



Product Notification according to Article 45 Classification Labelling and Packaging in Ireland

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Ireland

Outline

- Article 45 CLP in Ireland: National Poisons Information Centre; who we are, what we do.
- Current Product Notification Process
- The Journey towards Jan 2021- Key resources
- Challenges
- Future Product Notification Process

Article 45 EU Regulation 1272/2008

“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.



Chemicals Act 2008 Amendment 2010

“(3) The following are competent authorities in the state for the purposes of the CLP regulation:

(a) the Authority,

(b) the minister for Agriculture, Fisheries and Food, in respect of pesticides

(c) Beaumont Hospital Board, for the purpose only of Article 45 of that Regulation.”



- Health and Safety Authority: Competent Authority
- Representation at EU, ECHA, OECD, and UN
- Liaise with Industry
- Enforcement role



Beaumont Hospital

- Large academic hospital
- Serves 290,000 people
- Designated Cancer Centre
- National Referral: Neurosurgery, Renal Transplant, Cochlear implantation.
- **National Poisons Information Centre**



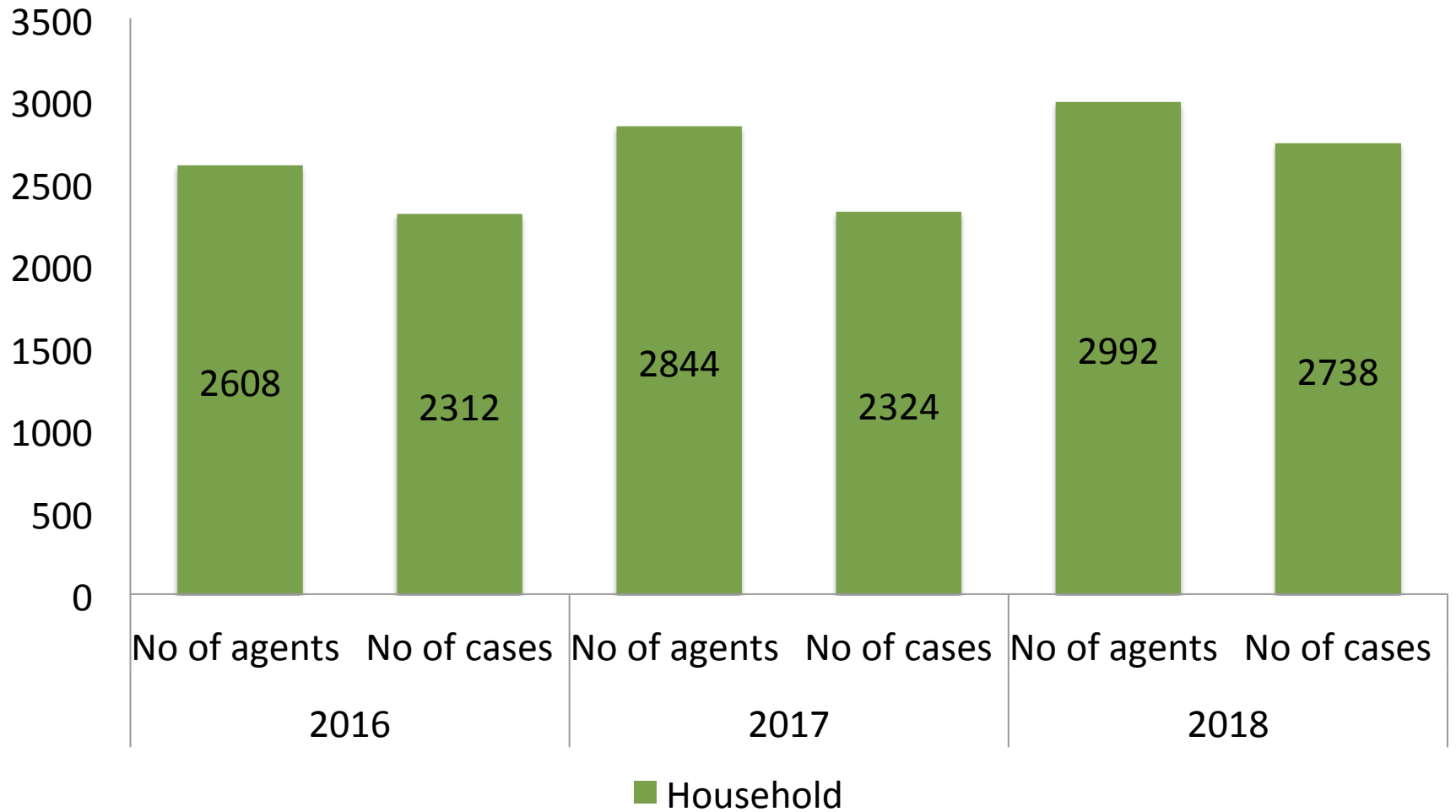


National Poisons Information Centre

- >10,000 calls/yr
- 4.5 WTE Poison Information Officers
Secretary, Manager & Director (PT)
- Provide information to assist in the
management of poisoning
- 8am - 10pm members of public & health
care professionals
- 10pm-8am: National Poison Information
Service in UK



