



8th Bfr User conference on product notification

Product notification according to article 45
CLP regulation in Belgium



The Belgian poison Centre in a nutshell



Statute

- 📌 Founded in November 1963, first call in February 1964
 - 📌 Royal Foundation of Public utility
 - 📌 List of emergency medical services : access emergency line free of charge
-





Tasks

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- 🗨️ Emergency information service Belgium + GD Luxembourg
 - 🗨️ 24h access by phone (toll free)
13 physicians + 2 pharmacists
 - 🗨️ Appointed body [Art 45 CLP regulation](#)
 - 🗨️ Access to antidotes
 - 🗨️ Toxicovigilance (alert function)
-



Tasks

Public (78%)

- First aid advice
- Triage: reassurance or referral to appropriate medical treatment

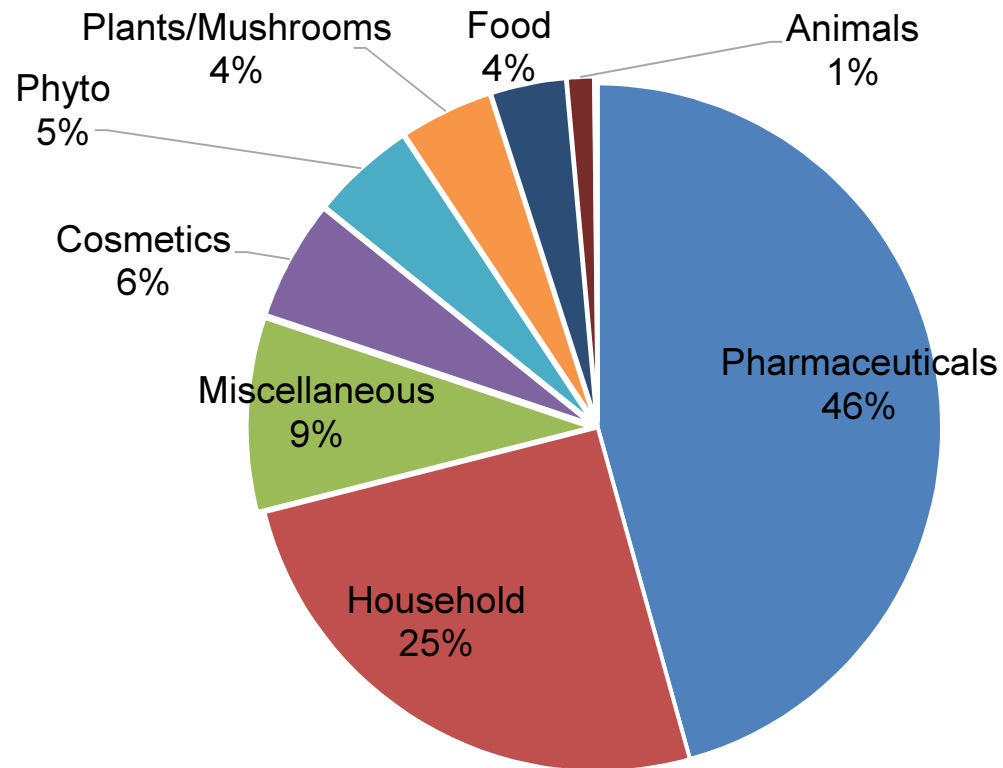
Medical professionals (18%)

- Risk assessment
 - Product properties
 - Symptoms to be expected
 - Specific treatment, analysis
-



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Products involved





Access to product information

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🗨️ Pharmaceuticals

no declaration procedure, compendium available online.
Contact with the industry on a case by case basis

🗨️ Dangerous mixtures :

April 2016: Poison Centre appointed body for art 45 CLP
mandatory declaration of dangerous mixtures (health or
physical hazard)

🗨️ Other mixtures : hazardous for environnement, unclassified: declaration on voluntary basis



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Access to product information

- ❏ Biocides : after authorization by public health authorities, mandatory declaration to the Poison centre by the marketing authorization holder (MAH)
- ❏ Pesticides : data transmission to PC by public health authorities.
After authorization, picture of the label send to PC by MAH
- ❏ Cosmetics: access to CPNP data base



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From 1964 to art 45 of CLP

A brief history



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Pre-regulation period

Pre-legislation period 1964 -1993 :

1964 – 1980: Contact with Belgian Industry : data declaration of confidential data on voluntary basis

Complete composition, paper support, quality check at PC level

1986 -1989 : first EAPCC- industry working group
Harmonization of data to be transmitted to the Poison Centres.

