

Regulatory Day 2024

Updates on the European Regulatory Landscape

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Contents

Additives

Contaminants

Novel foods

Health claims

Labelling

Packaging & environment



Additives



Ban on smoke flavours

Maturity	Evolving 	Driver	Safety & quality 	Subject	Additives	Product category	All
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- In response to EFSA concerns about genotoxicity, a 'ban' on smoke flavours was proposed by the European Commission in November 2023
- It received endorsement from Member States in April 2024 and was adopted at the end of July
- Smoke flavours will be phased out in two waves. In products like crisps & sauces, that use smoke flavours for extra flavour the phase-out period is 2 years (by **1 July 2026**)
- Whereas products like ham, fish & cheese, which use smoke flavours in place of traditional smoking the phase-out period is 5 years (by **1 July 2029**)

- [Commission Implementing Regulation \(EU\) No 1321/2013](#) authorised 10 smoke flavouring primary products for a 10-year period, but these authorisations expired on 1 January 2024
- [Commission Implementing Regulation \(EU\) 2024/2067](#) of 31 July 2024 confirms that none of these authorisations will be renewed creating a *de facto* ban

New EU regulations on additives (last 12 months)

Additive	Category	Link
Tartaric acid, Sodium tartrates, Potassium tartrates, Sodium potassium tartrate, Calcium tartrate	New max levels in multiple categories	Commission Regulation (EU) 2024/1451
Trimagnesium Dicitrate	Food supplements	Commission Regulation (EU) 2024/346
Nitrites (E 249-250) and Nitrates (E 251-252)	Certain cheese, fish and meat products	Commission Regulation (EU) 2023/2108
Stearyl Tartrate (E 483)	Deauthorised	Commission Regulation (EU) 2023/2379
Buffered Vinegar	New. Max levels (to <i>q.s.</i>) in certain cheese products, cereal products, bakery wares and meat preparations	Commission Regulation (EU) 2023/2086

Contaminants



EU looking at acrylamide again

Maturity	Emerging 	Driver	Safety & quality 	Subject	Contaminants	Product category	All
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- The Commission and national experts have started discussions on the introduction of legally binding limits for acrylamide
- This would represent a change in approach from the current regime that uses generic performance indicators known as benchmark levels (BMLs)
- The discussions are at an early-stage, technical level
- Separately in June, Safe Food Advocacy Europe (SAFE) issued an awareness raising position paper on acrylamide calling for maximum levels potato to be established for crisps, breakfast products, French fries and baby foods

- SAFE Food Advocacy Europe – Position Paper - To protect consumers' health, we need legally binding limits for acrylamide in food (June 2024). [SAFE-position-acrylamide.pdf \(agricolae.eu\)](https://agricolae.eu/SAFE-position-acrylamide.pdf)

New EU regulations on contaminants (last 12 months)

Additive	Category	Link
Nickel	Tree nuts, nuts, seeds, vegetable, cereal products, chocolate products and food for babies, infants and young children	Commission Regulation (EU) 2024/1987
Ergot Sclerotia and Ergot Alkaloids	Unprocessed rye grains, milling products of wheat, barley, spelt and oats	Commission Regulation (EU) 2024/1808
T-2 and HT-2 toxins	Unprocessed cereal grains, cereals and milling products of cereal. Bakery wares, baby food and food for special medical purposes	Commission Regulation (EU) 2024/1038
Deoxynivalenol	Unprocessed grains of cereal, durum wheat, maize, oat. Milling products of maize and pasta	Commission Regulation (EU) 2024/1022
Perchlorate	Beans (<i>Phaseolus vulgaris</i>) with pods	Commission Regulation (EU) 2024/1002
3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters	Infant formulae, follow-on formulae and food for special medical purposes intended for infants and young children and young child formulae	Commission Regulation (EU) 2024/1003

