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Stakeholder 3Rs initiatives – a view from Animal Health

Belgian presidency public conference
'Advancing the 3Rs for regulatory testing of medicines'
Antwerp, 31st January 2024

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Animal use in Animal health

- Veterinary medicines support the health and welfare of companion animals, food producing animals as well as many other minor species.
- It is therefore both important scientifically and within regulation, that such medicines are tested in the target species to ensure both safety and efficacy
- However, the Animal Health industry is committed to the 3Rs principles within regulated studies as well within research and routine product release

Animal Use in numbers

Based on EU commission report*

from 2023, in 2022 animal use for regulatory purposes for Veterinary medicine was 22.8% of the total

(figure varies from 15-20% approx. since 2015)

*** COMMISSION STAFF WORKING DOCUMENT**
Summary Report on the statistics on the use of animals for scientific purposes in the Member States of the European Union and Norway in 2020

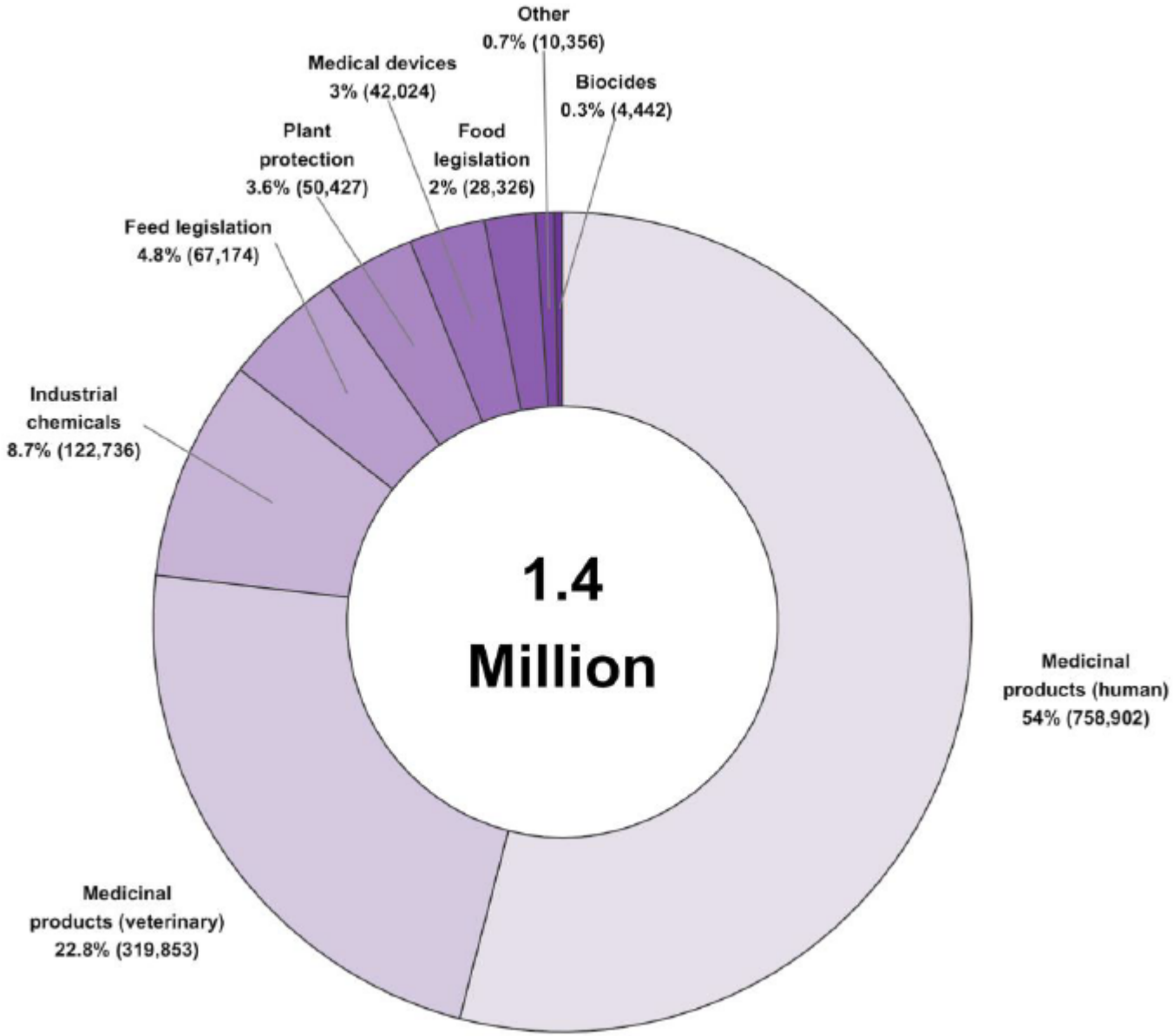
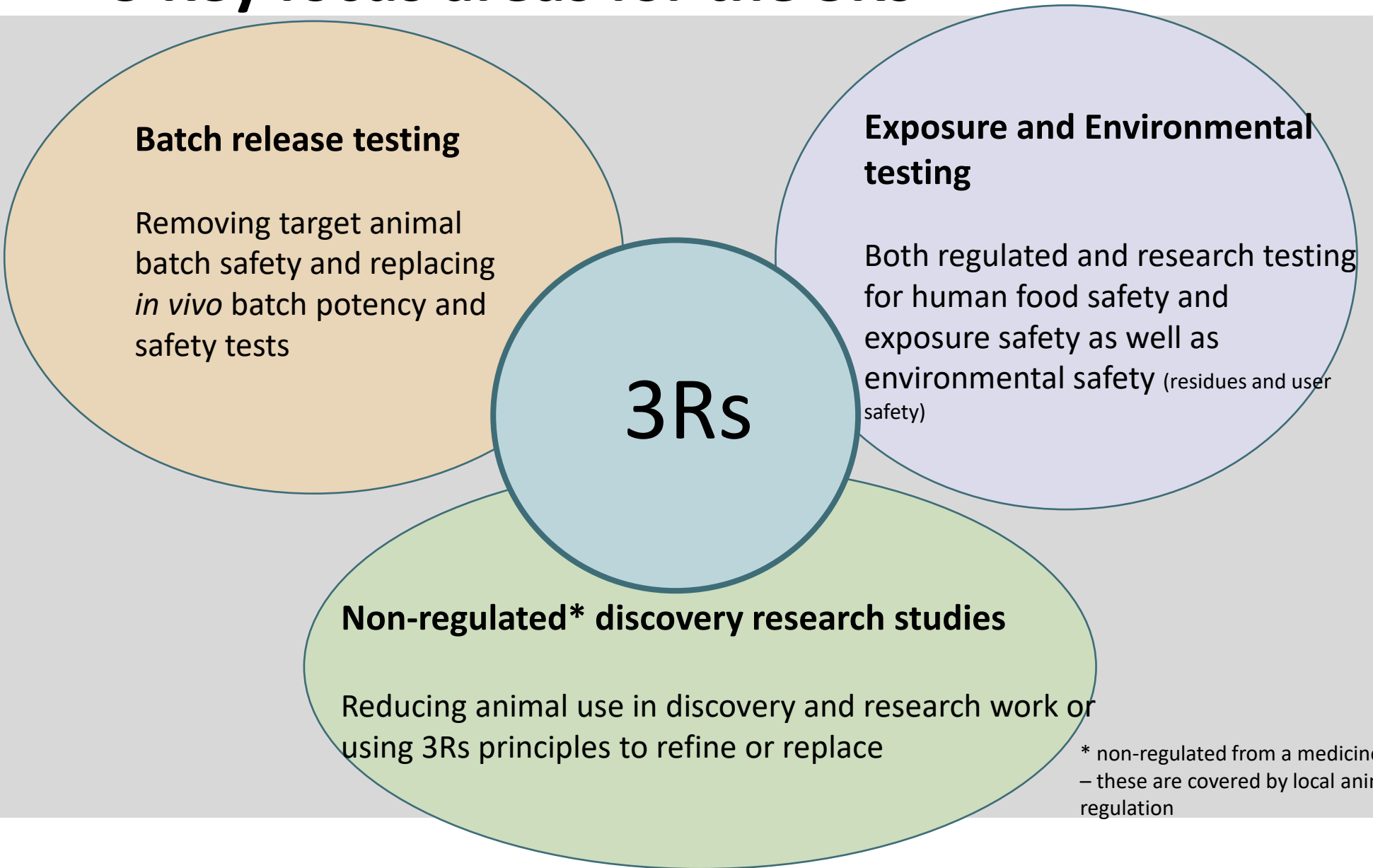


Figure 4: Regulatory uses by type of legislation in 2020

3 Key focus areas for the 3Rs



* non-regulated from a medicines point of view – these are covered by local animal use regulation

