

ROADMAP			
TITLE OF THE INITIATIVE	Proposal for a new measure on bisphenol A (BPA) in food contact materials		
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LIKELY TYPE OF INITIATIVE			
INDICATIVE PLANNING	2 <sup>nd</sup> Quarter 2016		
ADDITIONAL INFORMATION			
This indicative roadmap is provided for information purposes only and can be subject to change. It does not prejudice the final decision of the Commission on whether this initiative will be pursued or on its final content and structure.			

A. Context, Subsidiarity Check and Objectives
<p><b>Context</b></p> <p><b>Bisphenol A</b></p> <p>Bisphenol A (BPA) is a chemical substance used in the manufacture of certain food contact materials such as plastic (polycarbonates) and coatings (epoxy resins). Polycarbonate is mainly used in food contact applications such as water coolers and chocolate moulds, based on the properties that it provides compared to other plastics. BPA-based epoxy resin is used extensively as a component of the coatings applied to metal food and beverage cans to ensure the preservation of the packaged food. The resins are also used in coatings and varnishes on the caps and closures of food contact jars and bottles and on containers used in the production and industrial scale storage of food such as vats. BPA may also be present to some extent in some other food contact materials including printing inks, adhesives and in addition it may be present in recycled paper and board. BPA is also used in other consumer products such as thermal paper used for receipts, toys and medical devices.</p> <p><b>Regulatory framework</b></p> <p>The general rules on food contact materials at EU level are laid down in the basic act, Regulation (EC) 1935/2004<sup>1</sup> adopted by the European Parliament and the Council, which also provides the legal basis for setting specific measures for certain types of food contact materials. One such measure specifically authorises the use of substances in plastic food contact materials<sup>2</sup>, including the use of BPA, except where is banned in polycarbonate infant feeding bottles<sup>3</sup>.</p> <p>The use of a substance is often subject to a specific migration limit (SML), which is the amount of the substance that can migrate from the plastic food contact material into the food. As with the decision to authorise a substance, the SML is based on a specific risk assessment carried out by the European Food Safety Authority (EFSA). So far approximately 1000 substances have been authorised for use in plastics based on such assessments. BPA is currently subject to an SML of 0.6 mg/kg.</p> <p>In accordance with Regulation (EC) No 1935/2004, EFSA must be consulted on provisions on food contact materials liable to affect public health and the risk assessments provided by EFSA inform on the restrictions needed at risk management level, such as the SML.</p> <p>EFSA completed its first full risk assessment of BPA in 2006<sup>4</sup>, which established a Tolerable Daily Intake (TDI) of 50 micrograms/kilogram bodyweight (µg/kg bw), with exposure below this level. Since then, EFSA has reviewed new scientific information on BPA several times, each time confirming the TDI. Based on some uncertainty in the 2010 opinion<sup>5</sup>, a ban was placed on the use of BPA in polycarbonate infant feeding bottles on the basis of the precautionary principle.</p>

<sup>1</sup> Regulation (EC) No 1935/2004 of the European Parliament and of the Council

<sup>2</sup> Commission Regulation (EU) No 10/2011

<sup>3</sup> Commission Implementing Regulation (EU) No 321/2011

<sup>4</sup> EFSA 2006. Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to 2,2-bis(4-hydroxyphenyl)propane (bisphenol A). The EFSA Journal 2006, 428, 1–75

<sup>5</sup> EFSA Panel on Food Contact Materials Enzymes Flavourings and Processing Aids (CEF), 2010. Scientific Opinion on Bisphenol A: evaluation of a study investigating its neurodevelopmental toxicity, review of recent scientific literature on its toxicity and advice on the Danish risk assessment of Bisphenol A. The EFSA Journal 2010, 8(9):1829

In 2012, EFSA began a full re-evaluation of the risks to human health associated with exposure to BPA through the diet, taking into consideration the contribution of non-dietary sources to the overall exposure to BPA and reviewing all of the available data and scientific studies on dietary exposure published since the 2006 Opinion. EFSA consulted and engaged with national authorities and stakeholders during its risk assessment to incorporate all scientific views and information. It published its new updated opinion on BPA on 21 January 2015<sup>6</sup>, which is available on its website at [www.efsa.europa.eu/en/efsajournal/pub/3978.htm](http://www.efsa.europa.eu/en/efsajournal/pub/3978.htm).

