

CMR substances on the EU market

The CMR Report 2014

**11th Seminar on workers'
protection & chemicals**

26th June 2015

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What's a CMR substance?

- **C**arcinogen, **M**utagen and/or **R**eproductive toxicant (development/fertility)
- Categories:
 - 1A – known human toxicant
 - 1B – presumed human toxicant
 - 2 – suspected human toxicant
- CMR substances should normally have a harmonised classification (Annex VI to CLP)
- 1A/1B substances:
 - Banned in consumer products
 - Excluded from PPP/BP products
 - Candidates for substitution (SVHC)



The C&L Inventory

Manufacturers/Importers are obliged to notify: (Art. 39)

- All hazardous substances (regardless of tonnage)
- All substances subject to REACH registration...

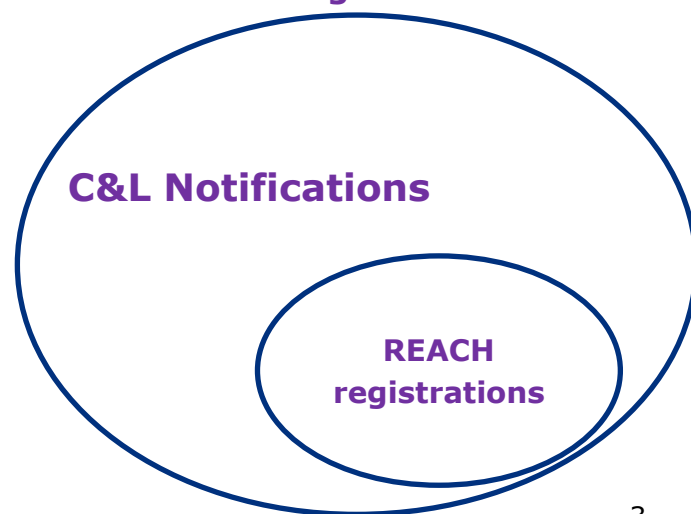
*...which are placed on the market,
whether on their own or in a mixture*

At time of analysis (May 2014):

- **6.2 million notifications** for
- **125.000 substances**



The C&L Inventory contains
REACH registrations...



The analysis...

Two main elements:

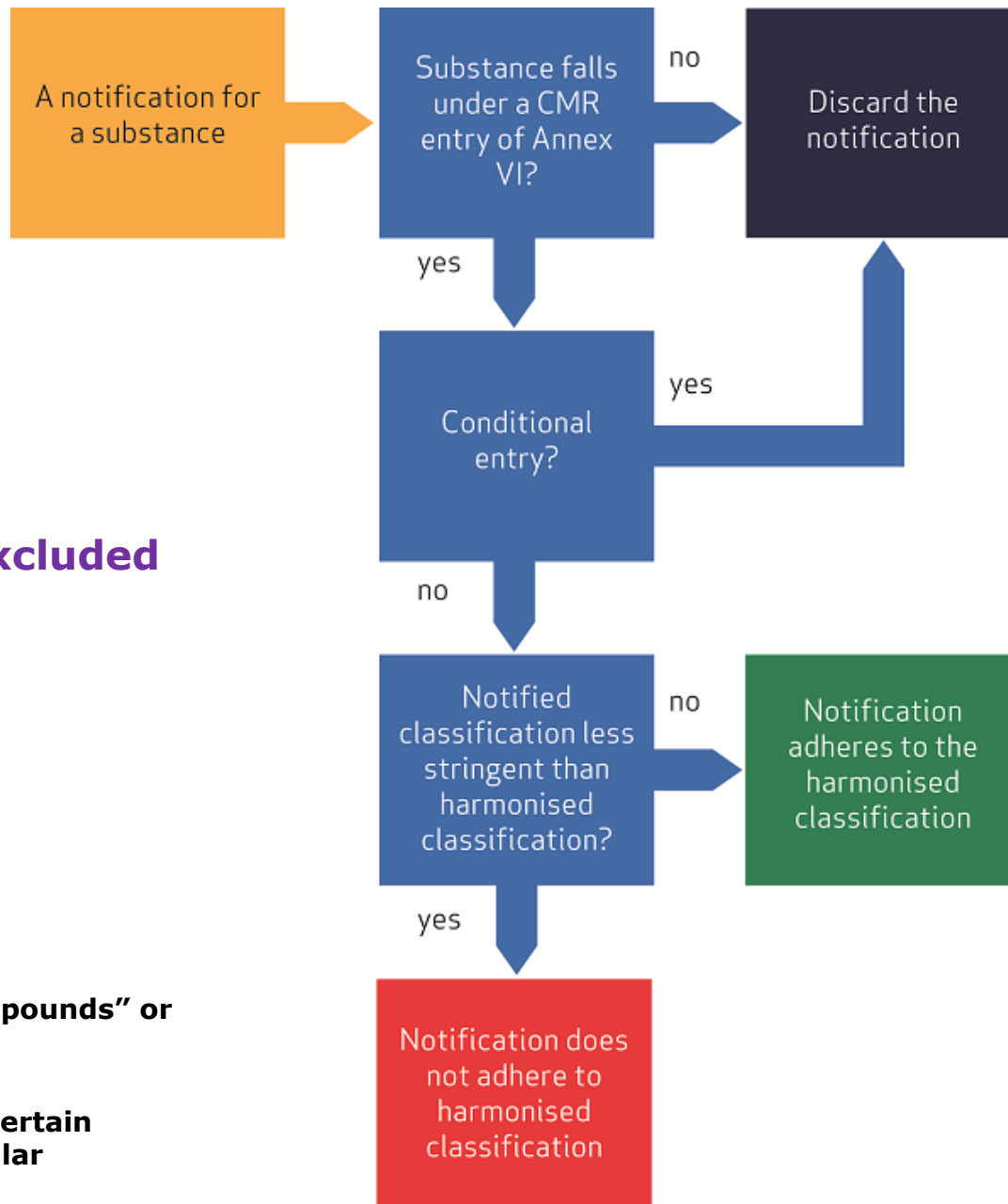
- How well do notifiers and registrants adhere to the harmonised CMR classification?
 - **“the old ones”**
- Are there CMR substances on the market which would need regulatory action?
 - **“the new ones”**

The old ones

How many notifiers/registrants adhere to the harmonised CMR classification?

