

# Food contact materials and chemical contamination



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**This briefing looks at health concerns related to chemicals in food contact materials in Europe. It addresses the current EU legislative system for these materials and defines what is missing in the existing system that must be changed if public health is to be protected. It also outlines the policy opportunities that are on the horizon.**

Have you ever wondered whether chemicals in the plastic wrapper on your meat or cheese can leach into the food you are about to eat? Or whether it is safer to buy your yogurt in a plastic pot or in a glass jar with a plastic lid? There are thousands of chemicals in food contact materials which can potentially migrate into food or drink and some are hazardous. Consumers tend to assume that they are protected from harmful chemicals in food and drink packaging, let alone the materials used in food processing and for cooking. In fact, current EU legislation on food contact materials is not fully effective in protecting public health.

## THE HEALTH PROBLEM

Currently, hazardous chemicals are present in plastics and other materials that come in to contact with food. These chemicals can leach or migrate into food and from there into our bodies.

Chemicals are especially likely to migrate into food or liquids when the food contact materials are exposed to high temperatures, when contact times are long and when the food to material contact ratio is high. Food chemistry is also important. Chemicals are likely to leach into fatty liquids for example. A recent study on plastic food containers by the Danish Consumer Council project "THINK Chemicals" [2] showed that chemicals can migrate from the plastic walls of the containers into warm fatty foods, such as gravy or lasagna.



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Avoiding packaged foods containing harmful chemicals reduces human exposure. A USA study showed that when people ate foods that have not been packaged, the levels of phthalates and bisphenol A (BPA) in their bodies went down significantly [1].

**A recent study on plastic food containers by the Danish Consumer Council project "THINK Chemicals" showed that chemicals can migrate from the plastic walls of the containers into warm fatty foods, such as gravy or lasagna [2]**

## HAZARDOUS CHEMICALS THAT ARE PROHIBITED OR SET FOR PHASE OUT UNDER OTHER EU LAWS ARE PERMITTED IN FOOD CONTACT MATERIALS.

Under the EU chemicals law REACH, chemicals belonging to six groups with harmful properties are being identified and required to undergo authorisation procedures for particular uses, the ultimate aim being to end those uses and move to safer alternatives [3].

Another law, on the authorisation of pesticides in the EU, directly prohibits three types of substances: endocrine disrupting chemicals, carcinogens and reproductive toxicants.

The general concept that has developed in the EU is: The uses of harmful chemicals that expose many people and the environment (“wide dispersive use”) must stop and safer alternatives found.



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Some 58 chemicals that under REACH legislation are recognized as “Substances of Very High Concern” (SVHCs) are permitted in food contact materials.

*Chemicals considered most harmful are those that:*

- *Cause cancer*
- *Affect DNA*
- *Harm reproduction*
- *Do not break down in the environment*
- *Are capable of building up in the food chain or bodies, and*
- *Other harmful properties, such as disrupting hormones.*

*Currently, there are chemicals from each of these six groups falling through the EU legislative net for food contact materials.*

## ENDOCRINE DISRUPTING CHEMICALS

**Of particular concern are endocrine disrupting chemicals (EDCs), which recent science has associated with various diseases and conditions, such as hormonal cancers (breast, prostate, testes), reproductive problems (genital malformations, infertility), metabolic disorders (diabetes, obesity), asthma and neurodevelopmental conditions (learning disorders, autism spectrum disorders).**

Alongside what the cumulative scientific evidence already shows, the concern exists because of the rising levels of many of these diseases in Europe and worldwide. In addition, the public are widely exposed to these chemicals from various sources, including food contact materials.

According to a US study, contamination of food from just one EDC - Bisphenol A, known as BPA – was estimated to be responsible for 12,404 cases of childhood obesity and 33,863 cases of newly incident coronary heart disease during 2008 [5].

Another recent study looking at Europe estimated that BPA in food contact materials and thermal paper was likely responsible for 42,400 obese 4-year-olds (with health costs of 1.54 billion euros per year) [6].

