

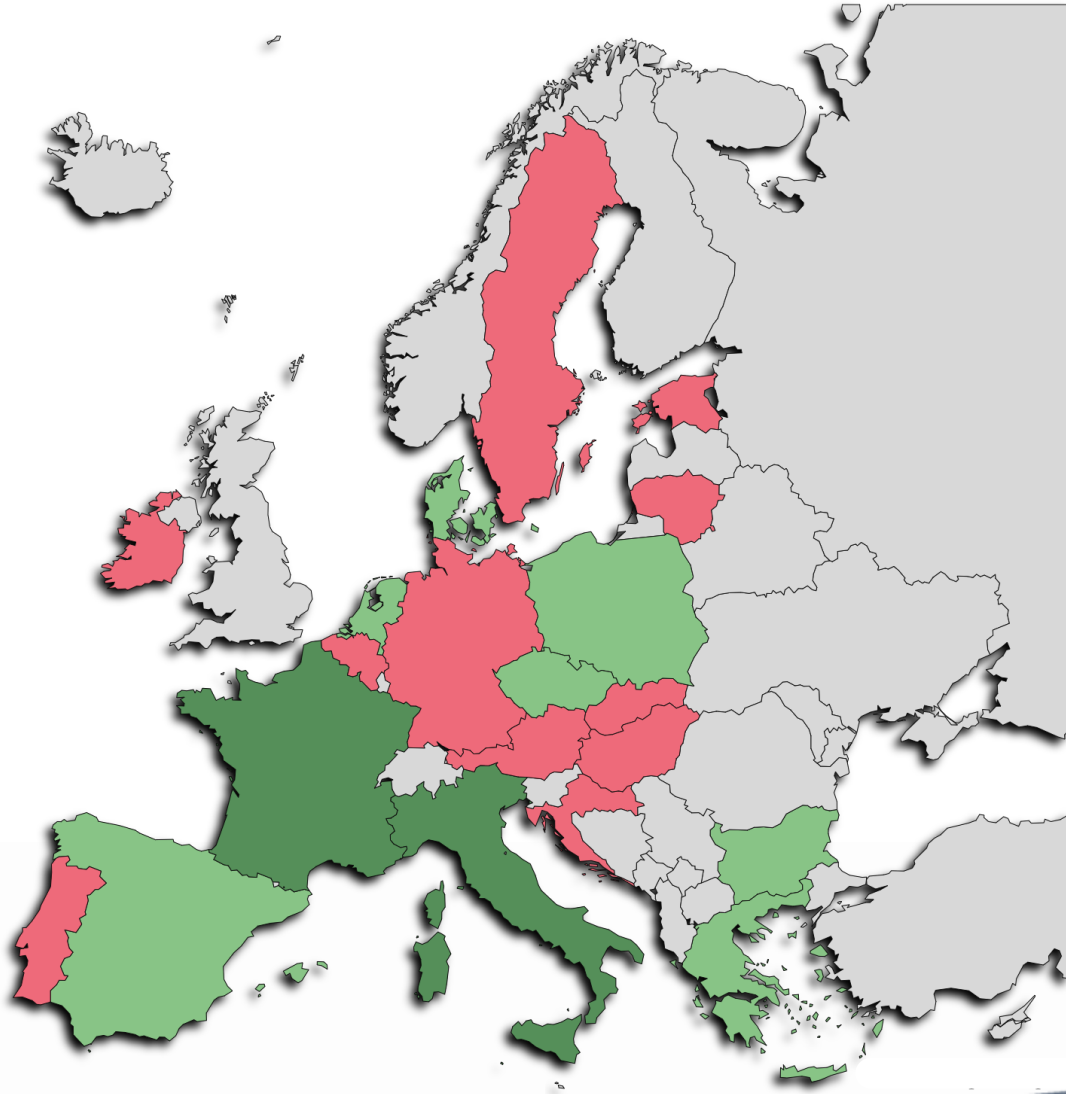
# Regulatory update on next-gen probiotics development

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The Hague, April 2024

# Number of countries allowing *probiotic* on labels has dramatically increased since 2021

**SANDWALK**  
Bioventures



Spain



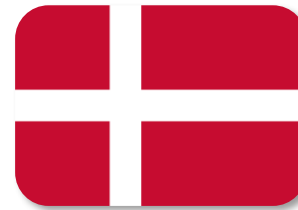
Italy



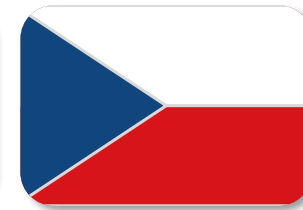
France



Netherlands



Denmark



Czech  
Republic



Greece



Bulgaria



Poland



Malta

# EU authorities seem to be talking more about probiotics

"Probiotic"\*

QPS List

QPS Scientific  
Opinion

Phenotypic AMR  
guidelines

WGS & EFSA's AMR  
reporting guidelines

Other (e.g. synthetic  
biology)

