1 April 2019

Overview of the EFSA Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain

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A structured pathway to assess potential nanospecific risks

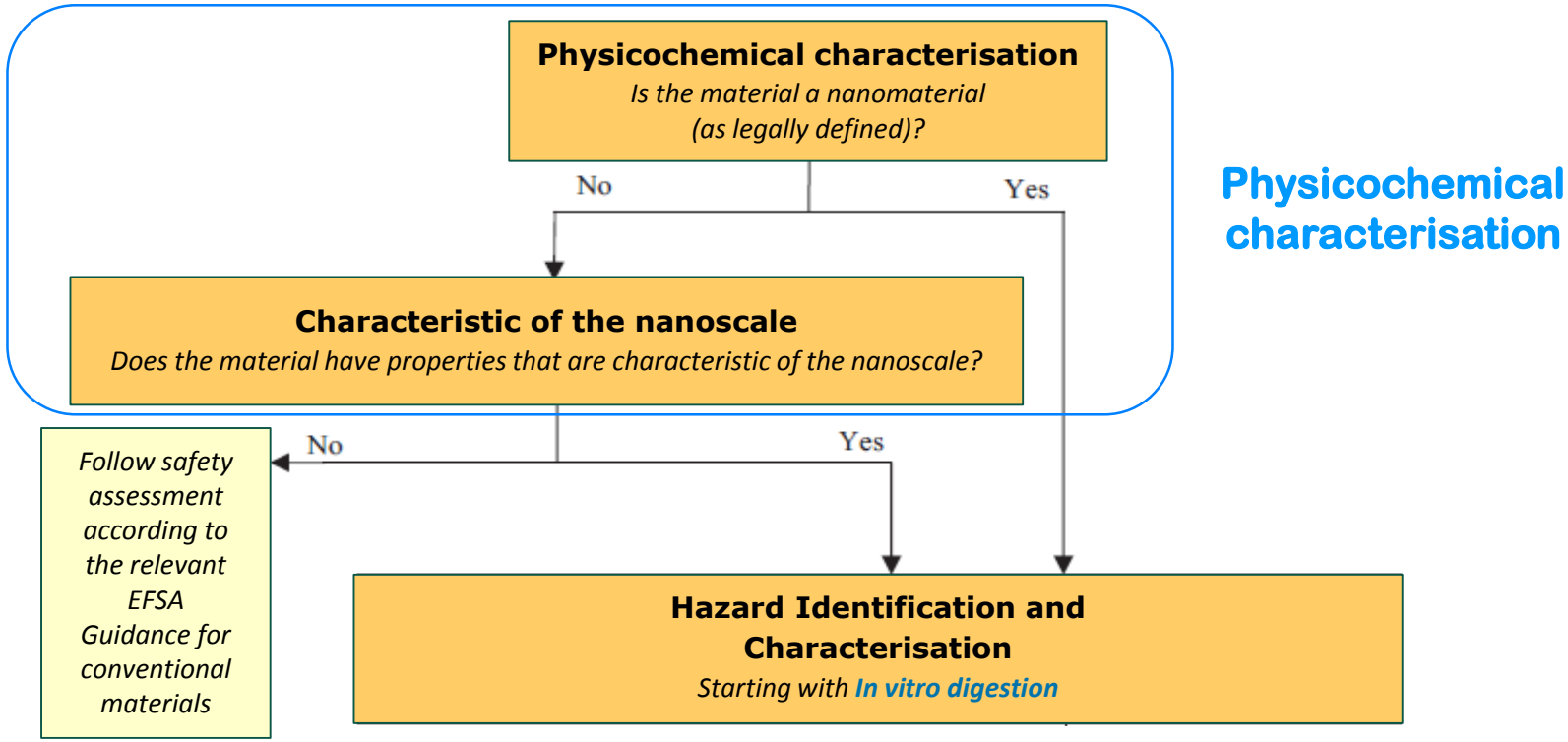
The EFSA 'NanoGuidance' provides applicants and risk assessors with a structured pathway to assess potential risks of

- **Engineered nanomaterials (as per legal definition)**
- **Any other type of substance falling under the food law that might present hazards related to the nanoscale, independently from regulatory definitions**

