Brexit: Ongoing impacts on the label and SDS

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ChemUK 2023

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How divergence affects classification, labelling and the SDS

- Many thanks to Mick Goodwin for his talk
- This presentation will answer these questions (and more):
  - Should we use a single SDS format for our products, and if so, should it be in the EU format?
  - When is it OK to use a single label for EU, GB and NI?
  - Can we put EU-REACH registration information on the GB-SDS?
  - How do we deal with substances which hold an HCL which is different to an MCL
- Ready? There's a lot of ground to cover

Divergence today

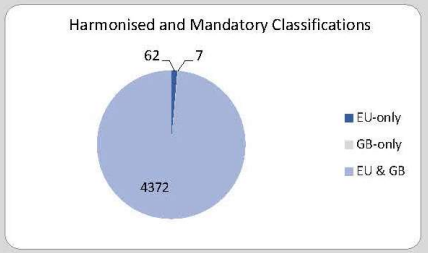
How does all of this actually affect my labels and SDSs?

- Harmonised vs mandatory classifications
- Restrictions
- SVHCs
- Authorised substances

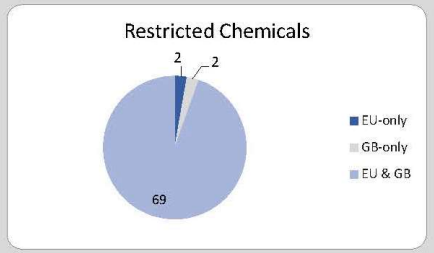
Let's start with the easy bit - labelling

CLP Mastery: Chemical Designations Divergence Dashboard

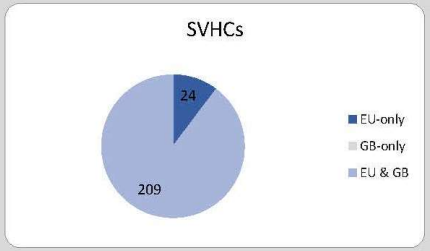
Date last checked: 13th April 2023



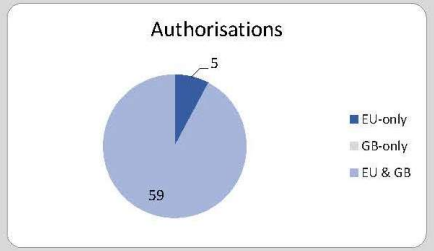
Noted Dates	EU HCs	GB MCs	Comments
22-Dec-2022	4334	4317	17th ATP to CLP (22
28-Oct-2022	4372	4317	18th ATP to CLP
13-Apr-2023	4372	4317	



Noted Dates	Restrictions	Restrictions	Comments
31-Dec-2020	71	71	Brexit
26-Jan-2021	69	71	Extension to Restriction no 63
29-Jan-2021	70	71	Substances in tattoo inks (Restriction no 75)
13-Apr-2023	71	71	EU only (#75, #76) GB Only (#22, #67)



Noted Dates	EU SVHCs	GB SVHCs	Comments
31-Dec-2020	209	209	Brexit
28-Oct-2022	224	209	N-(Hydroxymethyl)acrylamide
5-Jan-2023	224	209	
13-Apr-2023	233	209	0



Noted Dates	EU Authorised	GB Authorised	Comments
31-Dec-2020	54	54	Brexit
9-Jul-2021	54	54	
25-May-2022	59	54	EU adds 5 substances in April 2022
13-Apr-2023	59	54	

Labels covering EU, GB and NI

- Before 17th ATP CLP, this was relatively easy, as classifications of products were all the same; (and Authorisation Numbers were the same)
- Legal entity and address required for both jurisdictions (or Northern Ireland only for NIP-NOTs products)
- This still applies for products which are not affected by the 17th ATP to CLP changes:
  - Because they don't contain any affected substances
  - Or the substances are present in a mixture at concentrations which don't alter the classification and labelling information
- Remember - there are only 62 substances listed in 17th ATP to EU-CLP