\*Excluding references within those documents

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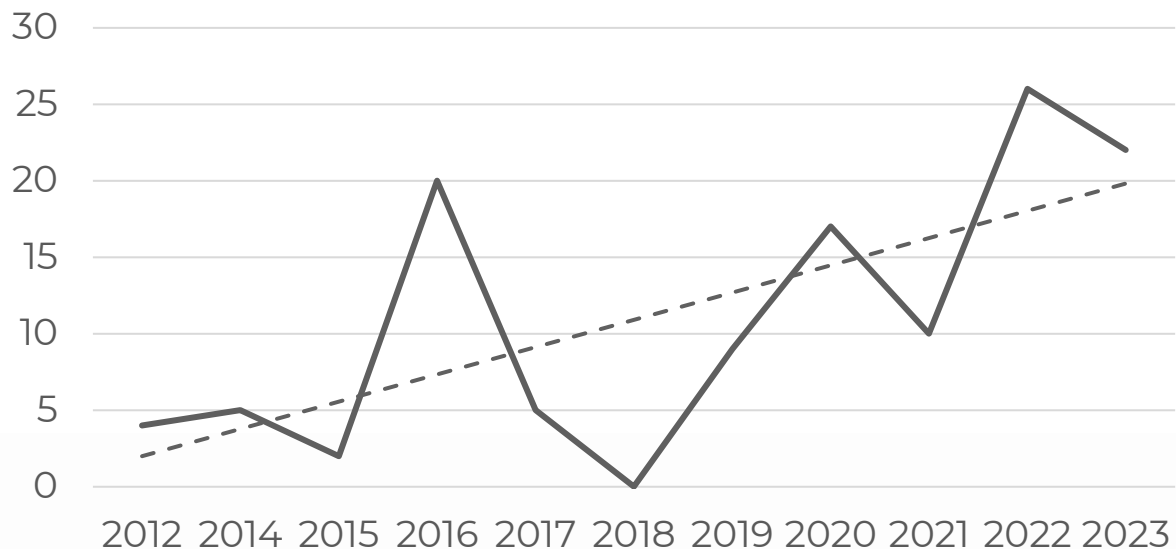
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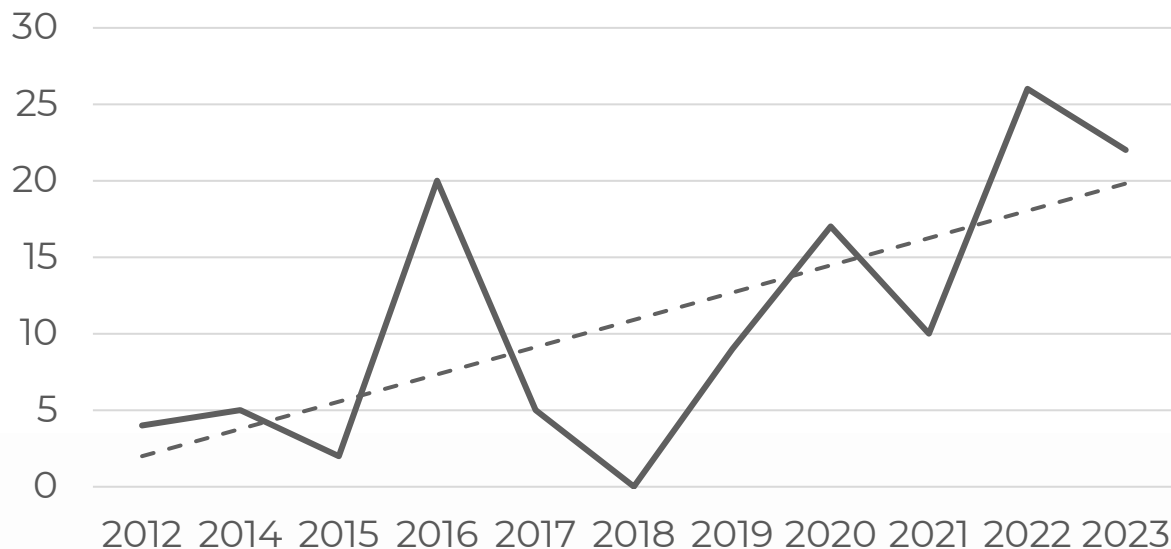
