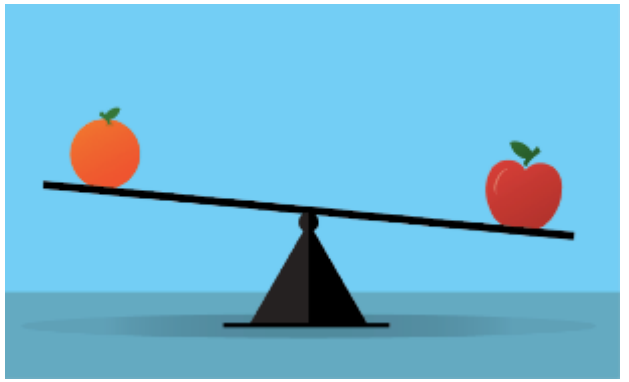
Post REFIT – Better implementation of Regulation 1107/2009

- Future of Comparative Assessment for substances listed as Candidates for Substitution.
- Regulatory translation of Cumulative Risk Assessment work done by EFSA : impact on innovation
- Improvements to the zonal system and Industry suggestions.

Future of Comparative Assessment for substances listed as Candidates for Substitution.

Comparative Assessment

- In its REFIT report of Regulation 1107/2009, COM announced its intention to simplify the comparative assessment of substances candidates for substitution.
  - Driven by the limited cases of actual substitution
  - This could take the form of a revision of the Annex IV of Regulation 1107/2009.

