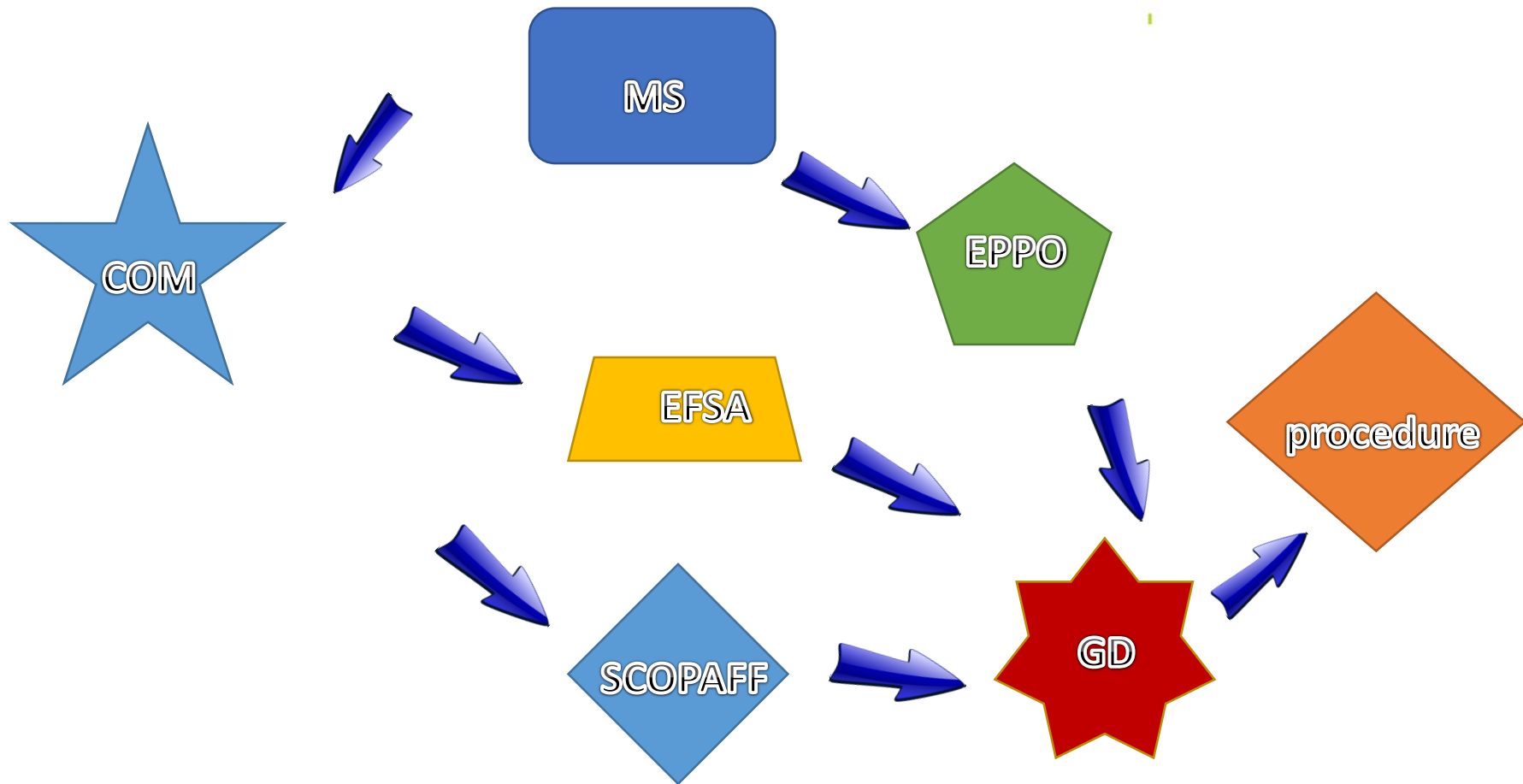


***Problems of using of Guidance
Documents in the evaluation of active
substances and PPPs***

Gábor Tőkés

Creating of Guidance Documents



Essence of Guidance Documents

- **Definition**

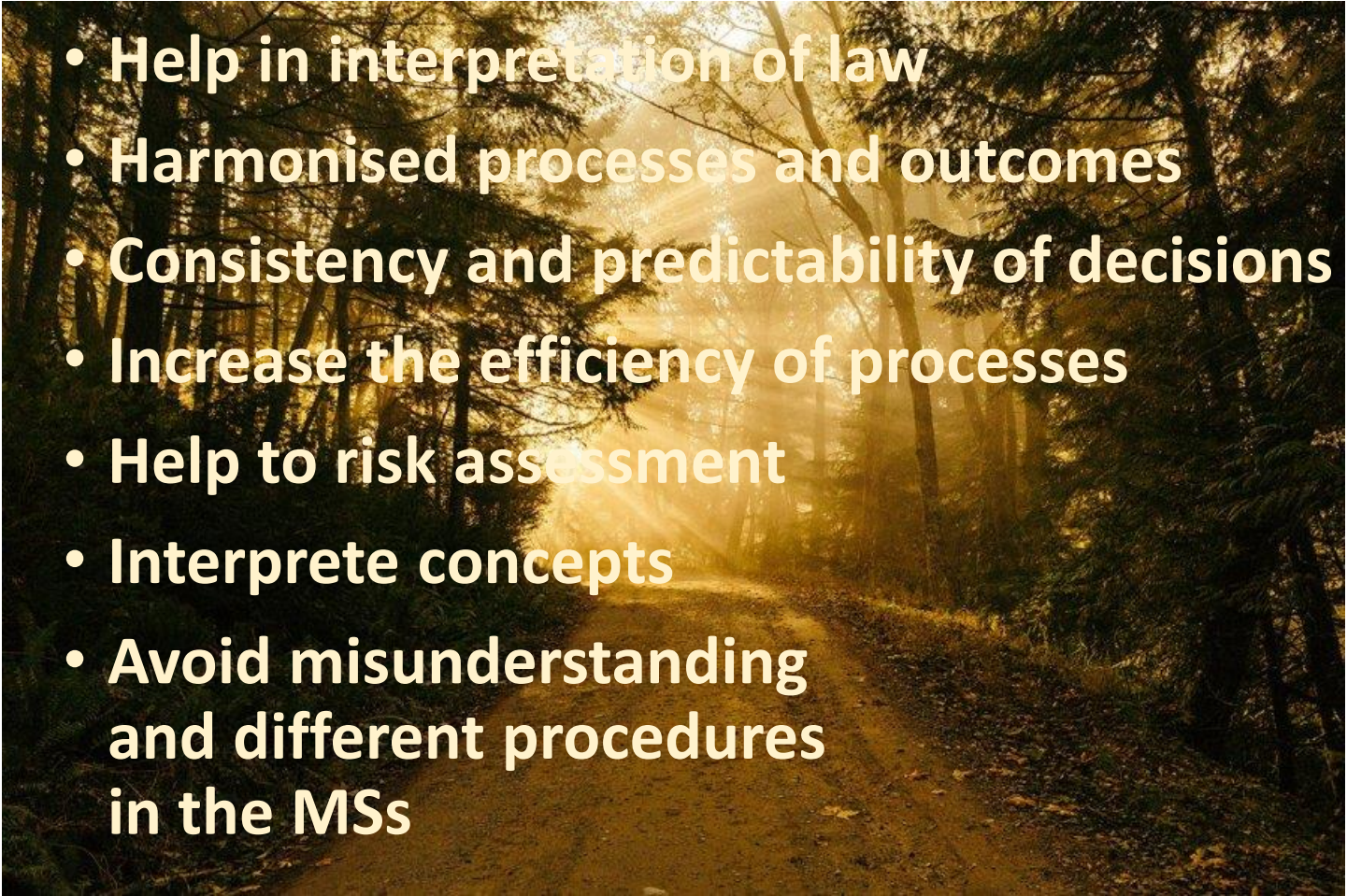
A publication containing a set of instructions, to explain and interpret uncertain or nonspecific parts of legislations and procedures

- **Why are they needed?**

To establish uniform performing of legislation or certain procedures within organisation or among more countries



Aim of GDs

- 
- **Help in interpretation of law**
 - **Harmonised processes and outcomes**
 - **Consistency and predictability of decisions**
 - **Increase the efficiency of processes**
 - **Help to risk assessment**
 - **Interpret concepts**
 - **Avoid misunderstanding and different procedures in the MSs**

It is not easy to overview what we have...



