

Best practices for PCN notifications according to the Poison Centres



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Introduction

Introduction

- Overview of actual problems
 - UFI
 - Product names
 - Substances
- Other problems
 - “Initial notification” vs. “New notification due to change of composition” vs. “Submission Update”
 - Etc...
- The main goal of the presentation is to show the industry how they could ease our work by adapting the way of notifying. We can't oblige the industry in anyway. We have no legal right for it.



| Actual numbers

Actual numbers

- All numbers are until October 31, 2023
- The Belgian Poison Centre is Appointed Body for Belgium and the Grand Duchy of Luxembourg

Actual numbers

Number of dossiers received

682.785 received dossiers

537.212 dossiers for Belgium

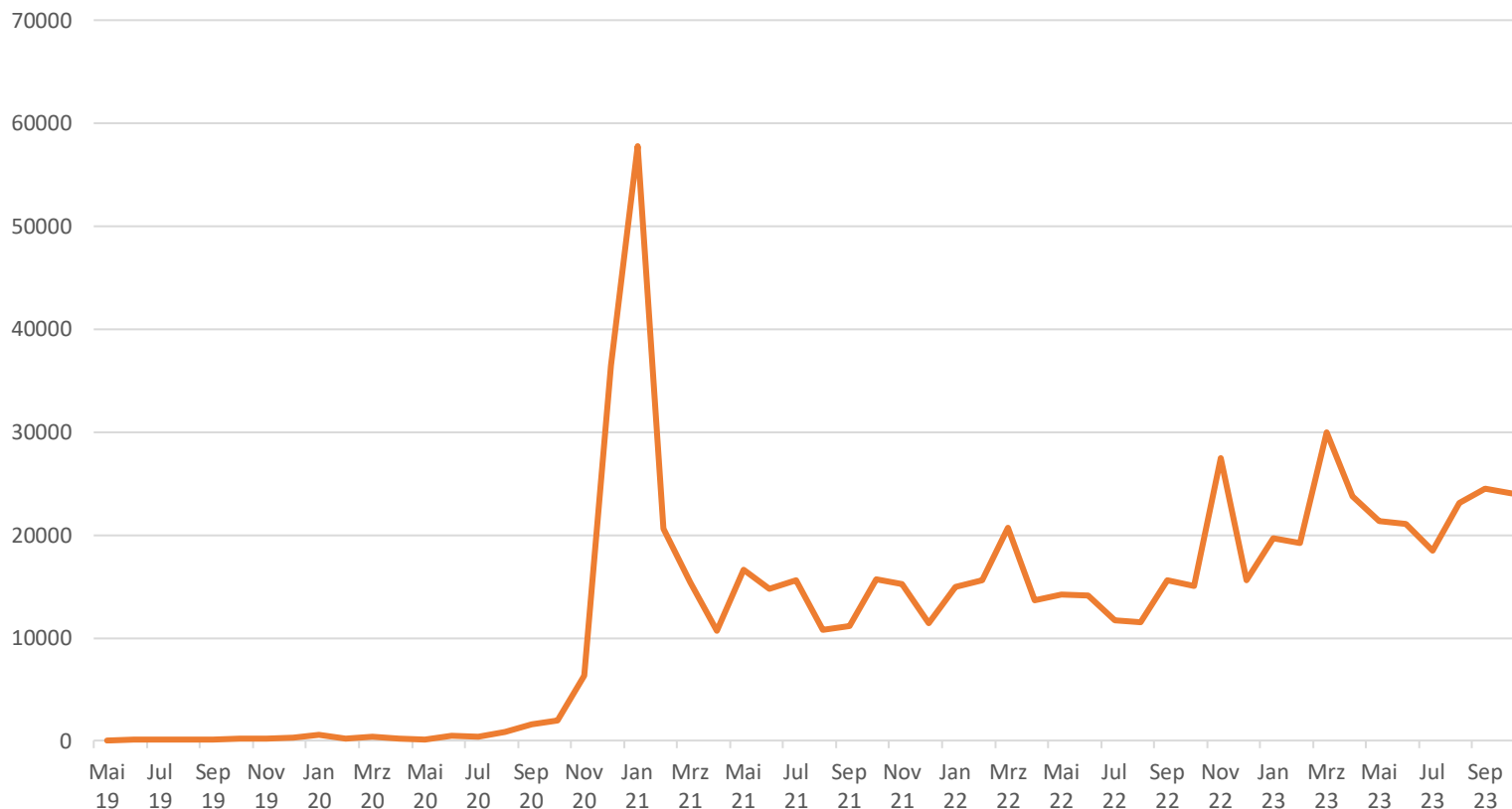
406.449 dossiers for Luxembourg

260.876 dossiers for Belgium and Luxembourg

Actual numbers

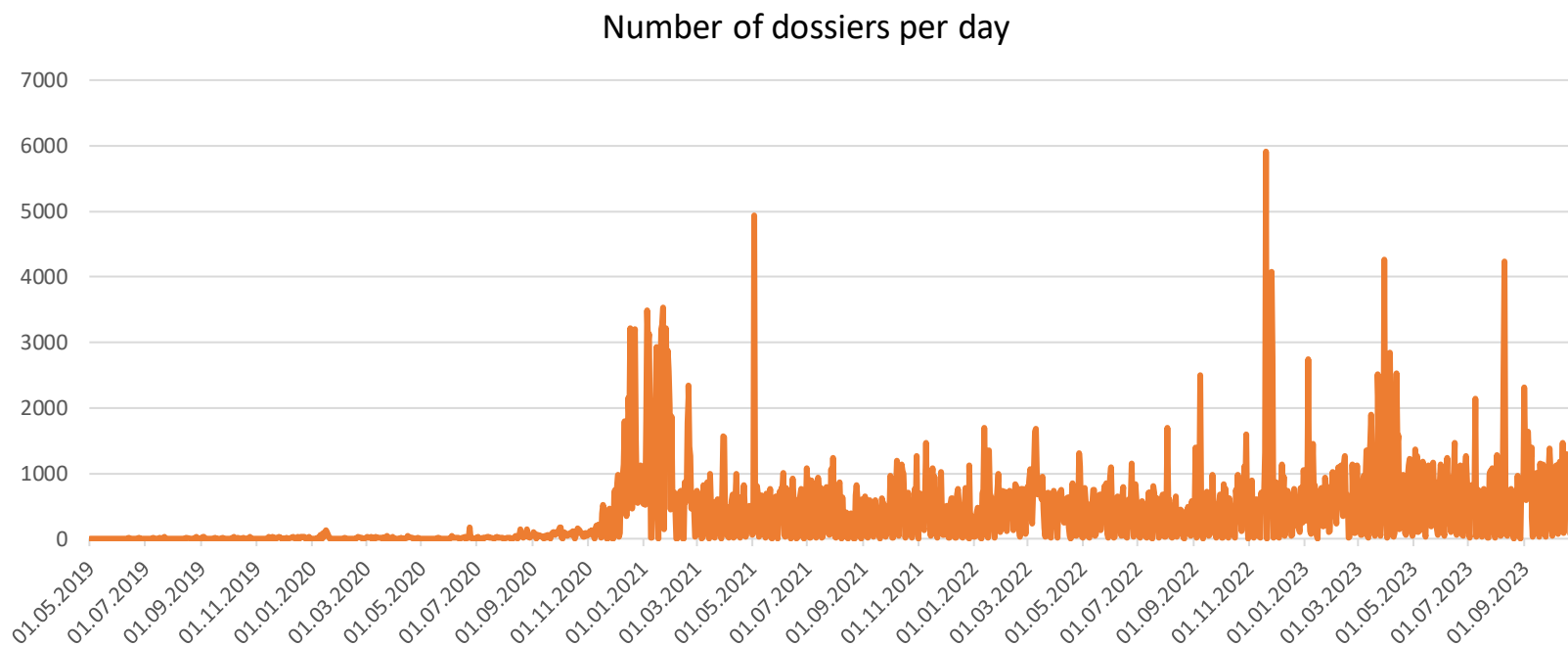
Number of dossiers received per Month

Number of dossiers received per Month



Actual numbers

Number of dossiers received per Day

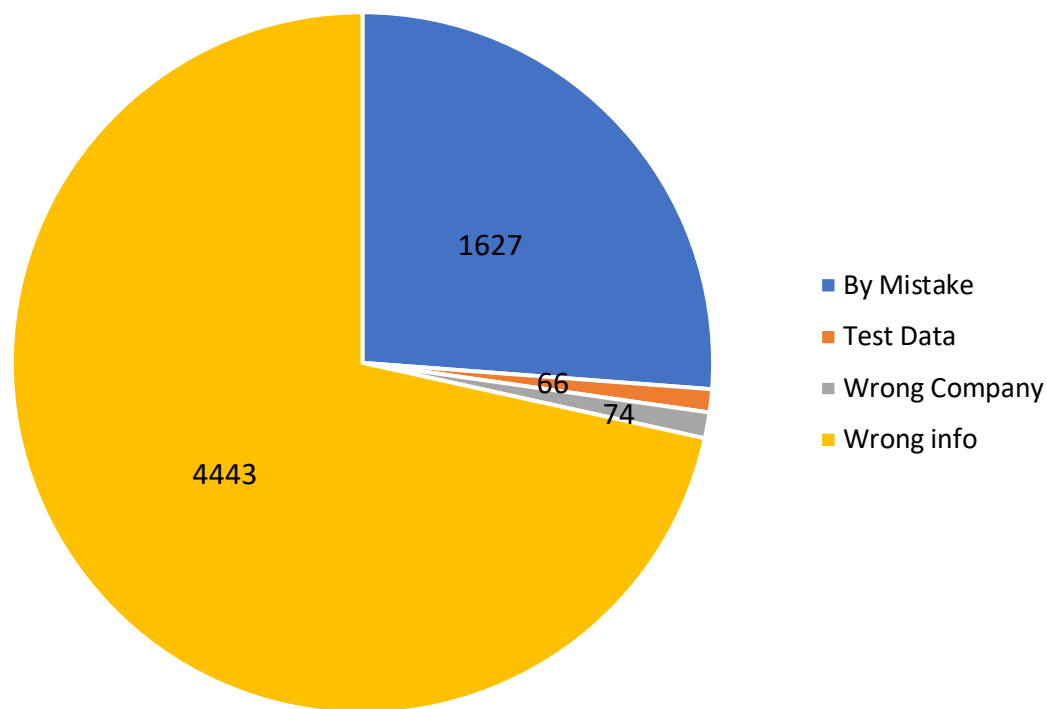


Maximum number of dossiers received on one day (November 19, 2022)