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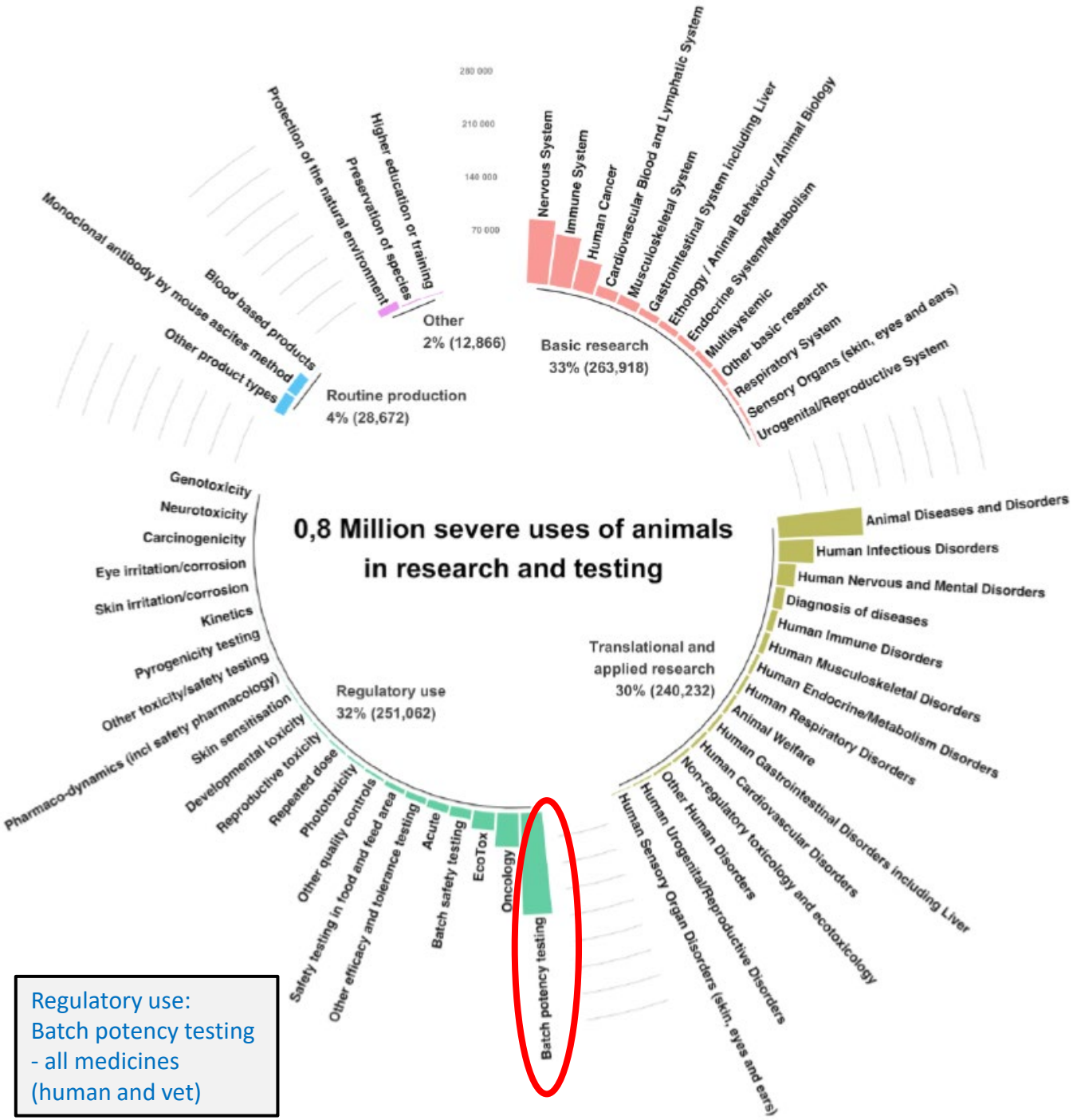
Batch release testing

Batch release testing

- Animal use for batch release testing is a key focus area for reduction and replacement
- Target animal batch safety testing in the EU is no longer required but work is still required internationally to phase out
- Many companies have targeted funded programs to replace *in vivo* batch potency tests with *in vitro* ones
- Partners in projects like VAC2VAC (IMI2) to promote and develop *in vitro* batch release tests

[Home | Vac2Vac (europevaccine.wixsite.com)](europevaccine.wixsite.com)



