Introduction

Workshop on Streamlining Applications for Authorisation

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Outline

1. Developments since Lessons Learned Conference
2. Key principles
3. Upstream application – some thoughts
4. Take home

1. Since Lessons Learned conference

- The process
- Applications costs
- ECHA’s actions
- Task Force

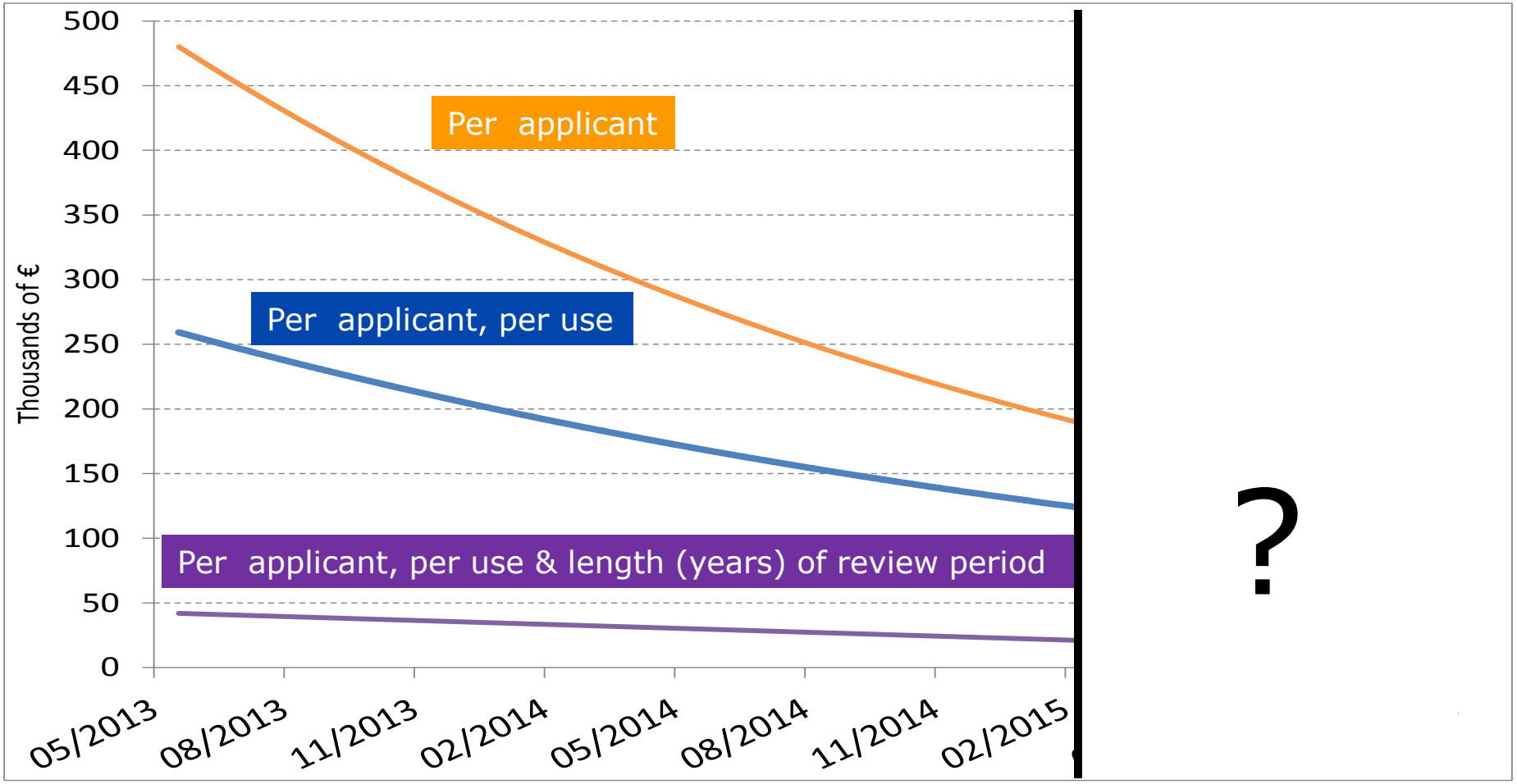
The process works

- ECHA's committees have completed 56 opinions
- The average time taken by the committees was 8 months
- Commission granted authorisation for 10 uses
- The process clearly has had positive impacts

