

The challenge of science-based decision making

Science is a key human activity, responsible for producing knowledge that has vastly benefitted our modern lives. As such, the process of investigation, publication and utilisation of this knowledge is essential. Industry has benefitted greatly from such scientific endeavours; from an innovation stand point as well as from a regulatory compliance point of view, proving that products are safe and not detrimental to the environment.

Regulators also rely on such science when drafting more technical legal texts. It should therefore be realised that science may become vulnerable during its transition from peer-reviewed publication into science-based legislation. As the vulnerabilities in the science-to-decision-making impact the Chlor-alkali industry as strongly as any other chemical industry sector, this document highlights the different steps in the process and provides some examples that detail its complexity.

As a foundation to the process, publication pressured, poor studies with outspoken, but not necessarily accurate results, may be submitted to peer-reviewed journals. Whereas the peer review process should filter out such poor studies, it is sadly noted that this does not always happen. The outspoken results may subsequently be 'cherry-picked' into review articles, which are typically selected by scientific committees as background information to issue an opinion to legislative bodies. Such governmental groups are highly exposed to popular opinion, which in turn are influenced by tabloid/ social media 'scare-mongering', and may also be lobbied by different parties with diverging interests. It is of great importance to industry that the different steps of the science-to-decision-making process are monitored by impartial, scientifically literate persons in order that those data produced are correctly interpreted, wisely used and continue to be of benefit to all.

Why is science essential?

As the key common ground for industry, regulators and academia, science is the foundation of our modern lifestyles. As a result, significant expenditure is made on it every year.

Alongside developmental expenditure, some of this money is allocated to studies that have increased the knowledge base on chemicals and how they behave in relevant ecosystems/ the human body. Given the importance of protecting human health and the environment, reflected in the data requirements of many chemical regulations, this has always been deemed to be money well spent.

It should be emphasised, however, that it is not only studies performed by industry that play a key role in decision making. These studies are often complemented by experiments conducted by the wider research/ academic communities. These are usually taken on board as additional, objective information packages that help national and international scientific committees to interpret existing information. Subsequently these committees inform legislators as to the current state-of-the-art. If requested, they also advise on those legislative measures to be taken.

The science-to-decision-making matrix

The process of taking into account a scientific publication in a piece of European legislation is described in Figure 1 and involves the following steps:

Positive influence

- ❖ High political level: avoiding horse-trading
- ❖ Involving technical experts
- ❖ Performance of reality checks
- ❖ Avoiding too much political influences
- ❖ Constituting balanced and knowledgeable expert team(s)

- ❖ Ensuring good review system
- ❖ Avoiding concerned parties (friends or opponents)

- ❖ Good scientific practice
- ❖ Decreased publication pressure
- ❖ Encouraging 'negative result' publishing

- ❖ Ensuring a good review system
- ❖ Avoiding concerned parties (friends or opponents)

- ❖ Good epidemiological practice
- ❖ Good scientific practice
- ❖ Decreased publication pressure

Level of decision-making process

Legal measures (legislation, guidelines, ...)
(Inter-)National 'experts', politicians

Interpretation of published data/reviews for decision making
(Inter-)National Scientific Committees, appointed scientists, ...

Publication of reviews & meta-analyses
Specific editors & reviewers

Reviews and meta-analyses
University Depts, Scientific Institutes, consultants, ...

Publication of fundamental research
Specific editors & reviewers

Fundamental research, incl. epidemiological studies
University Depts, research centres, industry (e.g. pharma companies), ...

Negative influence

- ❖ Inadequate impact assessment
- ❖ Insufficient technical knowledge
- ❖ Unrealistic expectations, political agenda

- ❖ Insufficient scientific knowledge on the subject
- ❖ Incomplete data sets
- ❖ Precautionary principle-driven analyses

- ❖ No sound review performed
- ❖ Blind trust in 'known' authors or biased view
- ❖ Insufficiently competent reviewers

- ❖ Bad practice, e.g. cherry-picking
- ❖ 'Strong-result-oriented' research, e.g. only including positive results

- ❖ No sound review performed
- ❖ Blind trust in 'known' authors or biased view
- ❖ Insufficiently competent reviewers

