Data Protection

from an industry perspective

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Why is data protection important

Safety

A high level of protection to human health, animal health and the environment

Recital 3 of BPR

(3) The purpose of this Regulation is to improve the free movement of biocidal products within the Union while ensuring a high level of protection of both human and animal health and the environment. Particular attention should be paid to the protection of vulnerable groups, such as pregnant women and children. This Regulation should be underpinned by the precautionary principle to ensure that the manufacturing and making available on the market of active substances and biocidal products do not result in harmful effects on human or animal health or unacceptable effects on the environment. With a view to removing, as far as possible, obstacles to trade in biocidal products, rules should be laid down for the approval of active substances and the making available on the market and use of biocidal products, including rules on the mutual recognition of authorisations and on parallel trade.

Why is data protection important

Level playing field

A level playing field should be established as quickly as possible on the market for existing active substances

Recital 58 of BPR

(58) A level playing field should be established as quickly as possible on the market for existing active substances, taking into account the objectives of reducing unnecessary tests and costs to the minimum, in particular for SMEs, of avoiding the establishment of monopolies, of sustaining free competition between economic operators and of equitable compensation of the costs borne by data owners.

Data Protection under the BPR – Art 60

2. The protection period for data submitted with a view to the approval of an existing active substance shall end 10 years from the first day of the month following the date of adoption of a decision in accordance with Article 9 on the approval of the relevant active substance for the particular product-type.

Article 60

Data protection periods

1. Data submitted for the purposes of Directive 98/8/EC or of this Regulation shall benefit from data protection under the conditions laid down in this Article. The protection period for the data shall start when they are submitted for the first time.

Data protected under this Article or for which the protection period under this Article has expired shall not be protected again.

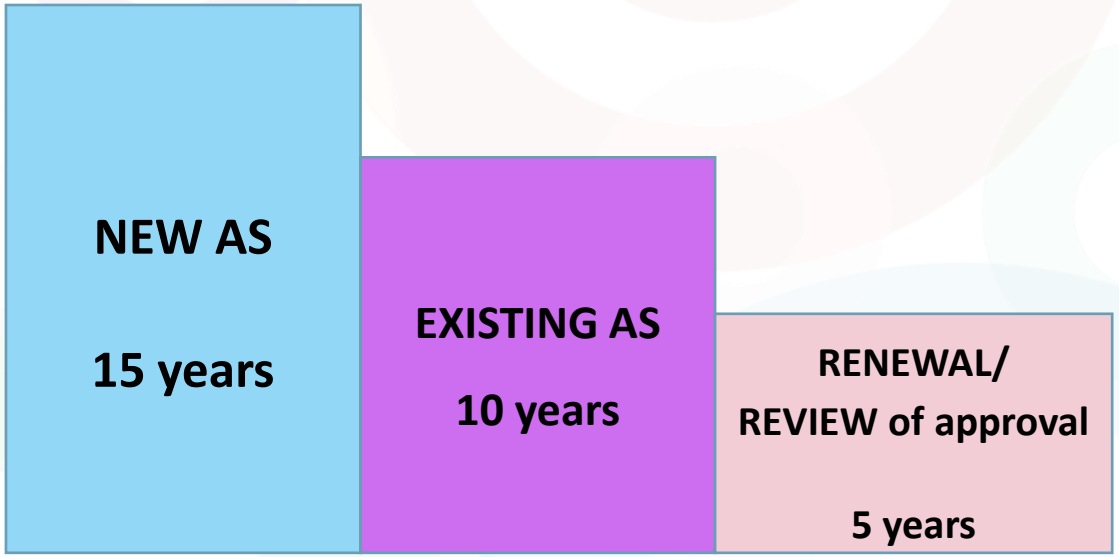
2. The protection period for data submitted with a view to the approval of an existing active substance shall end 10 years from the first day of the month following the date of adoption of a decision in accordance with Article 9 on the approval of the relevant active substance for the particular product-type.

The protection period for data submitted with a view to the approval of a new active substance shall end 15 years from the first day of the month following the date of adoption of a decision in accordance with Article 9 on the approval of the relevant active substance for the particular product-type.

The protection period for new data submitted with a view to the renewal or review of the approval of an active substance shall end five years from the first day of the month following the date of the adoption of a decision in accordance with Article 14(4) concerning the renewal or the review.

