Ignorant by Design:

Regulatory Science, Comitology and the Agrochemical Industry

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POLLINIS
STOPPONS L'EXTINCTION DES POLLINISATEURS

Overview

OBJECTIVE

To highlight some of the agrochemical industry's strategies to maintain control over the epistemic form of pesticide risk assessment procedures in the EU, by defining what qualifies as "sound science" and "valid data-knowledge".

ANALYSIS

The case history of the Bee Guidance Document, published by the European Food Security Authority (EFSA) in 2013 but never adopted at European level, due to the lack of approval by the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), a crucial but little-known component of the EU decision-making chain ("comitology").

- The EFSA Bee GD 2013 represented a groundbreaking change in the epistemic form of risk assessment for bees, which did not meet with industry approval.
- In order to deconstruct the consensus around this GD, the industry deployed a multifold strategy, undermining in particular certain scientific assumptions of the GD.
- The deconstruction of consensus took place especially in the opaque environment of comitology, which presumably had an important role in the 10-year blockage of the document.

Guidance documents (GDs)

A KEY ELEMENT OF PESTICIDES REGISTRATION PROCESS

> GDs are “soft law” technical directives detailing the regulatory science applied in the framework of regulatory risk assessment procedures of pesticides.

> They outline the required evidence, data formats, and study protocols necessary for evaluating risks.

> In the context of the EU Environmental Risk Assessment (ERA), GDs also define **Specific Protection Goals (SPGs)**—the acceptable levels of pesticide impact on non-target organisms.

GDs thus shape what we “officially” know about pesticides and their effects, defining what qualifies as valid data-knowledge.

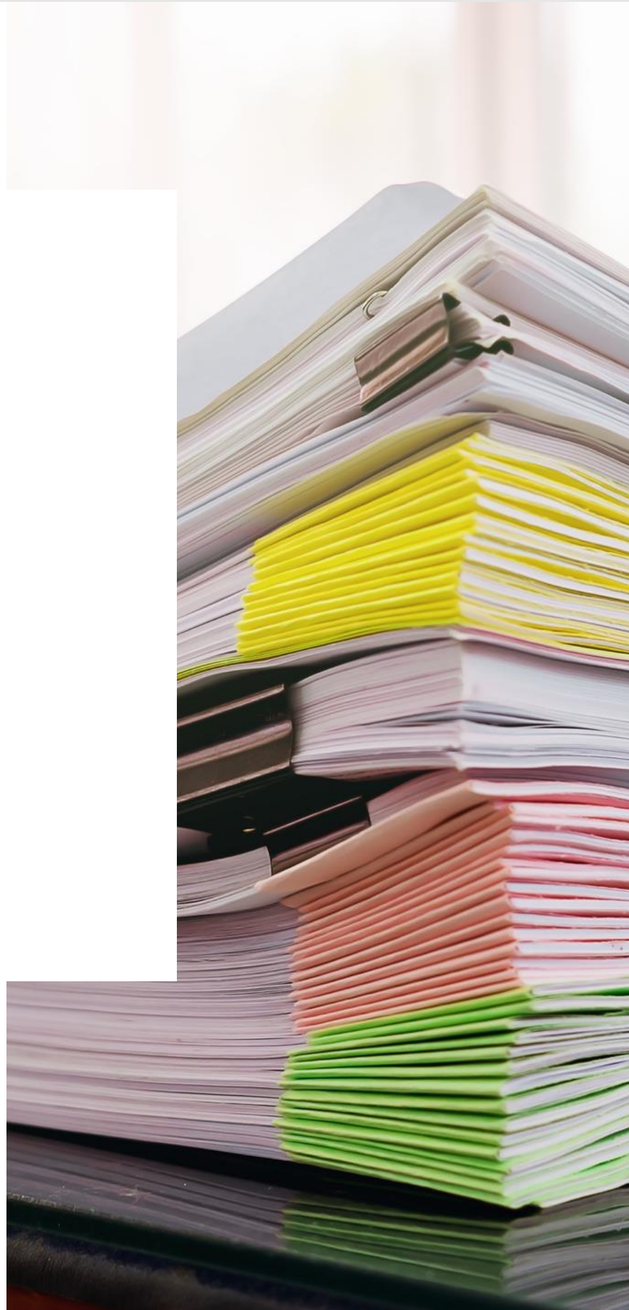
Industry and guidance documents

THE EPPO TEST METHODS EXAMPLE:

The agrochemical industry has historically been involved in the production of guidance documents, and has exercised a long-standing cultural hegemony over the founding principles of regulatory science.

The current EU risk assessment for bees (EPPO tests methods) is no exception: these tests methods are based on the work of a group of experts (the ICPPR's bee protection group) whose many conflicts of interest have been repeatedly denounced since 2007.

EPPO tests are a good example of a GD “ignorant by design”: they ignore certain routes of exposure, chronic and sublethal effects, impacts on juveniles and on bees other than honey bees, though these elements are crucial to apprehend the real toxicity of pesticides on pollinators, as highlighted by academic research from the 2000s onwards.



The EFSA Bee Guidance Document: A regulatory science revolution

European Food Safety Authority

EFSA Journal 2013;11(7):3295

GUIDANCE OF EFSA

EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)[1]

European Food Safety Authority[2,3]

European Food Safety Authority (EFSA), Parma, Italy

This scientific output, published on 04 July 2014, replaces the earlier version published on 4 July 2013*

The groundbreaking approach of the GD:

1) THE ECOTOXICOLOGICAL PERSPECTIVE

- New routes of exposure (water, dust, etc.)
- Long-term (chronic) toxicity
- Accumulative toxicity
- Larval toxicity
- Risk from metabolites present in pollen and nectar
- Specific protection goals (SPGs), i.e. the magnitude of effect that can be tolerated (7% of colony reduction)
- New test protocols, devised by EFSA when internationally agreed ones were lacking

The groundbreaking approach of the GD:

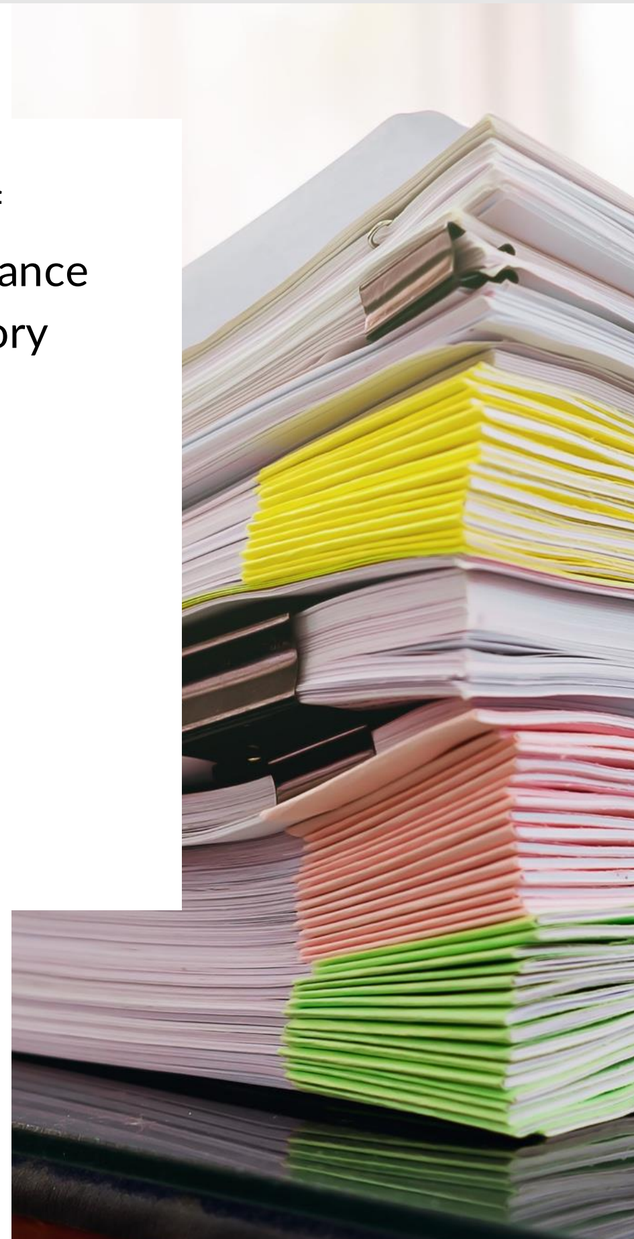
2) THE EPISTEMOLOGICAL PERSPECTIVE

Reversing many of the founding assumptions of “classic” epistemic form of **regulatory science**, which had been responsible for the production of ignorance by not allowing for certain kinds of knowledge to be considered by regulatory science.

Displacing borders between “done” and “undone” science, by
1) integrating as much as possible the results of recent academic research
2) conceiving protocols to assess effects for which internationally validated guidelines are not yet available.

Adopting a **precautionary approach** to address potential risks.

A major shift of the dominant “regulatory culture”



However...

To be adopted at the EU level, GDs on pesticides need to be endorsed by the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), which is made up of representatives of Member States and presided by the EC.

EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.g.3(2024)1730507

Standing Committee on Plants, Animals, Food and Feed

Section *Phytopharmaceuticals - Legislation*

The SCoPAFF and the comitology system

SCoPAFF is part of the comitology system, i.e. the “technical” procedures through which the EC implements EU laws once they are adopted by the Parliament and Council. SCoPAFF mandate covers the entire food supply chain, including pesticide authorisation and risk management.

Despite comitology being presented as primarily technical, there exists significant leeway for varied interpretations of the legislation to emerge during the process.

A decision-making process behind closed doors

The comitology system is not submitted to the transparency rules which apply to other EU institutions:

- debates take place behind closed doors
- names of participants are not public
- individual MSs' votes are confidential
- minutes of deliberations are not detailed

The industry’s lobbying

The EFSA Bee GD was published in 2013 and, at its inception, it enjoyed a wide scientific, institutional and political consensus.

However, between 2013 and 2019, the EFSA Bee GD was discussed around 30 times within the SCoPAFF, which never adopted it, due to the lack of a qualified majority.

Documents obtained through “Access to Documents” (A2D) requests show that ECPA (European Crop Protection Association, now CropLife), the powerful association of the agrochemical industry, carried out an intensive lobbying from 2013 onwards to oppose the adoption of the Bee GD.

A2D documents seem to indicate that the industry had open access to, and personal acquaintances with, the SCoPAFF members, despite the fact that their names are strictly confidential and inaccessible to other stakeholders and citizens.

A privileged access?

EMAIL FROM ECPA TO EC, 18 SEPTEMBER 2013

From: [mailto @ecpa.eu] **On Behalf Of**

Sent: Wednesday, September 18, 2013 1:00 PM
To: (SANCO)
Cc: MIKO Ladislav (SANCO); (SANCO);
(SANCO); (CAB-BORG); @gov.si;
@bmelv.bund.de; @jordbruksverket.se;
@minrol.gov.pl; @bmelv.bund.de;
@msz.gov.pl; @agriculture.gouv.fr; @dfa.ie
@minbuza.nl; @dfa.ie; @agriculture.gouv.f
@land.gov.sk; @ansvsa.ro;
dfa.ie; @svssr.sk; (SANCO);
@hse.gsi.gov.uk; @sanita.it;
@agriculture.gov.ie; @dgadr.pt; @hse.gsi.gov.uk
@tukes.fi; @dfa.ie; @madr.ro;
@msssi.es; @agri.ee; @agriculture.gouv.fr;
@agriculture.gov.ie; (SANCO);
@ctgb.nl; @bvl.bund.de;
@vaad.gov.lv; @msa.org.mt;
@mattilsynet.no; @magrama.es;
@msz.gov.pl; @pma.agri.ee;
@mgszh.gov.hu; @agriculture.gouv.fr;
(SANCO); @reper-portugal.be; @minszw.nl; @msa.org.mt;
@vatzum.lt; (EFSA);
@diplomatie.gouv.fr; @sgae.gouv.fr;