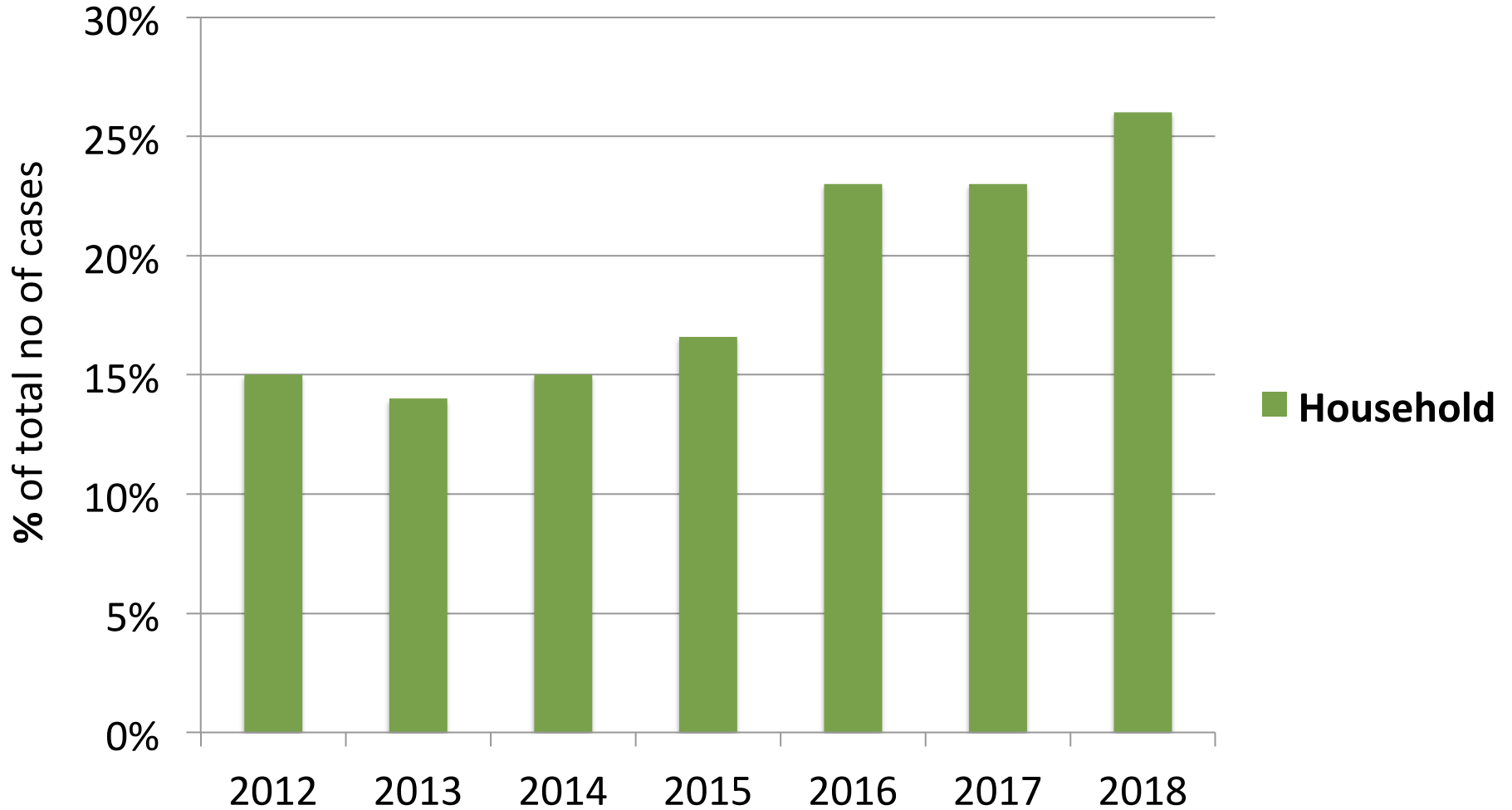
Enquiries concerning Household Chemicals



Household products: 76% of calls - 0-9yrs Industrial products 58% of calls – 0-9yrs

Household & Industrial calls

Household





INFORMATION CENTRE OF IRELAND

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Industry

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Call us if you think your child
has been **poisoned**

01 809 2166



8am -10pm
7 days a week

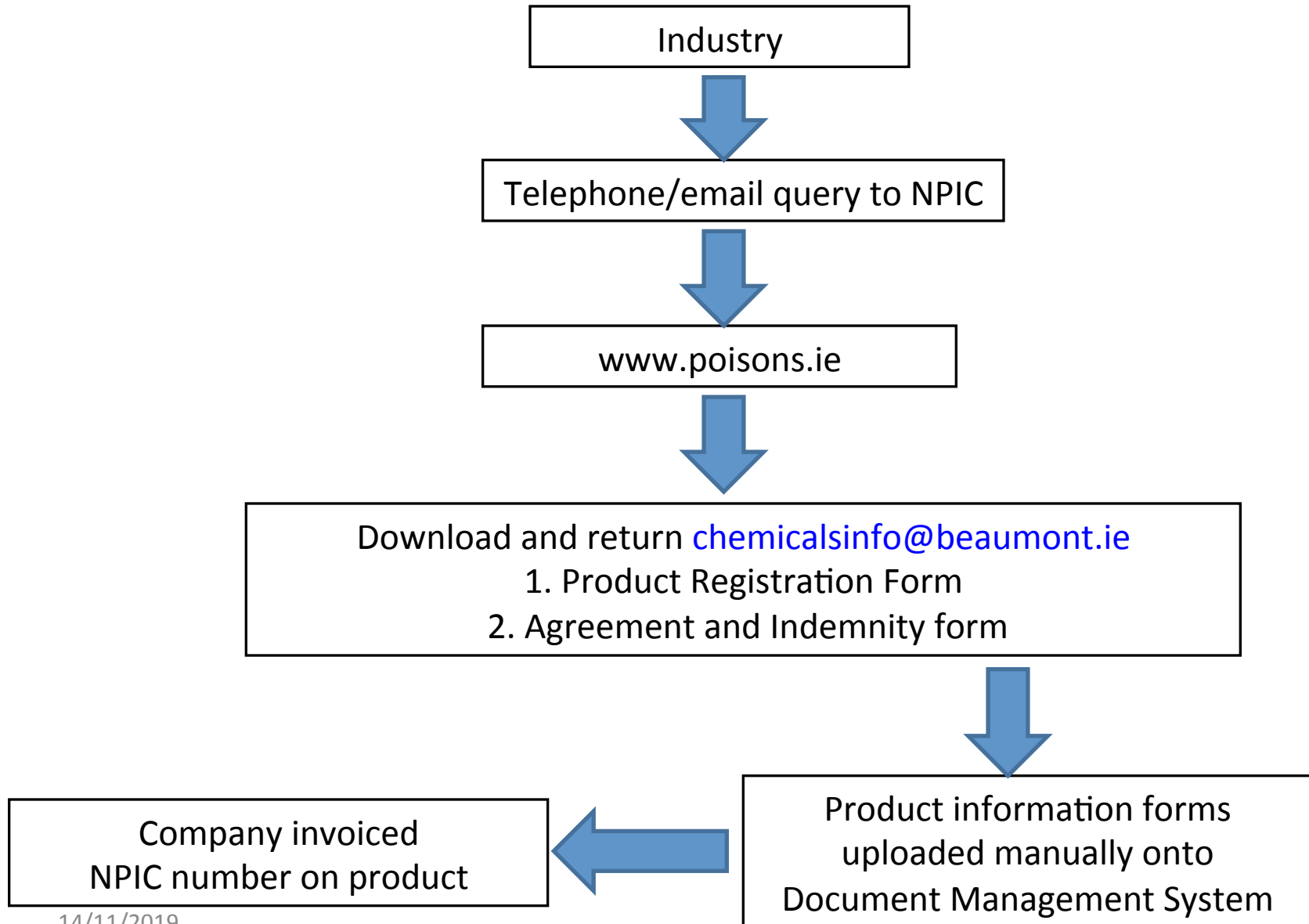


Healthcare
Professionals



Call us: 01 809 2566

Current Notification Process in Ireland



Product Notification Form

Trade name of product	Click here to enter text.
Type of submission	Choose an item.
Other names, synonyms	Click here to enter text.
Unique Formula Identifier (UFI)	Click here to enter text.