BPA is used to make certain plastics (polycarbonates) and coatings used on the insides of aluminium and metal cans, and the lids closures of glass jars and bottles.



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**Hormone disrupting chemicals are also of particular concern because their properties generally evade our current risk assessment system.**

**This is because they have the following characteristics:**

- 1. Potential to cause harm long after an exposure stops;**
- 2. Potential for harm at extremely small doses which are usually not tested;**
- 3. Potential for harm dependent on timing of exposure (life phase);**
- 4. Potential for harm in subsequent generations; and**
- 5. Potential for additive effects or cocktail effects (the combination creates a stronger effect) [4]**

## EXISTING EU LEGISLATION NEEDS REVISION

The overall legislative architecture for all food contact materials is provided by

- EU Framework Regulation EC 1935/2004 [7]
- EU Regulation on Good Manufacturing Practices for materials and articles intended to come into contact with food (EC) 2023/2006.

These two laws cover materials and articles intended to come into contact with foods, and which are used in the food processing, storage, packaging, selling, cooking and serving phases.

This includes everything from tubes used in cow milking to food processing machinery (e.g. conveyor belts), bulk container vats, gloves worn by workers handling food products, to the final packaging in which food items are sold, plus kitchen cookware, cutlery and dishes. It also includes materials and articles in contact with liquids for human consumption [8].

There are 17 different types of food contact materials, such as plastics, metals, silicones, paper and board, and less obvious material types, such as printing inks, adhesives, and coatings (inside cans and lids).

*The purpose of the regulation is:*

*“to ensure the effective functioning of the internal market for materials and articles intended to come into contact directly or indirectly with food and provide the basis for securing a high level of protection of human health and the interests of consumers” (Article 1).*

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the basis for securing a high level of protection of human health and the interests of consumers” (Article 1). Article 3 stipulates that the migrating chemicals must not enter food in *quantities* which could endanger human health.

Given that the rapidly evolving science on endocrine disruptors is calling into question the established approach for identifying safe levels and that the current approach ignores combination effects, the EU legislation urgently needs revision.

Another problem is that particular EU rules don't exist for all types of food contact materials. The current Framework Regulation allows for more particular rules to be set for any of the 17 types of food contact materials. Such rules normally involve more specific requirements for safety assessment and limits for the maximum migration of chemicals into the food. However, specific EU laws have only been set for five of the 17 types.

Plastics, the most common food packaging material, is one of the five types regulated at EU level but that law has some important defects which are discussed below.



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## NATIONAL LAWS AND ACTION

**Some Member States do have their own national rules for 3-5 types of materials. They include the Netherlands, Germany, France, Italy, Spain, Czech Republic and Slovakia. Some countries have also taken measures on particular chemicals.**

To protect public health, BPA has been banned from use in all food packaging in France. BPA has been banned in the packaging of foods intended for children under 3 years old in Sweden, Denmark and Belgium. Germany is currently reviewing the need for legislation on inks in food packaging materials.

However, the majority of Member States do not have specific legislation. The situation is such that the EU Commission Directorate General for Health (DG SANTE) has asked the Joint Research Centre for a “baseline” study to be completed in the first half of 2016 [9]. In the absence of both EU and national law for a specific type of food contact material, industry must conform to the general safety requirements in the Framework Regulation: it is left to decide which tests, standards and other methods to use to conduct its safety assessments and to set migration levels.

As a result of mounting concern from the scientific evidence, some isolated legal measures on the food contact uses of certain phthalates and BPA have been introduced at EU level. Since July 2008, the European Commission has limited the use of certain phthalates in food contact materials made of plastic [10] and in 2011, it banned the use of bisphenol A in baby bottles [11].

