

Don't Panic About...

The new EU SDS Format (EC 2020/878)

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Introduction

Welcome to the first factsheet in our new series, "Don't panic about... UK chemical regulations"

These are summaries of chemical regulations from the perspective of companies based in mainland GB and NI, and who may be trading into the EU.

These factsheets may also be of interest to companies in the EU and outside the EU who wish to trade into GB and NI as well.

We've noticed that since Brexit, and especially since the Northern Ireland Protocol was introduced (at the last minute), that there are a lot of changes to the regulatory text between EU and UK (or GB) versions of the same legislation.

Some of these changes are simply to account for differences in how EU and UK law operates, but some of them actually change the meaning of the law and therefore how it should be applied in GB.

It has been quite difficult for many of us, me included, to get our minds round the fact that there are quite so many changes to UK law after Brexit, whether these are intentional changes or accidental (Annex VIII to CLP, I'm looking at you!).

So these factsheets distil our current understanding of various situations to help industry out.

Some topics move quite quickly, so we recommend you also keep up to date by signing up for our weekly email newsletter or monthly LinkedIn summary newsletter (links on the inside back cover of this factsheet).

As I say to everyone in the Chemical Regulations Self Help Group, and all of our lovely CLP Mastery Trainees:

- There's no such thing as a silly question, and
- Even one chemical regulation like REACH or CLP is more than any one brain can understand

So if you have a question, or think we've got something wrong, or have a different interpretation, please do email me on janet@ttenvironmental.co.uk .

Hope this is useful!

Kind regards,

Janet

Janet Greenwood, TT Environmental Ltd, 18th October 2022

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What this regulation does and where it comes from

The new EU format Safety Data Sheet alters the framework of SDSs by

- Introducing new sub-headings
- Changing the text of other sub-headings
- Adding in more compulsory information in section 3 and section 9
- Introducing new content for nanomaterials and endocrine disruptors
- Including the UFI in Section 1 for products notified to Poison Centres when handled in bulk
- and some administrative alterations to tidy up the text

It was brought into EU law by EC 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

This replaces the previous Annex II of REACH completely (although most of the text is the same as before).

Download the legal text: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0878&from=EN>

What are the differences between GB, NI and the EU?

There are significant differences:

- GB – this legislation does not apply (but see “other things I should know”, below)
- NI – this legislation does apply in full, while the Northern Ireland Protocol is in operation
- EU – this legislation does apply in full

(Note – if the NI Protocol fails, Northern Ireland would presumably revert back to UK law, but there is no information available about this).

What businesses and products does it apply to, and when does it apply?

This applies to businesses within the EEA, placing chemical products on the EU market, who have **legal liability** under the REACH regulation for the Safety Data Sheet:

- either as manufacturers and importers, when the product enters the EU market,
- or even as distributors and resellers.

This regulation may apply to businesses outside the EU (including GB) if they have a **contractual liability** to provide their EU customers with an SDS which takes this format.

The regulation is currently being phased in until the end of December 2022, and all SDSs for products available on the EU market should comply by 1st January 2023. In theory, any new products should already have SDSs issued in the new format, but products already on the EU market can use the phase in period.

How can I check if my business is affected?

Your obligations will depend on where your business is operating from:

- If you have a legal entity in the EU, all of your SDSs must be in the new format by 1st January 2023, and your new products should have this new format SDS if they were introduced during 2022. This is a legal requirement, and if you don't comply, there could be criminal proceedings against your company. The SDSs should display the EU entity in Section 1.
- If you have a legal entity in Northern Ireland, the same rules apply as for the EU (but note that NI SDSs require EU-wide WELs, and also UK WELs as the national OELs). The requirement for this new SDS type is also a legal requirement under criminal law.
- If you only have legal entities in the UK or any other non-EEA jurisdiction (apart from Northern Ireland), you may have a contractual obligation, which may be enforceable under civil law. But you don't have a legal requirement, as this falls on the Importer(s) of your products into the EU.

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You will need to check your individual contracts with your EU customers to see if you have contractual liability. (Your own legal liability is for SDSs in your jurisdiction's format, which in the UK is SI 2019/758, as amended, <https://www.legislation.gov.uk/eur/2006/1907/data.pdf>) .

Top tips if you are based outside the EEA or NI:

- don't assume you have this liability, read the small print
- don't take on this liability if you don't have to, because SDSs need keeping up to date
- your requirement to keep SDSs up to date only covers products supplied in the last year, so you should only look at products supplied into the EU within that time frame (e.g. October 2021 onwards). Of course, if someone you supplied previously asks you for a new-format SDS, you may choose to provide one, but don't make work for yourself

Any other things I should know?

For companies domiciled in GB, the HSE have said that they won't enforce against you if you choose to use the new EU SDS format.

However, we at TT Environmental believe that this would place your company outside UK law, and therefore put your business at risk if you had a civil lawsuit involving a product with that type of SDS.

The reason why we think this is a bad idea for UK businesses is because of the alterations to existing sub-headings text. SDS section headings and sub-headings are written into the legal text in Annex II of REACH (both EU and UK versions). The UK version of REACH uses the "old" SDS headings and sub-headings, and there are currently (October 2022) no signs of a change to these.