Other identifiers (e.g. PCS number, company product code)	Click here to enter text.
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Mixture components (list first components classified as hazardous)

Chemical Name or Trade Name of component if Mixture in Mixture (insert extra rows if needed)	Concentration (see Annex VIII for permitted ranges)	CAS number (where applicable)	EC number (where applicable)	UFI (for Mixture-in-Mixture only)
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
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Classification of the mixture and label elements (see https://pubchem.ncbi.nlm.nih.gov/ghs/#_atop for GHS codes)

Hazard class	Choose an item.
Hazard category	Choose an item.
Hazard pictogram code	Choose an item. Choose an item.
Signal word	Choose an item.
Hazard statement codes, including supplemental hazard information codes	Click here to enter text.
Precautionary statement codes	Click here to enter text.

Toxicological information: Description of the toxicity of the mixture or its components (as required in Section 11 of the Safety Data Sheet in accordance with Annex II to Regulation (EC) No 1907/2006)

[Click here to enter text.](#)

Additional information on the mixture

Colour	Click here to enter text.
pH (where applicable)	Click here to enter text.
Physical state	Click here to enter text.
Packaging (type and size)	Click here to enter text.
Intended use (see European product categorisation system at https://poisoncentres.echa.europa.eu/eu-product-categorisation-system)	Click here to enter text.
End-Use	Choose an item.

Contact details of submitter

Company Name	Click here to enter text.
Address	Click here to enter text.
Telephone no.	Click here to enter text.
Email address	Click here to enter text.
Contact Name	Click here to enter text.
Position	Click here to enter text.
Outside office hours telephone number (if limited submission)	Click here to enter text.

Contact details of importer or downstream user, if different from submitter

Company Name	Click here to enter text.
Address	Click here to enter text.
Telephone no.	Click here to enter text.
Email address	Click here to enter text.
Contact Name	Click here to enter text.
Position	Click here to enter text.
Date form completed	Click here to enter a date.

Return this form by e-mail to chemicalsinfo@beaumont.ie

Document Management System



Beaumont Hospital
Document Management System

Search Poisons



Advanced search

Home Administration Medical Nursing Executive Intranet Clinical Services Non-Clinical Services Wards Help Centre Directorates

You are here: BH dms » Poisons » MSDS Sheets

Add new item ...

Poisons

New Folder contents Edit Metadata Local roles Manage boxes Manage portlets Notifications Management Subscriptions

MSDS Sheets

Created by admin. Last modified 07/18/2005.

Unsorted

Objects: 1 - 20 of 289

Type	Title	Size	Date	Author	Status	Version
<input type="checkbox"/>	3M Science.	1 K	11/23/2018 11:36 AM	annettecooke	work	v-1 English
<input type="checkbox"/>	A. Narducci SPA [Welding Products]	1 K	08/24/2017 10:24 AM	annettecooke	work	v-1 English
<input type="checkbox"/>	ABC ABRASIVES	1 K	07/03/2018 12:50 PM	annettecooke	work	v-1 English
<input type="checkbox"/>	ABCON Industrial Products	1 K	08/10/2017 03:56 PM	annettecooke	work	v-1 English
<input type="checkbox"/>	Ackerman Group PLC	1 K	07/06/2010 10:20 AM	annettecooke	work	v-1 English
<input type="checkbox"/>	ADVANCED ENGINEERING	1 K	05/10/2019 12:48 PM	annettecooke	work	v-1 English
<input type="checkbox"/>	Advanced Engineering Ltd	1 K	08/13/2014 02:02 PM	johnherbert	work	v-1 English
<input type="checkbox"/>	AGFA Graphics	1 K	02/22/2018 01:10 PM	annettecooke	work	v-1 English
<input type="checkbox"/>	Air Products and Chemicals Inc.	1 K	06/09/2015 12:27 PM	annettecooke	work	v-1 English
<input type="checkbox"/>	AIREDALE Chemicals	1 K	11/22/2017 02:37 PM	annettecooke	work	v-1 English
<input type="checkbox"/>	AKZONOBEL	1 K	05/08/2019 09:51 AM	admin	work	v-1 English

289 company folders: 39,000 products on the DMS

DMS log-in screen

Beaumont Hospital
Document Management System

Search the DMS [Advanced search](#)

[Home](#) | [Administration](#) | [Medical](#) | [Nursing](#) | [Executive](#) | [Intranet](#) | [Clinical Services](#) | [Non-Clinical Services](#) | [Wards](#) | [Help Centre](#) | [Directorates](#)

Name

Password

[Forgot your password?](#)

User name

Password

Remember my name

Setting the 'Remember my name' option will set a cookie with your user name, so that when you next log in, your user name will already be filled in for you.
Having trouble logging in? Make sure to enable cookies in your web browser.
help_user_name_password_unknown_lost /dms/account_lost_password_form
Don't forget to logout or exit your browser when you're done.

Hospital Document Management system

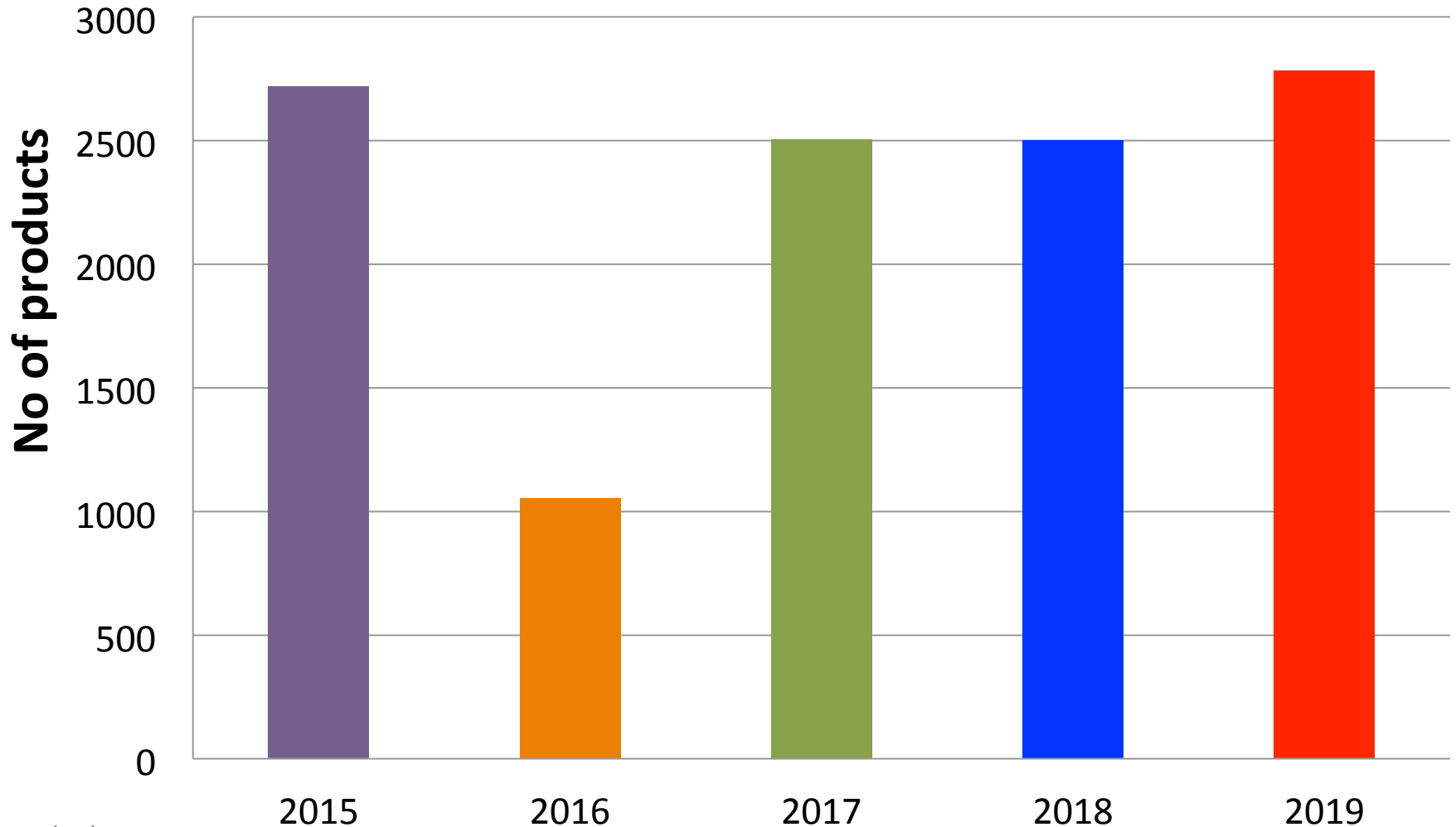
NPIC folder: only accessible by NPIC staff