In addition, there are two EU measures that set specific migration levels for some epoxy derivatives (found in coatings), and nitrosamines in rubber teats and soothers. But the EU system as a whole is still permitting massive daily exposure of the public both to an unknown number of chemicals, whose potential for harm is still unexamined, and to chemicals known to be harmful to human health.

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## WHAT ARE THE REGULATORY GAPS?

**MOST MATERIALS ARE NOT COVERED:** The majority of chemicals in the 17 types of food contact materials are not covered by any legislation at EU level (called the 'non-harmonised' Food Contact Materials or FCM), and are not covered at the national level for many EU countries. In essence this means there is no single or unified market for most food contact materials; and the high level of protection of human health, let alone consumer interests, is not being secured.

Migration testing guidelines are only set for plastics, so currently the food contact materials manufacturers are borrowing inappropriate practices from plastics for other materials, and developing their own guidelines for other materials.

### BOX: Which materials are regulated?

EU laws exist for only five of the 17 different types of food contact materials.

Regulated	Not regulated	Not regulated, high priority
Ceramics	Cork	Paper and Board
Regenerated Cellulose Film	Adhesives	Varnishes & Coatings
Active & Intelligent Materials	Silicones	Printing Inks
Plastics	Elastomers & Rubbers	
Recycled Plastics	Glass	
	Metal & Alloys	
	Ion Exchange Resins	
	Wood	
	Textiles	
	Waxes	

**MANY CHEMICALS ARE NOT ASSESSED FOR SAFETY BY PUBLIC AUTHORITIES:** The so-called non-intentionally added substances (NIAS) are chemicals present in food contact materials as impurities or as by-products of manufacturing processes. Although the total number of NIAS in food contact materials is unknown, there have been suggestions that NIAS could be the majority of chemicals in any given material [12].

Although the framework legislation requires that non-intentionally added chemicals be put through risk assessment, in practice this may only be happening for a few non-intentional chemicals because not all NIAS in the final food contact article are identified. Moreover, explicit guidance on how companies should do the risk assessment (what is usually termed a technical guidance document) [13] is not yet available and there are concerns about the approaches currently being developed by the European Food Safety Authority being insufficient to address the potential harms to health [14]. This large gap on NIAS applies both to materials already regulated at EU level, such as plastics, and those materials for which there is no harmonised legislation at EU level.

**HARMFUL CHEMICALS ARE OVERLOOKED:** Some 58 chemicals that under REACH legislation are recognized as “Substances of Very High Concern” (SVHCs) (listed on page 2) are permitted in food contact materials [15]. It is a blatant contradiction that the health risks from food contact uses are less stringently addressed in laws on food contact materials. Under REACH, these chemicals are to be phased out and meanwhile put through strict permission procedures for uses still needed in the interim until safer alternatives are available. As the list of SVHCs grows, the list of harmful chemicals currently permitted in FCM is likely also to become longer. Again, the gap on harmful chemicals also applies both to materials already regulated at EU level, such as plastics, and those materials for which there is no harmonised legislation at EU level.

**ENDOCRINE DISRUPTING CHEMICALS ARE NOT ADDRESSED:** Endocrine disrupting chemicals are currently permitted and used in food contact materials in the EU [16]. The test methods required for those types of food contact materials that have specific laws, such as plastics, generally do not capture anything other than the most evident carcinogenicity, mutagenicity or reproductive toxicity effects. The requirements for timings, doses, extrapolations to safe levels and types of adverse effects tracked are not suitable to detect anything other than a very limited range of endocrine disruption effects. But the accumulation of animal, laboratory and epidemiological studies over the past 20 years point to the harm to health from endocrine disruptors. World Health Organization and United Nations Environment Programme experts and hundreds of other scientists have called for action on reducing people’s exposure to EDCs in order to protect health. Estimates of the costs of exposures to these chemicals (from multiple sources, not just food contact materials) have been conservatively estimated for Europe at 157 billion Euros per year [17].

