Acrylamide is a chemical that naturally forms in starchy food products during high-temperature cooking (frying, baking, roasting and also industrial processing at +120°C and low moisture). It mainly forms from sugars and amino acids (mainly one called asparagine) that are naturally present in many foods. The chemical process that causes this is known as the Maillard Reaction; it also 'browns' food and affects its taste.

An overview of EFSA’s risk assessment: What are the risks for consumers of acrylamide in food?

In June 2015, EFSA issued a scientific opinion following a thorough risk assessment of the public health risks of acrylamide in food, and concluded:

- Based on animal studies, EFSA confirms previous evaluations that acrylamide in food potentially increases the risk of developing cancer for consumers in all age groups.
- Since acrylamide is present in a wide range of everyday foods, this concern applies to all consumers but children are the most exposed age group on a body weight basis.
- Possible harmful effects of acrylamide on the nervous system, pre- and post-natal development and male reproduction were not considered to be a concern, based on current levels of dietary exposure.
- The most important food groups contributing to acrylamide exposure are fried potato products, coffee, biscuits, crackers and crisp breads, and soft bread.
- The ingredients, storage and processing conditions (particularly temperature) greatly influence acrylamide formation in food.
- Home-cooking choices can have a substantial impact on the level of acrylamide humans are exposed to through the diet.
What happens to acrylamide in the body?

Following ingestion, acrylamide is absorbed from the gastrointestinal tract, distributed to all organs and extensively metabolised. Glycidamide is one of the main metabolites resulting from this process.

Laboratory animals orally exposed to acrylamide have an increased likelihood of developing gene mutations and tumours (among others, in rats – mammary gland, testes and thyroid gland; and in mice – Harderian and mammary glands, lung, ovaries, skin and stomach). Glycidamide is the most likely cause of these types of adverse effects in animals. Acrylamide exposure can also lead to harmful effects on the nervous system (including hind-limb paralysis), pre- and post-natal development and adversely affect male reproduction.

Results from human studies provide limited and inconsistent evidence of increased risk of developing cancer (of the kidney, endometrium and ovaries) in association with dietary exposure to acrylamide. An inverse relation between acrylamide exposure and birth weight and other markers of fetal growth is reported in two studies. EFSA’s experts concluded that more research is needed to confirm these results from human studies. Studies on workers exposed to acrylamide in the workplace show an increased risk of disorders to the nervous system.

Is there a “tolerable dose” of acrylamide?

Acrylamide and its metabolite glycidamide are genotoxic and carcinogenic. Since any level of exposure to a genotoxic substance could potentially damage DNA and lead to cancer, EFSA’s scientists conclude that they cannot set a tolerable daily intake (TDI) of acrylamide in food.

Instead, EFSA’s experts estimated the dose range within which acrylamide is likely to cause a small but measurable tumour incidence (called “neoplastic” effects) or other potential adverse effects (neurological, pre- and post-natal development and male reproduction). The lower limit of this range is called the Benchmark Dose Lower Confidence Limit (BMDL\textsubscript{10}).

For tumours, experts selected a BMDL\textsubscript{10} of 0.17mg/kg bw/day. For other effects, neurological changes were seen as the most relevant with a BMDL\textsubscript{10} of 0.43 mg/kg bw/day.

By comparing the BMDL\textsubscript{10} to human dietary exposure to acrylamide, scientists can indicate a “level of health concern” known as the margin of exposure.

What is the margin of exposure?

The margin of exposure (MOE) approach provides an indication of the level of health concern about a substance’s presence in food without quantifying the risk. Use of the MOE can help risk managers in defining possible actions required to keep exposure to such substances as low as possible.

EFSA’s Scientific Committee states that, for substances that are genotoxic and carcinogenic, an MOE of 10,000 or higher is of low concern for public health. The MOEs for the cancer-related effects of acrylamide range from 425 for average adult consumers down to 50 for high consuming toddlers (Table 30, page 210). These ranges indicate a concern for public health.

For non-genotoxic substances, an MOE of 100 or higher normally indicates no concern for public health. The MOEs for neurological effects range from 1,075 for average adult consumers to 126 for high consuming toddlers. EFSA’s experts concluded that, for these effects, current levels of dietary exposure are not a health concern, although for toddlers and children with high dietary exposure the MOE is close to the values that might be of concern for these effects.
Which foods contribute to acrylamide exposure?