Are some substances more challenging than others?



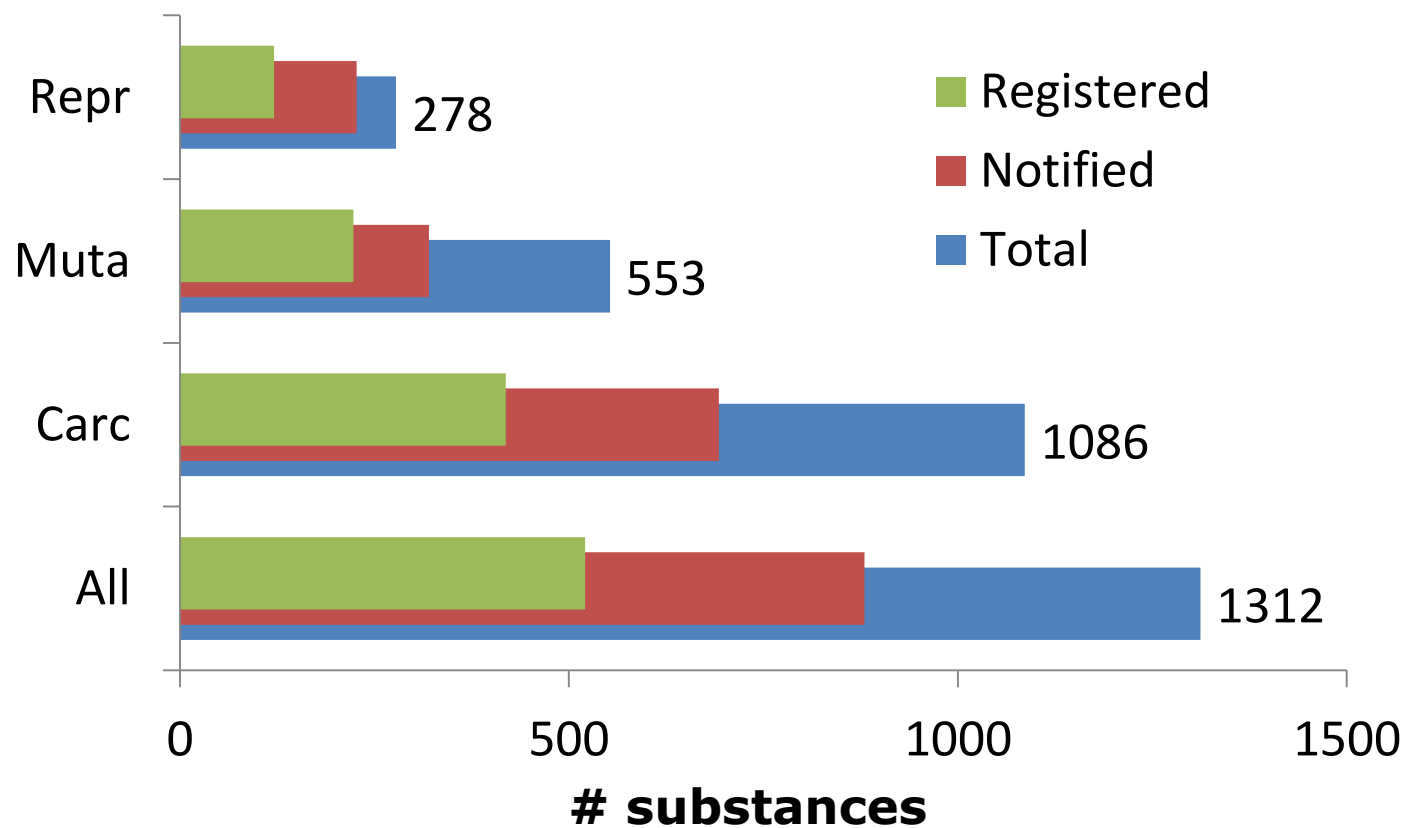


Group entries* included
Conditional entries excluded**

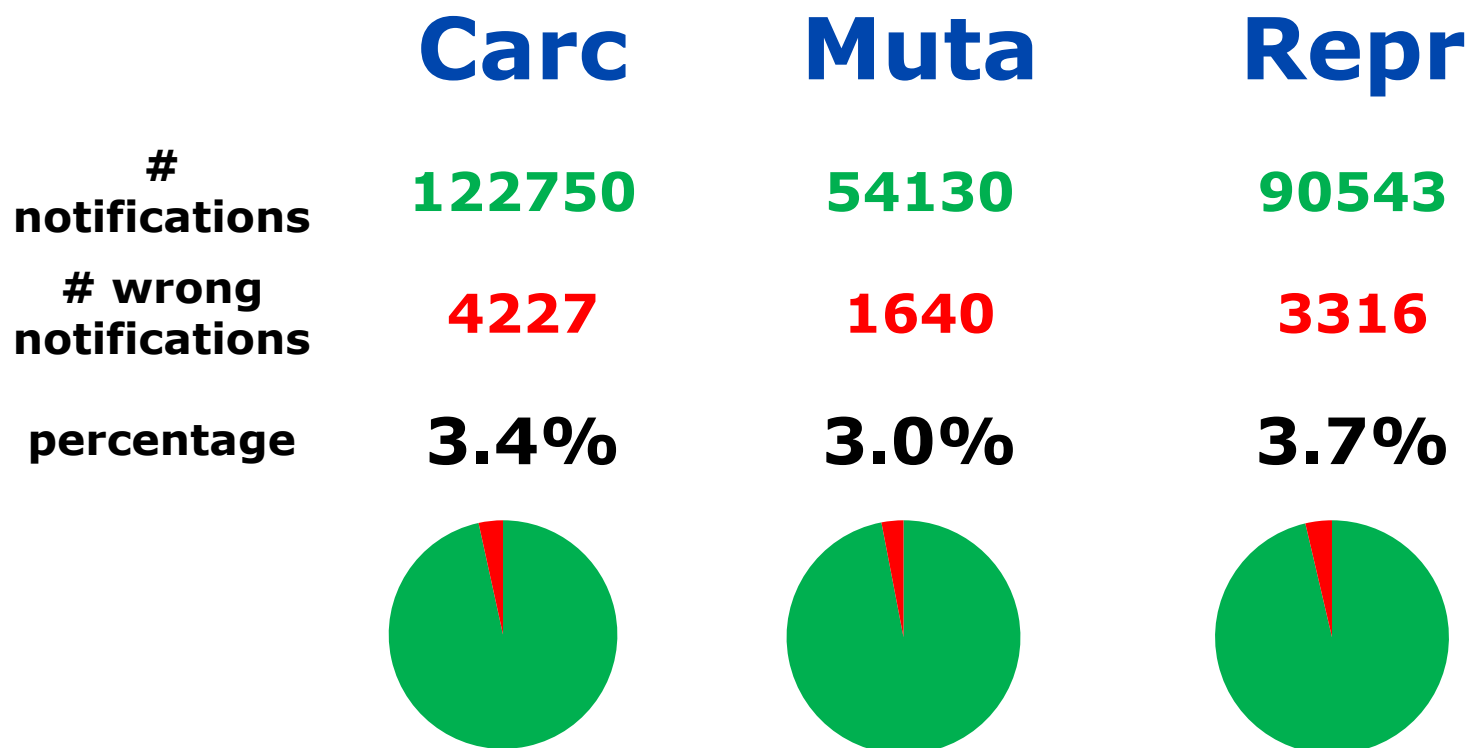
*** Open entries such as "Lead compounds" or "Arsenic acid and its salts"**

**** Entries that only apply under certain conditions such as when a particular constituent is present**

How many harmonised CMR entries have been notified/registered?

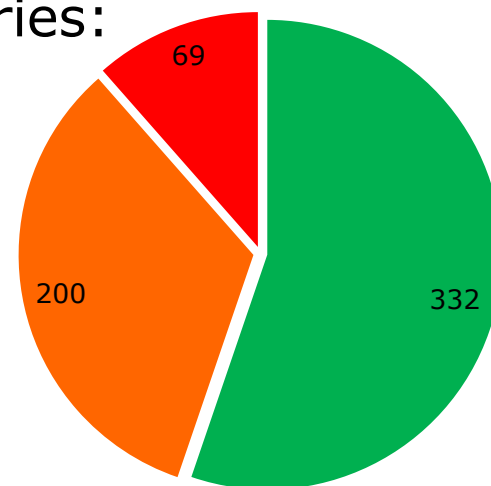


How many notifiers have got it wrong?



Where are the errors?

- Out of 601 notified non-conditional entries:
 - **332 – perfect**
 - **200 – some errors**
 - **69 - > 5% notifiers got it wrong**



Which entries stand out?

