

# Experiences with Product Notifications in Spain

*"15<sup>th</sup> BFR User Conference on Product Notifications"*

5<sup>th</sup> November 2024

Berlin

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Facultativo Servicio de Información Toxicológica

Sección de Documentación

Instituto Nacional de Toxicología y Ciencias Forenses (INTCF)



SIT SERVICIO DE INFORMACIÓN  
TOXICOLÓGICA  
915 620 420



MINISTERIO  
DE LA PRESIDENCIA, JUSTICIA  
Y RELACIONES CON LAS CORTES

- 1) INTCF: Appointed Body
- 2) Notification procedures to the INTCF
- 3) Working process of the Spanish AB/PC
- 4) INTCF: Poison Centre/Servicio Información Toxicológica (SIT)
- 5) Impact of art.45 CLP implementation

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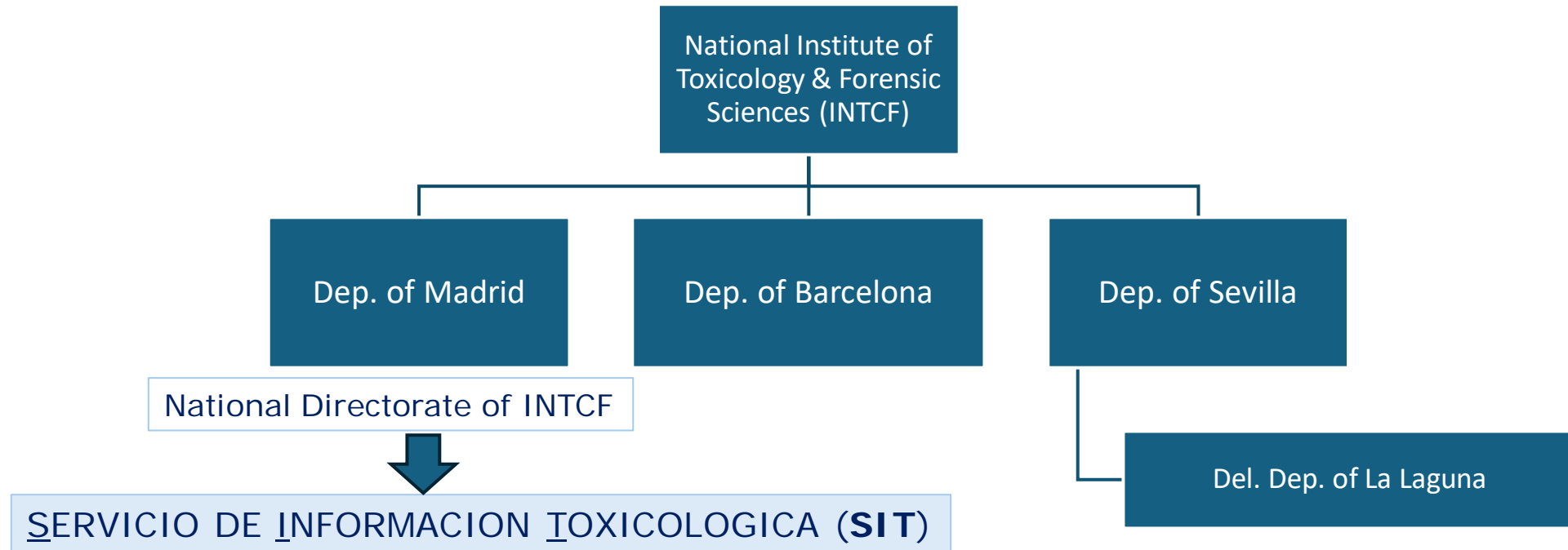
5) Impact of art.45 CLP implementation

# Structure of the INTCF

## Instituto Nacional de Toxicología y Ciencias Forenses (INTCF)

MINISTERIO DE LA PRESIDENCIA, JUSTICIA Y RELACIONES CON LAS CORTES  
SECRETARIA DE ESTADO DE JUSTICIA  
SECRETARIA GENERAL PARA LA INNOVACIÓN Y CALIDAD DEL SERVICIO PÚBLICO DE JUSTICIA  
DG PARA EL SERVICIO PÚBLICO DE JUSTICIA

- Scientific-technical body of the Administration of Justice attached to the Ministry of Justice



**REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006**

**TITLE VI: COMPETENT AUTHORITIES AND ENFORCEMENT**

**Article 45**

***Appointment of bodies responsible for receiving information relating to emergency health response***

**1.**

Member States shall appoint a body or bodies responsible for receiving information relevant, in particular, for formulating preventative and curative measures, in particular in the event of emergency health response, from importers and downstream users placing mixtures on the market. This information shall include the chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, including the chemical identity of substances in mixtures for which a request for use of an alternative chemical name has been accepted by the Agency, in accordance with Article 24.

**INTCF was nominated as the Spanish Appointed Body**

**Ley 8/2010**, de 31 de marzo, por la que se establece el régimen sancionador previsto en los Reglamentos (CE) relativos al registro, a la evaluación, a la autorización y a la restricción de las sustancias y mezclas químicas (REACH) y sobre la clasificación, el etiquetado y el envasado de sustancias y mezclas (CLP), que lo modifica.

Disposición adicional tercera. Informaciones al Instituto Nacional de Toxicología y Ciencias Forenses.