- **Size-dependent properties and biological effects** of potential **concern for human health**, e.g. toxicokinetic behaviour and particle–cell interactions, are **not rigidly related to specific (legally defined) size thresholds**
- Whereas physical, chemical and biological properties of materials may change with size, there is **no scientific justification for a single size limit** associated with these changes that can be applied **to all nanomaterials**
- **Potential risks** arising from specific properties related to the nanoscale have to be assessed **focusing on such properties and potentially related hazards**, which may be independent of the proportion of particles constituting the material with a size below 100 nm

Physicochemical characterisation: the first stage of the scientific assessment

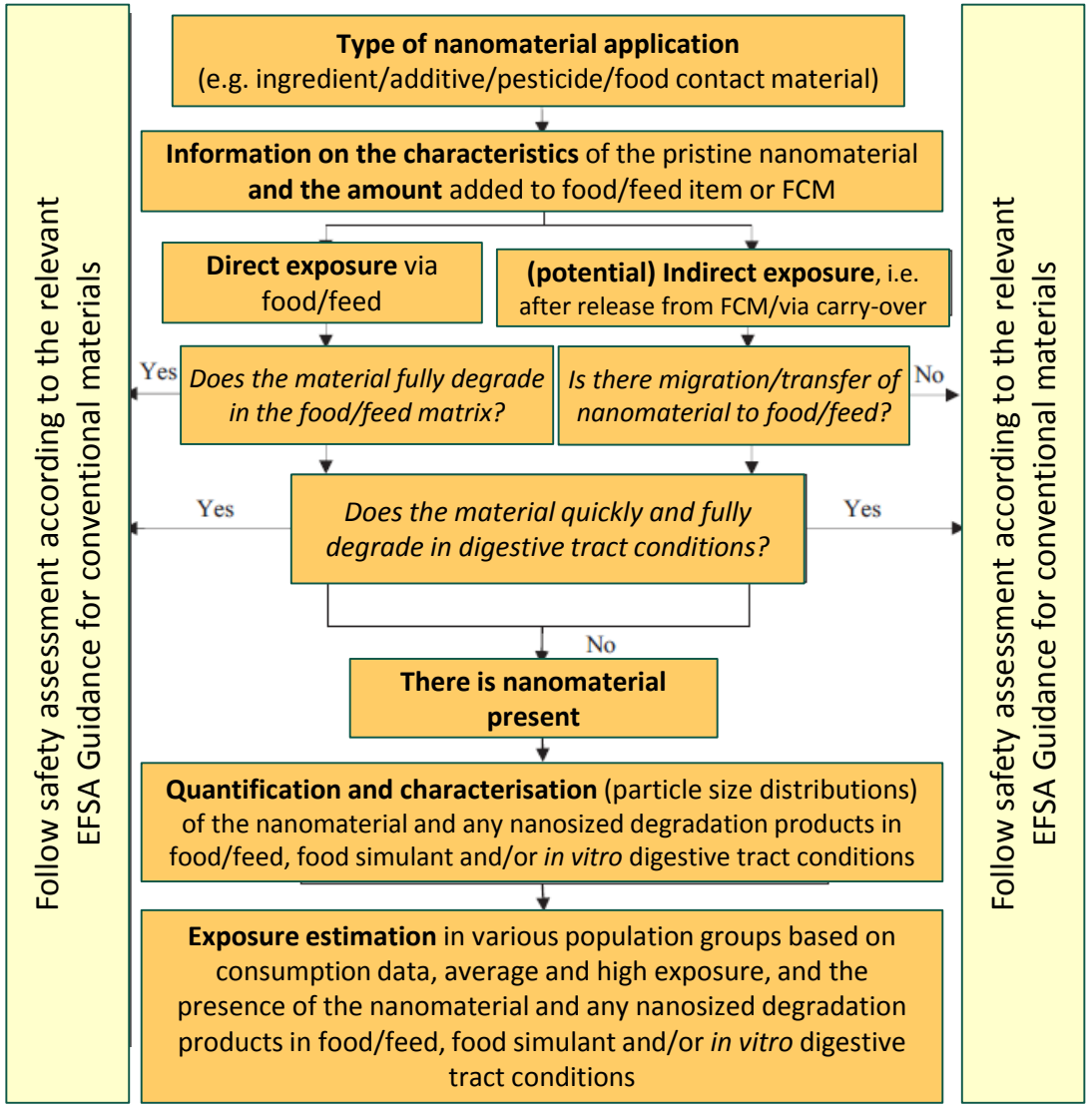
It **answers the first question**: is nano-specific risk assessment (starting with hazard identification and characterisation) needed or not?



