EuropaBio™

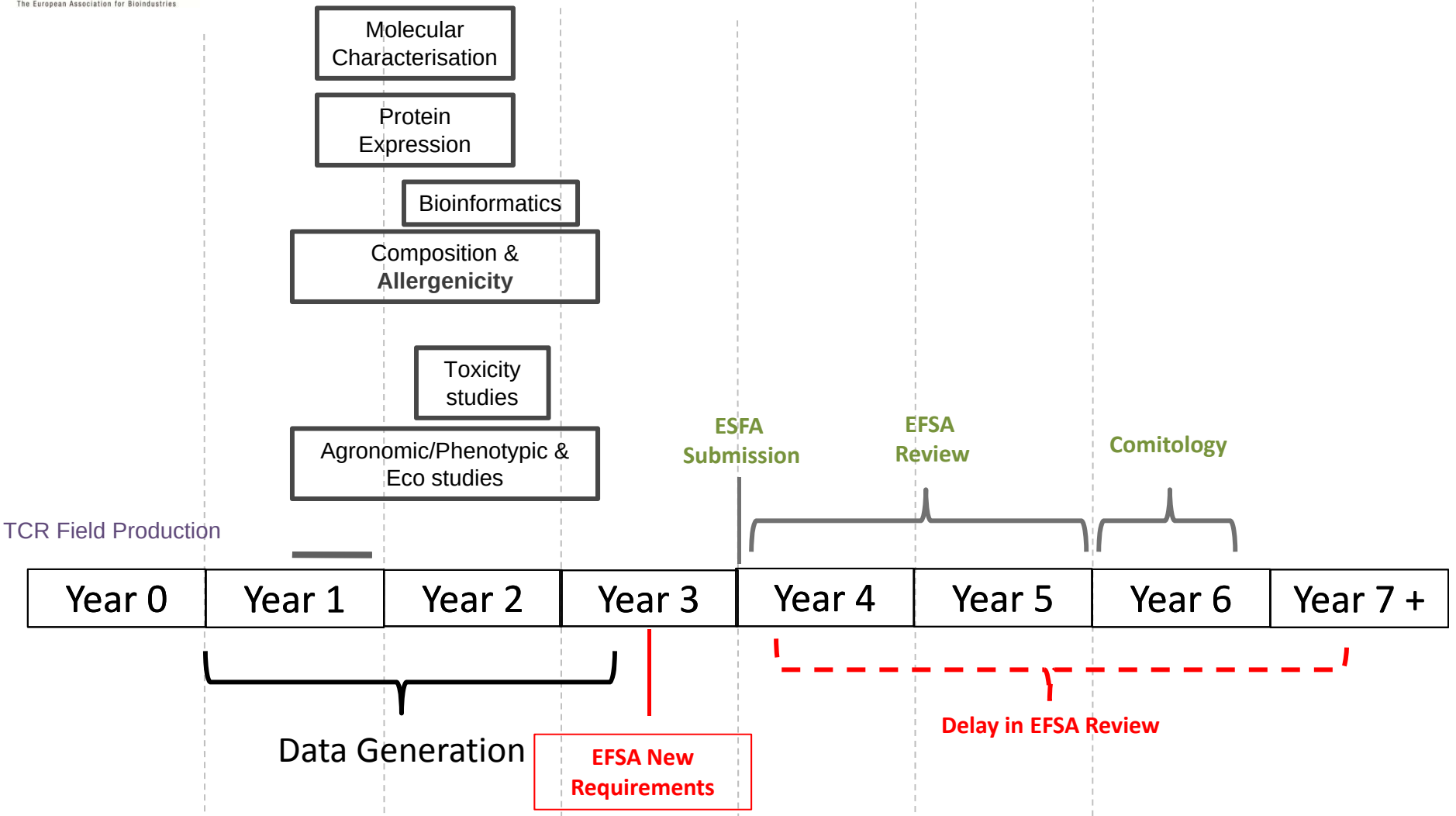
The European Association for Bioindustries