Regulatory use:
Batch potency testing
- all medicines
(human and vet)

Batch release test success stories

- Working with EDQM on BSP projects for C.septicum safety testing (BSP 130)
  - Work in this area also resulted in the deletion of final product residual toxicity test from 3 Clostridial monographs
- Rabies potency tests – revisions to the Ph.Eur. to support in vitro batch potency tests and most companies now have in vitro potency test approval in the EU
- Removal of the target animal batch safety test from all EU requirements
  - Successful collaboration with EDQM and the regulatory network
- Supporting training for regulators on approaches to developing and transitioning to *in vitro* batch testing
- Ph.Eur chapter 5.2.14 provides good guidance for industry

The Global Picture

One of the biggest challenges is global acceptance of *in vitro* batch release testing

Through HealthforAnimals industry is working to promote regulatory acceptance

- Mapping acceptance of batch safety test removal and focusing effort
- Mapping acceptance of *in vitro* batch release testing
- Collaboration with IABS and AFSA to promote regulatory acceptance and develop targeted action plan
- Engaging with WOAH to understand how partnership can be used to support global regulatory acceptance
- AnimalhealthEurope proposed a VICH GL on *in vivo* to *in vitro* transition (this concept was approved)

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Exposure and Environmental safety testing

Areas of Focus

In addition to data on target species many product development programs require data on human food safety, user safety and environmental safety

These aspects touch on animal use purposes that are common across the Human and Veterinary medicines area as well as the chemicals and pesticides sectors

The Animal Health industry is working with both the EMA 3Rs WP as well as through EPAA partnerships to contribute to developing methods and promoting regulatory acceptance in all of these areas

Recent examples

- **Participating in EPAA Partners forum on exposure assessment**
  - Promoting use of PBK modelling, QIVIVE and other ways to assess data
  - Represented in follow up project

- **Exploring the use of big data and AI to reduce animal use in safety assessment**
  - Can data from historical control groups be used to reduce animal numbers (already being used in Human Health)

    Hartung T (2023) Artificial intelligence as the new frontier in chemical risk assessment. *Front. Artif. Intell.* 6:1269932. doi: 10.3389/frai.2023.1269932

- **Engaging with the PARC consortium collaboration through EPAA**
  - Many important cross sectorial aspects that can impact Animal Health – for example NGRAroute (task 2,2) where stakeholder engagement is critical as new technology evolves to support this approach but also to ensure this approach does not result in additional safety factors that could impact withdrawal periods

[Partnership for the Assessment of Risks from Chemicals | Parc (eu-parc.eu)]

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Discovery Research

Areas of early research for Animal reduction

- Using RWE/Big Data and AI analysis tools to leverage existing data in discovery
- Using modelling technology to predict *in vivo* activity on early screening
- Exploring the use of external control arms in studies
- Working to understand *in vitro/ex vivo* models for disease or organs for early screening for toxicity and understanding mechanism of action

  Establishment and Characterization of Novel Canine Organoids with Organ-Specific Physiological Similarity

  Christopher Zdyrski, Vojtech Gabriel, Oscar Ospina, Hannah Wickham, Dipak K. Sahoo, Kimberly Dao, Leeann S. Aguilar Meza, Leila Bedos, Sydney Honold, Pablo Piñeyro, Jonathan P. Mochel, Karin Allenspach

  bioRxiv 2022.07.15.500059; doi: https://doi.org/10.1101/2022.07.15.500059

- Refinements to avoid challenge studies in early vaccine research

Committed Support for 3Rs initiatives

- AnimalhealthEurope (AhE) is a member of EPAA (in addition to individual company members)
- 3Rs Task Force within AhE to engage with and support activity of the EU Regulatory network and partnerships like EPAA
- AnimalhealthEurope participated in the EMA 3RsWP Stakeholder consultation in 2023
- AnimalhealthEurope is actively supporting and promoting VICH Guidelines supporting 3R principles
  - AnimalhealthEurope will be topic leader for work on a new VICH 3Rs guideline
- Global 3Rs Task Force under HealthforAnimals
  - Partnerships with AFSA and IABS, and engagement with WOAH

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An overall view

Commitment to Animal welfare and the 3Rs

- Our products directly support animal health and welfare
- Commitment to achieve animal free batch release testing
- Commitment to engage with regulatory and academic and cross sectorial projects to reduce or replace animal use in exposure and environmental studies
- Committed to reducing animal use in early research wherever possible
- Follow 3Rs principles in all we do

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