**RECYCLED INPUTS ARE NOT ASSESSED:** Although recycled plastics are regulated at EU level, when recycled inputs are used to manufacture another material, such as paper and board, and no specific (EU or national) law for that material prohibits certain chemicals, then harmful chemicals can end up in the final food contact article. A recent testing of pizza boxes by the Danish Consumer Council

found fluorinated chemicals, mineral oils, phthalates, bisphenol A and nonylphenol in pizza boxes [18].

**RISK ASSESSMENT PROCESS IGNORES PEOPLE’S REAL EXPOSURES AND ADDITIVE EFFECTS BETWEEN CHEMICALS:** Mixtures of chemicals in one food contact material or the finished food contact article are not assessed. Safety levels are determined regardless of combinations arising from exposure to multiple food contact materials, and regardless of total mixed exposures produced by exposure to food contact material chemicals and to other sources of contamination (e.g. from other consumer products such as hygiene /cosmetics, electronics, etc.). When specific migration levels are set for certain food materials, the existing reality of a cocktail of exposures is treated as non-existent.

**INADEQUATE RESOURCES FOR COMMISSION IMPROVEMENT AND ENFORCEMENT OF EXISTING LAWS:** The Directorate General for Health, DG Sante, which is responsible for administering and overseeing the EU laws on Food Contact Materials, has insufficient personnel and resources to address the magnitude of this problem. Current indications are that the Commission is leaning towards allowing a roulette of ‘Mutual Recognition’ [19] between highly varying national laws to prevail, and claiming that the general provisions in the framework regulation suffice to ensure health protection.

**LACK OF TRANSPARENCY AND INSUFFICIENT ACCESS FOR PUBLIC INTEREST WATCHDOGS:** No regular EU institutional forum that includes all the necessary parties exists for exchange and steering of general and specific policy development issues for food contact materials. For plastics, the Commission hosts a technical expert group with industry and Member States only. This contrast poorly with the REACH chemicals system, where NGOs have been constructively participating since the outset in both overall steering (the ‘Competent Authorities’ group) and various technical bodies (European Chemicals Agency committees), alongside industry representatives.

## WHAT SHOULD BE DONE – HEAL RECOMMENDATIONS

### PROPERLY REGULATE ALL TYPES:

Twelve types of food contact materials are not covered by any specific legislative measures at EU level. These EU must urgently address these types, starting with those types that have a larger share of the market or where chemical contamination problems have already arisen, e.g. printing inks migrating into food, bisphenol A, fluorinated substances, and other harmful chemicals in paper/board packaging. The EU cannot rely on a system of the “Mutual Recognition” of various national laws if it is to ensure the “high level of health protection” that the EU treaty stipulates. Because paper and board cover a large proportion of the food packaging market, it should also be one of the priorities for attention, particularly given the contaminants being introduced from recycling inputs. The current EU drive for the circular economy and resource efficiency should not compromise public health.

*A system of ‘Mutual Recognition’ of widely varying national food contact laws cannot ensure the high level of health protection that the EU treaty stipulates.*

### PROHIBIT OR PHASE OUT REACH SVHCs:

Numerous chemicals identified as “Substances of Very High Concern” (or SVHCs) under REACH legislation are currently authorized in food contact materials or de facto allowed by the absence of prohibitions. The current or possible data collection, risk assessment work, and decision-making under REACH must be synergized with improved safety measures and revisions to food contact material laws, in order to protect health, promote policy coherence and avoid duplication of efforts. A clear phase out of SVHCs should be stipulated, with dates and targets for all material types and included in a fully revised Framework Regulation.

### BAN ALL EDCs:

Apart from the isolated measures taken on BPA and phthalates, the existing EU legislation does not address the health risks posed by endocrine disrupting chemicals. To eliminate EDCs from food contact materials, the latest science must be used in risk assessment and appropriate testing required so that relevant data is available. A clear prohibition of EDCs should be stipulated, with dates and targets for all material types, and included in the revision of the Framework Regulation. For example, BPA should be prohibited in all types (Option 5 of the November 2015 BPA Roadmap).

