## Regulatory Day 2023

Technical update on European Union food regulations

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### Additives



#### Titanium dioxide ban is now in place but the debate about it's safety continues



- In a judgment delivered on 23 November 2022, the General Court of the European Union has ruled that titanium dioxide (TiO2) is not a category 2 carcinogen by inhalation
- The ruling means that TiO2 is not classified as a hazardous substance in the EU but does not impact the food ban because it was established under different Regulations
- The EU (and France) is appealing the ruling
- The UK has not replicated the ban. The FSA's scientific advisory committees reviewed the EFSA opinion and found that the evidence did not support the conclusions made

<u>Commission Regulation (EU) 2022/63</u>
 banning titanium dioxide was
 published in January 2022. The
 Regulation includes a six-month
 transitional period which ended on 7
 August 2022

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Additive	Category	Link		
Ascorbic acid, Sodium ascorbate, Calcium ascorbate	Tuna New Max Levels (from <i>q.s.</i> )	Commission Regulation (EU) 2022/1923		
Carbomer	Food Supplements	Commission Regulation (EU) 2023/440		
Glucosylated steviol glycosides (E960d)	All Categories (Intense Sweetener)	Commission Regulation (EU) 2023/447		

# Contaminants



#### A new regulation on contaminants has come into force – the old one has been revoked



- Commission Regulation (EU) 2023/915 on contaminants was published in April and it revokes Regulation 1881/2006
- The reason given for the new Regulations was because 1881/2066 had been amended substantially many times
- Regulation 2023/915 maintains continuity and does not implement any new approach
- It has already been amended

<u>Commission Regulation (EU)</u>
 <u>2023/915</u>

STOP PRESS – Mineral Oil Hydrocarbons - EFSA re-evaluated the risk of exposure to MOH through food. EFSA conclude that MOSH do not pose a risk to public health at the current levels of exposure. More research needed for MOAH

#### New EU regulations on contaminants (last 12 months)

Additive	Category	Link		
Arsenic	Rice products, infant formula, juice & salt	Commission Regulation (EU) 2023/465		
Perfluoroalkyl substances	Eggs, fish, shellfish, meat, offal	Commission Regulation (EU) 2022/2388		
Dioxins and dioxin-like PCBs	Eggs, meat, offal, milk	Commission Regulation (EU) 2022/2002		
Cadmium Tiger nuts, fungi		Commission Regulation (EU) 2023/151		

# Novel food



# European Commission issues a proposal to update EU rules to reflect the greater precision of new gene editing techniques



- In July 2018, the Court of Justice of the European Union (CJEU) ruled that organisms obtained by newer methods of directed mutagenesis such as genome editing should be treated as GMOs and are not excluded from the scope of the EU GMO directive
- Under the new proposal, the EU's restrictive rules on genetically modified organisms (GMOs) will no longer apply to plants obtained using techniques such as CRISPR, as long as the modifications made are comparable to those that can be achieved using conventional breeding
- The Commission's proposal on new genetic techniques (NGTs) was released on 5 July as part of its 'Sustainable use of natural resources' package, designed to strengthen the resilience of EU food systems and farming
- <u>gmo\_biotech\_ngt\_proposal.pdf</u> (europa.eu)

#### New novel food authorisations (last 12 months)

Galacto-oligosaccharide (changes to conditions of use)	Commission Implementing Regulation (EU) 2022/1381
Bovine milk β-lactoglobulin	Commission Implementing Regulation (EU) 2022/2534
<i>Antrodia camphorata</i> mycelia (freeze- dried powder form)	Commission Implementing Regulation (EU) 2022/2535
Vitamin D <sub>2</sub> mushroom powder	Commission Implementing Regulation (EU) 2023/4
Acheta domesticus (house cricket) partially defatted powder	Commission Implementing Regulation (EU) 2023/5
Pea and rice protein fermented by <i>Lentinula edodes</i> (Shiitake mushroom) mycelia	Commission Implementing Regulation (EU) 2023/6
Lacto-N-tetraose produced by derivative strains of <i>Escherichia coli</i> BL21(DE3)	Commission Implementing Regulation (EU) 2023/7
3-Fucosyllactose produced by a derivative strain of <i>Escherichia coli</i> BL21(DE3)	Commission Implementing Regulation (EU) 2023/52
Alphitobius diaperinus larvae (lesser mealworm) (frozen, paste, dried and powder forms)	Commission Implementing Regulation (EU) 2023/58
Xylo-oligosaccharides (authorisation) 3'-sialyllactose sodium salt (authorisation)	Commission Implementing Regulation (EU) 2023/65
3'-Sialyllactose sodium salt produced by derivative strains of <i>Escherichia coli</i> BL21(DE3)	Commission Implementing Regulation (EU) 2023/113