Concerning other food contact materials which utilise BPA, including coatings and varnishes, in the absence of specific EU rules, the general rules on food contact materials apply. Regulation (EC) 1935/2004 requires food contact materials to be manufactured so that they do not transfer their constituents to food in quantities which could endanger human health, bring about an unacceptable change to the composition of the food or deterioration in the organoleptic properties e.g. taste and smell. National specific rules may also apply in the absence of EU specific rules (Article 6 of Regulation (EC) 1935/2004 'National specific measures'). Some EU Member States have, for example, set an SML for BPA in coatings.

Article 18 of Regulation (EC) No 1935/2004 foresees that as a result of new information or a reassessment of existing information, an EU Member State has detailed grounds for concluding that the use of a material or article endangers human health, it can temporarily suspend or restrict the application of specific EU rules such as those for plastics (Article 18 of Regulation (EC) 1935/2004 'Safeguard measures'). According to the same rules the Commission is then under the obligation to decide whether these measures are necessary, where appropriate after obtaining an Opinion from EFSA and take action to either adopt or decline them.

Recently, some EU Member States have introduced national bans on the use of BPA in both plastic food contact materials under these safeguard measures, as well as for other materials such as coatings. Denmark and Belgium have introduced national bans on the use of BPA in food contact materials for infants and young children; Sweden has introduced a ban on BPA only in coatings and varnishes for food contact materials for infants and young children and France has banned BPA in all food packaging, containers and utensils. The legal obligation for the Commission to act applies to those Member States who have invoked such grounds as to use Article 18, namely France, Denmark and Belgium<sup>7</sup>. All these Member States as well as Sweden notified their measures insofar as they are relevant for materials for which no specific harmonised measures exist at EU level as required by the 98/34 notification procedure.

No post analysis of existing EU policy has been carried out although Regulation 10/2011 is updated on a regular basis to reflect new scientific advice from EFSA.

## Issue

### **Risk management measures are at present not aligned with the current scientific opinion**

Based on new data and methodologies, EFSA has lowered the Tolerable Daily Intake (TDI) from 50 to 4 µg/kg bw and is temporary (t-TDI), pending the outcome of further studies. Therefore, a new SML is in turn warranted on the basis of this new t-TDI.

As previously stated, the Commission uses EFSA opinions as a basis on which to derive restrictions, where appropriate, for the use of substances in food contact materials. Risk management decisions should be taken based on the new risk assessment and the SML for BPA should therefore reflect the new t-TDI taking into account information in the new EFSA opinion on its use in and migration from food contact materials.

It should be noted however, that EFSA's scientific opinion shows that the level of BPA that consumers of all ages are exposed to is well below the t-TDI and concludes that there is no health concern for any age group from dietary exposure and low health concern for aggregated exposure, which includes sources other than food.

### **Uncertainty as regards the legal status of the use of BPA in food contact materials and negative effect on consumer confidence**

Uncertainty has been created as the existing risk management measures do not reflect the updated scientific advice. Diverging laws in some EU Member States have created uncertainty as to what products that use or contain BPA can be placed on the market since they are different from the rules at EU level. Confusion has arisen as to which ones apply to BPA in food contact materials following the introduction of national rules, as

<sup>6</sup> EFSA Panel on Food Contact Materials Enzymes Flavourings and Processing Aids (CEF), 2015. Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs. The EFSA Journal 2015;13(1):3978