Novel food



Novel food application for cultivated foie gras

Maturity	Evolving 	Driver	Safety & quality 	Subject	Technology	Product category	All
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- Paris-based company Gourmey announced on 26 July that it had submitted a pre-market application to the European Commission to sell its cultivated foie gras in the EU
- This is the first application for cultivated meat in the EU. Parallel applications have been made in Switzerland, the UK, Singapore, and the US
- The application is now undergoing a risk assessment by the EU's food safety authority (EFSA) but is likely to face opposition by Member States anxious about the impact on traditional farming

Food that had not been consumed in the EU before 15 May 1997 is considered to be novel and requires authorisation before it can be sold.

The food must also fall under at least one of the ten listed categories set out in Regulation (EU) 2015/2283 on novel foods. One of which is

- food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;

New novel food authorisations (last 12 months)

Schizochytrium limacinum (TKD-1)	Commission Implementing Regulation (EU) 2024/2049
Juice of the stems of the Angelica keiskei plant (Ashitaba stem juice)	Commission Implementing Regulation (EU) 2024/2061
Schizochytrium sp. (CABIO-A-2) oil	Commission Implementing Regulation (EU) 2024/2101
Seeds and seed flour of Vigna subterranea (L.) Verdc.	Commission Implementing Regulation (EU) 2024/2047
2'-Fucosyllactose produced by a derivative strain of <i>E. coli</i> W (ATCC 9637)	Commission Implementing Regulation (EU) 2024/2036
Lacto-<i>N</i>-fucopentaose I and 2'-Fucosyllactose mixture produced using a derivative strain of <i>E. coli</i> K-12 DH1	Commission Implementing Regulation (EU) 2024/2090
Isomaltulose powder	Commission Implementing Regulation (EU) 2024/1611
Calcidiol monohydrate	Commission Implementing Regulation (EU) 2024/1052

Beta-glucan from <i>Euglena gracilis</i> microalgae	Commission Implementing Regulation (EU) 2024/1046
3'-Sialyllactose sodium salt produced using a derivative strain of <i>E. coli</i> W (ATCC 9637)	Commission Implementing Regulation (EU) 2024/1047
Protein concentrate from <i>Lemna gibba</i> and <i>Lemna minor</i>	Commission Implementing Regulation (EU) 2024/1048
Monosodium salt of L-5-methyltetrahydrofolic acid	Commission Implementing Regulation (EU) 2024/1037
Apple fruit cell	Commission Implementing Regulation (EU) 2023/2847
Partially hydrolysed protein from spent barley (<i>Hordeum vulgare</i>) and rice (<i>Oryza sativa</i>)	Commission Implementing Regulation (EU) 2023/2851
6'-Sialyllactose sodium salt produced with derivative strain of <i>E. coli</i> W (ATCC 9637)	Commission Implementing Regulation (EU) 2023/2215