Data set (paper) format and guidelines



Pre- harmonization period Dangerous preparation directive

- May 1993: dangerous preparations directive 88/379/EEC transposed into Belgian law (RD 11/01/1993, OJ 17/05/1993)
 - Art 13: BPC to receive « *the composition of the preparation and all information necessary to perform its tasks* »
 - No technical guidelines, no format : EAPCC data set and guidelines available
 - Information added on SDS or provided in a separate document
 - Industrial products: SDS sufficient if 24/7 contact available
 - 1995 : Increase in data volume, unworkable on paper support
 - Seeking electronic data transfer solution. Several format developped, SGML language, MS access data base....
 - Excel table for data transfer : still in use



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Current system



Current system

PRODUCT DECLARATION

DECLARATION FORM EDF (EXCEL FILE)

FOR EACH PRODUCT :
PDF DOCUMENTS
SDS, COMPOSITION, LABEL

EDF 2.0 DANG: tableau à compléter et à renvoyer avec les fichiers associés à depot@poisoncentre.be

Identification					Documents fournis (Noms des fichiers associés)			
Dénomination(s) commerciale(s)	Code interne à la firme	Usage exclusivement professionnel	Mélange classé comme dangereux sur base du règlement (CE) n° 1272/2008 en raison de ses effets sur la santé ou de ses effets physiques.	Nouvelle déclaration	Type de mélange H.Ménager I.Industriel P.Peinture	Fiche de données de sécurité SDS visée à l'article 31 du règlement REACH	Composition chimique complète du mélange	Étiquette
Obligatoire	Facultatif	(O ou N)	(O ou N)	(O ou N)		Obligatoire	Obligatoire	Obligatoire

+



Transmission by mail (CD/DVD...) or by e-mail



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Current system

 BUBBLES_IN_A_BOX_COMPO.PDF

 BUBBLES_IN_A_BOX_LABEL.PDF

 BUBBLES_IN_A_BOX_SDS.PDF

EDF 2.0 DANG: tableau à compléter et à renvoyer avec les fichiers associés à depot@poisoncentre.be

Identification		Documents fournis (Noms des fichiers associés)						
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Obligatoire	Facultatif	(O ou N)	(O ou N)	(O ou N)		Obligatoire	Obligatoire	Obligatoire
Bubbles in a box;Boîte à bulles; Bubbledoosje		N	O	O	H	BUBBLES_IN_A_BOX_SDS.PDF	BUBBLES_IN_A_BOX_COMPO.PDF	BUBBLES_IN_A_BOX_LABEL.PDF



Conversion of Product-data into the import-format for Seconde

Clipboard :

MOMA BUBBLE FACTORY, 17/11/2017 (Key=57597)

Restart

See list of all Sendings

Create a new Sending

Search a Sending

with RED Nr:

with BLACK Nr:

with

Delete Red Nr

End

Control L2-rule : YES

G:\Pr\Pr_Electronic\PR06.exe (_PRParameters.txt)

Seconde - 9

Situer Adresse Produit Terme Ref. biblio Appel Dose/Sympt 0

Recherche de produits

Créer

produit

Pour K2R, tapez: K]2]R] Avez-vous essayé les 'Jokers': ! ? * Au téléphone: S = F !

Mots à chercher : BULLES BOITE

Chaîne à chercher :

limiter la recherche

Catégorie : toutes

Mode de recherche

tel quel mot phonétique. Ajouter "*" au besoin

Zone cherchée

nom+synonymes famille groupe
 composition nom d'organisme forme solide

OK Annuler Effacer

Seconde - 9

Situer Adresse Produit Terme Ref. biblio Appel Dose/Sympt 0

Résultats de vos recherches

1:1 prod.ménager BULLES BOITE

1. 2017 «BOÎTE À BULLES» (MOMA BUBBLE FACTORY)

Situer Adresse Produit Terme Ref. biblio Appel Dose/Sympt 0

1/1 prod.ménager

2017 BUBBLES IN A BOX (MOMA BUBBLE FACTORY)

Numéro 4066212

Nom BUBBLES IN A BOX
Synonyme BOÎTE À BULLES
BUBBLEDOOSJE

Fabricant MOMA BUBBLE FACTORY (NEDER-OVER-HEEMBEEK, BELGIUM)