(SANCO); @gov.si; @kemi.se; @pzh.gov.pl;
@vatzum.lt; @vaad.gov.lv; (SANCO);
@kemi.se; @da.moa.gov.cy; (EFSA);
@health.fgov.be; @mae.etat.lu;
@minrol.gov.pl; @mmediu.ro;
(SANCO); @hse.gsi.gov.uk; @uksup.sk;
@gov.si; @lebensministerium.at;
@magrama.es; @magrama.es; (SANCO);
@srs.cz; @bmelv.bund.de; @asta.etat.lu;
@ctgb.nl; @MST.DK; @mfa.gov.lv;
@diplomatie.gouv.fr; @sanita.it; (SANCO);
@gov.mt; @pest.srs.cz;
@efsa.europa.eu; @kemi.se;
uksup.sk; @nsrz.government.bg;
@vaad.gov.lv; @sanita.it; @ages.at;
@bvl.bund.de; @kemi.se; @minlnv.nl;
@mattilsynet.no; @ages.at; @minagric.gr;

@minagric.gr; @bmgfj.gv.at;
@bmelv.bund.de; @hse.gsi.gov.uk;
@ntai.ontsz.hu; @mmm.fi;
@msa.org.mt; @brue.auswaertiges-amt.de;
@brue.auswaertiges-amt.de; @vatzum.lt;
(SANCO); @CTGB.nl; (SANCO);
@bmelv.bund.de; @agriculture.gouv.fr;

Subject: ECPA Comments on EFSA Guidance Document on the Risk Assessment of PPPs in Bees
Importance: High

Or selective opacity?

Given the planned discussion on this issue in the July Standing Committee, I am copying this letter to members of the SCOFCAH-phytopharmaceuticals group (in bcc). I am also copying it to the Commission's Secretariat General as the implementation of this guidance document raises important wider issues that require further consideration.

I would welcome the opportunity to discuss these issues with you during a coming meeting.

Please let me know if you require any clarification or further information .

With my best regards

[redacted]

European
Crop Protection

Deconstructing consensus

In order to deconstruct the consensus around the GD, the industry deployed a multifold strategy, undermining in particular certain scientific assumptions of the GD.

ECPA's position on the EFSA Guidance Document on the Risk Assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)

Undermining scientific assumptions

The main points of the scientific approach of the GD contested by the industry were:

1. the chronic toxicity test, and in particular its related trigger value
2. its SPGs, judged too conservative
3. the criteria for field tests, considered to be “unrealistic”
4. the use of experimental test protocols not validated by the OECD
5. its overall “complexity”

Based on these arguments, the main objective of the industry was to require a revision of the EFSA Bee GD.

The chronic toxicity test and the Specific Protection Goal (SPG)

I will consider the scientific contestation of two elements which are at the center of the industry's disagreement with the GD:

> **The chronic toxicity test**

> T**he SPG => the chosen level of protection** (7% max reduction of the colony size)

- SPGs have a key role in risk assessment, as all trigger values are calibrated on them.
- They must be approved by the SCoPAFF before being included in a GD. Therefore, at the time of publication of the EFSA Bee GD, there was a consensus among Member States on the 7% limit.

Contesting EFSA science: The industry impact analysis

The industry delegitimization of the chronic toxicity test is mainly based on an impact analysis of the pass/fail rate of the GD first tier by pesticides already on the EU market.

