

REACH >1000t POST-REGISTRATION SERVICES



TNO triskelion bv

Following submission of your registration dossiers in 2010, some follow-up activities may be necessary. TNO Triskelion can review the communications from ECHA regarding your substances in order to develop appropriate and timely responses. Where needed, we can also communicate with the co-registrants in the SIEF to come up with an agreed position and will also be happy to co-operate with your lawyers if technical support is needed for a rebuttal.

TNO TRISKELION POST-REGISTRATION SERVICES

- Communication with the Authorities
- Amended test plans
- Review of IUCLID 5 files
- Refinement of human & environmental safety assessments
- Strengthened read across arguments
- Incorporation of additional uses
- Unsafe uses – support with authorization/restriction
- Advocacy and legal advice

EXAMPLES

The following are typical examples of situations that may arise in connection with 2010 registrations:

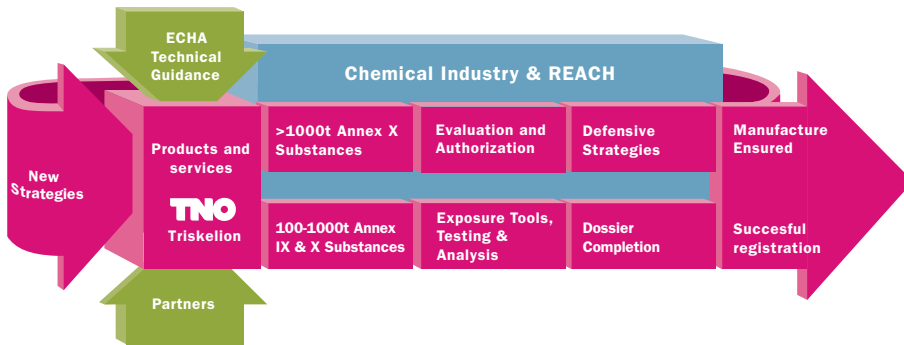
A. Test plan

1. ECHA has reviewed your test plan and does not agree with your approach, stating that the additional testing you proposed is not needed because you

can read across to another substance (with a higher classification).

However, you want to test to remove any uncertainty and avoid classification by read-across. TNO Triskelion can help you in constructing the right argument to perform the test, and can interpret the results when they are ready.

2. For another substance, ECHA considers that your test plan is incomplete and requests a two-generation reproduction toxicity test. We can help you to strengthen your arguments, based on our in-house knowledge of testing, as well our familiarity with the way of thinking of ECHA as a regulatory agency. If there is no alternative we can carry out the test to the OECD 416 guideline for you.



REACH AND TNO TRISKELION: SUCCESSFUL REGISTRATION 'WITHIN REACH'

The aim of REACH is to describe the safe-use of chemicals throughout the product chain. All High Production Volume Chemicals and priority substances must be registered by 2010 or 2013. TNO Triskelion can assist your company in achieving this with our proven expertise in the fields of risk assessment, registration and testing. With TNO Triskelion, your technical dossiers, exposure scenarios and Chemical Safety Reports are safe in our hands.

The added value of TNO Triskelion's REACH services is based on decades of experience with registration and safety studies for the Chemicals Industry. TNO Triskelion is actively involved in the rgw ongoing work of developing technical guidance for REACH and has broad contacts with ECHA and the EU Member State Competent Authorities.

B. IUCLID

ECHA has reviewed your IUCLID file, and is requesting an update of your robust study summaries to enable a full-scale evaluation. We can review your original IUCLID, and on the basis of the study reports, we can update the summaries.

C. Chemical Safety Report

ECHA has reviewed your CSR, and does not agree with the parameters you have chosen for emission in your EUSES calculations. TNO Triskelion can look for additional arguments and data, even perform site visits to measure the actual situation. We can re-run the EUSES model with new data where needed, strengthen the CSA arguments and update the CSR.

D. Read across

You have made use of extensive read-across in your dossier to avoid new testing. However, ECHA has challenged your arguments. You may need to further substantiate those arguments with a kinetics and metabolism or degradation study to demonstrate lack of exposure and then resubmit your IUCLID. TNO Triskelion can design and carry out an appropriate study, and can take care of re-submission of the IUCLID.

E. Additional uses

Since your dossier was submitted, new uses have come up. It looks like they will be associated with higher exposures, for which it may not be easy to demonstrate control of risk. We can explore the possibility of more realistic exposures/emissions or can re-evaluate your DNEL's/PNEC's, looking for additional room in the risk balance. With that new information, we can then amend the CSR.

F. Unsafe uses – Restrictions - Authorization

Together with one of the Member States, ECHA has made a full-scale evaluation of the dossier and is of the opinion that a number of your uses are not safe. This situation could lead to restrictions being imposed, or even to a need for authorization. TNO Triskelion has all the expertise needed to gather additional information in order to re-assess the uses and look for 'safe use'.

We can perform higher-tier exposure modelling (for example with the ART and EUSES models for worker and environmental exposure respectively). If we can prove, to the satisfaction of the authorities, that the uses are safe and you may avoid the unpleasant consequences of authorization measures.

CONCLUSION

TNO Triskelion can assist you with any questions that may come up during an ECHA substance or test plan evaluation. We can help you with the written response, but also with identifying and sourcing data or, in a worst case in setting up any additional testing that may be needed. We can bring the considerable expertise of our hazard and exposure risk assessors, for human health and environment and our regulatory affairs experts to come up with the most favorable response to ECHA for your company.

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TNO TRISKELION BV

TNO Triskelion BV is a wholly-owned subsidiary of TNO: Europe's largest independent research institute for technological and strategic research and consultancy. By translating scientific knowledge into practise, we increase the innovative power of industry.

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