

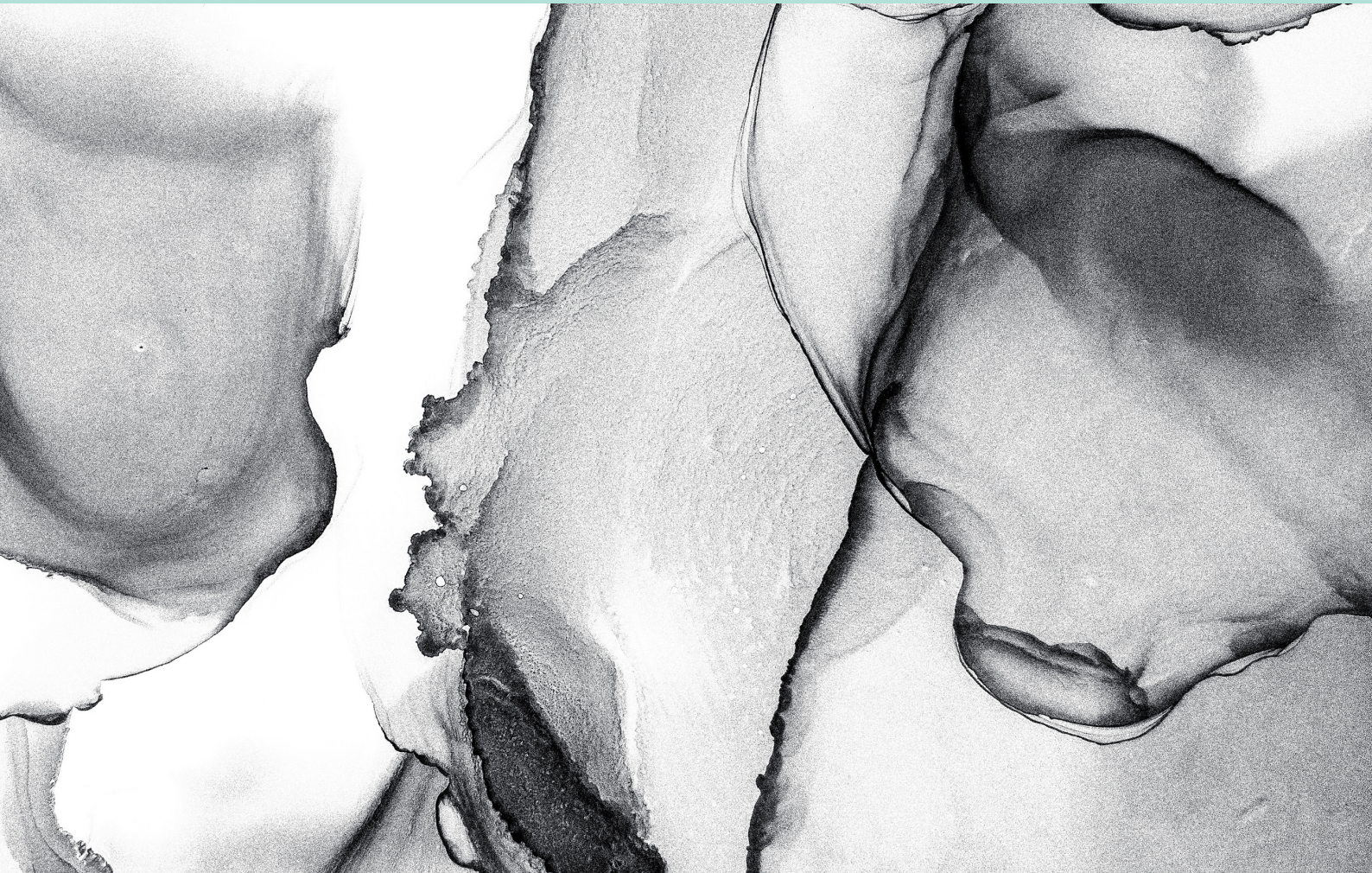


Netherlands Institute  
for Sustainable Packaging

**FACT SHEET**

# **NIAS – Non-intentionally added substances in packaging**

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PART OF THE DOSSIER ON FOOD SAFETY

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# NIAS – Non-intentionally added substances in packaging

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Food packaging may contain substances that have not been added intentionally and may pose a food safety risk. These substances are often referred to as NIAS, or non-intentionally added substances. Non-Intentionally Added Substances were included in the Plastics Regulation (10/2011) of the European Commission in 2011 (1). Since then, the Member States of the European Union have paid more and more attention to these substances, because they can migrate into the packaged food.