**The INTCF shall be the body responsible for receiving from importers and downstream users placing mixtures on the market the relevant information referred to in Article 45(1) of Regulation (EC) No 1272/2008.**

**REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006**

**TITLE VI: COMPETENT AUTHORITIES AND ENFORCEMENT**

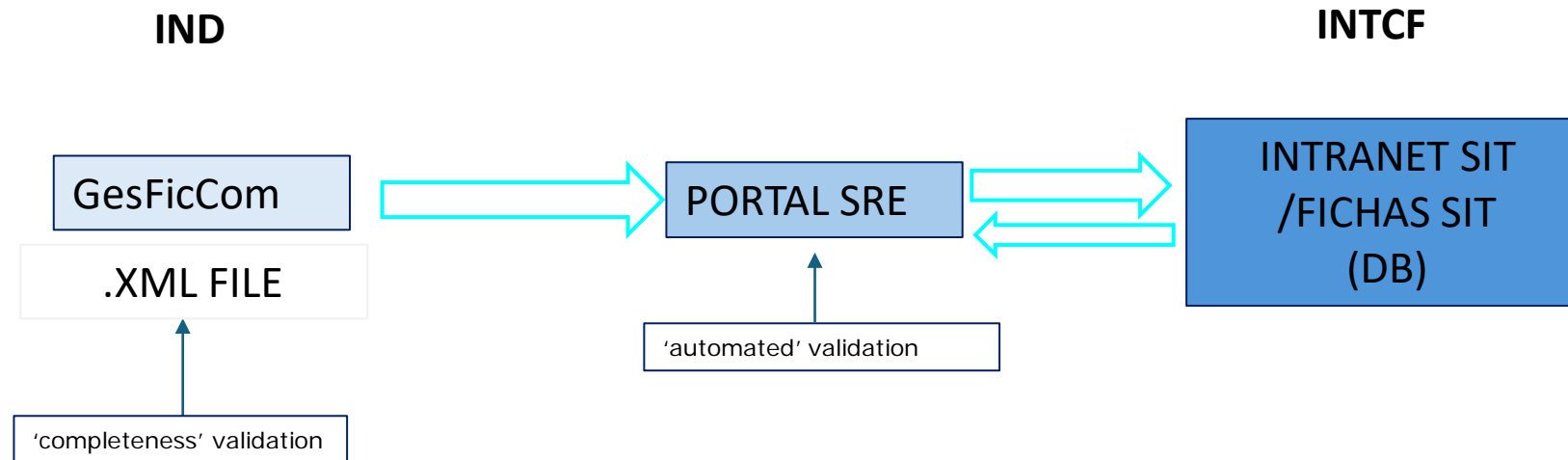
**Article 45:** Appointment of bodies responsible for receiving information relating to emergency health response

2. *The appointed bodies shall fulfill all requisites to guarantee the **confidentiality** of the information received.*

- a) to meet medical demand by formulating preventative and curative measures, in particular in the event of an emergency;
- b) where requested by the Member State, to undertake statistical analysis to identify where improved risk management measures may be needed.

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# Previous national procedure: SRE-GesFicCom



- Fees
- Acknowledgement of receipt from INTCF



## Timeline: notification procedures to INTCF



# Implementation of Annex VIII in Spain



Overview of Member States decisions in relation to implementation of Annex VIII to CLP Regulation (Poison Centre Notification)

August 2023

Version 12.1

## Submission *via* ECHA Portal

MS	Readiness to accept <i>via</i> ECHA portal	Submission system option	Notification language	fees	Placing on the market mixtures notified <i>via</i> ECHA portal
Spain			Spanish or English		

Duty holders can notify their mixtures through the **ECHA Submission portal**

Once confirmed they are accepting, MS will **only accept via ECHA portal**

Duty holder may **choose** notification language

**NO fees**

Duty holder can start placing on the market **only after confirmation** in the submission report **that the dossier has been received by the AB.**

# Harmonised notification procedure to the INTCF: transfer to national legislation

- **Orden JUS/288/2021**, de 25 de marzo, por la que se regula el procedimiento de notificación de sustancias y mezclas químicas al Instituto Nacional de Toxicología y Ciencias Forenses
  - **NO fees** for harmonised notification procedure
  
- **Orden JUS/877/2023**, de 21 de julio, por la que se modifica la Orden JUS/288/2021, de 25 de marzo, por la que se regula el procedimiento de notificación de sustancias y mezclas químicas al Instituto Nacional de Toxicología y Ciencias Forenses.
  - **NO acknowledgement of receipt** by INTCF

## Obligation to notify to INTCF under national legislation (not subject to Annex VIII)

- Bleaches  
*(Real Decreto 349/1993, de 5 de marzo, por el que se modifica la Reglamentación Técnico-Sanitaria de Lejías aprobada por el Real Decreto 3360/1983, de 20 de noviembre)*
- Detergents and cleaning products  
*(Real Decreto 770/1999, de 7 de mayo, por el que se aprueba la Reglamentación técnico-sanitarias para la elaboración, circulación y comercio de detergentes y limpiadores)*
- Further legislations for mixtures (not classified for health and/or physical hazards) establishing supplementary labelling and/or SDS requirements  
*(Orden JUS/288/2021):*
  - SIT emergency phone number on LABEL
  - SIT emergency phone number in section 1.4 of the SDS