Based on this impact analysis, the industry claimed that 100% of substances would fail the tier 1 risk assessment:

Excerpt - E-mail from ECPA to SANTE - May 26, 2015

From: [redacted] [mailto:[redacted]@ecpa.eu]
Sent: Tuesday, May 26, 2015 11:10 AM
To: [redacted] (SANTE)
Cc: [redacted] (SANTE); [redacted] (SANTE); [redacted]
Subject: ECPA letter on Bee GD

Dear [redacted]

Please find enclosed a letter regarding the *EFSA Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees).* Despite discussions on a possible phased implementation, the fundamental issue of the built in conservatism of this document is still unresolved. As we already shared with the Commission, our detailed impact analysis indicates that 100% of substances fail the tier I risk assessment.

EFSA disproval of the industry impact analysis

Excerpt - E-mail from EFSA to SANTE - September 10, 2013:

From: [redacted] [redacted]@efsa.europa.eu]
Sent: Tuesday, September 10, 2013 5:14 PM
To: [redacted] (SANCO)
Subject: RE: Pass/failure assessment

Hi [redacted],

We have the pass/fail rate analysis almost ready. Below the outcome of the pass/fail rate analysis. Given the importance of this issue in the upcoming discussions I think it is good to check if everything was done correctly. I think that we can send you the final version beginning next week at the latest.

As you can see below the screening+first tier in the scheme is not overly conservative as always claimed by industry. Even 50% of the insecticides pass the acute assessment and 30% the chronic assessment (maybe we are not conservative enough? :-)
There is only one problem – it is the scenario of weeds in the treated field. It creates a lot of failures of herbicides in the chronic assessment. This has to do with high exposure factors of weeds in field. The chronic risk from herbicides is certainly overestimated from this scenario (in reality there will not be so many weeds in the treated field which are flowering at the time of application that bees exclusively feed on these weeds in the treated field) and we need to think about how to solve this problem.

EFSA assessment pass/failure rates

Excerpt - EFSA assessment pass/failure rates:

Overall pass rates substances
(at least 1 save use at the first tiers)

10 Insecticides, 10 Fungicides, 11 Herbicides

	Insecticides	Fungicides	Herbicides
Acute contact	50 %	100 %	100 %
Acute oral	50 %	100 %	100 %
Chronic oral	30 %	70 %	27.3 %

Overall pass rate of uses of these substances:
18 insecticidal uses, 16 fungicidal uses,
21 herbicidal uses

	Insecticides	Fungicides	Herbicides
Acute contact	50 %	100 %	100 %
Acute oral	50 %	100 %	100 %
Chronic oral	35 %	56.2 %	23.8 %

The challenge against the SPG: The BEEHAVE model analysis

Excerpt - ECPA email to the EC (SANCO) 12 May 2014:

First results show that honeybee colonies are much more resilient than predicted by the Khoury model used by EFSA to develop the guidance document:

- The model estimates explicitly that an effect level of 20-30% for honeybees (3 times higher than the current EFSA proposal of 7%) would be a negligible impact on colony strength and over-wintering success.

The demand of the industry: revise the Bee GD

> Since its publication, the industry repeatedly demanded to revise the Bee GD, claiming the existence of new scientific tools, e.g. the BEEHAVE model.

> In order to unblock the adoption of the GD, on May, 2019, the EC finally mandated the EFSA to revise it.

> Following the industry's demand, BEEHAVE was employed "to derive a threshold of acceptable effect on colony size based on background variability" (i.e. the SPG) in the new GD.

Excerpt - ECPA mail to the EC 17 June 2014

Dear Dr Miko

Please find enclosed an ECPA letter highlighting our concerns on the proposed adoption and use of the EFSA guidance document on the Risk Assessment of Plant Protection Products on bees.

The letter highlights the unworkability of this document:

- ***The political need to adopt a guidance document, irrespective of its workability, is deplorable and will create further uncertainty for applicants and jeopardise the harmonisation effort. We would ask the Commission to consider these points before the adoption of the guidance document.***

Concerns remain with the protection goals in this document, and more recent tools like the BEEHAVE model have been developed and needs to be urgently considered.

