

Reductionism in EFSA Risk Assessments: How Can EU science (and policy) meet its democratic legal mandates?

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Session 3

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Summary of this Session:

- The purpose of RA is human health and environmental protection
- Reductionism and good science – conflicting scientific values
- Precision: realism: scope....all norms of good science (**precision = reduction of scope - *apriori* exclusion of salient questions and dimensions. Also, NON realism**)
- These criteria not all mutually consistent. Eg: Precision Realism, or Scope
- Reductionist choices in EFSA RA science are ***choices***, not essentials
- They are choices which reflect values; and they can be *different* choices, which would create different EFSA RA science. The choices need justification, cf *policy* aims
- Copious examples of scientific choices in EFSA RA/science from Sessions 1 and 2 – and with alternative, good science choices which were not made
- **Why science alone is not enough:**
 - RAP and concealed policy choices in RA ‘science’ (How could this possibly be trusted?)
 - Scientific uncertainties/contingencies in RA – why benefits questions and alternatives must also be considered (rigorous science!)
 - EFSA RA and the Precautionary Principle: Governing *Innovation*, not just Risk!

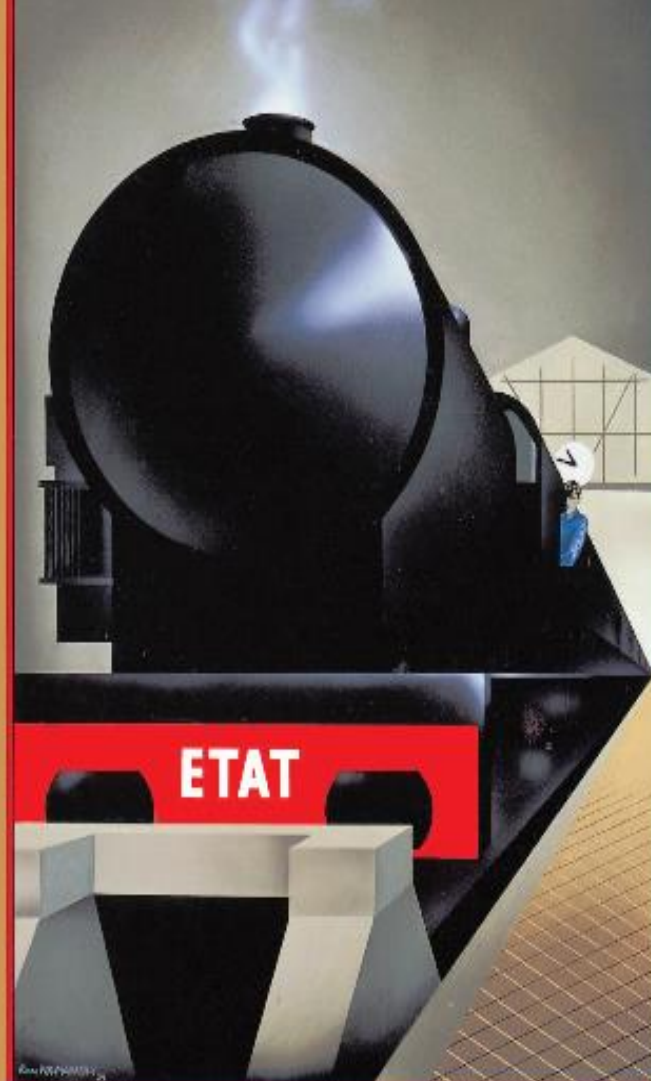
The EU's Democratic Legislative and Constitutional Mandates for EFSA RA/Science (from Erik Millstone, Session 2)

- Include long-term, cumulative, indirect
- including biodiversity;
- Pose questions about “ALL possible harms..”
- Scientific assessments “of the highest possible standard”
- All decisions, all domains, require fulfilment of the Precautionary Principle
- (there are also, agreed processes and practices, norms, for qualifying as proper science – eg, Merton, 1971, C U D OS)

• T H E • V A L U E S • O F •
PRECISION



EXACTITUDE



Edited
by

M.
Norton
Wise

Norton Wise, ed., *The
Values of Precision*, 1999,
Princeton University Press

– **precision is
one value
amongst several
which define
good science**



To Begin: Philosophy of Science 101...