In legislation, food packaging is referred to as food contact materials. In the Netherlands, the National Institute for Public Health and the Environment (RIVM) advises the Ministry of Health, Welfare and Sport on the authorization of substances in food contact materials. RIVM has a central role in the Netherlands in preparing the substance assessments (2). Compliance with this is monitored in the Netherlands by the Netherlands Food and Consumer Product Safety Authority (NVWA). The NIAS should be included in the risk assessment to determine whether a food contact material is suitable for its intended use.

In this fact sheet, KIDV provides more information about the origin of these substances and the possible risks for food safety.

## Description

Non-intentionally added substances can end up in packaging materials in several ways. In order to better understand and assess the origin of these substances, the group can be divided into three categories:

### 1. By-products

Packaging materials are often composed of different types of materials that are produced and

combined in separate steps. Reactions can occur during the production of the raw materials, but also in all further stages of production. This may result in by-products, which eventually end up in the packaging material.

An example of such a by-product arises during the production of multi-layer glued plastics. Adhesives are used for gluing the different layers. Certain chemicals in these adhesives can cause a reaction during the process that creates chemical compounds. These chemical compounds, for example primary aromatic amines, are by-products (3). Within the group of primary aromatic amines are a number of substances that are considered to be potentially carcinogenic to humans (4).

## 2. Degradation products

Additives used during the production of packaging materials can form degradation products, for example because of chemical reactions. The formation of these degradation products can be caused by several factors, such as radiation and heat treatment and contact with food and/or oxygen. The degradation products remain in the material and may migrate to the food.

For example, degradation products are formed when using UV hardening inks (5). These inks contain substances that are intended to ensure that the inks on the substrate harden during the UV treatment (6). However, the hardening agents are not always fully utilized or removed after the hardening process. As a result, possible decomposition products remain on the surface.

## 3. Contamination

Contamination of packaging materials can have various causes. The contamination can occur at any stage of production and final use. For example, contaminants can arise from impurities in used raw materials, such as the presence of heavy metals or other environmental contaminants. The raw material silica sand for glass production, for example, contains lead (3).

Another possible source of contamination from unintentionally added substances is the use of recycled materials. The recycling streams contain non-food materials, which can introduce unwanted substances into the recycled product. Examples of this are mineral oils, originating from printing inks from recycled cardboard.

Furthermore, contaminants can enter the product during the production process of packaging materials. For example, incorrect use of cleaning and/or lubricants or of residues of substances left behind from previous productions.

Based on the above description, the contaminants can be divided into two groups:

1. Contaminants from a process, such as lubricants and contaminants during storage. These substances are known, but the amount of contamination is unknown.
2. Unknown and unpredictable environmental contaminants. These substances are unknown and the amount of contamination is also unknown.

## **NIAS in different types of packaging materials**

Non-intentionally added substances have no specific application in food packaging materials. However, unintentionally added substances do occur in all different types of material. Here are some examples:

### Plastics

Additives used in the manufacture of plastics may contain unexpected impurities. These impurities can be present in the final plastics as a by-product or degradation product. A great deal of knowledge is already available about some additives and their degradation products; these degradation products are even included in EU-legislation. In other cases, there are so many by-products or breakdown products that it is not possible to identify them all (5).

### Metal and glass

Heavy metals are a potential risk for packaging materials made of metal and glass. The metals are present in the raw material and thus end up in the final packaging material (5).

### Paper and cardboard

When using recycled materials, contamination can occur because non-food materials may be used in the recycling process. A known contaminant is mineral oils from inks, but also substances such as PCBs (polychlorinated biphenyls) and artificial dyes with primary aromatic amines.

Paper and cardboard that do not include recycled materials may also contain unintentionally added substances. These are possible by-products or degradation products that arise when printing or gluing the paper and cardboard (7).