Health claims



Monacolin K from red yeast rice cholesterol claim revoked

Maturity	Established 	Driver	Safety & quality 	Subject	Claims	Product category	Supplements
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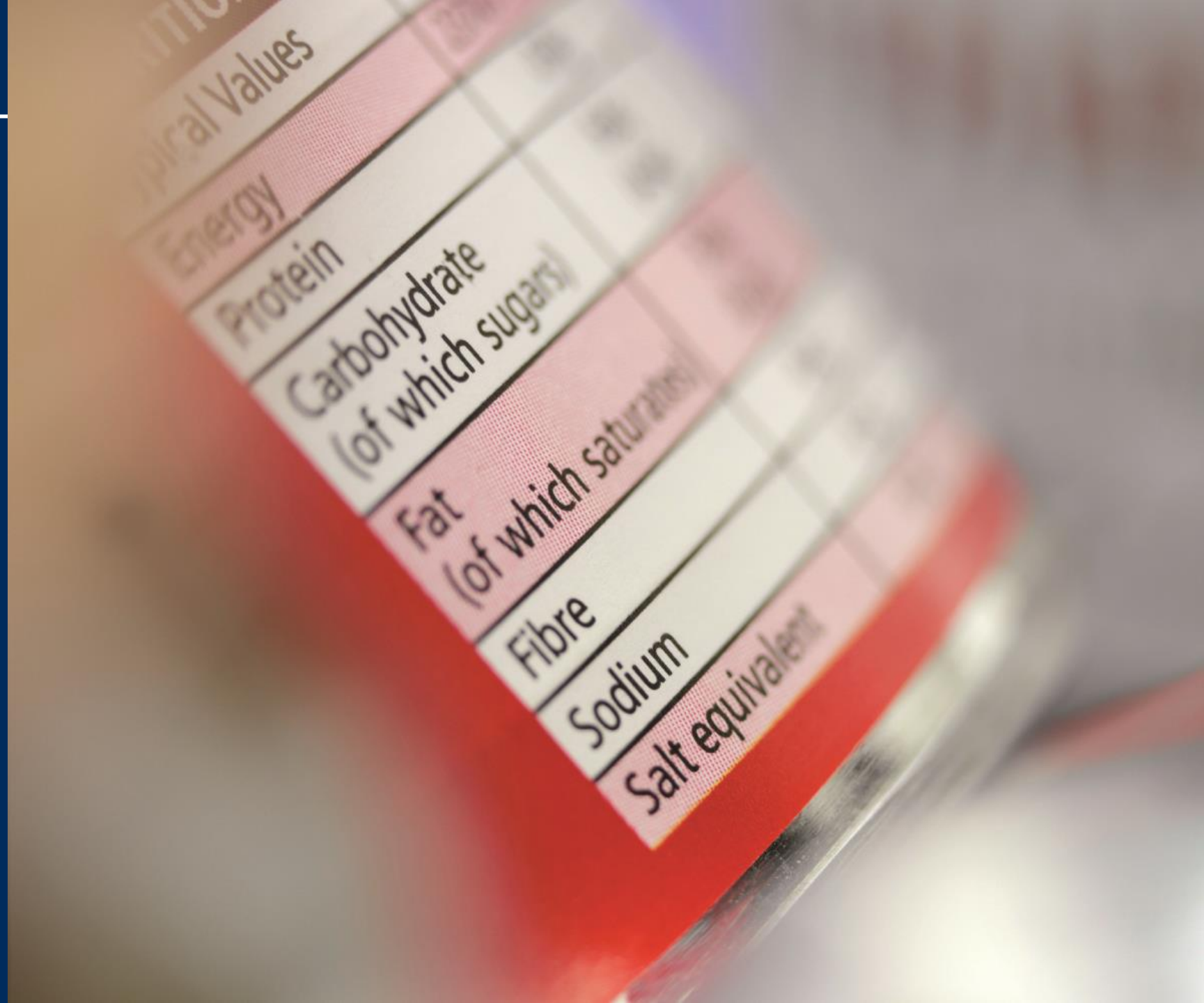
- The previously authorised claim - *Monacolin K from red yeast rice contributes to the maintenance of normal blood LDL-cholesterol concentrations* – has been revoked
- The revocation follows a reduction in the safety intake limit for Monacolin K from red yeast rice being reduced to 3mg per day
- Given that the dose required for the health claim effect was 10mg/day the claims became untenable

- [Commission Regulation \(EU\) 2024/2041](#). In the Annex to Regulation (EU) No 432/2012, the entry for *Monascus purpureus* (red yeast rice) is deleted

New health claim authorisations (last 12 months)

Food ingredient	Claim	Link
Isomaltulose (Art. 13.5 including request for proprietary data protection)	Isomaltulose contributes to normal energy-yielding metabolism – REJECTED	Commission Regulation (EU) 2024/2105 of 31/07/2024
Monacolin K in SYLVAN BIO red yeast rice (Art. 13.5 including request for proprietary data protection)	Monacolin K from red yeast rice contributes to the maintenance of normal blood LDL-cholesterol concentrations – REVOKED	Commission Regulation (EU) 2024/2105 of 30/07/2024