- **Precision** is typically taken for granted as THE epistemic principle which defines good science, universally – in virtually all science (not only at EFSA)
- Precision requires us to: control – stabilise - all variables except the one of interest as possible causal factor; vary that one factor in controlled manner; then observe the effects on end-point of interest ('harm')
- Such a degree of control requires artificial conditions (physics; molecular biology; mathematical simulation models)
- Precision thus requires *ab-initio* exclusion of some factors, maybe relevant ones = **Reductionism**. These are unannounced – denied - value-choices
- Science can be *very precisely* incorrect! Other choices can be made
- Controlled lab (or field) conditions are *artificial, unrealistic*
- **Realism, and (greater) Scope**, also important epistemic values for good science

Sessions 1 and 2 gave many examples of reductionist RA scientific and framing choices made by EFSA, but concealed as such:

- Pesticides

- Relevant constituents excluded (also GMOs)
- Mixtures unexamined for possible synergistic effects (also GMOs)
- Independently emitted, downstream (env., food-chain, etc) combinations assessed in isolation (also GMOs)
- Toxicity-assessment limited to short-term, acute exposures and effects, even when harm observed for longer-term, *lower* exposures. These studies dismissed – “not Good Lab Practice” (yet they are *better*!)
- Glyphosate synergetic harmful effects with (commercially undisclosed) adjuvants excluded (Gunatilake *et al*, 2019)
- ‘Real exposures’ in RA often derive from EFSA scientist “expectations”, not data (also GMOs)
- Modes of (harmful) action inadequately known, yet assumed to be same, allowing neglect of poss. synergies
- Soil microbiota and soil fertility effects badly defined and inadequately studied (also GMOs)

- GMOs

- ‘comparative safety assessment’ = discredited, inadequate, “Substantial Equivalence”
- Defining ‘harm’ frames RA science: requires defining the comparator. EFSA GM RA assumes ‘normal’ (no harm) is dominant, unsustainable, industrial monocrop ag. For EU-mandated high standards of protection, why not (sustainable) *organic*?
- Herbicide-tolerant GM RA excludes *herbicide*, even though real technology is GM-herbicide *combination*
- Stacked transgenics assumed to act in isolation. Interactions btw different transgenic inserts not tested
- Superweed development with HR GM monocrops (→ yield-losses, greater herbicides-uses) - excluded
- Unrealistic RA test-conditions, eg purified isolated Cry-proteins to represent full Bt GM plant – presumes full control (no unknown remainder) over transgenic insertion process, and only intended effects.

Incomplete list – just for illustration

These reductionist scientific commitments occur both within the risk assessment scientific knowledge-construction, and also in the framing of the scientific risk questions (RAP: Session 1) They are NOT obligatory!

Those scientific choices themselves should be comprehensively reviewed and amended so as to render them consistent with the legally and constitutionally mandated norms defining the aims of EU regulatory science: such as, long-term, indirect, and cumulative possible harms, not merely short-term and directly observable harms. This requires greater scope in trade-off with precision. EFSA risk assessment science is also legally required to fulfil the EU commitment to high standards of health and environmental protection, and to the Precautionary Principle (PP). Again, greater scope and realism are required to fulfil such higher scientific RA standards. These norms can be given priority in RAP (Codex 2003, US NRC 1983, Millstone et al, 2009)

As shown before, and contrary to EC claims (later slide), EFSA RA science is not consistent with the PP, indeed is often anti-PP. This can - and to be consistent, let alone lawful, must - be changed.

Reductionism in Framing of RA questions
generates (and mutually reinforces with)
reductionism of disciplinary paradigmatic
scientific inputs.

