The use of EPPO codes by the INRAE biosafety information system

INRAE/DSI/SolApp/Dev@Science
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INRAE is France's new National Research Institute for Agriculture, Food and Environment, created on January 1, 2020, It was formed by the merger of INRA, the National Institute for Agricultural Research, and IRSTEA, the National Research Institute of Science and Technology for the Environment and Agriculture.

Staff > 13,000; 14 scientific departments, 18 research centers, 268 units/labs

Scientific activities covered by > 40 sets of regulations

Unknown exact number of « objects » handled or kept in collection

A number of research activities with « objects » that carry various kind of potential risks (for Human, animal, plants, the environment…)

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BioSec project: generalities

- **Users:**
  - members of the Biological Security team
  - INRAE units concerned with biological safety (DU, PC, staff)
- **Piloting:**
  - Biological Safety and DSI / SolApp team
- **Production :**
  - DSI / SolApp / Dev@Science: 3 internal + 2 external
- **Volumetry:**
  - > 2,500 regulatory texts,> 250,000 regulated objects,> 1,000 entities,
    all INRAE staff involved
- **Planning**
  - first module in the 2021 summer for tests in September
  - total estimated duration of development and test > two years
- **Advancement**
  - collection and analysis of needs, drafting of specifications, mock-up / prototyping

BioSec project: purpose and challenges

- **Help units / laboratories to comply with all regulation associated with scientific activities :**
  - an Information System to keep staff and management informed, to facilitate regulatory processes, to help the implmentation of new scientific activities, to help maintaining regulatory dossiers updated, to keep records of all supporting procedures and documents…

  ↳ *Need to identify objects or groups of objects*

- **Help direction to check and prove compliance, to better imagine consequences and needs associated with potentiel future scientific priorities, to support development of skills :**
  - an information system to better understand and supervise the INRAE ecosystem, to accompany change, to better address the needs of researchers

  ↳ *Need to derive from objects that could be used the regulatory consequences (containment, authorizations…)*

- **Help team scientific regulated activities/ biosafety / biosecurity to better help INRAE management and researchers :**
  - an information system to manage a dynamic risk maping, to provide access to all requested regulatory documentation that are necessary to properly answer requests from our internal clients, to support laboratory internal audits

  ↳ *Need to associate units/labs – objects – regulations*

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The « BioSec » project and EPPO codes

Research with objects that can be living organisms (plants, animals, microbes, viruses…) but also substances (food, additives, drugs…) or parts of human origines (cell lines, tissues…)….

↳*Need for reference sources of information to maintain an updated list of objects (with synonyms, old names, father and children…)*
↳*Need for identification of objects that make possible robust relations with regulations*