Labelling



New legislation amending the labelling and naming of honey, fruit juices, jams and dried milk

Maturity

Established



Driver

Safety & quality



Subject

Labelling

Product category

Honey, fruit juices, jams & dried milk

- New rules for breakfast items are brought in to reduce food fraud, increase transparency on the origin of products and allow consumers to make more informed choices
- **Honey** - the country of origin where the honey has been harvested must be labelled. If the honey originates in more than one country, these countries must be indicated in the principal field of vision, in descending order by weight & with the percentage that each represents
- **Juice** - new categories available: reduced-sugar fruit juice, reduced-sugar fruit juice from concentrate, concentrated reduced-sugar fruit juice
- **Jam** - minimum fruit content to be increased from 350 to 450g per kilo in jams, and from 450 to 500g per kilo in extra jam
- **Milk** - lactose-free dehydrated milk products allowed

- Directive (EU) 2024/1438 amends various 'vertical' directives on breakfast items including honey, fruit juices, fruit jams, jellies and marmalades and dried milks
- Member States must transpose the changes by 14 December 2025
- Products placed on the market or labelled before 14 June 2026 may continue to be marketed until the exhaustion of stocks

Packaging & environment



PPWR edges closer

Maturity	Established 	Driver	Environmental sustainability 	Subject	Packaging & food contact	Product category	All
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Measures include

- Limiting packaging to the minimum level necessary to ensure functionality. There will also be a maximum empty space ratio of 50%
- Strict limits for PFAS in food contact packaging
- Requiring packaging in some sectors to be reusable / refillable
- Introduction of harmonised labelling in 3 areas - material composition, if reusable & if compostable
- Minimum recycled content for plastic packaging (e.g. 30% for single-use plastic beverage bottles made from PET/plastic)
- Certain packaging formats will be prohibited (hotel toiletries, fruit & veg packaging, sauce sachets)

- The PPWR text was endorsed by the Council and Parliament (in April). Final approval by the (newly elected) EU Parliament and EU Environment Ministers is expected in late 2024.

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							

Progress on key EU environmental measures

Measure	What does it do	Status
Sustainable Use of Pesticides Regulation (SUR)	Delivery of the target to reduce the use and risk of chemical pesticides by 50% in 2030	Withdrawn (February 2024)
Sustainable Food Systems Framework (SFSF)	Sets out rules for sustainability labelling & minimum criteria for sustainable public procurement of food	Uncertain. Due to be tabled at the end of 2023 but didn't happen
EU Deforestation Regulation (EUDR)	Requires companies trading in certain commodities, to conduct extensive diligence to ensure the goods do not result from recent deforestation	Passed & imminent (30 December 2024)
Empowering Consumers for the Green Transition ("EmpCo Directive")	Amends the Unfair Commercial Practices Directive (UCPD) and prohibits generic environmental claims like green, environmentally friendly, eco-friendly, etc.	Entered into force 26 March 2024. Member States must apply the new rules by 27 September 2026
Green Claims Directive	Combats greenwashing by establishing minimum criteria (i.e. on substantiation, communication, and verification) that companies must meet when making claims	In progress. Final agreement is expected at the end of 2024 or beginning of 2025 at the earliest
Corporate Sustainability Due Diligence Directive (CSDDD)	Creates enhanced due diligence obligations for companies to identify, prevent, mitigate and account for adverse human rights and environmental impacts	Entered into force on 25 July 2024. Must be transposed into national laws before 26 July 2026
Waste Framework Directive amendment	Reduce food waste by introducing mandatory food waste reduction targets for Member States by 2030	In progress. Triologue negotiations are due to start

Questions?



Thank you

leatherhead food research

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