Introductory Remarks

Implementation

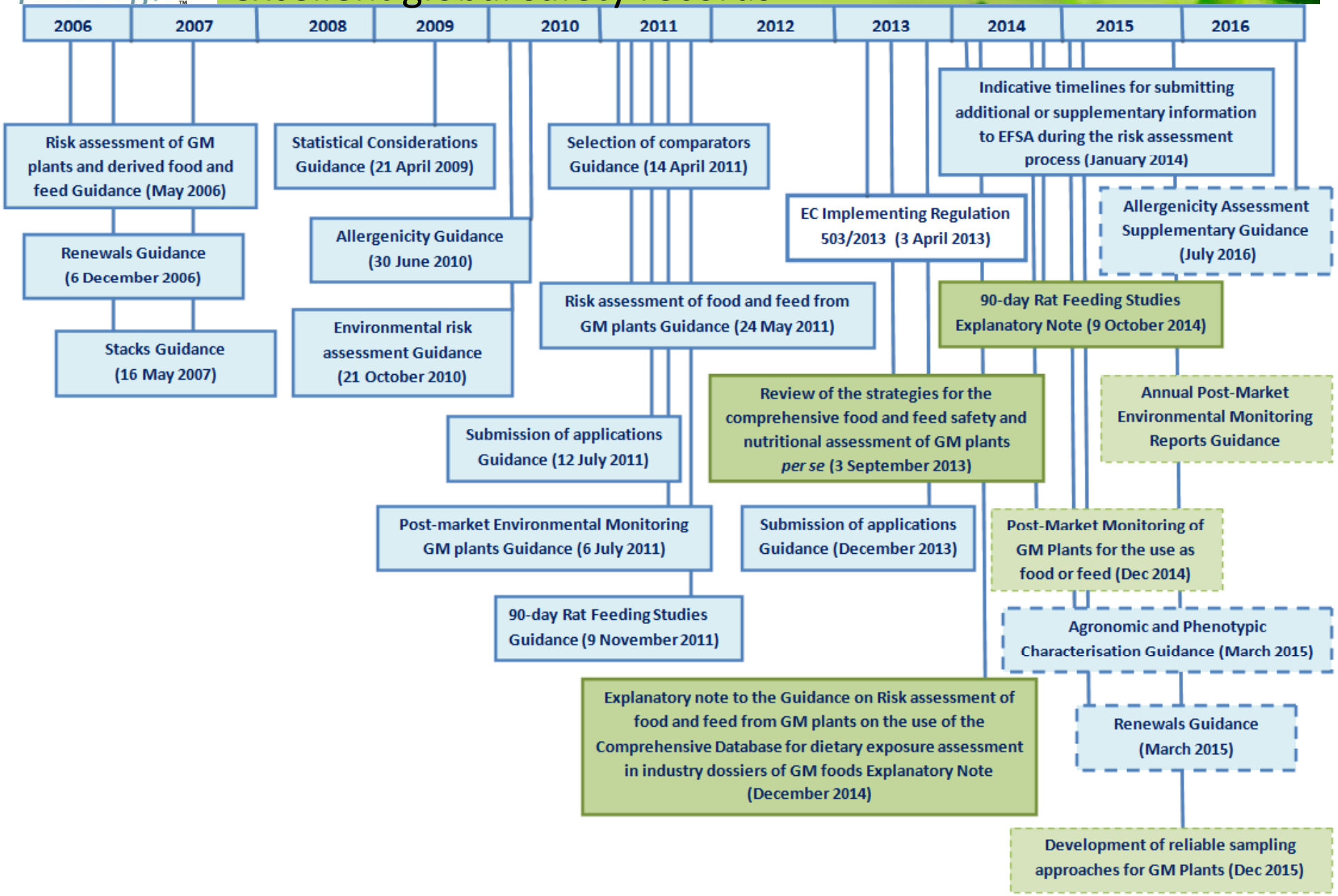
- Need for **a standard procedure** for **clear and timely communication** of new requirements to applicants
- Need for **sufficient and realistic transition periods** before attaining mandatory compliance with the requirements set out in new guidance documents
- EFSA guidance should **not** be applied retroactively
- Need to justify the **relevance for risk assessment** (hazard x exposure)
- EuropaBio welcomes EFSA's "*multiannual project to develop a customer-oriented approach for regulated products*"

Impact of any new development



Sufficient and realistic transition period warranted

Exponential increase in requirements in the EU despite excellent global safety records



Thank you!