# Overview of EFSA assessment for endocrine disrupting properties of pesticide active substances

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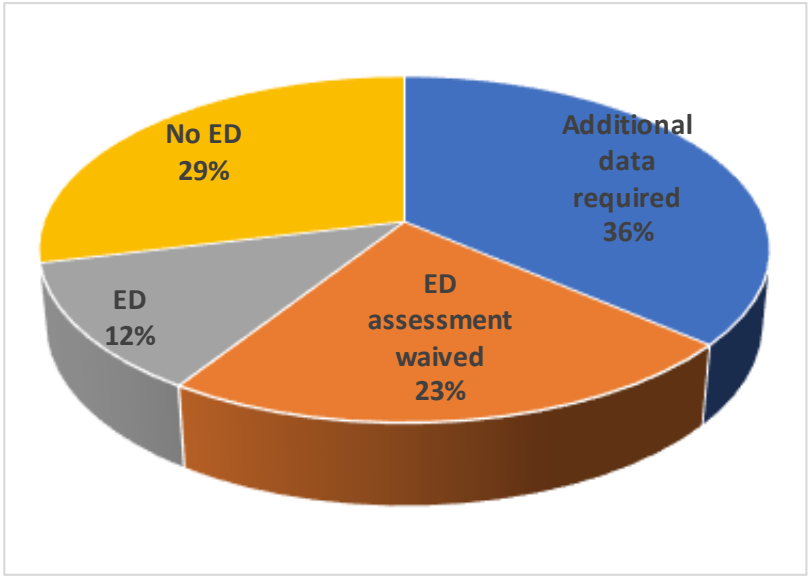
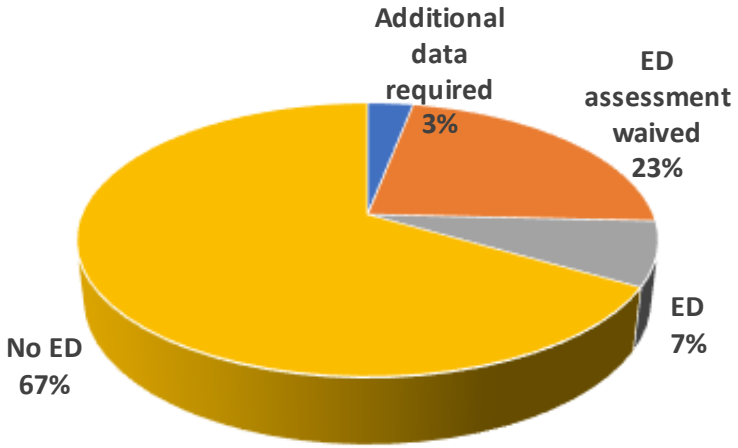
efsa
European Food Safety Authority

# Summary of the ED assessments for HH

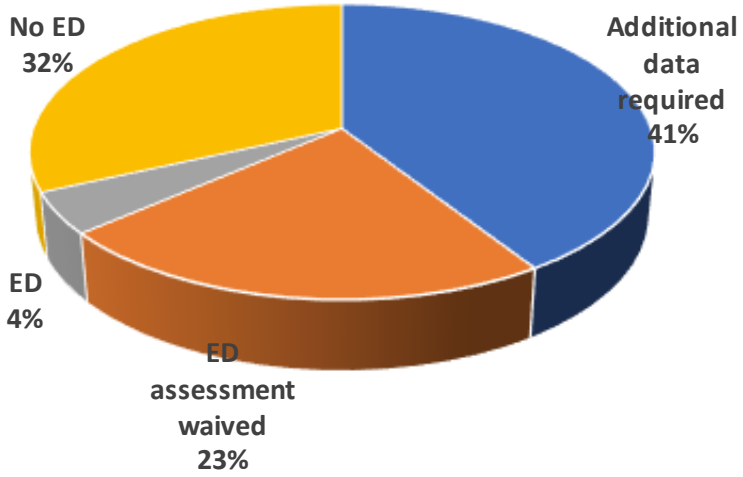
## Human health (HH)-overall conclusions for EATS-modalities