User Administrator

Searchable Database (limited)

Cumbersome and resource intensive to upload documents

Product Notifications to the NPIC



Article 45: The journey so far



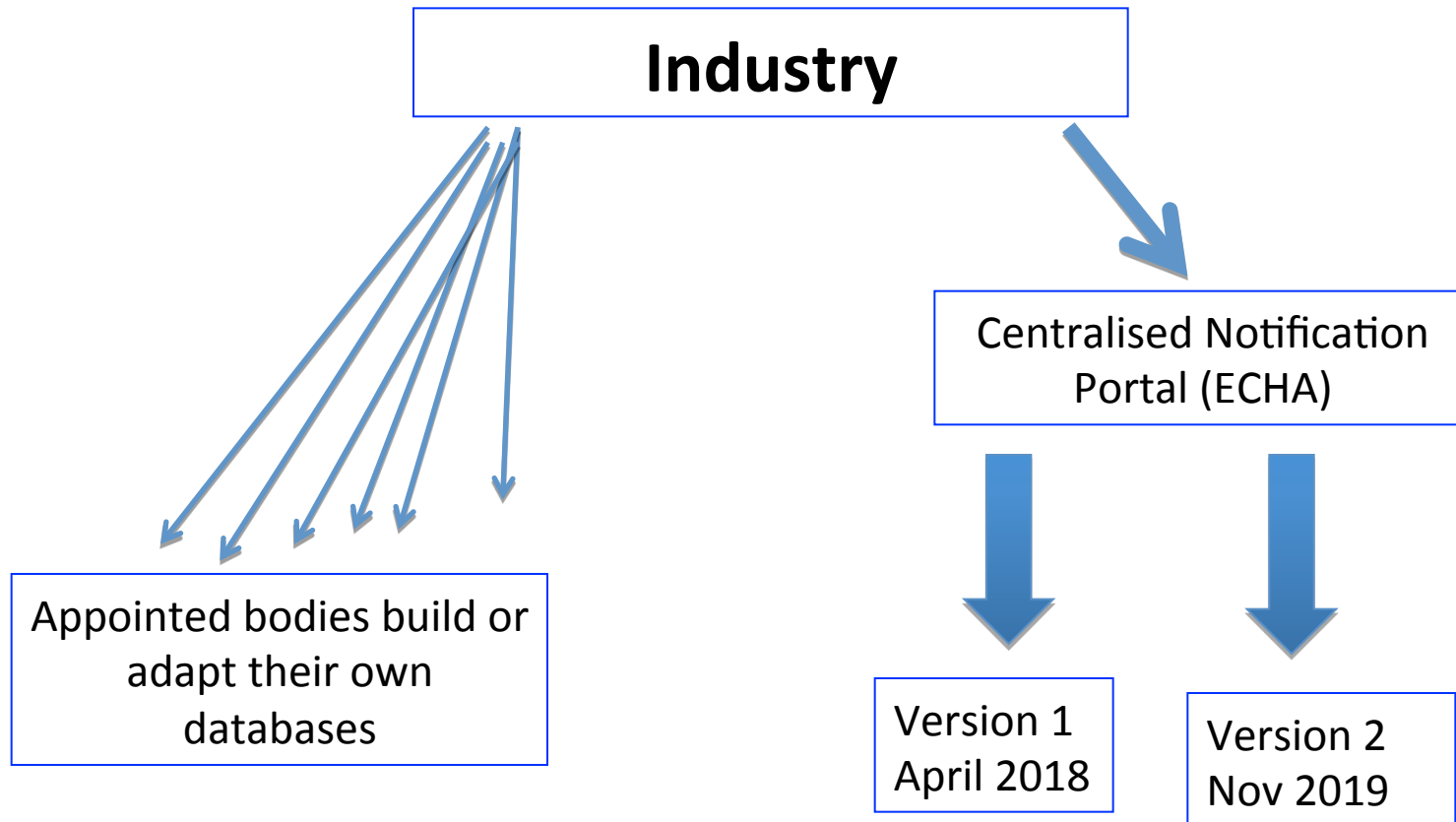
- 2008: 1 Whole Time Equivalent (WTE);
2019: 5 members 2 WTE
- EAPCCT- Representation PC Activities/European Regulatory WG -2012
- European Commission meetings: Harmonisation of PC information – 2013
- Webinar: provide guidance on Annex VIII to CLP.
- ECHA Poisons Centre database consultation process

➤ Participated in:

- a) “Study on harmonisation of information to be submitted to Poison centres, according to article 45 (4) of the regulation (E) No 1272/2008 (CLP regulation).” – undertaken for the EC by Amec Foster Wheeler and the National Chemical Emergency Centre UK.

- b) “Study on workability issues concerning the implementation of Annex VIII of Regulation EC No 1272/2008 on harmonised information relating to emergency health response and preventative measures”. Undertaken by EC by Wood.

