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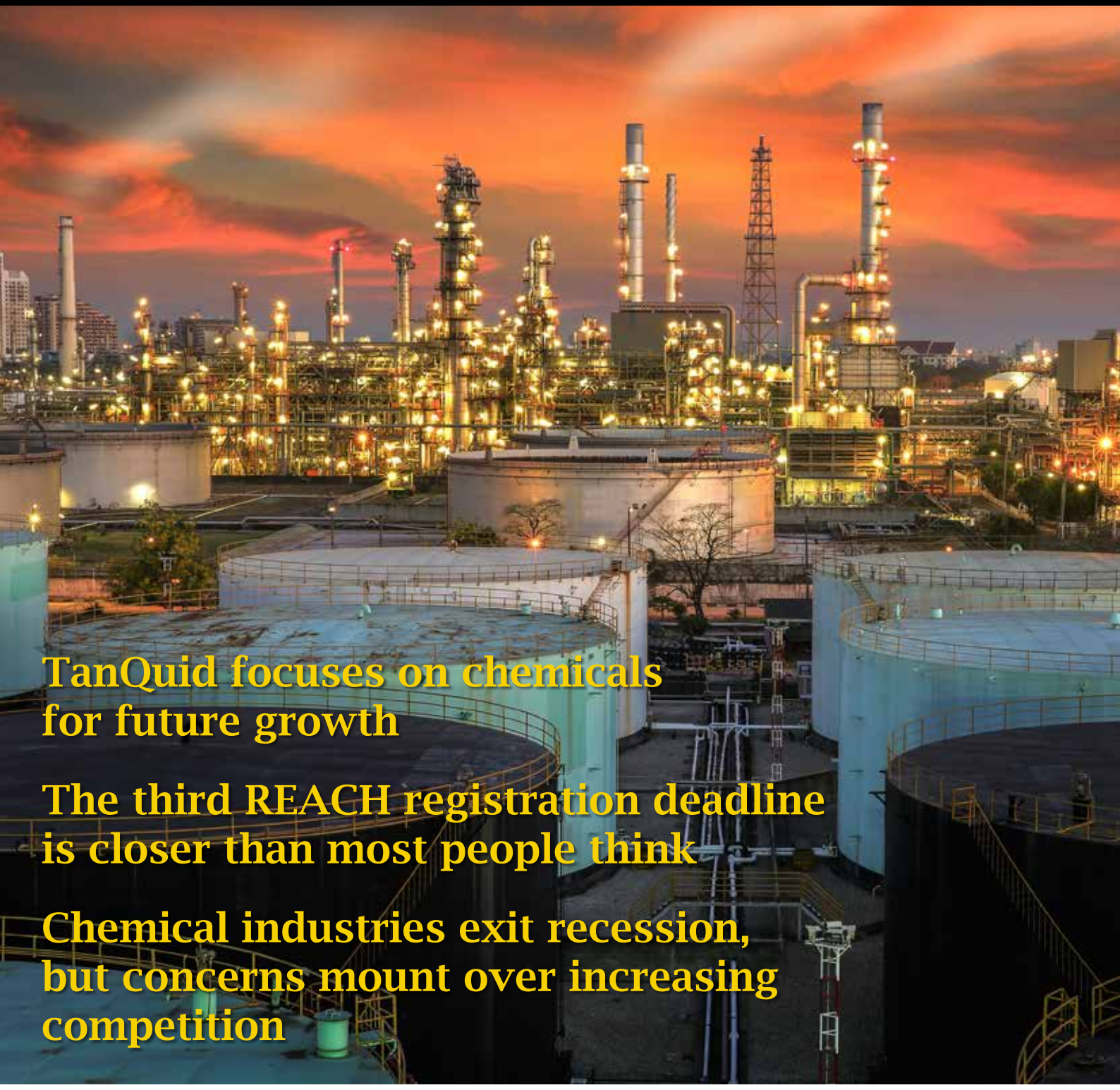
Chemical Storage Edition



TanQuid focuses on chemicals for future growth

The third REACH registration deadline is closer than most people think

Chemical industries exit recession, but concerns mount over increasing competition

CHEMICAL STORAGE

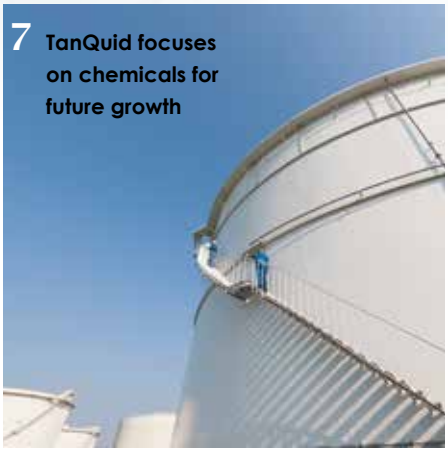
Chemical storage comment

It wasn't that long ago that chemical producers were facing the doom and gloom of economic uncertainty and the Euro crisis, leading to a substantial drop in chemical production. Now, economic prospects are on the up and, more significantly, the shale industry is booming.