## AB support for the harmonized notification procedure

- Information available in dedicated INTCF\_SIT webpage:

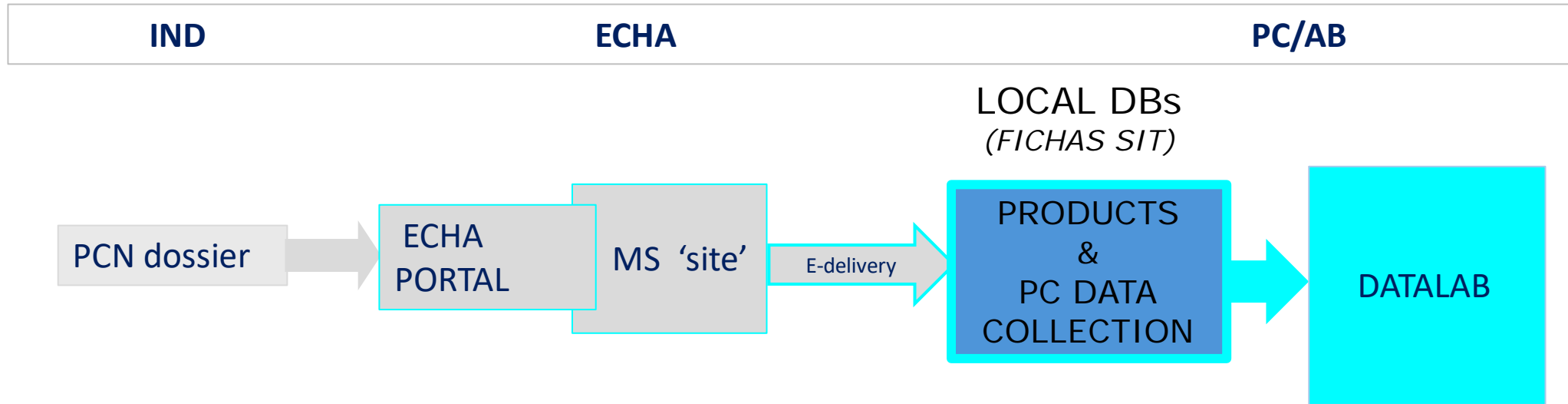
<https://www.mjusticia.gob.es/es/institucional/organismos/instituto-nacional/servicios/servicio-informacion/fichastasis-toxicologicas>

- Further support:

- Documentation section (SIT) : by e-mail [intcf.doc@justicia.es](mailto:intcf.doc@justicia.es) & telephone
- Helpdesk Spain  
Website: <https://helpdesk.reach-pir.es/>  
Email: [info@reach-pir.es](mailto:info@reach-pir.es)

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# Global working process of the Spanish AB/PC



- Notification procedure by IND
- Data collection by PC
- PC data statistical analysis (Datalab)





Bienvenido/a a la Intranet de Trabajo del Servicio de Información Toxicológica (SIT)