## T-modality

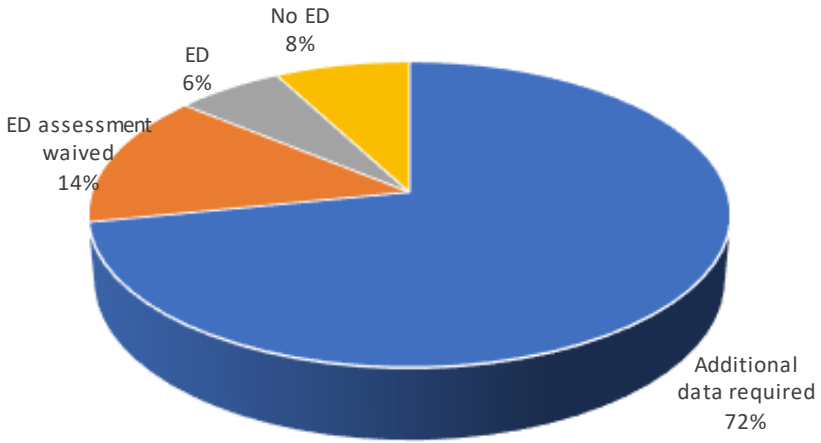



## EAS-modalities

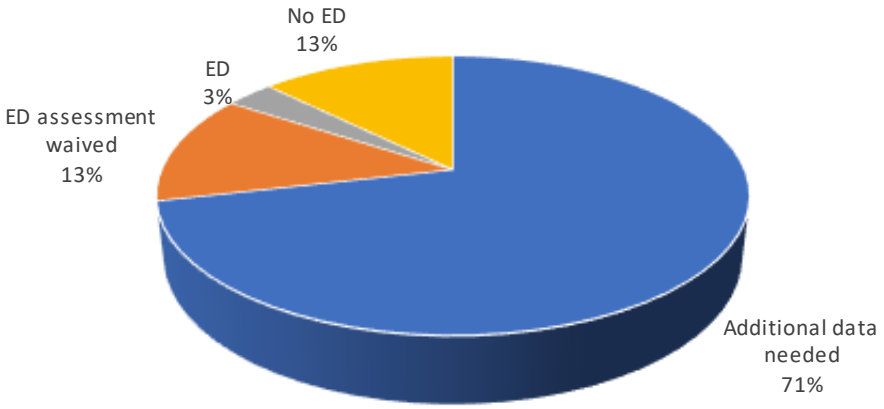


# Summary of the ED assessments for NTOs

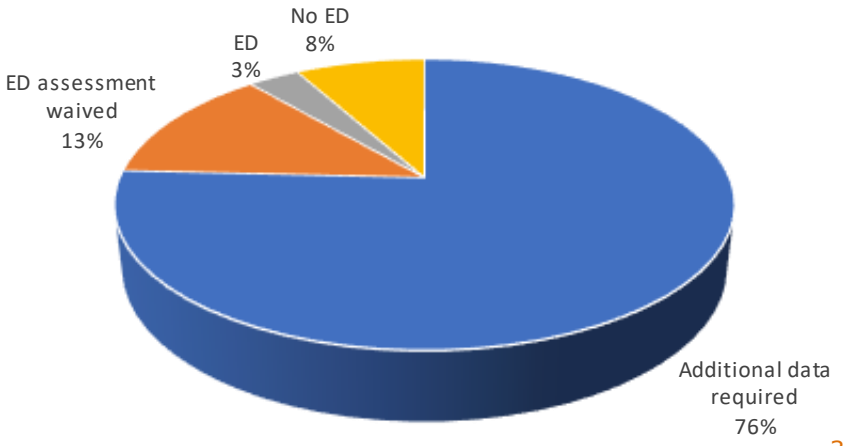
## Non-target organisms - overall conclusions for EATS-modalities