Dried nuts of Canarium ovatum Engl. (Trad food 3 <sup>rd</sup> country)	Commission Implementing Regulation (EU) 2023/267	
Bovine milk osteopontin	Commission Implementing Regulation (EU) 2023/463	
Roasted and popped kernels from the seeds of <i>Euryale ferox Salisb.</i> (makhana) (Trad food 3 <sup>rd</sup> country)	Commission Implementing Regulation (EU) 2023/652	
<i>Canarium indicum L.</i> dried nuts (Trad food 3 <sup>rd</sup> country)	Commission Implementing Regulation (EU) 2023/667	
Phosphated distarch phosphate produced from wheat starch	Commission Implementing Regulation (EU) 2023/937	
Cellobiose	Commission Implementing Regulation (EU) 2023/943	
6'-Sialyllactose sodium salt produced by derivative strains of <i>Escherichia</i> <i>coli</i> BL21(DE3)	Commission Implementing Regulation (EU) 2023/948	
Iron milk caseinate	Commission Implementing Regulation (EU) 2023/949	
Aqueous ethanolic extract of <i>Labisia</i> pumila	Commission Implementing Regulation (EU) 2023/972	



# Health claims



#### New health claim authorisations (last 12 months)

Food ingredient	Claim	Link	
Combination of artichoke dry leaf extract with caffeoylquinic acids, monacolin K in red yeast rice, sugar cane derived policosanols (etc.) (Art. 14.1(a), disease risk reduction claim)	Reduces blood LDL cholesterol concentrations. High LDL cholesterol is a risk factor in the development of coronary heart disease – <b>AUTHORISED</b>	Commission Regulation (EU) 2023/648 of 20/03/2023	
<b>Organic Foods</b> (Art. 14.1(b), children's development and health)	Organic food (lower levels of pesticide residues than those in conventional food) contributes to the protection of body cells and molecules (lipids and DNA) from oxidative damage – <b>REJECTED</b>	Commission Regulation (EU) 2023/1101 of 06/06/2023	
<b>Beta-glucan sourced from Oats and/or barley</b> (Art. 13.5 including request for proprietary data protection)	Consumption of beta-glucans from oats and/or barley in a ready-to-eat breakfast cereal contributes to a reduction of the blood glucose rise after that meal – <b>REJECTED</b>	Commission Regulation (EU) 2023/1141 of 01/06/2023	
<b>Affron® aqueous saffron extract</b> (Art. 13.5 including request for proprietary data protection)	Contributes to maintain a healthy mood by reducing the negative traits of depressive and anxiety feelings – <b>REJECTED</b>	Commission Regulation (EU) 2023/1141 of 01/06/2023	
MegaNatural® BP California grown grape seed extract (Art. 13.5 including request for proprietary data protection)	Helps to maintain healthy blood pressure – <b>REJECTED</b>	<u>Commission Regulation (EU)</u> 2023/1141 of 01/06/2023	
<b>Frutalose® chicory oligofructose</b> (Art. 13.5 including request for proprietary data protection)	Contributes to regular bowel function by increasing stool frequency – <b>REJECTED</b>	Commission Regulation (EU) 2023/1141 of 01/06/2023	

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#### No white smoke from EU on mandatory front-of-pack nutrition labelling