## Local DB (FICHAS SIT)


Familias 

Sustancias 

Productos 

Empresas 

Solicitudes Empresas 

Pago Manual 

Envíos 

Incidencias 

FT 2 

  
Emergencias y consultas toxicológicas  
915 620 420



Consultas 

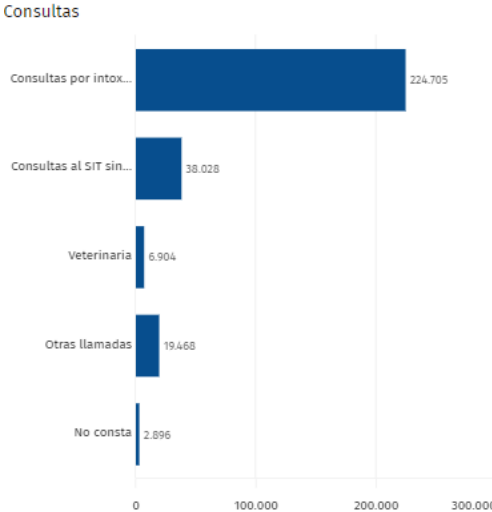


Perfil del intoxicado

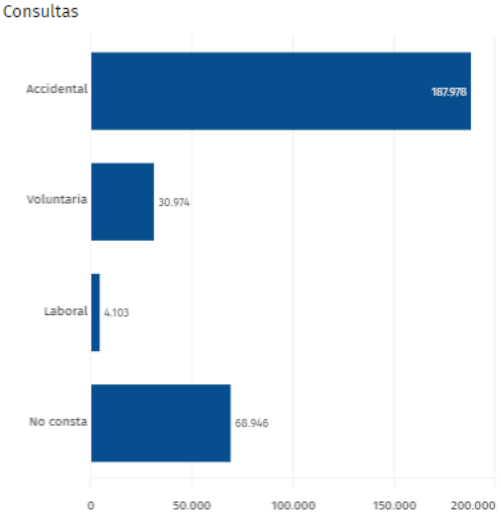


Valores absolutos  
 Valores relativos

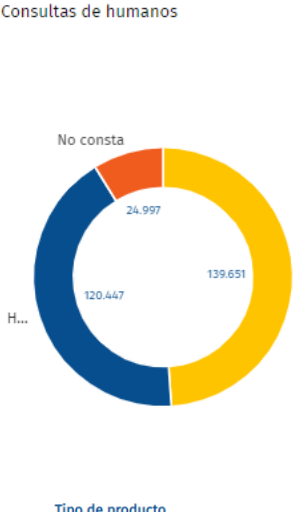
Motivo de la consulta



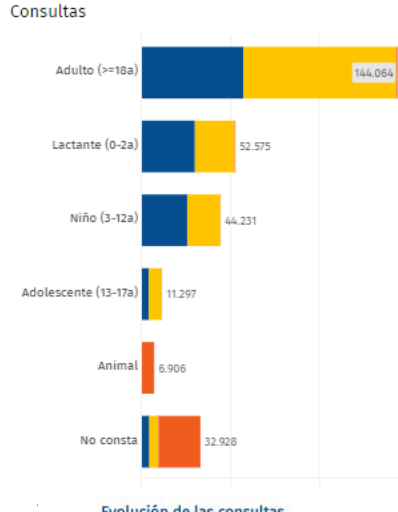
Tipo de etiología



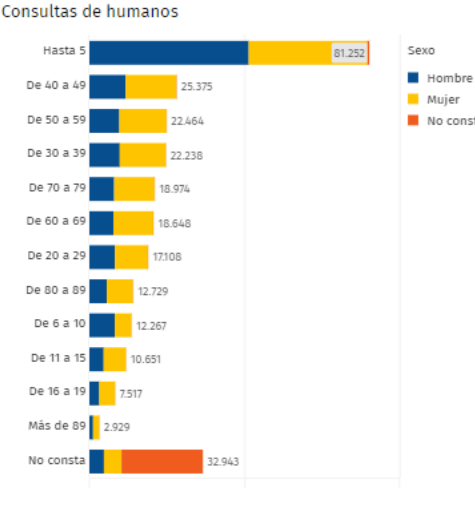
Sexo del intoxicado



Tipo de intoxicado y sexo



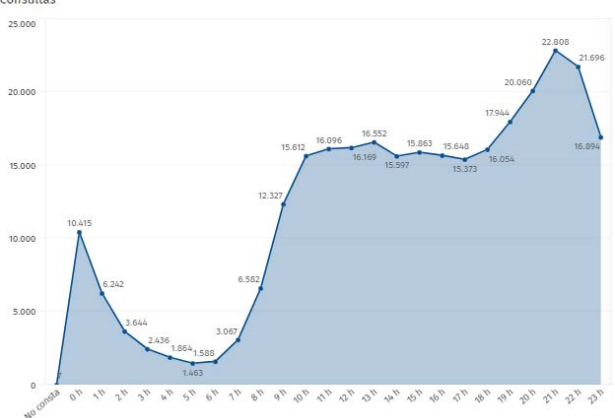
Rango de edad y sexo



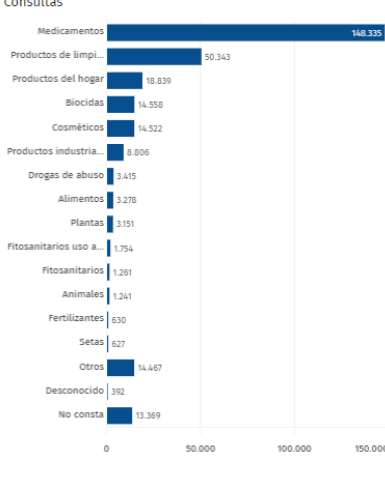
Distribución geográfica



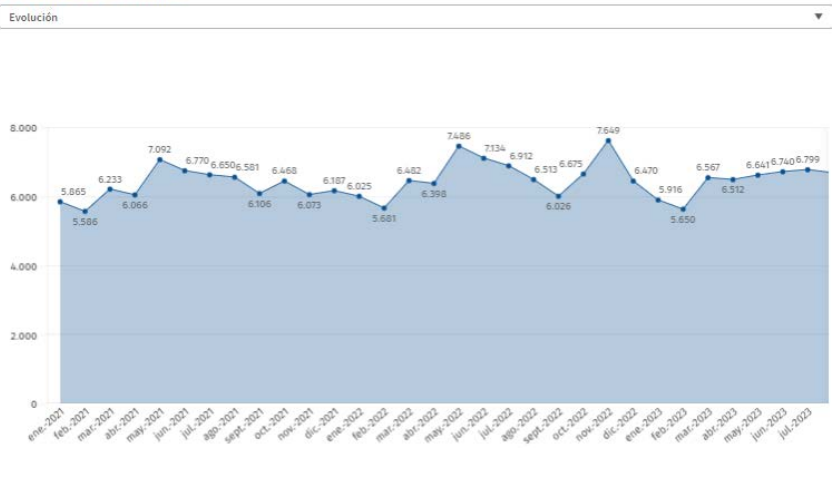
Evolución horaria



Tipo de producto



Evolución de las consultas



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# INTCF

APPOINTED BODY



## SERVICIO DE INFORMACION TOXICOLOGICA (SIT)

POISON CENTRE



Head of SIT (PC)