<sup>7</sup> The measure in Sweden does not concern specific EU measures (i.e. plastic food contact materials) and the procedure laid down in Article 18 of Regulation (EC) No 1935/2004 has therefore not been applied to it. Member States must still notify to the Commission draft technical regulations which fall within the scope of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services (OJ L 204, 21.7.1998, p. 37) under the notification procedure provided in this Directive. However, this is a separate procedure and the obligations laid down to the Commission in Article 18 of Regulation (EC) No 1935/2004 do not apply in this context where the measure has not been notified as a safeguard measure under that Article

demonstrated by requests to the Commission to clarify which laws are indeed valid. In the absence of an authoritative EU decision on its use in this domain, consumers may also be confused and concerned by the presence of BPA in food contact materials.

### **The introduction of different measures in EU Member States is affecting the proper functioning of the internal market for food contact materials that utilise BPA**

Differences between national laws, regulations and administrative provisions concerning the safety assessment and authorisation of substances used in the manufacture of materials and articles intended to come into contact with food can also hinder the free movement of those materials and articles, creating conditions of unequal and unfair competition.

The use of BPA in food and beverage cans is particularly significant, as the majority of cans (around 80%) utilises the BPA based epoxy-resin technology as a coating. The canning industry is an important one in the EU, with approximately 90 lines operational, in particular in the UK, Germany and Spain as well as in France. Around 50 billion beverage cans and 20 billion food cans are produced in the EU each year; in the latter case the estimated value of this market in 2010 was €30 billion in the EU.

Whilst there is a distinction between placing products on the French market and elsewhere in the EU, in practice EU industry using affected products has reported difficulties since there is a need to maintain flexibility in order to manage stock rotation and distribution throughout the EU, to avoid waste for example. The different national laws reduce this flexibility compared with those that only supply to EU Member States that do not have such national laws on BPA.

Differing rules in EU Member States also present a confusing and challenging regulatory regime for third country exporters to follow. This matter has already been raised on several occasions in the WTO SPS Committee, most recently in July 2015. For example, imported canned fruit and vegetables are often brought to a centrally located EU country and from there, they are distributed to other EU countries. Special production and distribution chains are now having to be established in order to specifically comply with individual national rules, introducing additional costs and practical challenges in the separate production and distribution of these goods. Such production chains were previously set up and functioning to comply with already established specific or general EU rules, applicable throughout the Union.

Risk assessment bodies from third country trading partners such as the US FDA have also come to the same or similar views as EFSA as regards BPA.

### **Negative effects on innovation and efficacy**

According to correspondence from manufacturers of food contact materials that use BPA to the Commission, the recent introduction of national laws has not allowed industry sufficient time to fully evaluate and test alternative products and for 90% of those packed food products for which BPA is used in food contact materials, substitution is under investigation with trials ongoing at different stages. Industry also states that for a further 10%, there are currently no viable substitutions foreseeable.

Industry has indicated that many of the replacement products being prepared in order to comply with laws banning BPA do not meet the same quality standards as those based on BPA-technology and are not as efficacious. The alternative options could for example hinder the performance of the packaging, the durability of the food and in turn potentially affect the organoleptic properties of the foodstuffs that the packaging is intended to protect. One significant impact reported by industry such as those manufacturing metal cans on the switch to using alternative substances is a decrease in the shelf life of many products, which if not addressed may in turn lead to increase in food waste. Industry has claimed that the switch to alternative substances may reduce the shelf-life of food in cans by 1 – 2 years.

Furthermore, the food contact material market is generally not segmented for different EU Member States and industry packaging needs are typically developed for the internal market as a whole rather than for specific national markets. This means that trying to switch to viable alternative substances and adapting production lines in order to meet the specific requirements of national laws entails significant extra costs.

In addition to this, industry faces uncertainty on which standards to apply and therefore how to ensure compliance with differing laws. Consequently, industry argue that resources are being spent on trying to develop products that meet the same level of performance as those using BPA-based materials, diverting resources away from possible investment on new and innovative approaches that may benefit consumers both in terms of the quality of the food and efficiency of the packaging.