Type of GDs in plant protection



- **COM**

- type: technical and procedure GDs
- published by European Commission, DG SANTE (SANCO)

- **EPPO**

- type: Standards on plant protection products
Standards on phytosanitary measures
- published by European and Mediterranean Plant Protection Organization



- **EFSA**

- explanation of evaluation and data requirements
- published by European Food Safety Authority accepted by COM



... and some more options

- OECD guidelines for testing chemicals



Used by laboratories and trial institutes

- OECD guidance documents
- EPA guidances



Used in EU procedure if no COM or EFSA or EPPO GD is available

EPPO standards

← → ↻ https://www.eppo.int/index



European and Mediterranean Plant Protection Organization
Organisation Européenne et Méditerranéenne pour la Protection des Plantes

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Overview

PM1

PM3

PM4

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PM9

PM10

PP1

PP2



EPPO standards on plant protection products

Efficacy Evaluation of Plant Protection Products (PP1): standards on how to evaluate the efficacy of insecticides, acaricides, fungicides, herbicides, plant growth regulators...

***Number: 305** Specific standards only for fee (400-2000€/year)!
General standards freely available*

Good Plant Protection Practice (PP2): standards on optimal practice in protecting specific crops against their pests, including pathogens and weeds.

Number: 33

Environmental Risk Assessment of Plant Protection Products (PP3): withdrawn in 2018 !

Number: 12

„old bee GD” included

Dose expression in high crops

Arable crops: Ground area = Area of application

High growing crops: Area of application \neq Ground area

Solution: Counting with leaf wall area (LWA)

Efficacy: can be weak in orchards with high LWA

Phytotoxicity: can be higher in orchards with low LWA

PP1/239 (modified in 2012)

Workshops and discussions in 2016-17

Revise the standard in the light of recent discussions



COM guidances

https://ec.europa.eu/food/plant/pesticides/approval_active_substances_en

European Commission > Food, farming, fisheries > Food Safety > Plants > Pesticides > Approval of active substances >

Plants

PESTICIDES

EU Pesticides database

Sustainable use of pesticides

Approval of active substances

Application & report

Guidelines

EFSA procedure

Renewal of approval

EU legislation on PPPs

Authorisation of Plant Protection Products

Maximum Residue Levels

REFIT Evaluation

ALL TOPICS

Guidelines on Active Substances and Plant Protection Products

Technical guidance

Phys-chem analytical methods

Efficacy

Toxicity

Residues

Fate and behaviour

Ecotoxicology

Crop specific

Procedural guidance

Dossier and draft assessment report

Post approval issues

Procedures



QUICK LINKS



GMO register



EU Pesticides database



Procedure to apply for authorisation of a PPP



Plant variety database



Community Plant Variety Office (CPVO)



Health and food audits and analysis



Access to documents project



European Food Safety Authority (EFSA)



E-news



Press Releases



Infographics and factsheets

- **Technical: 30**
- **Procedural: 38**

• List of obsolete Guidance Documents - rev-0 - July 2015 , uploaded June 2016

COM guidances - technical

PESTICIDES	Guidelines on Active Substances and Plant Protection Products
EU Pesticides database	Technical guidance
Sustainable use of pesticides	Phys-chem analytical methods
Approval of active substances	Efficacy
Application & report	Toxicity
Guidelines	<ul style="list-style-type: none">Assessment of exposure of operators, workers, residents and bystanders  - 24 January 2017Acceptable operator exposure levels  - 7531 rev 10 - 7 July 2006Dermal Absorption  - 19 March 2004Dermal absorption  - 18 April 2012 - "Applicable from 1 December 2012/1 June 2013 depending on whether the guidance document does not trigger/triggers new studies to be submitted"Acute reference dose  - 7199/VI/99 -5 July 2001
EFSA procedure	Residues
Renewal of approval	Fate and behaviour
EU legislation on PPPs	Ecotoxicology
Authorisation of Plant Protection Products	
Maximum Residue Levels	
REFIT Evaluation	

◀ ALL TOPICS

- *Since 2009 step by step replaced by EFSA GDs*
- *Take care of overlapping*
- *List of obsolete GDs*