### Poison Information Centre-PIC

20 Physicians

### Documentation Section

Head of Section  
3 officers

AB management

- Administration staff
- IT Staff

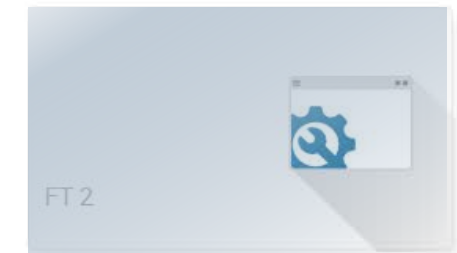
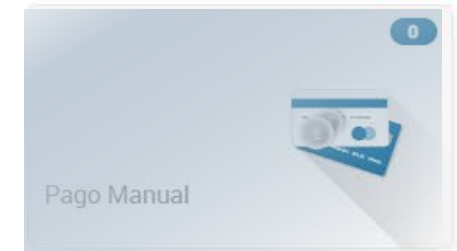
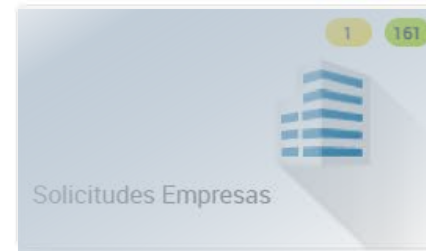
### Single PC in Spain (pop: 47,500,000)

- 24/365
- health professionals & general public

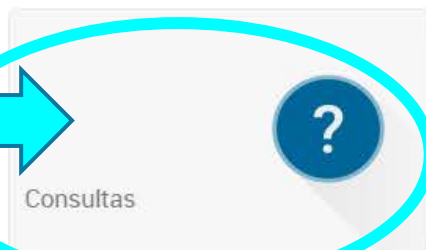


## Local DB (FICHAS SIT)

Bienvenido/a a la Intranet de Trabajo del Servicio de Información Toxicológica (SIT)



Emergencias y consultas toxicológicas  
915 620 420





Histórico de Consultas



Estadísticas



Auditoría

Consulta Productos Exp. tóxica/Intoxicación Evolución

Guardar Finalizar Volver

MOTIVO

Motivo Consulta  Fecha 08/10/2024 Hora 12:20

SOLICITANTE

Tipo de Solicitante  Formación Sanitaria Sin formación sanitaria Hospital/Institución   
Código postal  Provincia  Municipio

INTOXICADO

Sexo  Varón  Mujer Peso  Kg Teléfono  Vía   
Edad  Años Tipo intoxicado Afectados   
Observaciones  Zona de inoculación   
Alerta

- Oral
- Cutánea
- Inhalatoria
- Mucosa bucal
- Mucosa ocular
- Intradérmica
- Intramuscular
- Intrarraquídea
- Intracardiaca
- Intravenosa
- Mucosa nasal
- Mucosa ótica
- Mucosa rectal
- Mucosa vaginal
- Subcutanea
- Otra
- Desconocida



Histórico de Consultas | Alta Consulta |

Consulta | **Productos** | Exp. tóxica/Intoxicación | Evolución

Guardar Finalizar Volver

Búsqueda Estructurada

Búsqueda Libre

Nombre	<input type="text" value="Trade name"/>
UFI	<input type="text"/>
Composición	<input type="text"/>
Fabricante	<input type="text" value="Legal entity"/>
Tipo Producto	<input type="text" value="Product type"/>

Limpiar Ayuda Histórico Buscar

PRODUCTO/MEDICAMENTO	BÚSQUEDA	TIPO	ATC	CANTIDAD	PAUTA	PRESENTACION	ACCIONES
<input type="text"/>	Med. - Ppio Activo	Tipos de Producto		<input type="text"/> Seleccione...	<input type="text"/>	Seleccione..	<b>Añadir</b>

Total 0



Producto | Ver Producto |

Identificación Composición Cuantitativa Adjuntos Toxicidad Clínica Tratamiento Histórico de Cambios

Nombre Etiqueta

DRP/PCN

UFI

pH 8.4 - 9.2

En Solución al 100

## INGREDIENTES

Denominación	Información adicional	Observaciones	Tipo Ingrediente	Porcentaje	Enlace	CAS / EC
			No Clasificado	49.7%		
Water			No Clasificado	49.3%		7732-18-5 / 231-791-2
Ethanediol			Peligrosidad 2	0.51%		
MiM- 1000L	Proveedor: <input type="text"/>		Mezcla	0.2%		/
			Peligrosidad 2	0.15%		
MiM- <input type="text"/>	Proveedor: <input type="text"/>		Mezcla	0.09%		/
Reaction mass of 5-chloro-2-methyl-2H- isothiazol-3-one and 2-methyl-2H- isothiazol-3-one (3:1)			Peligrosidad 1	0.01%		

Baja Definitiva

Modificar

Atrás

Producto | Ver Producto |

Identificación Composición Cuantitativa Adjuntos Toxicidad Clínica Tratamiento Histórico de Cambios

Nombre Etiqueta

DRP/PCN

LISTADO DE INGREDIENTES DE MIM ECHA : MIM-

Denominación	Información adicional	Tipo Ingrediente	Porcentaje	Enlace	CAS / EC
Water		No Clasificado	98.3%		7732-18-5 / 231-791-2
Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)		Peligrosidad 1	1.7%		55965-84-9 / 611-341-5

