



**CHEMTrust**

Protecting humans and wildlife  
from harmful chemicals

# Policy Briefing

## Chemicals in food contact materials: A gap in the internal market, a failure in public protection

### 1 Executive summary

Food packaging, factory equipment, food utensils - almost everything we eat has been in contact with one or more of these items. The EU's laws should ensure that chemicals used in these materials are safe, but they do not go far enough and contain holes.

These holes – for example a lack of harmonised rules on paper and card, inks, coatings and adhesives – mean that public health is not properly protected, and also lead to disruption of the internal market.

This briefing outlines the key problems, and proposes some solutions.

#### 1.1 Key problems and recommendations:



**For many food contact materials - including paper, board, coatings, inks and glues – there is no harmonised EU legislation on the chemicals that can be used. There are harmonised rules on food contact plastics and some other materials.**

- There is also no obligation to assess the health impacts of uses in food contact materials in the EU's main chemicals legislation REACH.
- Research has found that chemicals identified as being of very high concern (SVHCs) in REACH are used in food contact materials.
- Public health is not being effectively protected.



**Regulation of chemicals in non-harmonised materials is dependant on national legislation. This is inefficient and disrupts the EU's internal market.**

- It's estimated that more than 5000 chemicals are used in inks, and Germany is working on an inks ordinance. If Germany bans inks used in other EU countries, how will this affect the internal market in food products?



**In addition to thousands of deliberately used chemicals, a wide range of other chemicals migrates into food from food contact materials.**

- These 'Non Intentionally Added Substances' (NIAS) come from impurities in chemicals, and reaction and degradation products. They are often of unknown structure, and can be at levels far higher than pesticide residues.
- NIAS add to the complexity of the mixture of chemicals we are exposed to, and need to be addressed with urgency.

**It's clear that the current situation is not tenable, either for public health or for the food industry. The European Commission – led by DG Santé – must now work on a harmonised system, that will provide a high level of protection for human health, and also facilitate the effective working of the internal market.**

**Without a new approach the risks to public confidence in Europe's food system and food manufacturers are high. There is no scientific justification for inaction in this area.**

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## 2 Introduction

Our food comes into contact with a whole range of food contact materials made from industrial chemicals, from food packaging to pipes. These materials are made up of thousands of different chemicals, some of which may migrate into food, or may react to form other chemicals that may migrate into food.

The EU has laws to control the use of chemicals, in particular REACH as the main law for industrial chemicals. However, most aspects of the regulation of chemicals in food contact materials are handled by specific food contact regulations. These regulations are incomplete for many food contact materials, and largely ignore some key issues. This means that for many materials – such as paper, card, ink and coatings – controls are mainly from legislation in individual Member States

The lack of effective EU regulation creates risks to public health, uncertainties for manufacturers and retailers, threatens the development of a circular economy and could lead to major disruption of the EU's internal market.

There is increasing discussion about the need for harmonised, effective, EU regulations on chemicals for all food contact materials. However, to date, there has been no commitment from the European Commission to ensure that this will happen.

This briefing examines some of the key issues.

## 3 How the EU regulates chemicals in food contact materials

The EU's main REACH chemicals legislation exempts consideration of the human health impacts of use of chemicals in food contact materials from chemical safety reports and from authorisation. These aspects are instead addressed by a 2004 regulation "*on materials and articles intended to come into contact with food*" [1].

This regulation created a general safety requirement for packaging and other items that come into contact with food (e.g. tubes and other factory equipment):

*"Materials and articles, ... shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:*  
*(a) endanger human health;..."*

This law also puts in place a process for more comprehensive EU regulation of different food contact materials, including an authorisation process for chemicals, limits on impurities etc. Some food contact materials are covered by this EU harmonised approach, with the most substantial being the 2011 regulation "*on plastic materials and articles intended to come into contact with food*" [2].

However, there are still no EU-wide specific rules covering chemicals in important food contact materials such as paper, card, ink, coatings & adhesives. Individual countries will have some regulations, but these vary in terms of their scope and level of protection.