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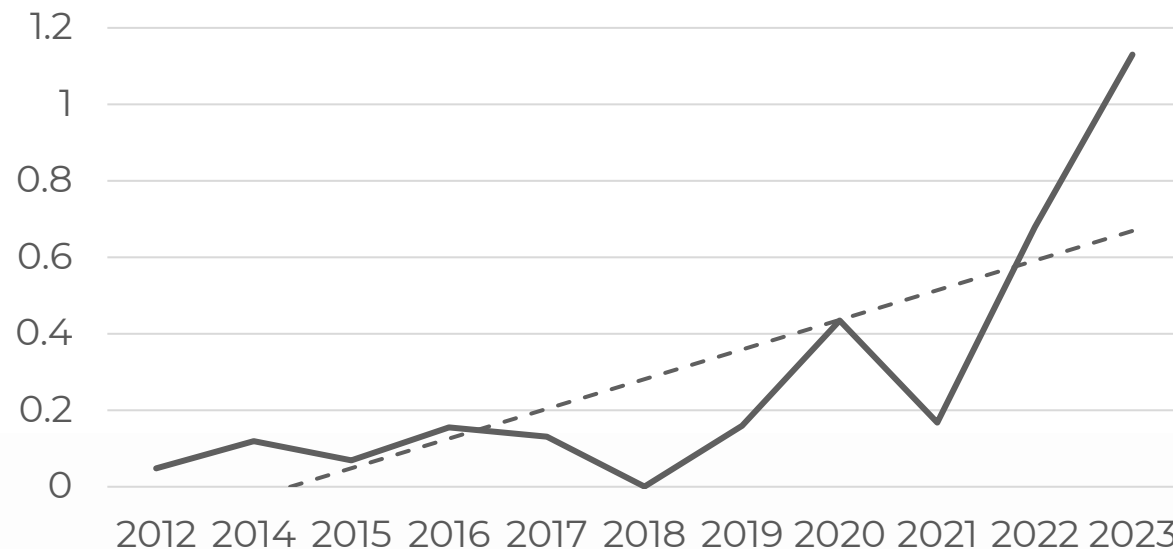
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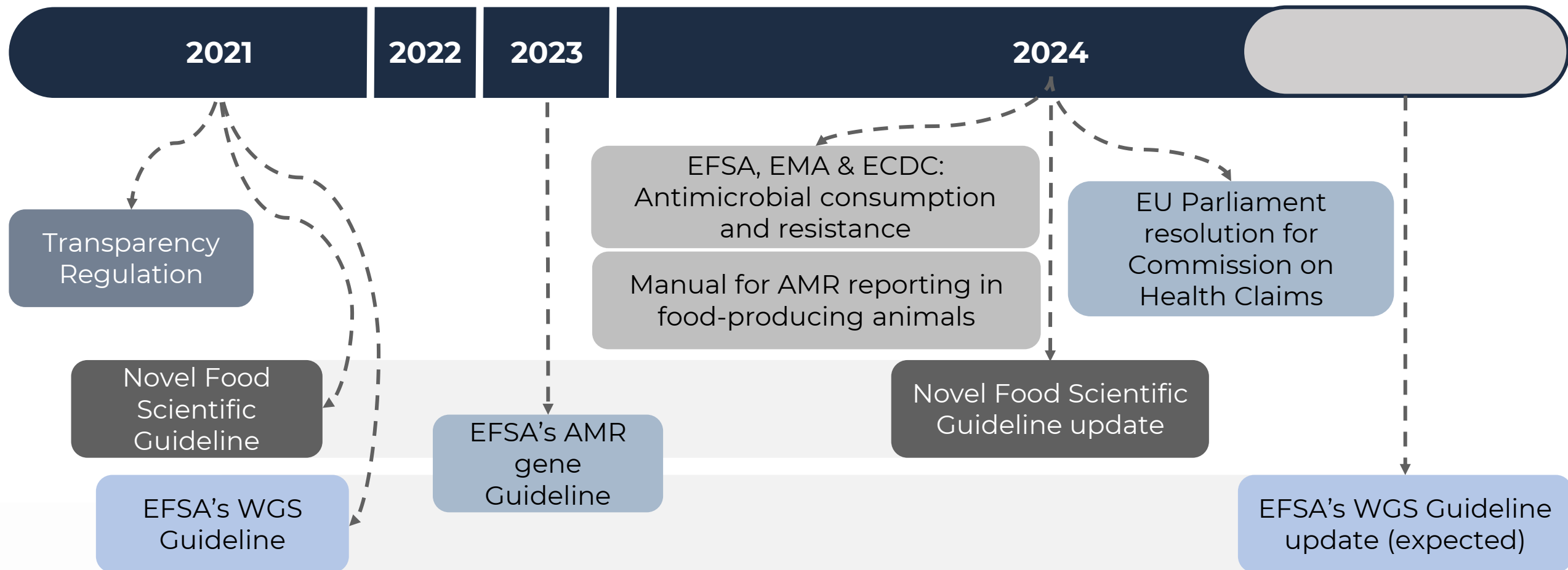


