Article 26 Inquiries - GB and EU REACH

Introduction

Although those used to the REACH Registration process will be familiar with the use of IUCLID software and the procedures to follow, UK based companies who have been able to rely on DUINs or who need to import into the UK for the first time, or who are helping EU customers with EU REACH to allow export, may be facing the need for Registration for the first time.

With the exception of Production and Process Research and Development derogations, the first step for Registration needs to be an Inquiry. This step is needed to establish the identity of the substance and to determine if other Registrations are held. In the case of GB REACH, this only currently links to Registered substances (Grandfathered or new submission) and there is no link to substances declared as DUINs.

In terms of software skills, completing the IUCLID takes only a couple of hours for an Inquiry (although for new users, mastering IUCLID will take longer), but the difficult part is ensuring that the analytical data presented is sufficient to confirm the substance identity and purity.

One area of IUCLID that can lead to problems is the way in which components are reported in Section 1.2. The way this is completed is dependent on the type of substance being Registered.

The process is not difficult once the software is mastered and if some simple rules are followed.

Substance identity

The initial evaluation of the substance is essential for all those registering a chemical substance and who need to demonstrate that their substance has the same identity and purity as other members of a potential Joint Submission.

To file an Inquiry to ECHA or HSE (EU and GB REACH are the same in this respect), basic substance identity details are required. PPORDs also need such analysis, although in this case, material used for analysis may itself be under development and may need further confirmation before final Registration.

For all analytical reports, it is essential to include details of the sample used (source, batch number, certificate of analysis etc), details of the testing laboratory and date, the methods followed, types of equipment etc. The level of detail should be good enough to allow the work to be repeated by other laboratories at a later date.

This report needs to be added to the IUCLID dossier file in Section 1.4 and the list of methods / analysis types covered in the report are selected using a tick-list of options. IUCLID Section 1.4 is itself a repeatable file if multiple reports need adding, but it is recommended to consolidate all analytical data into a single report that is topped-and-tailed with conclusions and interpretation to help the reader.

The advice is to show a copy of any such report to a sales' manager or accountant in the company to see if they can follow it; a well written report should be understandable to non-specialists.

The types of analysis will depend on the nature of the substance, whether organic, inorganic, unknown reaction product or biological extract etc. The legal text (EU and GB) does not specify the type of testing, but in reality, there are expectations to have the Inquiries accepted.

The two types of analysis are defined as 'qualitative' (identity) and 'quantitative' (purity) and the methods will need to be identified as appropriate.

Spectral evaluation

The purpose is to provide evidence for the identity of the substance by spectral analysis, typically IR, UV-Vis, NMR or MS. Even in cases where it is not possible to interpret the results fully, the spectra will at least provide a 'fingerprint' for future reference.

Although not essential in all cases, it is recommended that if checking the UV-Vis spectra of a water-soluble material, evaluation should be at three pH levels. The reason for this, is that the substance may dissociate at different pH levels, and this can be sometimes detected on the UV-Vis spectra – dissociation at pH 4, 7 or 9 may influence subsequent chromatography methods and also impact on the environmental risk assessment.

The reports should include methods, types of equipment etc and the results should include attempts to interpret the findings; for Carbon NMR, bonds such as C-H, C-C, C=C etc can be seen and then these checked against the proposed structure. IR will pick up key groups, including hydroxyl and even in cases where it is not possible to see a spectra (such as UV of fatty acids) then a flat line will show an absence of impurities or unexpected constituents.

Chromatography

A number of qualitative and quantitative methods can be used to confirm identity and purity, including HPLC, GC. The analysis must be sufficient to demonstrate that the substance you are registering has no impurities of concern and typically, that means identifying key impurities down to 0.1%. This is not possible in all cases, but if methods of synthesis (including identity of starting materials) suggest substances of high concern can form, or if residual materials could be present, then care is needed to confirm the presence or absence of such substances.

In the case of UVCB, attempts must be made to identify minor components (isomers, higher or lower molecular weight components, by-products etc) and this is key in determining if your UVCB is equivalent to others you are sharing the Registration with.