Cancelar

pH 8.4 - 9.2

INGREDIENTES

Denominación

Water

Ethanediol

MiM- 1000L

MiM-

Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

CAS / EC

7732-18-5 / 231-791-2

107-21-1 / 203-473-3

/

/

Peligrosidad 1 0.01%

55965-84-9 / 611-341-5



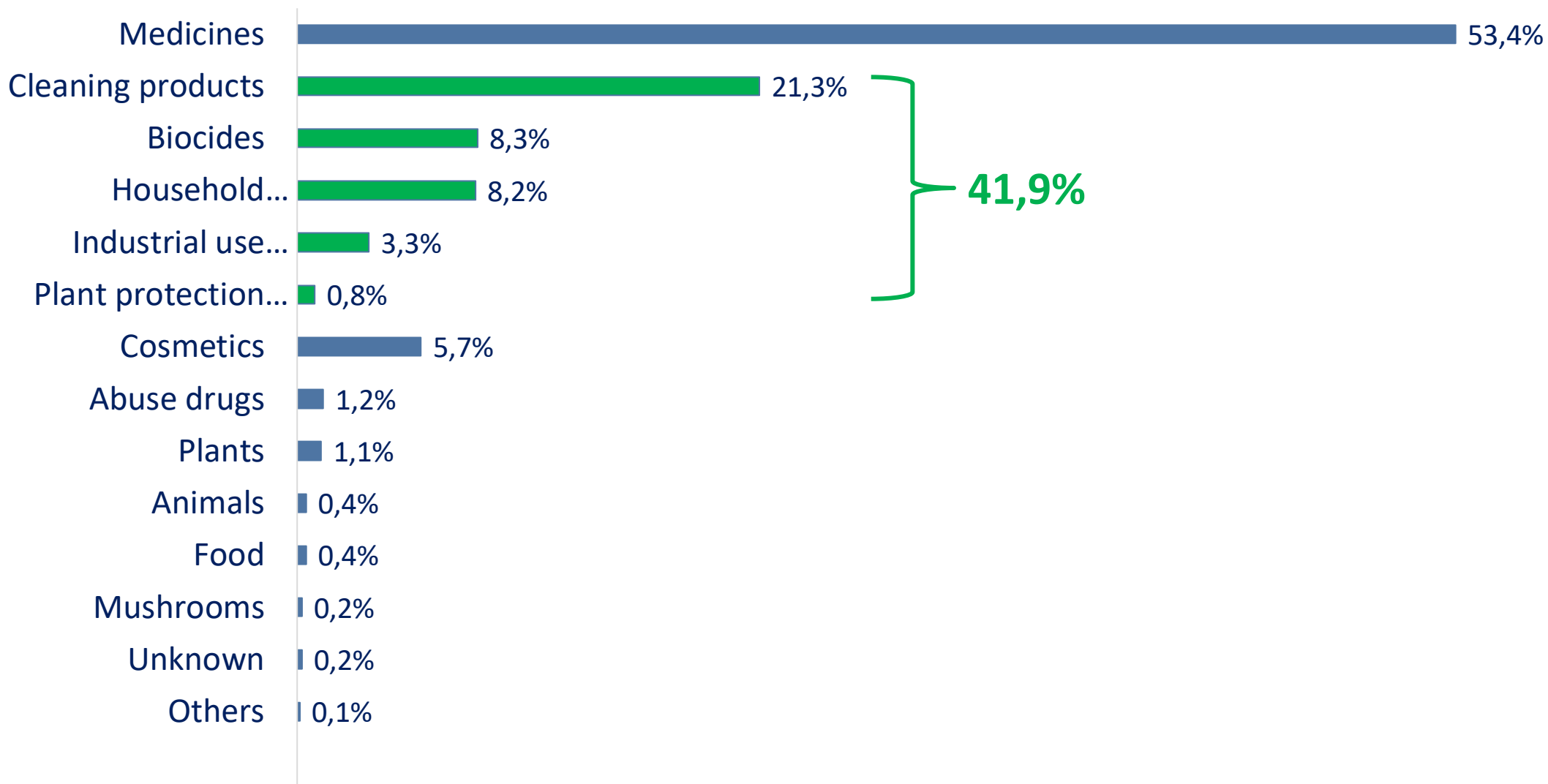
# Incidence of poisoning cases by 'Annex VIII-products'

## PC categorisation for data collection in emergency calls

1 <sup>st</sup> level	2 <sup>nd</sup> level	3 <sup>rd</sup> level
MEDICINES		
PPP		
BIOCIDES		
HOUSEHOLD PRODUCTS		
PROF & IND PRODUCTS		
CLEANING PRODUCTS		
COSMETICS		
ABUSE DRUGS		
ANIMALS		
MUSHROOMS		
PLANTS		
FOOD		
Others		
Unknown		