5.914

Actual numbers

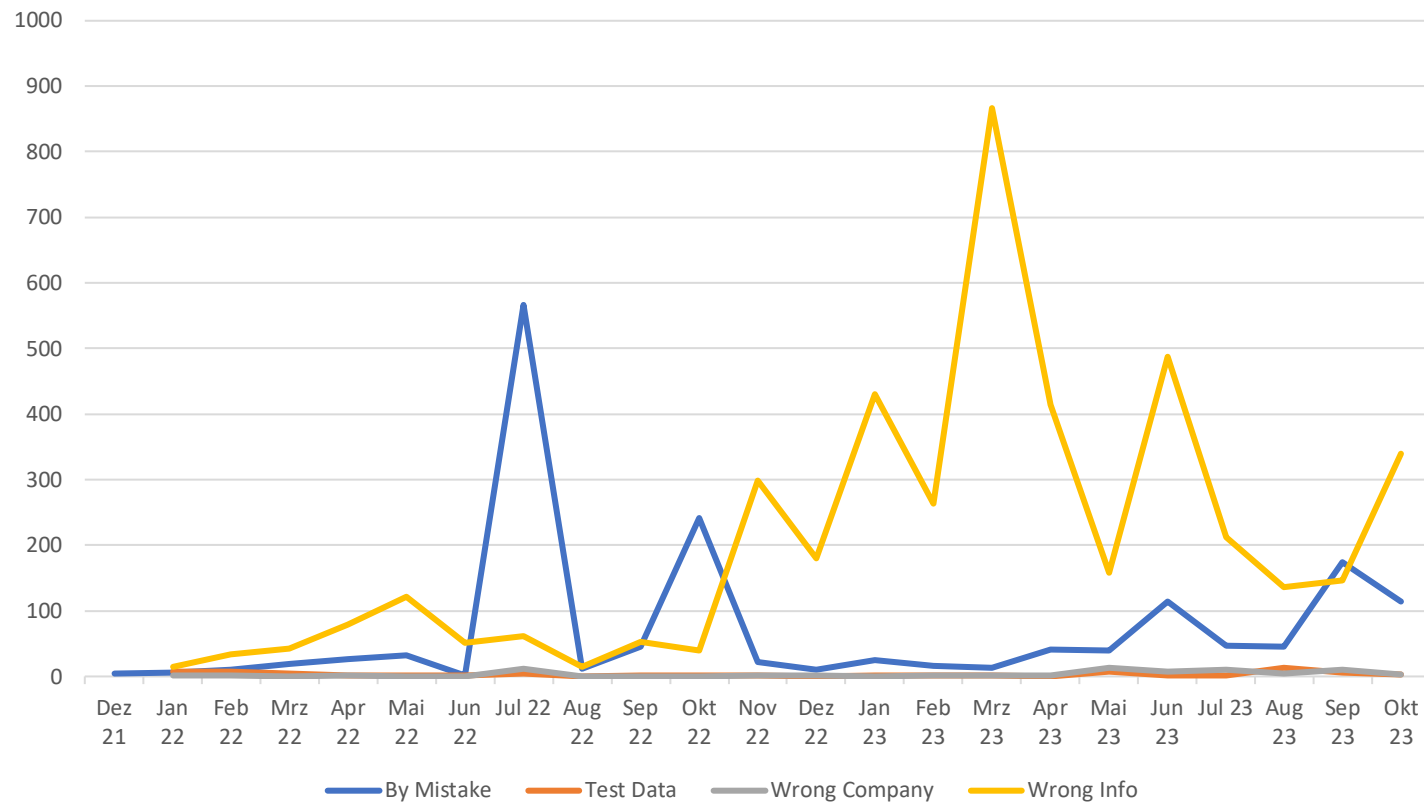
Number of disable requests



Total number of disable requests : 6.210

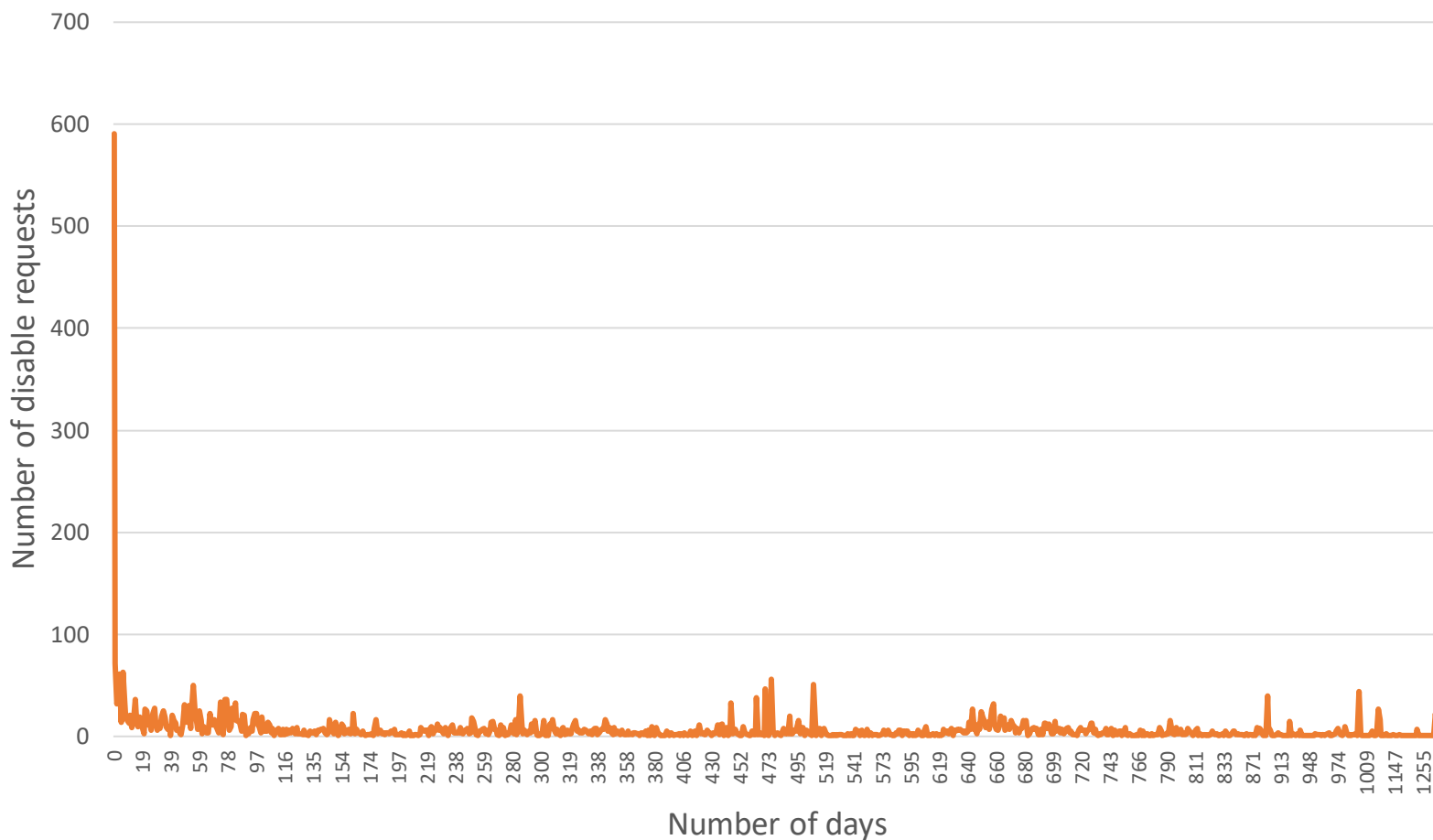
Actual numbers

Number of disable requests per month