- A proposal was due end 2022. This was pushed back to Q2 2023
- Both dates have passed without an announcement
- In April the Commission stated An impact assessment is currently in preparation, involving a wide-ranging evidence and data gathering exercise. Additional evidence gathering and analytical work are recommended to ensure consumer needs and perceptions are properly taken into consideration, in order to allow the design of balanced proposals
- The Nutriscore algorithm has undergone an update focussed on beverages. This follows the update for general foods in 2022

- Harmonised front of pack nutritional labelling is a Farm to Fork strategy commitment. Nutriscore was the initial front runner
- Proposal revision Regulation of FIC (europa.eu)

#### Other developments

- In February the European Economic and Social Committee published an opinion on recommendations for rules on sustainability labelling for food. Such rules would initially be voluntary and involve some sort of rating scale (link). This is related to the framework for sustainable food systems (FSFS) – one of the flagship initiatives of the Farm to Fork Strategy
- Ingredient & nutrition labelling for wine is still on course to become mandatory on 8 December. Most producers are likely to indicate this online via a QR code on the bottles
- The Technical Regulation Information System (TRIS) review of Ireland's draft regulation for health warning labels on alcohol generated no objections and the law was passed and will become effective in May 2026



# Packaging & environment



#### EU proposal for packaging published November 2022



Some key measures

- Limit packaging to the minimum level necessary to ensure functionality (e.g. reducing empty space, removing unnecessary layers, etc.)
- Plastic packaging to include a minimum amount of recycled content.
  Different targets for different sectors some as high as 30% from 2030 and increasing in 2040
- Packaging in some sectors (e.g. beverages & food service) to be reusable / refillable
- Introduction of harmonised labelling on material composition to facilitate customers to sort waste. Could be via QR code
- Packaging format prohibitions (hotel toiletries, fruit & veg packaging, sauce sachets)

- The delayed proposal to replace the Packaging & Packaging Waste Directive was published at the end of 2022
- As expected it will be enacted as a regulation with direct effect in all MS and it contains many new provisions & targets
- Proposal Packaging and Packaging
  Waste (europa.eu)

#### New due diligence rules on commodities at risk of being obtained through deforestation



- The EU's new Deforestation Regulation requires companies trading in certain commodities, to conduct extensive diligence on the value chain to ensure the goods do not result from recent deforestation
- The EUDR covers seven commodities cattle, cocoa, coffee, palm oil, rubber, soya, wood and products derived from them
- Businesses are expected to put in place a due diligence programme that includes (i) collecting information, (ii) conducting risk assessments and (iii) implementing risk mitigation measures
- The EU deforestation-free regulation is part of the EU Green Deal and a broader EU strategy to protect the world's forests
- <u>Regulation (EU) 2023/1115</u>

#### There is a lot of EU activity in the packaging & sustainability space

Extended producer responsibility	Packaging & packaging waste	Deposit return schemes	Single use plastics	Sustainable use of pesticides	Advertising & green claims	Net zero	Food waste	Deforestation
Packaging design	Recycled content targets	Beverage containers	SUP bans	National reduction targets	Green Claims Directive	Carbon footprint labelling	Reduction targets	Due diligence reporting
EPR reporting	Disposal advice labelling	DRS labelling	SUP charging	Pesticide bans	CMO Green Claims Code	Emissions reduction	Food waste labelling advice	Targeted ingredients
Compliance schemes	Packaging taxation	DRS logistics	Tethered caps	MRL reductions	Green washing			
	Excessive packaging				Full lifecycle impact analysis			
	Packaging re- use							



# Key dates



#### Key dates

Measure	Date	
Ingredient & nutrition labelling for wine becomes mandatory	8 December 2023	
End of transitional measures for pyrrolizidine alkaloids (a contaminant)	31 December 2023	
EU only FBO address no longer sufficient for UK food packs	1 January 2024	
EU elections	6-9 June 2024	
Tethered caps on beverage containers will become mandatory	3 July 2024	
Deforestation due diligence requirements in force	30 December 2024	
Deforestation due diligence requirements in force (SMEs)	30 June 2025	
Transition period for beverage labels with old Nutriscore algorithm ends	December 2025	
Health warning labels on alcohol (Ireland)	May 2026	
All packaging to be reusable or recyclable in an economically viable manner	2030	



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# Questions?