### ADDRESS THE COCKTAIL EFFECT:

It is imperative to recognise that exposures occur in other product sectors (consumer products, medical devices, toys, etc.) and environmental compartments (air, water) as well as between various food contact articles. Introduce measures in food contact materials legislation to initiate risk assessment of mixtures, including revision of previously established safe levels (specific migration levels). Address the Non-Intentionally Added Substances (NIAS) and require the testing of finished food contact articles. This will involve investment into research and development to develop and improve the biological testing methods for food contact materials, but this should not postpone introducing requirements straight away to assess the risks from the cocktail effect and take steps to reduce and eliminate it.

### SUPPORT INNOVATION FOR SAFER MATERIALS AND ALTERNATIVES:

A greater proportion of efforts and funding at EU and national level should go towards safer innovations in food contact materials. Better alternatives may include safer chemicals, but also alternative processes and product designs. The EU should ensure that there are incentives for companies to swiftly place safer materials and alternatives on the market; and promote exchange of best practice and dissemination of successful pilot projects. A crucial component of ensuring the transition to safer materials is ensuring assessments of alternatives ‘upstream’, not just attempting ‘drop in’ replacements of problematic chemicals downstream in the material production process.



## POLICY OPPORTUNITIES

### 1. EUROPEAN PARLIAMENTARY REPORT ON FOOD CONTACT MATERIALS:

The European Parliament should give a strong demand for action to eliminate harmful chemicals in its implementation report on food contact materials. Undertaken by the Committee on Environment, Public Health and Food Safety, the report is scheduled for consideration by the Committee in mid-March 2016. Voting in Committee is expected in May and in Plenary (whole parliament) in June 2016. The report should address the problems of non-harmonised materials, harmful chemicals in all materials (Substances of Very High Concern and Endocrine Disrupting Chemicals), the cocktail of exposures, and support for safer materials, and make recommendations for swift strong actions to reduce the public's daily exposure to chemicals from food contact materials.

### 2. JOINT RESEARCH CENTRE REVIEW:

The European Commission states that the aim of this review, due in early 2016, is to ensure that gaps are addressed in EU Better Regulation agenda [20]. Parliamentary scrutiny of and input on the Commission's use of the Joint Review Centre review will therefore be important

### 3. CONSULTATION ON 'REFIT' OF CHEMICALS LEGISLATION:

Chemicals in food contact materials will be included in the European Commissions' 'REFIT' work on chemicals legislation (not including REACH). Here also Parliamentary scrutiny and demands for better safety controls to eliminate the gaps between REACH, pesticides and food contact laws will be important. There will be a public consultation, where especially inputs from public health proponents will be needed.

### 4. BPA IN FOOD CONTACT MATERIALS:

The Commission has published a Roadmap on options for addressing BPA in food contact materials [21]. Views on the five options from the European Parliament and from other stakeholders representing the public interest or from the public health community will also be useful [22]. HEAL has given a submission noting the weaknesses of the current analysis and the insufficient examination of public health benefits of option 5 (banning BPA in all food contact materials).

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The Health and Environment Alliance (HEAL) is the leading not-for-profit organisation addressing how the environment affects human health in the European Union (EU) and beyond. HEAL works to shape laws and policies that promote planetary and human health and protect those most affected by pollution, and raise awareness on the benefits of environmental action for health.

HEAL's over 70 member organisations include international, European, national and local groups of health professionals, not-for-profit health insurers, patients, citizens, women, youth, and environmental experts representing over 200 million people across the 53 countries of the WHO European Region.

As an alliance, HEAL brings independent and expert evidence from the health community to EU and global decision-making processes to inspire disease prevention and to promote a toxic-free, low-carbon, fair and healthy future.