- EPPO provides on line access to a reliable, very large, well-organized and up-to-date list of objects of interest for INRAE. The system allows us to synchronise our IS on demand.
- EPPO codes are now used by EU regulation to identify plants pests and plants, that makes interpretation of regulation easier.
- Other sources of information will be used to extend the « objects » database (ICTV for viruses for instance, Anses for animal drugs…).
- Other code sets could be added later (codes from customs for instance).
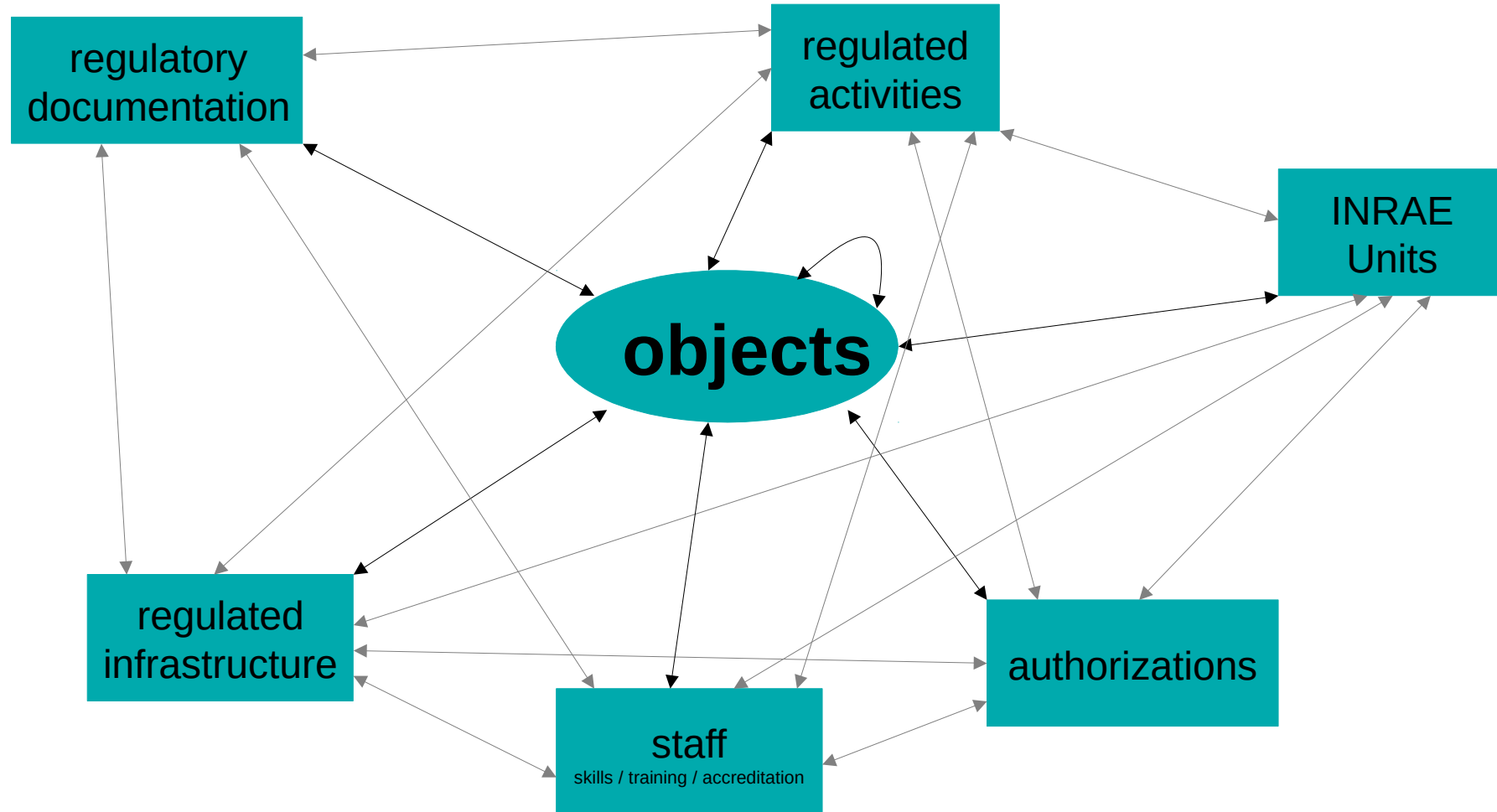
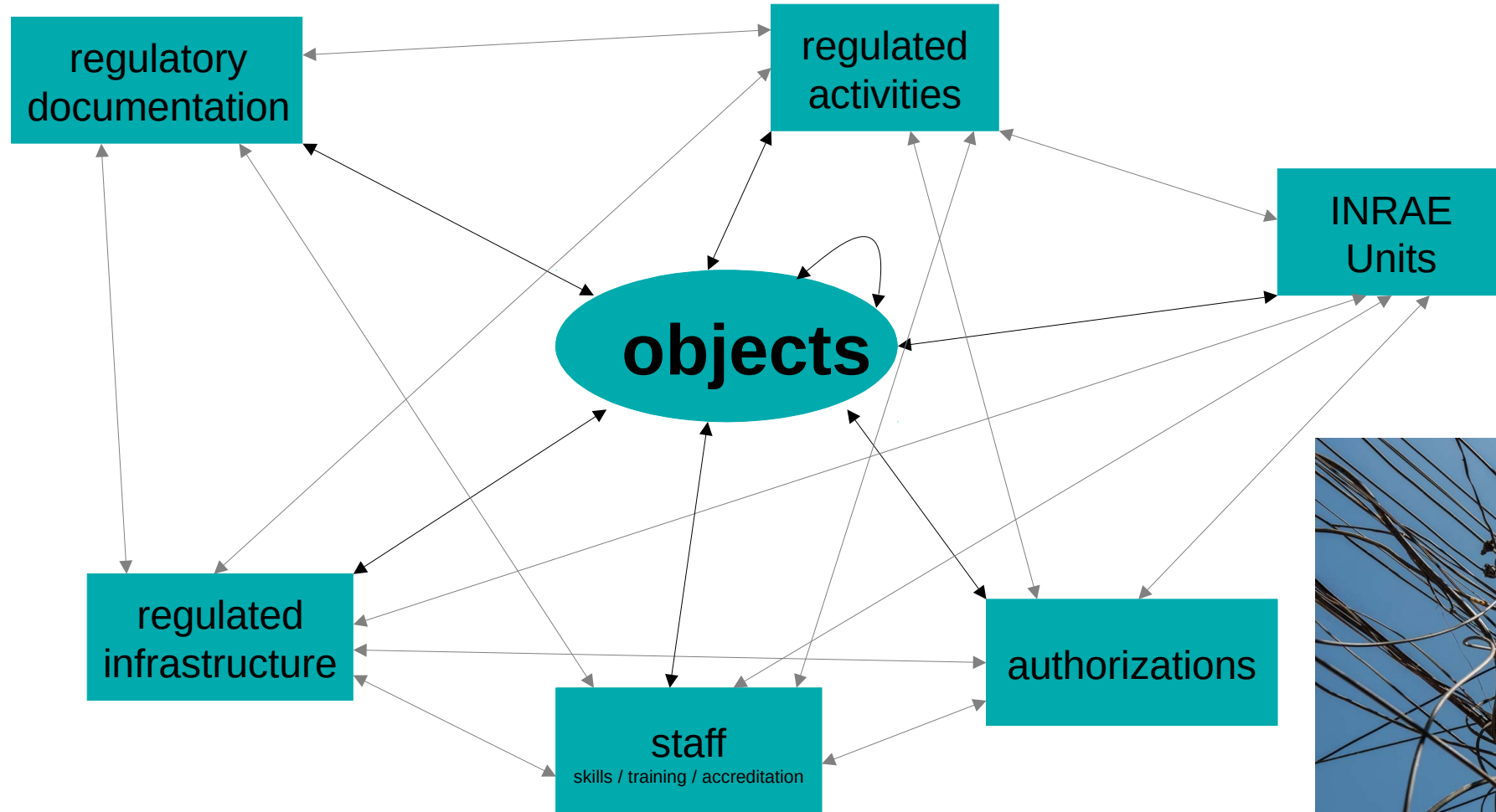**INRAE**