It is expected that when performing chromatography, the process is run for at least 2 minutes after the last peak to confirm a 'flat line' and these chromatographs included in the report.

Other analysis

Further analysis is generally needed; one of the most useful is MS (usually combined with chromatography) to look at the mass of the substance and fragments separated by chromatography.

For inorganic substances, the choice is more limited, but key is elemental analysis and to examine structure, X-Ray Diffraction can differentiate between crystal forms. Typical methods will include ICP, AA etc.

Optical rotation may need to be confirmed if relevant.

Impurities and further evidence can be picked up by other methods including classic chemistry such as titration, TLC, TOC, and Karl Fischer (water). There is no limit to the work that can be done. Functional examinations (e.g., boiling range) can also help determine equivalence.

Nano-forms
Where nano-forms of a substance are to be Registered, the particle size and shape need to be considered. Details of the outcome of such parameters must be included in Section 1.2 of IUCLID and include details for fibres and other shapes. These physical parameters can impact on the properties of substances and separate data sets may be needed accordingly.

It is recommended to take specialist advice if planning to Register substances in nano-form.

Methods of synthesis
In the case of UVCB, the methods of synthesis or extraction can be critical in specifying the nature of the substance and equivalence to other materials on the market. For example, if one starting material is simply described as C14 - 16 fatty acid, then there may be a difference in the end product if the fatty acid source has a wider range with significant levels of C12 and C18, of if a higher level of saturation or branching. Defining raw materials is an important part of the identification of UVCB reaction products.

Temperature of processing can also make a difference; a substance manufactured from formaldehyde, for example, is unlikely to have residual formaldehyde if heated to 110 C in a drying process, but if made and supplied in water where process temperatures remain low, then significant residues may remain.

Section 1.2 of IUCLID allow for a description of processes and it is recommended a short report is attached showing reaction mechanisms to confirm the synthesis route.

Outcome of analysis / Substance Identity

The first outcome of the process is to identify the type of substance; the IUCLID dossier provides a choice through drop-down menus and typically the substance is:

- Mono-constituent
- Multi-constituent
- UVCB

Further options exist, including polymer and mixture; these are not to be used in substance Registration but are important for Poison Centre Notification and for regulatory programmes other than REACH (IUCLID is international and covers more than just REACH).

If importing a mixture, then REACH Registration is for the ingredients of the mixture (i.e., do not select 'mixture') and if importing polymers, Registration is for the monomers and other reagents (again, do not select 'polymer').

The outcome of the three choices above will impact on how Section 1.2 of IUCLID is completed.

The legal text does not strictly define these, but guidance is provided by ECHA. The final outcome can be debatable, but it is recommended to work with other Registration holders to agree a substance identity and definition.

Note that separate guidance is provided on nano-forms.

Mono-consistent substances

The expectation that if a substance is a single molecule at over 80% purity, then it should be regarded as a 'mono-constituent substance' with other constituents considered as 'impurities'. Although this may not apply to substances with minor levels of 'related' substances present which also have a function, it is sometimes easier to go with this convention (although legally, these can be 'multi-constituent')

Where substances are synthesised in water or other inert carriers and supplied at under 80% (including hydrates), then the water can be ignored, and the tonnage Registered relates to dried or anhydrous forms. This has implications for testing and also implications for classification - the classification in the dossier must be for the dry actives.

With mono-constituent substances, the Reference Substance in Section 1.2 of IUCLID and in Section 1.1 need to be the same. Impurities can be added as needed.

Multi-constituent substances

If supplying a substance that is synthesised as less than 80% of a main constituent (for example, 70% component A and 30% B). but not mixed after synthesis, registrants effectively have a choice – make one registration on the mixed components, by testing the substance as manufactured, or register separately as A and B. The advantage of two registrations is that if other Registrant holders have data on A and B separately, data can be shared with them.