Sessions 1 & 2 also noted double-standards in risk assessments, systematically downplaying or dismissing evidence of harm, while selectively emphasising evidence of safety

EFSA has even used fraudulent “ghost-written” scientific papers in its glyphosate risk assessment

These are anti-scientific - worse even than reductionism, which selectively excludes salient and legally-required questions and factors from testing, and biases data-interpretation against precaution
So too do the documented conflicts of interest of numerous EFSA scientists (Corporate Europe Observatory)

In addition to process-reductionism and substantive contents-reductionism with EFSA RA science, there are legal-procedural norms which contravene proper scientific procedures

- For example, applicants' dossiers are not allowed to be communal scientific materials, openly accessible for independent peer scrutiny and testing. They are accessible only to the EFSA expert panel and the receiving M-S.
- Moreover, the data therein are themselves produced, selected and edited by the applicant, and under such tight commercial demands for speed and economy, that full open scientific peer-review, even access to key R&D and RA information (like identification data), is prevented
- Confidential Business Information (CBI) which legally exempts salient data about all materials in products from scrutiny, should *de minimis* exclude data for health and environmental safety questions (Session 1, glyphosate adjuvants, one example)

Of all the reductionist and anti-precautionary scientific choices in RA which undermine the reliability of EFSA RAs, some may be justifiable on pragmatic grounds that more inclusive questions or framing processes are currently beyond technical feasibility, or impossibly expensive. However most of these are quite arbitrary choices, and not a few, particularly examples of double-standards, are simply unacceptable. Each such choice should be (a) recognised as a choice, (b) compared with alternatives (often more realistic, or comprehensive), and justified against other options. Many scientific assumptions not justified in the applicant documentation, and not validated (or refuted) by testing, could simply be required by EFSA to be tested, and amended accordingly. But it is often EFSA scientists themselves, who are tacitly making such unaccountable and often anti-precautionary assumptions!

Why is it Necessary to Go Beyond the Science?

(...In order to gain a perspective from which to generate *better* science...)

- 1) the unacknowledged issues of Risk Assessment Policy (RAP), or Framing, explained in Session 1
- 2) scientific knowledge is not only *framed*, with normative commitments and consequences. *It is also contingent, and incomplete*
 - Risk assessment is about one crop-release, or chemical. Important harms may ensue from a **trajectory** of accumulated multiple effects, each single one of which may be insignificant. This question should be included in regulatory assessment. Its required expertise is much broader than for RA. “Cumulative impacts” required in law by Dir. 2001/18.
 - why does ‘uncertainty’ not encompass this problem ? (next slides)
- 3) much more is at stake than only ‘Risk’ as defined by RA scientists....

Risk Assessment Policy: US NRC 1983 'Red Book'

"RA contains some or all of the following steps:

- Hazard identification;
- Dose-response assessment;
- Exposure assessment;
- Risk characterisation

In each step, a number of decision-points...occur where risks to human health can only be inferred from the available evidence. Both scientific and policy choices may be involved in selecting from amongst different possible inference bridges... We have used the term *risk assessment policy* to differentiate these judgements and choices from the broader social and economic policy issues which are inherent in risk management decisions" (US NRC, 1983, *Risk Assessment in the Federal Government; managing the process*, p.3)

(Note that environmental issues amplify the significance of this point)

Red Book's key point – scientific grounds for judging causal effects are invariably incomplete (but this does not justify a 'safety' conclusion):

- Thus difference of scientific inferences is likely – and normal.
- And incompleteness means inevitable uncertainties, unknowns, and contingencies in the risk knowledge
- There are also inevitable *assumptions* which shape the resultant scientific judgements and conclusions: about what factors are most relevant; about the relative weights of different bodies of evidence; about what comparators define “safety” (what is normal?) and “harm”? And about what factors can be ignored?
- Good, accountable science would require that all these be openly accountable, inclusively debated between independent scientific peers; and their multiple policy aspects deliberated amongst stakeholders and public representatives.

PREDICTABLE RISKS AND *UN*CONTROLLED RISKS

RISK – know harm, and know probabilities: $R=p.C$

UNCERTAINTIES – may know possible harm-effects, but don't know probabilities

IGNORANCE – don't know possible effects (don't know which questions to ask: eg CFCs-stratospheric ozone)

AMBIGUITY – what is the *meaning* ? Framing? (eg, what are we trying to protect? from what? What factors are relevant?)

INDETERMINACIES - system complexities which escape repeatable deterministic control-prediction, even if known. Eg: How valid are lab data for different, uncontrolled *field*-conditions?

