From: [redacted] (SANTE)
Sent: 10 May 2016 15:31
To: [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE-EXT)
Cc: [redacted] (SANTE); [redacted] (SANTE)
Subject: BTO meeting Commissioner Andriukaitis with scientists delegation

[redacted]

Please find below a BTO of the meeting held on 3 May 2016 between the Commissioner Andriukaitis and a scientists delegation.

The BTO includes comments of [redacted] and of [redacted].

[redacted]

BTO meeting Commissioner Andriukaitis with scientists delegation
3 May 2016, Brussels

Participants

[redacted]

Commission: V. Andriukaitis, N. Chaze, [redacted]

Summary

The meeting was done on request of the visitors, who made clear they do not represent an interest group (all coming from academy). They believe some ongoing decisions in EU are taken ignoring basic scientific information and they suggested focusing the discussion on endocrine disruptors (EDs) as an example.

The main concepts mentioned by the visitors, all participating actively in the discussion, were:

- Drug/chemical effects on an organism are generally based on interaction with receptors, which require high potency and high concentrations to activate the receptor.
- More evidence-based examples are needed, which require reproducibility of results (decisions should not be taken based on one/few literature studies).
- The "consensus paper on EDs" to be published soon (BfR, 2016) achieved, in their views, some progress, i.e. highlighting that hazard identification is just the first step in risk assessment. Hazard identification always needs to be followed by considerations of potency and exposure in order to properly identify concerns for regulatory action.
- Identification of an *ED* requires evidence of an *adverse effects* which implies *exposure to certain doses*. Most EU legislation is risk-based with few controversial exceptions based on hazard decision making (e.g. PPP). The "consensus paper on EDs" states that considering potency is essential in any risk

assessment. Dose-responses curves are necessary to prove any effects possibly associated to EDs (e.g. reproductive toxicity, obesity), while labelling the substance as “ED” obscures the discussion and does not allow an objective assessment. The “consensus paper on EDs” mentions the "*one chemical substance-one toxicological assessment*", meaning that both synthetic or natural chemicals should be assessed for their endocrine disrupting properties. Natural substances have often high potency and have low margins of exposure.

- Some natural EDs are a daily “additive” to our food: to be consistent they should be regulated as other chemicals identified as EDs (e.g. sugar).
- Taking decisions only based on hazard is not scientific: e.g. epoxiconazole might be banned, although risk assessment demonstrates safe uses exist.
- Evidence shows that EDs are currently associated to few hormonal modalities, but a wider hazard-based interpretation of EDs (based on more hormonal modalities) may soon affect much more substances.
- They suggest applying to decision making an approach as expected from science: asking for solid data, consistent data, and reproducibility of data (experimental confirmation) of the adverse effects.
- Taking decisions on interventions without measuring the benefit of the intervention itself is highly dangerous. The alternative can be less safe than the replaced one.
- The 2012 WHO report on EDs does not assess reproducibility of studies and is based on single/few studies. It draws conclusions in the executive summary which are not supported by the evidence in the full report.
- The role of EFSA and other EU panels/fora/advisory groups should be strengthened and protected from unjustified stakeholders/press attacks which at the end weakens the EU system and any risk assessment system. They complained that nowadays scientists who agree with a scientific statement shared by industry are immediately accused of conflict of interest: this kills any scientific discussion and progress. Some of the visitors mentioned that they left EFSA and EU Scientific Committees because they felt personally attacked.
- They signalled contradictory approaches from public authorities: on one side all public authorities including DG RTD encourage public/private partnership on research and on the other side to be selected as an expert in scientific risk assessment bodies such as EFSA, there is more and more a need to have never worked or be in contact with industry.
- Based on the logic underlying science, proving absolute absence of risk or hazard is scientifically/experimentally impossible (proving the negative is impossible, it can only be shown that there is no evidence that something is unsafe). Science can only set, and where appropriate refine, measurable levels of confidence (margins of exposure) on which policy decisions can be taken.
- It was mentioned that in the last 20 years no "public health chemical issues" came out, which implies that the regulatory system in place works in an acceptable way. Public health issues linked to chemicals were linked to natural chemicals (e.g. contaminants, shellfish toxins).
- They acknowledged that scientists are not always the best fitted ones to efficiently communicate on science but stressed that an initiative should be taken

on their side in a context where there is an increasing and worrying trend of dissemination of biased information.

The Commissioner agreed with them that both scientists and COM should improve their communication to public and stakeholders, adapting the language to non-experts.

Next steps

The Commissioner welcomed the scientists' initiative to publish an editorial in a scientific journal and in the press in the coming weeks. The scientists welcomed the Commissioner’s support and suggested that they will use it in their communication.