Effectively, the material needs to be registered in the form that it is claimed it to be; if the registrant claims it is a mixed substance as a result of specific production processing, it should not be registered as two separate substances, but a product made in two stages that effectively involves blending two post-reacted materials is better considered as two substances with two registrations. The registrant will need to justify their position.

Xylene is often given as an example with registration possible as separate ortho- meta- or para-isomers or as n-xylene, and the four are listed separately on the ECHA website with separate EC List numbers. If registering n-xylene, it should be described as a mixed substance of three isomers; it is highly unlikely that it is made by blending each isomer separately.

When completing IUCLID, the Reference Substance in Section 1.1 (i.e., Registered substance) should not appear again in Section 1.2. Instead, the Constituents in Section1.2 should be separate Reference Substances for each separate molecule.

Impurities can be added for multi-constituent substances.

UVCB - Unknown, Variable Chemical or of Biological origin

The term UVCB covers a wide range of organic and inorganic substances. In most cases, the 'Variable' is caused by the use of naturally sourced starting materials like plant-based fatty acids or naturally mined minerals. Some of this starting feedstock are exempt from REACH Registration under Annex IV or Annex V criteria and are therefore not always properly defined themselves; i.e. 'Unknown' or 'Biological'.

In other cases, a complex reaction between substances with various reactive groups, such as sugar chemistry or as simple as citric acid will result in a range of possible permutations with not only Variation, but an Unknown aspect.

In such cases, attempts must be made to identify at least the majority of the constituents present in final product and if not possible to verify every minor component, then an estimated guess is required based on reaction schemes or known properties of starting materials.

In terms of quantification, the very definition as 'V' means batch to batch variation and ranges of components will be needed. However, there is an expectation in IUCLID to indicate a 'typical' concentration and to satisfy this expectation by the Regulatory agencies, fictitious numbers adding to a 100% should be entered even if there is in reality no 'typical' concentration range.

Where the composition can be deliberately manipulated through reaction processing or specific raw material sources and these reaction products supplied with specific 'grades', then there need to be justification that all these grades are indeed the same substance and not deliberate variants with specific desirable properties. Caution is needed since if selling one grade for a higher price or for a specific end use due to different properties, then how can you justify that the properties are the same for environmental or health effects?

It is expected that UVCB have no impurities; this is not in the legal text but is in guidance. This means that water, residual starting materials, undesirable by-products etc are all listed ‘components' to make up the 100% composition.

Purity details / impurities

Purity is a big issue for discussion for Joint Registrants if impacting on properties of the substance and especially if impacting on classification and it is possible to present different 'grades' of substances with different classification in Section 2.1 of IUCLID.

It is expected that impurities are identified to at least 1% and if there is a chance of hazardous impurities being present (e.g., heavy metals, formaldehyde, benzene) that could impact on classification at lower levels, then analysis need to confirm their absence down to concentration of concern (typically to < 0.1%).

Either way, the presence of a known hazardous substance, either impurity or component of a mixture, must be considered for classification and labelling and will need to be reported on the SDS.

In some cases, analysis will show the presence of minor unknown impurities, often through chromatography techniques, and to make IUCLID Section 1.2 add up to 100%, a generic impurity called 'other minor components or stating materials not impacting on classification' can be generated as a Reference Substance and used to make the maths work. Clearly, if this is over 1%, there will need to be support evidence that these minor unknown impurities are indeed not impacting on classification.

If there is residual solvent, such as toluene or water, that has the advantage of making the substance into a liquid that is easier to handle than a solid, then the material being supplied is effectively a mixture of substances and solvent. If importing a 70% pure substance with a solvent that is deliberately present to help improve ease of handling, the solvent is also being imported and needs Registration. However, it the solvent is an inconvenience and has no useful purpose, it can be considered an impurity and does not need to be registered.

Additives

The simple advice is that it is unlikely you will ever have to use this part of Section 1.2 in IUCLID. The definition of an 'Additive' is to allow the substance to be stabilised or made safe to transport and will be limited to strong oxidising agents, highly reactive substances or explosive materials.