## T-modality

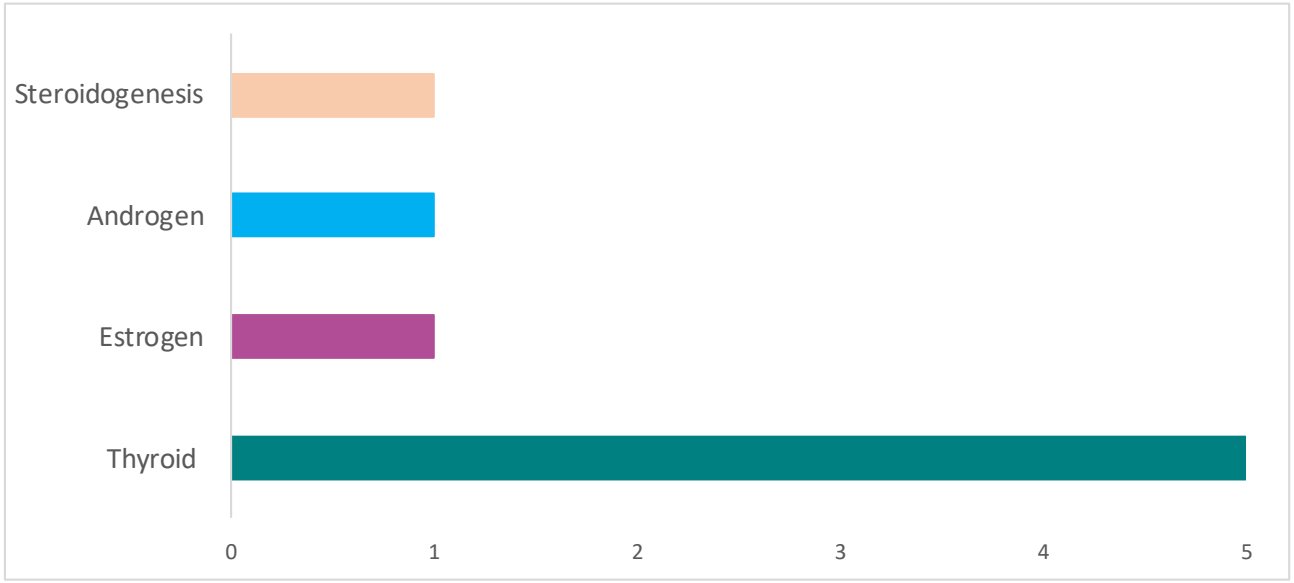



## EAS-modalities



# Substances identified as ED

**8 out of 66** active substances have been identified as **EDs**:




- The conclusion was always based on the identification of EATS-mediated adversity and when, available data on endocrine activity were used to further substantiate the MoA.
- For NTOs, the conclusion was based on adversity for mammals which was considered relevant at population level.

# Substances identified as no EDs

**19** out of 66 active substances have been identified as **no ED** for **HH** and **5** out of 64 for **NTOs**:

- Regarding T-modality:

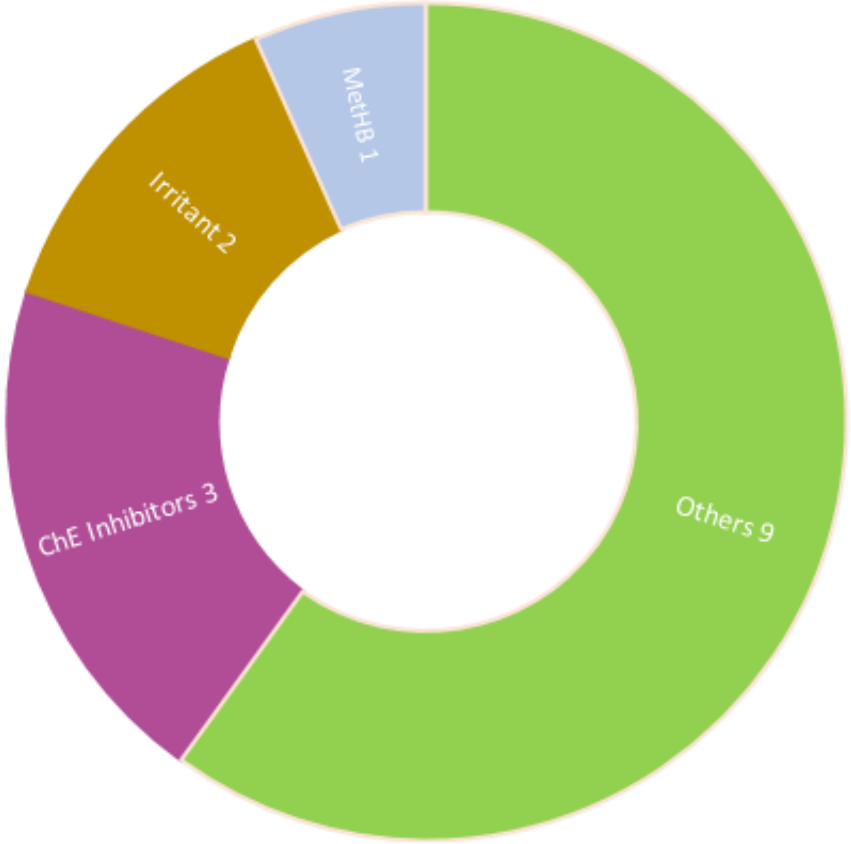
  the conclusion was always reached on the basis of no adversity observed *in vivo* for HH and on lack of endocrine activity based on level 3 studies for NTO.