Label information for dual EU&NI/GB

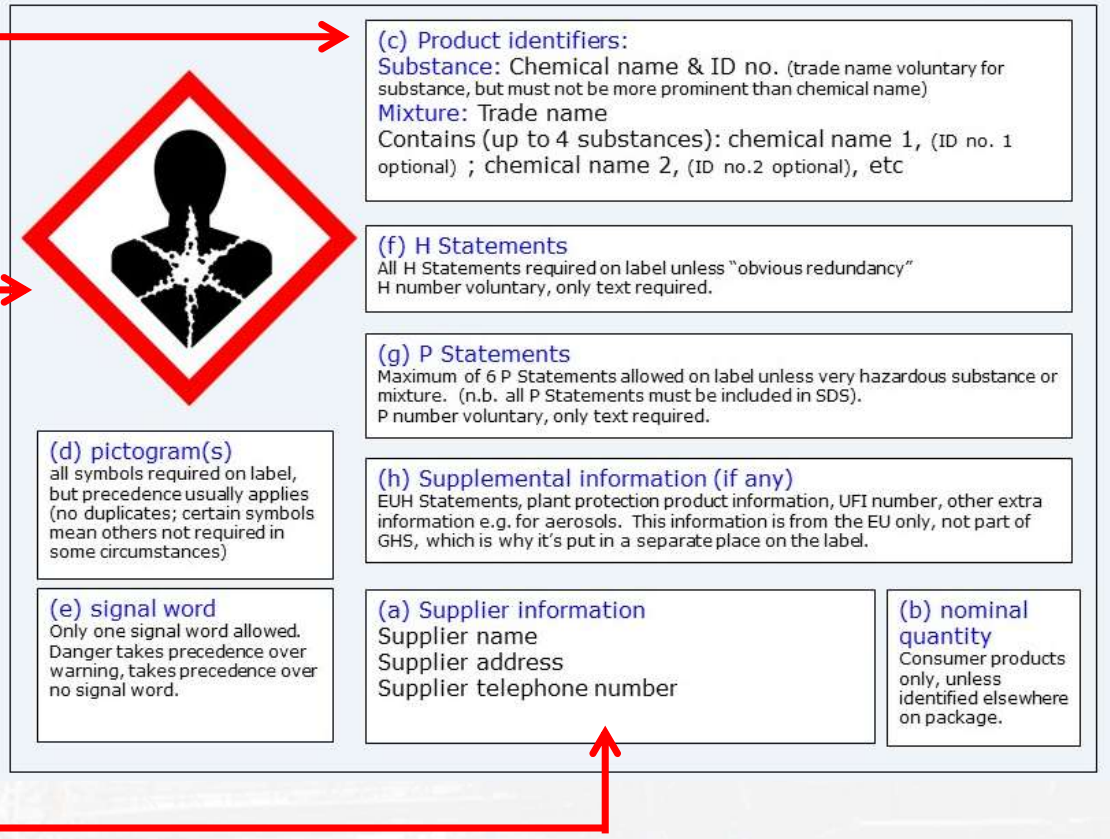
Identical product identifiers in all jurisdictions– substance name and ID number or mixture trade name and “contains” substances

Identical CLP label information in all jurisdictions – pictograms, signal word, H and P statements

Supplier name and address must be valid in both EU and GB:

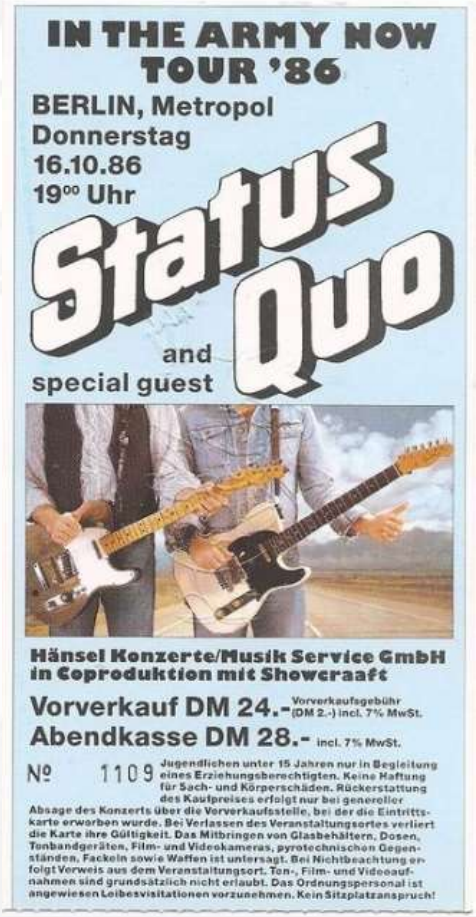
- NI legal entity and address (if NIP-NOTs applies in UK)
- EU and GB legal entities and addresses (phone number doesn’t need to be geographic)

n.b. UFI is not required in GB, but can be included on the label or package, and NPIS request it on the SDS