Groupe () FICHES PROD. NON VERIFIEES PAR LE CAP 41525

Prép. dangereuse

17/11/2017 E-mail New Fabricant - contact:MOMA BUBBLE FACTORY #13237
[Etiquette] [Fiche de Sécurité] [Fiche Compo]



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Current system Limitations

- 🗨 Unstructured data
- 🗨 Manual intervention by importation
- 🗨 Location of the product in the data base rely on brandname
- 🗨 Long list of results when yearly updates
- 🗨 Manual quality check at random
- 🗨 No search by ingredients, by category of use



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Current system Advantages

- Can be used for every type of mixture (dangerous, unclassified, biocides....)
- Easy to use by medical staff



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Preparing the future



Harmonization period Annex VIII CLP regulation

- 01/06/2015- May 2016: legal gap
no legal obligation of declaration of dangerous mixtures
- R.D 21/04/2016 (O.J 09/05/2016)
Belgian Poison Centre as appointed body for art 45 CLP
 - Dangerous mixtures (health or physical hazard)
48h before commercialization

Complete chemical composition

SDS according to art 31 REACH

Data on the label or copy of the label

All information necessary to perform its tasks

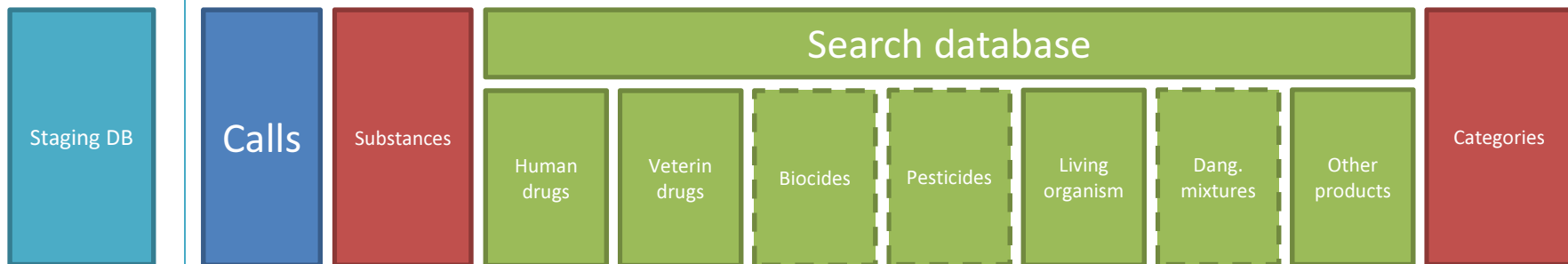


New system



Application Layer

Data Layer



 New system built on Microsoft SQL & Microsoft CRM



Intake

POISONfrancois

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Intake Number I-399

← ↓ ↻ 🗑️ ⚙️

- ▶ Intake
- ▶ Reporters +
- Reporter 1 -
- ▶ Agents +
- Agent 1 -
- ▶ Circumstances
- ▶ Victims +
- Victim 1 -
- Symptoms Treatments Examin
- ▶ Sources / Remarks

Announcements

General

Name Anonymous

Phone / email Language NL FR GE EN Other

Reporter type

Public	Doctors	Other professions
Family	Doctor in training	Dentist
Owner animal	General practitioner	Nurse
Victim	Medical student	Operator (call center)
Other	Occupational physician	Paramedics
	Specialist	Pharmacist
	Doctor unspecified	Poison information specia...

fwd by operator

Reporter location

Agriculture, horticulture	Hospital, clinic Emergency	Mobile Intervention Unit	Public pool
Army	Hospital, clinic Intensive...	Nature, park	Home for the elderly
Callcenter	Hospital, clinic Other	Other	Supermarket / shop
Creche	Hotel, cafe, restaurant	Pharmacy	Unknown
Educational institute	Institute	Practice	
Enterprise, workplace	Labo	Prison	
Home, garden	Means of transport, public...	Psychiatric institute	

Reporter country

Country Belgium Luxembourg Place

Belgium Postalcode

City

Agents

Agent relation

Combination Compounding Chlorine liberation Other combination Drug interaction Combination quantity

Agent 1

Characteristics

Quote Included (comb.) Doubtful

Alert product team Agent Categories

Exact agent name Quantity / Unit Unk...