Physicochemical characterisation

- Characterisation of **particle size and size distribution** is the first step to deciding whether the material has to be considered for nanospecific risk assessment
- It is required that the size parameter should always be measured by **at least two independent techniques, one being electron microscopy**
- If electron microscopy is not applicable (e.g. for some organic nanomaterials), it is recommended to use **another imaging technique** instead of electron microscopy
- For materials with a median particle size above 100 nm, **the presence of properties characteristic of the nanoscale** has to be assessed by the phys-chem characterisation
- Where a material is regarded to fall within the scope of the Guidance, a detailed phys chem characterisation is required for **unambiguous description of the material's identity** in pristine form and **relevant physicochemical properties**

Oral Exposure Assessment



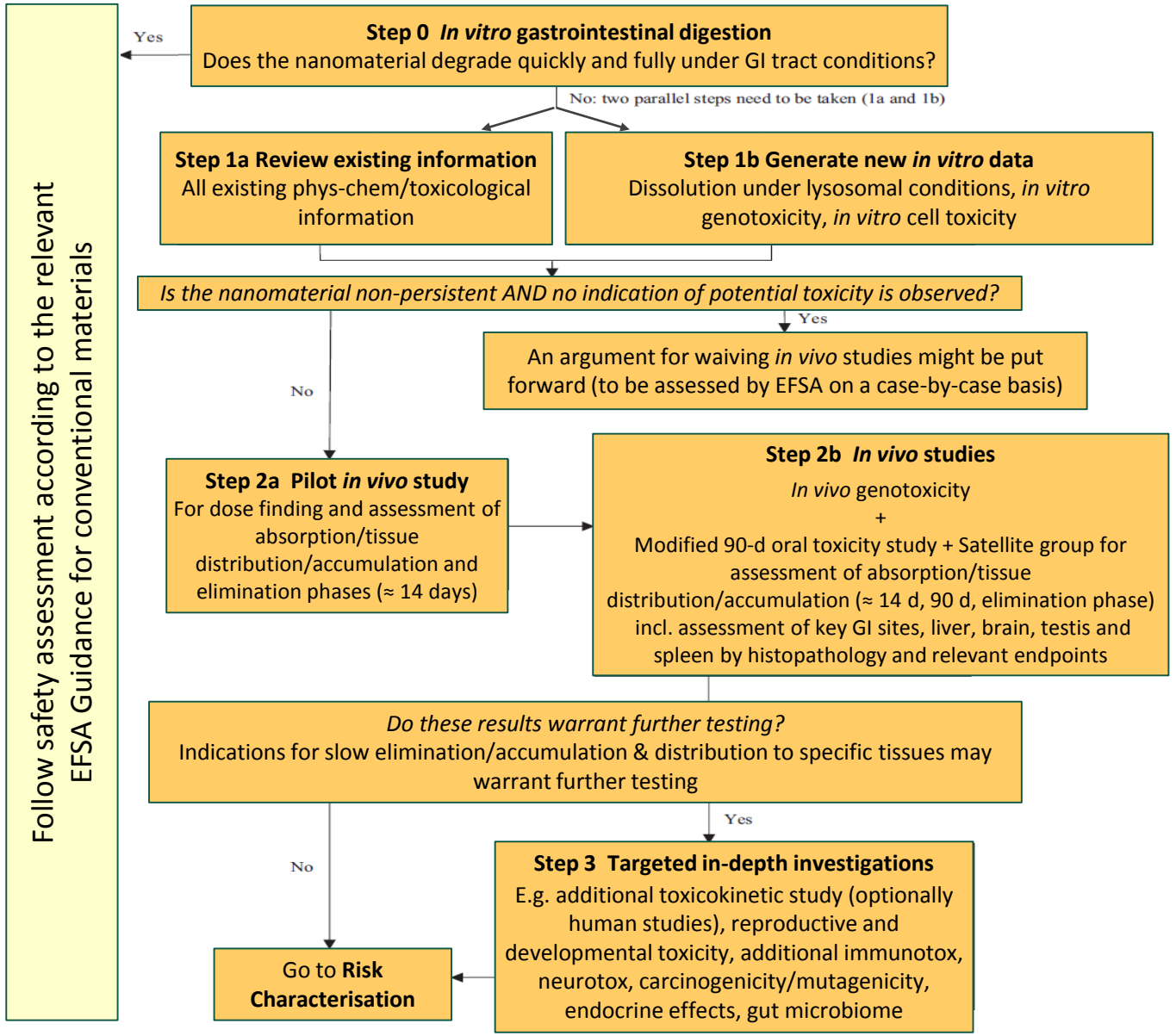
Hazard identification and characterisation