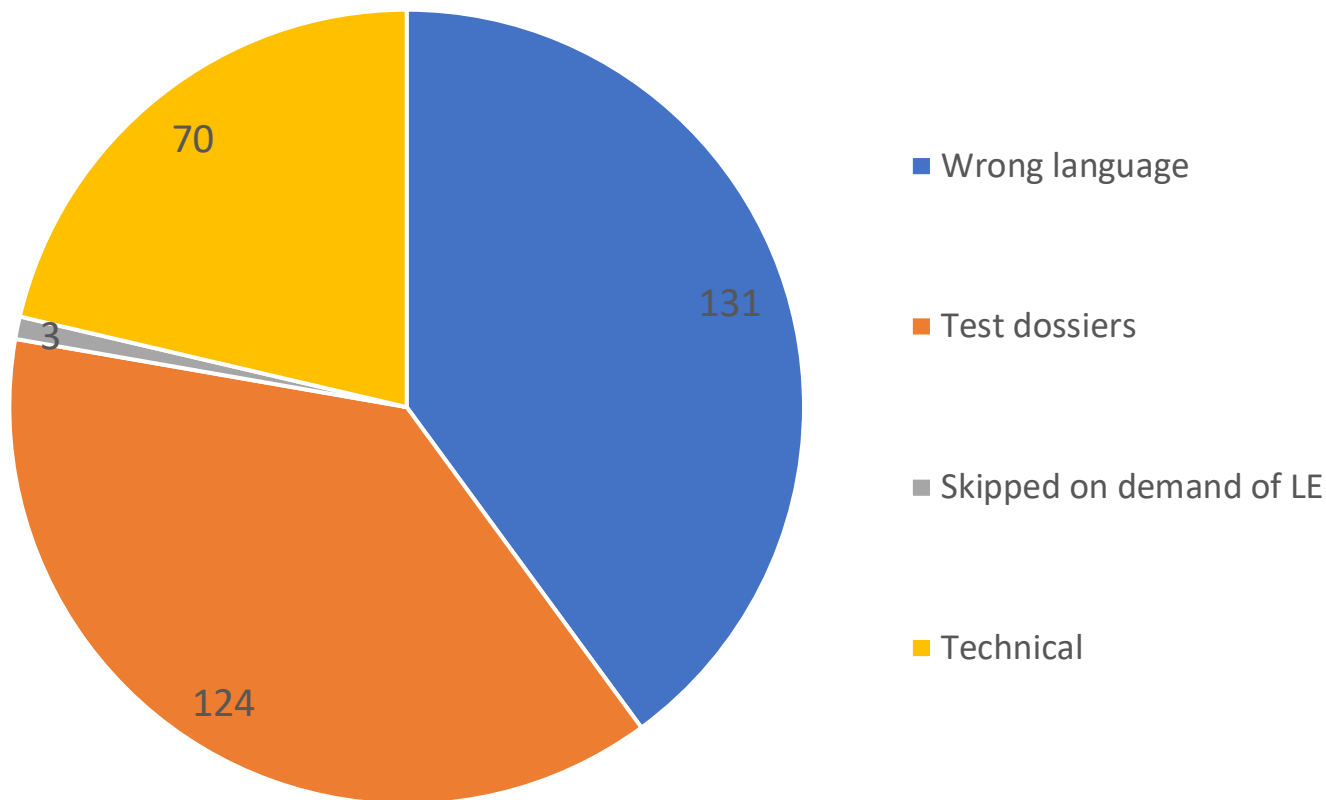
Actual numbers

Number of days between a submission and a disable request



Actual numbers

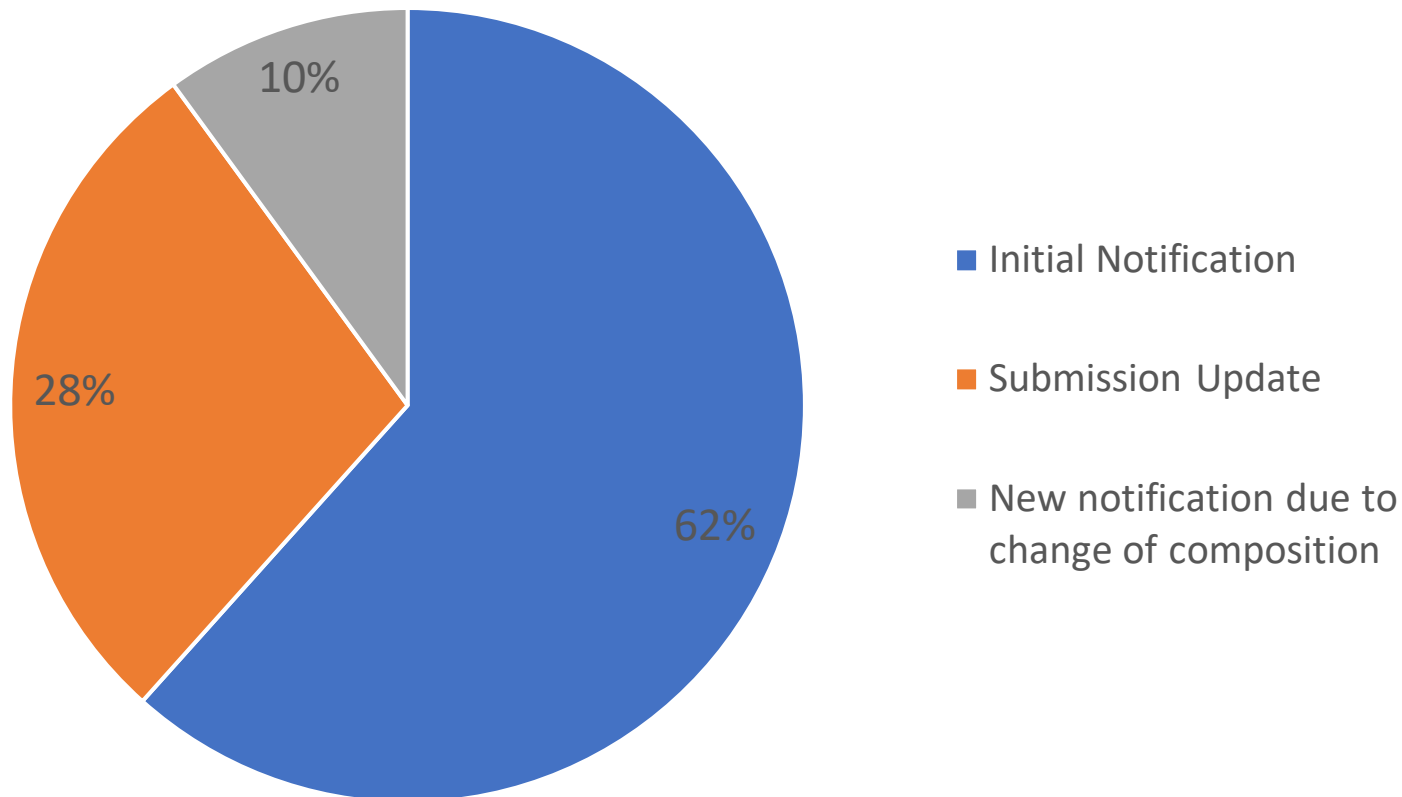
Number of not treated dossiers



328 dossiers have not been treated for several reasons.