Data Protection under the BPR – Art 60

- The protection period for the data shall start when they are submitted for the first time
- The protection period for the submitted data shall end **X** years from the first day of the month following the date of adoption of a decision



Data Protection under the BPR – Art 95(5)

Article 95

Transitional measures concerning access to the active substance dossier

5. By way of derogation from Article 60, all data protection periods for active substance/product-type combinations listed in Annex II to Regulation (EC) No 1451/2007, but for which a decision on inclusion in Annex I to Directive 98/8/EC was not taken before 1 September 2013, shall end on 31 December 2025.

Data Protection under the BPR – Art 95(5)

- **HARD**

31 December 2025

WORRIES INDUSTRY A LOT

Data Protection versus Review Programme

Intention

Review Programme finalized by 2014

⇒ALL existing Active Substances would benefit from 10 years data protection (Art 60)

Data Protection versus Review Programme

Reality

Review Programme NOT finalized by 2014 nor 2024

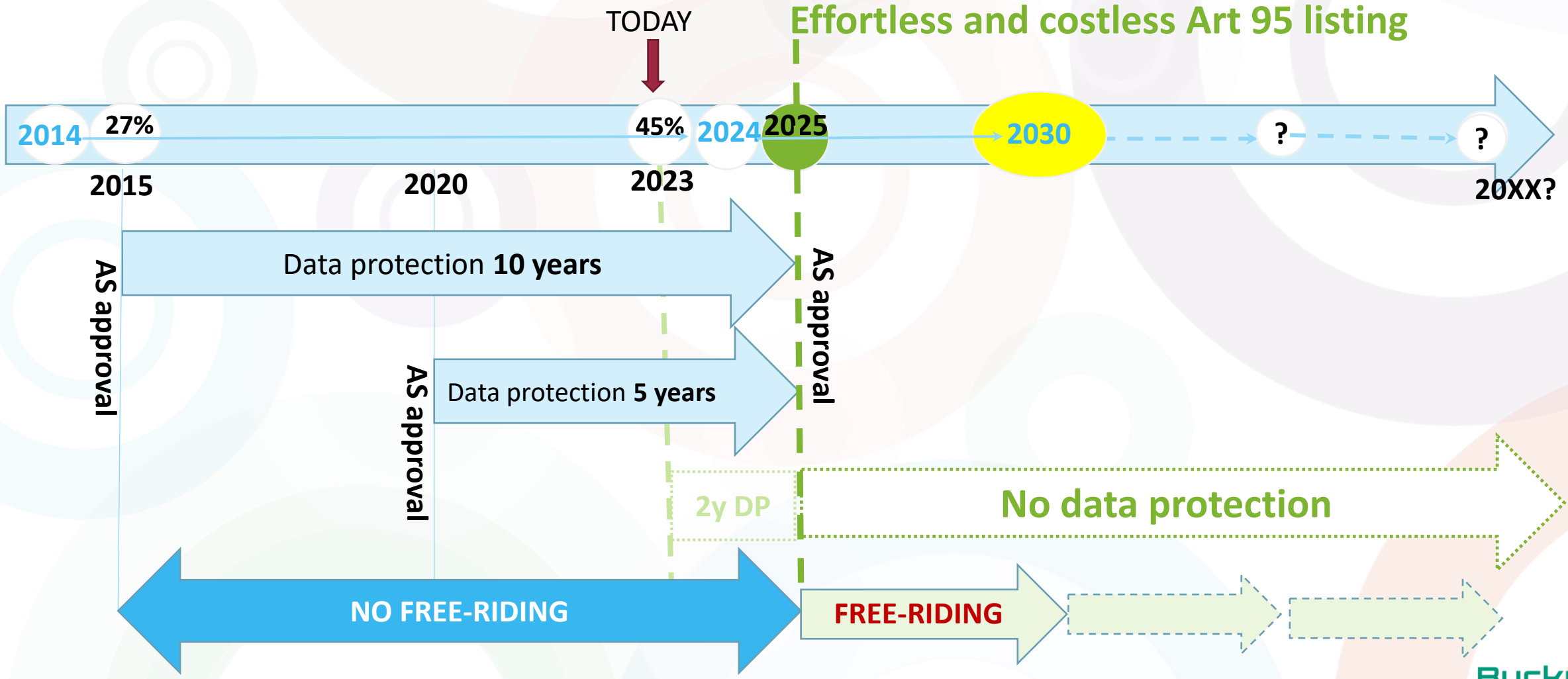
⇒Only 27% of existing Active Substances benefit

from 10 years data protection (Art 60)