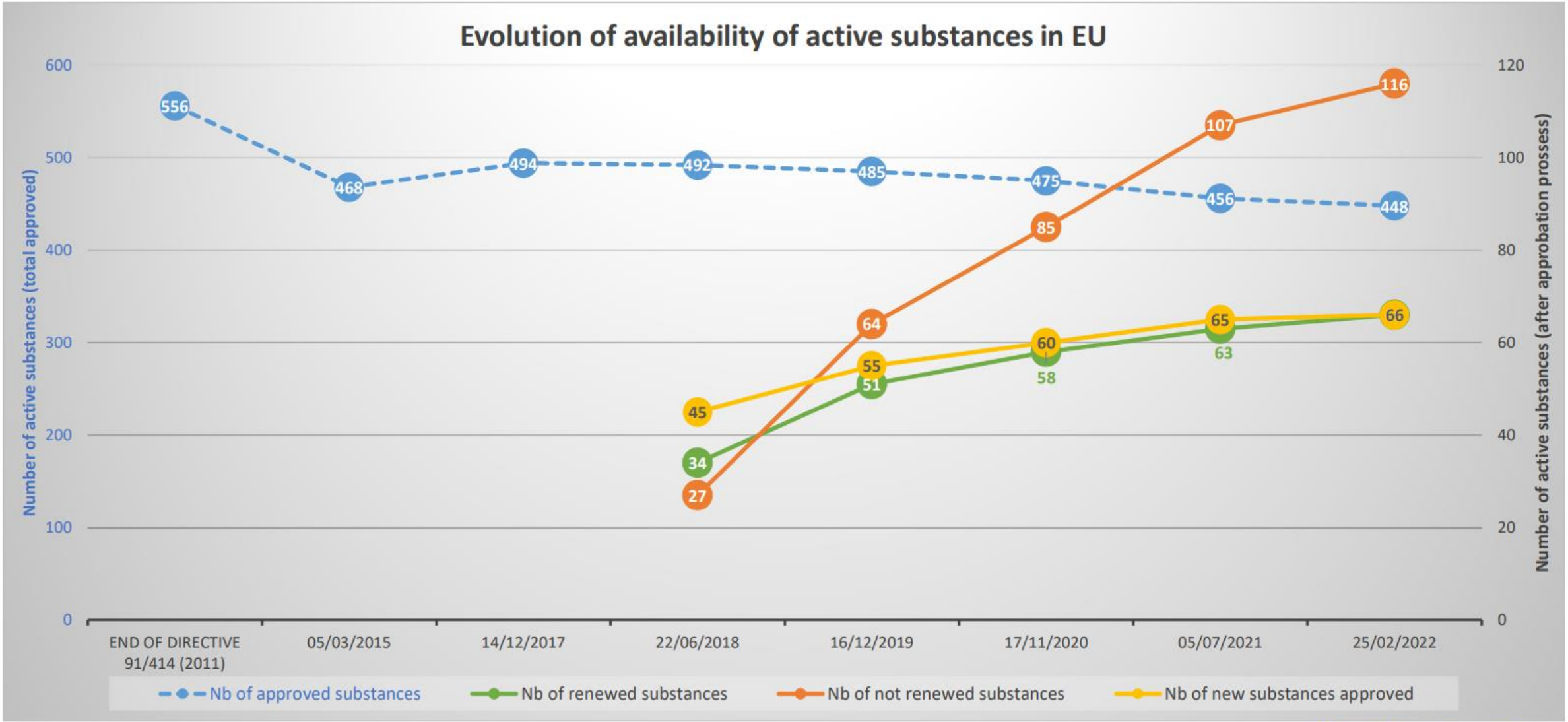


- **After more than 10 years of implementation of the regulatory framework in Europe, the number of efficient products available to farmers to protect their crops is at an all-time low**