Categories

Agent Remarks

Ways of exposure

Aspiration Extravasation Nasal Rectal

Exposure location

Agriculture, horticulture Hospital, clinic Emergency Mobile Intervention Unit Public pool

Web Application for fast input of phone calls



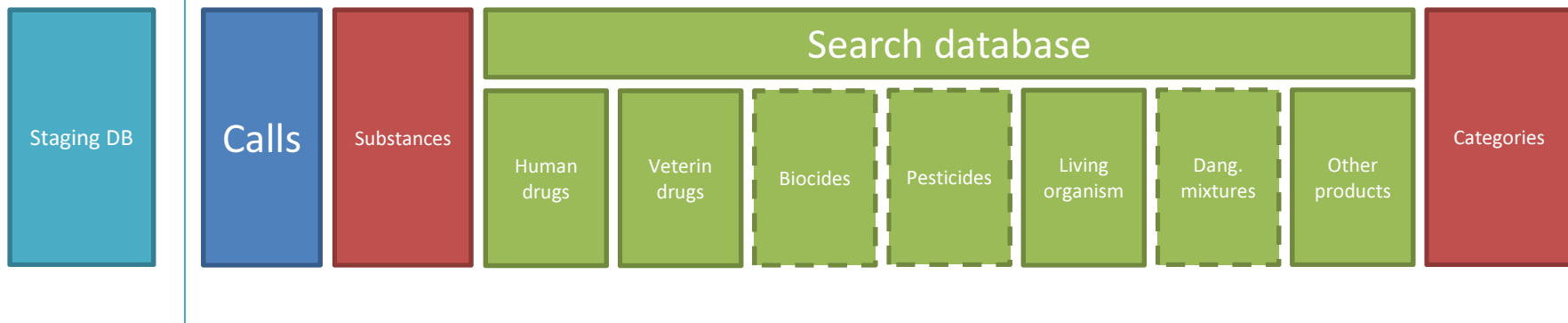
New system

MS CRM

Intake

Application Layer

Data Layer



- Each product family (biocide, human drug,..) receives its own tables based on data schema of provider
- Search database on top



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Product Families

- 🗨️ **Human Drugs : APB**
 - Fixed length text files via FTP
- 🗨️ **Veterinary Drugs : BCFI Vet**
 - XML files (Drupal) via email
- 🗨️ **Pesticides : Ministry of Health**
 - Panama platform (in production in 2018)
 - XML files via FTP
- 🗨️ **Biocides : Ministry of Health**
 - Under development
 - XML files via FTP (?)
- 🗨️ **Dangerous mixtures**
 - XML format
 - Through FTP, web service, (?)



