

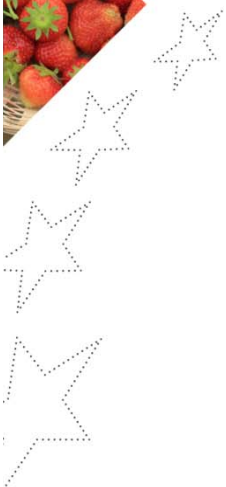


# EFSA's Role in the EU Risk Assessment for Pesticides

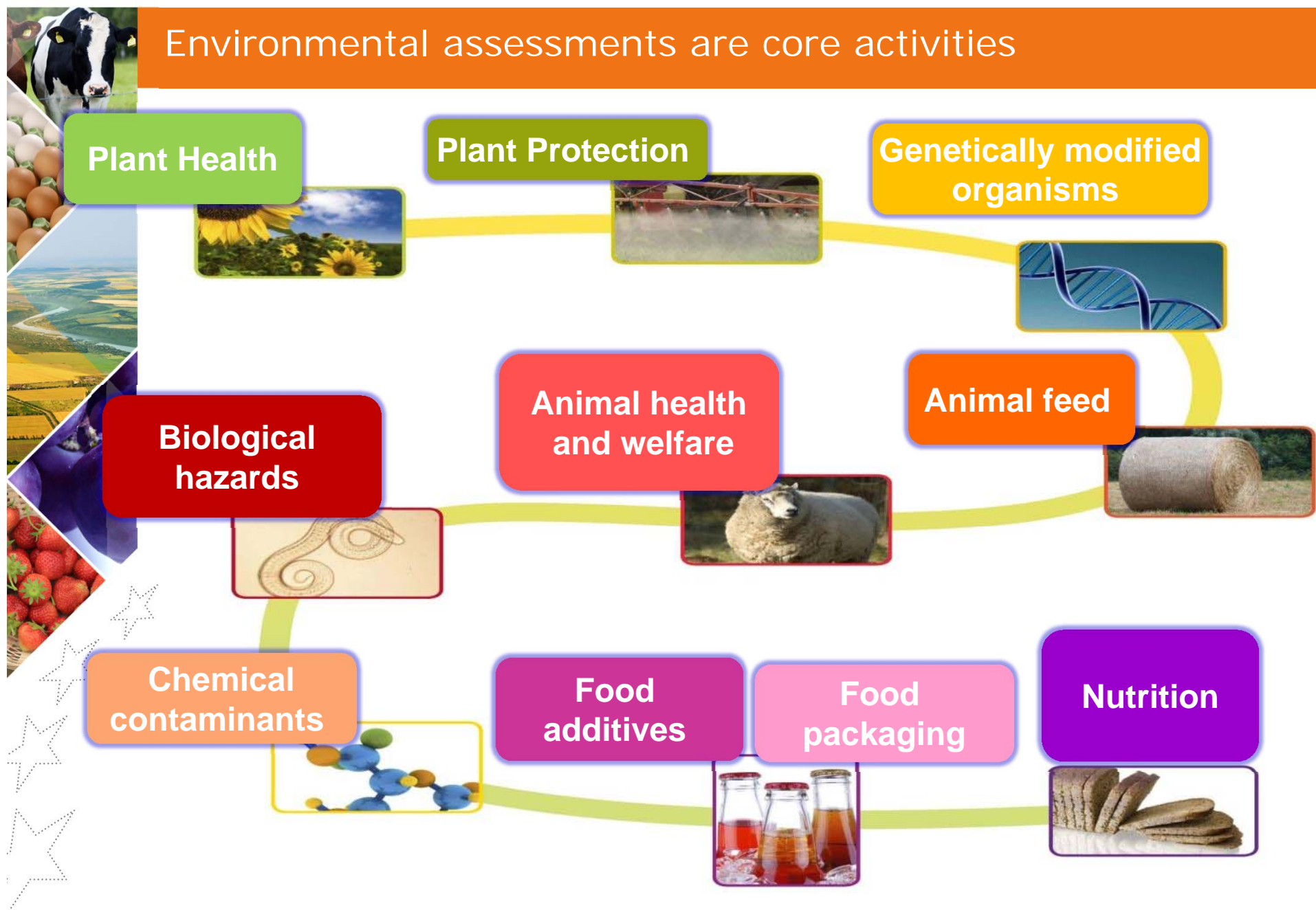
Jürgen Sturma – Conference on Pesticides  
Prague, 19 May 2016

## What is EFSA?

- **E**uropean • The European reference body
- **F**ood • Covers the entire food chain
- **S**afety • Assess, advise, communicate
- **A**uthority • Independent, trusted, based on sound science



# Environmental assessments are core activities



## Pesticides Unit

Coordinates the Peer Review of active substances

Provides **Conclusions** for single active substances to support the EU decision-makers