Label information *will not change* for some 17th ATP affected substances:

- In some cases, the new classification change doesn't affect the label information of a substance or its mixtures, e.g. clarifying Skin Sens. 1, H317 becomes Skin Sens. 1B, H317 (2 EU-HCL entries)
- In other cases, the 17th ATP only affects the classification of the substance in a mixture. The substance label would not change. (14 EU-HCL entries amend the ATE, M-factor or SCL only)



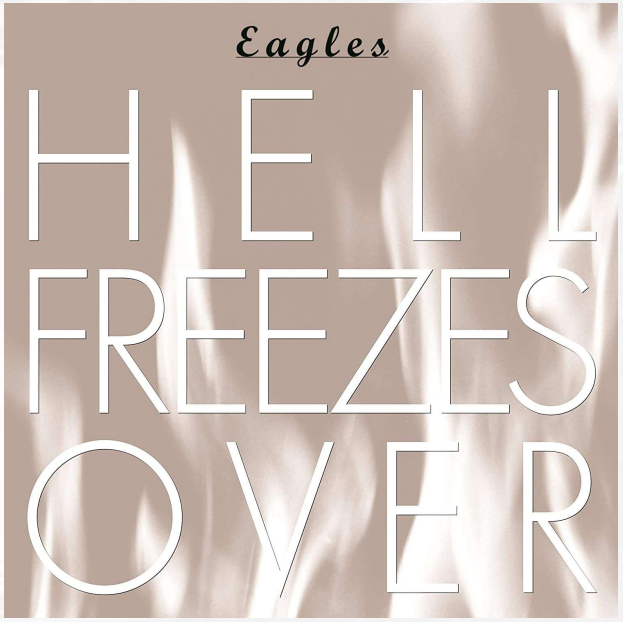
Permitted voluntary adoption of new EU-HCL classifications in GB

- Where there is a completely new entry to the Harmonised Classification List, which doesn't appear on the Mandatory Classification List, (22 EU-HCL entries, listed in the first 17th ATP table)
- Or where the new HCL is for a new hazard "end point" which didn't previously appear in the old HCL and MCL (7 EU-HCL entries)
- Adopting these EU-HCL classifications voluntarily will mean that your hazard classification is the same in both GB and the EU/NI. Your label CLP information will be the same, and you just need to make sure you have the correct legal entities for the label
- And where a HC is removed, you can still use it voluntarily in the EU (1 EU-HCL entry)

Will GB adopt the new EU hazard classes?

- That is PBT/vPvB; PMT/vPvM; and Endocrine Disruptors for Human Health and Environment as new EUH statements with Signal Word and P statements
- Question in parliament “only if adopted by GHS”
- In the meantime, we think that this would conflict with the GB classifications (e.g. new Signal Word), so we don’t think they should be adopted voluntarily.
- There are very long phase-in periods, it’s not an immediate issue

Will GHS ever adopt the new hazard classes?



Where adoption of new EU-HCL classifications in GB is not permitted, and why

- Where there is an alteration to an existing classification in the Mandatory Classification list, this is the HSE's opinion (via email in November 2022) "*wait until the UK adopts that new classification (or not)*" (only 16 EU-HCL entries)
- This is the first time the HSE have advised anyone to go against Duty of Care under HSWA 1974, which states that any new information, particularly about more serious hazards, should be transmitted down the supply chain as soon as reasonably practicable
- It's a legal double-bind – until new MCs are published, you could be prosecuted for not passing on new information, or for not using an MCL!
- But it's not the end of the story…

See into the future (or the HSE's mind)