Product Families

Living Organisms

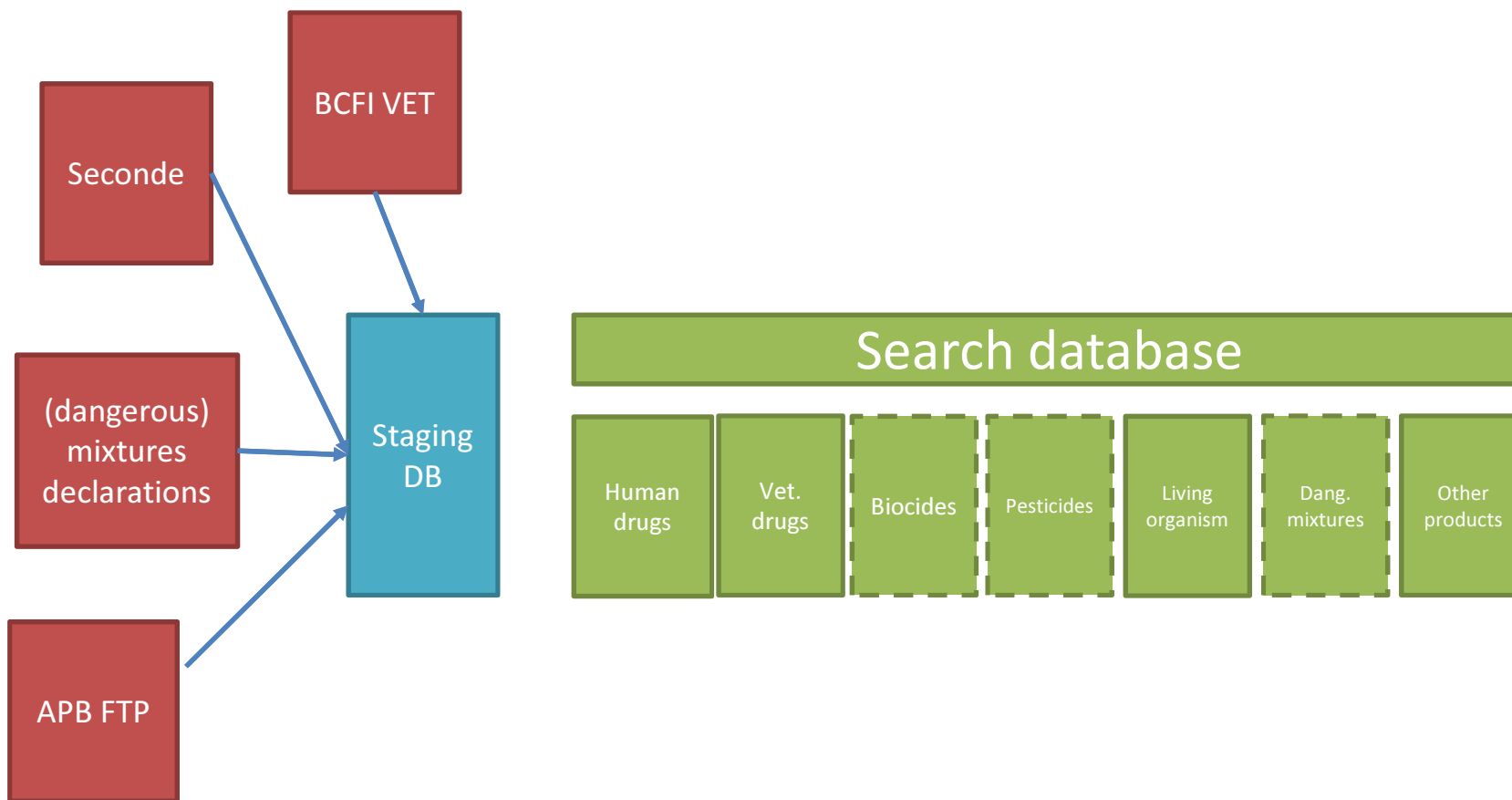
- Data inserted by Poisoncentre itself

Other Products

- Contains special agents such as coins, batteries, lamps,...
- Products found in Seconde will be created here when involved in a call
- Legacy products



New system





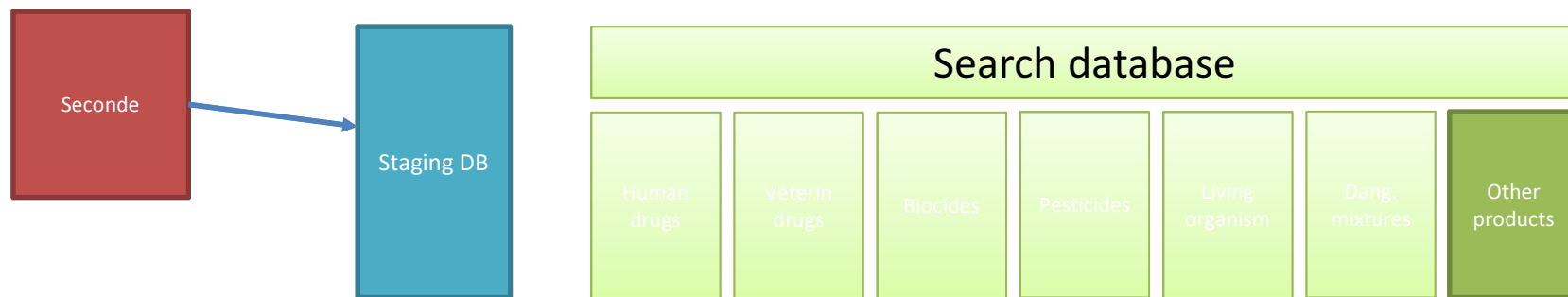
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Products received from industry (before 2020)