## **Risks**

The risk of non-intentionally added substances on food safety depends on the substance in question. The possible risks can only be determined per individual substance by means of a risk analysis. The following steps are followed (5):

1. Determining potentially present non-intentionally added substances

2. Hazard identification: conducting an evaluation of the negative health effects caused by a chemical. A possible source for this is studies from the European Food Safety Authority (EFSA) on substances.
3. Hazard Characterization: determining how much of a chemical will lead to a toxic effect.
4. Exposure assessment: determining exposure to a chemical by the consumer, for example through migration from packaging to food.
5. Risk determination: determining the risk based on the above relevant information.

## Migration

The release of components of the packaging material into foods is called migration. The amount that is allowed to migrate from the material to the food is (possibly) defined in migration limits. These migration limits are included in European legislation. The migration limits are based on risk assessments issued by EFSA, based on available literature. For some Non-Intentionally Added Substances, migration limits are included in the legislation. This is the case, for example, with known degradation products resulting from the production of plastics. Migration limits are set both in the European plastics regulation 10/2011 (1) as in the national Commodities Act on packaging and consumer articles (8).

## Legislation

All food packaging materials must meet the safety requirements for materials and articles intended to come into contact with food (9). These are written down in Article 3 of European Regulation (EC) No. 1935/2004. Non-Intentionally Added Substances may also not pose a risk to human health and must therefore also comply with Article 3.

As indicated in the 'Migration' paragraph, limits for non-intentionally added substances have been included in the European Plastics Regulation. However, due to the large number of by-products and degradation products, it is not possible to authorize and include all these substances in Annex 1 of the European Plastics Regulation (1). Article 19 states that for substances not included in Annex 1, a risk assessment must be carried out on the basis of internationally recognized scientific principles.

## Control measures

Conducting the risk assessment and implementing control measures on Non-Intentionally Added Substances is the responsibility of the manufacturer of the packaging materials. Important by-

products and degradation products are known from many processes. Such Non-Intentionally Added Substances can be easily controlled; its formation can even be reduced by changing the process parameters.

A manufacturer that produces packaging materials must comply with the requirements of Regulation (EU) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food (10). Manufacturing in accordance with GMP ensures consistent production and control, to achieve compliance with safety and quality requirements. GMP pays attention to the selection and assessment of raw materials and to performing a risk analysis on processes. The Non-Intentionally Added Substances must be considered here. Procedures and work instructions are established to prevent or reduce the possible formation of by-products, degradation products and contaminants.

As a buyer of packaging materials, it is important to purchase from reliable suppliers. These suppliers indicate that they work in accordance with the GMP regulation (2023/2006). Purchasing from a supplier that is certified according to the food safety standard focused on packaging materials (such as BRCGS packaging (11) or IFS Pack secure (12)) may provide additional certainty. These standards contain requirements regarding risk analyses and the use of cleaning agents and lubricants.

## Finally

KIDV has drawn up this fact sheet in collaboration with Riskplaza. Riskplaza is a database with information on the food safety of ingredients, as well as measures to control food safety hazards.

The greatest possible care has been taken in compiling the text; see also the appendix for the sources consulted. No rights can be derived from the texts.

If you still have questions after reading the fact sheet, please ask them in the [questionnaire](#) on the KIDV website.

## Interesting links

- [Non-intentionally added substances | Food Packaging Forum](#) [Background information]
- [Guidance on Best Practices on the Risk Assessment of Non-Intentionally Added Substances \(NIAS\) in Food Contact Materials and Articles|ILSI](#) [Apply risk assessment]
- [NIAS Screening | Mérieux NutriSciences](#) [Analytical methods]

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### **KIDV fact sheets Food Safety**

This fact sheet is part of a series of KIDV fact sheets on food safety. There are fact sheets on the following subjects:

- Mineral oils in packaging materials
- Bisphenol A in packaging materials
- Microplastics in packaging materials
- Heavy metals in packaging materials
- NIAS – Not-intentionally added substances
- Legislation on food contact materials

See also our [dossier page on Food Safety](#) on the KIDV website.