ANNEX 3 – WORKSHOP DRIVER MAPPING DATA

Context

This document compiles the information gathered during the Animals in Science Committee (ASC) Futures Working Group (FWG) workshop on 29 July 2021. Workshop attendees were allocated to three subgroups, facilitated by an ASC Member. First, each subgroup was presented with a number of drivers under different themes relevant to the topic of animals in science and asked to map these onto axes of importance and uncertainty. Then, each subgroup was asked to select 1-3 priority drivers from the “high importance, high certainty” and “high importance, low certainty” quadrants of their mapping exercise. For each driver, the groups identified and discussed any additional risks or opportunities that had not been identified in the scan. The groups then discussed actions that could be taken to mitigate the risk or exploit the opportunity.

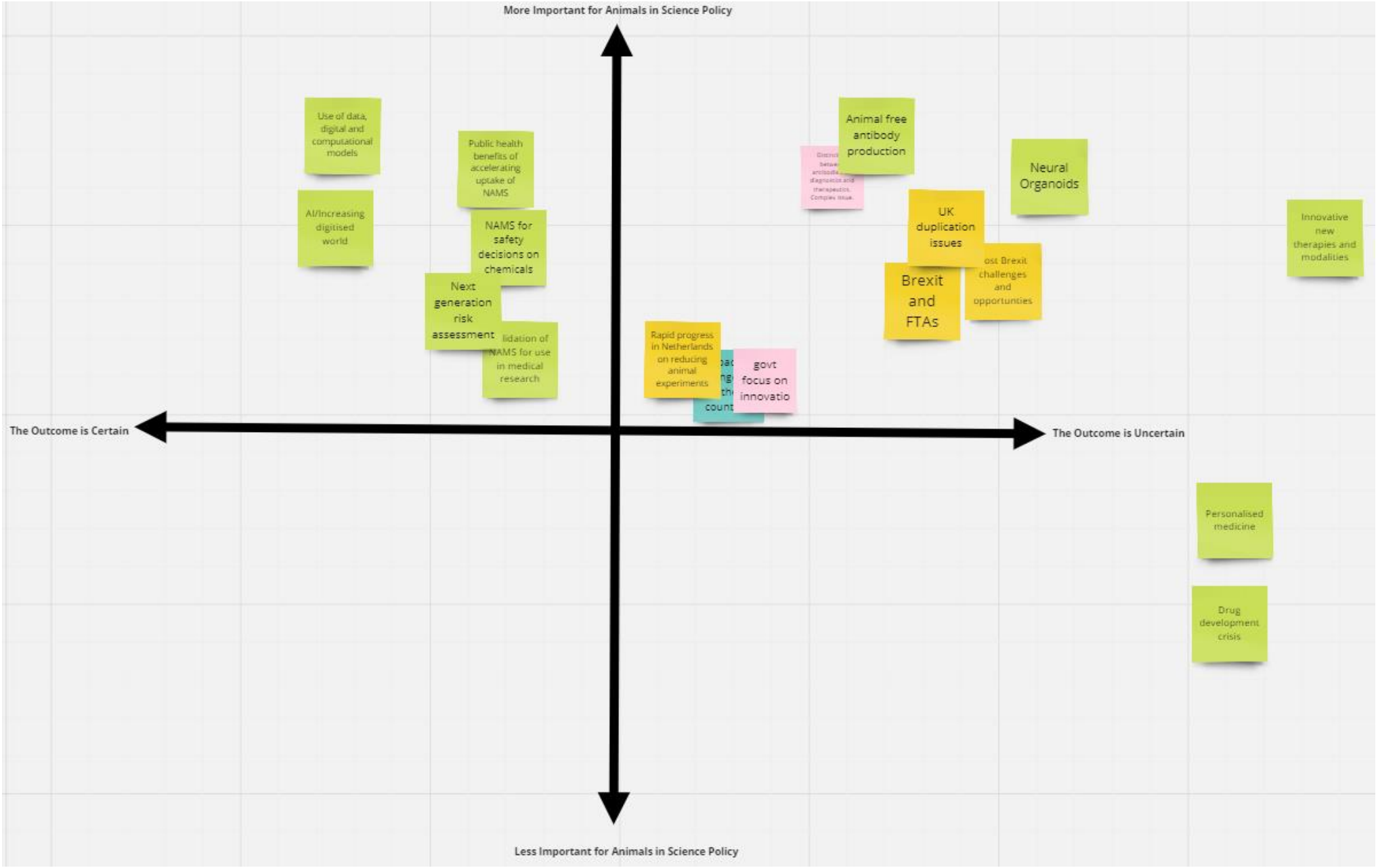
The following themes were allocated to the subgroups:

- Subgroup 1
  - New Approach Methodologies (NAMs)
  - UK policy in an international context
- Subgroup 2
  - Preclinical/toxicological regulatory issues
  - Societal concerns
- Subgroup 3
  - Sentience
  - Climate Change
  - Issues affecting establishments

Summary

Issues which require action (top left quadrant)	*Issues which require scenario planning (top right quadrant)*	*Issues which require tracking (bottom quadrants)*
• Use of data, digital and computational models • Public health benefits of accelerating uptake of NAMs • Artificial intelligence (AI) / increasingly digitised world • NAMs for safety decisions on chemicals • Next generation risk assessment • Validation of NAMs for use in medical research • Thematic review • Public and political interest in a phase-out programme • Increasing public concern about the use of animals in research • Second species testing • Section 24 and transparency • Review of membership profile of ASC • Increase in household product testing • Project licences for e-cigarettes • Ethical consumerism • Culture of care • Sentience • Decapods • Use of genetic modification (GM) technology • Global food sustainability • Complexities of genetically-altered (GA) or genetically-engineered (GE) animals and subsequent overbreeding • Animal research and sites other than licensed establishments • Transport and supply of animals • Can anaesthesia go green? • Sustainability • Increased automation in management: housing, care, and welfare of laboratory animals • Veterinary retention	• Animal-free antibody production • Neural organoids • UK duplication issues • Post-Brexit challenges and opportunities • Brexit and free trade agreements (FTAs) • Government focus on innovation • Rapid progress in Netherlands on reducing animal experiments • Impact of changes in other countries • Distinction between antibodies for diagnostics and therapeutics • Mental health • Pre-clinical testing of novel medical devices using large animals • Heterogeneity	• De-extinction • Societal contributions • Pollution and health

Subgroup 1 (“New Approach Methodologies” and “UK policy in an international context”)



Priority Driver 1: Post-Brexit UK

Are there are additional risks or opportunities not identified in the scan?

More flexible and nimble regulatory system for registration of chemicals and drugs (defra and Mhra)

Availability of resources to validate new methods. Need to maintain connections to what is happening in EU.

Risk of UK becoming isolated and lose benefits of non-Uk collaboration. Eg IMI, Horizon 2020. Also potential for EU to lose out because of lack of UK expertise

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What needs to be done to mitigate the risk/exploit the opportunity? For example, what evidence gaps need to be filled?

Ensure resources available to validate new methods

Maintain strong connections to what is going on in EU

bringing together cross-functional groups to apply multiple expertise to problems.

Priority Driver 2: NAMs

Are there are additional risks or opportunities not identified in the scan?

- Other organoids
- Innovation and commercialisation environment for NAMS and follow-on costs for research
- Incentives to use Needs of researchers
- Incentives to research (funding)

What needs to be done to mitigate the risk/exploit the opportunity? For example, what evidence gaps need to be filled?

- Centralised repository of knowledge for researchers, inspectors
- ASRU - training of inspectors re NAMS
- Standardisation
  - reproducible methods
  - validation

  Relevant to international research enviroment
- More general training in NAMS
  - researchers, students etc

Priority Driver 3: Data access and use

Are there are additional risks or opportunities not identified in the scan?

Access to data - MTAs

Duplication of research

Publishing and ethical approvals
Pre-prints and communication
Interpretation, representation and understanding/expertise

Commercialisation environment including patents/data exclusivity
- impact on access to innovation
- impact on reduction of animals
- costs etc
- NC3Rs
Confidentiality and trade secrets

What needs to be done to mitigate the risk/exploit the opportunity? For example, what evidence gaps need to be filled?

