



- paper), and potential relevant projects being conducted in academic institutions;
- ii) Based on objective 2.i (above), list all relevant organisations that could serve as potential partners of PERA along with the knowledge, expertise, data, tools and methodologies they would bring either to PERA or for the transition to next generation, systems-based ERA, or both;
  - iii) Based on objective 2.ii (above), identify the needs of the potential partners of PERA in the field of regulatory ERA and for the development and implementation of systems-based approaches for next generation ERA, as well as the needs of PERA customers;
  - iv) Assess differences, commonalities and complementarities of any existing ERA partnerships of relevance to PERA and next generation, systems-based ERA identified above, with PERA;
  - v) Assess the relevance of existing systems-based approaches for ERA identified above, and their adequacy/suitability for next generation, systems-based ERA;
  - vi) Assess the strengths and weaknesses of IT platforms that can support PERA identified above.

**Objective 3: Identifying areas requiring further development (e.g. requiring further scientific development and/or implementation of specific policies)**

- i) Identify relevant working areas additional to what is included in the theme paper necessary to establish a systems-based approach for next generation ERA. Provide a clear justification on their relevance by taking the directions/opportunities into account as outlined in the theme paper (Annex 3);
- ii) Identify any further development that is needed in the working areas identified in the theme paper (i.e. scientific development and/or implementation of specific policies);
- iii) Identify directly relevant discontinuities and knowledge gaps with a clear justification on their relevance to reach the desired vision by 2030 and impact for EFSA;
- iv) Perform an analysis of the relevance and added value of the working areas that are listed in the theme paper as well as those additional ones that have been identified (see objective 3i, above) to achieve EFSA's vision as defined in the theme paper (Annex 3);
- v) Identify processes/methodologies and any other consideration of conducting ERA that can be improved within the frame of regulated products under different EU legislations and/or can benefit from sharing/accessing data, tools and methodologies;
- vi) Identify potential synergies that can add value to ERA methodologies in EU frameworks. These could include, for example, the possibility of combining predictive models and monitoring data in an integrated systems-based approach;