### **Who will be affected by it?**

- Industry operational in the EU, including manufacturers and users of food contact materials that utilise BPA;
- Third country trading partners including exporters of food contact materials using BPA to the EU;
- EU Member States, in particular those that have adopted specific harmonised measures on BPA in food

contact materials but also those that have not insofar as they would need to ensure sufficient enforcement of any additional EU measures on food contact materials;

- Consumers.

#### **Subsidiarity check**

The general requirements for food contact materials are already set at EU level in the basic act, Regulation (EC) No 1935/2004. This Regulation, having particular regard to Article 114 of the Treaty on the Functioning of the EU (ex- Article 95 of the TEC) empowers the Commission to set out specific measures at EU level which are necessary to ensure compliance with the general safety requirements laid down in that Regulation, including measures for substances for use in the manufacturing of materials and articles as well as the functioning of the internal market.

Different Member States have introduced measures to regulate the use of BPA in food contact materials, using both the provision on safeguard measures (Article 18 of Regulation (EC) No 1935/2004) and the provision on national specific measures under which they may act themselves in the absence of specific EU harmonised measures (Article 6), provided that they are in line with the Treaty. However, the differences between national laws and administrative provisions concerning the use of BPA in food contact materials are hindering the free movement of goods, causing difficulties to third countries seeking to export these materials to the EU as well as creating unequal and unfair competition and increased administrative burden to the business operators concerned. Therefore EU action would be justified on grounds of subsidiarity.

In light of the significant use of BPA in food contact materials throughout the whole of the EU, and the way that industry is set up to supply the internal market as a whole, a measure at EU level would help to stabilise a diverging market concerning the use of BPA in food contact materials. It would also provide legal certainty and one set of clear rules from which all actors in the industry supply chain could work to as well as establish a mutually high level of protection for all consumers throughout the EU.

#### **Main policy objectives**

##### **General objectives:**

- Secure a consistent and high level of protection for human health and the interest of consumers in the EU;
- Ensure the functioning of the internal market and the absence of unjustified barriers to trade.

##### **Specific objectives:**

- Ensure that a level of risk management is applied to the use of BPA in food contact materials which is appropriate and in line with the new scientific opinion and consistent with current specific EU rules;
- Reinforce consumer confidence and trust in the safety of food contact materials on the EU market;
- Ensure that there is no burden to market operators from diverging laws from different Member States in relation to the placing on the market of food contact materials that contain BPA and provide legal certainty to actors in the supply chain concerning the use of BPA in food contact materials;
- Help to provide a regulatory environment for businesses to concentrate their resources towards innovation and sustainability particularly for those within the food contact material manufacturing chain;
- Fulfill the legal obligations laid down in Article 18 of Regulation (EC) No 1935/2004.

The objectives do not imply developing policy in new areas since EU policy on food contact materials already exists, including legislation which empowers the Commission to achieve these objectives. Concerning plastic food contact materials, Commission Regulation (EU) No 10/2011, as amended already sets out specific provisions for the use of BPA in plastic food contact materials. In this respect the proposal would entail an amendment of this Regulation. Concerning other food contact materials, no specific EU measure on BPA currently exists although Regulation (EC) No 1935/2004 allows the Commission to make such measures to achieve these objectives, which the Commission has previously done outside the scope of plastic food contact materials.

## **B. Option Mapping**

### **Option 1 – No policy change**

No action at EU level would maintain the current authorisation of BPA, applicable to all Member States, as a monomer in plastic food contact materials together with the restrictions laid down in Commission Regulation

(EU) No 10/2011, including the current SML of 0.6 mg/kg. However this does not respect the new scientific advice.

EU Member States would be able to keep or introduce their own national laws on BPA in other materials than plastics such as coatings and varnishes.