Colourants, wetting aids, anti-caking aids etc are not 'Additives' and if present, then the material is a 'mixture' and all components of the mixture > 1 tonne will need Registration in their own right.

Other substance types

Annex IV and Annex V of REACH allow for certain exemptions from Registration - however, other parts of REACH (such as provision of SDS) will still apply in full.

'Natural' products

Substances dug out of the ground or squeezed from plants are considered 'natural' chemicals. Some of these are helpfully listed in Annexes IV (or described in Annex V) of the legal text, but most are not. There are also complications if a natural material is processed in some way in that some types of process are considered acceptable to keep the material 'natural' and others are not.

It must also be noted that the exemption for natural materials in Annex V is on the condition that they are non-hazardous; therefore, some testing may be necessary to prove a point.

As with many substance identity issues the advice is to see what other suppliers in the industry are doing and attempt to find a common position (there is safety in numbers). If a common position can be found within industry, use this to consider whether registration is required or not. Many natural (exempt) materials were pre-registered and it has subsequently been left to industry to justify if natural and exempt or not.

Processed natural products are difficult to consider, especially if reacting them with chemicals to product a derivative; for example, hydrolysing cellulose or adding reactive groups to clays. In these cases, the advice is that all starting materials going into the reaction should be registered (unless exempt) and for purposes of registration, the registrant should consider the product as a mixture.

Polymers

Polymers are exempt from REACH and do not need pre-registration. However, anything that goes into the reaction process at > 2% to make the polymer will need pre-registration, including monomers and other substances. There is still a mistaken belief that only 'free monomer' or 'residual starting materials' over 2% need to be registered and the monomer or other reagent that has been used to make the polymer that is being imported do not need Registration – this is incorrect and even if bound into the matrix of a polymer, any chemicals used at over 2% in the starting mix needs to be registered.

Of course, polymer manufactures in EU/UK will need REACH Registered starting materials.

The biggest source of uncertainty is the boundary between polymer and article and careful consideration of the key function must be made. As with metals, a simple starting point is that if the imported material is melted, ground up, flattened or in any way has its shape changed, it is unlikely to be an article.

Monomers and other starting chemicals do not need to be Registered if exempt under other Annex IV or V of REACH, such as polymers based on sugars.

Salts
It is allowable to adjust the pH of substances and preparations and in doing so, consider only the substances in the mixture; for example, adding a little citric acid to reduce the pH of a potassium phosphate solution can be considered a mixture of citric acid, potassium phosphate and water where the two substances need to be considered individually for pre-registration (water being thankfully exempt). However, if a claim was made that the substance being supplied was potassium citrate, this would need registration as a substance in its own right; effectively, it is what is claimed to be.

As with any materials covered by Annex V or REACH, it is the decision of the registrant to consider a material to be a mixture containing acids and bases or if it is a 'deliberate salt'. The decision needs to be possible to justify to any Competent Authority that asks and more importantly from a business point of view, it would also be necessary to convince customers that your product had been correctly registered.

Justification
As indicated above, any final decision to register a substance or not will need to be within the scope of the legal text, hopefully following the guidance documents and be justifiable. The simple rule is if it is not implicit in the legal text or guidance, put the reasons in writing in case questions are received from a regulatory agency or customer to justify why the substance has not been pre-registered or registered. Put this on file somewhere to cover the decision in case of dispute at a later date; even if the decision is in hindsight wrong, at least it demonstrates action taken in good faith with the best available information at that time.

Completing IUCLID

Whether preparing a PPORD or an Article 26 Inquiry (and of course working towards full Registrations for GB or EU), Section 1 of IUCLID is necessary.

This short guide does not intend to provide software support, but only help in including details expected by the ECHA or HSE.

The 'Working Context' of course needs to be set to the correct Registration type, whether Inquiry, PPORD, Joint Submission etc., noting that for GB REACH, we still use the EU REACH templates.