Actual numbers

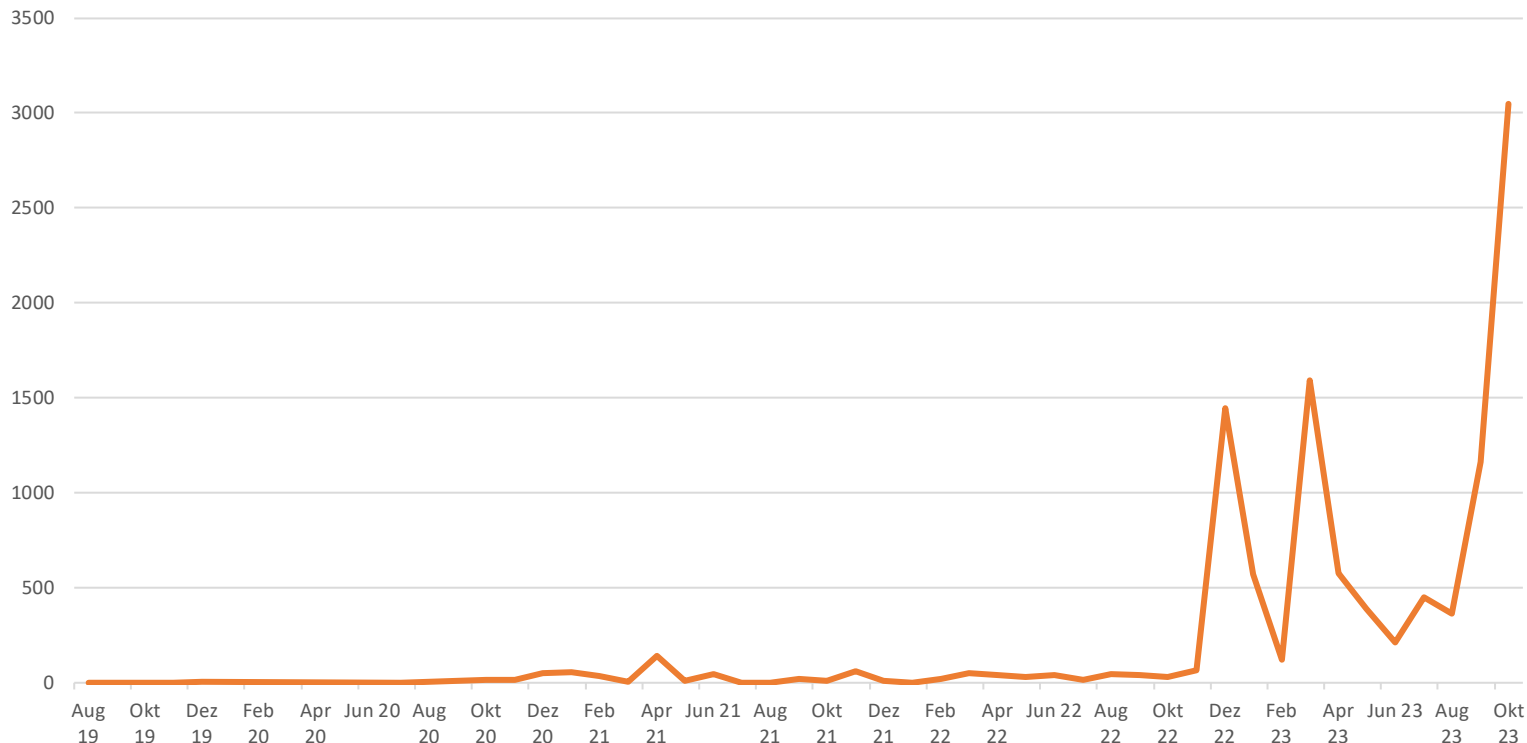
Type of submissions



- 6,5% of the submission updates are in fact initial notifications. The update concerns defining Belgium and/or Luxembourg as a new market.
- 2,3% of the submissions are voluntary

Actual numbers

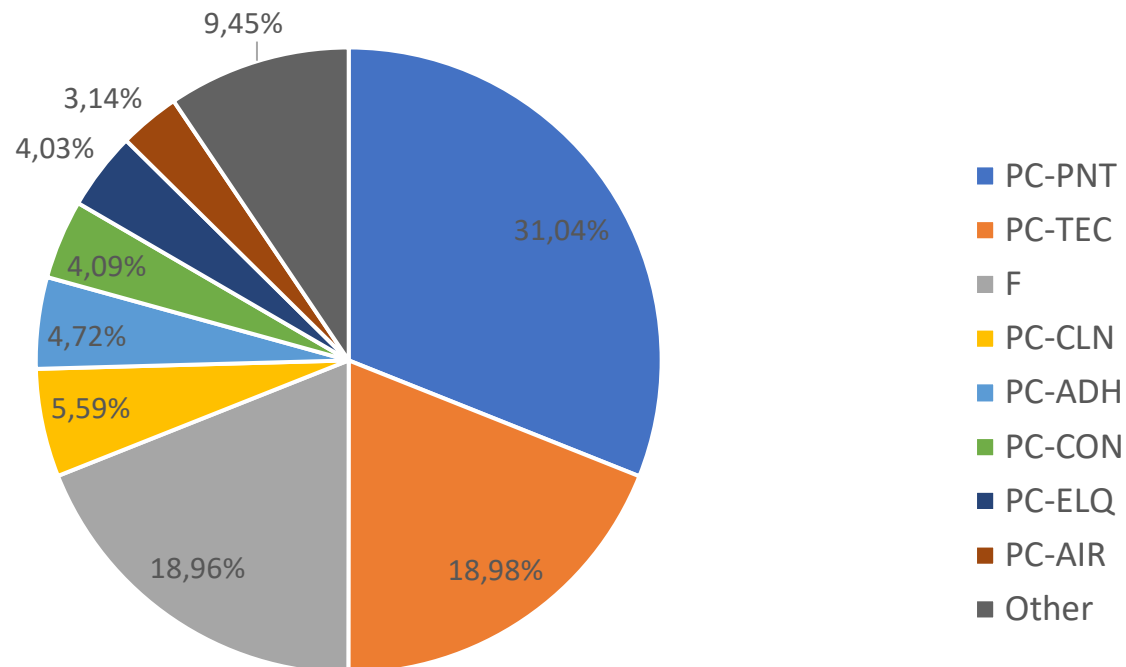
Number of limited submissions per month



- 10.816 (1,6%) limited submissions have been done. As January 1, 2024, is approaching, we are seeing an increase of the number of submissions.
- Limited submissions can only be used for submitting mixtures for industrial use
- Disabled submissions are not included in the above chart

