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FOOD CONTACT MATERIALS AND CHEMICAL CONTAMINATION

There are multiple health concerns related to chemicals in food contact materials in Europe. This briefing looks at the current legislative system in the European Union for these materials and defines what is missing in the existing system and what 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, the current European Union (EU) legislation on food contact materials is not fully effective in protecting public health.

01 THE HEALTH PROBLEM

Currently, hazardous chemicals are present in plastics and other materials that come into 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 materials that come in contact with food 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. For example, chemicals are likely to leach into fatty liquids. A study on plastic food containers by the Danish Consumer Council project "THINK Chemicals" [2] showed that chemicals can migrate from the plastic walls of containers into warm fatty foods, such as gravy or lasagna.

Avoiding packaged foods containing harmful chemicals reduces human exposure. A study from the United States 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].

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.

02 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 [7].

Another law, on the authorisation of pesticides in the EU, directly prohibits three types of substances: endocrine disrupting chemicals (also known as hormone disruptors or EDCs), carcinogens and reproductive toxicants.

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

At least 58 chemicals that under REACH legislation are recognized as "Substances of Very High Concern" (SVHCs) are permitted in food contact materials.

Chemicals found in food contact materials:

A 2018 collaborative research project found that at least 148 substances present or used in the manufacturing of food packaging are hazardous to human health (63) and/or the environment (68) [3].

A 2015 Danish consumer test of pizza boxes made of recycled paper and board found fluorinated substances in all of the tested materials; along with mineral oils, phthalates, bisphenol A and nonylphenol also suspected to come from recycling material [4].

A 2016 EU JRC analysis of paper napkins found leaching carcinogenic primary aromatic amines from half of the tested items [5].

Further consumer tests of chemicals presence in fast food packages (2017) found fluorinated compounds at amounts exceeding the Danish recommended limit value in almost all of them and toxic chemicals in half of the sampled products (including chemicals listed as Substances of Very High Concern - SVHCs) [6].

0 3 ENDOCRINE DISRUPTING CHEMICALS

Of particular concern are endocrine disrupting chemicals (EDCs). Recent science has associated EDCs 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 is widely exposed to these chemicals from various sources, including food contact materials.

Contamination of food from just one EDC - Bisphenol A, known as BPA – has been estimated to be responsible for 12,404 cases of childhood obesity and 33,863 cases of newly incident coronary heart disease during 2008 [9].

Another study estimated that BPA in food contact materials and thermal paper was likely responsible for 42,400 obese 4-year-olds in Europe (with health costs of 1.54 billion euros per year) [10].

BPA is used to make certain plastics (polycarbonates) and coatings used on the insides of aluminum and metal cans, and the lids closures of glass jars and bottles. With the identification of BPA as toxic for reproduction and an endocrine disruptor for human health and the environment, other bisphenols are increasingly being used as a replacement. However, there is increasing scientific evidence that these might lead to irreversible and serious changes in organisms and that they might have endocrine disrupting properties too [11].

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:

- Potential to cause harm long after an exposure stops;
- Potential for harm at extremely small doses which are usually not tested;
- Potential for harm dependent on timing of exposure (life phase);
- Potential for harm in subsequent generations; and
- Potential for additive effects or cocktail effects (the combination creates a stronger effect) [8]

In a statement released in July 2018, the American Academy of Pediatrics warned against the effects of exposure to toxic chemicals – including EDCs - via food for children's health.

They are now calling for more rigorous testing and regulation of those substances [12].

Chemicals used for food packaging or manufacturing process that are flagged up for concern include:

- Bisphenols
- Phthalates
- Nonpersistent pesticides
- Perfluoroakyl chemicals (PFCs)
- Perchlorate

04 EXISTING EU LEGISLATION NEEDS REVISION

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

- EU Framework Regulation EC 1935/2004 [13]
- 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 [14].

There are 17 different types of food contact materials. These include plastics, metals, silicones, paper and board, but also less obvious materials such as printing inks, adhesives, and coatings used 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). 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 do not 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.

