

Ciba Specialty Chemicals

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Ciba[®] Expert Services

Preparing for REACH

Guidance for Small and Medium European
Manufacturers of Chemicals



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Value beyond chemistry

Preparing for REACH

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1 Introduction

On 1st June 2007 REACH entered into force. REACH is the “Regulation of the European Parliament and of the Council concerning the **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **C**hemicals”. REACH leads to a wide-ranging and fundamental revision of the European Union’s chemical control legislation, that is, the Dangerous Substances Directive (DSD), including the notification scheme for new substances, the Dangerous Preparations Directive (DPD), the Existing Substances Regulation and the Marketing and Use Directive.

A General introduction into the subject is given in a separate brochure of Ciba[®] Expert Services.

There has been much discussion about the potential impact of REACH on small and medium manufacturers¹ of chemicals.

Small and medium manufacturers of chemicals are often characterized by the following features:

- Diverse range of products, occasionally with high volumes
- Limited production runs
- Specific and frequently confidential product use
- Few or no safety-data owned by the company.
- Lack of experience with the present new substance legislation.
- Lack of experience with the existing substance legislation or existing substance related voluntary initiatives (e.g. HPV)
- Little experience and resources available for substance evaluation or risk assessment
- Highly sensitive to costs of REACH

Some of these features could make small and medium manufacturers of chemicals vulnerable to the implications of REACH. This brochure addresses specifically such companies and suggests actions to be prepared REACH.

¹ The term small and medium manufacturer is used here in a broader sense than the term SME in the definition of the European Union (headcount <250, etc.).

2 Business implications

REACH has strong implications on chemical businesses. The main implications for small and medium producers of chemicals are summarized in Table 1.

Table 1: Main obligations/implications of REACH implementation for small and medium manufacturers of chemicals

Obligation	Implication	Comment
Pre-registration of substances produced in amounts above 1 t/a is necessary (between 1 st June and 1 st December 2008)	When no pre-registration is done, immediate registration is necessary to remain in business in the EU ²	After pre-registration registrants will enter a SIEF ³ to exchange animal test data.
Registration of all substances produced in amounts above 1 t/a is necessary, including safety assessment for the whole lifecycle of the substances	No registration, no market	Certain raw materials will no longer be profitable
Intermediates need to be registered, but requirements may differ	The registrant has to prove that the intermediate is well-controlled, which involves considerable administrative and/or technical efforts.	Technical expertise necessary
Authorization of substances of very high concern	Performance of risk assessment, socio-economic assessment and substitution plan	Enhanced regulatory pressure on substance of concern. (Such as persistence, bioaccumulation, carcinogenic, mutagenic or toxic to reproduction).
Exchange of information along the supply chain	Preparation of SDS with exposure scenarios	The intensified flow of information might influence your commerce as certain confidential information will become available to suppliers, competitors or customers.

² When a substance is pre-registered, it can remain on the market until registered according to the tonnage deadlines (See - Ciba[®] Expert Services "REACH – Overview").

³ SIEF Substance Information Exchange Forum

Obligation	Implication	Comment
Switch of classification and labeling towards the Globally Harmonized System (GHS)	Update of classification and labelling (update SDS)	In general, the classification under GHS will tend to be more severe than under the present system, which will impact marketability of products
Registration of new chemicals	Testing requirements on volume thresholds are reduced	Under certain circumstances it becomes more feasible for small and medium companies to develop and sell new substances.

In order to fulfil the requirements of REACH additional staff and/or outsourcing is needed. This will lead to additional costs. The tests necessary to fulfil the data requirements will generate most (about 80%) of these costs. In addition, considerable resource and intensive and administrative efforts are considered necessary. The cost profile and the payment dates will vary significantly depending on the substance portfolio and structure of the company.

All existing chemicals in the lower tonnage bands (below an annual volume of 100 t per year) must be registered 11 years after the start of REACH (before 1st June 2018), which gives the manufacturers time to prepare and adjust the portfolio. The consequence will be that certain raw materials will no longer be profitable (especially if the use of the substance requires authorization) and will disappear from the market.

Small and medium sized manufacturers of chemicals should take these effects into account when drafting their business strategy. If a small and medium manufacturer adapts to the changing market situation smartly, it could take advantage over competitors. A pro-active approach towards REACH will make the decisive difference.

3 Preparation for REACH

Agreement on REACH was reached in December 2006. The text of the REACH regulation was published in the Official Journal of the European Union on 30th December 2006 (Regulation (EC) 1907/2006, corrigendum on 29th May 2007). The regulation entered into force 1st June 2007.