#### **Option 2 – Modify legislative restrictions for BPA in plastic food contact materials at EU level**

The current authorisation and restrictions on the use of BPA as a monomer in plastic food contact materials laid down in Commission Regulation (EU) No 10/2011 is based on previous risk assessments. Risk management measures on BPA for which specific harmonised measures already exist at EU level should therefore take into account the updated opinion from EFSA on the human health risks from BPA.

Apart from the ban of BPA in polycarbonate infant feeding bottles, the main risk management measure currently laid down in Commission Regulation (EU) No 10/2011 for BPA is the SML of 0.6 mg/kg. As stated above, this is based on a previous risk assessment, which has now been updated.

This option would therefore be to lower the current SML of 0.6 mg/kg for BPA in plastic food contact materials to reflect the new t-TDI and in doing so, amend Commission Regulation (EU) No 10/2011. In recognition of the contribution of sources other than food contact materials to BPA exposure as identified in the new EFSA opinion, consideration should also be given to the contribution of BPA from such sources in deriving an SML.

A new SML for plastic food contact materials would be applicable to all EU Member States. As above this would leave EU Member States free to keep or introduce their own national laws on BPA in other materials such as coatings and varnishes.

#### **Option 3 – Modify legislative restrictions for BPA in plastic food contact materials at EU level and introduce measures for BPA in coatings and varnishes at EU level**

Currently there is no authorisation nor any specific restrictions for BPA in food contact materials other than plastics at EU level. However, in light of the significant use of BPA in other food contact applications in particular in coatings and varnishes; and in order to better achieve the objectives of the initiative, risk management measures concerning BPA should also be considered for other materials for which there are currently no specific measures at EU level.

In addition to modifying the restriction for the use of BPA in plastic food contact materials, this option would also set an SML for the presence of BPA in coatings and varnishes, such as for the use of coatings in metal packaging and varnishes on screw caps. A new SML for coatings and varnishes would also be based on the updated t-TDI set by EFSA and determined in the same way as for plastic food contact materials. Such a measure would be set out in a new Commission Regulation, made under Article 5 of Regulation (EC) No 1935/2004.

A new EU SML for coatings and varnishes would be applicable in all EU Member States.

#### **Option 4 – Modify legislative restrictions for BPA in plastic food contact materials at EU level and introduce measures for BPA in food contact coatings and varnishes as well as other food contact materials in which BPA may be present**

In addition to its use as a monomer in plastics and coatings and varnishes, BPA may be present in smaller quantities in other food contact materials. For example, although its use in inks is no longer common, it may be used upstream in the manufacture of certain raw materials used in the composition of the inks. It is also listed as an evaluated monomer permitted for use in food contact materials under the Swiss Ordinance on printing inks. The most likely source of BPA from printing inks are those that are used for UV curing, the same technology employed for some varnishes also used on food packaging.

BPA is also used in the production of some adhesives although there is little information to suggest that it is intentionally used in food contact applications. Furthermore, because of the use or incorporation of BPA in other products, in particular its use in thermal paper, it may be present in the recycling stream used to make recycled food contact paper and board if these are not removed prior to the recycling process.

As with coatings and varnishes, there is currently no authorisation nor any specific restrictions for BPA in food contact materials such as inks, adhesives or paper and board. This option would also set an SML for the presence of BPA in other food contact materials in which BPA may be present, including paper and board, inks and adhesives, in addition to its use in plastics and coatings and varnishes. A new SML for all of these food contact materials would also be based on the updated t-TDI set by EFSA. Such a measure would be set out in a new Regulation, as per Article 5 of Regulation (EC) No 1935/2004.

A new EU SML for all relevant food contact materials would be applicable in all EU Member States.

#### **Option 5 – Ban on BPA in food contact materials at EU level**

Of all the national laws that have been introduced by individual EU Member States, the law in France is by far the most wide-reaching since it bans the presence of BPA in all food contact packaging, containers and utensils.