BioSec project: links with other IS
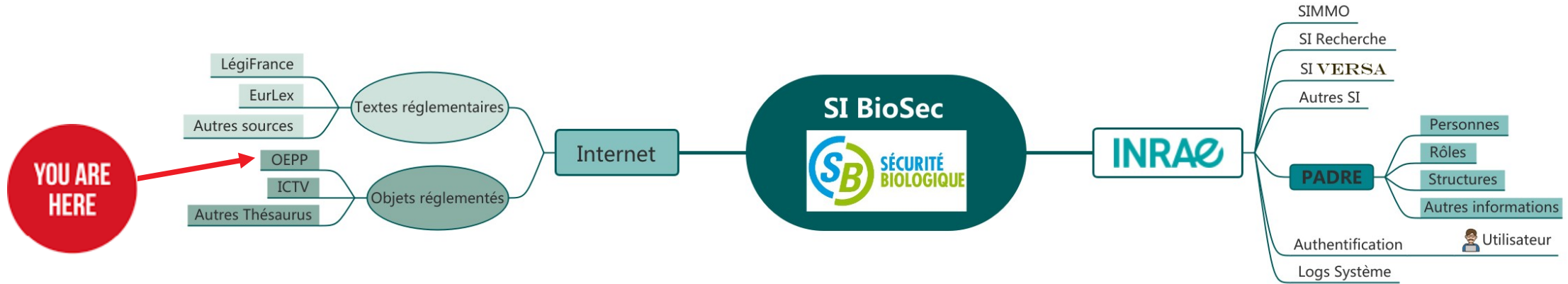
Numerous connections to INRAE and external ISs with different levels of needs and / or services (API query, download of repositories, subscription to updates, etc.)

BioSec project: objects

BioSec project: objects

BioSec project: EPPO objects

Objects are at the center of the BioSec project.