Mentions / page / year

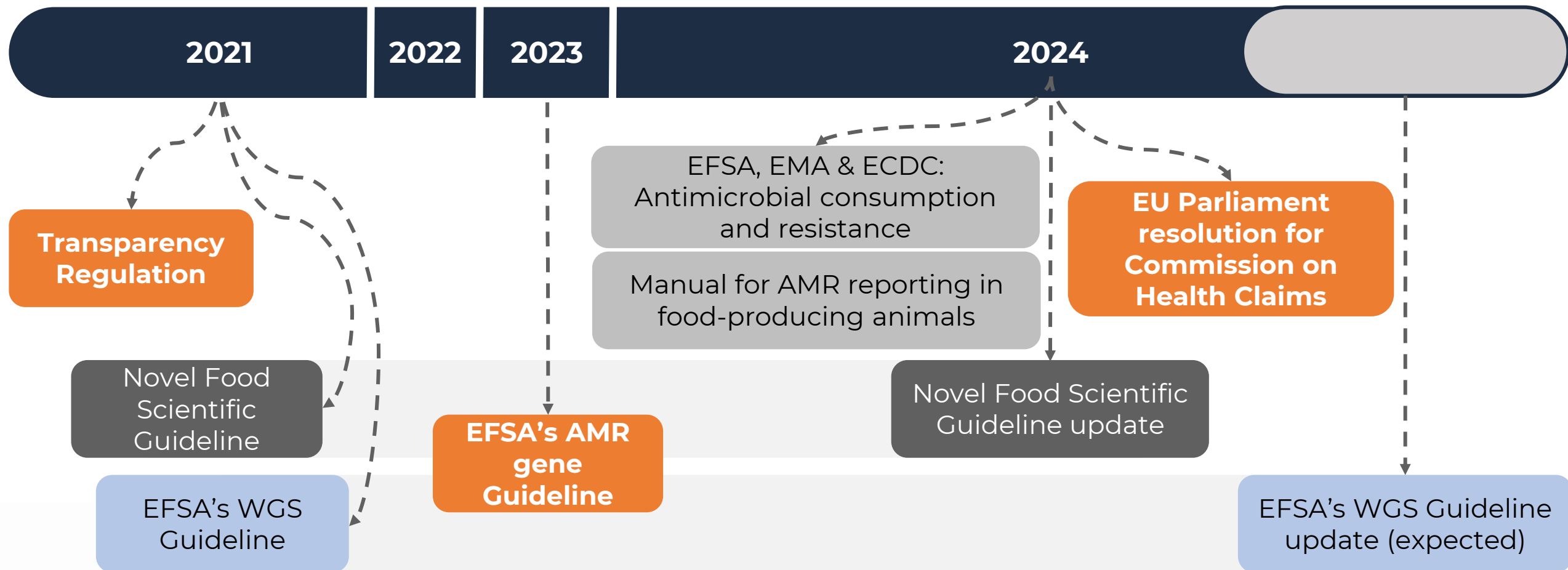


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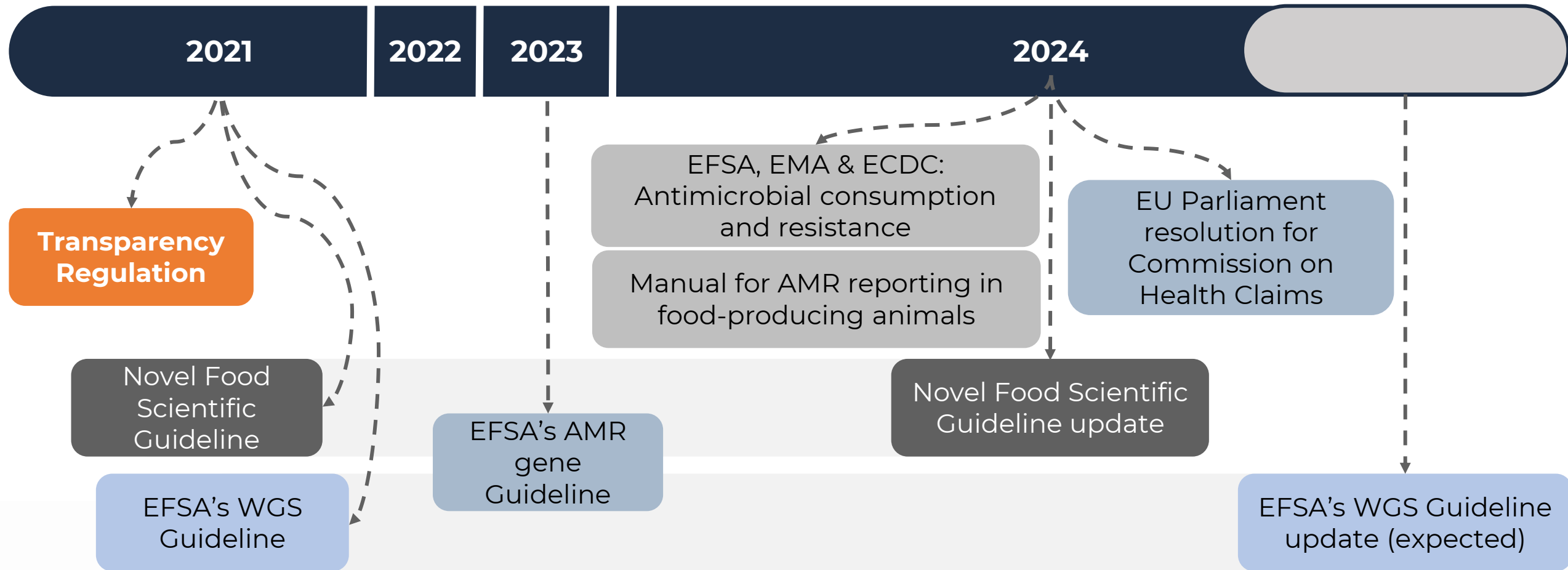
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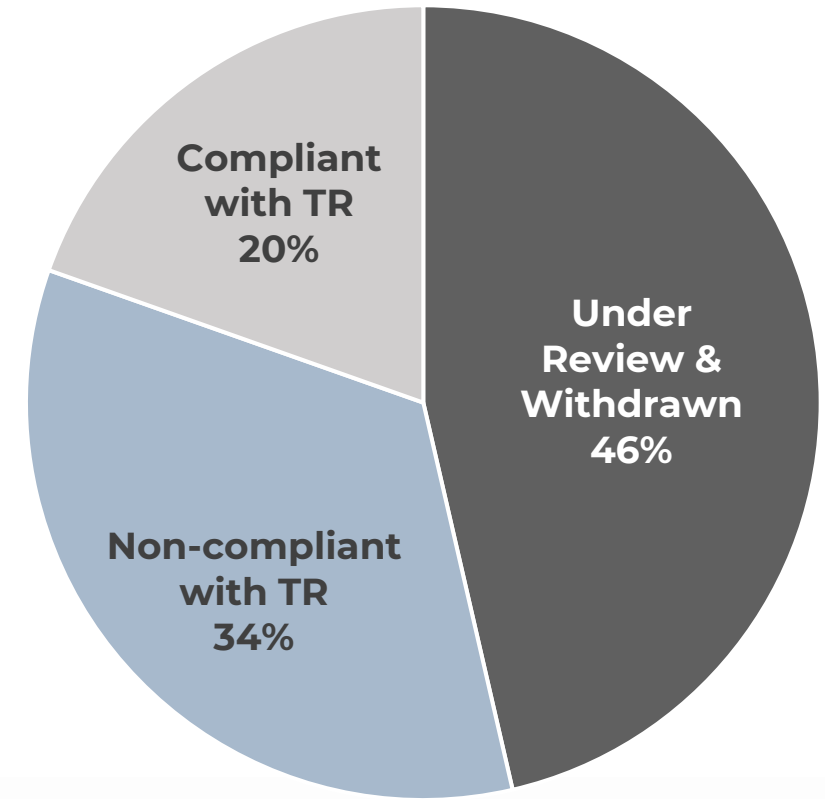


# Over 60% of the new Novel Food applications are non-compliant with the Transparency Regulation

- Foods or ingredients not present in the EU before 1997 mostly fall within the scope of Novel Foods → Market authorization required
- Case-by-case determination → Most (a//) next-generation probiotics (novel taxonomies)
- Regulation 2019/1381 (***Transparency Regulation***) became applicable on March 27<sup>th</sup>, 2021
- It forces developers to notify studies to EFSA before they are initiated
- Non-compliance involves a 6-month time penalty in the NF process