As laid down in Article 18 of Regulation (EC) No 1935/2004, the Commission must examine and consider whether such action is justified and whether such amendments to the relevant specific measures are necessary in order to ensure the protection of human health. It is also appropriate to examine the bans on BPA in other types of food contact materials since it is used extensively in, for example coatings and varnishes. This option would prohibit the presence of BPA in food contact materials at EU level. This could be restricted to those materials for which BPA is intentionally added but this option would need to be carefully assessed in the light of the proportionality principle since EFSA has identified a level of BPA below which it considers exposure to be safe.

A ban would be applicable in all EU Member States.

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Soft law instruments such as industry self guidance are not viable options. In addition to the legislation in place at the EU level on the use of BPA in plastic food contact materials, industry guidance already exists for other sectors such as coatings, but is not sufficient to address the difficulties that have been introduced by diverging laws on the use of BPA in food contact materials in different EU Member States i.e. they are superseded by the national laws.

## **INITIAL ASSESSMENT OF OPTIONS**

### **Option 1 – No policy change**

No action would mean no amendments or further EU measures concerning BPA in food contact materials. This would maintain the current authorisation with restrictions for BPA in plastic food contact materials and therefore the new updated opinion from EFSA on BPA would not be taken into consideration. This option would address the diverging laws in different EU Member States insofar as a decision would be made to retain the current measures at EU level and not those of the safeguard measures introduced by individual Member States.

There are no tangible benefits associated with this option, in particular it does not respect the new risk assessment from EFSA and does not achieve consistency in the way in which plastic food contact materials are currently regulated. Industry has indicated that the current situation is also not sufficient for the functioning of the internal market.

This option would be counterproductive to simplification, since it would leave the current situation concerning the regulation of BPA in food contact materials somewhat fragmented and confusing. It would also leave considerable administrative and practical burdens in place for industry who would continue to be faced with diverging laws from different EU Member States on BPA in food contact materials.

### **Option 2 – Modify legislative restrictions for BPA only in plastic food contact materials at EU level**

Lowering the SML for BPA in plastic food contact materials would have the benefit of updating risk management measures to take into account the updated scientific advice on the risks from EFSA. This would ensure a consistent approach is made throughout Commission Regulation (EU) No 10/2011 on plastic food contact materials, since restrictions on substances authorised for use in plastic food contact materials take into account any safe exposure levels established by EFSA.

This would provide the plastics food contact industry with one, clear, harmonised set of rules to work from and create a level playing field for them across the EU. This option would help to clarify the legal situation for industry who would no longer have the practical and administrative burden of complying with different laws in different Member States. It would however leave other sectors of the food contact materials market as well as the food industry with the difficulties of diverging national laws on the relevant materials.

The plastics industry has indicated that levels of BPA migrating from plastic food contact materials are well below the current SML in all cases and it would therefore be possible for industry to be compliant with a new lower SML. Data are available for example in the EFSA opinion, demonstrating the typical migration levels of BPA from plastic food contact materials to inform on this decision making process.

This option would only provide a step towards simplification, clarifying a common and harmonised standard for the use of BPA in plastic food contact materials, reducing the current administrative and practical burden for the affected businesses.

### **Option 3 – Modify legislative restrictions for BPA in plastic food contact materials at EU level and introduce measures for BPA in coatings and varnishes at EU level**

The introduction of an SML for BPA in coatings and varnishes as well as plastic food contact materials would have the added benefit of extending the updated scientific knowledge on the risks from BPA to other materials which utilise BPA as a starting material as for plastics but contribute a significantly greater proportion of overall dietary exposure. In this case the risk assessment is better translated into risk management.