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NOTES:

1. Rudel et al 2011, "Food Packaging and BPA and Bis(2-Ethylhexyl) Phthalate Exposure: Findings from a Dietary Intervention", <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3223004/>
2. <http://kemi.taenk.dk/bliv-groennere/test-chemicals-plastic-food-containers-migrate-warm-fatty-foods>  
See the full test in Danish here: <http://kemi.taenk.dk/bliv-groennere/test-kemi-i-madkasser-og-opbevaringsbokse>
3. Carcinogens; mutagens; reproductive toxicants; persistent, bioaccumulative and toxic or very persistent & bioaccumulative; or of equivalent concern.
4. See United Nations Environment Programme and World Health Organization (2013) report, State of the Science of Endocrine Disrupting Chemicals – 2012. <http://www.who.int/ceh/publications/endocrine/en/>
5. Trasande L, Further Limiting Bisphenol A in Food Uses could provide Health and Economic Benefits, doi: 10.1377/hlthaff.2013.0686, HEALTH AFFAIRS 33, NO. 2 (2014)
6. Obesity, Diabetes, and Associated Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union. Legler et al., J Clin Endocrinol Metab. 2015 Apr;100(4):1278-88. doi: 10.1210/jc.2014-4326. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4399302/>
7. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32006R2023>
8. The term does not cover fixed public or private water supply equipment
9. [http://ec.europa.eu/food/food/chemicalsafety/foodcontact/emerging\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/emerging_en.htm) "This information will allow the European Commission to assess the efficiency and effectiveness of the current situation, including the benefits as well as the administrative burdens and costs of the existing situation on businesses. ... Thereafter, the Commission will evaluate the results and consider what, if any, possible steps need to be taken in the future concerning the regulation of food contact materials in the EU."
10. See <http://www.foodpackagingforum.org/food-packaging-health/phthalates>,
11. Commission Directive 2011/8/EU, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:026:0011:0014:EN:PDF>
12. See for example <http://www.foodproductiondaily.com/Safety-Regulation/Food-safety-trust-FCMs>; and Grob, K. 2014 Food Control 46 (312-318) "Work plans to get out of the dead lock..."
13. Article 19 of the plastics law stipulates that "any potential health risk in the final material or article arising from their use should be assessed by the manufacturer in accordance with internationally recognised scientific principles on risk assessment", but no specific guidance exists on how to do this.
14. The recent EFSA draft opinion seems to omit much of the recent science particularly on endocrine disruption. HEAL submission to EFSA public consultation, October 2015.
15. Food contact substances and chemicals of concern: a comparison of inventories. Geuke et al., Food Addit Contam Part A Chem Anal Control Expo Risk Assess. 2014; 31(8):1438-50. doi: 10.1080/19440049.2014.931600.
16. See Geuke et al 2014 as referenced in footnote above.
17. See Trasande et al, Estimating Burden and Disease Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union, J Clin Endocrinol Metab. 2015 Mar 5;jc20144324. <http://www.ncbi.nlm.nih.gov/pubmed/25742516>
18. 19 October 2015: Test: Unwanted chemicals found in pizza boxes <http://kemi.taenk.dk/bliv-groennere/test-unwanted-chemicals-found-pizza-boxes>
19. Mutual recognition is a system of market access for products that are not subject to 'harmonised' laws at EU level. It allows any product lawfully sold in one EU country to be sold in another, even if the product does not fully comply with the technical rules of the other country. See [http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/index\\_en.htm](http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/index_en.htm)
20. [http://ec.europa.eu/food/food/chemicalsafety/foodcontact/emerging\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/emerging_en.htm)
21. [http://ec.europa.eu/smart-regulation/roadmaps/docs/2015\\_sante\\_534\\_bpa\\_measure\\_en.pdf](http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_sante_534_bpa_measure_en.pdf)
22. [http://ec.europa.eu/smart-regulation/roadmaps/index\\_en.htm#fbform](http://ec.europa.eu/smart-regulation/roadmaps/index_en.htm#fbform)