Companies need to start preparing for new legislation now. Being able to comply with the new legislation is essential for business continuity. Preparation and provision of resources is necessary.

3.1 Actions to be taken now

3.1.1. Assess your product portfolio

a) Identify products

Identify all products (substances, preparations, semi-finished goods) produced in the European Union and therefore potentially falling under REACH. Additionally identify all raw materials or substances imported from outside the EU.

Identify the uses of these products you are aware of. Collaboration with customers is indicated but not mandatory at this point in time.

b) Create an inventory of individual chemical substances.

Break down products to substance level (under REACH, substances are regulated even if contained in preparations). Identify CAS numbers and, if possible, the EINECS or ELINCS numbers.

Check whether any of the substances are likely to be exempt under REACH or could be filtered out for later consideration. Examples are:

- Substances in Annexes IV and V (certain non-dangerous commodity chemicals, as well as specific types of reaction products, coal, crude oil, etc.)
- Substances already notified under Directive 92/32/EEC (7th amendment of Directive 67/548/EEC)⁴ by your company.
- Polymers that meet the REACH polymer definition (monomers need to be registered)

c) Intermediates.

Identify all intermediates, either meeting the definition of isolated or transported intermediates. These intermediates will have certain but reduced requirements under REACH.

d) Confirm the total annual volumes of these substances.

Define the volume bands they fall under (>1 tpa, >10 tpa, >100 tpa, >1000 tpa,) for export into the European Union.

e) Collect all available data on these high volume substances

- intrinsic properties (in-house, publicly available)
- assess quality of test data
- classification & labelling information
- Safety Data Sheet compliant with existing legislation⁵.

⁴ ELINCS new substance notification
Vers 6/07 11 October

f) Identify data gaps for the high volume substances

Evaluate available data against the requirements set forth in Annex VII-XI of the regulation⁶ to identify missing data.

g) Identify substances of highest concern

Screen for CMR⁷, PBT⁸ and vPvB⁹ as well as endocrine disrupters on the basis of available and predicted data.

Substances potentially falling under authorization requirements will require special attention for support under REACH. For such substances, substitution possibilities should be evaluated. If those should be further supported, information on application and use, and respective risk management measures should already be known in detail (e.g. technical, personal, protective equipment and measures limiting emission to the environment).

3.1.2. Establish a REACH Master-plan taking into account the following points:

a) Prepare for pre-registration

Based on the inventory of the portfolio, it is possible to select substances for which pre-registration is necessary. Look whether or not structural analogues for these substances are available and suitable for read-across.

b) Identify possibilities for consortia formation

Conduct a primary evaluation on whether other companies have an interest in the same substance, which quantities they currently manufacture and market, and what data they may have available. Mandatory sharing of (animal) data at a fair cost split is part of REACH.

c) Plan the implementation of REACH

- Start with a step-wise plan now, doing those things easily available as described above. Then do more detailed planning as more information becomes available.
- Define possible direct costs associated with the REACH process by determining quantities manufactured or imported, uses and potential exposures, likely information needed per substance, information and data already held and the possibility for consortia formation.
- Establish a time plan (what needs to be done by when and by whom).
- Estimate respective resource during REACH implementation.
- Possibilities for grouping, family formation, read-across to reduce costs.
- Define business opportunities.
- Define areas where confidentiality is critical.

3.1.3. Further actions

- Analyze commercial implications of REACH.
- Decide on products, potential substitution strategies, business opportunities.
- Initiate, if necessary, consortia formation.

⁵ The SDS as such is not part of the registration dossier, but it is the key tool for communication in the supply chain

⁶ For more info see Ciba[®] Expert Services General REACH brochure

⁷ carcinogenic, mutagenic and toxic for reproduction

⁸ Persistent, bioaccumulating and toxic substances

⁹ Very Persistent and very bioaccumulating substances

- Assemble readily available information on uses and conditions of uses for the substance or preparation, i.e. exposure of the environment, your own workforce, at your customers' workplaces and eventually in end-uses.

At this stage, it is sufficient to indicate for each substance or preparation a broad use category:

- industrial use
- professional use
- consumer use

3.1.4 After pre-registration

After the pre-registration period, the list of pre-registered substances becomes available on the website of the Agency (January 2009). When you are a downstream user and your substance does not appear in this list, you may notify the Agency of your interest in the substance. The Agency shall publish on its website the name of the substance and a request to companies to pre-register for this substance (the Agency can provide a potential registrant with the name and contact details of the downstream user (only after permission is given)).