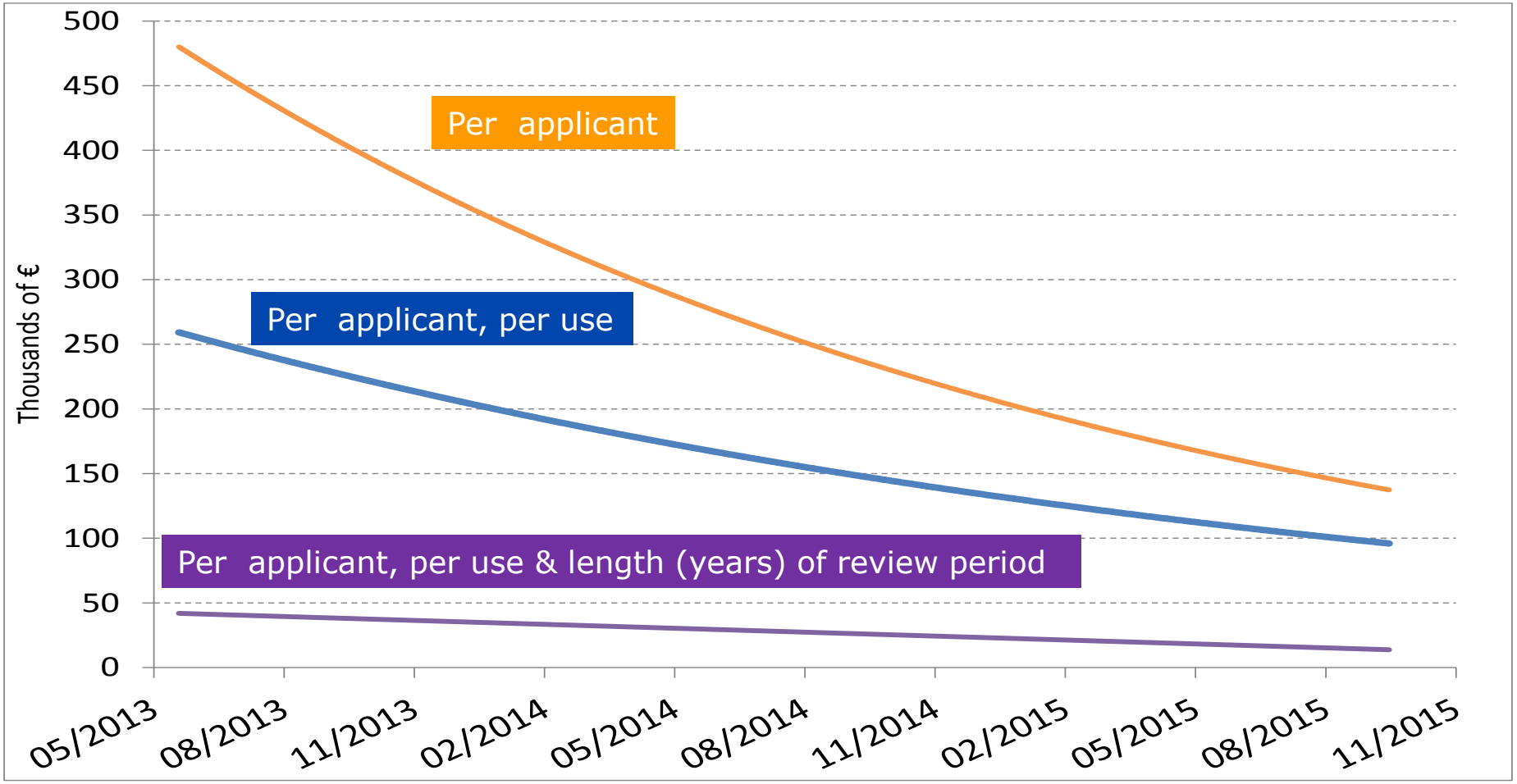
We can do better

- The applications need to be even more 'fit for purpose'
- The task force on the workability of AfA will make suggestions

Application effort and costs per applicant, per use and per length of review period…



… have about halved in 2 years



ECHA's actions

- Seminars/workshops
- Guidance, clarification notes, reference DNELs/Dose-Response Relationships
- Continued to hold Pre-Submission Information Sessions (PSIS)
- Made available examples of Analysis of Alternatives and Socio-Economic Analysis

Task force on workability of applications

- 2 special cases:
  - Low volumes: Commission preparing an implementing act
  - Legacy spare parts: the Commission plans to propose an extension of the latest application and sunset dates
- Addressed other issues
  - Discussions with automotive, aviation and process chemicals industries
  - Essential nutrients
- Meeting on 18 November, 2015