# Distribution of emergency calls according to PC categorisation for data collection

2023 PC data (56,708 calls due to poisoning cases in humans)

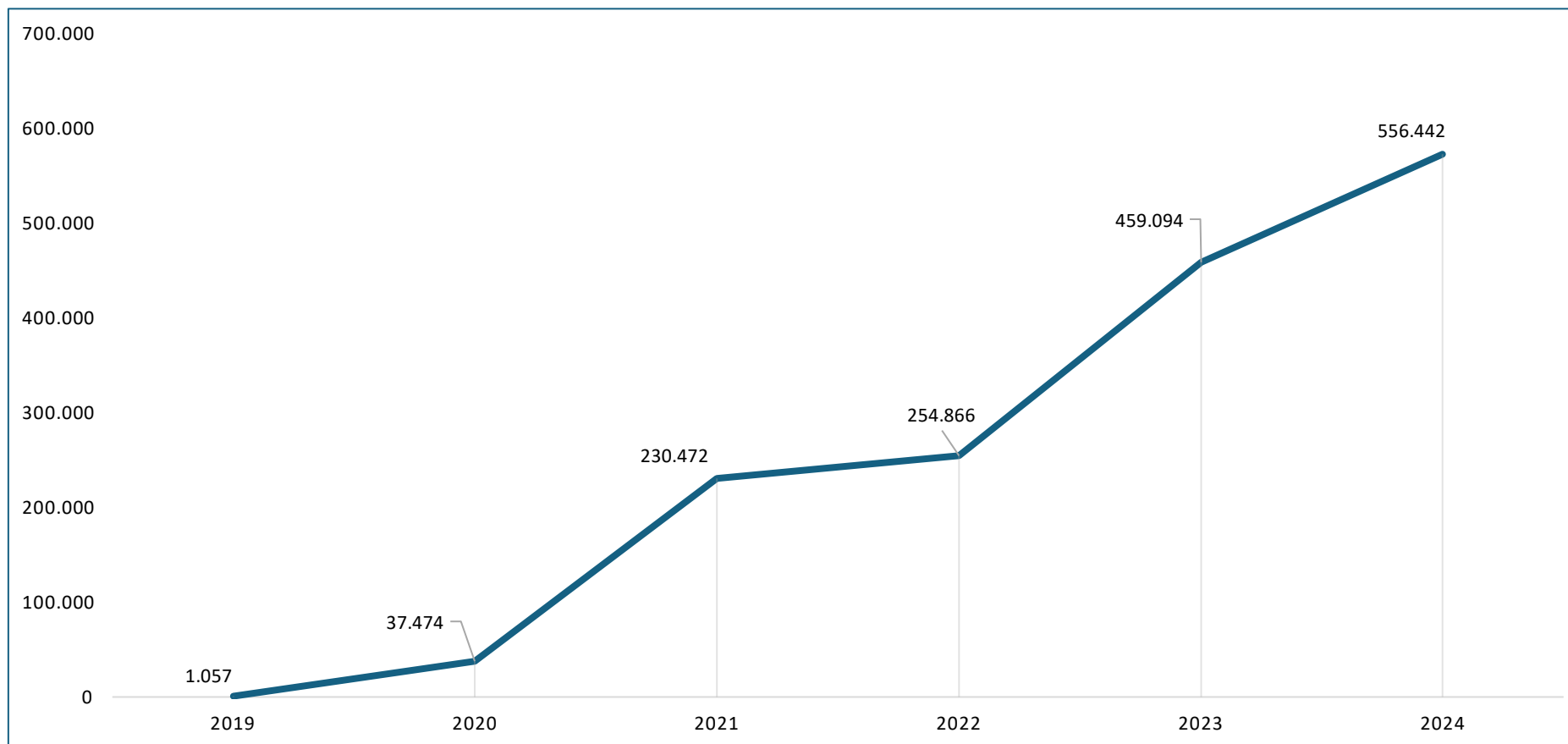


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## Notifications received by the INTCF (2019-1oct 2024)

≈2.000.000 notifications in Fichas SIT:

- **426.853** previous procedure along **10 years**
- **1.500.874** harmonized procedure since 1<sup>th</sup> Jan 2021



➤ **Type of notification:**

Initial → **937.701**

Significant change composition → **236.049**

Updates → **331.596**

Type of update	
New toxicological information available	173.360
Expansion of market area	60.148
Correction/deletion trade name	49.200
Cease product on market	41.325
Change in product identifier	37.396
Other	37.093
Change in mixture classification	26.454
Correction of error	26.331