A **stepwise framework** for nano-related hazard identification and characterisation is outlined in the Guidance to **avoid any unnecessary testing**

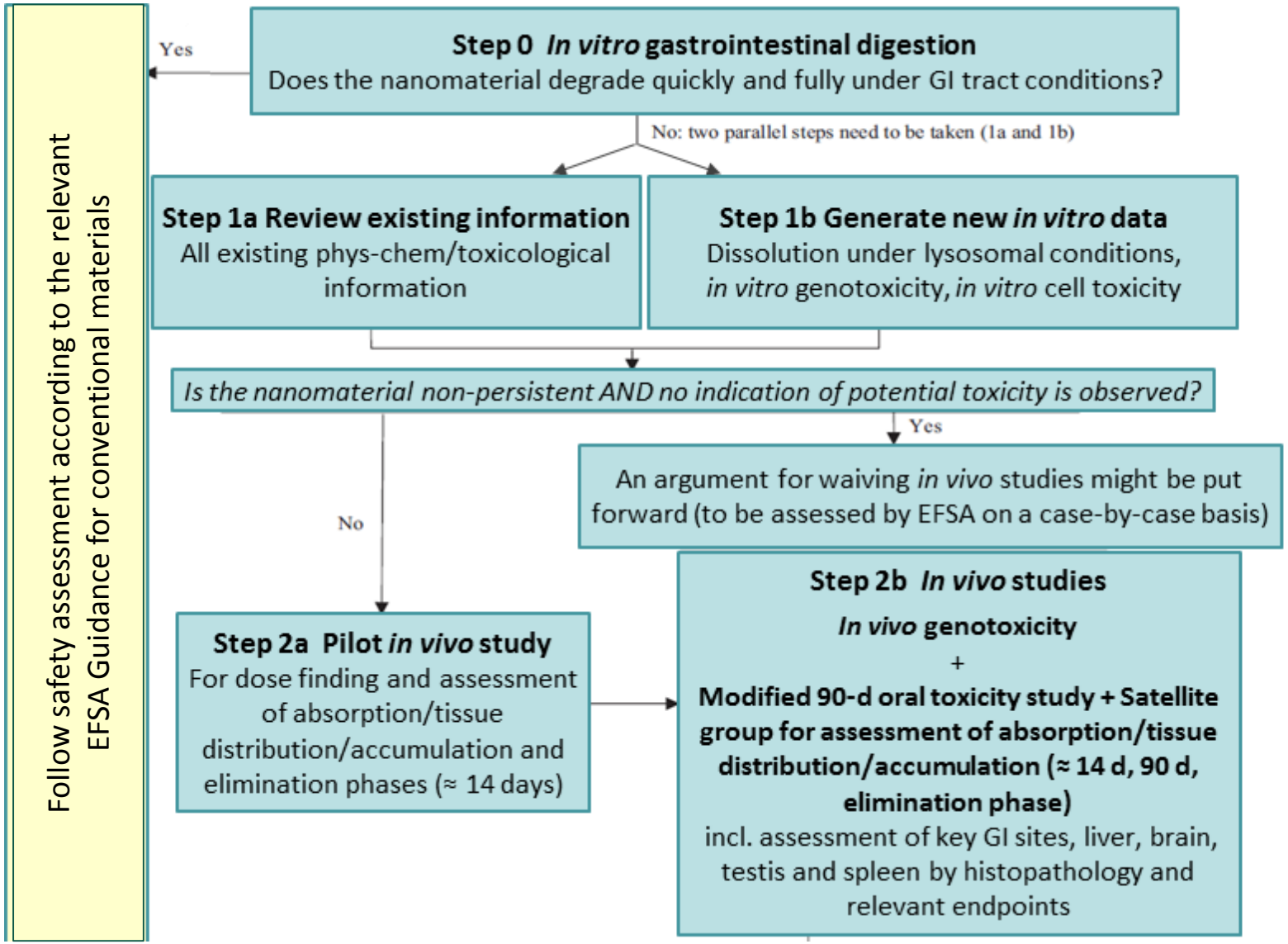
Even around or within the nanoscale, there may be **considerable fluctuation in the toxicity** of a given nanomaterial due to **variations in particle size**: it is therefore crucial that there is **complete correlation between the material as produced and as tested**, and that the size and properties of the manufactured material used in the specific application lie within the narrow range covered by the risk assessment