due to moving goal posts, e.g. continuously changed rules during the evaluation

It was not expected that RP would not even be finalized by 2024

Data Protection versus Review Programme



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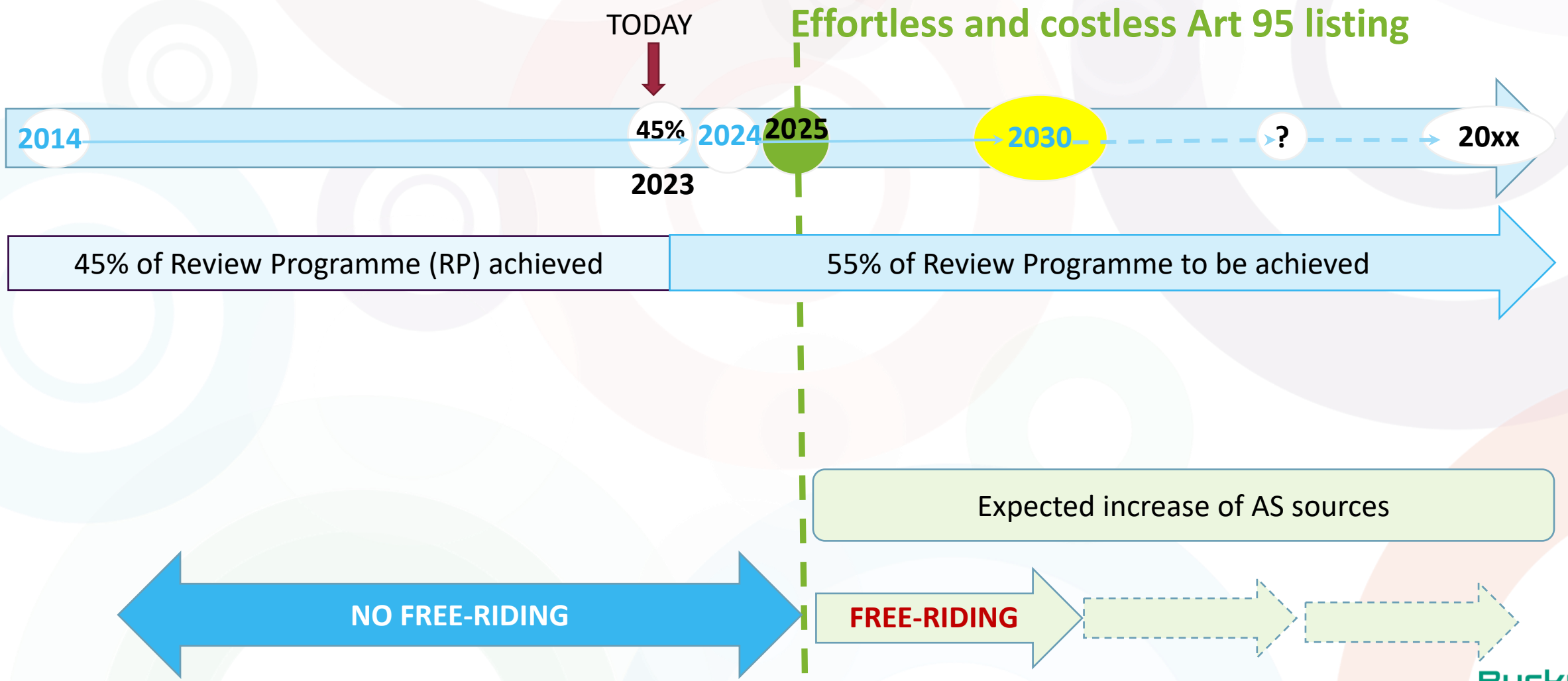
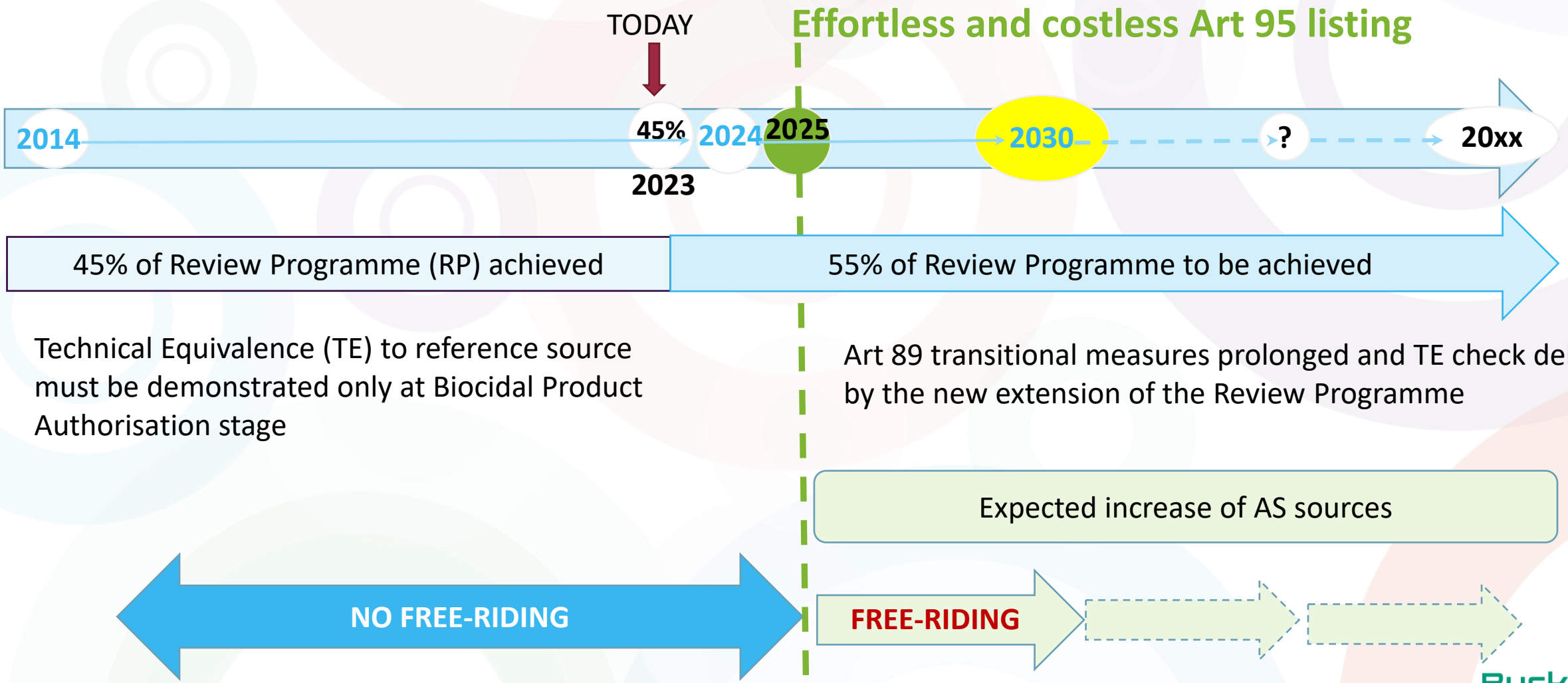
Chemistry, connected.