Having said that, western Europe is still lagging behind the likes of North America, Asia, the Middle East and South America, causing a knock on effect on the demand for chemical storage on the continent. The likes of Tanquid Tepsa and LBC are all growing and adapting their storage facilities to cater for future growth in this area. We hope you find this supplement informative and as always welcome your feedback for next time.

Best wishes,
Margaret

CONTENTS



The third REACH registration deadline is closer than most people think

The European REACH Regulation[1] entered into force on 1 June 2007 and since then has tremendously impacted the chemical industry, not only in Europe but worldwide. With REACH an entirely new approach for managing chemicals was introduced in Europe, targeting to assess all chemicals on the EU market in relevant amounts (> 1 MT/a) by 1 June 2018. In 2007 it was estimated that approximately 30,000 chemicals relevant to the EU market would have to undergo such an assessment, i.e. having to be registered under REACH by all manufacturers and importers using these substances in amounts of 1 MT/a and more. By April 2014 approximately 12,400 unique substances were registered by industry, resulting in approximately 48,000 registrations (on average four registrations per substance).

When looking at the numbers, there are only four years left for roughly 18,000 substances to become registered – an ambitious goal to achieve.

REACH registration

In REACH a transition period is defined in Article 23 for what is called 'phase-in substances'. Phase-in substances, in a nutshell, are substances that were legitimately on the market in the EU member states when REACH came into force[2].

Besides phase-in substances, New Substances, listed in ELINCS[3], were legitimately on the market but these do not require a new registration by their previous notifiers as the previous notification were converted into REACH registrations by REACH Article 24. Only when a tonnage band increase occurs or new data becomes available do these dossiers require updating.

For phase-in substances, transitional periods were defined to allow the industry to adapt to the new legislation.

1. Phase-in substances manufactured or imported
   a. in amounts of more than 1000 MT/a, or
   b. in the range of 100 – 1000 MT/a and being considered very toxic to the environment with long lasting effects (chronic aquatic toxicity category 1 resp. N, R50/53), or
   c. being considered carcinogenic, mutagenic or reprotoxic category 1A or 1B in more than 1 MT/a were required to become registered by December 1st 2010 (first registration deadline).
2. The remaining substance manufactured or imported in 100 – 1000 MT/a were required to become registered by June 1st 2013 (second registration deadline).
3. The residual substances in the tonnage band 1 – 100 MT/a are to be registered by June 1st 2018 (third and final registration deadline).

In order to be allowed to manufacture/import such phase-in substances up to their respective registration deadline, the manufacturers and/or importers had to pre-register their substances by December 1st 2008 (see REACH Article 28). It is important to note that a pre-registration or a registration under REACH is specific to a chemical substance and to the manufacturer/importer, so every manufacturer or importer has an individual (pre-) registration obligation. As a result, as of June 1st 2018 only registered substances will be allowed to be manufactured or imported in 1 MT/a or more by those that have registered these substances. For information on which substances are exempt from REACH registration obligations one should consult REACH Article 2 for the exemptions (e.g. pure water, non-isolated intermediates, medicinal products, etc.).

Whereas the substances required to be registered by the first and second registration deadline were mainly of high tonnages, the substances to be registered by the third registration deadline usually are specialty chemicals, often used by numerous smaller companies in small amounts. Thus, it is expected that many smaller chemical manufacturers / importers only using small amounts of chemicals will become involved with the REACH registration obligations now.

Experience from the first two registration deadlines has shown that it is an onerous task to establish a registration dossier and many experimental data (including animal test data) are required. Such data have to be consolidated and assessed requiring expertise and experience in doing so. As manufacturers and importers of the same chemical substance have to collaborate in so-called SIEFs[4] in order to avoid duplication of animal testing, contractual agreements and communication/management skills are required to coordinate such groups, which in some cases can have 1,000-plus members. Hence, establishing a registration dossier is not only a scientific exercise but also a managerial challenge. Although all registrants of one substance shall work collectively (One Substance One Registration (OSOR) principle) every registrant has to submit their own registration and will receive their individual registration number once the registration is accepted.