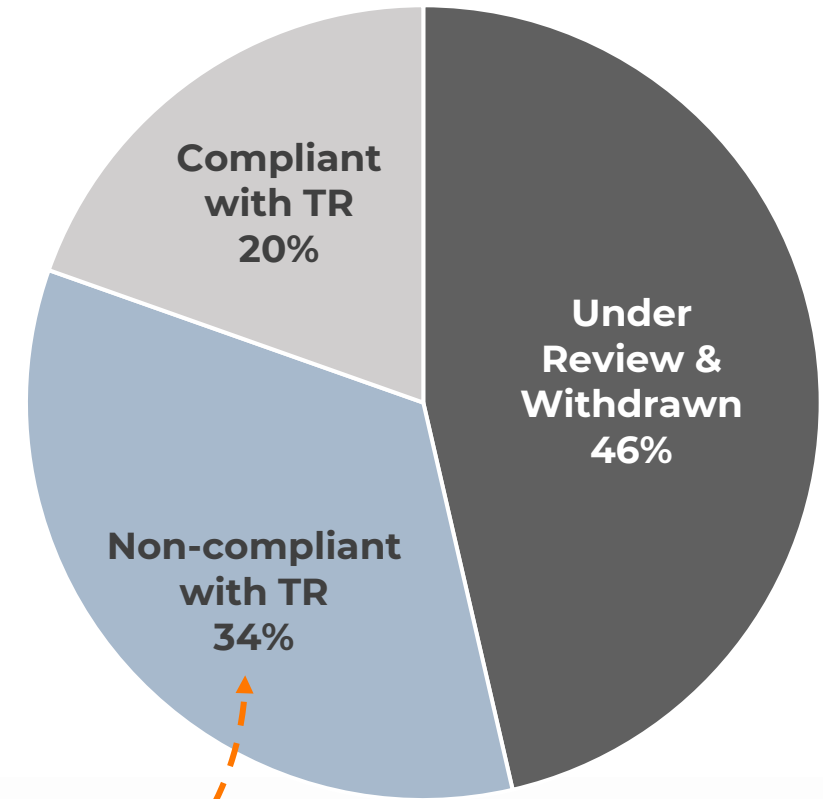
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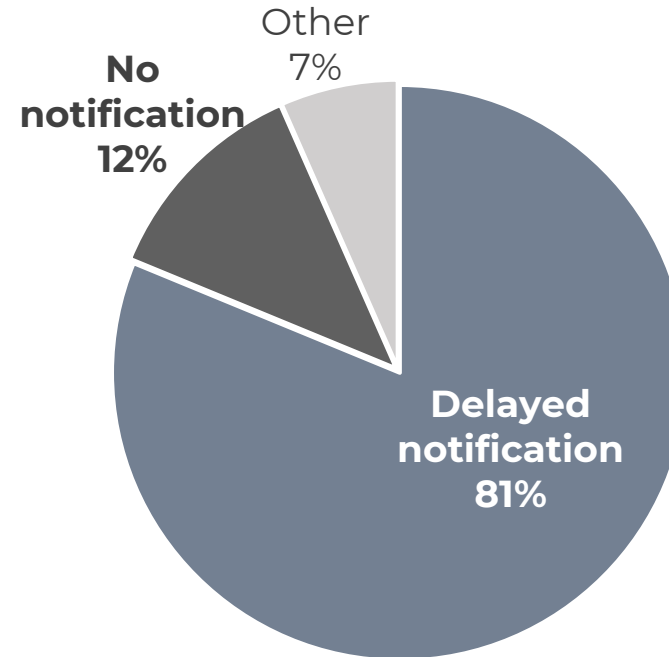
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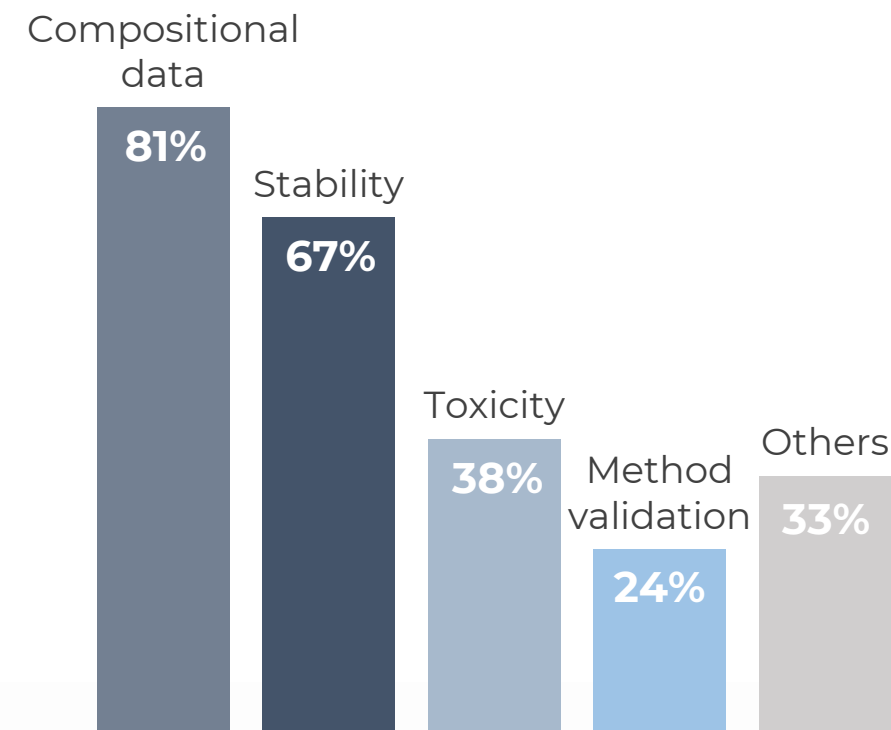
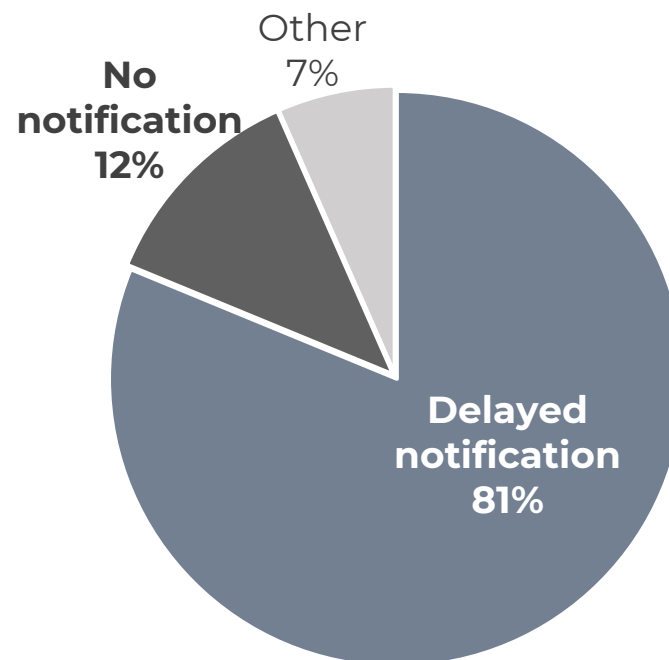
**This is 60%+ of processed applications!**

