

## **NOVEL CARBOHYDRATES AS NOVEL FOODS: CHALLENGES AND PERSPECTIVES IN RISK ASSESSMENT**

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### **INTRODUCTION**

The challenges faced by our food system trigger the need for a holistic approach towards sustainable solutions. Ensuring a high level of food safety and access to healthy diets, while mitigating climate change and building resilient communities, are priorities in the policy agenda of the European Union (EU). Carbohydrates are a key component in our diets, being set at 45-60 % of energy intake by the European Food Safety Authority (EFSA) as the dietary reference value for children above 1 year of age and adults. Advances in the food sector enabled the development of novel carbohydrates from unconventional sources, which attained commercial interest due to their prospective sustainable use in the food industry. Some of these sources and products created therefrom are considered novel foods and their safety must be proven before they are authorised by risk managers for placement on the EU market. EFSA is the EU body responsible for evaluating the safety of novel foods for consumers. This project tackles the challenges in the risk assessment (RA) of novel carbohydrates as NFs by focusing on compositional and nutritional characterisation, proposed uses and anticipated intake, as well as toxicological data.

### **METHODOLOGY**

NF applications referring to novel carbohydrates assessed by EFSA were retrieved from the OpenEFSA Portal, by using the filters 'Nutrition' and 'Novel Foods' for the food domain, 'fibre' and 'oligosaccharide' as descriptors. The safety assessment requirements of novel foods are outlined in the EFSA 'Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283'. The respective outputs were screened to collect the scientific information referring to the identity of the source, manufacturing process, compositional data, proposed uses and toxicological data. Data on (potentially beneficial) health impacts was excluded since such information is outside the remit of the NF assessment.

## RESULTS

The novel carbohydrates assessed by EFSA comprise fibre from new sources and human identical milk oligosaccharides (HiMOs), but also carbohydrates intended to replace sugar. These innovative products were obtained from various sources such as plants or parts thereof and vegetal biomass (e.g. carrot pomace, kelp of brown seaweed), animal sources (e.g. crustaceans), microorganisms, fungi or algae, by means of chemical or enzymatic synthesis, hydrolysis of polysaccharides or fermentation. The implications for the safety assessment outline the importance of compositional characterisation of the novel carbohydrates, including data on potential substances of concern to human health (e.g. process-related compounds, anti-nutrients, viable microbial cells, toxins). Another key element in the risk assessment refers to an appropriate exposure assessment when the NF is used as an ingredient in different food categories. In the particular case of HiMOs, the anticipated intake is considered safe when the consumption of the NF does not exceed the natural intake from breast milk in infants. Toxicological aspects should be addressed following a tiered approach to limit the use of animals and resources

## DISCUSSION

Novel carbohydrates aiming to enter the EU market may pose challenges to traditional risk assessment approaches, which demonstrates the need for advanced tools and methodologies to be used. For instance, when assessing oligosaccharides (e.g. lacto-N-tetraose) obtained by fermentation using a microorganism for which qualified presumption of safety (QPS status) was not granted, evidence for the absence of acquired antimicrobial resistance genes by whole-genome sequencing analysis was needed to reach a conclusion on the safety of the NF. Regarding NFs intended to replace sugar obtained by enzymatic reactions, the ongoing safety evaluation of food enzymes by EFSA will help risk managers in establishing a Union list of approved food enzymes. Finally, concerning toxicological challenges, the default approach is not always possible, for example in the case of non-digestible carbohydrates, due to difficulties in discriminating between toxicological and metabolic/adaptive effects in rodents. A move towards holistic approaches to new/advanced tools and updated methodologies for the RA, encompassing the latest scientific developments, is therefore needed in order to tackle challenges in the risk assessment of novel carbohydrates.