- ❖ 'Poor' science
- ❖ Fraud (Publication pressure)
- ❖ Decreased funding

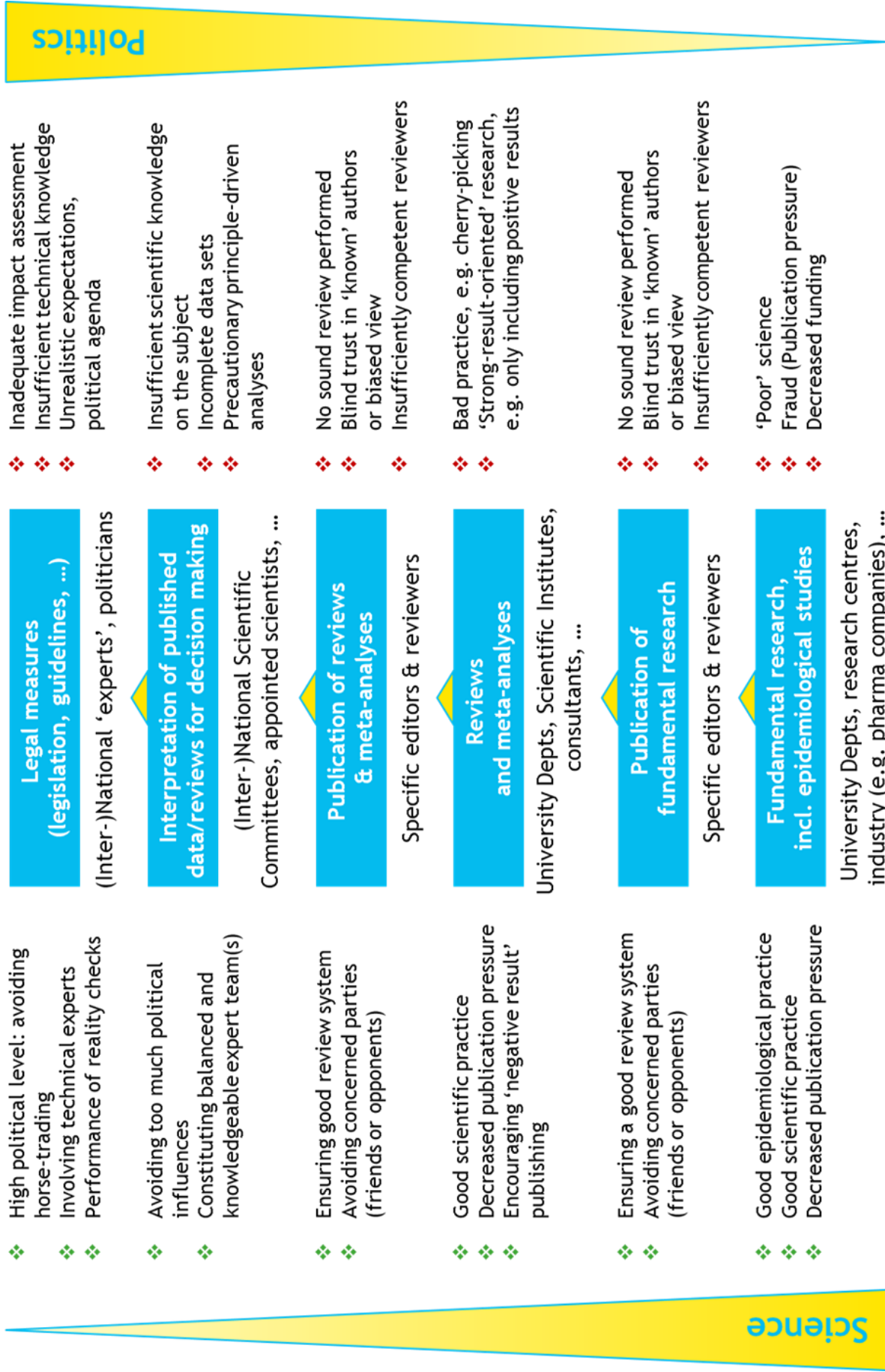


Figure 1. The science-to-decision-making matrix

1) Fundamental research

Universities and research centres are presumed to perform high-quality studies under good laboratory practices that respect any required norms (e.g. ISO). Nevertheless, there has been increasing publication pressure and reduced funding of fundamental research over the past 20 years, which has led to some unfortunate cases of the premature publication of results or even to fraud. It is up to the academic world to tackle this issue and fortunately many initiatives have already been set up in this area.

2) The publication process

Peer-reviewed journals work with a set of trusted reviewers who perform their task to the best of their knowledge. In highly specialised fields, however, reviewers may work in the same area (and on the same topic) as the authors. It is therefore possible that a reviewer might deliberately delay publication or give negative advice on a paper because it contradicts their own findings. On the other hand, if the reviewers do not work in the same field, they may not be able to detect any inconsistencies in the results or any inaccurate/premature conclusions. This problem can never be entirely solved and is already tackled by some journals by involving 2 to 3 independent reviewers per submission. Researchers also often encounter problems when trying to publish negative results in peer reviewed journals particularly as even when negative results get published, other researchers appear to have a low tendency to reference them.

3) Reviews and meta-analyses

These compile the published literature on a chosen subject and form the typical introduction section of many PhD theses. The problem with such reviews is that publications may be 'cherry-picked' to fit any hypothesis to be examined by the author(s) in later research. This is exacerbated by the preferential referencing of positive results. Another danger lurks in only reading the abstracts and missing any important nuances described in the discussion. This is a non-intentional misinterpretation of the original authors' results. As is the case for a research publication, a review article needs then to pass peer review, with the known pitfalls described in step 2.