A, I, I, and U are confused and reduced (by experts) to “Risk” . Even worse, risk scientists assume, mistakenly, that risk is the only public concern, the natural meaning of the public issue

Research science may deal with U, I, A, but “science for policy” does not; it typically claims/implies that risk knowledge covers all the questions

Publics typically understand that there are always unpredicted things occurring that they have to adapt to or maybe avoid. They are also aware that experts don't know it all (there is ignorance) and surprises happen. Being aware that they are inevitably dependent on unknown 'authorities' to respond to those surprises in the public interest, their first question is often: who will be in charge? The next one, quite rationally, is: And can we trust them? This then leads to: what is their track-record?

Thus we have naturally, logically, moved from a technical question about "Risk", through implicit awareness of limits to scientific knowledge, to a social question of Trust.

It is sometimes Risk scientists themselves who are least able to talk about Scientific Ignorance.....

DOES SCIENCE KNOW ITS OWN UNCERTAINTIES... ??

“[AEBC]: Do you think people are *reasonable* to have concerns about possible ‘unknown unknowns’ where GM plants are concerned?

[ACRE Chair]: *Which* unknowns?

[AEBC]: That’s precisely the point. They aren’t possible to specify in advance. Possibly they could be surprises arising from unforeseen synergistic effects, or from unanticipated social interventions. All people have to go on is analogous experience with other technologies....

[ACRE]: I’m afraid it’s impossible for me to respond unless you can give me a clear indication of the unknowns you are speaking about.

[AEBC]: In that case don’t you think you should add health warnings to the advice you’re giving ministers, indicating that there may be ‘unknown unknowns’ which you can’t address?

[ACRE]: No, as scientists, we have to be specific. We can’t proceed on the basis of imaginings from some fevered brow....”

[AEBC public meeting, London, 2001]

Even experienced public scientists like the Chair of UK ACRE (this one was a terrestrial ecologist) *have no language* for speaking about scientific ignorance, or inability to predict (and thus control). This very culture is shaped by the legal terms of reference for such advisory science, which is prohibited from refusing an application for environmental release on the grounds that there are likely to be unpredicted, thus by-definition unspecifiable, effects on the environment or human health. Effects, and causes, have to be precisely specified and justificatory evidenced given. Notice also, the burden of proof is on the environment, not on the commercial beneficiaries.

Many examples (eg, EEA *Late Lessons*., vols I and II, 2002, 2013) have occurred where major environmental and health harms have been inflicted from human products previously risk-assessed as safe and approved for social use, but where science was simply ignorant of even the pertinent *question(s)* the RA should have asked. CFCs and stratospheric ozone depletion is one such major example. Scientific guru of Gaia declared in 1979 that “there is no conceivable harm which can result from the release of CFCs into the global atmosphere”. Six years later Farman et al published their *Nature* paper on the ozone hole and CFCs as cause, previously unknown mechanisms.

..... >30,000 melanoma deaths

Why does scientific ignorance generate public trust concerns?

- Ignorance, usually denied, as with the ACRE chair, means unpredictability = surprises
- Normal publics appreciate this, from everyday life situations
- So they ask Qs like? “Where is their plan-B? Do they *really* think they don’t need one?” (None is usually apparent). “And, when they happen, who will be in charge of responses on our behalf? – & can we trust them to act properly?”
- The trustworthiness public question is said to be a soft-headed touchy-feely emotional concern. But it arises rationally from the reality of unacknowledged scientific ignorance underlying RA science. Ignorance is itself not always grounds for criticism. That – and consequent mistrust - comes from its normal *denial* by scientific and policy ‘authorities’.
- This problem has never in my knowledge been aired in relation to EFSA’s science. Yet EFSA’s problems of public mistrust are serious, and central - and not only for EFSA but for EU policy institutions more generally

A specifically EU Dimension of Science Playing an Unacknowledged, thus Dishonest, Political Role