2. Key principles

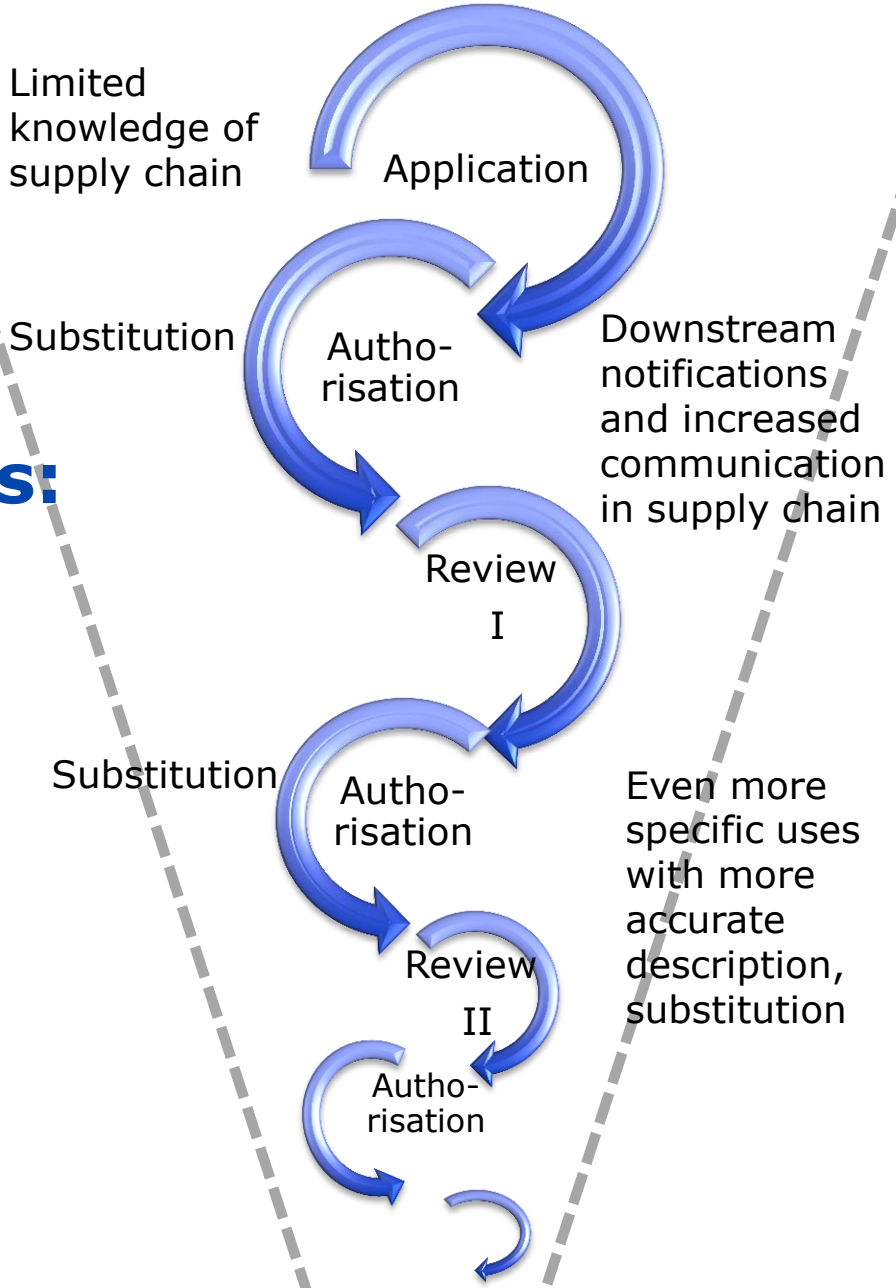
- Application effort should (always) be “fit for purpose”
- Appropriate scrutiny of the applications
  - Have high competence in ECHA including its Committees
  - Have clear, well justified and consistent opinions that the Commission can use without delay
- Trust of all
  - Transparency and overall scrutiny of stakeholders

3. Upstream applications

- Essential to keep the system manageable
- Main challenge: collect and present information from – possibly very complex – supply chains
- The use descriptions and their scope have usually been (very) broad
- Typical or representative sites/exposure scenarios could be a way out
  - Comprehensive description of the OCs/RMMs backed by measured data
  - These are the conditions that the DUs need to adhere to

Upstream applications:

Increased incentive to apply for more specific uses while subst-ituting and reducing the risks



4. Take home

- The process works and has had visible positive impacts
- Application effort and costs have halved
- We need to improve in particular for “upstream” applications
  - Hope that this workshop will give ideas on how to do this
- Task Force will work on this, too

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