AND
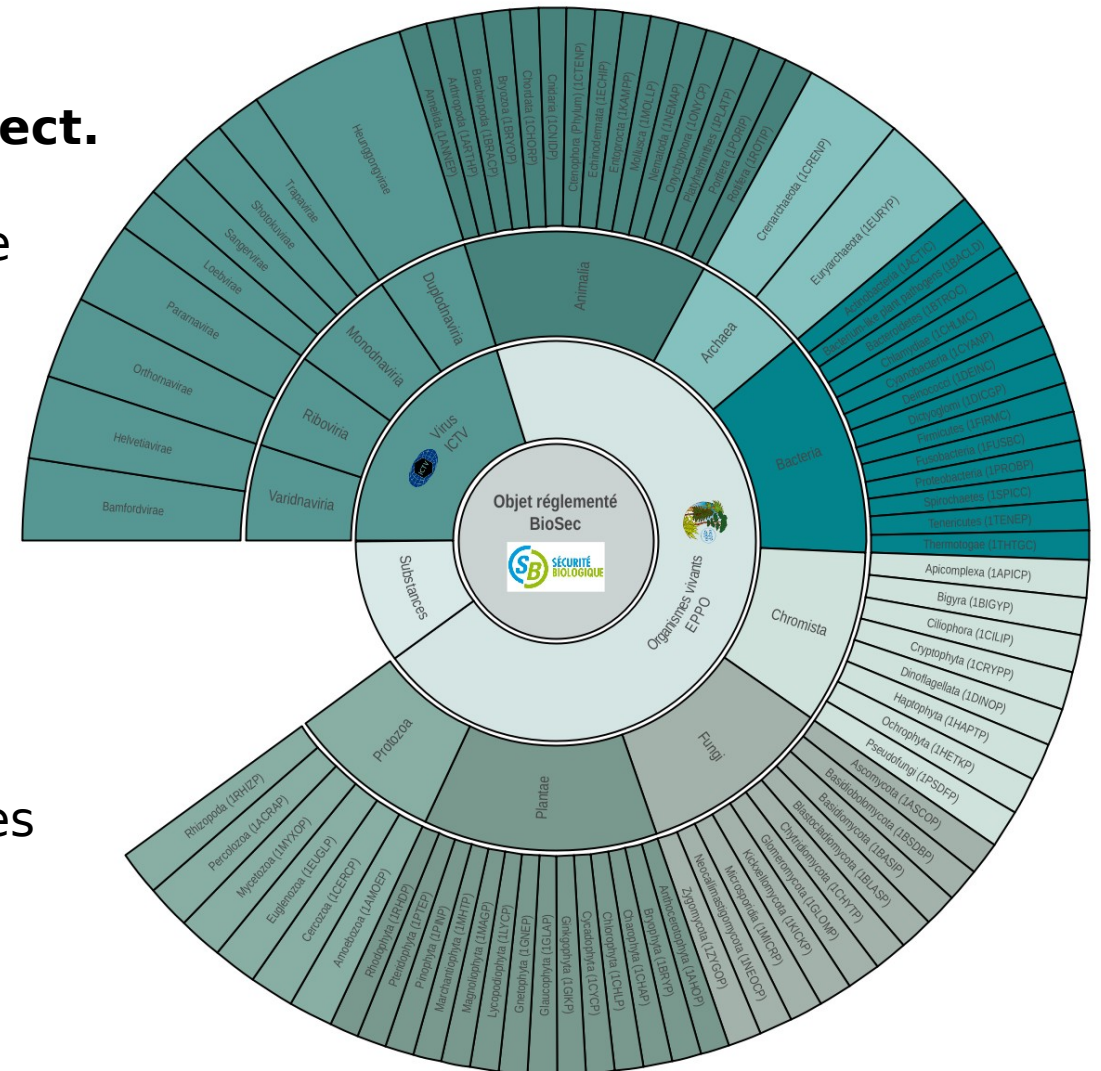
structuring of EPPO objects is at the center of the management of objects of BioSec IS

EPPO database is the first contributor to the BioSec IS « objects database »

ICTV database is the reference for viruses in the BioSec IS « objects database »

BUT

EPPO viruses will be connected to ICTV viruses, the goal is to keep EPPO_Code for legal references

BioSec project: The « objects database »

list of work in progress

- local copy of EPPO database
- transfert of EPPO database into BioSec « objects database » schema (except viruses)
- local copy of ICTV database

- automated update of BioSec « objects database » with adapted EPPO LogShipping method
- transfer of ICTV database into BioSec « objects database » schema

- addition of EPPO viruses into BioSec « objects database » schema
    (into ICTV viruses schema and with preservation of homonyms)
- addition of substances and equipments (when the standards has been chosen)
- addition of customs tariff numbers from the European Custum portal

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BioSec project: Thanks EPPO !