This would provide not only the plastic food contact industry with one, clear harmonised set of rules to work from



<p>but also the metal packaging and coating industry as well as the users of such packaging including the food industry. This option would create a level playing field for several industries who would no longer have the practical and administrative burden of complying with different laws in different Member States.</p> <p>The industry using coatings and varnishes has indicated that levels of BPA migrating from coatings and varnishes are well below those that they currently work to i.e. the current EU SML for plastic food contact materials and it would therefore be possible for industry to be compliant with a new EU SML based on the new t-TDI. Data are available for example in the EFSA opinion, demonstrating the typical migration levels of BPA from coatings and varnishes to inform on this decision making process.</p> <p>This option would provide significant simplification of the current rules since it would include a common set of rules on the two main uses of BPA in food contact materials i.e. plastics as well as coatings and varnishes, whilst reducing the current administrative and practical burden for the affected businesses.</p> <p><b>Option 4 – Modify legislative restrictions for BPA in plastic food contact materials at EU level and introduce measures for BPA in food contact coatings and varnishes as well as other food contact materials in which BPA may be present</b></p> <p>The introduction of an SML for BPA in all relevant food contact materials would have the added benefit of extending the updated scientific knowledge on the risks from BPA to other materials which may also contain BPA. This would provide all relevant food contact industries including the food industry with one, clear harmonised set of rules to work from and create a level playing field across the EU. While for paper and board, thermal paper is estimated to be a major source of contribution of BPA to the recycling stream, large amounts are lost during this process and in practice, the contribution of these materials as a source of BPA from food contact materials is likely to be minimal compared with, for example coatings and varnishes.</p> <p>An SML set out in EU legislation for paper and board would be likely to increase costs and moreover cause difficulties in the supply chain for industry who report large variations in levels in paper and who already follow their own best practice based on current EU legislation for plastic food contact materials.</p> <p>The additional benefits that this option brings are likely to be minimal and disproportionate to the financial and administrative burden, particularly for the paper and board industry, which makes up approximately 40% of all food packaging, although this is not all from recycled material.</p> <p>This option would not have any significant additional impact on simplification since the contribution from other sources is relatively small and these sectors have not been impacted by national measures. This option may increase administrative burden and could be more difficult for Member States to enforce.</p> <p><b>Option 5 – Ban on BPA in food contact materials at EU level</b></p> <p>The introduction of a ban on BPA in food contact materials would not reflect the current scientific advice from EFSA. Whilst EFSA has lowered the t-TDI, the new value continues to represent a level below which health effects are not considered to occur and this threshold can therefore be used to derive limit values for the migration of BPA from food contact materials.</p> <p>Industry are currently reliant on the characteristics that BPA provides, which give both integrity and quality to the food packaging and which cannot readily be replaced by a similar substance. A ban on BPA in food contact materials and in particular in coatings and varnishes would require industry to replace BPA with substances that in part at least do not function as well and have not been tested to the same standards. Consequently, shelf-life and quality of products may also be affected.</p> <p>This option is unlikely to simplify the situation and would have a significant administrative and practical burden on industry. Enforcement of this option may also pose a significant challenge, for example where quantities of BPA may come from other sources and may still be present at low levels.</p>
<b>Proportionality check</b>
<p>The objectives do not imply developing policy in new areas since EU policy on food contact materials already exists, including legislation which empowers the Commission to achieve these objectives. Concerning plastic food contact materials, Commission Regulation (EU) No 10/2011 already sets out specific provisions for the use of BPA in plastic food contact materials. In this respect the proposal would entail an amendment of this Regulation. Concerning other food contact materials, no specific EU measure on BPA currently exists although the current basic act on food contact materials allows the Commission to make such measures to achieve these objectives, which the Commission has previously done outside the scope of plastic food contact materials.</p>
<b>C. Data collection and Better Regulation instruments</b>
<b>Data collection</b>
<p>A significant amount of information is available in EFSA's opinion, which totals over 1000 pages. Information has</p>