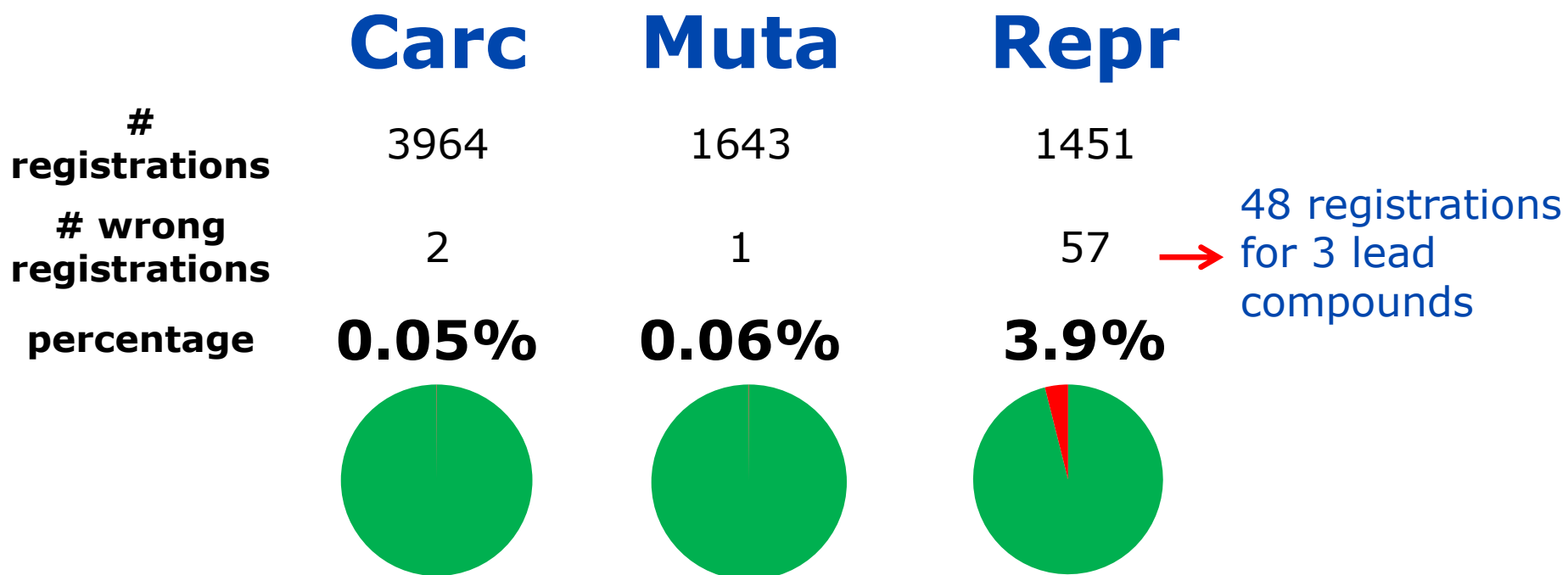
Total $69/601 = 11.5\%$

Group entries $7/22 = 31\%$

ATP03* $11/13 = 85\%$

* Third adaptation to technical progress.
Fully applicable as from December 2013

How many registrants have got it wrong?



10 substances affected
Usually only 1 registrant per substance got it wrong

Conclusions

- All in all, adherence with harmonised CMR classification very high, especially among registrants
- Group entries and recently harmonised substances remain challenging
 - All notifiers/registrants are alerted when a public consultation for a CLH proposal is launched for their substance
 - Long-term: Mapping of substances to group entries in the C&L Inventory?

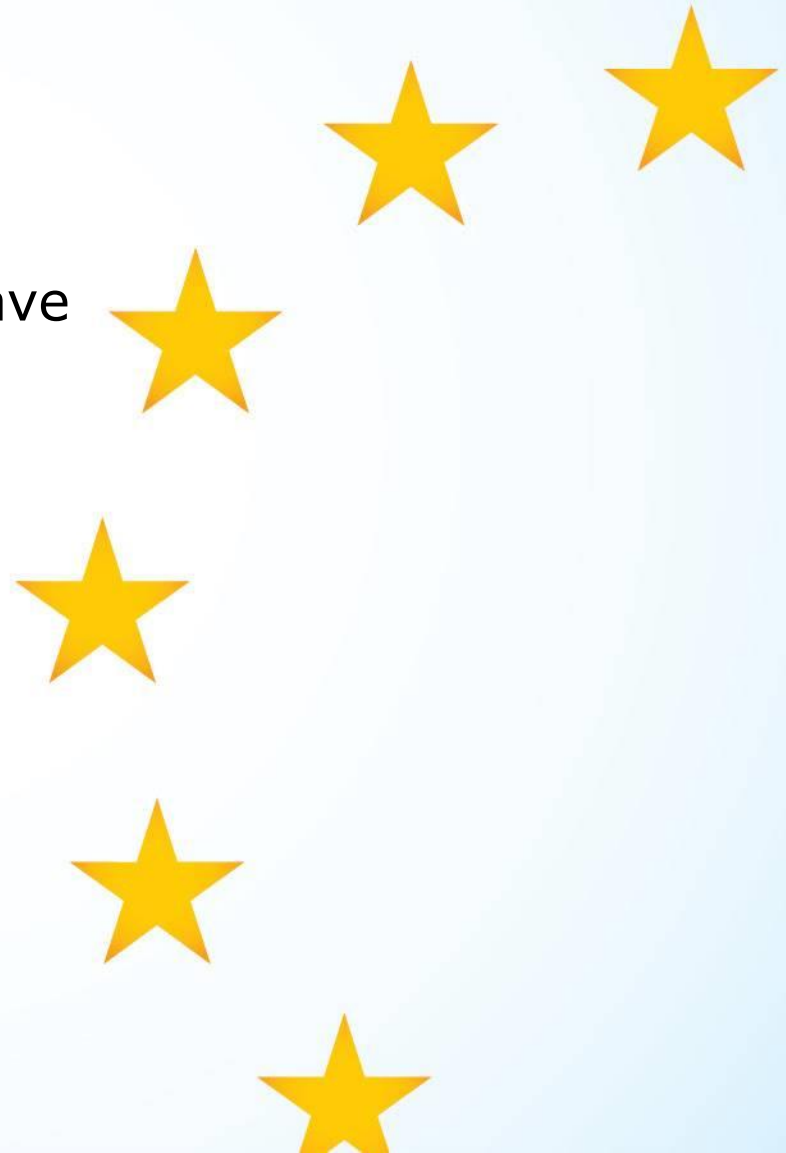
What to do with the bad apples...?