- Firstly, visit https://www.hse.gov.uk/chemical-classification/gb-mcl-list.htm to view:
  - the Agency Opinion, on whether it should be adopted or not, excel file "GB MCL Agency Opinion" (summarises technical views)
  - If you want more info, download the Technical Opinion, as excel file "HSE GB CLP publication table"
- Secondly, through checking the WTO submission the UK has made recently, https://members.wto.org/crnattachments/2023/TBT/GBR/23_8939_00_e.pdf (*publication expected Q4 2023, mandatory from Q4 2024*)

Summary – WTO notification of proposed amendments to GB-CLP

Overall analysis	WTO & 17th ATP CLP differences	WTO & 18th ATP CLP differences	Total changes	Possible actions
Removed from both HCL and MCL	1	0	1	Adopt early
Same as EU ATP – new classification or end point	42/40*	42	82	Adopt early
Different from EU ATP	7	7	14	Separate labels & SDSs
In EU ATP, not in WTO	12	8		Use voluntarily
MCL changes from HCL			2	Separate labels & SDSs
Total differences	62	57	99	

*GB MCL combines 3 entries into one

Where there are differences between HCL and MCL

- These may be:
  - either changes to the classification of the substance itself
  - and/or changes to the substance data (ATEs, SCLs and M-factors)
- This means that mixture classification may be impacted, so formulators and importers need to be aware as well
- Where a product contains a substance with divergence, you need to check the classification and substance data for your jurisdiction, especially for mixtures
- If in doubt, request the full formulation from your supplier (NDA or via third party)

What might happen if you choose to go against the HSE's legal advice….

- …. And adopt a more precautionary classification coming out of the EU-HCL (14 entries) (we don't recommend you adopt either of the two reduced HCs until they are brought into GB/UK law)
- Do you think that an HSE prosecution would succeed against a company adopting a classification in the WTO document? Particularly if adopting a more hazardous classification meets Duty of Care?
- Remember - it is your choice as to whether to adopt a new EU Harmonised Classification in this way
- This situation is likely to occur again with 19th/20th ATP unless GB moves more quickly than for 17th/18th ATP

CLP label information today:

- You can use a dual EU/NI and GB CLP label if:
  - the classifications are the same (or very similar), and
  - if a valid legal entity name and address is provided for both jurisdictions
- We've looked at how to deal with differences between GB Mandatory Classifications and the new EU Harmonised Classifications:
  - Some classifications are the same, or similar enough to use in both jurisdictions
  - Others may require a decision on whether to adopt EU classifications voluntarily ahead of GB adoption

What about the draft EU label proposals?

- The EU are amending CLP to bring in the new hazard classes, and have sneaked in proposals to introduce minimum font sizes etc.
- Currently waiting to hear if the EU Parliament's suggestions for smaller minimum sizes are adopted
- These changes:
  - don't affect the content legally required under CLP
  - but would definitely take up more label space,
  - make it more difficult to include multiple languages on the label
  - worst-case scenario: fold-out or booklet labels (would not meet current standards)
- GB could adopt the new label format voluntarily

What about divergence and SDSs?

- It's more complicated than for labels – as we've just seen, the label may be the same, but information on the SDS may be different (e.g. due to new mixture information with SCLs, ATEs or M factors)
- There's the difference between EU-REACH and UK-REACH registrations to consider
- Occupational Exposure Limit differences
- The REACH designations of SVHC, Authorisation and Restriction which are starting to diverge
- The most obvious differences are between the GB (old EU) format SDS and new EU format SDS

Is a substance EU-REACH and/or UK-REACH registered in your supply chain?

- Regardless of whether you are supplying 1, 2 or even 3 different format SDSs for the EU, GB and Northern Ireland, we think it's vitally important to acknowledge the EU-REACH registration status, and include information relevant to that registration as well on the SDS
- You also need to include any UK-REACH registration number, although UK data is not publicly available at the moment
- REACH registration is effectively a company asset, as it permits you to legally export a product back into the EU (or back into GB) without further registration or notification

How can you tell if a substance is registered in your supply chain?

