# leatherhead food research

part of SAGENTIA REGULATORY

### Updates on European Regulatory Landscape

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# Environmental sustainability



### Deforestation Regulation (EUDR)

Driver

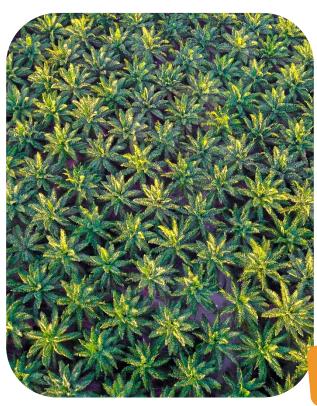
Environmental sustainability

Maturity

Established

### Product categories

Timber, rubber, soy, palm oil, coffee, cocoa and cattle



#### The story

- The EUDR establishes rules to guarantee that the products EU citizens consume do not contribute to deforestation or forest degradation worldwide
- The EUDR legislation entered into force on June 29, 2023 and was initially scheduled to become applicable on December 30, 2024. However, shortly before it was due to take effect, the EU Parliament and the Council agreed to the Commission's proposal to delay its application by one year to give companies and authorities more time to better prepare for its implementation
- A further 12-month delay is now being actively discussed which would push the compliance date to 30 December 2026 will have to

### Regulations

Regulation (EU) 2023/1115
 on the making available on
 the Union market and the
 export from the Union of
 certain commodities and
 products associated with
 deforestation and forest
 degradation

### Deforestation Regulation (EUDR)

Only commodities listed in Annex I of the Regulation are in scope. EUDR affects seven commodities – cocoa, coffee, soy, palm oil, wood, rubber, and cattle – as well as select products derived from these goods.

Products not listed in Annex I are not subject to the Regulation, even if they contain commodities listed in Annex I.

For example, soap will not be covered by the Regulation, even if it contains palm oil.

Note also that packaging material used to support, protect or carry another product placed on the market is not relevant within the meaning of Annex I, regardless of the CN code under which it falls.

Commodities and products covered by the Regulation may not be marketed or exported in or from the EU, unless all the following conditions are fulfilled:

- They are deforestation-free
- They have been produced in accordance with the relevant legislation of the country of production
- They are covered by a due diligence statement

Companies can submit their due diligence statement in the EU's information system.

In April 2025, the Commission published an updated <u>Guidance Document</u> (37 pages) and <u>the fourth version of FAQs</u> (81 pages) on EUDR.

#### Sourcing risk tiers

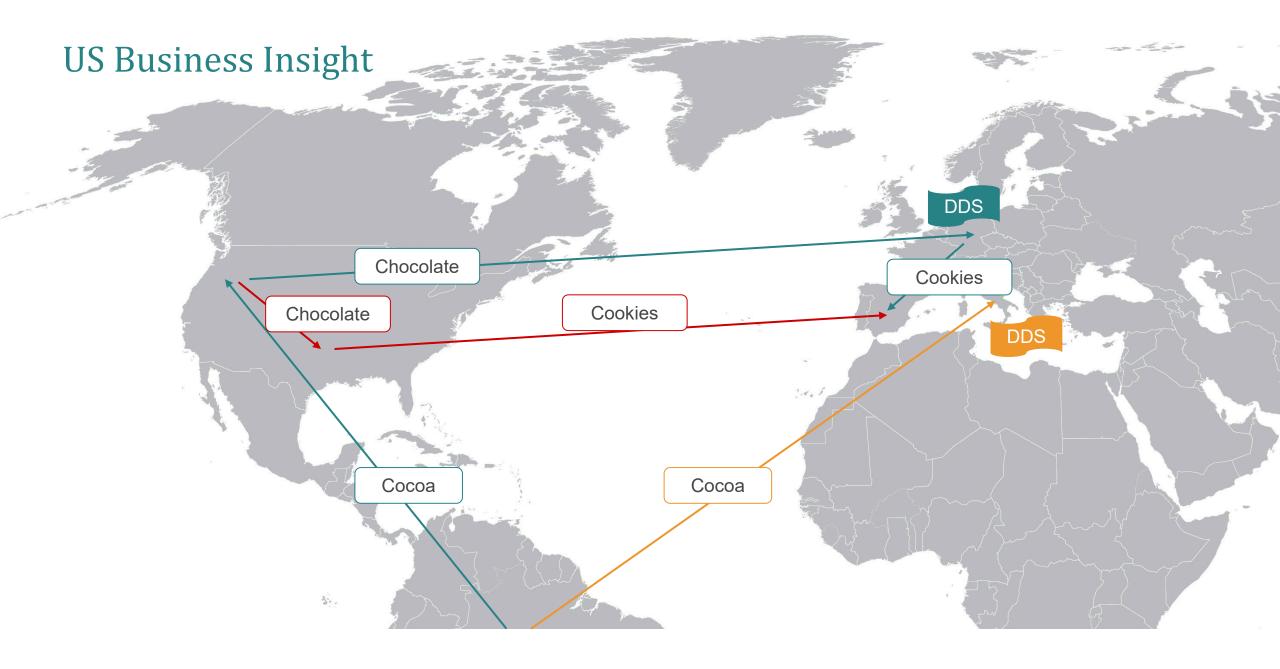
The EU benchmarking system classifies countries according to the level of risk of producing commodities covered by the scope of EUDR that are not deforestation-free.