NUMBER of COM PROCEDURAL GUIDANCE DOCUMENTS

Total procedural GDs (including working documents etc.)	38	
Valid procedural GDs (including templates)	23	
GDs - Update required or going on	7	E.g.: Art 43., Zonal Evaluation and Mutual recognition Data Protection
New draft GDs	3	GD for the authorisation of PPPs for seed treatment Guidance Document on Minor Uses GD on Data Matching

Changes in procedural GDs

- PAI guidance documents will become **Commission Notices** under the new procedures
e.g. Zonal Evaluation on Mutual Recognition GD, Art 43 GD, deata Protection GD
- new GDs or revisions will be transmitted in the future for comments to **stakeholders** (industry, NGO - environment or consumer protection) via the Advisory Group - Food Chain and Animal and Plant Health.
- GDs containing interpretations of 1107 must be adopted by the whole COM based on EU treaties. Actually, only the European Court of Justice may write **interpretations** of legal texts.



EFSA Guidances

www.efsa.europa.eu/en/publications



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- ☐ Food ingredients and packaging (9)
- ☐ GMO (18)
- ☐ Methodology (15)
- ☐ Nutrition (12)
- ☒ Pesticides
- ☐ Plant health (4)

Type *

- ☐ Conclusion on Pesticides (537)
- ☐ Event Report (7)
- ☐ External Scientific Report (62)
- ☒ Guidance
- ☒ Guidance of EFSA
- ☐ Reasoned Opinion (764)
- ☐ Scientific Opinion (71)
- ☐ Scientific Report of EFSA (26)
- ☐ Special Issue (2)
- ☐ Statement (2)
- ☐ Statement of EFSA (16)
- ☐ Technical Report (186)

Date ▼

Search

Scientific Outputs

EFSA publishes all its scientific outputs, including its scientific opinions, in the EFSA Journal. It also issues a range of supporting publications. See also Definitions of EFSA Scientific Outputs and Supporting Publications.

EFSA Journal on Wiley

Outputs at a glance

Results 1 - 10 of 20

[Use of EFSA Pesticide Residue Intake Model \(EFSA PRIMo revision 3\)](#)

Guidance of EFSA | Pesticides | 15 January 2018

[EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil](#)

Guidance of EFSA | Pesticides | 19 October 2017

[Guidance on dermal absorption](#)

Guidance of EFSA | Pesticides | 30 June 2017

[Reporting data on pesticide residues in food and feed according to Regulation \(EC\) No 396/2005 \(2016 data collection\)](#)

Guidance of EFSA | Pesticides | 03 May 2017

[Establishment of the residue definition for dietary risk assessment](#)

Guidance | Pesticides | 22 December 2016

[Reporting data on pesticide residues using SSD \(2015 data collection\)](#)

Guidance of EFSA | Pesticides | 30 May 2016

[Reporting data on pesticide residues using SSD \(2014 data collection\)](#)

Guidance of EFSA | Pesticides | 13 July 2015

[Guidance for predicting environmental concentrations in soil](#)