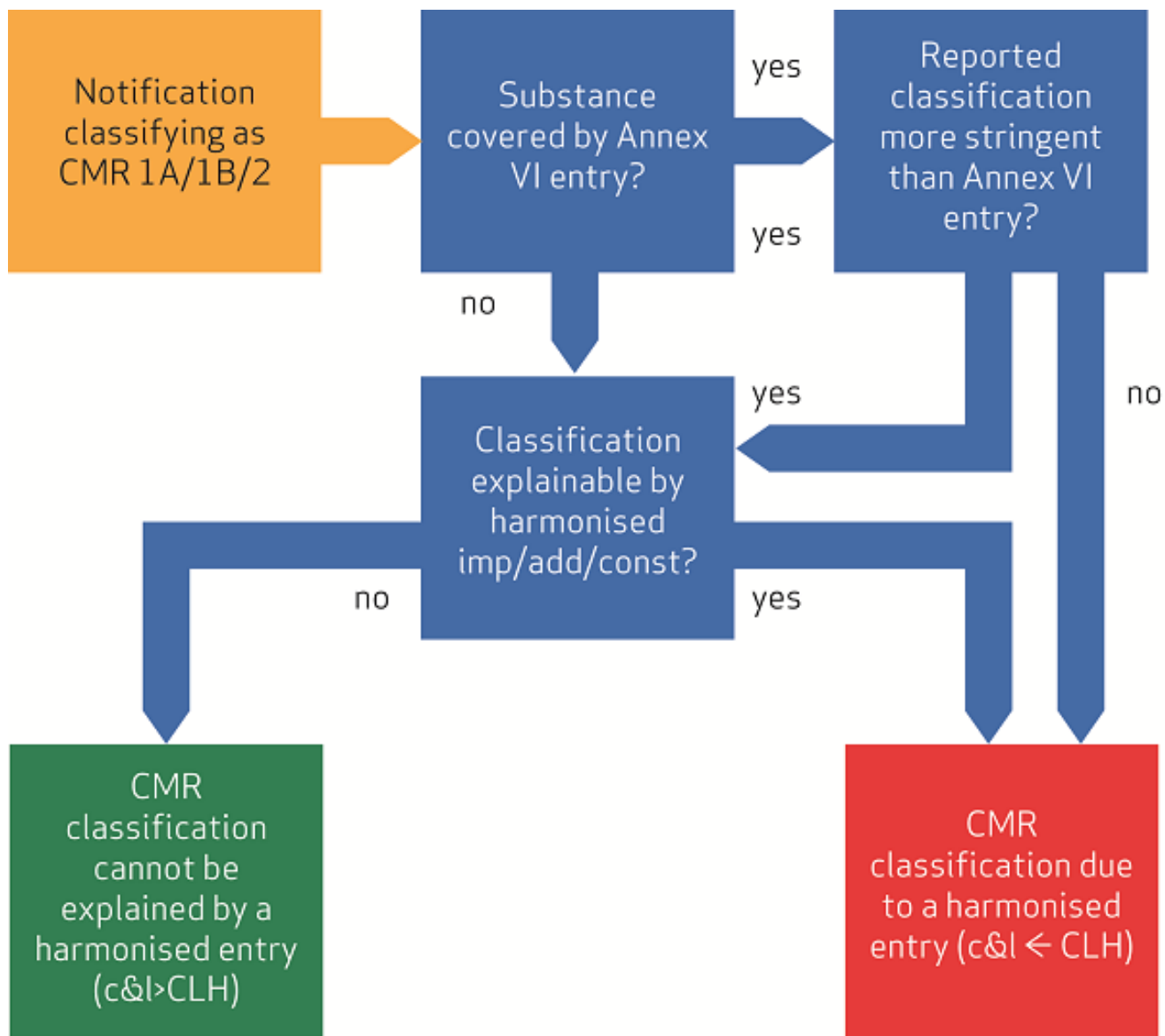
- **Registrations** not adhering to Annex VI:
 - Simple cases – collaboration with Forum to enforce classification
 - Complex cases – letters to companies asking for justification or clarification
- **Notifications** not adhering to Annex VI:
 - Difficult audience to reach
 - Selected substances targeted in pilot project between ECHA, COM and IND associations.

The new ones

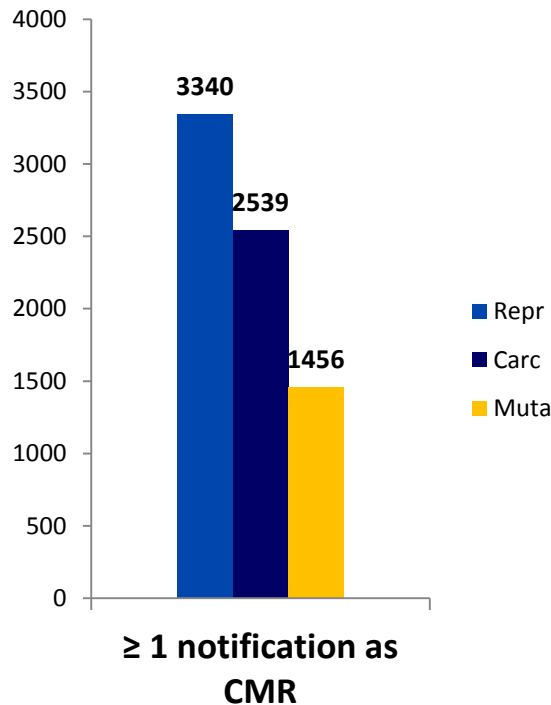
Can we find substances that should have a harmonised CMR classification?

How should we prioritise them for regulatory action?