- An unstated but powerful RAP choice for EFSA RA is for EU-wide standardisation over real local variation, eg of multiple receiving environments (as in 2001/18) - Realism, and scope, thus devalued. Especially for Env RA, this is a key failing. Alternative choices can be made!
- David Byrne, EC Commissioner, inaugural EFSA MB mtg, 2002: “[EFSA’s] reputation for independence and excellence in scientific matters appertaining to food will put an end to competition in such matters among national authorities in the Member States” ie, it will reinforce **political** unity through **scientific** unity – an informal ‘policy’ agenda dressed in scientific language and organisation.
- After highly polarised, unresolved conflicts between several M-Ss and EC over EFSA GM approvals refused by M-Ss, in 2009 EU Council of Ministers asked EC for new Directive to allow M-S divergence (“free-for-all”) from any EC-EFSA GM approval. EC proposals early 2010 attempted to prohibit use of (anti-EFSA) scientific grounds for justifying any such M-S legal prohibition. EP (advised inter alia by ENSSER!) refused this illegitimate political orchestration of EU science, and amended final Directive (2015) to remove this.
- The EC was attempting to prohibit political fragmentation of EU (over GM) by *politically* preventing genuine scientific conflict btw MSs, and btw MSs & EC/EFSA, by legally allowing only *non-scientific* (non-EFSA) grounds for MS refusal. Thus it attempted to use scientific authority and tacit myths of science as unified and universal, as a political-cultural mechanism for European unity in face of mounting GM disintegration, and EFSA-MS confrontations through EU Courts. Scientism at this level as well as EFSA’s scientism in promotion of corporate GM agenda (WEF, global food chain control as business model). Recall EC Commissioner Byrne on EFSA’s role for EU (above); also Levidov and Carr, “Europeanising Expert Advice..”, 2007

EC itself was schizophrenic on what counts as “good science” – standardisation (unity), or realism (next slides..)

HIDDEN UNCERTAINTIES

**What the European
Commission doesn't want us
to know about the risks of
GMOs**



GREENPEACE

April 2006

EC to WTO, 2005 (in US 'moratorium' complaint):

“It is not scientifically reasonable to simply translate and extrapolate the limited risk assessment results on the toxicity of [GM] Bt maize to human and non-target organisms from USA, Australia or some other non-European countries because the

- regional growing environments;
- scales of farm fields;
- crop management practices;
- local/regional target and non-target species considered most important in the agri-ecosystem;
- interactions between cultivated crops; and surrounding biodiversity;

each could differ from published non-European studies, *and could*

differ substantially between regions and countries within the EC”

EC, confidential submission to US WTO Disputes Panel

Starkly opposite to EC stance in EFSA RA science, from which all this *less reductionist, more realist, and greater scope* RA was deleted. Why?

“As the Commission’s evidence to the WTO disputes panel shows, there is the potential for serious and irreversible harm from the use of GMOs, considerable uncertainty exists and gaps in knowledge are extensive. Normally the Commission conceals the extent of this from the public and member states when it accepts the advice of EFSA. In giving the biotechnology industry, rather than the environment, the benefit of the doubt, the Commission is failing to implement the precautionary principle as required in law. **The Commission must acknowledge that under a precautionary approach to environmental protection, bans or restrictions on GM crops are legitimate. It must also prioritise environmental protection, not the biotech industry, in its interpretation of the implications of uncertainties and gaps in knowledge”** FoEE, GPE, *Hidden Uncertainties*, 2006

The Precautionary Principle and EFSA RA

PP originally introduced by German government in 1970s, for North Sea marine chemical pollution policy (“Vorsorgeprinzip”). OSPAR Convention resulted

The iconic definition:

“Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation”

Rio Earth Summit Declaration, 1992

*“The precautionary principle, which is essentially used by decision-makers in the management of risk, should not be confused with **the element of caution that scientists apply in their assessment of scientific data.**”* (EC 2000, my emphasis)

(<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52000DC0001>)

Thus the PP is described in formal legal terms by the EC as a science-guided *policy* (RM) measure, and *not as a scientific risk assessment measure*. Thus RA knowledge itself is exempted from scrutiny with respect to its own detailed framing questions, protection-goals, end-points, definitions of harm, comparators, practical epistemic criteria, and interpretive judgements. In this way, risk assessment science is supposedly ‘protected’ from any imagined policy or other normative influence. *Yet it is riddled with such tacit influences, which are left unaccountable by the EU’s covert framing processes and choices*

This EU statement (above) is thus in practice a normative declaration of (a desired) ‘reality’. As a description of EU EFSA science it is plainly false.