Actual numbers

Number of mixtures in the database



- There are **493.396** mixtures in the database. Disabled mixtures are not included
- Identical mixtures can appear in the database as the database contains the mixtures for Belgium and the Grand Duchy of Luxembourg
- Top 3
 - Paints and coatings (31%)
 - Products for chemical or technical processes (19%)
 - Mixtures for further formulation (19%)

| UFI



UFI

- In February 2023 Belgium noticed a UFI code was linked to two totally different mixtures.
- An in-depth investigation done by Belgium, France, Germany and the Netherlands revealed that this misuse occurs regularly
- ECHA and the European Commission were informed of the problem in September
- An investigation is currently ongoing to determine what causes the problem
- The problem will be discussed during the next CARACAL

Quality Rule QLT618

- The problem has been investigated by examining the presence of Quality Rule QLT618
- QLT618 : “The UFI provided may relate to different mixture composition already notified (UFI corresponds to different PCN number). In case this mixture composition is different provide a new UFI.”
- QLT618 may for example occur in the following cases:
 - The same mixture has been notified multiple times for notifying different commercial products (same cleaning product for VW, BMW, Citroën,...)
 - The same mixture has been defined by the producer and by a repackager using the same UFI code
 - Etc...

Way of investigation

- Searched for all mixtures (PCN Numbers) where the quality rule QLT618 exists.
- Retrieved the UFI codes of the above mixtures
- Retrieved all defined mixtures (PCN Numbers) for the above UFI codes
- Compared mixtures (PCN Numbers) with the same UFI code by
 - Number of main components
 - GHS signal word and GHS symbols
 - EuPCS category
 - Legal Entity
 - pH
- Last check has been performed with data imported before May 9, 2023

PCN Number = a unique complex number generated during the first notification of a mixture. The number is kept when making additional submission updates.

Numbers

- **±412.000** defined mixtures existed in the database when doing the investigation
- **± 28.000** defined mixtures contained the quality rule QLT618
- Found differences
 - Different number of main components : **± 5.100** UFI codes
 - Different GHS symbols : **± 1.750** UFI codes
 - Different number of main components + different GHS symbols : **± 1.000** UFI codes
 - Different number of main components + different GHS symbols + different EuPCS category : **± 350** UFI codes (*)
 - Different number of main components + different GHS symbols + different Legal Entities : **± 160** UFI codes
 - Differences between pH : **± 430** UFI codes
 - $\Delta\text{pH} > 5$: **46** UFI codes
 - $\Delta\text{pH} > 10$: **9** UFI codes

(*) Checked 105 examples manually, Revealed 100 UFI codes with totally different mixture compositions. Only 5 UFI codes concerned incomplete data (quality issue).

Interpreting the numbers

- The number of UFI codes with differences doesn't always mean that the mixture compositions are different. It could also be related to the quality of the data. For example :
 - Differences in number of components can be caused by a missing component
 - Differences in GHS symbols can be caused by an oversight
- The actual numbers on the previous slide give only an idea of the size of the problem. They don't give the exact number of problematic UFI codes.

UFI

Example 1

	Mixture A	Mixture B
EuPCS	PC-DET-1.2	PC-CLN-10.4
Colour	White	Yellow
Amount of water	77,5% - 79,5%	No water
pH	3	13,5
Usage	Consumer	Professional
Signal Word	-	Danger
Corrosion	No	Yes
Health Hazard	No	Yes

PC-DET-1.2 : Laundry detergents – household use

PC-CLN-10.4 : Over, grill or barbecue cleaners

UFI

Example 2

	Mixture A	Mixture B
EuPCS	PC-PNT-2	PC-PNT-6
Colour	Many colours	Many colours
Amount of water	25% - 45%	No water
pH	8,0 – 9,0	7
Usage	Consumer	Professional
Signal Word	Warning	Danger
Flame	No	Yes
Exclamation Mark	Yes	Yes
Health Hazard	No	Yes

PC-PNT-2 : Paints/coatings – Decorative

PC-PNT-6 : Factory-applied coatings

UFI

Cause

- The actual cause of the misuse is currently under investigation.
- The problem occurs for all kind of industries and in all sectors
 - SME and Multinational
 - Painting, Construction, Cleaning, etc..
- Causes could be (*)
 - The application used by the submitter doesn't give a warning when QLT618 occurs.
 - Submitter is neglecting QLT618 as he/she doesn't know the importance of the message.
 - Algorithm from the UFI generator isn't reliable. Maybe the algorithm is creating identical UFI codes when using different VAT numbers.
 - Etc..

(*) Purely suggestive



Product names

Product names

Quality of the received data

- The product name is the most important property to identify a commercial product in the Poison Centre database
 - It's the first thing a caller tells when describing a product
 - Most of the time, it's easy to find on the package. Certainly, compared to the UFI code
 - Well known commercial products are sometimes known by the person answering the phone, which helps him/her finding the product more efficiently
- In many cases the quality of the received product names leave much to be desired. Some companies don't give the commercial name or the brand name of a product, which makes it sometimes extremely difficult to find the correct product. Examples: "*grey spray*", "*allzweckreiniger*", "*vettlöser*"
- It is impossible for a Poison Centre to check the quality of the received product/trade names as we don't have enough resources and we mostly don't have the package label to compare

Product names

Quality of the received data

Tips when filling in the product names

- Ask yourself which words on the package a caller will give to the Poison Centre when calling
- Ask yourself which words are important to identify the product
- Give the complete commercial name. The Poison Centre is not searching on the Legal Entity name as it is most of the time not part of the commercial name
- Keep in mind!!! The product name is used to identify the commercial product, not to identify the use of the product. That's where the EUPcs category is for.

Product names

Example 1



Incomplete :

Grillreiniger

Complete :

Maxxi Clean Backofen Grillreiniger

Picture found on the internet with the goal of explaining the problem.