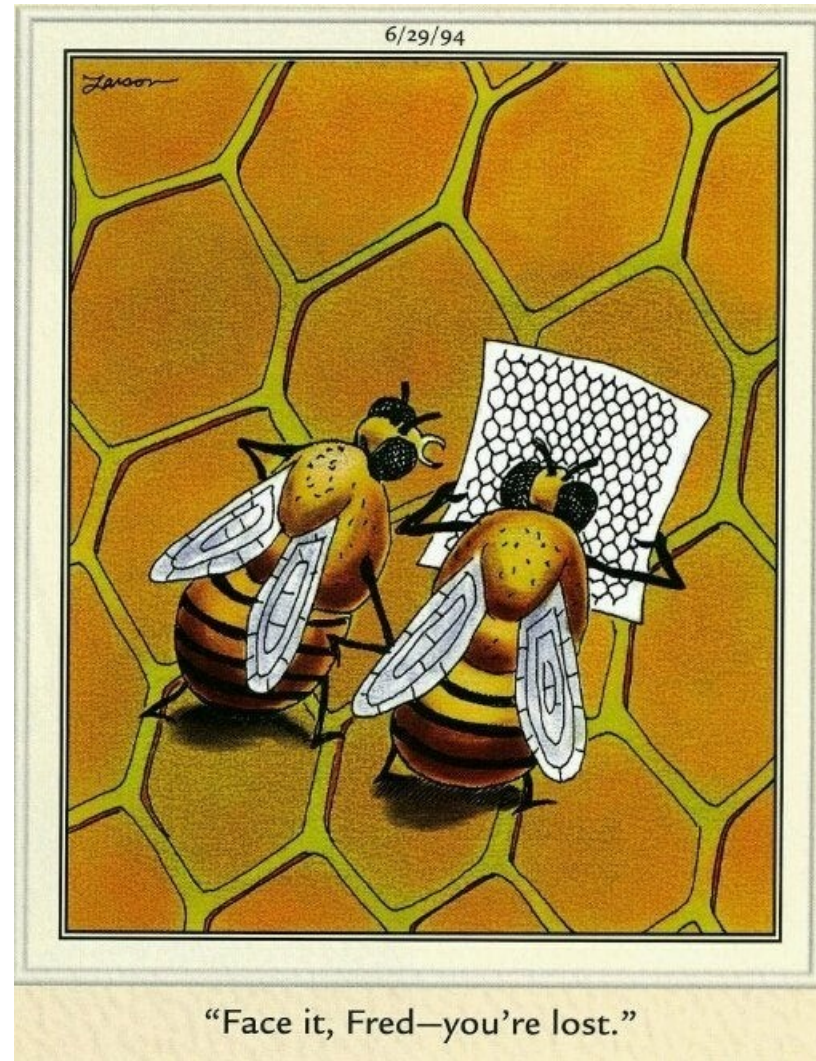**What we like about the EPPO data services :**
- massive SQL download
- LogShipping mechanism
- technical support by email

What we would like :
- a system for sharing synchronization jobs with other databases
  (exemple : ICTV)
- a users group, or forum, or Git, or ...

Questions…

Planches optionnelles...

BioSec project : goal

Build up an up-to-date knowledge base
- regulatory documentation,
- possible regulated activities in the units,
- **objects** held or handled,

  Some regulations target **living organisms** (species, subspecies, genera, classes, orders, etc., therefore different taxonomic levels), **substances** (toxins, narcotic or psychotropic products, food additives, plant extracts …). All these targets ar called **objects**.

  These objects can have "**filiation links**" which must be taken into account (for example, if a regulation targets vertebrates, all species of the "vertebrate" cluster must be de facto concerned).

  They can be **linked to taxonomic levels** (such and such an object is of the species, order, etc.) or **grouped in various ways** ("livestock animals", "model animals", etc.).

  - the authorizations available,
  - existing regulatory infrastructure

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BioSec project: « customer » needs

Build up an up-to-date knowledge base

- regulatory documentation,
  - Facilitate knowledge and monitoring of regulatory documents
    - FR / EU legal texts, official documents relating to the unit or unit agents, ...
  - Analyze documents
    - extraction of relevant data
  - Alert in the event of an update of regulatory documents
  - Facilitate the search in terms of regulatory documents
- possible regulated activities in the units,
  - Know the regulatory obligations concerning scientific activities
    - for biological safety
  - Facilitate the drafting of files
    - declaration, request for authorization or approval with automatic recovery of existing data in the IS for insertion in CERFA / files
  - Facilitate the follow-up of regulatory files
    - where the file is, due dates, alerts, documents from the files, personnel to be declared, monitoring of regulatory powers, etc.
  - Provide access to dynamic and up-to-date dashboards of regulatory files
    - different regulated subjects with various views, deadlines, ... allowing the manager to request if necessary and to anticipate (inspections, ...)

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