The EC Treaty, incorporating provisions already introduced by the Maastricht Treaty of 1992, and more specifically Article 174 thereof, states:

— "2. Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay ..."

EC 2000, Communication on Precautionary Principle (continued)

"Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent."

(Grounds 63).

Article 130r(2) provides that "the policy is to aim at a high level of protection and is to be based in particular on the principles that **preventive action should be taken** ..." (Grounds 64).

Order of 30 June 1999 (Case T-70/99), President of the Court of First Instance: This judgement contains an explicit reference to the precautionary principle and affirms that **"requirements linked to the protection of public health should undoubtedly be given greater weight than economic considerations."**

The EU 2000 *Precautionary Principle* Communication gives grounds for regulatory intervention, for situations:

“where preliminary objective scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen for the [European] Community”

Moreover, echoing the US 1983 Red Book philosophy,

“The precautionary principle should be considered within a structured approach to the analysis of risk which comprises three elements: risk assessment, risk management, risk communication. The precautionary principle is particularly relevant to the management of risk.”

European Environment Agency and the Precautionary Principle: 2002 - 12 late lessons

Original 'Vorsorgeprinzip' of 1970s included a principle of prevention. Applied in 1980s Oslo-Paris Convention, for marine pollution, but now 'gone AWOL'...

David Gee initiated the EEA *Late Lessons from Early Warnings* project in 1999 – gathering case-studies from 1896-2000, where harm was not prevented as early warnings were ignored or rejected. 14 cases vol I (2002); 20 vol II (2013), plus updates on some vol I cases.

EEA *Late Lessons* vol II also made the point that PP properly conducted is not, as incorrectly claimed, anti-innovation, nor anti-science. It is only against innovation which causes undue harm and (often) unfulfilled promises of benefit, and does not meet genuine priority social needs. Well done, it reorients and invigorates innovation

This also refutes the political claims of "The Innovation Principle", whose definition effectively limits "innovation" only to that of certain global corporations whose innovation and R&D visions reflect their own commercial monopoly ambitions, and are problematic with respect to sustainability and equity – and antithetical to good, diverse and open scientific R&D

EEA, 2002, Twelve Late Lessons, on PP

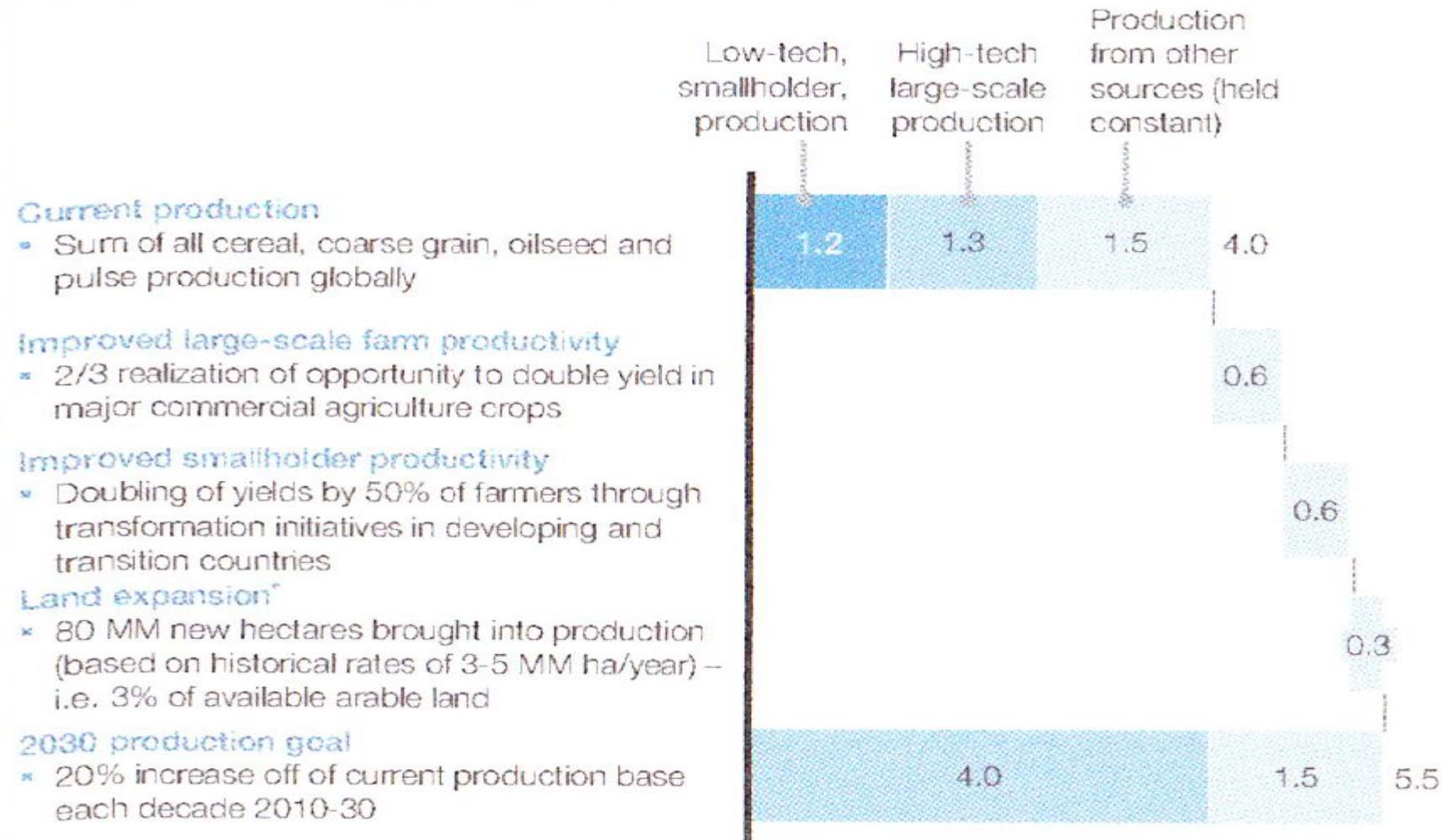
(some of these intersect, or follow-on, with others)