The current product is just an example. Showing it, doesn't mean that it has been notified in Belgium or that the eventually received submission contains incomplete product names.

Product names

Example 2



Incomplete :

Allzweckreiniger

Complete :

Dettol AntiBakteriell Allzweckreiniger 3xPower

Picture found on the internet with the goal of explaining the problem.

The current product is just an example. Showing it, doesn't mean that it has been notified in Belgium or that the eventually received submission contains incomplete product names.

Product names

Submitting in different countries

- There are three ways for submitting a mixture in different countries
 - Multiple dossiers. One for each country separately.
 - One dossier with multiple products. One product per country
 - One dossier with one product for all countries
- A product can have one or more product names
- “Product Name” field property
 - IUCLID v6.3 multilingual text field
 - IUCLID v6.4 and later normal text field
- If a product is created for multiple marketplaces, that product can have more than 20 different names (Ελληνικά, Nederlands, Polski, Français, Italiano, English, Magyar, Deutsch, عربي, Svenska, ..)

Product names

Submitting in different countries (Example)

Submitting a mixture “White Bear Allzweckreiniger” in Belgium, Germany, Greece and Sweden. Names of the product in the different languages:

- Dutch Witte Beer Allesreiniger
- French Nettoyant Tout Usage Ours Blanc
- German White Bear Allzweckreiniger
- Greek καθαριστικό για όλες τις χρήσεις λευκής αρκούδας
- Swedish vit björn allrengöringsmedel

Product names

Submitting in different countries (1st way)

4 different dossiers. One for each country

- Belgium (Dutch, French and German product names)
- Germany (German product name)
- Greece (Greek product name)
- Sweden (Swedish product name)

Querying for UFI code AAAA-BBBB-CCCC-DDDD in Belgium gives the following result

Name	UFI
Nettoyant Tout Usage Ours Blanc	AAAA-BBBB-CCCC-DDDD

Only one product is found. The one submitted in Belgium. First known product name is shown. The French name is understandable for our physicians. Other product names (Dutch and German) are shown when opening the content.

Product names

Submitting in different countries (2nd way)

One dossier. 4 different products. One product per country :

- Belgium (Dutch, French and German product names)
- Germany (German product name)
- Greece (Greek product name)
- Sweden (Swedish product name)

Querying for UFI code AAAA-BBBB-CCCC-DDDD in Belgium gives the following result

Name	UFI
καθαριστικό για όλες τις χρήσεις λευκής αρκούδας	AAAA-BBBB-CCCC-DDDD
White Bear Allzweckreiniger	AAAA-BBBB-CCCC-DDDD
Nettoyant Tout Usage Ours Blanc	AAAA-BBBB-CCCC-DDDD
vit björn allrengöringsmedel	AAAA-BBBB-CCCC-DDDD

4 products are found. All the same mixture. The French name is understandable for our physicians. Belgian product can be identified. Other product names (Dutch and German) are shown when opening the content.

Product names

Submitting in different countries (3rd way)

One dossier. One product for all four countries. Language product names

- 1st name : Greek language
- 2nd name : French language
- 3rd name : Swedish language
- 4th name : Dutch language
- 5th name : German language

Querying for UFI code AAAA-BBBB-CCCC-DDDD in Belgium gives the following result

Name	UFI
καθαριστικό για όλες τις χρήσεις λευκής αρκούδας	AAAA-BBBB-CCCC-DDDD

One product is found. First known product name is shown. Greek name isn't understandable for our physicians. Content must be opened to check if it is the correct one. This can be very tricky if we knew only a part of the UFI code and the query gives several other results.

Product names

Submitting in different countries (conclusions)

- Submitting a mixture in different countries with only one product defined for it makes it for Poison Centres tricky to identify that mixture.
- Unfortunately, ECHA changed the name field into a simple text field instead of multilingual field. The multilingual field would solve the problem immediately.
- The poison centres have no legal right to ask the industry to create a dossier where a product is created per country. We just can ask the industry to take this inconvenience into account when adapting their submission system in the future. It would help us a lot.
- Providing the labels of a product can also help our physicians to find the correct product if they have any doubts. Being able to compare a description of the label (given by the caller) with received labels can really help in such situations.

Product names

Multiple names

- Multiple product names can be defined for one product. Each name can be defined in its own field
- The name field of a product is limited to 500 characters. Longer fields make the product name difficult to read
- There are companies who are defining multiple product names in one field instead of using a field per product name. They are separating the names by using a delimiter (examples: “;” , “:” , “-” , “\n” , “&” , etc..)
- By placing multiple names in one field, the length of the name is sometimes more than 500 characters.
- Human intervention is needed when importing such names in our database as submitters are using different delimiters
- Conclusion!!! Make use of multiple fields to define multiple names or at least limit the length to 500 characters. This would ease the import for the Poison Centres and make the names easier to read.



| Substances

Substances

- A weakness in the current system is that IUCLID accepts that a reference substance is recreated each time when a new submission is made
- A good defined substance is important for the Poison Centres. The poison centres noticed that currently this is not always the case.
 - Wrong name of the substance
 - Typographical errors for the CAS number or EC number
 - Wrong CAS number and/or EC Number
 - Extremely long substance names without any additional information
 - Wrong GHS classification

Substances

Example 1

- Water (H₂O)
 - Correct CAS Number : 7332-18-5
 - Correct EC Number : 231-791-2
 - More than 100.000 hits in the reference substance table
- Querying the database by CAS Number or EC Number results in 114 different definitions

Name	ECNumber	CASNumber
Wasser, chemisch rein	231-791-2	7732-18-5
Вода	231-791-2	7732-18-5
ungefährlicher Stoff	231-791-2	7732-18-5
Decaglycerollaurat	231-791-2	34406-66-1
Phrase('500252') nicht gefunden	231-791-2	7732-18-5
10100500	231-791-2	7732-18-5
Non-Hazardous Ingredients		7732-18-5
Emulsifier	231-791-2	34406-66-1
WATER	231-791-2	107-21-1
Serine protease (aep)	231-791-2	37259-58-8

Substances

Example 2

- Water (H₂O)
 - Correct CAS Number : 7332-18-5
 - Correct EC Number : 231-791-2
 - More than 100.000 hits in the reference substance table
- Querying the database for the word “water”

Name	ECNumber	CASNumber
Water	231-791-2	7732-18-5
Water	232-455-8	7732-18-5
Water	686-299-4	7732-18-5
Water		00-00-0
Water		
Water		7732-18-5
Water	231-791-2	7732-18-5
Water	231-791-2	107-21-1
Water		7722-84-1

232-455-8 White Mineral Oil
107-21-1 Ethane-1,2-diol
7722-84-1 Hydrogen peroxide

Substances

Example 3

Water (H₂O)



DANGER

Defined as such in a received submission !!!