Section 1.1
This includes the name of the substance, including other identifiers and try to be consistent with public names used by other potential Registration holders. The Registrant's legal entity is also needed and for EU REACH, it is important that an 'official' legal entity file (LEOX) is imported into IUCLID and used the unique user identifier (UUID) must match the REACH ITY legal entity details. If not the same, the dossier will bounce back within minutes of an attempted submission.

The UUID will typically start with 'ECHA-…..' and can be found on your EU REACH IT account under company information.

For GB REACH, it is possible to create your own Legal Entity in IUCLID and as the GB 'Comply with REACH' Gateway does not link to the UUID, it is essential to complete contact details in the IUCLID dossier itself (in Section 1.1)

A Reference Substance needs to be completed with the substance identifiers (EC / CAS numbers) and IUPAC name and a structure with molecular weight. For multi-constituent substances of UVCB, a nominal (typical) molecular weight is needed, including a range and ideally a nominal structure. If it is not possible to complete key parts of the reference substance details, remarks can be added to explain why it was not possible.

There are also options for designating the type of substance (mono- or multi-constituent or UVCB) and if organic, inorganic etc.

Section 1.2
The completion of this depends on whether mono- or multi-constituent or if UVCB, but in all cases the submitter needs to select the option as 'Legal Entity Composition' (as 'type of composition'). If you are a Lead Registrant, then Section 1.2 needs repeating, and the parallel section designated 'Boundary Composition'. The Joint Registration holders need to agree a boundary composition with a range of constituents and impurities as needed.

Note, to repeat the field, a big time saver is to complete it as needed and then use the 'copy' function in IUCLID and make the copy your Legal Entity entry. The Legal Entity field is confidential and will include personal specification.

All Registration holders need to be within the boundary Composition, although if there is a dispute other member of the Joint Submission do not agree with your specification (e.g., too impure), then appeals can be made to ECHA or HSE.

There is a chance to describe the substance in a free-text field and although should be used for all substances, it is essential for UVCB to describe starting materials, production processes, purification methods etc. Further details can be attached.

For mono constituent substances, there will be one Constituent with the same References Substances as used in Section 1.1and other components will be 'impurities'. Each impurity will need a Reference Substance creating - of course, this is only done once and you will soon have a library of References Substances to call on when making further Registrations.

For multi-constituent or UVCB, two or more Constituents are needed with their own References Substances, and these cannot be the same as the Reference substance used in Section 1.1.

As already noted, UVCB are not expected to have Impurities.

If selecting 'nano-form' in the 'state/form' options, new fields open up to allow descriptions of the particle sizes and shapes.

The entries on polymers can be ignored for EU/GB REACH so even if importing a polymer, resist the temptation to complete this section. Remember that for polymers, it is the monomer being registered.

Section 1.3
This section is not needed for PPORD or Inquiry and only applies when updating to a Full Registration when you put the Inquiry number in to link it back to the original dossier.

Section 1.4
A series of options for analysis types and whether methods and/or results are allowed (including 'other' for more obscure methods) and a corresponding report needs adding. All attachments should be as .pdf (even though it is possible to add different file types).

Optical activity needs to be specified (if applicable) and if there is optical rotation, then analysis demonstrating this is of course needed.

Section 1.6 / 1.7
These are not needed for EU REACH, but for GB, the HSE like to see details of the supplier of the substance if being imported (not suppliers of raw materials!) and if acting as Only Representative, then the non-UK 'sponsor' who has appointed you needs including as well.

Section 1.8
For a GB PPORD, the HSE expect to see names and contact details of recipients of the development materials. If exporting to EU, the EU Registration holder can be named as recipient and any onward supply by them needs to be covered by their EU Registration.

ECHA do not expect this but is good practice to include recipients.

Section 1.9
PPORD justification and an attached document detailing process, tonnages, dates etc. Further guidance can be provided for this as needed.

Section 2.1
For a PPORD, proposed classification is required and if the substance is already on the market by other suppliers (i.e., already REACH Registered), then the 'agreed' classification is needed.

Section 11
For a PPORD, guidance on safe use is expected and this needs to match the SDS being use. Remember, even if a PPORD, other parts of REACHA apply in full and correct CLP labelling is required.