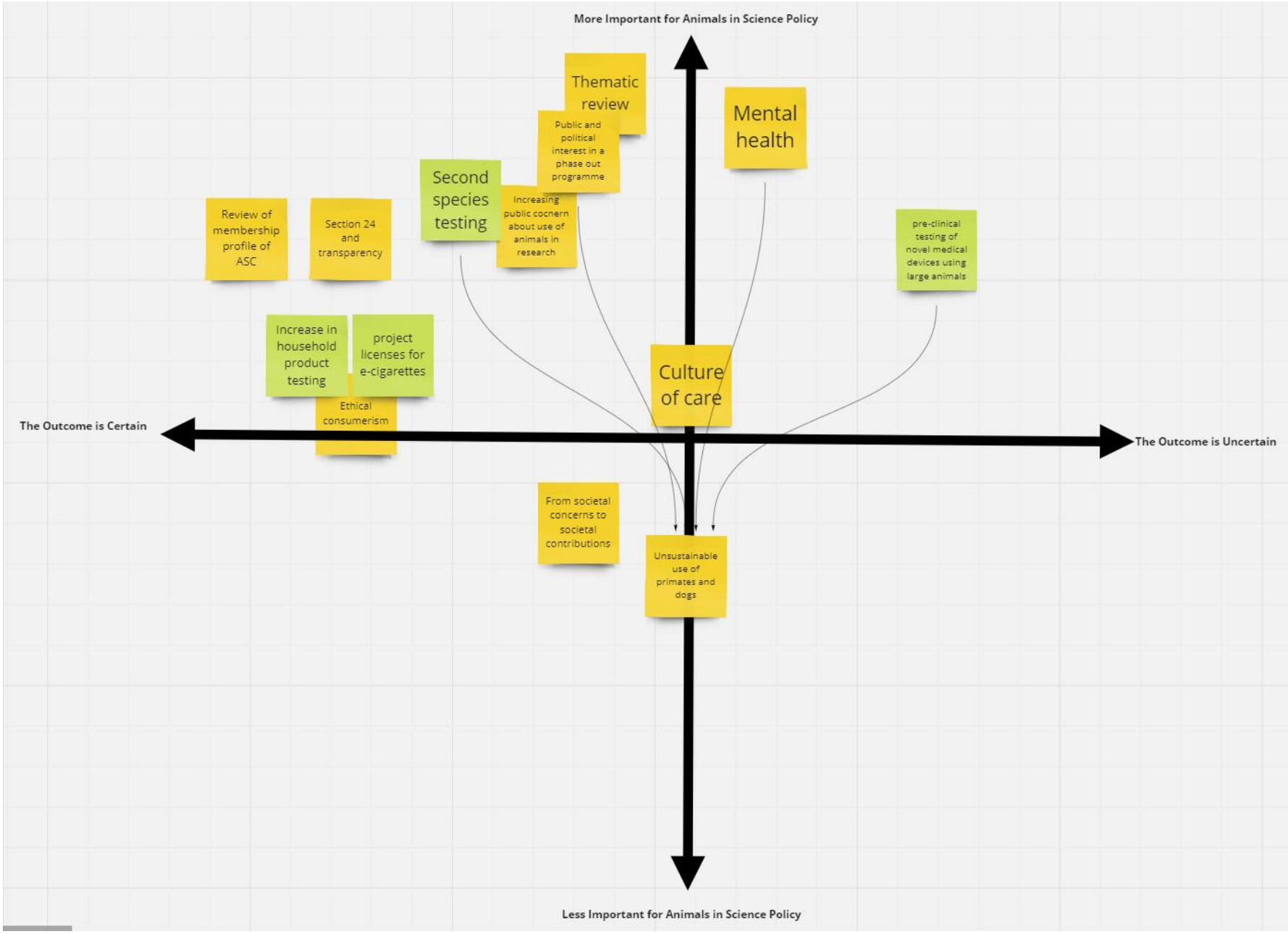
Central repository of regulatory data, mining and predictability of toxicity pathways

Publishing
- effective application of ethical approvals and other protocols

Patent and data exclusivity
- eligibility of subject matter; access to data; exceptions and limitations

Defining duplication

Subgroup 2 (“Preclinical/toxicological regulatory issues” and “Societal concerns”)