- EU and/or UK REACH registration number(s) given on the SDS:
  - Section 1.1 for substance
  - Section 3.2 for substances in a mixture
- Mandatory EU-REACH information present on the SDS, depending on level of registration (we have an infographic!)
- For non-hazardous products which don’t require an Article 32 “supply chain communication” document, or an SDS on request, you have to ask your supplier about REACH registration status

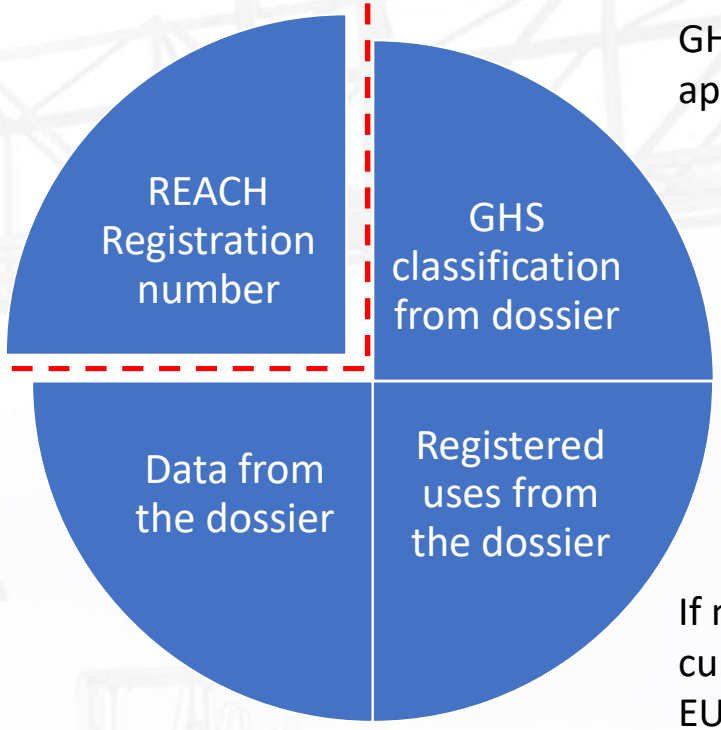
REACH info on the SDS for substances REACH-registered in your supply chain

Only this UK-REACH data available, unless Grandfathered or New UK-REACH registration

Registrants: full registration number including last 4 digits.

Downstream Suppliers: Registration number with last 4 digits obscured.

EU and UK Registrations: UK No. has UK-prefix but same format.



GHS hazard classification which appears in the dossier

If Chemical Safety Assessment:

- Section 9 & 10 + Section 11 & 12 data from the dossier.
- DNELs and PNECs in section 8.2, or in Annex.
- Exposure scenarios content in SDS or Annex.

If intermediate registration, must state intermediate use only (product type helpful)

If non-CSA 1 – 10 tpa registration, uses currently not registered (proposed for EU-REACH)

If non-CSA registration, 1- 10 tpa or intermediate:

- Section 9 & 10 data from the dossier

If CSA registration, uses must be consistent with Exposure Scenarios

Let’s tackle the SDS format divergence next

- Sub-heading changes
  - New – 11.2 and 12.6
  - Altered 11.1; 12.7 was 12.6; 14.7
- Section 3 now requires published ATEs, SCLs and M-factors to be included (i.e. info in HC list, plus any manufacturer or REACH-dossier versions)
- Some substances require inclusion in S 3.2 **and** trigger an SDS for non-classified products (EUH210, Safety Data Sheet available on request)

Mixtures containing…	Great Britain	Europe and Northern Ireland
Substance with Endocrine Disrupting Properties	Does not require SDS	SDS required => 0.1%
Respiratory/Skin Sensitiser 1, 1B	SDS Required => 1%	SDS required => 0.1%
Respiratory/Skin Sensitiser 1A	SDS Required => 0.1%	SDS Required => 0.01%
Repro Tox. 1A, 1B	SDS Required => 0.3%	SDS Required => 0.1%
Repro Tox. 2, Lactation Effects	SDS Required => 1%	SDS Required => 0.1%

Should you use the new EU-SDS format in GB?

- At TT Environmental, we generally like these changes, especially the inclusion of non-generic mixture information, BUT because the headings and sub-headings are listed in UK law, that means the new and altered EU sub-headings are not strictly legal
- The HSE have stated that they “won’t enforce against GB companies using the new EU format”
- It depends on your appetite for risk; and if you get a civil lawsuit, the incorrect format could be used against you
- But will your software company support both SDS formats, and the underlying data eg HC/ MC lists?