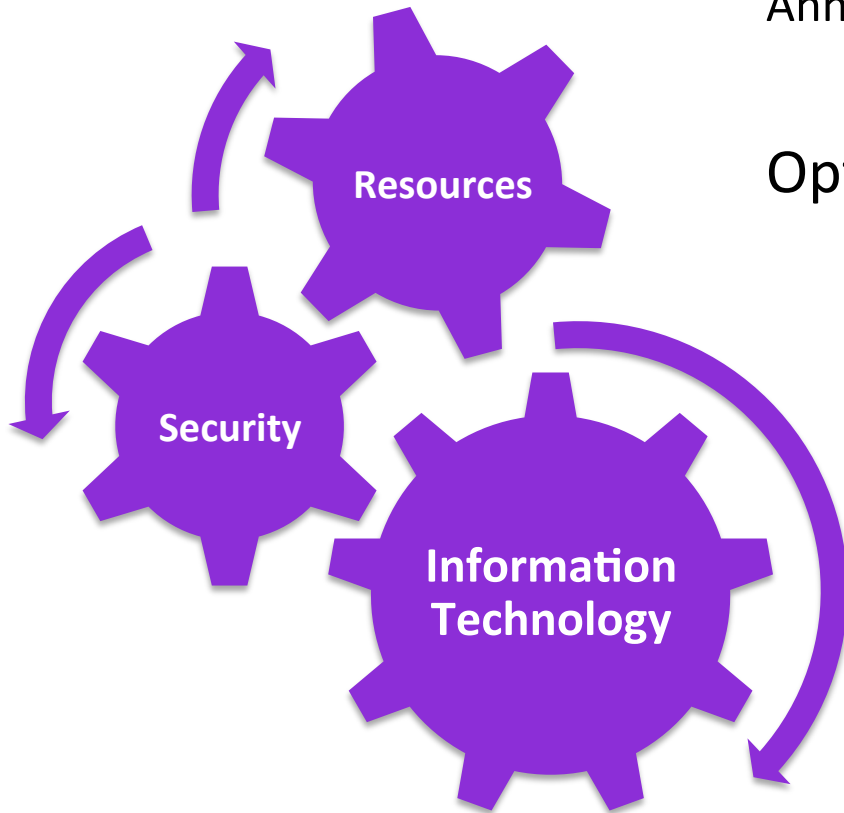
The options



NPIC and Article 45 CLP

Information Technology

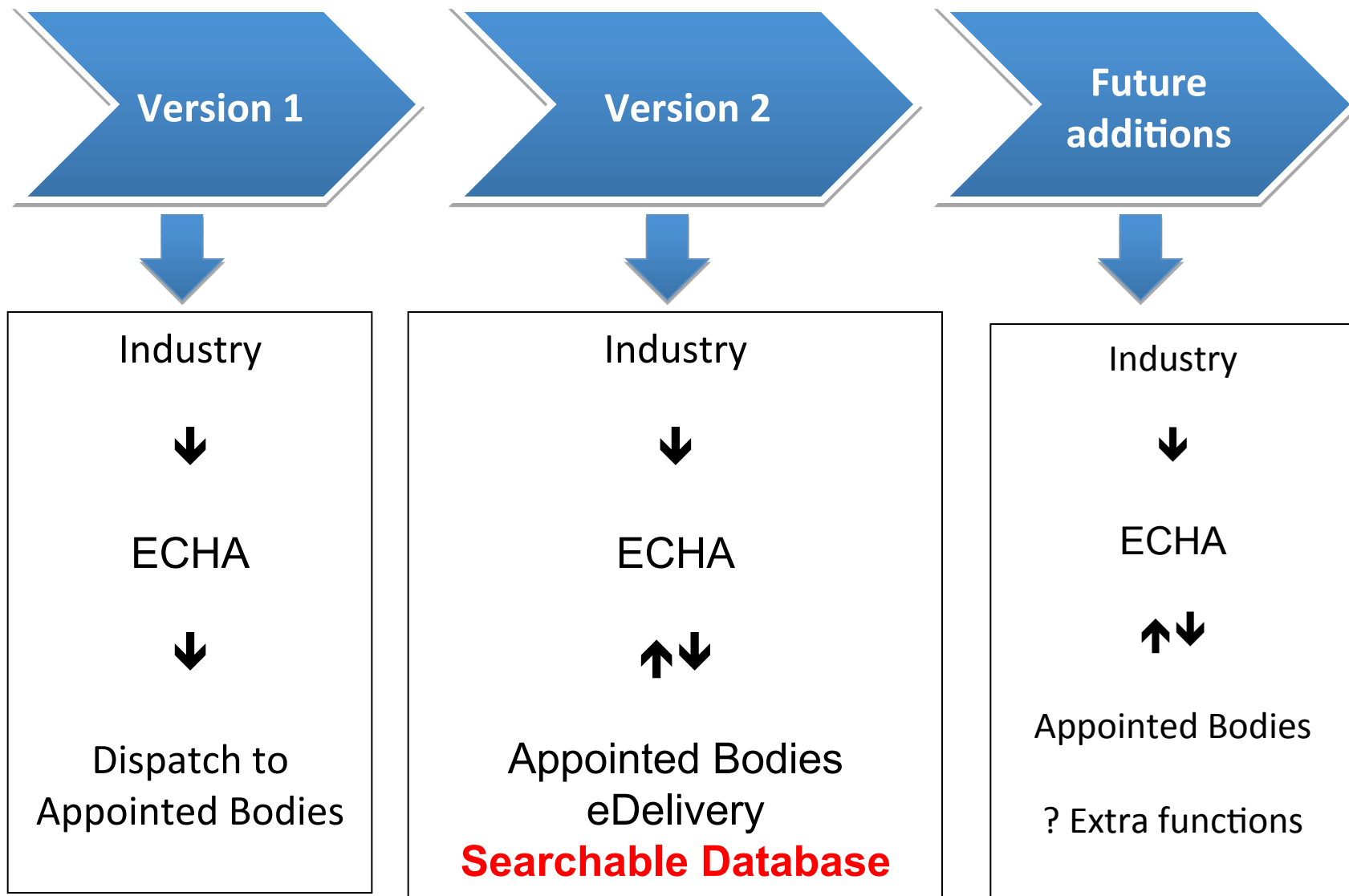
Harmonised information: XML format defined by Annex VIII of the CLP regulation

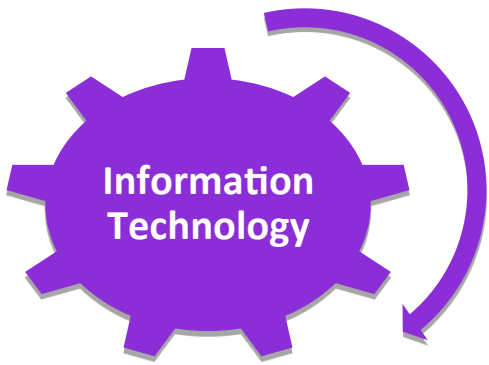


Options :