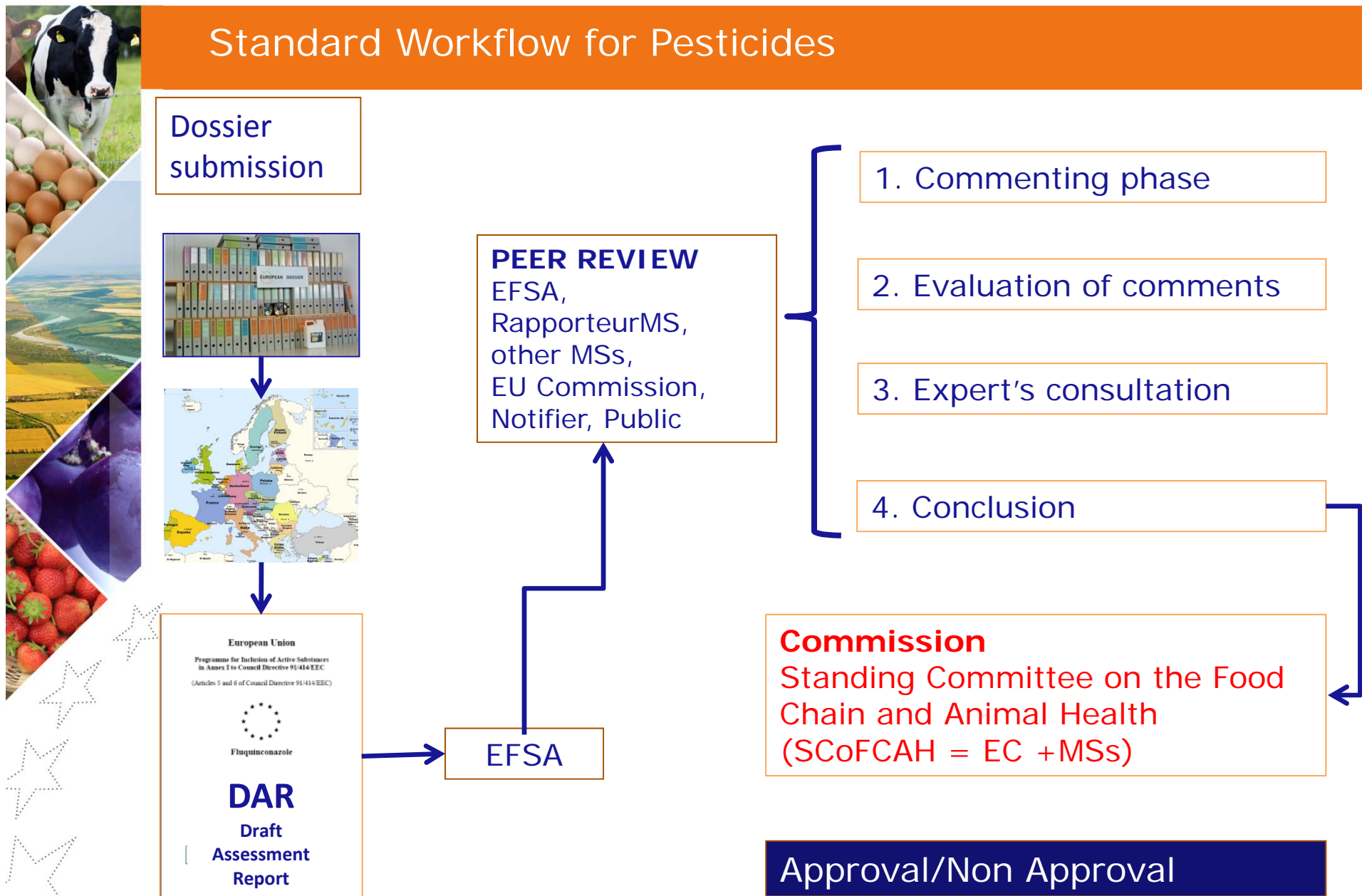
Supports the Scientific Panel for pesticides PPR (Plant Protection Product and their Residues).

- Opinions
- Guidance documents

Maximum Residue Levels MRLs

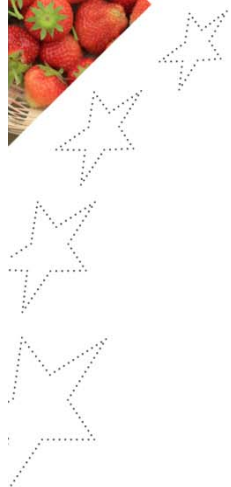
- Reasoned Opinions
- Annual report

# Standard Workflow for Pesticides



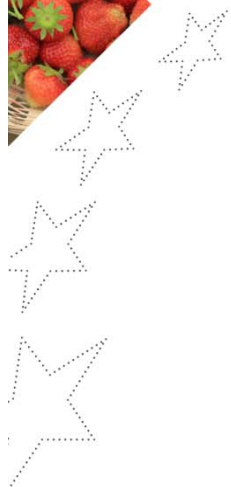
## Dossier Regulation (EC) No 1107/2009

- Summary dossier
- Complete dossier
  - with full text of individual tests and study reports (studies involving deliberate administration to humans are not accepted)
  - In line with the data requirements
- Scientific peer-reviewed open literature over the last 10 years (active substance & metabolites)