- New products are imported in Seconde
- If product in Seconde is needed during call, health professional copies **name of product** and **Seconde ID** in the case. “Alert product team checkbox” is also checked
- Product team creates selected product semi-automatically in “Other Products” DB
 - Links towards documents, Biocide categorisation, etc.. are imported through inhouse written application
- Product team marks in Seconde that product has been imported in CRM
- Doctor can find a product in CRM through the **Seconde ID** if it is already imported in the “Other Products” DB



Transition period





Transition period

- As long as a manufacturer is not ready to supply the XML format, their data will be imported in Seconde and when needed, be transferred to the “Other Products DB”
- Once a manufacturer can supply the XML format, new delivered products will be stored in the new “dangerous mixtures” database.



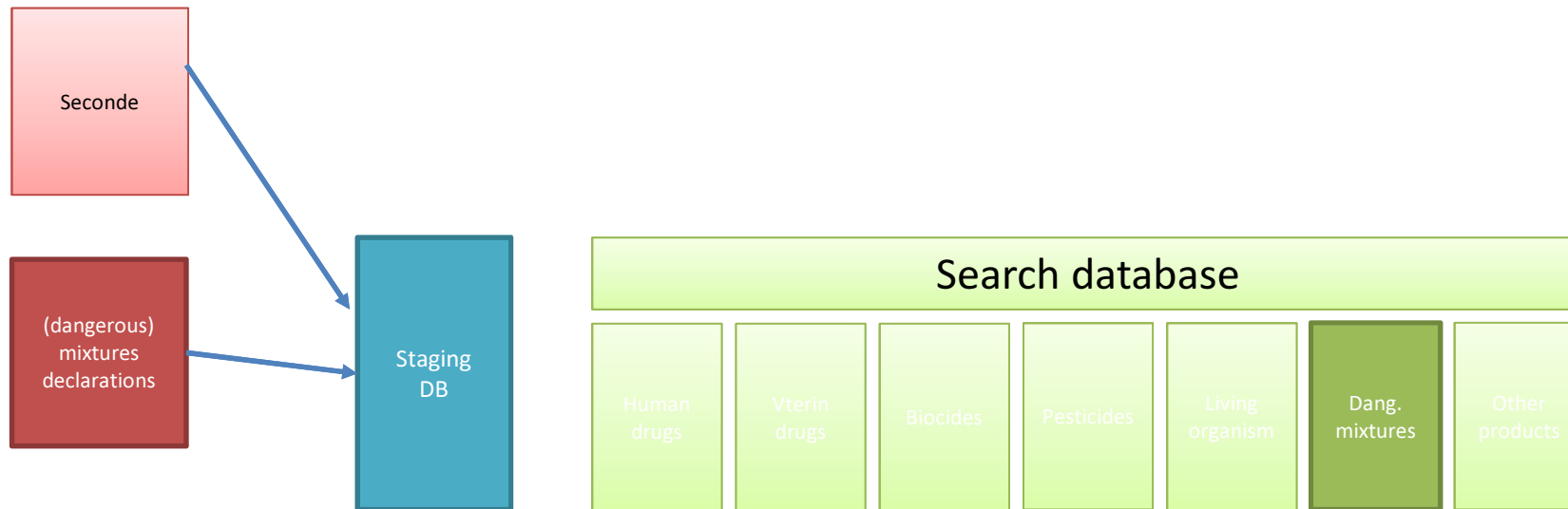
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Dangerous mixtures when portal in place (From 2020)

- A new DB for the dangerous products will be created based on the XML schema of Europe
- Data will be imported through web service, FTP service,...
- Data will be transferred to CRM through the “Staging database ”
- An additional categorization field will be foreseen in CRM that contains a copy of the categorization field filled in by the industry and that can be adapted by the Poison Centre
- The Royal decree will remain into force
- Local submission on XML European format still possible



Final situation





Voluntary submissions

- 📌 Voluntary submissions (unclassified, dangerous environment....)
- 📌 Local submission preferably on XML format



Expectations from harmonization

- 🗨️ UFI: ideal tool for product identification
Need for an information campaign

- 🗨️ Categorisation system:
 - better reporting, comparable data between Poison Centre
 - allow search for comparable formulations when product not found in data base

- 🗨️ Structure of the data: search by ingredient