



Lessons from the EU legislative process

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Introduction

What is the problem?

Hopes and fears

Towards zero risk

Impact and consequences

ED – What is the problem?

Alligators in Lake Apopka

Sperm count

Diabetes, obesity, autism (health costs)

Neurodevelopment and IQ (cost of inaction)

Thyroid





Hopes and fears

« Those who know what's best for us must rise and save us from ourselves »

“Ignorance and prejudice, and fear walk hand in hand”

(Rush, “Witch Hunt”)

“And the things that we fear are a weapon to be held against us”

(Rush, “The Weapon”)

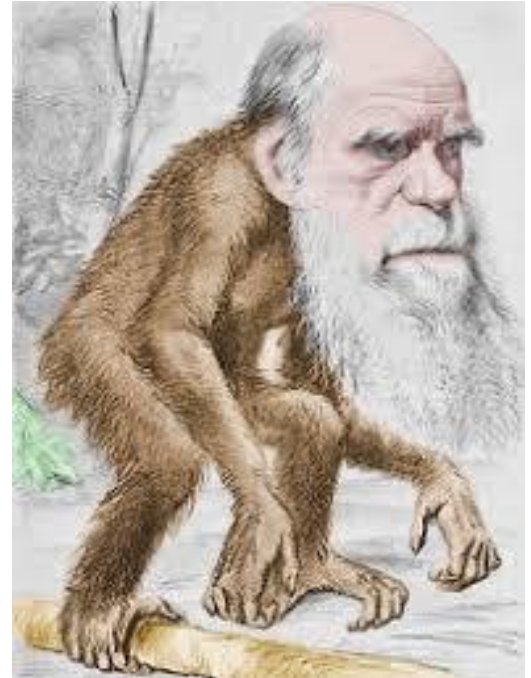
The scientist asks questions and seeks answers

The scientist brings hope!





It's not always easy being a scientist





There is always an element of doubt or uncertainty

If you give me six lines written by the hand of the most honest of men, I will find something in there which will hang him »

Cardinal Richelieu

How often has this tactic been used to misrepresent scientific articles with alarmist headlines?





Golden Rice – have we really come to this?



GMO rice that produces B-carotene, a precursor to Vitamin A. Vitamin A deficiency in developing countries results in blindness and death, especially among children.

« Opposition based upon dogma contradicted by data must be stopped. »

June 2016 letter signed by >100 Nobel laureates



Fundamental flaws in the hazard-based approach

Rodenticides – the rat is the model for mammalian toxicity; biocide derogations.

Vitamin D3



Iodine

Essential at certain doses, dangerous at others
(too much or too little). Mandatory supplements.
Union Authorisation

Insect Growth Regulators – targeted on specific, non-mammalian mode of action

All avoidable when you apply risk assessment and consider the benefits



Negligible risk derogation – why the fuss for pesticides???

Where hazard is high (cut-offs CMR and ED), exposure must be very low for risk to be acceptable

Negligible exposure is implicit, but negligible risk is quantifiable and consistent with regulating « low hazard » substances where exposure could be dangerously high.

Negligible risk – Ok for REACH, OK for biocides

Negligible exposure – voted in 2009, but nowhere near agreement on Guidance, yet.

Portrayed as a gift to industry, although any uses would be extremely limited at national level.

Real problem is that EP would reject for procedural/legal reasons.



A level playing field????? Equal treatment?????

Copper: EFSA report 2018 data gaps for all representative uses; high risk for all representative uses for birds, mammals, aquatic organisms and soil macro-organisms. Critical areas of concern. No evidence of ED potential in mammals at « **realistic levels of copper exposure** ». No specific data for other non-targets. One paragraph on risk to bees Insufficient data to conclude.

Commission proposes renewing this candidate for substitution. 4kg/ha. Not credible.

Since when was the level of exposure a component of the ED criteria?????

If this was glyphosate or a neonic, there would be an outcry.



Impact assessments and ED

Very comprehensive and avoided opinion

Provided lists of substances that might meet ED criteria according to policy options

In spite of disclaimers, over 1000 consumer products in France we listed as « might be ED »

Concluded option 4, with potency consideration, would have least impact on agriculture, no differences between different options for human health

Selected option 2, hazard identification only; no categories.

Politically acceptable compromise for scientific criteria. Why do the risk assessment?



Considering the impact

A tendency to believe that banning pesticides will remove the risk

Fails to consider the benefits. Fails to consider the consequences – what will the farmer do?

ED Guidance describes an ideal data set if submitted today Sufficient to conclude

Much less helpful to deal with dossiers already submitted All available evidence

Signs that Guidance will introduce *de facto* data requirements (new 2-gen, EOGRTS)

Now NGOs want more data on each *product*. Already a challenge for ED and biocides.



Impacts and consequences – ED and non-mammalian testing

.If we follow the Guidance that recommends a fish test and an amphibian test to have the EATS modalities appropriately covered and we consider that 80% of the actives on the market are concerned.?

600 substances, 210 million euros to have the EATS modalities sufficiently investigated covered for non-mammalian vertebrates, with a fish test and an amphibian test,..350 years of work for testing...