- Local IT Depart:
2015 (developing in-house IT platform)
- National
(2016 proposals mandate HSE: Office of the Chief Information officer)
- European:
ECHA Poisons Central Notification portal

ECHA Poisons Central Notification Portal





ECHA Version 1

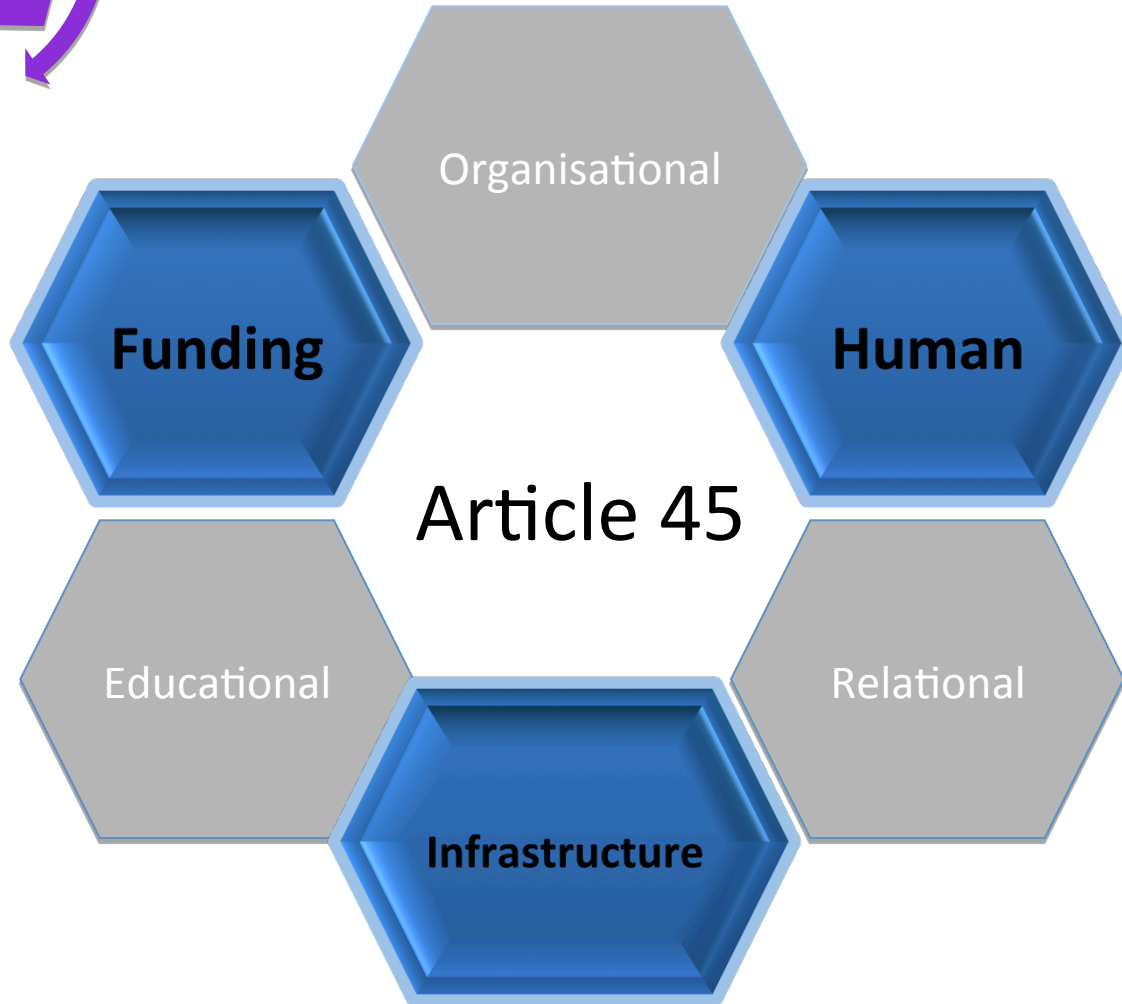
- Applied for version 1: April 2019
- ? Unsure if it was a requirement for Version 2 (available Oct/Nov 2019 - tight deadline)
- Unable to download notifications to xml format
- Short time frame (weeks)



- ECHA security requirements
- Legal Representative: Declaration of Commitment (security aspects)
- User Administrator: NPIC manager
- Security Officers Network: IT Department (Data Protection Officer)

Security Requirements

- ✓ Many in place due to hospital environment
- ✓ Automatic locking of computer screens
- ✓ Accountability of who is using/accessing the system
- ✓ Risk of malware infection mitigated
- ✓ Access from untrusted networks controlled.
- ✗ Two factor user authentication system in place



December 2018

Business Plan to prepare implementation of CLP Regulation

Poison Information Officers (PIO): role of user administrator (UA), annual audits, reports to the EC and awareness activity.

Notifications expected to ↑ 3 fold (30k – 100k)* with mandatory reporting

Estimated at least 3% of products audited per year (3k): 3 WTE

Requested funding for 1 poison information officer and 1 clerical officer

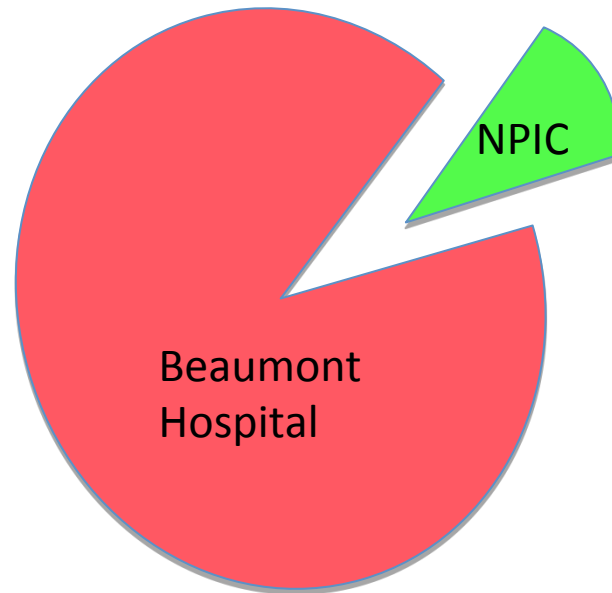
Staffing requirements to be resized with data after implementation of CLP