A regulatory system already eroding the farmers

EVOLUTION OF AVAILABILITY OF SUBSTANCES IN EU

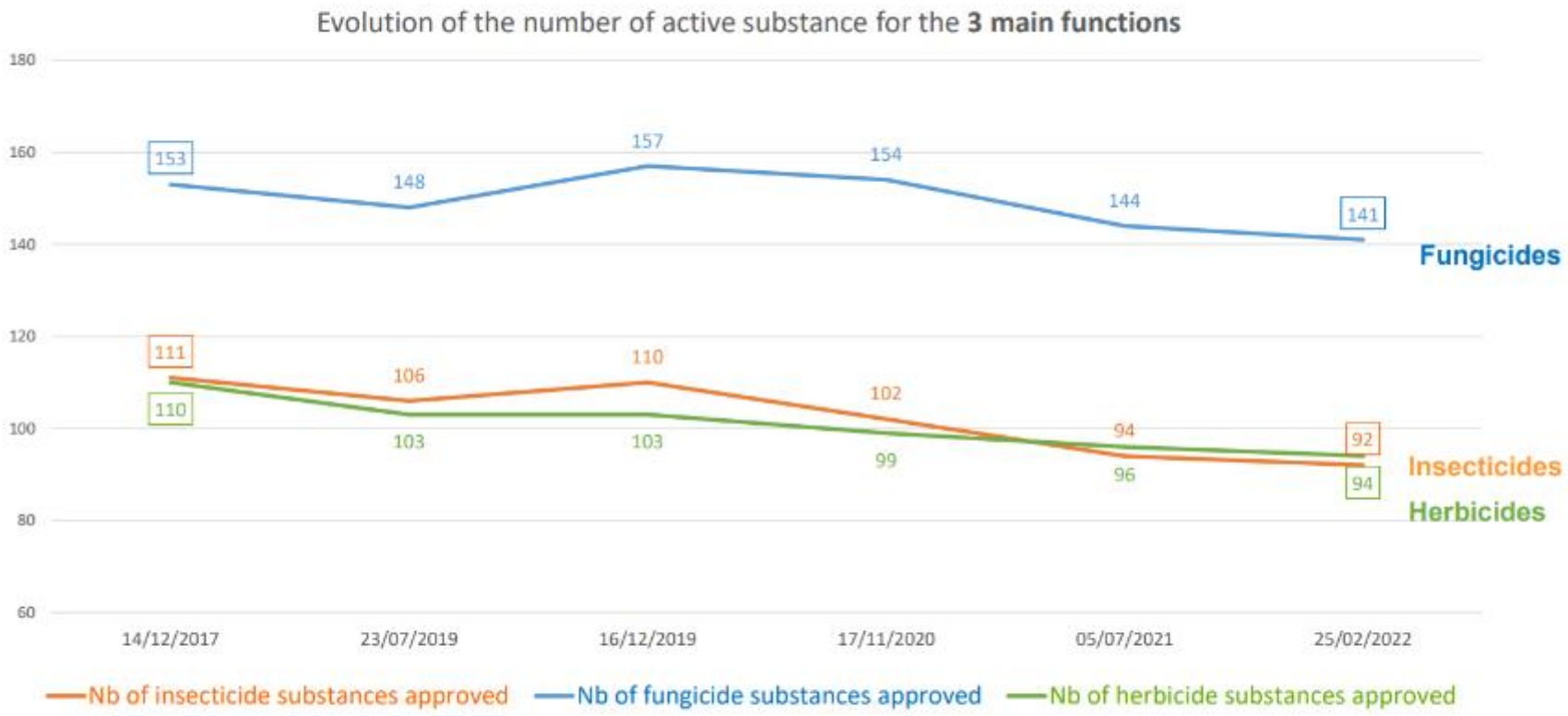
UNDER REG 1107/2009



A regulatory system already eroding the farmers toolbox

EVOLUTION OF AVAILABILITY OF SUBSTANCES IN EU

UNDER REG 1107/2009



Remark: **The increase in the number of substances in 2019** is due to a dissociation of substances previously counted into groups (different strains of *Trichoderma* sp., *Bacillus* sp., etc.).

CEG Fruits & Vegetables
2-3/03/2022

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Key messages

- **CropLife Europe does not support a revision of the provisions on Comparative Assessment within the Regulation 1107/2009.**
  - We believe amending Annex IV of the Regulation is irrelevant as the regulatory system is already achieving a constant shrinking of the farmers toolbox and the number of Candidates for Substitution keeps decreasing.
- **A revision of Annex IV and simplification of Comparative Assessment will not facilitate substitution if alternatives showing safety and equal level of efficacy are not available on the EU market.**
- **We believe any revision should first consider the impact it will have on national authorities workload and ability to meet legal timelines.**
  - Impact on the design of local Integrated Pest Management strategies is also important if key tools would end up being substituted.

Cumulative Risk Assessment (CRA)

The Importance of Considering Innovation in the Implementation of Cumulative Risk Assessment