The fact that the sub-headings are in the legal text means that they cannot be altered without taking your UK SDS out of compliance with the UK REACH regulation (unless you are domiciled in Northern Ireland, in which case EU-REACH applies to your business under the terms of the NI Protocol).

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Note that this only applies to the sub-headings where the text has been altered, which are 11.1, 12.6 and 14.7.

As a half-way house, you could legally add in one of the two completely new EU-REACH sub-headings (11.2) to your GB SDS and include the extra information in Sections 1, 3 and 9 voluntarily on your SDS. (There's no point adding in new sub-heading 12.7 as that would give you two sub-headings called "Other adverse effects").

In fact, we think it's a good idea to include this information and believe it would benefit your downstream users.

But it is not advisable to alter the text of the SDS sub-headings in your UK SDS. This effectively means you need two separate SDS frameworks/templates for the EU and UK (or three, if you include NI separately, as those SDSs need to use both the EU community Workplace Exposure Limits, and the UK WELs).

What should we do to comply with this regulation?

The help you need will depend on where you are domiciled. Remember that this isn't just a change in headings, more detailed information is required, particularly in sections 3 and 9.2.

For EU and NI businesses, you will need to alter the SDS framework you use from the "old" framework, to the new one.

The method you use will depend on how you generate your SDSs. That is either in your classification and authoring software, or in your manual system.

If your software system has not already been updated, then you should ensure it is as quickly as possible. Your legal obligation is to have the new SDSs in place on 1st January 2023, not to start the process. The phase in period is all of 2022, and it isn't going to be extended.

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If you are generating SDSs manually, you need to update your method to comply now (if you haven't already done that).

For GB and other non-EU businesses

Firstly, look at how big the problem actually is for your business:

- Are you contractually obliged to provide EU-framework SDSs? (remember, an EU-framework SDS without an EU supplier address is not a legally valid SDS. Does the contract require something which you could supply when the UK was part of the EU, or does it no longer apply?)
- How many products do you sell into the EU which do require the new framework under contract terms? (and can you have the contract altered?)

You may find that your contractual obligations are less than you thought they might be. Then look at how you can meet these as quickly and cost-effectively as possible.

If you are using software:

- Can it be updated to include an EU-framework SDS as well as continuing to use the old EU/ current UK-framework SDS?

If you can't use your existing software, for example it's no longer being supported because it's being withdrawn, or you can't afford the upgrades etc:

- if you have a few products affected, can you amend the UK format/ old EU format SDSs in a pdf editor like Adobe Acrobat, or even drop a pdf into Word and amend it there?

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If you have many products to convert to the new EU format:

- Can you group the products by hazard, and then create SDSs which you can mail-merge information into, e.g.:
 - Non-hazardous (voluntary SDS)
 - Non-hazardous mixture but requires a mandatory SDS
 - Hazardous – group these further by hazards and use type
- Or could you update your existing UK (or old-format) SDS to include the new EU SDS information but retaining the old SDS headings, and then update them to the new EU-SDS headings in a pdf editor like Adobe Acrobat? (The compromise approach discussed earlier)

If you aren't using software:

- Can you amend your existing UK format SDSs?
- Or do you need to remake SDSs from scratch?

In either case, grouping your products by hazard can be really helpful.

Going through the grouping exercise usually shows companies that it can be easier to produce multiple SDSs than they originally thought.

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Where can we get more help?

The EU's guidance on SDSs was updated in December 2021 to include all of the new format SDS guidance, see https://echa.europa.eu/documents/10162/2324906/sds_en.pdf/01c29e23-2cbe-49c0-aca7-72f22e101e20

If you use software, (especially if you have a maintenance contract), your software company should be the first company you call.

If you're looking for help with changing software programs, or buying your first software program, you can book either a 20 minute or 1 hour pre-paid consultancy call with our expert Alison Potts. (For the 20 minute call, please have a list of your product types, approximate number of products in each type, and jurisdictions you need to cover so Ali can review this before the call).

Links below:

<https://calendly.com/tt-environmental/20-minute-quick-consultancy-call-ap>

<https://calendly.com/tt-environmental/1-hour-quick-consultancy-call-ap>

If you're not used to compiling SDSs and think your staff may need training or a refresher, there are also a number of options available, and just like software, they won't be suitable for everyone. We would be happy to provide a list of suggestions upon request (including our own CLP Mastery 😊).

We can also advise you on options if you want to outsource your SDS compilation to a third party, as many small and larger consultancies offer this.

I hope this factsheet has been helpful! Feel free to email me with any queries about this issue on janet@ttenvironmental.co.uk .

Janet

Janet Greenwood, TT Environmental Ltd

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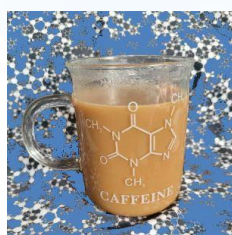


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<https://www.linkedin.com/newsletters/6968832776280137729/>

Join industry colleagues in the Chemical Regulations Self Help Group

Chemical
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Group

Quarterly confidential live and Zoom discussion meetings on REACH, CLP, Divergence, and other related chemical regulatory and trade topics. There's no such thing as a silly question!

<https://www.chemselfhelp.co.uk/> . Membership by invitation.

This guidance has been compiled to the best of our knowledge at the time of writing to help chemical making, chemical-using and chemical-selling companies in the UK meet their legal obligations, but does not constitute legal advice.

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