Assuming you do want to use the EU-SDS format, what are the other things to consider?

- Firstly, you need to use the EU-format SDS itself, so you include all of the extra EU-only information ✓ just discussed
- Remember to include references to both EU and UK regulations to show it's a dual SDS in S. 15.1. Some people update the (voluntary) citation at the start of the SDS as well, but if you do this, remember to amend the SDS content as well!
- Secondly, you need the exact same things as a dual label: ✓ covered earlier
  - Same or very similar hazard classification (section 2.1), giving rise to the
  - Same label information (section 2.2), and
  - Legal entity names and addresses for each jurisdiction (section 1.3)
- Finally you need to add in all the information which varies according to the jurisdictions you're selling into

× to review

Local REACH designations

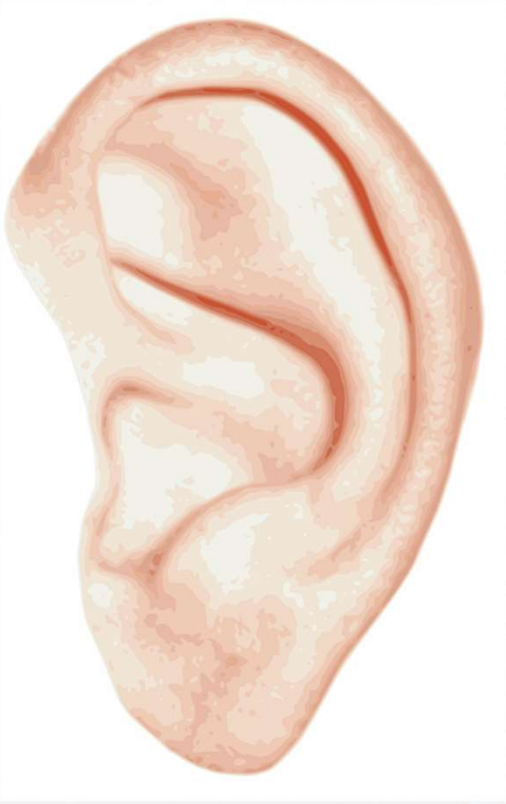
- The REACH “designations” (our terminology) are
  - Restrictions (triggers voluntary supply chain document if not SDS-liable)
  - SVHC (triggers SDS and mandatory disclosure in section 3 at or above 0.1%)
  - Authorisations (triggers SDS and mandatory Authorisation number on label and Section 2.3 of the SDS; and also disclosure in Section 3.2 of the SDS for mixtures)
- Where these exist in the EU but not in GB, they can be voluntarily included on the GB SDS or dual SDS
- Where these exist in GB but not in the EU (e.g. removed restrictions), they can also be included voluntarily – we think….
- If a designation is only in EU but not GB or vice versa, you should make this clear on the SDS as your end user's obligations may be affected

Local regulatory information: Poison Centre contacts, OELs / WELs and local regulations

- If your product is a particular type, it may be required to use a local Poison Centre contact telephone number in Section 1.4 of the SDS (whether it's been notified as a hazardous mixture or not)
- All OELs/WELs need to be listed in Section 8.1 of the SDS
- Union WELs trigger the SDS in the EU; Member state OELs do not trigger the SDS but require reporting
- Only one type of WEL in GB exists, automatically triggers the SDS
- Specific local regulations like the German WGK water hazard class go into section 15.1

A word in your ear about EU and NI SDS…

- Did you know that the local OELs are the main difference between EU and NI SDSs?
  - You can sell into NI on an EU-only address
  - And using EU-wide OELs to trigger the SDS etc
  - But you need to use UK WELs from EH40 as the local OELs!
- Also, the local Poison Centre for NI is NPIS in Birmingham
- As long as you include these pieces of information, then your EU SDS is NI compliant - relatively easy