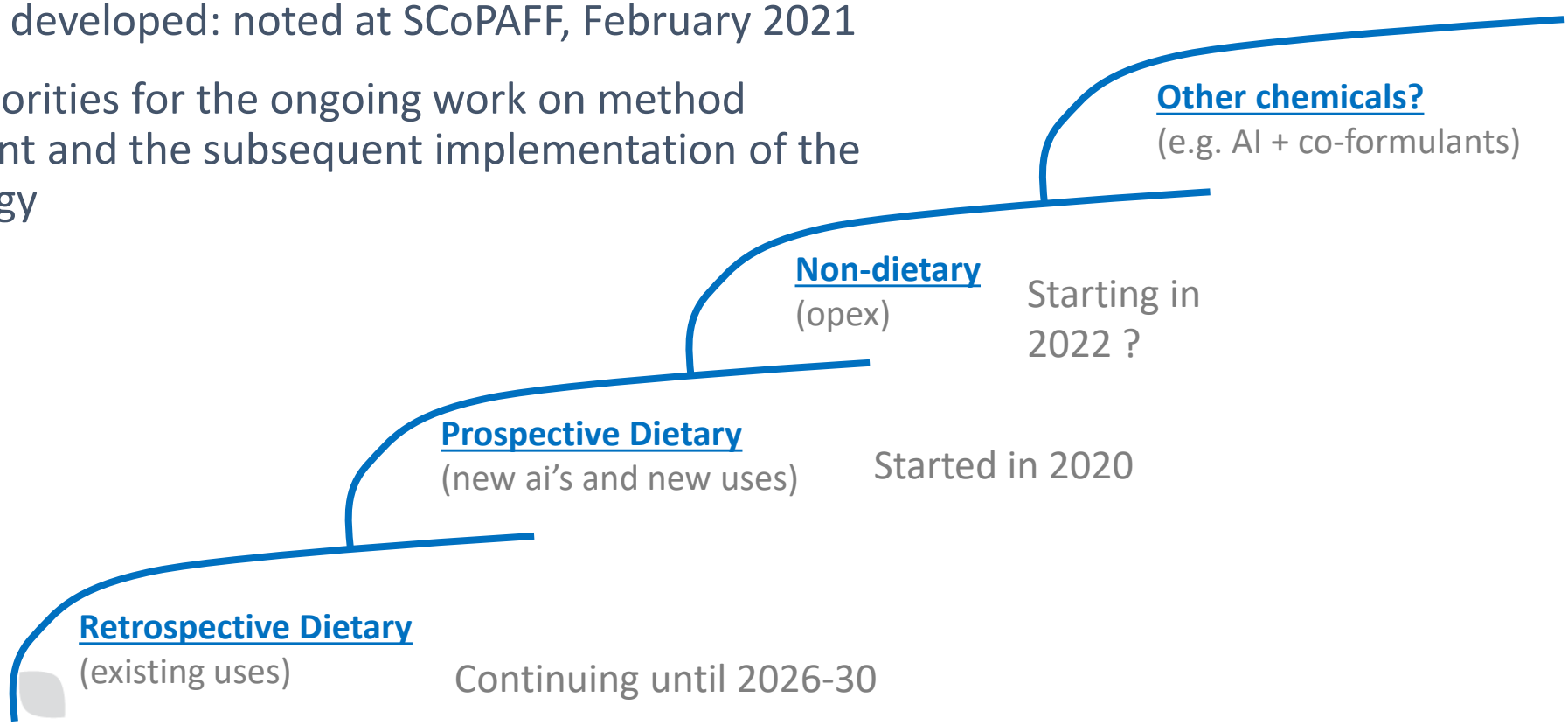
Progress in the EU

- **Regulations 1107/2009 & 396/2005 include the requirement to assess risk of co-exposure to multiple pesticides in food**
- **Development of methodology complex**
- **Three EFSA reports to date**
- **Retrospective cumulative dietary risk of pesticides that have**
  - Acute effects on the nervous system
  - Chronic effects on the thyroid
  - Chronic effects on acetyl-cholinesterase inhibition

- **Conclusion - cumulative exposure does not exceed the threshold for regulatory consideration for all the population groups considered**

EFSA – SANTE Action Plan

- DG SANTE and EFSA committed to speed up cumulative risk assessment
- Action Plan developed: noted at SCoPAFF, February 2021
- Sets out priorities for the ongoing work on method development and the subsequent implementation of the methodology