- ***We would formally request that EFSA be given the mandate to review this information, and that this be carried out urgently to allow necessary refinements to be made to the guidance document before its application.***

BEEHAVE results on background variability (SPG)

Percentile of the variability as lower limit of the OR	% fraction of colonies retained in the OR	% difference between the mean colony size and the lower limit of the OR			
		Median and ranges for all EU			
		Full year	Spring	Summer	Autumn
Whole range (FOR)	100%	23.2 (20.0–31.1)	20.9 (17.4–28.2)	18.6 (10.4–47.1)	28.6 (19.1–44.5)
5th perc.	95%	12.8 (9.9–17.9)	11.5 (9.1–14.8)	8.5 (4.9–26.4)	16.6 (11–27.2)
10th perc.	90%	9.7 (7.3–13.3)	9.0 (7.0–12.0)	6.0 (3.8–18.3)	12.3 (8.2–20.8)
20th perc.	80%	6.3 (4.8–9.1)	5.9 (4.4–8.4)	3.9 (2.5–9.6)	8.9 (5.2–16.9)
30th perc.	70%	3.9 (3.0–6.2)	3.6 (2.6–5.4)	2.0 (1.5–6.1)	5.3 (3.3–12.7)
40th perc.	60%	1.9 (0.8–3.6)	1.6 (1.1–2.6)	0.9 (–1.0[(a)]–2.8)	2.9 (0.3–8.1)
50th perc.	50%	0.0 (–1.4[(a)]–1.2)	–0.2[(a)] (–0.4[(a)]–0.1)	–0.3[(a)] (–3.1[(a)]–0.3)	0.5 (–2.8[(a)]–3.1)

(a): Value > mean, should not be considered for threshold derivation.

The ball is back in the SCoPAFF's court

BEEHAVE didn't provide any clear basis for a decision that was, from the start, a political one (i.e. "what is an acceptable reduction of bee colonies?"); therefore, SCoPAFF members had to choose one of these different percentages, in order to set the SPG for honey bees.

