BIVDA Response to UK Reach ISA Statement

1. **Do you think the ISA statement provides a clear explanation on how ISA will be used by the Agency?**
   No

2. **Please briefly explain why you don't think the statement is clear regarding how ISA will be used by the Agency**
   BIVDA members raised the concern that that the HSE's low reaction time needs to be acknowledged.
   This initiative goes in the right direction of addressing the large volume of the registrations, authorization requests they have received since beginning of the year and the survey aligns with the promises of transparency and industry support.
   Merging the scientific opinion forming process into one ISA rather than what feels heavier in EU with the RAC & SEAC opinions is also likely to lead to a reduced cycle time when it comes to REACH authorizations.
   While this is great from a user experience point of view, it also seem to hinder the number of opportunities that a company or a sector will have when advocating their cases.
   By being faster and more efficient at opinion forming, it will also mean they can move on faster to new substances assessments and therefore put heavily regulated industry with complex supply chains such as IVDs at risk. Since substitution, reformulation and then product re-registrations are fairly lengthy and expensive. The IVD industry accounts for a limited amount of SVHCs releases.

3. **Do you think the ISA statement provides a clear explanation on how the Agency will ensure a high degree of transparency when carrying out its functions under UK REACH?**
   No

4. **Please briefly explain why you <u>don't</u> think the the ISA statement provides a clear explanation on how the Agency will ensure a high degree of transparency when carrying out its functions under UK REACH:**
   HSEs ability to recruit sufficient numbers of relevant 'experts' within the UK to act as panel experts. How panel member's independence is safeguarded and capacity for the HSE to conduct these processes efficiently, transparently and at what cost to industry. There is some concern that the ISA is only advisory, and that there is only limited opportunity for Stakeholders to contribute.

5. **Is there anything else related to ISA you would like to include in the statement?**
   More clarity into timescales, resource and capacity and mechanisms to re-dress if information is slower.
   The IVD sector currently has specific derogations / exemptions because of specific needs which are separate to those of the medical device sector.

6. **Please briefly detail what else should be included in the statement in terms of ISA:**
   N/A

7. **If you have any further observations or comments about the ISA statement, please briefly detail these below.**
   N/A

8. **What is the main focus of your business / your employer's business**?
   Trade Association – BIVDA – British In vitro Diagnostics Association

9. **How many people work in your organisation?**
   5
10. **Please provide your job title**:
    Chief Operating Officer
11. **As part of this research HSE may want to contact you again to: a) clarify any responses you provided; and b) to get further information on some of the responses you provided. Are you happy for HSE to re-contact you?**
    YES
12. **Please provide a work e-mail address:**
    helen@bivda.org.uk