

Note to the EFSA Management Board

Update on the MATRIX project

The global market place needs effective regulation to ensure that products available on the market are safe for consumers, operators and the environment. The regulatory process is coming under increasing scrutiny and in response there is a need for robust and reproducible scientific risk assessments and dissemination of the evidence base. To achieve this, there is a need for secure transmission of an application in an internationally agreed structured format, alignment with the European Interoperability Framework and a single point of information for all actors on the status of an application throughout the authorisation process.

In 2013 a feasibility study identified a number of options for the implementation of the MATRIX project. In 2016, a "partially structured data oriented, flexible, short-term" approach was started via an out-sourcing contract. For a variety of reasons the deliverables from this contract only partially met expectations. However this did provide the opportunity for EFSA to engage with OECD Expert Group on the Electronic Exchange of Pesticide Data (EGEEP) on the further development of OECD Globally Harmonised Submission and Transport Standard (GHSTS). This XML transport standard largely carries administrative data and analysis showed that it is extensible to other regulatory domains besides pesticides.

In parallel with EFSA MATRIX activities, ECHA released IUCLID 6 and a cloud solution for SMEs, a revision of the harmonised templates was published by the OECD and the EC launched an e-submission portal for Novel foods. In 2018, the REFIT exercise of the General Food Law identified a need for more transparency and more reliable, independent studies. With regard to the proposal for a register of studies, linked to a request from the ENVI Committee, EFSA in collaboration with ECHA had already proposed a feasibility study in this area. This proposal is currently being reviewed by the EC for funding.

To adapt to the current regulatory environment, EFSA needs to focus and make significant progress with MATRIX by collaborating with other parties working on regulated dossier management. A review of the project plan led to the definition of two goals. These were presented to the MATRIX stakeholder discussion group.

- Goal 1: Adopt a common standard for Applications and Dossiers;
- Goal 2: Implement a single European Public Service for the Regulated Products Applications.

To achieve Goal 1 the suite of chemical safety products developed by OECD working groups (Harmonised Templates, GHSTS and IUCLID) appear to be the obvious solution in this area. Goal 2 has already been started by SANTE with their development of the Food system Common Authorisation Procedure application. EFSA is working in partnership with SANTE to review the novel food process and develop the system to receive flavouring, enzyme and additive applications.