Guidance of EFSA | Pesticides | 28 April 2015

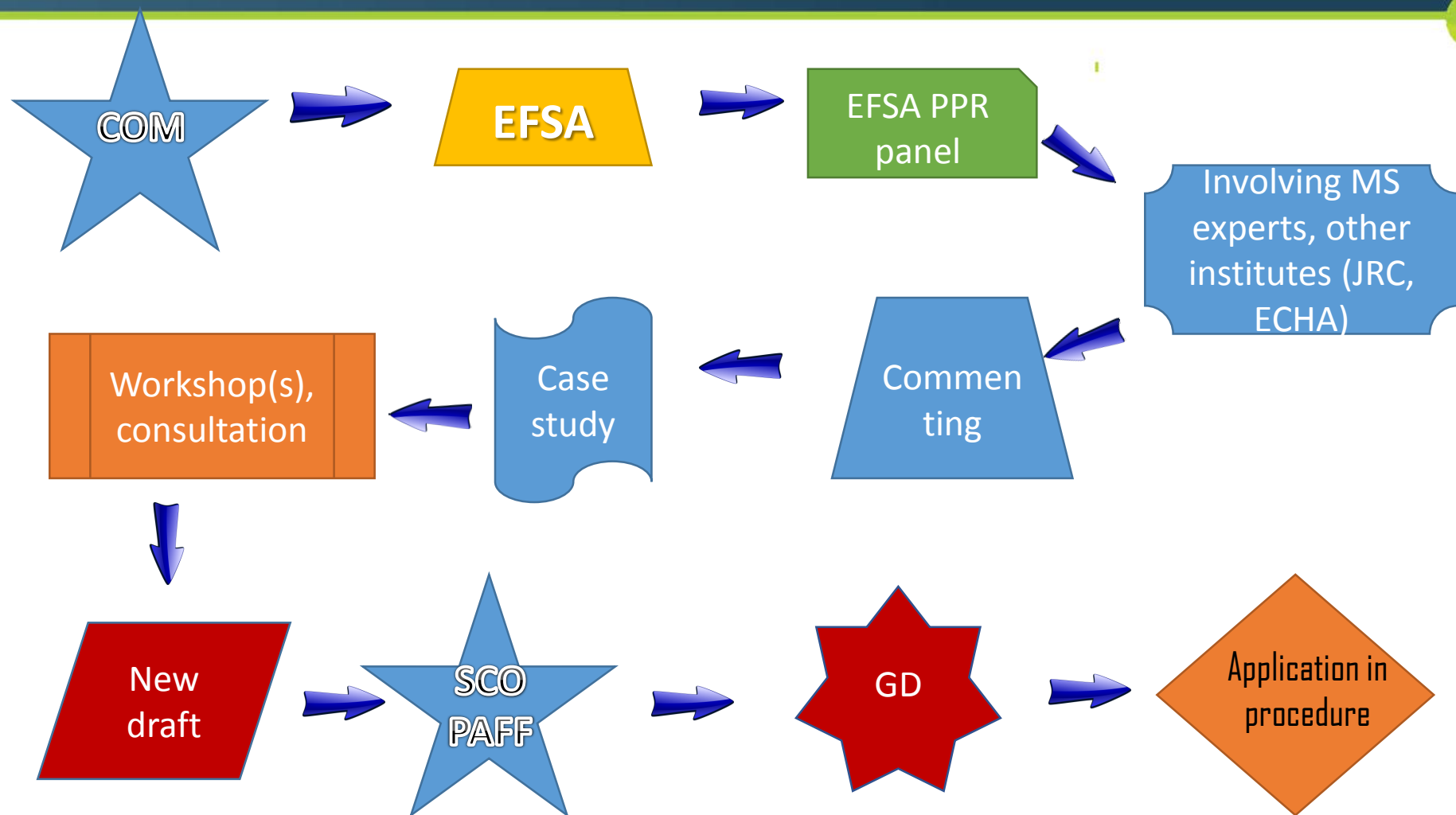
• **GD: 22**

-Since 2009
-should be
noted on
SCOPAFF (COM)

• **Scientific
opinion: 74**

Since 2004

Draft way of an EFSA GD



Main problems with GDs

- Information overloading - difficult to follow
- Need more and more experts to deal with them
- Parallel papers – scientific opinions, draft GDs GDs
GD is not enough for an evaluation !
- Smaller firms are not aware
- Contradiction between GDs - e.g. bee GD and Seed treatment GD (none of them is noted)
- Creating is long and needs high skills



Do we need more GDs ?

- New GDs are inevitable for application of rules and new science
- Old GDs must be renewed according to present knowledge
- New challenges must be handled
- Unify information in new GD, instead of using many different papers



Can MSs cope with the GDs?

- Reading and using GDs need time, effort and staff.
- Smaller MSs need them more, but they need more time to apply
- Specification is needed among experts – how to solve with 1-2 expert / area?
- COM should push smaller MSs to have more experts.
Art 74 and 75 is not enough.



Modification of GD- which version to apply?

1107/2009 PPP authorisation Article 36 (1)

*‘The Member State examining the application shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents **available** at the time of application.’*

More versions are available....

Time of application is a legal principle !