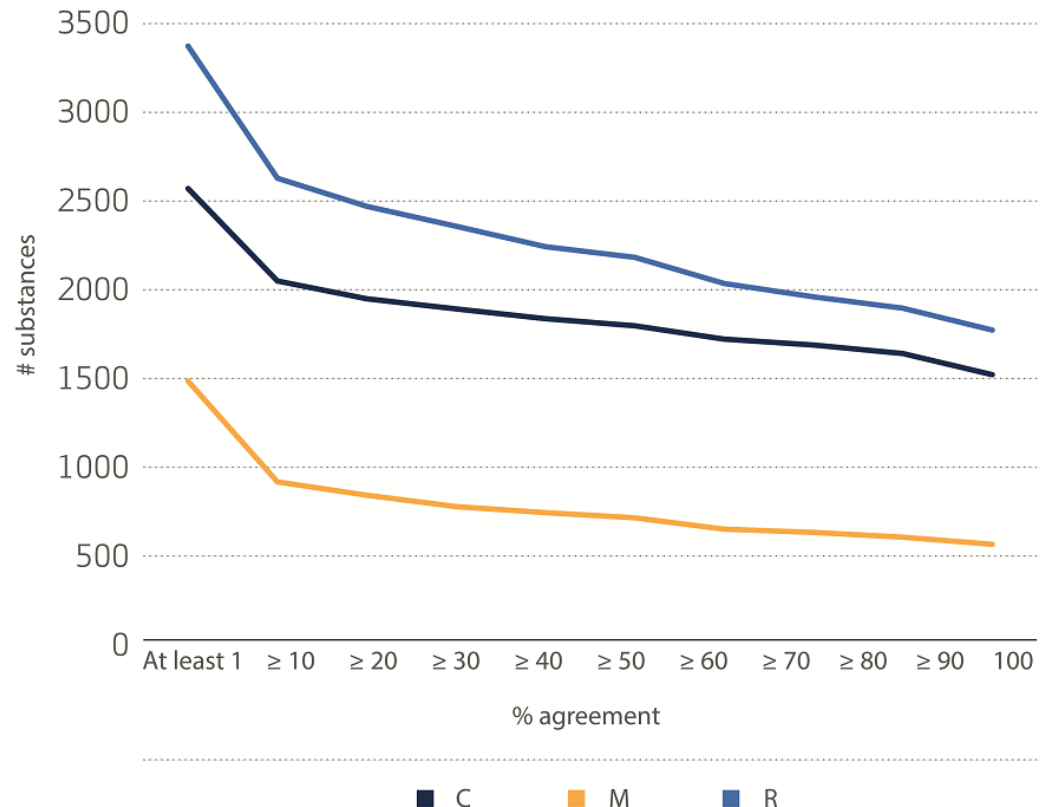




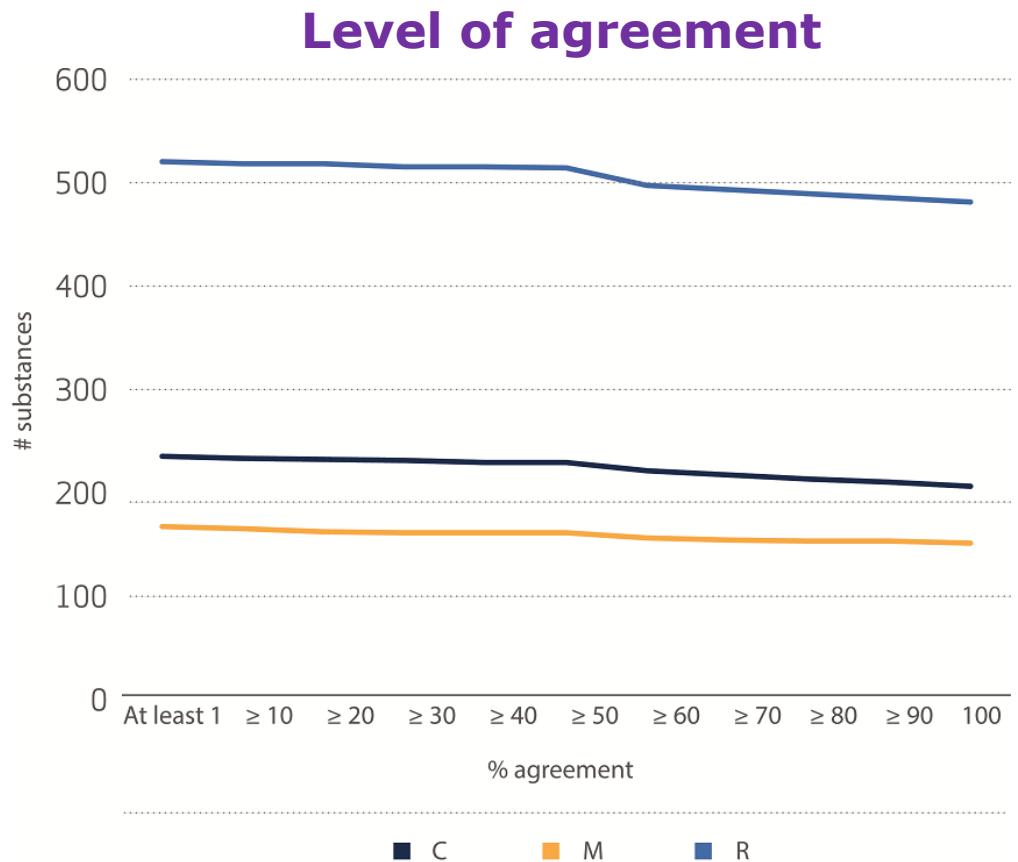
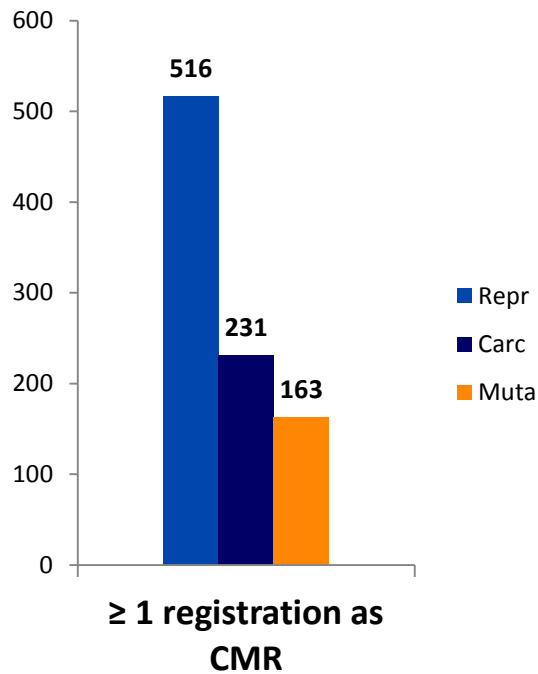
Out of the 125 thousand notified substances... ... 5675 are notified as new C, M and/or R