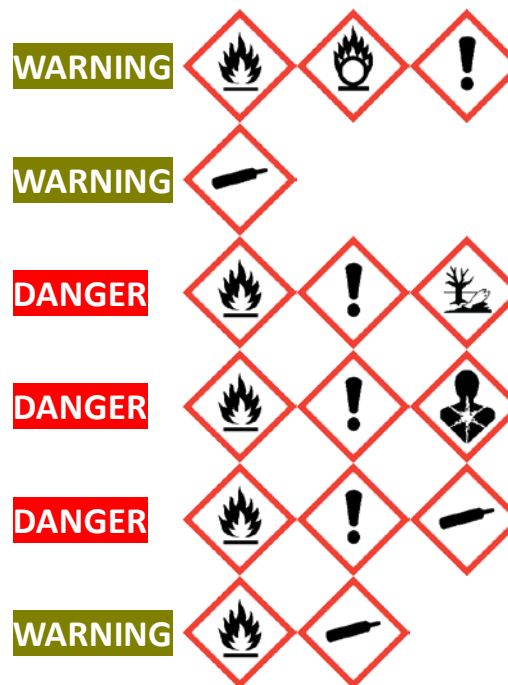
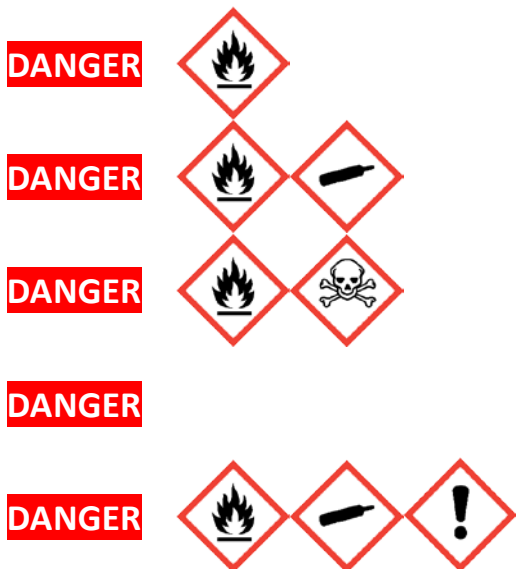
Substances

Example 4

Dimethyl Ether

- CAS Number : 115-10-6
- EC Number : 204-065-8
- Almost 5300 hits in the database
- 12 different GHS classifications

Not classified



| Other



Notification Types

1. Initial notification

- Used to notify a new mixture
- Creates effectively a new mixture in the database
- The mixture receives a unique PCN number
- If an initial submission is used to submit an already existing mixture, the mixture will appear twice in the database

2. New notification due to change of composition

- Used to notify an already existing mixture of which the composition has changed
- Submitter needs to give the PCN number of the original mixture
- Creates effectively a new mixture in the database, but a link toward the previous mixture is kept
- The mixture receives a unique PCN number
- The UFI codes of the new mixture must be different from the UFI codes of the original mixture
- Compared to a “Submission update”, it must be used when the composition changes.

Notification Types

3. Submission update

- Used to update an existing mixture. An update can be
 - Adding toxicological information
 - Adding UFI codes
 - Adding trade names
 - Updating the GHS classification of a component, without changing the quantity of the component
 - Adding, removing marketplaces
 - Etc..
- The PCN number of the original mixture is kept
- If the mixture already exists in the database, the previous version of that mixture is deactivated, so that only the last correct version is consultable
- Existing UFI codes of previous notification must be defined in the submission update

Notification Types

Problems

- Some submitters aren't using "Submission Update" for performing mixture updates, but are performing a new "Initial Notification"
 - This results in several different consultable versions of a mixture in the database
 - The physician answering the phone can risk to consult an incomplete version of the mixture, which can have big consequences if for example parts of the toxicological information are missing
 - Doing an "Initial Notification" has great consequences for the fees that must be paid in Belgium 😞
- Some submitters are reusing the UFI codes of an "Initial submission" during a "New notification due to change of composition"
 - This is forbidden. A change of composition means in fact a new composition!

Other

- Entering a UFI code in the field provided for this purpose
 - “AAAA-BBBB-CCCC-DDDD” OK
 - “UFI : AAA-BBBB-CCCC-DDDD” NOT OK
- Giving an Exact pH value of 12
 - Exact value pH = 12,0 OK
 - Minimum value pH = 0 & Maximum pH value = 12 NOT OK
- GHS phrase H314 “Causes severe skin burns and eye damage.” is missing regularly for liquid mixtures where $0 < \text{pH} \leq 1$

Other

- An ICG or an “Interchangeable Component” is not a group submission and is certainly not created with the purpose of defining multiple different mixture compositions for one commercial product. If a commercial product can have multiple different mixture compositions, make an additional notification of type “New notification due to change of composition” and give it a different UFI code.
- Almost 9000 mixtures exist in our database that contain only one substance. Many of these substances give only a descriptive name. This information is for unusable
 - huile essentielle de cèdre de l'Atlantique cedrus Atlantica bark oil
 - Orange, sweet, extract
 - Portlandzement
 - Biocide

Other

Mixtures where the composition hierarchy is very deep (for example “MiM in ICG in MiM in MiM”) makes it for our physicians extremely difficult to analyse that mixture during a call.

Try to simplify the representation of the composition!!!

If this is difficult, notify MiM’s that are found deep in the composition hierarchy and that are used in multiple mixtures as a separate mixture.

Composition hierarchy of Belgian database

- Standard Formula
 - Standard Formula
 - Substance
 - MiM
 - Substance
 - Substance
- InterChangeable Component
 - MiM
 - Substance
 - Substance
- MiM
 - Substance
- Substance

The following schema has been created after several discussions with people of ECHA and that before everything went into production.

About 40 notifications (<0,006%) can't be imported because of our defined schema.

The cost of adapting it for such a small number of submissions is irresponsible.

What about the fees when creating additional mixtures for defining a Mixture in Mixture?



070 245 245

| Q & A

Thank you for your attention.

Let's stay in touch!



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