Whereas the REACH

registration obligation only applies to substances, mixtures cannot be freely imported. Only if all ingredients[5] (i.e. substances) in a mixture are (pre-) registered, a mixture is allowed to be placed on the market. Also polymers, although substances, can only be manufactured/imported if all monomers they are made of are (pre-) registered[6].

Besides these basic REACH principles as described, there are uncounted special cases, exemptions, derogations and additional requirements to fill libraries with and indeed the amount of guidance documents to manage REACH is tremendous[7].

REACH in storage

For companies running tank farms and tank storage facilities, it is important to know how REACH affects them and this can be in many ways:

- In industrial manufacturing facilities, chemicals are often stored in storage tanks. Such chemicals may be stored to become converted in chemical processes (intermediates) or for further use in a manufacturing process as processing aid or solvent or as final product for distribution. Hence, such companies often have the role as importer (when importing chemicals from outside the EEA[8]) and of course the role as manufacturer for the substance they do produce. In both cases they have to ensure that the chemicals imported or manufactured are pre-registered respectively registered.
- Tank storage facilities and warehouses not associated with a manufacturing plant have no activities in manufacturing but often do import chemicals from abroad and thus their owners/operators can be responsible for the import having a (pre-) registration obligation. As import is defined in REACH Article 3 (10) as 'physical introduction into the customs territory of the Community'[9] storage of chemicals from abroad in a bonded warehouse is not considered import. However, once the substance leaves a bonded warehouse e.g. to be supplied to an EEA customer, the substance becomes imported and the importer will have a (pre-) registration obligation.

Accordingly, companies running tank farms can easily be confronted with REACH registration obligations and thus should be aware at all times, whether they have a role as manufacturer or importer under REACH for every chemical substance they do handle. Such awareness typically is facilitated by IT systems used for storage and distribution management and such systems should be capable of managing data on a substance level, even if mixtures are handled.

If unsure whether all substances imported are registered or pre-registered one should act immediately. Some companies have already been severely fined for non-compliance with REACH obligations. Ensure that you know about all substance you do import and do not focus solely on the main ingredient of mixtures. Often, additives may easily add up to 1 Mt/a and more and also are required to be registered unless they are added solely for the purpose of preserving the stability of the substance they are added to[10]. If your non-EU supplier has appointed an Only Representative for the substance you import, you are relieved from your registration obligations under REACH and are considered downstream user for this substance. However, ensure you have documentation in writing for this. If you find out you have missed some substances and you have not (pre-) registered these already, you need to react immediately. The same applies if you want to import a new product/substance you have not imported before. In this case a late-pre-registration[11] may still be possible.

Even if you have pre-registered all substances you do import/manufacture but have not registered them yet you should start to take actions to prepare registrations. Although there are four years left until the last registration deadline, there is good reason to act now and not to wait for the last minute. It is expected that resources will become limited the closer we approach the final registration deadline

- as many companies will come in a hurry,
- as many companies want to spend registration costs as late as possible,
- consultancy resources are limited,
- numbers of registrations are expected to increase significantly (see above),
- more companies will be affected by REACH and we do expect much more registrants per substance to become active and
- test facilities required for data generation of phys-chem, toxicological, or ecotoxicological data have limited resources which might prohibit closing data gaps in your dossier(s) in time.

Even if you do not have to prepare an entire dossier, as someone else already has registered the substance and offers a letter of access to their submitted dossier, you should not underestimate the work in preparing your joint-registration dossier.
You will still have to:

- Submit your own analytical data (and may have to generate those first)
- Acquire a letter of access and financially compensate the lead registrant
- Prepare your own exposure scenarios and risk assessment if this is not shared by the lead registrant
- Establish and submit your own co-registration dossier.

So, there are good reasons to start now planning and implementing your registration activities and not to wait for the last minute. If required, get professional support. The third registration deadline in 2018 is the final registration deadline – there is no second chance and missing it is not an option.

For more information:
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References

1 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Official Journal of the European Union, L136/3, 29.05.2007)

2 For details please refer to REACH, Article 3(20)

3 EUROPEAN LIST OF NOTIFIED CHEMICAL SUBSTANCES ELINCS (see also http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/5430/1/reqno_jrc52455.pdf)

4 SIEF = Substance Information Exchange Forum

5 Those individually imported in more than 1 MT/a

6 See REACH Article 6(3) for more details

7 See http://echa.europa.eu/support/guidance

8 EEA = European Economic Area, where REACH applies

9 As REACH is also adopted in Iceland, Liechtenstein and Norway this should be read as EEA

10 See REACH Article 3(1) definition of „substance"

11 See REACH Article 28(6)