Low risk countries will benefit from a simplified due diligence process.

Low risk
UK, EU Member States, US, China, Japan
and Australia

Medium Risk
Brazil, Colombia, Côte d'Ivoire, Indonesia,
Malaysia and Mexico

**High Risk**Myanmar, North Korea and Russia



### Environmental claims & greenwashing

Driver

Environmental sustainability

Maturity

Established

Product categories

All



#### The story

- The Commission proposed the Green Claims Directive (GCD) in March 2023 to protect consumers from misleading environmental marketing practices
- It would combat greenwashing by establishing minimum criteria (i.e. on substantiation, communication, and verification) that companies must meet when making claims
- It would work alongside the Empowering Consumers for the Green Transition ("EmpCo Directive") which entered into force March 26, 2024
- On June 20, 2025 the Commission announced that it intends to withdraw the proposal. The third trilogue, scheduled for June 23, 2025 was cancelled

### Regulations

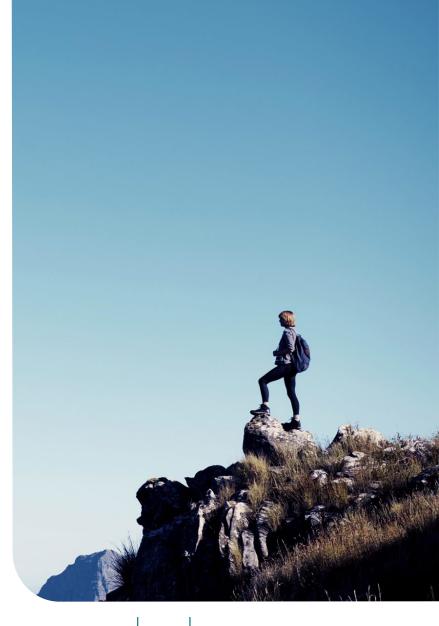
- <u>Directive (EU) 2024/825 as</u>
   regards empowering
   consumers for the green
   transition through better
   protection against unfair
   practices and through better
   information
- Member States must apply EmpCo by September 27, 2026

### US Business Insight

Despite the reverse on the Green Claims Directive the EU is going to become more hostile to the use of environmental claims

Remember the following are prohibited under Empco

- Making 'generic environmental claims' unless you can demonstrate "recognised excellent environmental performance". For example – 'environmentally friendly', 'eco-friendly', 'green'
- The use of 'zero carbon' type claims that rely on offsetting
- Partial environmental claims that concern only a certain aspect of the product or a specific activity of the trader's business
- Using sustainability marks and labels unless they are based on a third-party certification scheme or established by a public authority



# Packaging



### Bisphenol A (BPA) ban

Driver

Environmental sustainability

Maturity

Established

Product categories
Food contact materials

#### The story

- On December 19, 2024 the European Commission adopted a ban on the use of BPA in nearly all food contact materials
- BPA was already banned for use in infant feeding bottles
- BPA now banned in plastics, coatings, adhesives, inks, rubbers & other applications with just two limited exceptions\*
- Various transitional arrangements are in place, the main one being that single and repeat-use final food contact articles complying with the old rules shall be allowed to be placed on the Union market until July 20, 2026

\*Polysulfone filtration membranes used in filtration assemblies Epoxy coatings in large vessels (>1000 litres)

#### Regulations

Commission Regulation
 (EU) 2024/3190 on the use
 of bisphenol A (BPA) and
 other bisphenols and
 bisphenol derivatives

# Labelling & claims



### EU Ombudsman review of probiotics

Driver
Labelling & claims

Maturity Established

Product categories
Functional foods



#### The story

- The EU has long maintained a de facto ban on 'contains probiotics' claims which it believes are health claims
- Since the Commission has rejected all applications for the authorisation of health claims concerning probiotics, statements such as 'contains probiotics' are not authorised
- The International Probiotics Association complained to the EU Ombudsman that the Commissions' position was wrong
- The Ombudsman provided their assessment in December 2024 and ruled in favour of the Commission, describing the Commissions' position as reasonable and in line with the main goal of the legislation

