

## Notes from Group 2: Engagement of Stakeholders

Call for greater procedural clarity, including time frame and sequence of events.

### Setting mandates to EFSA

Clarity of the mandate is a matter for which DG Sanco is responsible, but it is important for EFSA and other stakeholders. Greater engagement by stakeholders in setting and clarifying the mandates.

Too often mandates from Sanco to EFSA are not always conspicuous, and eg consumer groups often fails to notice the mandates until it is too late to engage. Request that EFSA draws relevant stakeholders to those mandates.

Important to clarify which organisations are deemed to be relevant stakeholders. Maybe also a declaration of interest for stakeholders.

The mandates from DG-SANCO to EFSA should be openly available for deliberation with an opportunity for all relevant stakeholders to comment before they are set by SANCO.

Cf Codex says of **Risk Assessment Policy**:

**“Determination of risk assessment policy should be included as a specific component of risk management. Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties... The mandate given by risk managers to risk assessors should be as clear as possible.”**

### Pre-submission meetings

Industry (and Business Industry NGOs = BINGOs) want clarity about what should be in a submission. In the USA there can be pre-submission discussions with the FDA. (as at the EMA) But for Public Interest NGOs (PINGOs) those meetings were criticised as potentially not transparent. Confidential pre-submission meetings could diminish trust in part because they are not transparent. If pre-submission meetings are to take place they should be open and transparent.

Some post-submission discussions have taken place in open workshops with firms and BINGOs, and they are deemed more acceptable by PINGOs.

The EFSA application desk's role is problematic as between a fire-wall or an office to assist applicants and facilitate approvals.

ISA representative drew attention to the fact that the Applications Desk does not have a role in relation to re-evaluations. Another participants suggested that maybe a separate unit will be required for re-assessments.

The Applications Desk could address technical questions on which kinds of studies and data would be **necessary** but it should play no role in commenting on what would be **sufficient**. The applicant would then not be able to say that it had been reassured that its data set was sufficient in ways that would preclude risk assessors from requesting and/or requiring further studies and data.

The role of the Applications Desk should be transparent, and the rules under which it operates.

Firms and BINGOs want more of a dialogue with EFSA, especially with the Applications Desk, but PINGOs require the scope of those dialogues to be restricted. Maybe an explicit protocol is required for the scope and limits of the Applications Desk.

When firms are asked for further data or studies, the terms of those requests are not always clear, and see a need for improved clarity and the right to request and obtain clarifications. The exchanges should moreover be on the record.

Some counterpart to the protocol on anti-trust rules, which preface meetings of BINGOs, would be desirable to provide clarity.

Firms and BINGOs was no ban on pre-meetings, but acknowledge a case for accountability, eg with a member of the Management Board in attendance, to ensure proper conduct. Maybe also an EFSA Ombudsperson would be desirable.

An EFSA Management Board member drew attention to the resource costs of further meetings and transparency.

IBFN representative strongly urged against one-to-one meetings between applicants and EFSA staff, proposing instead publicly available records of written exchanges, to which other stakeholders can comment would be desirable and beneficial.

Is there a place for stakeholders in deliberations on Self-Tasked topics?

BEUC has from time to time argued to EFSA that the terms of its activities have been framed too narrowly and so would encourage EFSA to be more proactive in self-tasking to complement tasks assigned by DG SANCO.

EMA has protocols that help with 'efficiency' of procedures.

Minutes of Panel sessions could be fuller and less enigmatic.

EFSA procedures could be live-streamed or recorded and made available on-line. Leaving unresolved the problem of multiple languages.

An individual member of EFSA Management Board argued for closed confidential scientific meetings. Asked which stages could or should be open.

Heated difference of opinions of the extent to which expert panels could or should be live-streamed and or recorded and made publicly accessible. Helps scientists and citizens understand how decisions are reached.

Proper care to be taken to ensure that industry commissioned studies are recognised as an effective form of indirect engagement and should be subject to particularly careful scrutiny.