# Transparency Regulation: Reasons for non-compliance



\*Stats performed using publicly available data

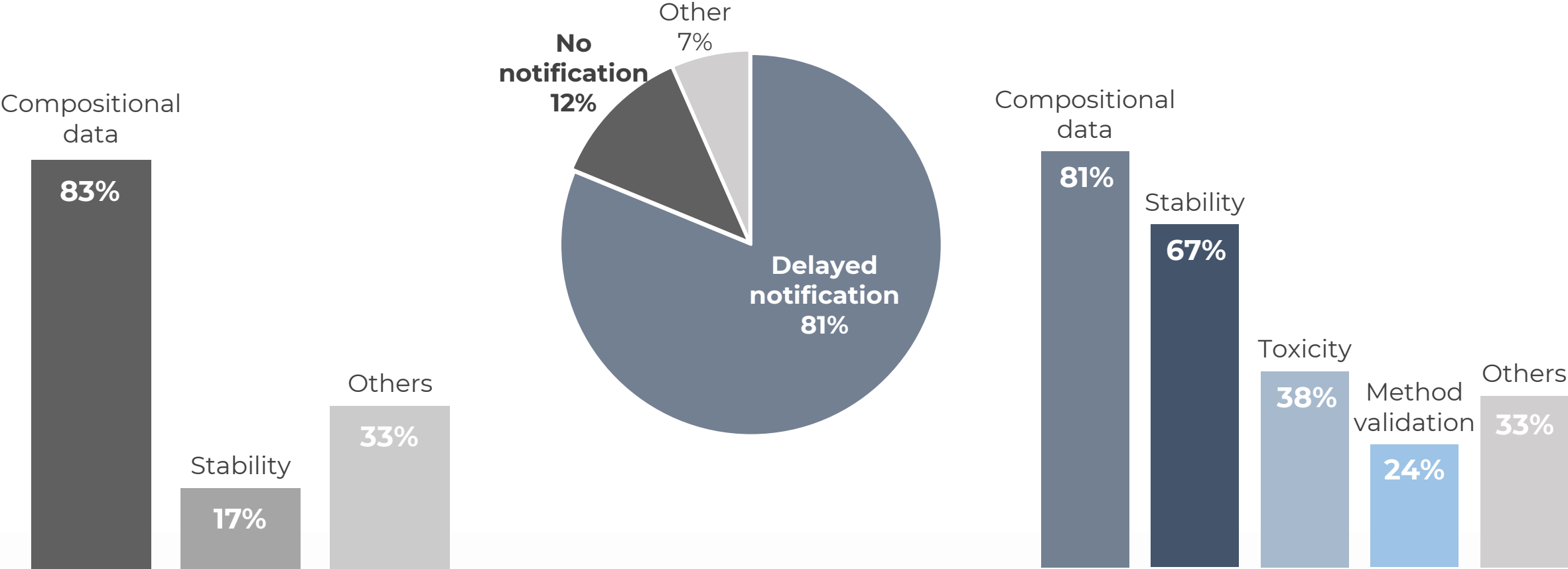
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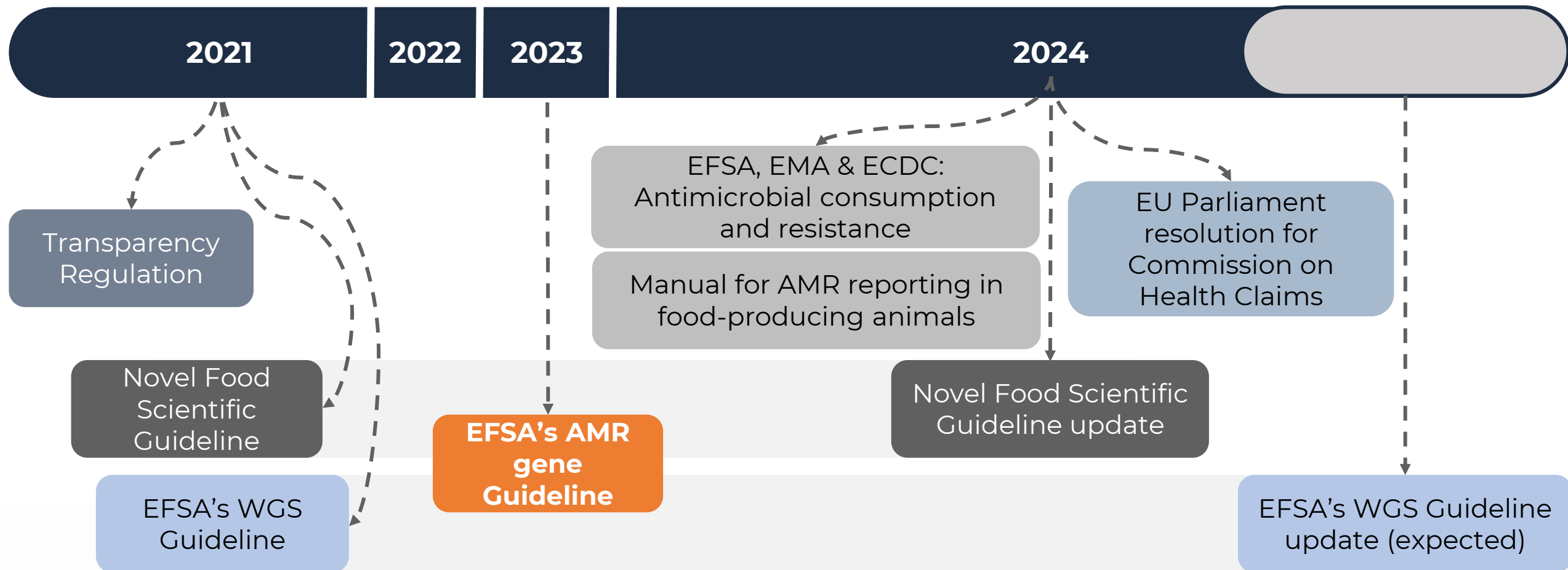
\*\*Figures over 100% because multiple applications have several reasons for non compliance

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# Genotypic AMR: Requirements & Implications