## Dossier Regulation (EC) No 1107/2009

- No format specified or recommended in the legislation
- pdf, word files
- CADDY (Computer Aided Dossier and Data Supply)
  - 2.0, xml
- GHSTS (Globally Harmonised Standard Transport System)
  - under discussion at OECD level

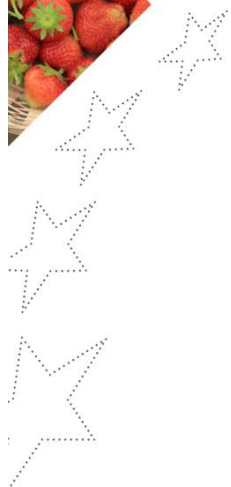


## Data requirements

### New data requirements:


- Regulation (EU) No 283/2013
  - Active substances
- Regulation (EU) No 284/2013
  - Products
- Applicable as from 1<sup>st</sup> of January 2014

### Old data requirements for some workflows



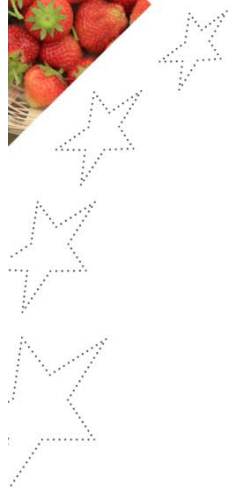


## Various workflows

- 
- Applications for the approval of an active substance – NAS (Art. 7)
  - Applications for an amendment to the conditions of an approval (Art. 7)
  - Renewal of an approval
    - AIR II (e.g. Glyphosate)
    - AIR III (137 substances - currently ongoing, e.g. Linuron)
    - AIR IV (212 substances, starting)
  - Review of approval (Art 21)

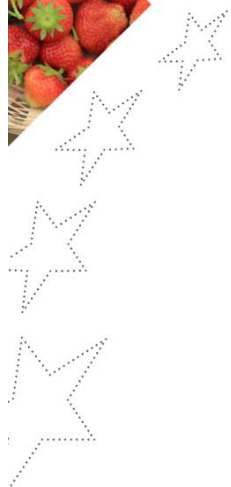
## Various workflows

- Basic substances (Art. 23)
- Confirmatory data
- Scientific and technical assistance (Art. 21)
- Requests under Art. 31 of Regulation (EC) No 178/2002 (food law)
- PAD (Public Access to Documents) requests



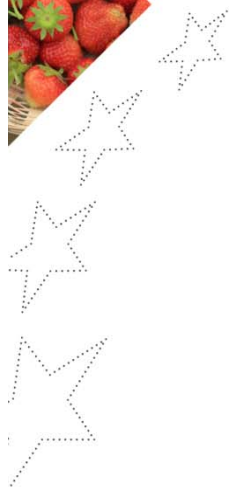
## Challenging situations

- AIR II
  - Starting under 91/414
    - old data requirements
  - Assessed under 1107/2009
    - new approval criteria
- Applications for an amendment to the conditions of an approval
- Substances that have a harmonised classification (cut-off criteria)



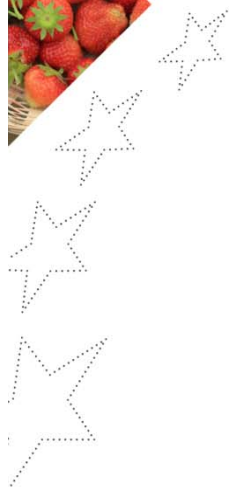
## Challenging situations

- AIR III
  - Availability of the original dossier
  - Change of applicant
- AIR IV
- Quality of the Assessment Reports
- Draged into “other” discussions, e.g. glyphosate



## The Pesticides Unit is involved in...

- Matrix Project
- Data base for the list of end points
- OECD WG on GHSTS (globally harmonised standard transport system for pesticides data)
- ... and others

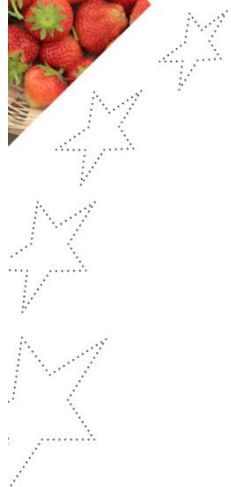


## The Pesticides Unit is open ...

- to support
- to discuss
- to co-operate

In the light of a successful evaluation of the active substances.

We need the dialogue.





## EFSA & You

Make a difference to Europe's food safety



Thank you for your attention.

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