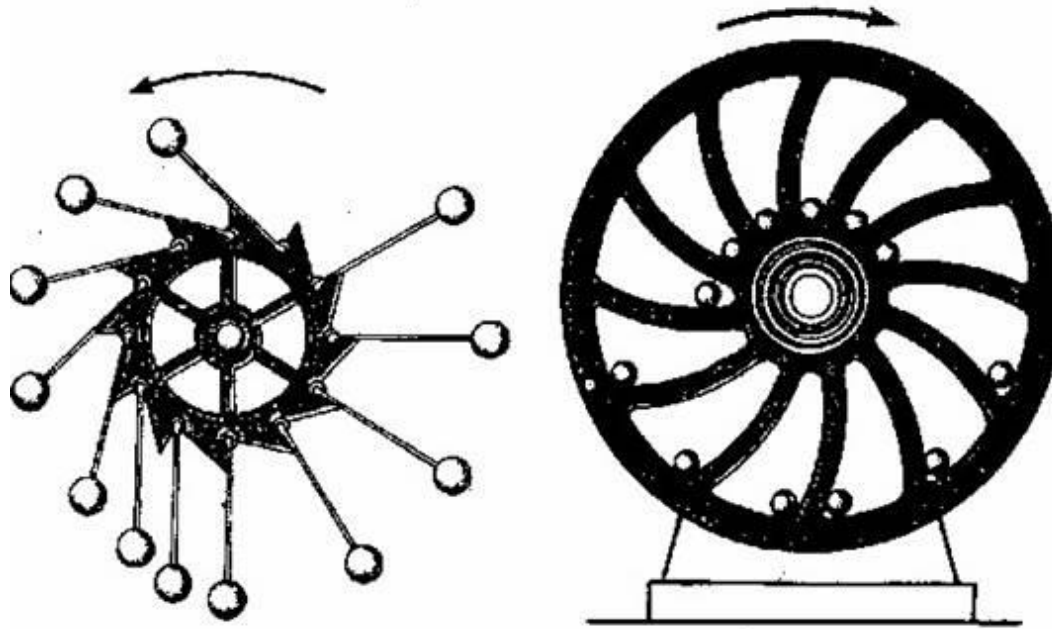
The newest obligatory?

Different endpoint for the same products if registered later for different applicant...

Art 34 !! - new GD – new evaluation for generics?



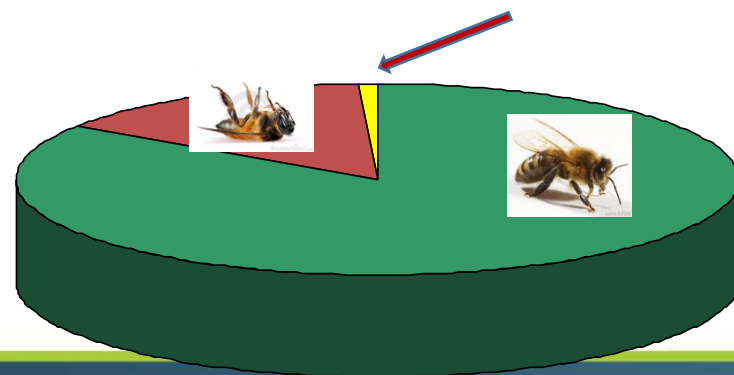
Funny examples for implementation of science



If working in theory, will it work in reality?

Bee guidance – science and practice

- Not accepted by COM (SCOPAFF) but EFSA applies
- Not clear legal situation
- Too complex
- Can lead to rejecting most of insecticides
- Unrealistic requirements for field tests
- ‘magnitude of effects on colonies should not exceed **7%** reduction in colony size’
- Science and practice can not meet
- 2018 Oct:
14 MSs want revision !



Glyphosate - science and politics

- IARC claims carcinogenity
- RMS + EFSA + ECHA proves safety
- All of 12 tox. trials shows no sign of problem
- Political pressure for non-approval
- 5 years instead of 15, almost failes to stay on positive list
- Science is suppressed by politics



New EU regulation for yield enhancers under final discussion



- Trade and use without registration
- Standardization of materials and products
- COM (DG Grow) proposed a very liberal system compared to PPPs
- Cadmium – carcinogenic, highly toxic and endocrine disruptor element – never would be approved as impurity in PPP in same dose
- Scientifically acceptable level: 20 mg/kg in P fertilisers
- Majority of Council wants 60-80 mg/kg
- Reason: pressure of industry and politics
- EFSA ? Greenpeace ?



How to improve managing GDs?

- MS authorities should keep a folder for quick access of GDs
- Experts and coordinators must know the relevant GDs !
- Trainings - COM and EFSA (how to interpret)
- EFSA should be more practical
- Case study is often necessary



Thank you for attention