- Regarding EAS-modalities:

  Both high level *in vivo* data and mechanistic information (*in vitro* and *in vivo*) were used to reach conclusion for HH. For NTOs the conclusion was mainly based on the lack of endocrine activity.

# ED assessment waived

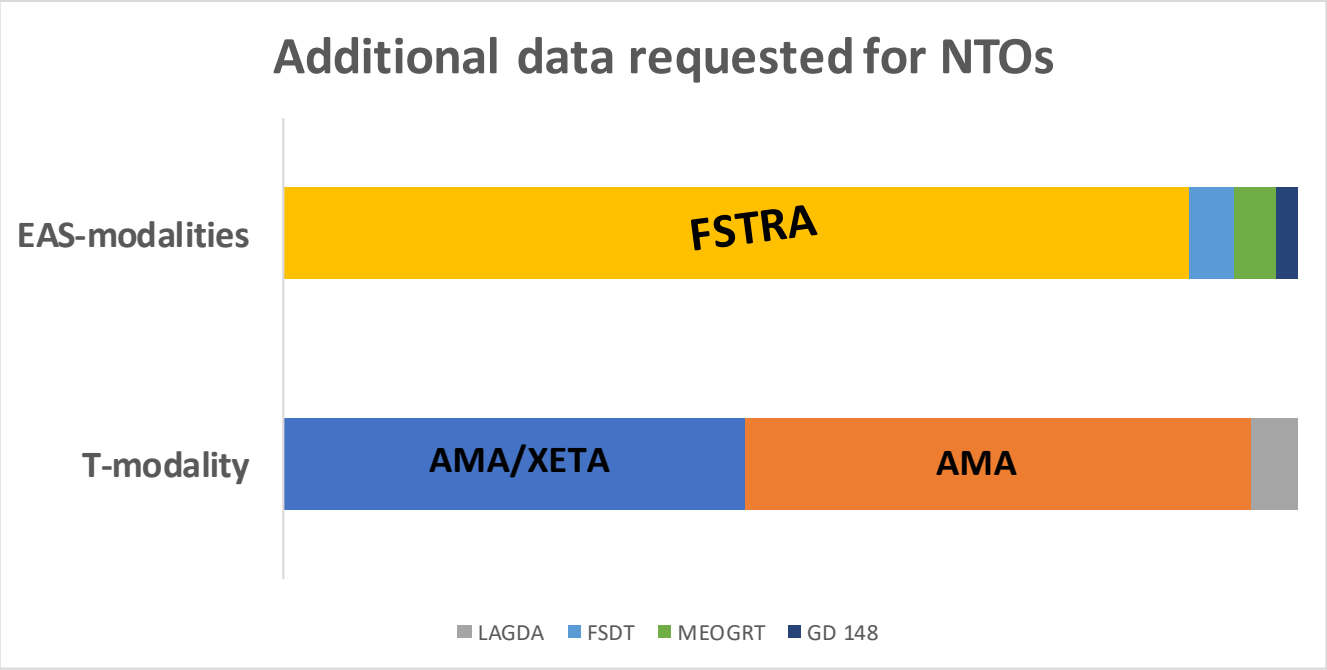
*"There may be cases in which due to the knowledge on the **physico-chemical and (eco)toxicological properties** of the substance an **ED assessment does not appear scientifically necessary or testing for this purpose not technically possible**.*




For 15 active substances the ED assessment was waived for human health and for 9 substances for NTOs

# Additional data required

- For HH, additional data to conclude on ED were required for 24 substances:
  - In all cases, the additional data were required to conclude on EAS-modalities. Only for 2 substances, data were requested also for T-modality.
- For NTOs additional data were needed in 73% (46 substances) of the cases and in many cases level 3 have been requested



# Conclusions

- **15** substances **EFSA conclusion** is publicly **available;**
- **For most** of the active substances additional data have been requested (3-30 months);
- **ECHA-EFSA Guidance** was **always followed;**
- **Differences** in the assessment between human health and non-target organism (availability of data, conditions for waiving).
- For **NTOs**, population relevance of adverse effects in mammals is always debatable, especially in the case of T-modality

# EFSA EXPERIENCE SO FAR…


EFSA has built a **database** with the assessments done so far which has been shared with MSs and ECHA

# WHAT'S NEXT?

An Annex on how to consider the **XETA** (OECD TG 248) in the assessment strategy will be published earlier next year

EFSA has established a **Working Group** on ED

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