Note that the use of individual chemicals in all food contact can be controlled at EU level, either through a REACH restriction (which can include food contact uses, unlike REACH authorisation), or by setting specific migration limits, as is being proposed in the Commission's roadmap on bisphenol A in food contact materials. [3]

The European Food Safety Authority (EFSA) held a workshop on chemicals in food contact packaging in November 2014, and their summary of this workshop [4] confirms the weakness of the current regulatory system in Europe and the lack of knowledge about the chemicals used:

*"Did you know that plastics and some ceramics used in food contact materials are regulated at European level and evaluated by EFSA for safety but a wide*

*range of other materials – coatings, paper and board, adhesives, printing inks and rubber – are not? Small traces of these materials used in packaging, containers, cutlery and other articles can enter food and may pose a potential health risk to consumers. However, there is a lack of detailed science information about many of the substances found in these materials that makes this area of food safety particularly challenging.”*

One of the main purposes of regulation 1935/2004 on food contact materials and articles is “securing a high level of protection of human health and the interests of consumers”. In CHEM Trust’s view this purpose is not being achieved. The following section gives some examples.

## 4 Areas of concern to health

This section looks at the following issues of health concern:

- A lack of adequate regulation for chemicals used in many food contact uses.
- The uncomfortable reality that a large number of other chemicals are found to migrate from food contact materials into food or food simulants. These are made up of oligomers [short chain polymers], reaction products and impurities (ORPIs), though they are often called ‘Non Intentionally Added Substances’ (NIAS).
- The fact that we are exposed to mixtures of chemicals, and to chemicals from multiple sources, yet risk assessments tend to ignore the first and often don’t adequately consider the second.
- Problems created by lack of consideration of the impacts of a circular economy, and an inconsistent approach to the safety implications of using food contact materials made from recycled products.
- A continued use of a number of chemicals of particular concern, such as persistent chemicals and endocrine disrupters.

### 4.1 Lack of adequate regulation for chemicals in many food contact materials

Around 1000 chemicals have been authorised by the regulatory process for chemicals in food contact plastics. However, this list is not problem-free as it includes substances that have hormone-disrupting properties [5].

Hormone (or endocrine) disrupting chemicals (EDCs) interfere with the delicate hormone system in our bodies and have been associated with a number of hormone related diseases; these chemicals are a key cause of concern for CHEM Trust. For more information, see our Hormone Disrupting Chemicals FAQ:

- [www.chemtrust.org.uk/what-are-hormone-disrupting-chemicals-or-endocrine-disrupting-chemicals-edcs/](http://www.chemtrust.org.uk/what-are-hormone-disrupting-chemicals-or-endocrine-disrupting-chemicals-edcs/)

Many more chemicals are used in non-harmonised food contact materials, for which there is no EU-wide authorisation list.

An 2012 analysis for EFSA identified 2800 substances used in the manufacture of paper and board, printing inks, coatings, rubber, colorants, wood and cork [6]. This analysis also points out:

*“These materials are not covered by a specific regulation and thousands of substances used to manufacture them have not been evaluated for their safety at the EU level”*

Other sources have estimated that more than 5000 chemicals may be used in inks alone [7].

## 4.2 Oligomers, Reaction Products & Impurities or NIAS

In addition to the chemicals that are deliberately used to make food contact materials, research has shown that a large number of other chemicals will migrate from food contact materials into food or food simulants (a material that is analytically simpler than food, though should have similar properties). These chemicals come from the following sources:

- Non-intentionally added Oligomers (short chain polymers)
- Reaction products
- Impurities

These can be abbreviated to ORPIs, though they are more often called 'Non Intentionally Added Substances' or NIAS. They are most commonly identified by placing a food simulant in contact with the food contact material, then analysing what has migrated.

NIAS can make up the majority of the substances migrating from plastic food contact materials, and in many cases the structure and identity of these migrating chemicals is not known [8].

Research has found 97% of the material migrating from can linings can be NIAS, generally of unknown structure [9].