Level of agreement



Out of the 13 thousand registered substances... ... 707 are registered as new C, M and/or R



What next?

High number of substances of potential concern possibly warranting further regulatory action

We need to:

- Prioritise substances for action
- Verify whether there is a concern
- Decide on the appropriate regulatory action

 **The common screening approach**

Integrated screening of substances of concern

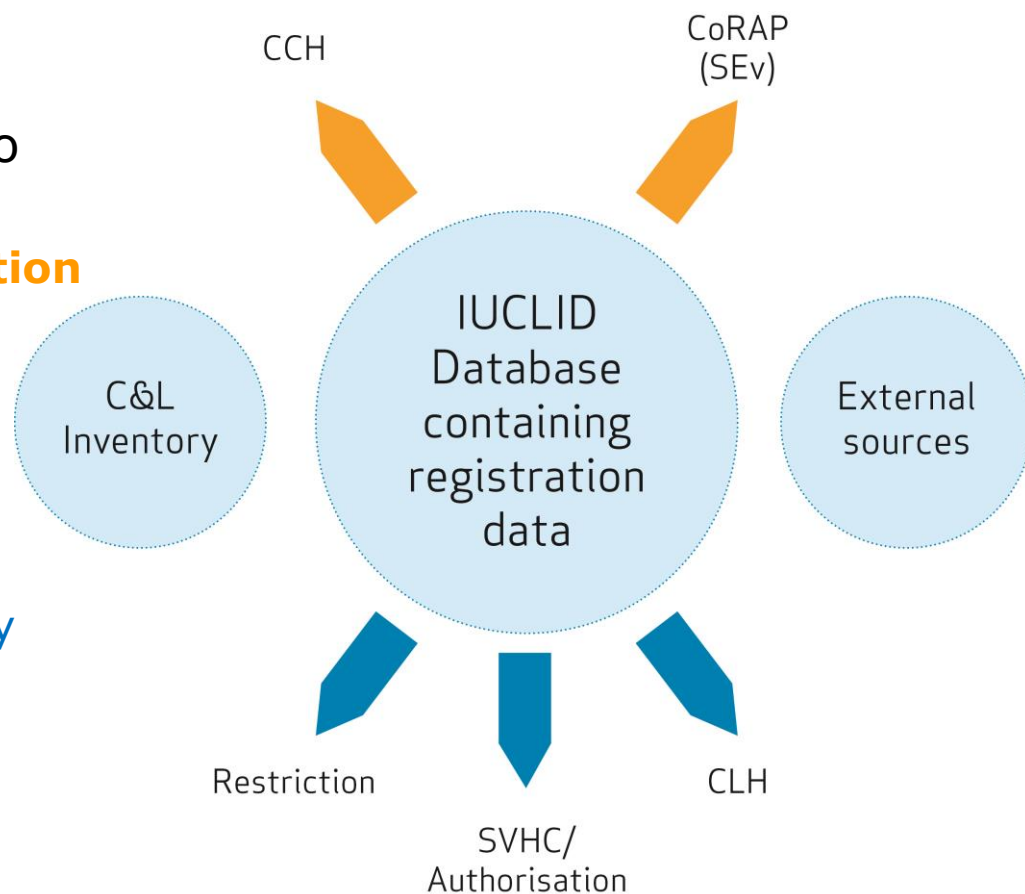
- Use of all available data
- Allocate identified substances to the appropriate process:

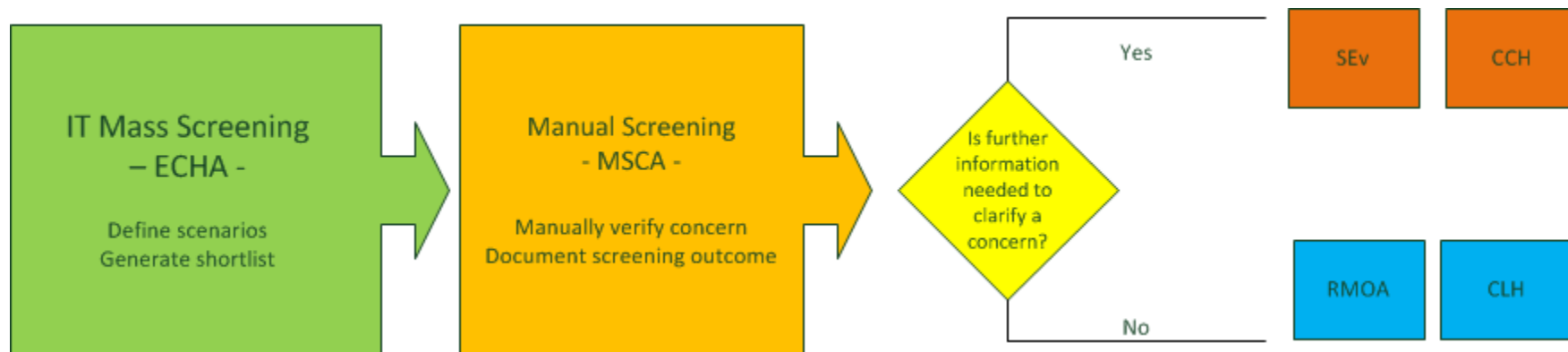
Generation of further information

- Substance evaluation (SEv)
- Compliance check (CCH)