Section 13
For a PPORD, an SDS can be attached, matching Section 11 and Section 2.1, of course.

Section 14
For an Inquiry, the type of Inquiry needs to be indicated and this will typically be for new submission (updates need Inquiries if new testing is required). You can also select the type of new testing needed, but if there are already other Registration holders, then you can indicate that no new data is needed as you will be sharing.

If it is a non-Registered substance and you are unaware of other data holders, the type of data needed should be indicated, especially when it comes to new potential animal testing.

Outcome of the Inquiry

Once the Inquiry is accepted (time frame can be up to 5 weeks for GB REACH), you will be able to see the identity of the Lead Registrant though EU REACH IT or though GB Comply with REACH.

For GB REACH, during transition, there may not yet be a Lead Registrant and in this case, NRES type Registration can be submitted; this is a Joint Submission 'working context' but with a promise to work with existing data holders who have not yet prepared a coordinated data set for GB REACH. A NRES 'waiver' statement is added in Section 13 - a few simple words to agree to work towards an agreed data set before the respective tonnage deadlines.

This applies for any GB Registration where there is an existing Registration in EU REACH.

For novel substances not yet EU or GB REACH Registered, the EU will provide a new EC List number (starting with '9') and this will need importing into your IUCLID and linking to your Reference Substance in Section 1.1 for any subsequent full Registration.

The UK HSE do not issue any numbering system, but of course if issued with an EU number, this is a good substance identification for future reference. CAS numbers have no legal status in EU/GB and are not mandatory.

Further guidance

Note that most of the guidance from ECHA will apply also to GB REACH, although there is still close alignment between the EU and GB Legal Text, some divergence is being seen on practical matters.

IUCLID download and guidance
https://iuclid6.echa.europa.eu/

(Note that you will need an ECHA REACH IT account to obtain this - non-EU legal entities can create an account as a 'foreign user')

ECHA Substance Identification:
https://echa.europa.eu/documents/10162/2324906/substance_id_en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d?t=1525879053278

Nano-materials
https://echa.europa.eu/documents/10162/17250/how_to_register_nano_en.pdf/f8c046ec-f60b-4349-492b-e915fd9e3ca0?t=1646898473064

PPORD guidance (ECHA)
https://echa.europa.eu/documents/10162/2324906/ppord_en.pdf/22a12900-ad27-454c-aedd-82972ef2f675

Abbreviations

AA	Atomic Absorption
DUIN	Downstream User Import Notification (GB)
ECHA	European Chemical Agency (EU)
GC	Gas Chromatography
HPLC	High Performance Liquid Chromatography
HSE	Health and Safety Executive (UK)
ICP	Inductively coupled plasma
IR	Infra-red
IUCLID	International Uniform Chemical Information Database
IUPAC	International Union of Pure and Applied Chemistry
MS	Mass Spectrometry
NMR	Nuclear Magnetic Resonance
NRES	New Registration of an Existing Substances (GB)

PPORD	Production and Process Orientated Research and Development
TLC	Thin Layer chromatography
TOC	Total Organic Carbon
UVCB	Unknown, Variable Chemical or of Biological origin
UV-Vis	Ultraviolet-visible (spectrometry)

In conclusion…

The Inquiry process is an essential step in the process to register a non-phase-in substance or a phase-in substance without a valid pre-registration. However, it is not easy, and many have failed at the first attempt, often meaning a delay to registration and manufacture or import of the substance. It can take a considerable amount of time to complete the Inquiry dossier, collate the data and prepare the registration dossier (some have been several months). Even when all the existing data has been provided and no further information is needed, there is still much work involved in preparing the necessary registration documents.

Need guidance in understanding your position? Realise you need to submit an Inquiry dossier but don't know where to start? We offer training and consultancy to help you get to grips with your obligations. To find out how we can help you please contact the REACHReady Helpdesk at enquiries@reachready.co.uk or on +44 (0)207 901 1444.