### Regulations

Decision on how the
 European Commission deals
 with the labelling of foodstuff
 that contain probiotics as
 'health claims' (case
 2273/2023/MIK) | Decision |
 European Ombudsman

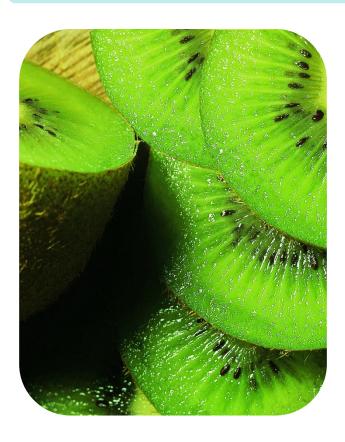
### Kiwi fruit claim approved

Driver
Labelling & claims

Maturity Established

Product categories

Kiwi fruit



#### The story

 In July, the Commission authorised a new health claim for green kiwi fruit:

Consumption of green kiwi fruit contributes to normal bowel function by increasing stool frequency

About 2 kiwis (200g) a day are needed to obtain the benefit

### Regulations

Commission Implementing
 Regulation (EU) 2025/1560
 authorising a health claim
 made on foods, other than
 those referring to the
 reduction of disease risk and
 to children's development
 and health, and amending
 Regulation (EU) No
 432/2012

### 'On-hold' claims

Driver

Labelling & claims

Maturity

**Evolving** 

Product categories

All



#### The story

- The 'on-hold' Register provides details of botanical claims in foods that have been documented but have not been authorised nor rejected. There are approximately 2,000 claims for botanicals substances that continue to be on hold since 2012 (not a typo)
- In April, the Court of Justice of the European Union (CJEU)
  delivered a judgment on the approach of the European
  Commission in relation to 'on-hold' health claims
- The judgment clarifies that 'on-hold' claims are not automatically permissible but are subject to the requirements of the NHCR – particularly the obligation for scientific substantiation and the avoidance of misleading information

### Regulations

• <u>CJEU judgment in case C</u> 386/23

### US Business Insight

- The use of the term "probiotic" and related health claims remains highly challenging within the European Union. While some Member States may permit limited claims, such claims are prohibited at the EU level
- When submitting an application for health claim authorisation, it is essential to pay close attention to the wording of the claim. Review the language recommended by EFSA for similar claims and comparable functional relationships to ensure alignment with regulatory expectations
- Although it is still possible to reference an "on-hold" health benefit claim, these claims have not been evaluated by EFSA and cannot be used without appropriate substantiation. To utilise such claims, the claimant must confirm that sufficient scientific evidence exists to support them. Leatherhead can assist in developing the necessary substantiation to meet these requirements



## Additives



### **Sweeteners**

Driver
Ingredients & compositions

Maturity Established

Product categories

All



#### The story

- Following a 2022 study that raised concerns about the safety of acesulfame K, EFSA completed its re-evaluation of the sweetener in April 2025
- The assessment reaffirmed the ace-k's safety and increased the Acceptable Daily Intake (ADI) from 9 mg/kg body weight to 15 mg/kg body weight per day
- Over the past year, EFSA has also concluded re-evaluations for saccharin and neotame, confirming their safety and raising their respective ADIs
- Re-evaluations are currently underway for nine additional sweeteners, including sucralose and the salt of aspartameacesulfame

### Regulations

 Re-evaluation of acesulfame K (E 950) as food additive | EFSA

# Novel food



### New genomic techniques compromise

Driver
Processing technologies

Maturity Evolving

Product categories
Fruits and vegetables



#### The story

- The European Union is progressing towards regulating New Genomic Techniques (NGTs), with member states approving a negotiating mandate on March 14, 2025
- The proposed Regulation creates two categories: NGT plants similar to conventionally bred ones would face less stringent rules, while those containing foreign DNA would follow existing GMO legislation
- Compromises have been made on the issue of patents and MS can request an opt-out from cultivation of NGT 2 plants on their territory
- Negotiations started on May 6

### Regulations

 Proposal for a Regulation on plants obtained by certain new genomic techniques and their food and feed

### US Business Insight

- Progress toward a more business-friendly regulatory framework for new genomic techniques in the EU remains slow and highly influenced by political considerations
- A clear picture of the status of food ingredients developed using NGTs is unlikely to emerge in the near future. Until such clarity is provided, these ingredients continue to fall under existing GMO regulations, including all associated labelling requirements
- It is important to note that, under EU law, GMO status is determined by whether the source material was genetically modified. The absence of GM protein in the final ingredient does not exempt it from being classified as GM



# Questions?

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