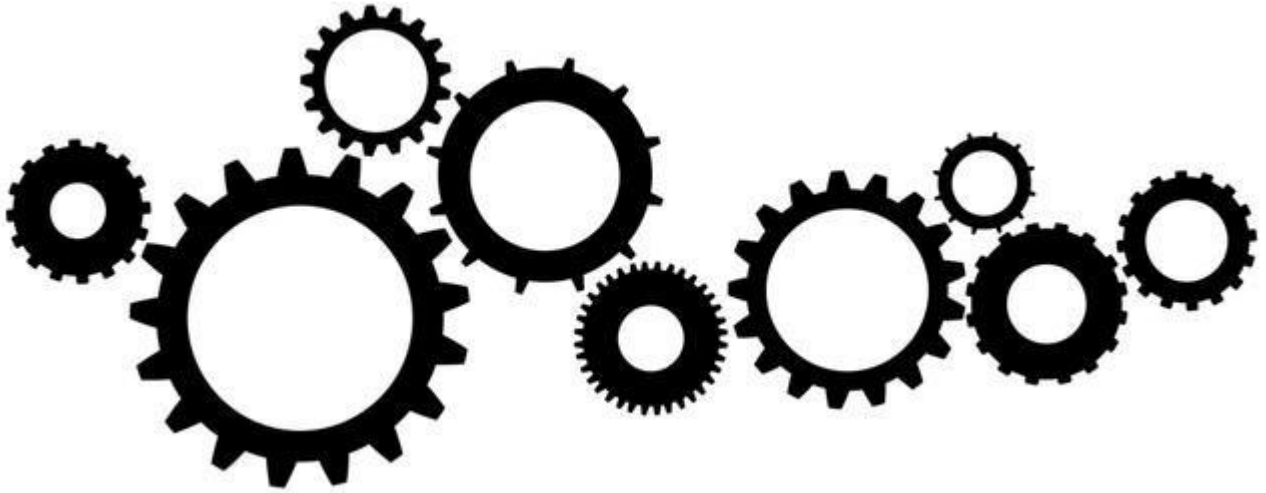


Importance of Innovation

- INNOVATION is critical to enable farmers to manage the ever-increasing threats from crop pests; in turn helping to provide society with food security
- Sustainable solutions are at the heart of the Farm to Fork Strategy
- **Essential that new Cumulative Risk Assessment methodologies and Risk Management processes do not hinder this innovation**

Prospective Assessments

- **CLE suggestions on Risk Management Process:**
  - If a prospective risk assessment fails, it should be refined and validated before decision taking
  - No need to conduct risk assessments for New Active Substances (NAS) where residues are at LOQ
  - Regular expert working group meetings (EFSA, COM, MS) required to facilitate introduction of NAS, new uses
  - If a risk assessment still fails, the following options could be considered by the risk managers:
  - Adaptation of GAPs for significant contributors to the risk cup?
  - Withdrawal of import tolerances?
  - Withdrawal of certain uses or AS?



Conclusions

- Significant public and political interest in the effects of combined exposure to mixtures of chemical substances
- CLE supports EFSA-SANTE initiative to develop robust & scientific cumulative risk assessment methodology
- Continued innovation in plant protection is critical to enable farmers to manage the ever-increasing threats from crop pests; in turn helping to provide society with food security
- Essential that CRA methodologies & risk management processes do not hinder this innovation
- CLE committed to working with EU Commission, EFSA & Member States to ensure methodologies & processes assure human safety and enable innovation

Improvements to the zonal system and Industry suggestions.

Realisation of effort and complexity: Procedures

- **Harmonisation does not mean ‘All follow me’**
- **No/limited harmonisation between countries in key items**
  - Farmers’ use patterns
  - Label use definitions
  - Mitigation options
  - Interpretation of legislation and guidance
- **Setup of local authorities not always appropriate for a zonal process**
- **National requirements - formal and technical**
- **Zonal dossiers are not the same as a country dossier times x**
- **Timelines not kept**

New challenges ahead

- **Evaluation of biopesticides**
- **High number of Art 43 product renewal submission foreseeable (post ED evaluation of AIs)**
- **New application technologies**
- **Digitalisation of plant protection**
- **Further increasing complexity in guidance documents**
  - How many Tiers can the system cope with?
  - Divergence in interpretation and higher tier acceptance between MS
  - Laboratory limitations to produce high number of complex studies
  - ‘Old’ lists of endpoints not fit for new guidance documents

What to do?

Increase the efficiency of the product authorisation system as well as the speed of adapting it to the changing agricultural, societal and regulatory environment.

How ?

By first gathering all players around the same table

Workshop proposal

→**Like in Dublin in 2015, a workshop involving Member States, Commission, EFSA and Applicants could look into practically advancing the following points:**

- **Realize efficiency options**
  - In country
  - Harmonize approaches within a zone as much as feasible
  - Eliminate national requirements
  - Make better use of interzonal options (Art 35): Chemistry, Tox, …..
- **Zonal mindset of all stakeholders**
  - No national action without having the zonal partners in mind
  - Develop and execute a zonal vision for the system executed by all stakeholders
- **Use technology to increase efficiency**
- **Introduce ‘fit for zonal process’ test - regulations, guidance documents and IT systems**
- **Clear appropriate rules instead of pragmatic workarounds**

→ **And address the resource issue amongst authorities…**