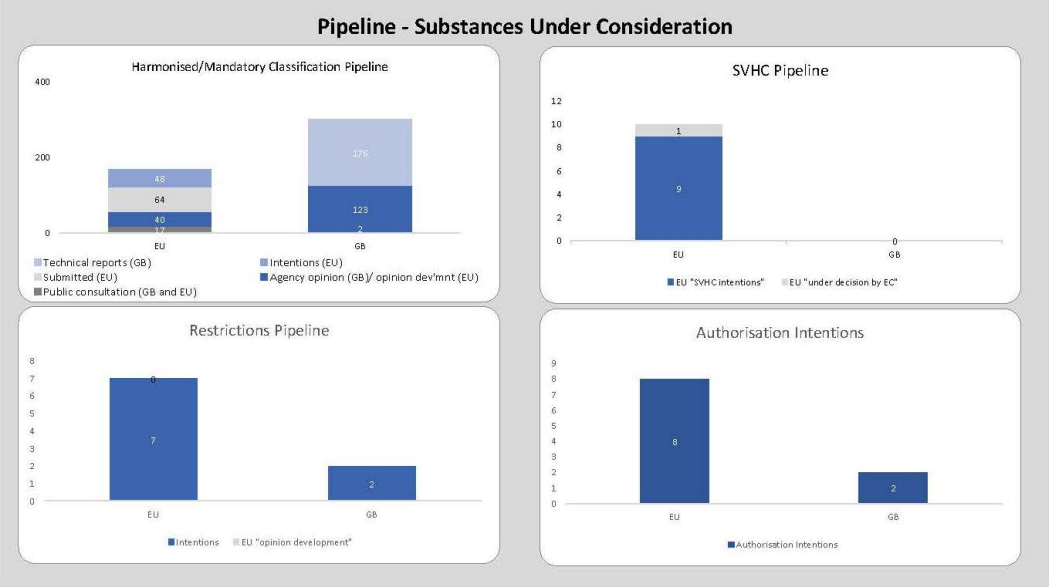


Summary of SDS divergence today:

- The EU SDS alters sub-headings, which means the EU format is technically not legal in the UK – use at your own discretion
- A dual SDS must have the same information as the label for CLP hazard information and valid suppliers for both jurisdictions. The hazard classification must give rise to the label information
- Other non-GB information can be added as it is voluntary
- In an ideal world, we would use two (or three) separate SDSs for GB and EU (with or without NI)

Looking to the future: divergence forever?

- EU-CLP legal changes
  - new hazard classes will affect label and SDS
  - proposed label changes may limit space on EU label
  - EU-SDS may need to alter for PMT/vPvM and HH EDs
- GB unlikely to adopt these; GB may not adopt EU SDS framework either, TBC
- Substance information changes on both sides, including WTO (GB) and 19th and 20th ATPs to EU-CLP



All figures checked monthly (For individual announcements keep an eye on the Newsletter!)

Unless there is some major change in GB policy on both REACH and CLP

- We will be stuck with divergence, then convergence, then more divergence in an endless dance
- It's possible that the GB regulators will end up disagreeing with a number of EU decisions, to the point that the two systems become distinct
- At least one multinational has prepared for this already, and has three separate SDS modules, for EU, GB and Northern Ireland
- We need to continue to review each change in every jurisdiction we sell into and assess its impact against our own product ranges

Keeping up to date with regulators

	EU	GB
Future regulations	European Commission https://commission.europa.eu/index_en European Parliament https://www.europarl.europa.eu/portal/en WTO submissions https://www.wto.org/english/thewto_e/countries_e/european_communities_e.htm	UK Parliament https://www.parliament.uk/ WTO submissions https://www.wto.org/english/thewto_e/countries_e/united_kingdom_e.htm
Current regulations	https://eur-lex.europa.eu/homepage.html Also links from the ECHA website	www.legislation.gov.k Also links from the HSE website and .gov.uk website
Current guidance	ECHA website https://echa.europa.eu/	HSE website www.hse.gov.uk Also the ECHA website

What other options are there?

- Your software company may keep you updated on changes, or the links to information within the package may alter
- Formal subscription services like Croner, LOLI, ChemicalWatch etc
- Trade or professional body memberships eg CBA, BCA, CIA, CRSHG; or CHCS
- Chemicals Coffee Time weekly email newsletter or monthly LinkedIn summary (both free!)

Thank you! Questions/ discussion

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