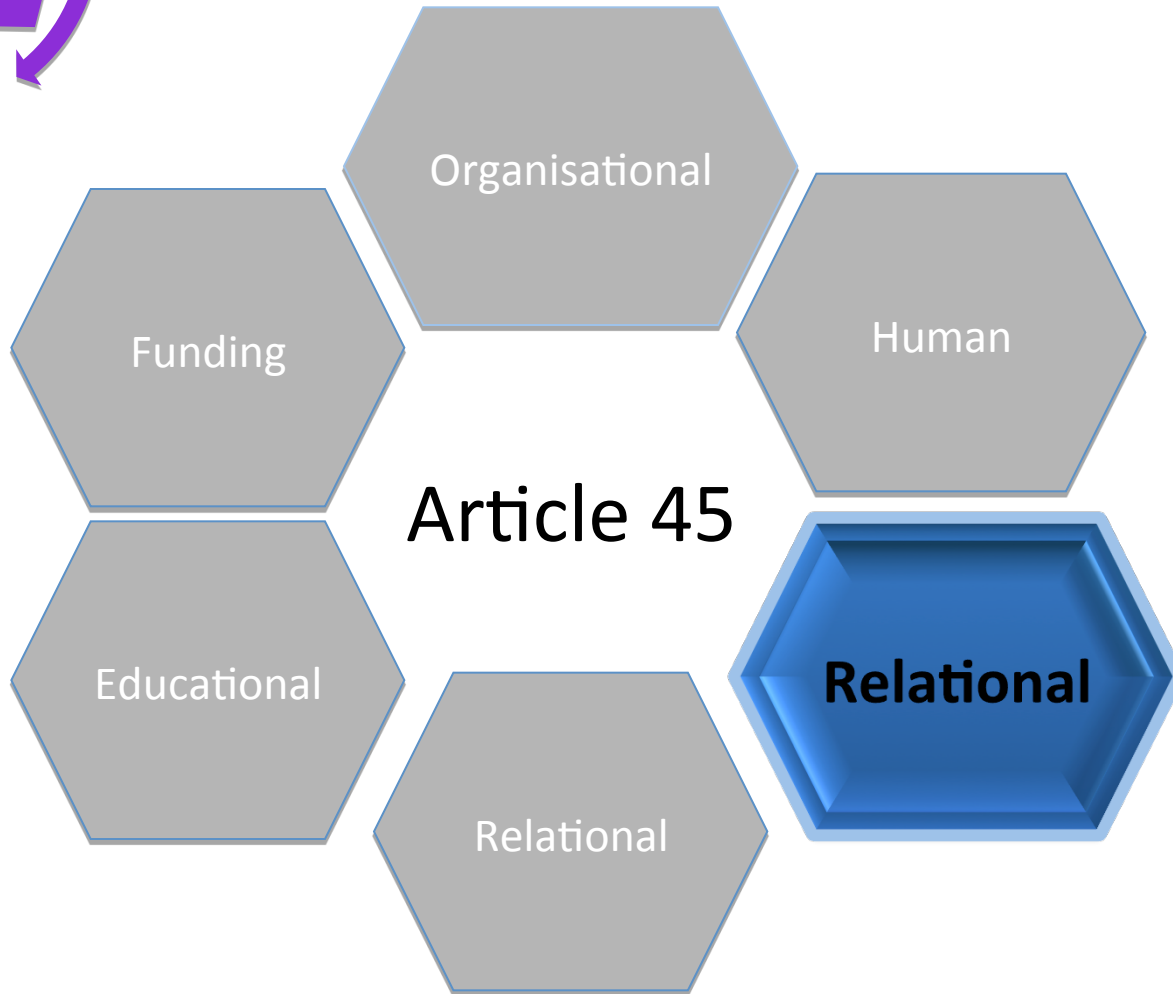
* Guesstimate as unknown how many hazardous products are placed on Irish market per year



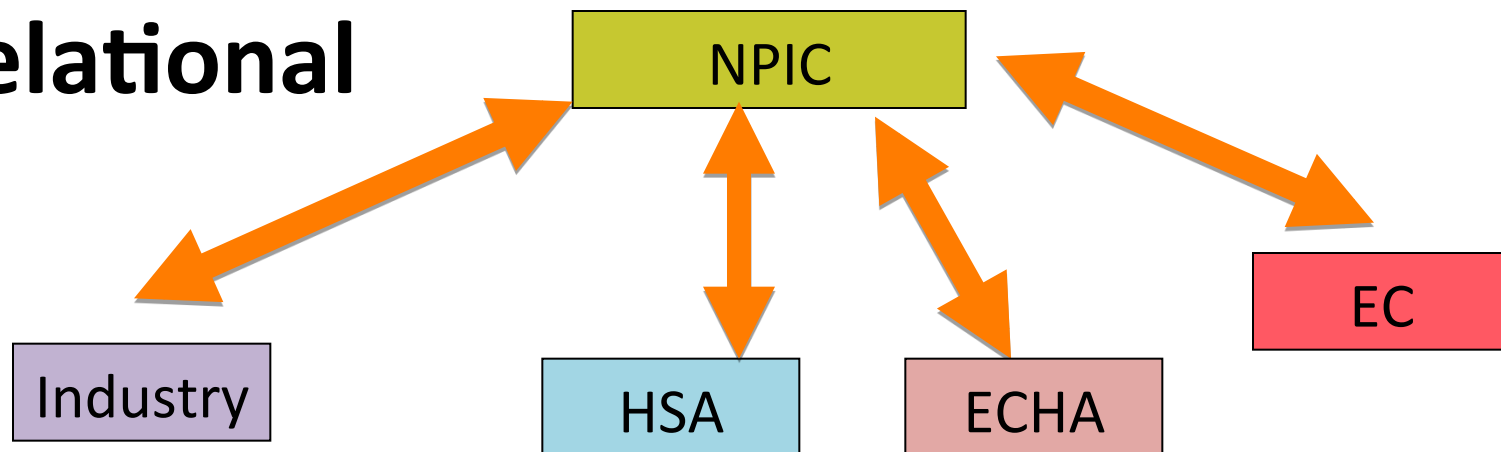
Organisational

- Clinical Governance Structure
- Policies and Procedures
- Data Protection: Confidentiality
- Security aspects
- Educational/Training





Relational



- Pre Jan 2021

- Information on website: update
- Participate in Workshops
- Service Level Agreement with HSA re enforcement
- ECHA requirements ? SLA

- Post Jan 2021

- Relationship with Industry
- Auditing (security/ notifications)
- Toxicosurveillance

Notification of hazardous chemical products to the National Poisons Information Centre in Ireland

Background: Importers and formulators of hazardous chemical products, placed on the Irish market, must notify certain information about the products to the National Poisons Information Centre (NPIC), Beaumont Hospital, as the responsible body appointed in Ireland for receipt of information in accordance with CLP Article 45(1). In addition, where the notified product requires a Safety Data Sheet (SDS), the importer or formulator must include the NPIC emergency telephone number in Section 1.4 of the SDS. This is explained in more detail below.

What chemicals products should be notified? A chemical product must be notified to the poisons centre in Ireland when all of the following conditions are met:

- ✓ **It is a mixture**, as defined by CLP Article 2(8)ⁱⁱ: ‘a mixture or solution composed of two or more substances’; and
- ✓ **It is classified as hazardous**, on the basis of its health or physical effects, as stated in CLP Article 45(1); and
- ✓ **It is placed on the Irish market.** CLP Article 2(18) defines ‘placing on the market’ as ‘supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market.’