Clearly it is hard to assess the hazard of such unknown chemicals. Even when the structures of NIAS are established, the industry-funded 'International Life Science Institute' admits that it's frequently hard to find toxicity data for these chemicals [10, page 40]:

*"It is frequently the case that limited or no toxicity data are available for the detected and identified NIAS, making hazard identification and characterisation very challenging."*

One simplified method of trying to address the toxicity of known chemicals is 'Threshold of Toxicological Concern' (TTC), but there are big problems with this approach. CHEM Trust has recently responded to an EFSA consultation on a revision of its approach to risk assessing chemicals in food contact materials, and we expressed serious concerns about the way that EFSA was proposing to use TTC to address NIAS, even the structure of a chemical was not known: [11]

*"EFSA needs to acknowledge the scale of the scientific challenges created by chemicals in food contact materials, including high levels of NIAS migrating into food. They must not try to brush them under the carpet by pretending that techniques such as Threshold for Toxicological Concern have a magic ability to create an accurate scientific answer as to the toxicity of an unknown or poorly understood substance."*

The reality of NIAS makes it hard to see how companies can really demonstrate that they are reaching the necessary safety standard for food contact packaging, i.e.:

*"Under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:  
(a) endanger human health;..."*

It has therefore been argued that it is not actually possible for industry to demonstrate compliance with this requirement in most cases, e.g. see [8] and [41].

## 4.3 The importance of addressing exposure to mixtures and multiple sources of chemicals

Risk assessment of chemicals tends to look one chemical at a time, and sometimes only looks at one route of exposure at a time – e.g. BPA from food can linings vs from dust vs from till receipts. Fortunately, EFSA's most recent assessment of the risks of BPA did attempt to

calculate the aggregated exposure, though they then misreported the results of this analysis [12].

In the real world, people are exposed to multiple chemicals, from multiple sources. The NIAS issue makes this particularly obvious. This reality cannot be ignored by regulators, as CHEM Trust pointed out in our response to the EFSA consultation, mentioned above [11]:

*“In addition, given that mixtures of migrating chemicals are the norm, not the exception, EFSA should be addressing the cumulative effects from combined exposures and the need to develop a cumulative risk assessment approach as an important part of this scientific opinion.”*

#### **4.4 Impacts on the circular economy**

The Commission has argued in its Circular Economy Action Plan that the EU should be aiming for “*non toxic material cycles*”. CHEM Trust supports this objective [13]. Looking at the food contact area, there are two notable problems achieving this aspiration:

##### **4.4.1 Lack of control of the chemicals going into recycled products**

Without adequate regulation of the chemicals going into food contact materials, including packaging, there is a risk that chemicals are being put in these materials which will contaminate recycling processes. For example, there are currently no automatic controls on chemicals identified as substances of very high concern in REACH, and the REACH authorisation process cannot address human health aspects of food contact uses.

One contradictory aspect of the current regulatory situation is that the EU is encouraging the recycling of packaging through binding recycling targets, but isn't properly controlling the chemical use in this packaging in order to ensure that recycling itself or the recycled products don't cause problems.

##### **4.4.2 Inconsistent and inadequate regulation of the quality of food contact materials made from recycled material**

A side effect of the inconsistent regulatory approach to different materials in food contact applications is a major difference in the way recycled plastic and recycled paper/card packaging is dealt with.

- In the case of plastic recycling processes, an EFSA committee assesses their safety [e.g. see 14]
- In the case of food contact materials made from paper and card there is essentially minimal regulatory oversight.

It is clear that this lack of oversight of paper and card materials is causing problems – see examples below. However, without proper regulatory controls we don't really know the scale of this problem.

##### ***EDCs and PFCs in Danish paper and board packaging***

A Danish study found that paper and board packaging contained the EDCs bisphenol A (BPA), phthalates, a range of PFCs – and two new chemicals with endocrine disrupting potential. [15]

##### ***Chemicals in Pizza boxes***

The Danish Consumer Council examined pizza boxes, and found the EDCs BPA, nonylphenol and phthalates [16]. They also found persistent perfluorocarbons (PFCs). They suggest that the chemicals are there due to the use of recycled card in the box.

##### ***Mineral oils in cereal, rice and pasta***

Food Watch in Germany has started a campaign about the migration of mineral oils from cardboard packaging into food. Their testing found mineral oils in rice, pasta and cornflakes [17], probably due to the use of recycled paper, with mineral oils coming from newspaper inks

and other sources. Food Watch is calling a compulsory barrier between the food and the cardboard to prevent this migration.

#### 4.5 Example chemicals of concern

As outlined above, there are many thousands of chemicals used in food contact materials, and beyond this, there are also the non-intentionally added substances, which are even less understood.