The 2016 European Parliament resolution on the implementation of the food contact materials regulation include the following:

- Food contact materials are a significant source of human exposure to chemicals of concern, including perfluorinated compounds (PFCs) and endocrine disrupting chemicals (EDCs). These have been linked to chronic diseases as well as reproductive problems, metabolic disorders, allergies and neurodevelopmental problems. The migration of these chemicals in food contact materials is of concern given their potential to cause harm even in extremely small doses;

- Increased effect on health that substances used in food contact materials can have on babies and young children are flagged up of particular concern;

- The current paradigm for evaluation of safety of food contact materials is deemed insufficient, with the role of food contact materials in food contamination being underestimated, and information on human exposure lacking.

The European Parliament is calling for the EU Commission to:

- Come forth with EU measures for paper and board, varnishes and coatings, metals and alloys, printing inks and adhesives;

- Extend the concept of vulnerable groups to pregnant and breastfeeding women and to include the potential effects of low-dose exposure and non- monotonic dose responses in the risk assessment criteria;

- Take into account the 'cocktail effect' or the effect of multiple concurrent and cumulative exposures from food contact materials and other sources;

- Ensure better coordination and a more coherent approach between the REACH and food contact materials legislation, in particular as regards substances classified as CMRs (categories 1A, 1B and 2) or SVHCs under REACH, and to ensure that harmful substances phased out under REACH are also phased out in FCMs;

- Consider identifying Bisphenol A (BPA) as one of the substances classified as an SVHC.

05 NATIONAL LAWS AND ACTION

Some EU Member States do have their own national rules for different 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. In 2016, Germany announced its intention to reviewing its legislation on inks in food packaging materials, but put the decision on hold in 2017 when the European Commission announced that it would come up with a measure to harmonize the regulation of printed food-contact materials with a priority for printed paper and paperboard [15].

As of today, the majority of EU Member States do not have specific legislation. The situation is such that the Joint Research Centre was asked to produce a “baseline” study by the European Commission. The review was published in 2016 and revealed significant loopholes and differences in the way Member States regulate food contact materials (e.g. through different approaches to risk assessment, risk management, or national controls).

The review also highlighted that inconsistencies between regulations are raising concerns for citizens’ health and the good functioning of the internal market - 13 out of 17 sectors are regulated at national level and depending on mutual recognition [16].

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.

The European Parliament has been a strong advocate of improved EU harmonized regulation to remedy the shortcomings exposed above. In 2016, it published a landmark implementation report on food contact materials, which led to a strong resolution adopted with a large majority support and highlighting the very concerns that HEAL and other public interest advocates have voiced for years as well as some of the inconsistencies pointed out in the review from the Joint Research Centre [17].

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 [18], although civil society groups have regretted that the 2018 restriction on the 4 phthalates DEHP, DBP, BBP, DIBP excludes food contact materials [19], while the majority of exposure to DEHP happens through food. The Commission banned the use of bisphenol A in baby bottles in 2011 [20] and recently lowered the permitted migration limit for BPA in coatings and varnishes used in FCMs - HEAL considers that it should have been fully banned [21].

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.

06 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.

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 [22].

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) [23] 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 [24].

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.

BOX: WHICH MATERIALS ARE REGULATED?

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

Regulated:

- Ceramics
- Regenerated Cellulose Film
- Active & Intelligent Materials
- Plastics
- Recycled Plastics

Not regulated:

- Cork
- Adhesives
- Silicones
- Elastomers and Rubbers
- Metal and Alloys
- Ion Exchange Resins
- Wood
- Textiles
- Waxes

Not regulated, high priority:

- Paper and Board
- Varnishes and Coatings
- Printing Inks

HARMFUL CHEMICALS ARE OVERLOOKED: Some 58 chemicals that under REACH legislation are recognized as “Substances of Very High Concern” (SVHCs) are permitted in food contact materials [25]. 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 food contact materials 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. For materials for which migration limits exist, actions to revise them as scientific knowledge expands, is overdue. This is notably the case for those relating to toxic lead and cadmium from ceramic food packaging, which were due by 1987 and for which the European Commission only launched a public consultation for doing so in May 2019 [26].