Priority Driver 1:Thematic Review & Interest in a phase out programme

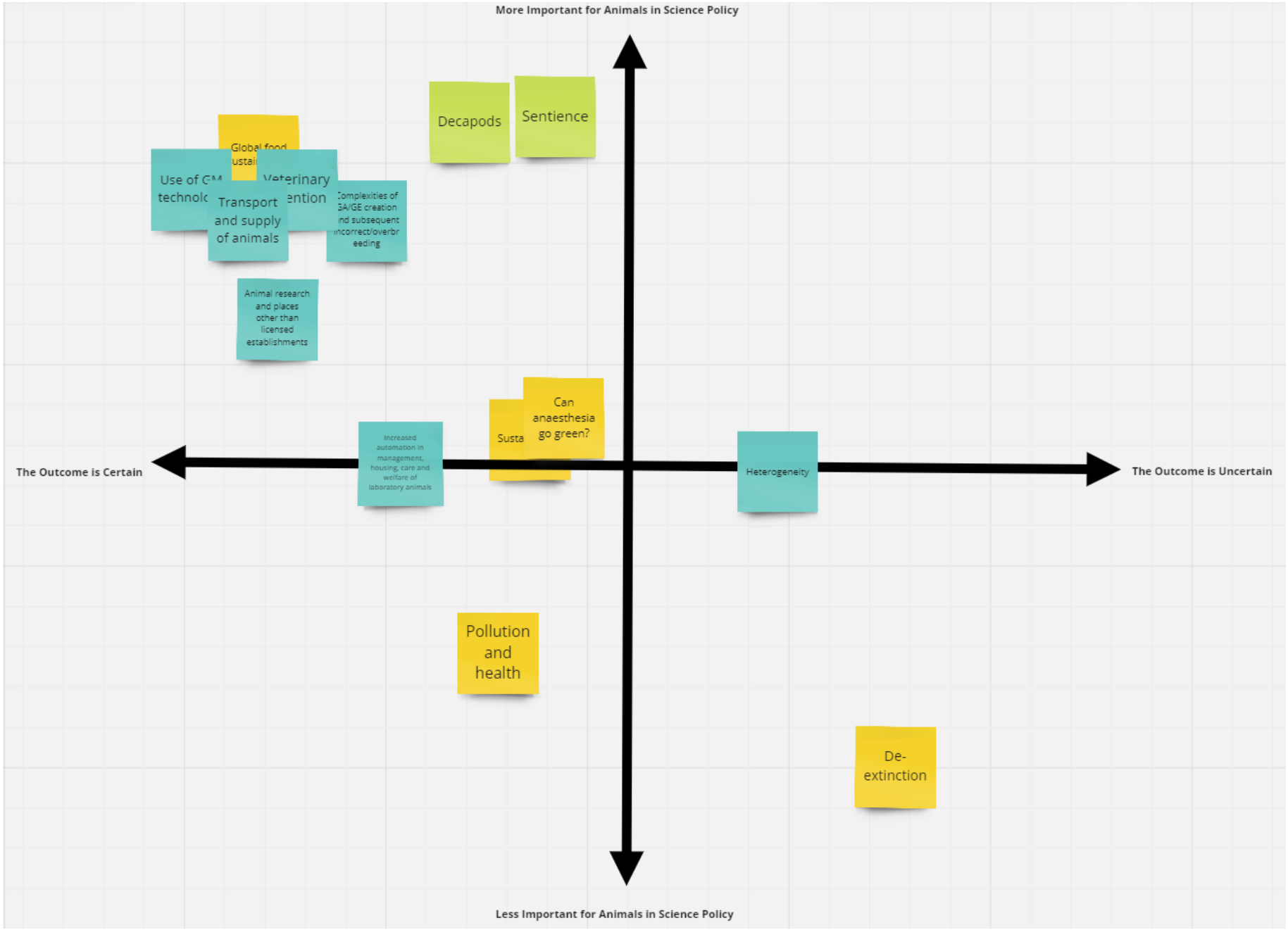
Are there are additional risks or opportunities not identified in the scan?

- To implement ASPA 'when practicable'
- The overarching goals of the directive is to replace the use of animals
- Opportunity to update UK policy
- Roadmap - Prioritising the order and scope of thematic reviews

What needs to be done to mitigate the risk/exploit the opportunity? For example, what evidence gaps need to be filled?

- Sustainable ownership of long term policies
- International consensus on what validation means (in the context of the relevant decision making)
- International consensus on the scope of key animal/new tech models
- Public and patient engagement (importance of speaking to not just for people affected by these issues)
- focusing the 'UK science powerhouse' towards supporting and funding the work on model development, validation and implementation

Subgroup 3 (“Sentience”, “Climate Change” and “Issues affecting establishments”)



Priority Driver 1: Sentience - scope and implementation of legislation, public concern etc

Priority Driver 2: GM technologies - increasing applications, plus management, training issues

Are there are additional risks or opportunities not identified in the scan?

Risk of GA technology being expanded without deep background expertise on species or genetics

Risk of lack of QC for GA strains (genotype) especially those imported into facilities

Lack of uptake for new and refined models because of historical experimental paradigms

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Risk of waste of commercial and intellectual resources which could be better applied to supporting other technologies

What needs to be done to mitigate the risk/exploit the opportunity? For example, what evidence gaps need to be filled?

Sharing of good practice e.g. colony management

Public interest

challenge scientific inertia in model development

Priority Driver 3: Ethical and practical issues relating to the supply and transport of animals for use in research and testing in the UK

Are there are additional risks or opportunities not identified in the scan?

- Risk animal work may have to be out sourced from UK if animals are not available. Welfare Implications
- Links with lack of potential NVS employment career pathways and OVI checks
- This is a current problem and lack of EHCs and legislation issues could get worse
- Disease spread / pandemic issues reducing opportunities for transport ? Will this increase?
- Ethical transport issues, welfare and germplasm
- Public concern and protests

What needs to be done to mitigate the risk/exploit the opportunity? For example, what evidence gaps need to be filled?

- Produce evidence on impact of pressure on supply of animals - new sources, welfare etc.
- Do we need to take another look at the roles of biobanking and sharing of materials and data i this context?
- Introduce methods to measure, and respond to, environmental/sustainability/global warming impact of animal science