
- Kunststoffverordnung from 14/10/2003 - BGBl Nr 476/2003 - as amended up to Aenderung der kunststoffverordnung 2003, BGBl Nr 452/2006.

BELGIUM:

- Royal decree of 11 May 1992, published in the Moniteur Belge / Belgisch Staatsblad of 24 July 1992 - as amended by the Royal decree of 3 july 2005 which is partly repealed by the Royal decree of 5 July 2006, Belgish Staatsblad / Moniteur Belge of 7 September 2006.

DENMARK:
- Bekendtgorelse nr 1102 af 9/11/2006 om materialer og genstands i kontakt med fodevarer.

FINLAND:
- Decree on Materials and Articles coming in contact with Foodstuffs - KTM 953/2002 of 12/11/2002 - as amended up to KTM 181/2005 of 10/03/2005.

FRANCE:
- Arrêté du 2 janvier 2003 relatif aux Matériaux et Objets en Matière Plastique mis ou destinés à être mis au Contact des Denrées, Produits et Boissons Alimentaires, as amended up to Arrêté du 19 octobre 2006.

GERMANY:
- BfR Empfehlung VII "Polypropylen" from the Bundesinstitut fuer Risikobewertung "BfR".

- Bedarfsgegenstaendeverordnung vom 10 April 1992, BGBl I.S. 866 Neugefasst durch die Bedarfsgegenstaendeverordnung vom 23.December 1997 (BGBl 1998 I S 5.) - as amended up to Zwoelfte Verordnung zur Aenderung der Bedarfsgegenstaendeverordnung vom 30.November.2006 (BGBl I.S.2730).

IRELAND:
- Irish Statutory Instrument S.I No 139 of 2006, European communities (Plastics and other Materials)(contact with Food Regulations 2006 and S.I. No 566 of 2006, European communities(Plastics and other Materials)(contact with Food)(Amendment) Regulations

ITALY:
- Decreto Ministeriale 21 Marzo 1973 - as amended up to Decreto 4 Maggio 2006, n.227 recipemento delle Direttive 2004/1/CE, 2004/13/CE e 2004/19/CE.
Gazette Ufficiale n. 159 del 11 Luglio 2006.

NETHERLANDS:
- Regeling van 20 November 1979, nr 147708, Stcrt. 1980,18, tot uitvoering van artikelen 2 en 5 van het Verpakkingen-en Gebruiksartikelenbesluit (Warenwet) (Stb.1979,558) (Regeling Verpakkingen en Gebruiksartikelen) - as amended and/or completed up to Regeling van 15/06/2006 Stcrtnr 114

NORWAY:
- Forskrift om Materialer og Gjenstander i kontakt med Naeringsmidler

FOR-1993-12-21 nr 1381 - as amended.

PORTUGAL:
- Decreto -Lei No 197/2007 of 15/05/2007

SPAIN:
- Spanish Real Decreto 118/2003 of 31/01/03 as amended up to the ORDEN SCO/3508/2006 and Resolution de la Subsecretaria para la Sanidad o November 4, 1982 - as amended.

SWEDEN:
- LIVSF 2003:2 from 06/02/2003 as amended up to LIVSF 2006:20 from 5/10/2006.

UNITED KINGDOM:
- S.I. 2006 No 1401 The Plastics Materials and Articles in contact with Food (England) Regulations 2006 and S.I. No 2687, The Plastics Materials and Articles in Contact with Food (England ) (No 2) Regulations 2006
- SSI 2006 No 314, The Plastics Materials and Articles in Contact withFood (Scotland) Regulations 2006 and SSI 2006 No 517, The plastics Materials and Articles in Contact with food (Scotland) (No 2) Regulations 2006
- SR 2006 No 251, The Plastic Materials and Articles in contact with Food Regulations (Northern Ireland ) 2006 and SR 2006 No 420 ,The Plastics Materials and Articles in Contact with Food (No 2) Regulations (Northern Ireland) 2006
- S.I. 2006 No 2982,The Plastics materials and Articles in contact with Food (Wales) Regulations 2006

# Monomer restrictions:

- None of the monomers present in this polymer is subject to a Specific Migration Limit (SML).

# Presence of additives with SML

- The above polymer grade does contain a/some additive(s) that is/are subject to a Specific Migration Limit (SML).

# Presence of dual use additives

- The above polymer grade does contain a/some additive(s) that is/are subject to a restriction in food as referred to in Article 1 point 7 (a) 1.(b) of EC Directive 2004/19/EC.

Note
For information purpose only

This note contains information relative to the presence of additives subject to a restriction according to Directive 2002/72/EC -as amended-, as described in this Statement.

Additive : N,N-Bis(2-hydroxyethyl)alkyl (C8-C18) amine
EC Ref. No : 39090
Max. conc.* : 70 ppm
Restriction : SML = 1.2 mg/kg food

Additive : Zinc Oxide
EC Ref. No : 96240
Max. conc.* : 250 ppm
Restriction : SML = 25 mg/kg food - Expressed as Zinc

Additive : Sodium Benzoate
EC Ref. No : Salt of 36700
Max. conc.* : 2400 ppm
Restriction : Dual use additive

Additive : Talc
EC Ref No : 92080
Max. conc.* : 1.8 %
Restriction : Dual use additive

Additive : Glycerol Monostearate
EC Ref No : Salt of 56585
Max. conc.* : 1.1 %
Restriction : Dual use additive

* This information is provided for general guidance purposes only and ExxonMobil Chemical provides no guarantees or warranties in respect of this information and has no responsibility or liability for any use by any third party of this information.

Note on Additives SML's (Specific Migration Limits)

The above polymer grade does contain some additive(s) that is/are listed in Annex III Section B of the EC Directive 2002/72/EC, as amended up to EC Directive 2007/19/EC and that is/are subject to a Specific Migration Limit (SML).

However, be informed, that for SML-subjected additives listed in Annex III Section B, the verification of compliance with the specific migration limits in simulant D or in test media of substitute tests as laid down in Article 3(1), second subparagraph of Directive 82/711/EEC -as amended- and Article 1 of Directive 85/572/EEC shall apply from 1 April 2008.

Note on Overall Migration Limit ("OML")

Finished plastics food-contact materials or articles, made from or containing this product as a component, need to comply with Overall Migration Limit ("OML") requirements - as specified in EC Directive 2002/72/EC - when tested on the food-contact surface with the appropriate food simulants and time/temperature test conditions. This is part of the responsibility of the user of this polymer product.

Indeed -and in addition to the above compositional compliance status certification-, appropriate overall migration ("OM") tests on the final material or article determine the regulatory suitability for

contact with different food-types (aqueous, fat/oil, alcoholic, ...) and various end-use conditions (material or article thickness, pure or in blends, volume, contact time of packaging, temperature of use, etc....), which are beyond control of EXXONMOBIL CHEMICAL.

General note

The manufacturer of food-contact materials and articles - made from or containing this polymer grade - must ascertain that these finished materials or articles meet the general regulatory requirement that they do not bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof.

In addition, the finished food-contact material or article must be technically suitable for the intended use.

VALIDITY DATE: This document is valid until the next relevant legislative and/or regulatory change with a maximum of one year as of the date of issue of the statement.

Reference Number: 0011933