Below we outline some concerns with three groups of chemicals – the PFCs, phthalates and bisphenols – as examples of the sort of chemicals that are used deliberately in, or have been found to contaminate, food contact materials.

##### 4.5.1 PFCs

Perfluorinated compounds (PFCs) are a group of man-made chemicals that include perfluoroalkyl sulfonates (PFAS) and long-chain perfluoroalkyl carboxylates (PFAC). They have been produced and used in consumer products for more than 60 years and are used in the manufacture of a vast array of products such as non-stick cookware, water resistant clothing, flame-retardants and stain resistant textiles. PFCs are also widely used in non-plastic food packaging for their grease-proofing properties most notably they're often used in takeaway pizza boxes and microwave popcorn bags [18]. They have been found to contaminate food via food packaging [19].

Despite the useful properties of PFCs, they are highly persistent, degrading very slowly – if at all – in the environment and are known to accumulate up the food chain. Due to the wide variety of PFC applications, their persistence and bio-accumulating properties, PFCs are found in human tissue and wildlife species all over the globe.

Research looking at the levels of PFCs in children in the Faroe isles has found that those exposed to higher levels of PFCs have a lower immune response to routine childhood vaccinations such as tetanus and diphtheria [20].

A recent peer reviewed statement on the effects of PFCs, found that in animal studies PFCs have been found to cause liver toxicity, disruption of lipid metabolism, affecting the immune and endocrine systems, adverse neurobehavioral effects, neonatal toxicity and death, and tumours in multiple organ systems. Other evidence showed associations with testicular and kidney cancers, liver malfunction, hypothyroidism, high cholesterol, ulcerative colitis, lower birth weight and size, obesity, decreased immune response to vaccines, and reduced hormone levels and delayed puberty [21].

The European Food Safety Authority (EFSA) has compiled an inventory of chemicals used for non-plastic food contact materials in all EU member states and their national legislations in which a total of 16 PFCs were listed, though this inventory provides no legally binding regulations [6].

The lack of legally binding regulations on PFCs in non-plastic food contact materials in the EU has led to one European business taking the lack of regulation into their own hands. Co-op in Denmark identified that all the microwaveable popcorn available from suppliers contained PFCs in the packaging. They therefore decided to remove this product from their shelves in May 2015, stating that the links between PFCs and miscarriage were of primary concern [22].

Since this move, the Danish Government announced new advisory (i.e. non binding) controls on PFCs, which if followed would prevent the use of PFCs in paper and card packaging [23].

One piece of good news is that a supplier has come up with a PFC-free alternative, and the Co-op in Denmark is now re-introducing microwave popcorn to their shelves [24].

The US FDA has also recently announced a ban on food contact uses of three classes of long-chain perfluorinated compounds [25].

### 4.5.2 Phthalates

Phthalates are a group of man-made chemicals that are used in a variety of consumer products, including food packaging. For certain phthalates (DEHP, DBP and DIBP) food is thought to be the main exposure source due to phthalates migrating from packaging into food [26].

In one study, 9 out of 29 food-packaging samples (31%) were shown to be non-compliant with EU regulations [26]. Another study has suggested that food packaging is a key way that children are exposed to high levels of phthalates [27]. In a recent study phthalates have been found in pizza boxes and sandwich wrapper packaging [28].

Many phthalates are EDCs, and are known to be developmental and reproductive toxicants. There are indications that phthalates may impact genital development, semen quality, libido, [29] children's neurodevelopment, male genital development [30] thyroid function, onset of puberty in females and that they could possibly cause respiratory problems [27].

A EU based biomonitoring study found different levels of different types of phthalates in the urine and hair of 3,688 Europeans, with children having higher levels than adults. DEHP, for example, is found at levels of 47.6 micrograms ( $\mu\text{g}$ )/litre (L) in children and 29.2  $\mu\text{g/L}$  in adults [31].

Since July 2008 the European Commission has limited the use of phthalates in food contact materials made of plastic [26].

### 4.5.3 Bisphenols

#### *Bisphenol A*

Bisphenol A (BPA) is used in the manufacture of clear polycarbonate plastic, and to manufacture other plastics, including plastic tableware, thermal paper (till receipts), and linings on tin cans [26]. It can also be found in food contact packaging and in a 2015 Danish study, researchers found BPA present in pizza boxes and sandwich wrappers.

