A future task in good hands

Bundesamt für Naturschutz

Input on Mandate on Gene Drive

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Comments on the mandate and structure of the EFSA document

- Gene drives are on many levels **substantially new** to RA and therefore we much welcome EFSA's activity.
- The current mandate covers synthetic gene drives in insects. In this regard the EFSA process will also be relevant to the **CBD process**, which however has a broader scope.
- **Technical details** for different gene drive systems could be supplemented by developmental status of the projects (Chapter 3).
- "**Ecology and population dynamics**" (Chapter 4) should also cover ERA.
- Basic challenges with the **comparative approach** illustrate the need for further scrutiny (Chapter 5).

ERA on gene drives in EFSA document

- The document does not discriminate between **efficacy** modelling and **ecological** modelling.
- Ecological effects need more consideration.
  - example: **heterogeneity** of receiving environments is seen as a challenge for the efficacy, but not for ERA.
- The discussion of effects on **non-target organisms** needs extension.
- Inadequate gene drive efficacy requires additional consideration for RA .

Where are we with modelling efficacy?

- R&D project of BfN evaluates gene drive modelling approaches.
- Models (always) run with simplifying assumptions (e.g. assuming random mating).
- Obtaining and implementing reasonable data into models can be challenging.
- An example why efficacy modelling is important for RA:
  - pulse chase dynamics for suppression drives leads to exposure for more than 1000 generations (Champer et al. 2019).

Where are we with modelling ecological outcomes?

- No ecological modelling work yet for gene drives.
- Modelling ecological impact is highly complex.
  - Biology and ecology of species
  - Ecosystem functions / variability of receiving environments
- Effect thresholds (limits of concern) / appropriate comparators to be defined
- Appropriate uncertainty analysis is crucial, verification by field trials is very challenging.

Robust ecological modelling for gene drives requires substantial research effort

Post-market environmental monitoring

PMEM is a mandatory *post-release* measure

- Use each step of the **step-by-step approach** to gain suitable scientific insight into potential adverse effects of GDMI before their release
- PMEM is **not a substitute** for proper risk assessment

CSM to confirm ERA's assumptions + efficacy of management measures

- Obtaining information about GDMI performance *is not its main goal*

GS aims to identify unanticipated and cumulative effects and contribute to long-term assessment of potential adverse effects due to GDMI release

- Should be planned to **cover wide areas**
- Needs to be implemented as **long-term surveillance**

Conclusions

- Time and space of release can be very long to infinite, how to perform proper **uncertainty analysis**?
- How to evaluate **negative environmental** effects in **natural populations** mostly outside of managed environments (ecological modelling)?
- Need for **research** and **guidance** to solve open question in **(environmental) risk assessment.**
- Need for **long-term monitoring** using suitable scientific methods and indicators to identify potential adverse effects of GDMI on the environment
- Changes by gene drives can be profound and require a **wider societal perspective**; e.g. on acceptable uncertainties, alternatives and common goals.

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Thank you for your attention