Who needs to notify? It is the importer of a chemical product (mixture) into the EU or the formulator of a chemical product within the EU, placing them on the Irish market that is responsible for notification to the poisons centre. Notwithstanding any contractual arrangements that a distributor may have with their importer or formulator, in accordance with CLP, a distributor has no direct role in the notification of a chemical product to a national poisons centre. The responsibility lies with the importer or downstream user (formulator), as set out in CLP Article 45. If in doubt, the distributor should make enquiries with their supplier to ensure the notification to the NPIC has been completed.

What information needs to be notified? The information requirements are set out on the NPIC website <http://www.poisons.ie/Manufacturers/Product-Registration>

Where is the notification sent to? The notifications should be sent directly to the NPIC at Beaumont Hospital. Tel: +353 1 8092566, email: chemicalsinfo@beaumont.ie website: www.poisons.ie

Will the information to poisons centres be harmonised? Yes it will; in accordance with CLP Article 45(4), Annex VIII ‘harmonising information relating to emergency health response’ⁱⁱⁱ was added to CLP in March 2017. The legal obligation for submission using this new harmonised format does not apply until 2020; however, the draft Poisons Centre Notification (PCN) format and editor versions of the tools, along with Q&A’s are already available on the ECHA website, along with the Unique Formula Identifier (UFI) generator. Please note that the NPIC is not yet able to accept submissions in the harmonised format. Further information is available at <https://poisoncentres.echa.europa.eu/tools>.

Liasing with Industry

Website: Production Notifications, FAQ, links to ECHA website.

Communication once notifications are central?

Fee charged to companies: NPIC number on their products

Enforcement

Challenges

- Brexit: NPIS (UK) answers calls from Ireland at night
 - ECHA portal
 - Jurisdiction

- Emerging from a recession: Financial constraints
 - Poison Centre: remit Department of Health:
 - Chemicals Act: remit of Department of Business, Enterprise and Innovation

- Enforcement: NPIC has no prior experience.

- No direct link our calls database to the ECHA database

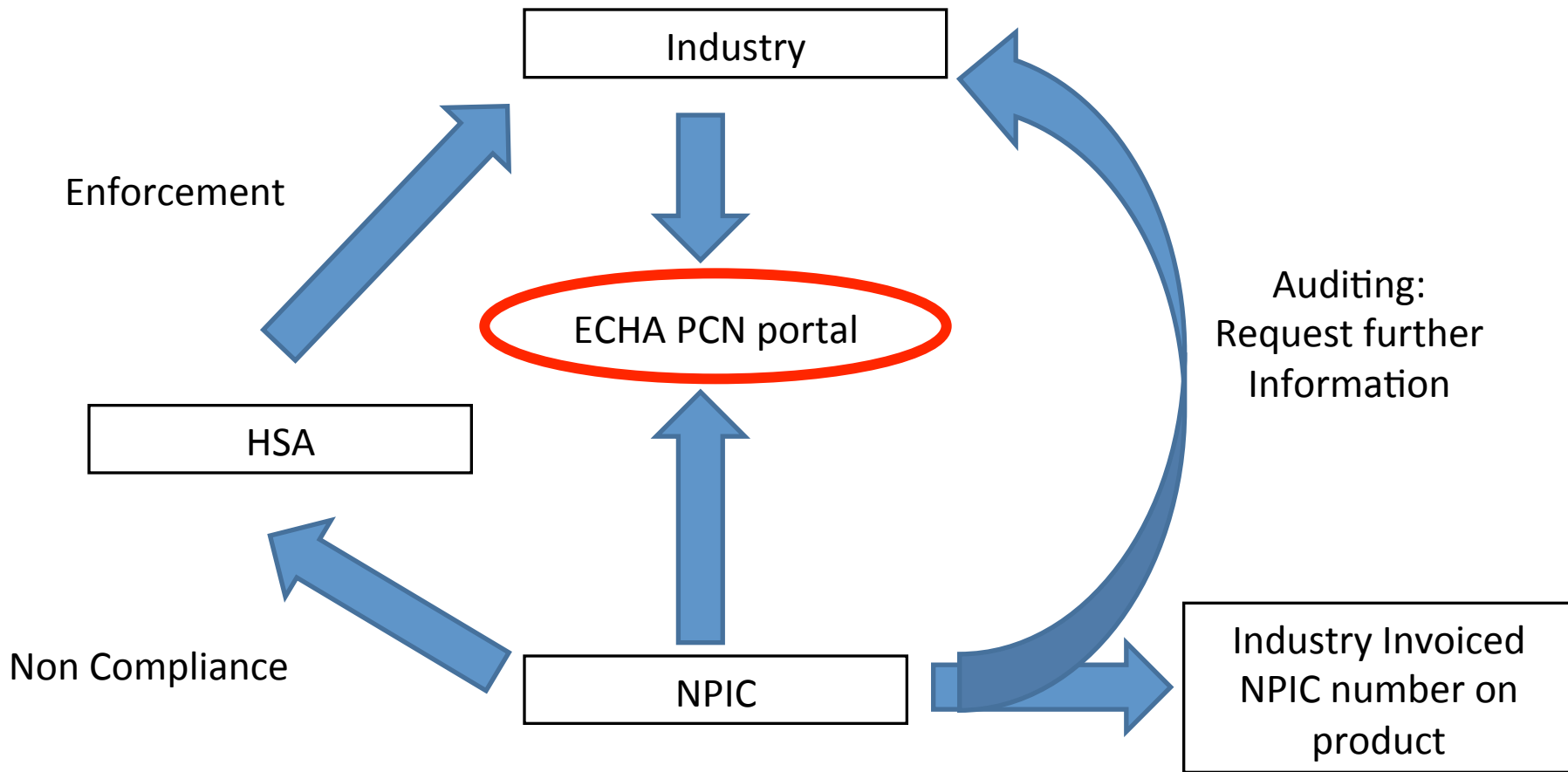
- Charge fee for using the NPIC number (no increase since it was introduced)



Advantages

- NPIC: Poison Centre & Appointed body for Article 45
- Hospital campus with IT Department/Security
- Close ties with the HSA, EAPCCT, other poison centres
- Low level of staff turnover
- Play a role in Toxicosurveillance

Future Notification Process in Ireland



Summary

- ECHA searchable database Version 2 (IT Department)
- Additional functions: Invoicing
- Security requirements: Internal & External Auditing
- Enforcement
- Strengthen relations with stakeholders
- Funding

Go raibh maith agat!



Acknowledgements: Staff of National Poisons Information Centre: Elaine Donohoe, Patricia Casey, John Herbert, Niamh English, Nicola Cassidy, Fergal O'Connor, Sinead Doyle.