Data Protection beyond 2025



Data Protection beyond 2025



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What does the biocide industry want

- **NO HARD STOP !!!**
- Equal and fair treatment of all players for new data generated and submitted under the BPR
- New data = data generated under the BPR such as :
  - The entry into application of the BPR
  - New / continuously changing guidance
  - Endocrine Disruptors (ED) Regulation/BPR Annexes amendments
  - Redefinition of an active substance …

What is impact on BPR goals ?

Safety

A high level of protection to human health, animal health and the environment

Beyond 2025

- Uncompliant sources
- Level of (relevant) impurities
- Technical Equivalence (TE) delayed due to Review Programme delays

What is impact on BPR goals

Level playing field

A level playing field should be established as quickly as possible on the market for existing active substances

Recital 58 of BPR

- Reintroduction of

FREE-RIDING

Data protection @other Regulations

Plant Protection Product Regulation

(EC)1107/2009

Test and study reports **->** data protection of **10 years data protection from the date of first authorisation** (13 years for low-risk plant protection products).

REACH

(EC) 19/07/2006

The study summaries and robust study summaries of studies submitted in the framework of registration **-> 12 years data protection from the date of the submission**

Data Protection under the BPR – Next

- No hard stop for the data protection !
- Equal and fair treatment for all players for new data generated and submitted under the BPR
- High level of protection

Data Protection under the BPR – Next

- Authorities to understand and acknowledge the importance of data protection and work together with industry for a solution

- MS and ECHA to support COM in using the most appropriate legal and regulatory tools to ensure data protection for new studies, matching the length of the review programme, in close dialogue with industry

Thank you !

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