Regulatory risk management

- Harmonised classification and labelling (CLH)
- Identification of SVHCs (possibly leading to Authorisation)
- Restriction





- Second year of common screening
 - Over 400 substances shortlisted for manual screening
 - For further information:
<http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screening>

Identification and prioritisation

Two-step approach

- Hazard identification
 - CMR, Sensitisation, STOT RE, ED, PBT, vPvB

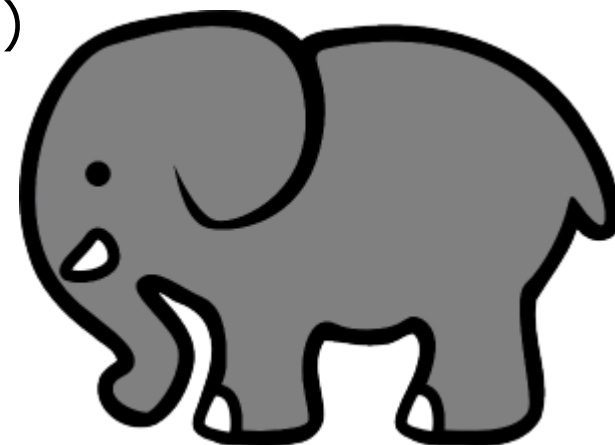
AND

- “Non-hazard” prioritisation primarily based on use and exposure information
 - **Widespread use** – used at many sites by many users, both professional and consumers – service life
 - **Wide dispersive use** – widespread uses with potential for exposure to humans or release to the environment

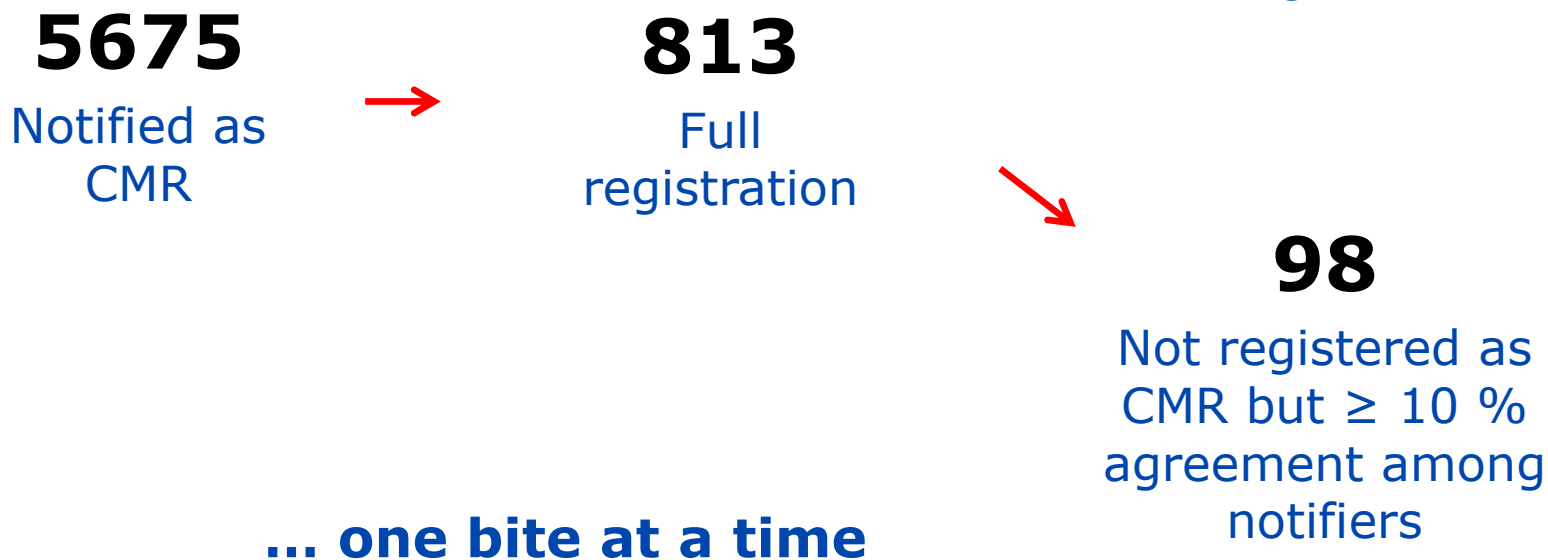
http://echa.europa.eu/documents/10162/19126370/screening_definition_document_en.pdf

How to prioritise the CMR substances?

- Further strengthening hazard concern
 - Classification in registrations
 - Agreement among notifiers
 - Structural alerts and external lists.
- Prioritise for action
 - Registration status (full/intermediate)
 - Widespread uses
 - Wide dispersive uses
- Group/type of substance?
 - E.g petroleum derived substances



Eating the elephant...



Conclusions

- Potentially hundreds of registered CMR substances warranting further attention
- ECHA and MSCAs are working on it in the common screening approach
- Registrants and notifiers are diligently self-classifying their substances

Thank you!

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