Considering that only two CRO's are currently able to conduct proper AMA, it will take about 175 years to have the 600 substances covered for the T modality in non-mammalian vertebrates.

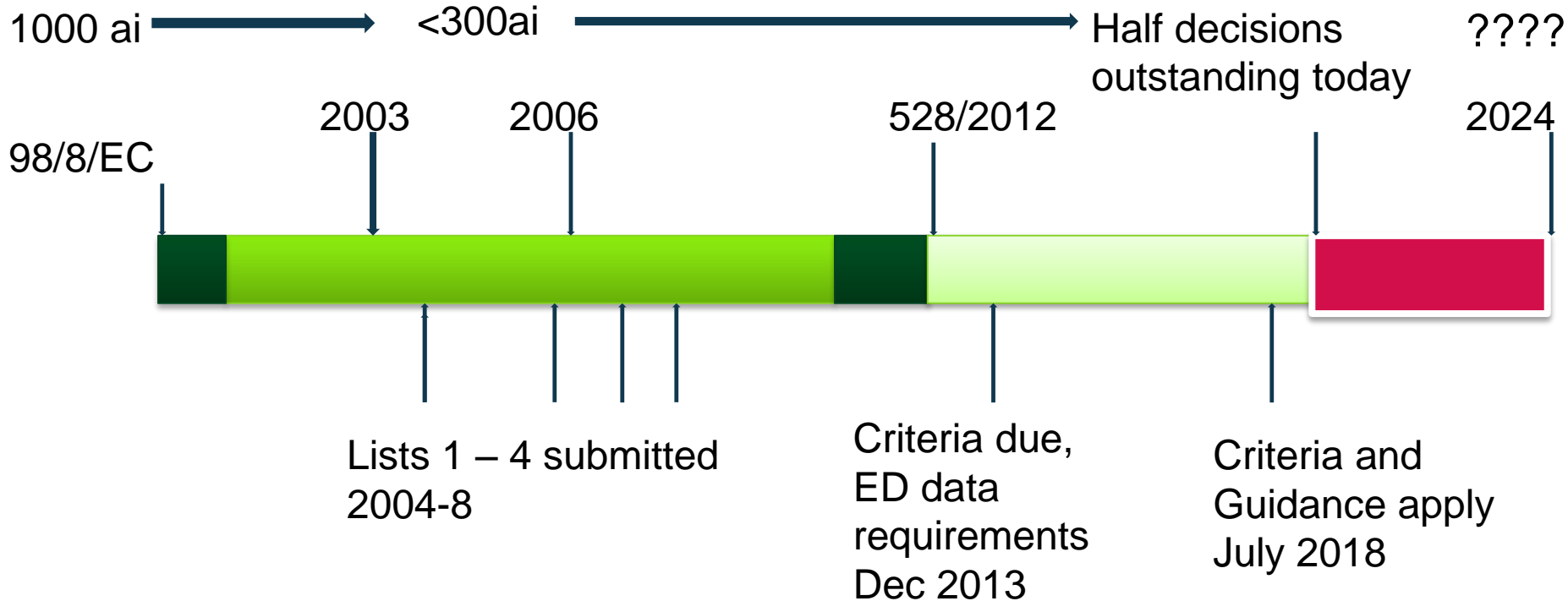
For fish, about 10 CRO's worldwide are able to do the tests. 35 years.

And just think about the several billions animals unnecessarily killed... we cannot blindly apply the ED guidance that requires one test for fish (FSTRA or MEOGRT) and one test on amphibians (AMA or LAGDA) for each substance.

Not forgetting REACH



Objectives and reality – a biocides timeline





Losing the plot?

Publish or perish

Government (public) funding in decline

Private (« industry ») funding and Contract Research Labs on the rise

Social media campaigning and petitions

Distrust of studies (and scientists) funded by industry

GLP required. Who else pays?

There is (grant) money in research that rings alarm bells (bees, glyphosate, vaccines, GMOs)

Why (how to) publish results that show « no effects »?





Following the rules ... while the game changes





Lessons learned

Always keep the objective(s) in sight – pragmatic and proportionate

what is the contribution of pesticides to endocrine-related conditions?

or ... what are the main causes of ??????

How much will proposed measures contribute to achieving the objective(s)

Impact assessments are essential – road test the options, believe in the study

« Cost out » the proposals (resources, implementation, alternatives ... consequences)

If science-based criteria are required, focus on science first and politics and public opinion second!



Concluding remarks

In Europe, political expediency and perceived public perception increasingly trumping science

While we focus on single issues we lose sight of the bigger picture. Impact assessments can help and we need to consider the consequences of any proposals (« cost it out »)

Today, in many EU MS, around 10% of family budget is spent on food. 50 years ago it was 30%

Too easy to take it for granted when we are more and more detached from farmers and farming.

In the meantime, while we make life more challenging for farmers, are we really any safer?

We don't know it all, but we do know an awful lot!!!!!!!

Room for optimism? Yes we can!!!