4) Interpretation of science for decision making

In Europe, independent scientific committees are appointed to assist Commission Officers in forming the bridge between science and regulation. These committees, consisting of scientists in relevant fields, are typically asked to provide personal scientific opinions to allow the regulator to draft or adapt a legislative text.

Examples of the matrix in action

It is self-evident that the process described in Figure 1 risks becoming 'less' scientific and more 'political'-based with each incremental ('vertical') movement of the original study.

This document provides two short examples, noted by the chlor-alkali industry, of science-based political decisions that encountered issues at particular levels of the 'science-to-decision-making matrix'. Whilst this does not suggest that the overall European decision making process is merely political, ignoring every scientific fact, it illustrates how each stage of the process is open to vulnerabilities which could have a significant impact on policy or legislation.

The conclusion is that the (re-)instalment of a scientific advisor at European level would significantly improve the overall process and reduce any unfortunate decisions that may cause unnecessary harm to the general public, industry, or both.

Example 1: Chlorinated DBPs and asthma

Over the past 15 years, there have been several papers published that suggest that the disinfection by-products (DBPs) generated during the chlorination of swimming pools were responsible for the rise in childhood asthma in industrialised countries. The publications were mainly issued by one Belgian research group and were brought to the attention of the Minister of Public Health, who considered strengthening the legislation on swimming pools. Before doing that however, the Minister sent an official request to the Belgian Superior Health Council to thoroughly review these data and to advise on the issue.

The Council's experts concluded that swimming in chlorinated pools remained highly advisable as the advantages of swimming under good hygienic

conditions in monitored pools outweighed the risk of toxicity linked to chlorine and its by-products (Belgian Superior Health Council, 2012). The experts even went further and engaged in formulating some critical notes on how research should proceed in future:

- Whilst retrospective studies on swimmers in chlorinated pools raised questions between exposure and disease, they showed no evidence for any causal relationship.
- Controlled studies are needed to confirm any causal relationship, particularly those that can determine the exposure to chlorine and its by-products.
- There are many confounding factors that should be accounted for (e.g. parental smoking) and considered during controlled studies.
- Historically, pneumologists have advised children with asthma to practice swimming so any historical asthma diagnosis should also be considered.

In this example, the vulnerable ascent of ‘incorrect’ science was halted by a referenced scientific statement of an official scientific expert committee that published a critical, yet independent opinion.

Example 2: Safe threshold for Persistent, Bioaccumulative and Toxic chemicals (PBTs)

This example is situated in the context of REACH and deals with Persistent, Bioaccumulative and Toxic chemicals (PBTs). These substances of very high concern are claimed by some regulatory advice committees to have no safe threshold. REACH guidance sup-

ports this by suggesting that such thresholds cannot be set “with sufficient certainty”. With this, the regulator ignores many scientific papers which demonstrate that a safe threshold can be set for certain PBTs. For example, in fish for human food consumption, safe levels (3 pg/g in seafood) have been set for PCBs, which are classified as PBT.

It is possible to fix safe levels for PBTs as SVHCs under REACH via a thorough quantitative risk assessment. Such assessment is indispensable in conducting subsequent objective ‘analyses of alternatives’ in a transparent, evidence supported and systematic way. Science should therefore form the basis for PBT assessment by international regulators. Unfortunately, as recent European Chemicals Agency (ECHA) PBT guidance seems to suggest, this science is vulnerable to being ignored in favour of making the (albeit complex) work of any regulatory assessment team easier. Independent scientific oversight at the highest European level might therefore be valuable in this discussion.

Conclusion

There is no magic solution that would allow safeguarding scientific integrity at all levels of the matrix depicted in Figure 1. The scientific community must strive for good scientific conduct, objective peer review, publication of negative results and a reduction in publication pressure. At a more political level, knowledgeable, independent technical experts could be involved in each step of the process. The global oversight of a European scientific advisor is most strongly advocated to ensure a transparent, harmonised approach to science-based decision making.

This Focus on Chlorine Science (FOCS) is part of a series of leaflets aiming to clarify and consolidate scientific research in the field of chlorine industry. With the FOCS series, we want to facilitate the knowledge gathering of scientists, regulators and key decision makers. For further Euro Chlor science publications, please consult <http://www.eurochlor.org/communications-corner/science-publications.aspx>

Euro Chlor

Euro Chlor provides a focal point for the chlor-alkali industry’s drive to achieve a sustainable future through economically and environmentally-sound manufacture and use of its products. Based in Brussels, at the heart of the European Union, this business association works with national, European and international authorities to ensure that legislation affecting the industry is workable, efficient and effective. Chlorine and its co-product caustic soda (sodium hydroxide) are two key chemical building blocks that underpin 55% of European chemical industry turnover.

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