WGS

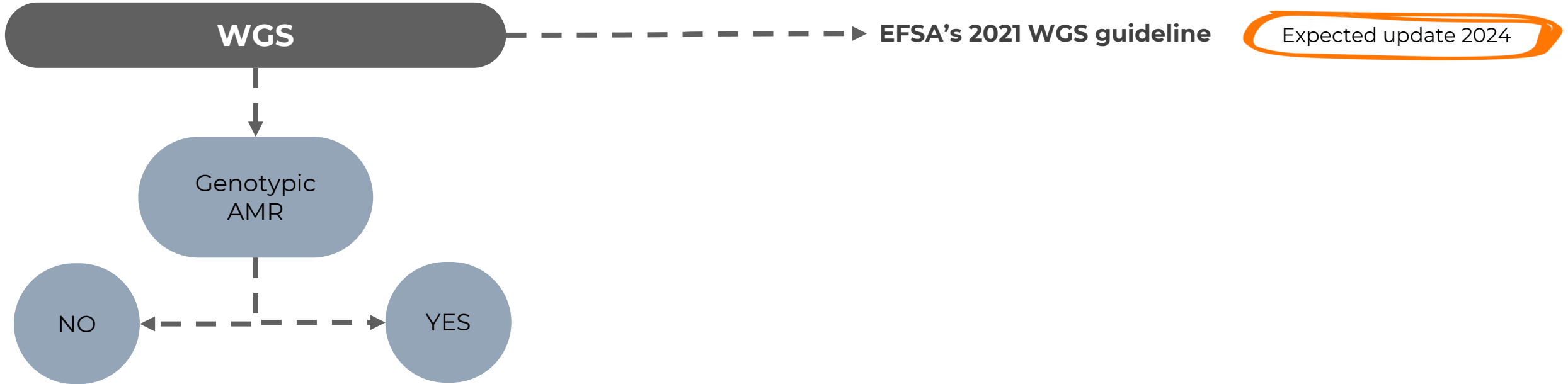
-----▶ EFSA's 2021 WGS guideline

Expected update 2024

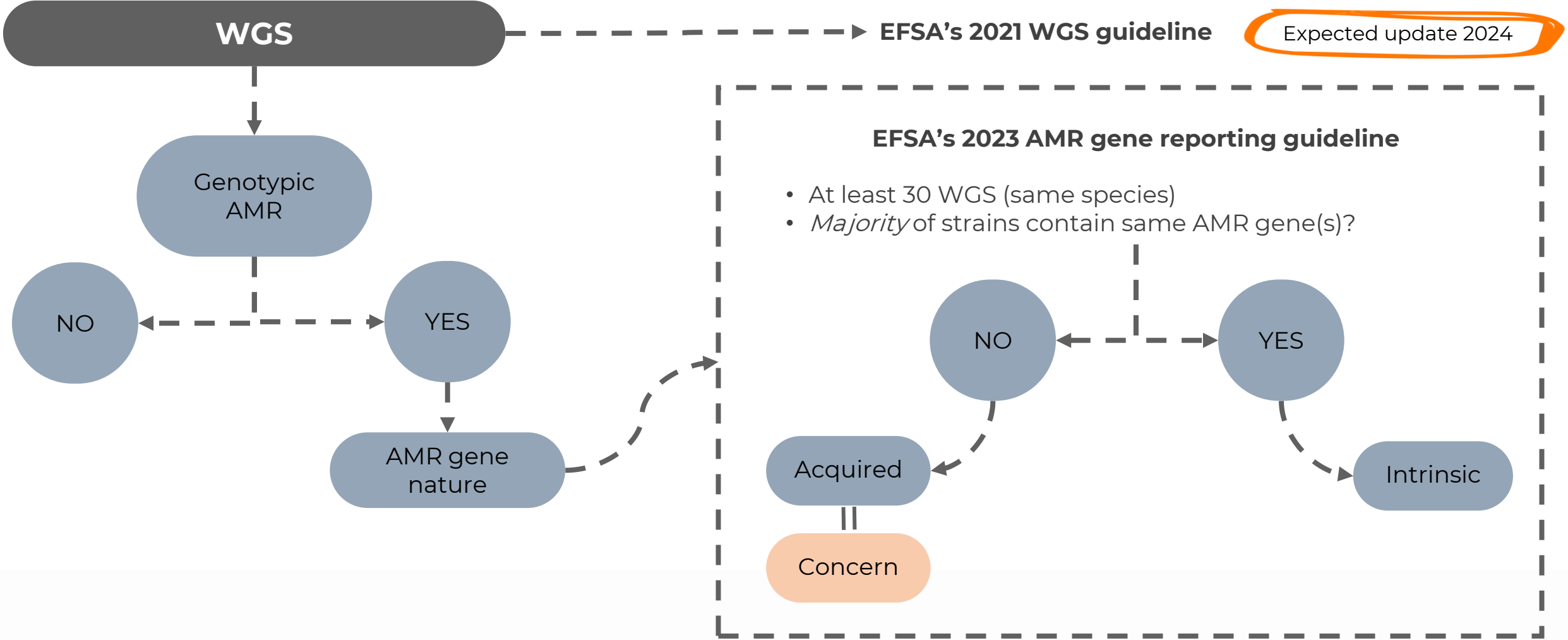




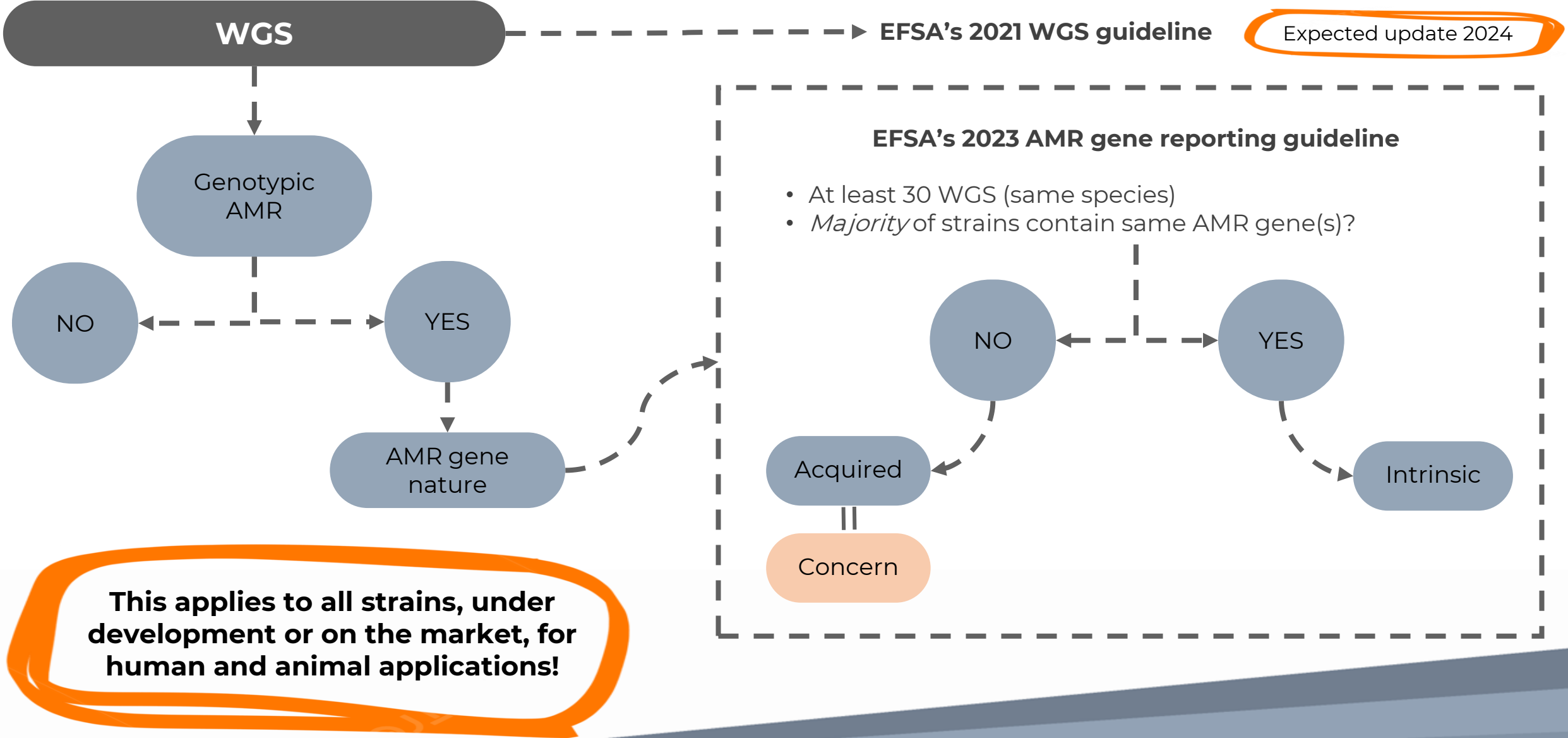
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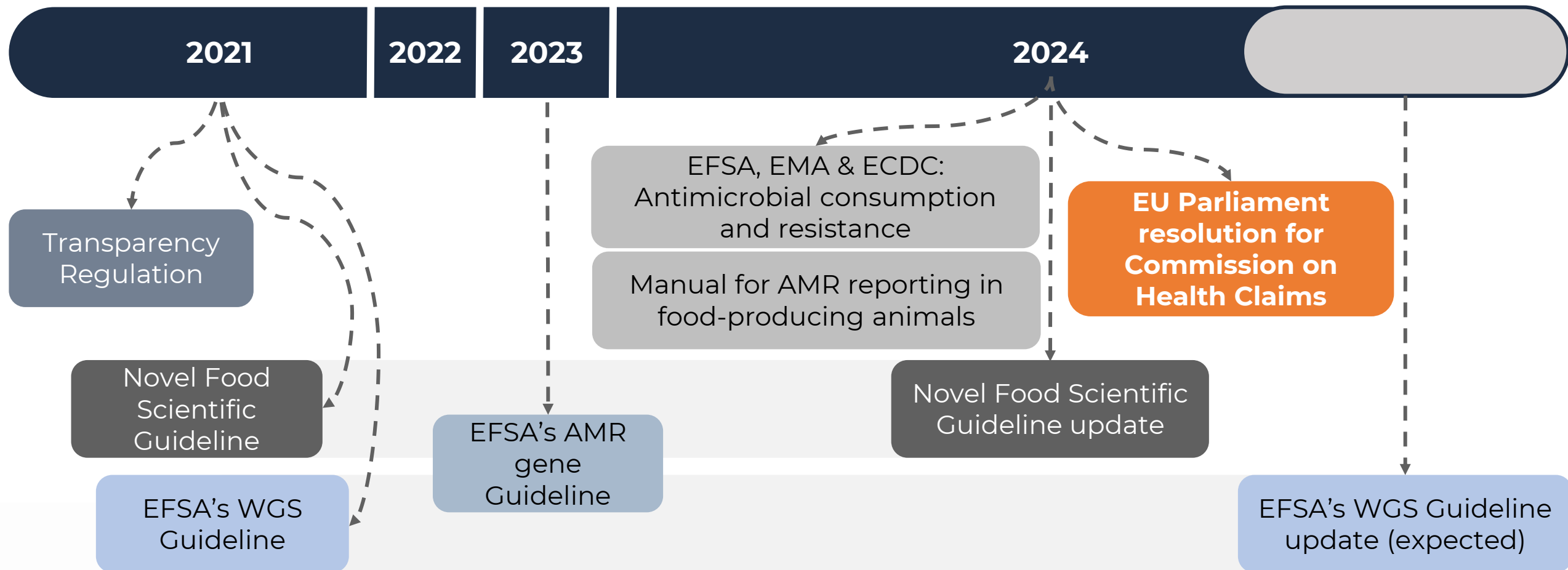
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# Regulations on communication and health claims under development and review

The **European Commission** and many national authorities are implementing online content screening to identify testimonials and endorsements that mislead consumers.

Focus includes food supplements



Ireland Spain Italy Denmark Sweden



Norway Poland Germany Romania Latvia



France

66% of investigated non-compliant  
Penalties up to 2 years in prison  
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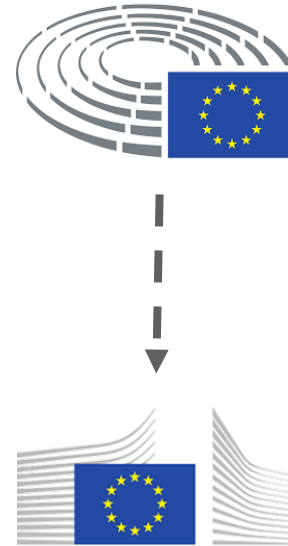


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On 18<sup>th</sup> January 2024, the European Parliament published a resolution on the implementation of Regulation 1924/2006 on nutrition and health claims urging on the European Commission to:

- Review the regulatory framework
- Harmonize
- Enforce the Regulation
- **Re-assess the nutritional status of Europeans to re-consider authorized health claims**
- ***Assess on hold* claims for botanicals**

# Take-home messages

1

EU and national authorities seem to be taking probiotics more seriously

2

Regulation is becoming more stringent, and relevant updates have been frequent recently – more expected

3

Three main challenges:

- **Transparency Regulation**, which forces developers to notify many steps of strain development before they are initiated
- **AMR gene guideline**, which:
  - Forces developers to check for AMR genes in at least 30 additional strains
  - May leave out many strains out of the market due to *acquired* AMR gene presence
- **Health claims** revisitation, which may make it more difficult to make indirect health claims

# SANDWALK

Bioventures

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Managing Director & Co-Founder  
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