BPA is an EDC and mimics the female hormone estrogen, a fact that has been known since the 1930s [32]. The health effects linked with exposure to BPA include: breast cancer, prostate cancer, endometriosis, heart disease, obesity, diabetes, altered immune system and effects on reproduction, brain development and behaviour, including behaviour in children [33].

The French government has proposed an EU-wide ban on BPA use in thermal (receipt) paper, and the European Chemical Agency's Risk Assessment Committee has agreed that it poses health risks to workers [34]. In 2011 the EU banned BPA from baby bottles and sippy cups [35].

#### *Bisphenol S and Bisphenol F*

Increasing concern over BPA as an endocrine disrupting chemical, and its possible effects on human health, has prompted the use of chemical replacements. Bisphenol S (BPS) and bisphenol F (BPF) are two such substitutes. Much like BPA, BPS and BPF are plastics used in food contact packaging like cans and plastic bottles.

Despite being initially proposed as a "safer" alternative to BPA, studies are starting to show this is probably not the case. In a recent systematic review, all current literature on BPS and BPF were analysed, finding that both BPS and BPF had endocrine disrupting properties. The study concluded that they were as hormonally active as BPA [36].

## 5 Business impacts of the current approach

In addition to the lack of public protection that occurs due to different levels of regulation in different Member States, there are also business impacts.

The Luxembourg presidency of the EU held a conference on food contact materials on 30th September 2015. The official notes from the event make it clear that many industry speakers at this event wanted more EU-level regulatory harmonisation: [37]

*“There was overall agreement that a greater degree of harmonisation of the rules on the FCM sector was desirable at EU level, although there is currently no clear way forward on how to achieve this.”*

*“For industry, harmonised rules at EU-level were clearly preferable. It was stated that divergent MS rules and risk assessments would hinder rather than foster the functioning of the internal market.”*

Business impacts occur due to a number of reasons:

### **5.1 The lack of an effective regulatory system makes it hard for businesses – of any size – to ensure that their packaging is really safe.**

Even a company the size of Nestlé finds the current system problematic. They have previously been affected by unexpected migration of ink components into baby milk in Italy [38], which caused them a great deal of problems.

It is difficult to see how SMEs can address these issues effectively when major multinationals find them problematic.

### **5.2 Regulations adopted at a national level have a potential to block trade in food products within the EU**

Given the clear lack of public protection due to lack of EU harmonisation of controls on many materials, it is hardly surprising that some Member States are putting in place their own regulations.

One example is the ‘inks ordinance’ that the German government is preparing, which will restrict the inks that can be used in food contact applications [39]:

*“The German Ordinance will become the de facto European standard,” says Janice Robinson, director of product regulations at the European Printing Inks Association (EuPIA). “We prefer to see European legislation specifically on the whole issue of food packaging safety. We don’t like the idea of having to work with a variety of national legislations, which makes the free movement of goods within the EU difficult.”*

### **5.3 Potentially unsuitable regulations may be adopted for materials at a national level, based on the EU harmonised regulations for plastics.**

A large number of trade associations representing non-harmonised food contact materials have come together to express their concern that test methods from the regulation on food contact plastics are being used for other materials: [40]

*“In the Plastics Regulation (10/2011) and supporting documentation, i.e. Migration Guidelines, some of the simulants, times and temperatures are inappropriate for non-harmonised FCMs (Food Contact Materials)*

*In the absence of harmonised regulations the conditions used in the Plastics Regulation are often applied to non-plastics.*

*National Regulations for non-harmonised FCMs are tending to adopt the conditions in 10/2011 – example proposed coating regulations for both Netherlands and Belgium”*

## **6 What should be done?**

In CHEM Trust’s view it is important to set an objective of a fully harmonised system for regulating the use of chemicals in food contact materials. This system should aim to achieve a high level of protection of human health, based on a precautionary approach.