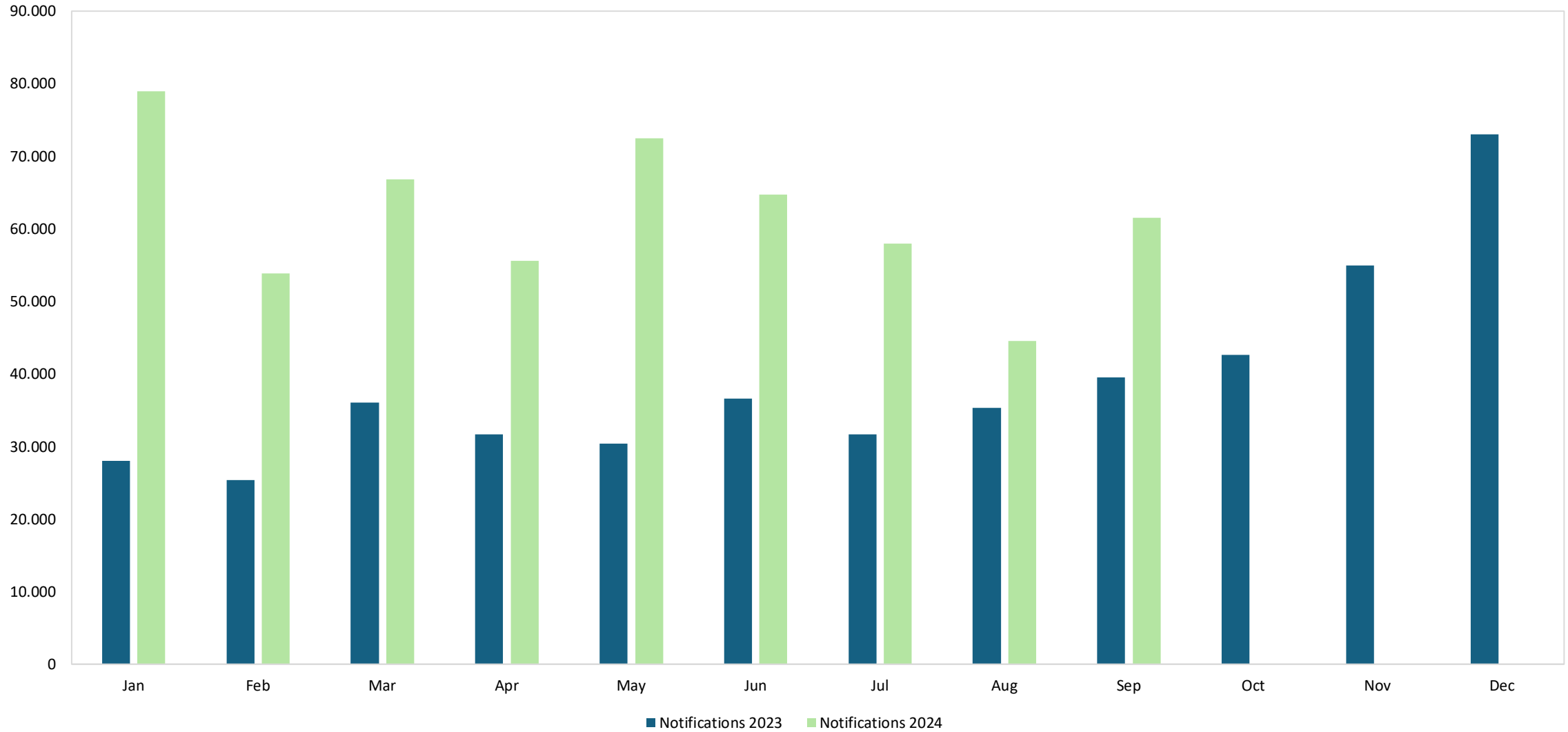
➤ **Submission status:**

Successful w/o warnings → **713.650**

Successful with warnings → **791.694**

Type of product	
PC-PNT	560.188
F	302.666
PC-TER	228.384
PC-INK	83.932
<b>PC-CLN</b>	<b>67.527</b>
<b>PC-AIR</b>	<b>42.219</b>
PC-ADH	40.572
PC-ELQ	36.711
PC-CON	25.522
PC-COL	24.778
PP	17.122
<b>PC-DET</b>	<b>16.486</b>
PC-FER	16.175

## 2023 versus 2024



## PC & AB: impact of Art.45 implementation

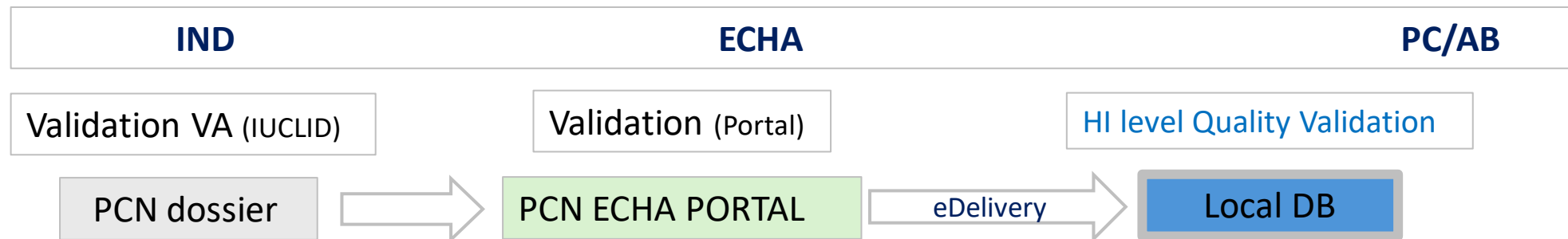
- Information received by the INTCF following implementation of Annex VIII (to be used by the PC):
  - The Spanish PC has not experienced a significant improvement, considering that the previous national notification procedure to the INTCF requested very similar (or even more stringent) information.
  - 
  - However, the introduction of the UFI identifier should/could represent a considerable advantage for the PC.
- Significant reduction of the support activity previously provided by the AB :
  - Basically, all the information on the tools of the harmonised notification procedure is currently provided by ECHA to the IND.
- 'Harmonized information' achieved by implementation of Annex VIII may favour future comprehensive 'harmonized' toxicovigilance among EU member states (regarding chemical products under annex VIII)

## PC & AB: impact of Art.45 implementation\_ major concerns

### ➤ Huge increase in number of submissions:

- Currently, of total 1,997,707 products in our db : approx. 400,000 were submitted by the previous national procedure along 10 yrs & 1,570,854 submitted since Jan 2021
- Currently, average of PCNs submitted per day : 5,000 (of which approx. 1,000 are INITIAL notifications)

**Complicates data management by the AB** (e.g.: hampers performing HI-quality validation in our local db)



- UFI: should be displayed in a differential & pre-determined “easy to spot” color in a restricted location on the label, preferentially close to the product trade name



Thank you for your attention