<p>also been provided to DG SANTE by stakeholders including European Professional Organisations on the uses and occurrence of BPA in food contact materials. Industry has provided some information to demonstrate that there would be no negative impacts of possible future EU measures on BPA in plastic food contact materials as well as coatings and varnishes as the levels of migration of BPA from these materials are mostly well below the current SML for plastics. There may potentially be positive impacts in terms of costs which are difficult to quantify, resources, simplification etc. This includes information on possible future compliance and information on the benefits of having one set of EU harmonised rules.</p> <p>The Commission will continue to collect further data and consult with industry as and when the specificities of such a measure are developed and further information will be sought where necessary. Discussions will also take place with the European Union Reference Laboratory (EU-RL) on testing methodology and with EU Member States for example, on the technical details of the measure and the implementation and enforcement of any additional rules concerning BPA in food contact materials as the details of the new measure are developed.</p> <p>The Commission will continue to engage with all interested parties including EU Member States, third countries, industry and consumer organisations on the initiative and communicate updates on the progress of the risk management process in view of the degree of interest on this particular issue.</p>
<p><b>Consultation approach</b></p> <p>The Commission holds a database of its stakeholders relevant to food contact materials and some dialogue has taken place with those affected by the issue i.e. industry stakeholders across the different sectors affected including those in the packaging and food sectors which also represent SMEs. Industry has provided information on the current situation including the current difficulties and challenges faced and how these could be improved.</p> <p>The Commission will continue to engage with and consult all relevant stakeholders including industry as well as with experts of the EU Member States via the Working Group meetings on food contact materials and the Standing Committee on Plants, Animals, Food and Feed (PAFF)<sup>8</sup>. It will continue dialogue in particular with those EU Member States which have introduced their own national measures on BPA in food contact materials. A presentation on the EFSA opinion was given at the PAFF in February 2015 where many Member States have already indicated their desire to urgently address the issue with risk management action at EU level.</p> <p>The Commission will also continue to engage with third countries at the various steps of the legislative process. The EU will also, at the appropriate time, notify any trade-related measures to other WTO members in line with its international obligations.</p>
<p><b>Will an Implementation plan be established?</b></p> <p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>No specific implementation plan is established as the process is routine, however the implementation will be discussed with all relevant stakeholders including EU Member States and industry during discussions on technical aspects.</p>
<p><b>Will an impact assessment be carried out for this initiative and/or possible follow-up initiatives?</b></p> <p>An IA will not be carried out for this initiative since the impacts would be small and since the practical options available to the Commission are limited in light of the EFSA opinion. This initiative relates only to the use of one substance in food contact materials and is therefore considerably limited in scope compared with other major initiatives, for example horizontal measures that apply to particular materials, such as the one for plastic food contact materials.</p> <p>Routine measures on substances in food contact materials, in particular for plastics, continue to be introduced based on EFSA opinions for the benefit of both businesses including SMEs and consumers, in full discussion with relevant stakeholders and EU Member States without the need for a specific impact assessment.</p> <p>In the case of possible impacts on industry, including SMEs, the Commission has already undertaken work to establish what the current situation is and what the impact would be on the affected parties of the different options. Evidence gathered from the affected actors shows that the envisaged option is not expected to have significant impacts in terms of costs and burden since industry are already working to and compliant with standards for the use of BPA in food contact materials which would not be affected by a new SML.</p> <p>Consultation and dialogue will continue with the relevant industry organisations such as those representing users of plastics and coatings and varnishes and other stakeholders on this issue as the technical details of the</p>

<sup>8</sup> [http://ec.europa.eu/dgs/health\\_food-safety/dgs\\_consultations/regulatory\\_committees\\_en.htm](http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/regulatory_committees_en.htm)



measure are elaborated on as well as with EU Member States.

Other DGs that have responsibility for the risk management of BPA in the scope of other regulatory regimes include DG GROW, DG JUST and DG ENV. DG SANTE will continue to liaise with these DGs and with other relevant services of the Commission including the SG and SJ and will ensure that they are consulted on the initiative in a timely manner going forwards.

None of the options will have an impact on the EU budget above € 5m.