Key elements of this new system should include:

- More effective integration with REACH, including improving data flows.
- A presumption against SVHCs and EDCs in food contact materials, with a system that leads to substitution of hazardous substances when safer alternatives are available.
- Full harmonisation, with a clear timeline put in place for all food contact materials to be covered, and interim systems to deal with any phase in period (for example an extension of chemical safety reports).
- Characterisation of ORPI/NIAS, along with efforts to reduce their levels and effective, precautionary, risk assessment of NIAS.
- An obligation on industry to provide analytical standards for all intentionally used chemicals, in order to make it easier to characterise ORPI/NIAS.
- Improving awareness among businesses, particularly SMEs, and providing clear guidance. This should be backed up by systematic monitoring and enforcement by authorities.

Please note that these are some initial ideas and we are open to discussions on this issue.

Others have also made suggestions for improvement, for example Koni Grob [41], of the Official Food Control Authority of the Canton of Zurich, Switzerland, who is an expert on analysis of ORPI/NIAS.

## 7 Where are we now?

### 7.1 A lack of enthusiasm for reform from the European Commission?

Chemical Watch's coverage [42] of the Luxembourg presidency event in September 2015 quotes the Acting Director of DG Santé's 'Safety of the Food Chain' Directorate, Dr Michael Flueh:

*"Only for plastics is there substantial harmonisation across the EU, Dr Flueh said, and he implied this represents the limit of what the Commission has the resources to achieve. "The rules for plastic are complex. This is where we have evaluated 1,000 substances. How much time would it take to evaluate 10,000 more?"*

*"Commission President Juncker wants us to focus on the big things, such as modernising and simplifying regulation. The Commission has less and less resources every year. Mutual recognition is the pillar of the single market and we aim to improve mutual recognition rather than engage in further harmonisation."*

It's worth noting that no-one really knows what 'mutual recognition' would mean in this case. For example, Switzerland has rules on ink in food packaging already in place, while Germany has rules under discussion. Would mutual recognition mean that the rest of the EU would rely on the Swiss or Germans to make and amend the rules? Or would Germany have to accept packaging that breaks its rules?

CHEM Trust wrote to the then Health Commissioner Tonio Borg in July 2014 raising many of the issues in this briefing [43]. We were informed that the Commission's Joint Research Centre were doing a study reviewing what was the situation for the non-harmonised materials in different Member States. We eventually managed to get the terms of reference of this study from DG Santé, by threatening to use the 'access to documents' procedure [44]; the study is due to be complete in early 2016.

However, at the start of 2016 DG Santé moved the chemicals in food contact materials team into a new "Food processing technologies and novel foods" unit. CHEM Trust hopes that this signals a more proactive approach from the Commission in this area.

## 7.2 An EU Parliament inquiry

The European Parliament's Committee on Environment, Public Health and Food Safety have decided to investigate the implementation of the EU's regulations on chemicals in food contact materials.

This investigation, led by the Danish MEP Christel Schaldemose, will be an excellent opportunity to examine the failures of this regulatory system, and recommend improvements.

## 8 Conclusions

The issues around chemical use in food contact materials have not been getting the attention they deserve. Many chemical experts have not been aware of the problems in this regulatory system, as they work on industrial chemicals for environment ministries, working mainly with REACH.

It is quite clear that the current situation is not tenable. There is no scientific justification for not having harmonised regulation of chemicals in food contact paper, card, inks, adhesives and coatings. There is no scientific justification for regulating recycled plastics in food contact applications but not regulating recycled paper and card in the same applications.

It does not make sense to have a situation where the identification of a chemical as being of very high concern under REACH has no regulatory impact on the use of this chemical in food contact. It also makes no sense for those selling chemicals to have to communicate how the human health risks of use can be 'adequately controlled' for uses other than in food contact, yet for the food contact rules to have no equivalent (or more demanding) safety assessment for use in many food contact materials.

If the wider public knew about the deficiencies in this regulatory system, they would be shocked. It is the responsibility of everyone in this field to sort out this unacceptable situation.

### 8.1 For more information

- Relevant stories on the CHEM Trust blog:
  - <http://www.chemtrust.org.uk/tag/packaging/>
- The Food Packaging Forum has in-depth analysis of latest scientific findings and EU regulations around chemicals in food contact packaging:
  - <http://www.foodpackagingforum.org>

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We intend to update this briefing when appropriate, the latest version will be at: <http://www.chemtrust.org.uk/foodcontact/>

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