The main contributors vary by age:

**Adults** – fried potato products (including French fries, croquettes and roasted potatoes) account for up to 49% of average exposure in adults, with coffee (34%) and soft bread (23%) the other most important dietary sources for adults, followed by ‘biscuits, crackers and crisp breads’ and ‘other products based on potatoes’.

**Children** (toddlers, other children, adolescents) – potato fried products (except potato crisps and snacks) account for up to 51% of all dietary exposure. Soft bread, breakfast cereals, biscuits and other products based on cereals or potatoes can contribute up to 25%. Processed cereal-based baby food represented up to 14% of exposure for toddlers, cake and pastry up to 15% for other children and adolescents, and potato crisps and snacks 11% for adolescents.

**Infants** – ‘baby foods other than processed cereal-based’, ‘other products based on potatoes’ and ‘processed cereal-based baby food’ (mainly rusks and biscuits) contribute up to 60%, 48% and 30% respectively.

Although some food categories, for example, ‘potato crisps and snacks’ and ‘coffee substitutes’ contain relatively high levels of acrylamide, their overall contribution to dietary exposure is limited based on a normal/varied diet.

Can exposure to acrylamide in food be reduced?

Although not the focus of its risk assessment, EFSA’s experts reviewed the available scientific literature and data on how the choice of ingredients, the storage method and the temperature at which food is cooked influence the amount of acrylamide in different food types. An overview is available in section 4.4, ‘Impact of raw material, storage and processing on acrylamide levels in food’, pp 52-57, of EFSA’s scientific opinion. This information could contribute to discussions on how to reduce acrylamide exposure from industrial food production, restaurants, catering and home cooking.

Is food the only source of acrylamide exposure?

No, acrylamide is present in tobacco smoke, which is, therefore, a non-dietary source of exposure for smokers and non-smokers (through passive smoking). For smokers, tobacco smoking is a more prominent source of acrylamide exposure than food. Also, acrylamide has a wide variety of industrial non-food uses and, therefore, for some people exposure in the workplace through dermal absorption or inhalation can occur.
What is new about EFSA’s risk assessment?
Why was it done?

In September 2012, organisations in Denmark, France, Germany and Sweden asked EFSA to consider new scientific findings on the possible carcinogenicity of acrylamide. Subsequently, EFSA accepted a request from the European Commission to provide a scientific opinion on the potential risks for human health of acrylamide in food.

This opinion is EFSA’s first full risk assessment of acrylamide in food. The Authority’s experts took into account new toxicological studies on acrylamide and glycidamide published since the 2005 risk assessments of the World Health Organization, as well as more recent studies of acrylamide and cancer in humans. The opinion also updates EFSA’s previous assessment of dietary exposure to acrylamide (last done in 2011), using new data on acrylamide levels in food and more recent food consumption data.

In July 2014, EFSA publicly consulted on its draft scientific opinion. This allowed EFSA’s experts to refine aspects of its assessment of dietary exposure and toxicological studies on humans. New studies (covering the period up to March 2015) were also appraised following the public consultation.

What happens next?

Currently, EU Member States monitor acrylamide levels in food and submit data to EFSA. The European Commission recommends that Member States carry out investigations in cases where the levels of acrylamide in food exceed so-called ‘indicative values’ set by the Commission as a guide.

European and national decision-makers will take account of EFSA’s scientific advice as well as other considerations in weighing up any possible measures to reduce consumer exposure to this substance in food.

Glossary:

- **Maillard Reaction**: a chemical reaction between amino acids and reducing sugars that browns food and enhances flavour
- **Glycidamide**: a metabolite of acrylamide that forms after consumption of acrylamide-containing foods
- **Genotoxic**: damages DNA
- **Carcinogen**: causes cancer
- **Neoplastic effects**: tumours, both benign and malignant (i.e. cancer)
- **Margin of exposure**: a ratio of the dose at which a small but measurable adverse effect is first observed and the level of exposure for a given population
- **Benchmark Dose Lower Confidence Limit (BMDL<sub>10</sub>)**: the minimum dose range of a substance that produces a clear, low level health risk, usually in the range of a 1-10% change in a specific toxic effect such as cancer induction.