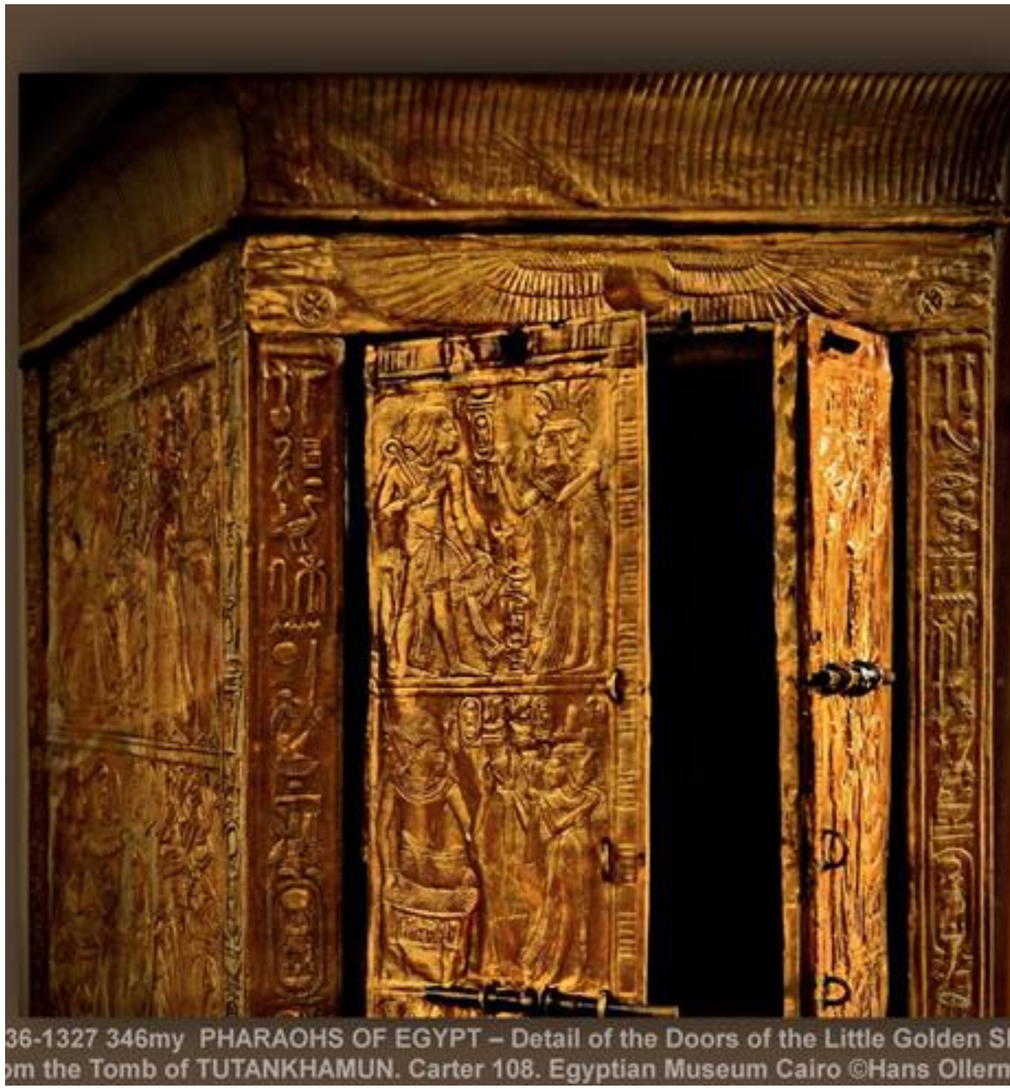
The discussion took place at the SCoPAFF meeting of 24-25 March 2021. SPG (% of acceptable colony size reduction) selected by MSs:

- 23% (4 MSs)
- 10% to 12.8% (11 MSs)
- 7% (4 MSs)
- NO OPINION (4 MSs)

Seeking a more transparent discussion on the SPG

To avoid the SCoPAFF opacity, the European Parliament (which was advocating keeping the 7% SPG of the 2013 GD) and civil society associations asked the EC for the issue to be discussed at a forthcoming meeting of the AGRIFISH Council, given the transparency rules which apply to this body.

The Council decision (June 2021): a clear majority of Ministers supported the Commission's proposal for a specific protection goal which limits the maximum permitted level of honeybee colony size reduction at 10% after the use of a pesticide.



Conclusions and epilogue

The 2013 EFSA Bee GD represented a **major shift of the dominant "regulatory culture" on** risk assessment for bees, which did not meet with industry approval. In order to block its adoption, the industry exerted intensive lobbying (also) on SCoPAFF members, taking advantage of its privileged access to this decision-making body, which is inaccessible to other stakeholders and to citizens in general.

This lobbying, which aimed at deconstructing the scientific consensus around the GD, was based on two "scientific" arguments, which proved to be either incorrect (the impact analysis) or useless (BEEHAVE model). However, this did not prevent the industry from obtaining its revision, which was its main objective.

Most of the industry's requests have been integrated into the revision.

It is probably thanks to the more transparent discussion on SPG (i.e. the possibility, for the public, to know the vote of each MS) that the selection of a disastrous SPG for bees was avoided.

The new EFSA Bee Guidance Document was published in 2023. From an ecotoxicological point of view, although it constitutes an obvious improvement on the obsolete EPPO scheme, is less ambitious than the previous one. From an epistemological point of view, the groundbreaking approach which characterized the epistemic form of the 2013 version has disappeared.

The new GD has not been adopted by the SCoPAFF yet.

Thank you for your attention!

Contact: Barbara Berardi Tadié (bbtadie@gmail.com)