ENDOCRINE DISRUPTING CHEMICALS ARE NOT ADDRESSED: Endocrine disrupting chemicals are currently permitted and used in food contact materials in the EU [27]. 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 [28].

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 [29].

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' [30] 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.

07 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. The 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. This includes 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.

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.

Five key principles for a health-protective regulation of food contact materials

In April 2019, civil society groups published five joint principles for a health-protective overhaul of the EU regulation on food contact materials that should guide EU's actions in the context of the ongoing evaluation [31].

A high level of protection of human health
A thorough assessment of chemicals in materials and articles
Effective enforcement
A clean circular economy based on non-toxic material cycles
Transparency and participation

08 POLICY OPPORTUNITIES

1 EUROPEAN COMMISSION EVALUATION OF THE FRAMEWORK LEGISLATION ON FOOD CONTACT MATERIALS REGULATION:

The European Commission has finally committed to launch an evaluation of the legislation, following years of civil society ringing alarm bells about the existing safety loops and building on the findings of the 2016 European Parliament report as well as Joint Research Centre (JRC) review that confirm these gaps. A roadmap for the evaluation was put forward for public consultation at the end of 2017, followed by an invitation to contribute to a public survey supposed to serve as a basis for the formal evaluation (May 2019). HEAL has used both opportunities to highlight our longtime concerns and proposals for improvement, although we regret that health protection still does not appear to be central to this review exercise [32]. According to the European Commission, building on consultations with and input from stakeholders, the outcome of the evaluation should be published by early 2020 [33]. We urge the European Commission to take our concerns into account and invite the newly elected European Parliament to scrutinize the process against the demands outlined in the 2016 resolution.

2 UPCOMING REVISION OF THE EU STRATEGY ON ENDOCRINE DISRUPTORS:

Exposure to endocrine disruptors through food contact materials is of increasing concerns among civil society groups, scientists and decision- makers alike. As illustrated by the European Parliament 2016 resolution on the implementation of the FCM regulation and the 2019 resolution on EDCs [34], national initiatives to regulate known EDCs such as BPA in food contact materials, or declarations by the European Commission [35] and the Council [36], endocrine disruptors are currently not properly addressed in food contact materials. The announced review of the EU strategy on endocrine disruptors – of which launch date remains unknown at the time of writing – is an opportunity to fix this loophole. We urge the European Commission to commit to addressing EDC regulation in FCM as part of this review and the Council and Parliament to scrutinize the process closely.

3 UPCOMING PUBLICATION OF THE OUTCOME OF THE 'REFIT' OF ALL NON- REACH CHEMICALS LEGISLATION:

Chemicals in food contact materials were included in the European Commissions' 'REFIT' work on chemicals legislation (except the REACH regulation). The publication of the outcomes of this REFIT were expected by end of June 2019 but it keeps being postponed. Here also scrutiny of the new European Parliament when it comes to implementing potential recommendations for future improvements and demands for better safety controls to eliminate the gaps between REACH, pesticides and food contact laws will be important.

4 EXPECTED LEGISLATION ON PRINTED FOOD CONTACT MATERIALS:

The European Commission is said to have initiated work for harmonized legislation on printed food contact materials since 2017 [37]. However to date, only industry stakeholders have been consulted, and the milestones announced by the Commission have not been met. No further details other than potential options based on those preliminary consultations have been released. We urge the European Commission to come forth with a transparent plan of action and a timetable for the development of the proposal for such legislation and we call on the European Parliament to ensure progress is made.

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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. www.env-health.org

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NOTES:

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19. https://www.chemtrust.org/wp-content/uploads/eeb-chemtrust-letter-reachcommittee-phthalates-july18.pdf ; http://ec.europa.eu/growth/sectors/chemicals/reach/restrictions_en
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23. 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.
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