In this light, **batch-to-batch variation** is of special concern and strict criteria should be followed to ensure **the manufactured material consistently presents constant physicochemical parameters** (i.e. those considered in the risk assessment)

Hazard identification and characterisation

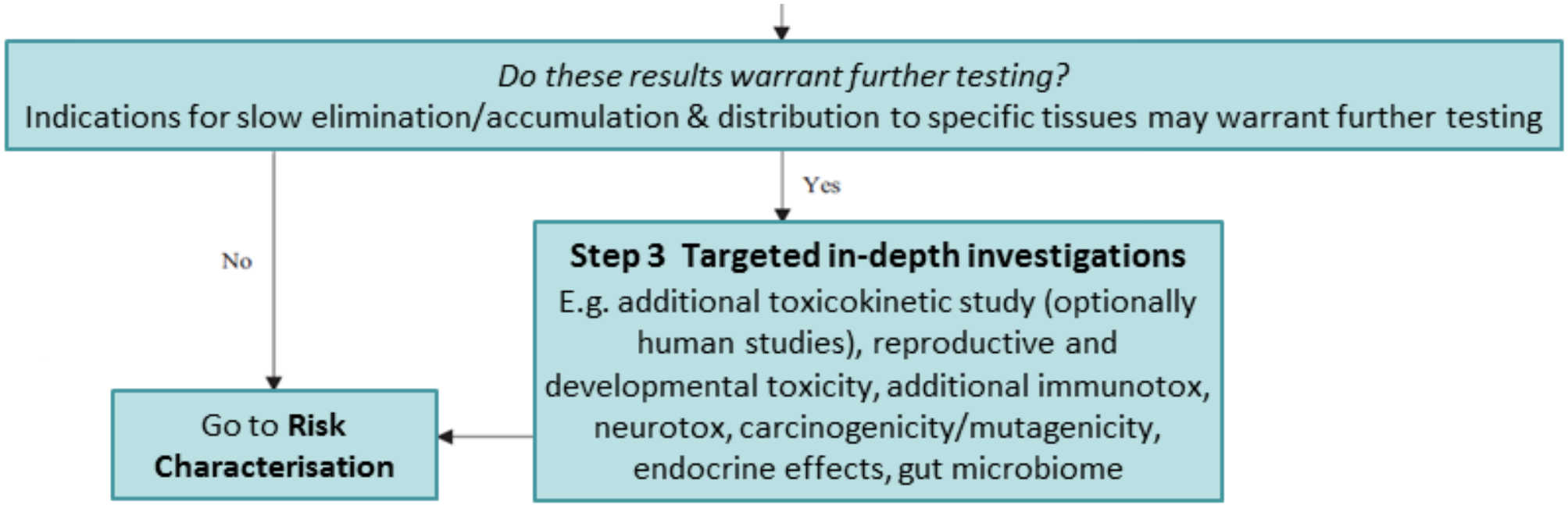


Hazard identification and characterisation



Hazard identification and characterisation

…continues from Step 2 (*In vivo* testing)



Conclusions

- The existing risk assessment paradigm for chemicals is also applicable to nanomaterials. However, testing of nanomaterials needs consideration of certain **nanospecific aspects** that are addressed by the NanoGuidance

- The Guidance proposes a structured pathway for carrying out safety assessment of **nanomaterials** and **any other type of substance falling under the food law that might present hazards related to the nanoscale**, independently from regulatory definitions, providing practical suggestions for the **types of testing** needed and the **methods** that can be used for this purpose

- Whenever possible **tiered approaches** or **circumstances under which data generation can be waived** are suggested, e.g. in phys-chem characterisation, in exposure assessement, and in hazard identification and characterisation

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