- Respond to ignorance as well as uncertainty;
- Research and monitor for early warnings;
- Search out and address 'blind spots' in scientific knowledge;
- Guard against interdisciplinary obstacles to learning (multiple scientific inputs essential, normally excessively limited);
- Ensure that real world conditions are fully accounted for in appraisal;
- Use relevant 'lay' knowledge as well as specialist expertise;
- Systematically scrutinise the claimed pros and cons (risks & promised benefits);
- Always evaluate the alternatives alongside the option under scrutiny;
- Take account of wider social interests and values;
- Maintain regulatory independence;
- Watch out for institutional obstacles;
- Avoid paralysis by analysis.

ALL THIS *INCLUDES*, BUT GOES BEYOND, THOROUGH RA & SCIENCE ALONE

Given current projections, it is feasible to achieve 20% production improvement each decade until 2030

Billions of mt of production



The preceding figure, taken from the McKinsey report to the Davos *World Economic Forum* 2012, shows the imagined 'progression' from 2010 (top), to 2030 (bottom) of aggregate global food (cereals and pulses) production, broken down into "low-tech smallholder" and "hi-tech large-scale" production (plus a notionally constant, "other" category).

Notice they envisage that by 2030, all small farmers, globally, will have disappeared! Despite the monumental importance, and huge contentiousness, of this claim, the report does not even discuss this.

Is this a *prediction*? Or is it a *normative imposition* ?
- recall the funders of this report.....(next slide)

McKinsey WEF *“New Vision for Agriculture”* report, 2012: the “stakeholders” (funders):

- “The New Vision for Agriculture initiative is led by 26 global Partner companies that span the full food value chain and beyond, including: AgCo, Archer Daniels Midland, BASF, Bayer CropScience, Bunge, The Coca-Cola Company, Diageo, DuPont, General Mills, Heineken, Kraft Foods, Metro, Monsanto Company, Maersk, Mosaic, Nestlé, PepsiCo, Rabobank International, SABMiller, Swiss Re, Syngenta, Teck Resources, Unilever, Vodafone, Wal-Mart Stores and Yara International. Each of these companies has contributed tremendous leadership and technical expertise...” (Archer Daniels Midland and Bunge are two of the global giants, with Cargill, of grain-trading)

Thank You !