3.2 Classification and labelling

- After pre-registration, registrants of the same substance will enter a SIEF not only to exchange animal test data, but also to agree on classification and labelling. Review your classification & labelling and compare and adjust, where necessary in agreement with other producers. By 1 December 2010 onwards classification and labelling should be notified to the Agency by manufacturer, producer of articles or importer, or group of manufacturers or producers of articles or importers. The Agency will establish and maintain a Classification and Labeling Inventory in the form of a database containing the notified substances. The information in this database will be publicly accessible. The obligation to notify the Agency on Classification and Labeling is not limited to substances subject to registration (thus > 1 tonne/year), but includes all classified substances (no tonnage limitations).

Evaluate changes brought by the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

The GHS requirements will change many classifications:

- In some cases your classification might not agree with that of the competitors.
- In some cases this will be easily rectified across producers.
- In other cases this may be difficult, especially where variations are due to impurities (marketing edge due to concept of safer product).

3.3 Safety Data Sheet

Due to the need to know more about the actual uses of a substance, communication along the supply chain will increase significantly. A downstream user is part of the supply chain and thus also the information chain. Under REACH, he is required to pass on information he holds, or which is communicated to him, up and down the supply chain. The tool to pass this information is the (extended) Safety Data Sheet.

- Downstream users of dangerous substances and preparations will receive safety data sheets (SDS) which will look like those provided today. In addition, under certain

conditions¹⁰, these SDSs will have an Annex containing a so called exposure scenario. This exposure scenario is a description of how the substance or preparation is to be used safely. If a downstream user receives such an exposure scenario, it is his obligation to ensure that the way he uses the substance or preparation does not pose a higher risk than prescribed by the exposure scenario of his supplier.

- A downstream user has the right to make his use known in writing to his supplier, to ensure that the use becomes an identified use and that the Exposure Scenarios he later receives are appropriate for him.

4 Conclusion

Now REACH is in force, all existing substances on the market (which are not exempt) with a volume above 1 tonne per annum must be registered according a tonnage-triggered schedule. New Substances above 1 tonne have to be registered according to REACH from 1st June 2008 onwards.

REACH has strong implications on chemical businesses because of the significant costs related to testing and registration which will without doubt trigger a conversion of the market. Small and medium manufacturers of chemicals should take the implication into account when drafting their strategy.

The intensified flux of information might threaten commerce as certain information, which is important for business, might become available to suppliers, competitors, or customers.

On the other hand, it is becoming more feasible for small and medium companies to develop and sell new substances. If the annual production volume is below 1 tonne since such new substances are not subject to registration. For substances with annual volumes below 10 tonnes the registration costs under REACH are significant lower than the notification costs under the present European New substance legislation.

If a small and medium manufacturer is adapting to the changing market situation smartly, it could take advantage over competitors. A pro-active approach towards REACH might make the decisive difference whether you belong to the winners or losers.

Thorough regulatory guidance in devising the testing program is needed to ensure that the technical dossier and Chemical Safety Report are of an adequate quality. As a consequence of REACH, advice may be helpful to adjust the company strategy towards the changing regulatory conditions. Usually REACH allows for several different approaches. Very often strategic commercial thinking is necessary to choose the right approach.

Ciba[®] Expert Services is the right partner for you to meet these challenges.

¹⁰ That is, if the substance itself or at least one of the substances in a preparation is classified dangerous, it is produced/imported in amounts exceeding 1 t/a per producer or importer, it is registered by the producer or importer, and if part of a preparation, it is contained in concentrations exceeding the limits defined in the dangerous substances or dangerous preparations directive or those specified in the REACH regulation.

5 Services for REACH by Ciba[®] Expert Services

- *Education and training*
We visit you, help in training, organize seminars needed on the imminent changes in legislation and their implications.
- *Strategic consulting*
We help you make decisions how to shape your chemical business in the European Union after REACH. We review product and development portfolios to help define properties of your substances and to identify problematic substances in advance.
- *Check if any of your substances may need authorization*
Our experts in the fields of human and environmental safety help in classifying product ranges on the basis of PBT and other criteria.
- *Consortia services*
We represent you in consortia, we provide you with technical advice. In addition, our experts consult consortia on technical matters.
- *Legal representation in the EU*
We act as your Third Party Representative or your Only Representative in the European Union.
- *Test strategy*
We tailor-make test strategies to minimize costs for the test program. We find the test houses with the best price/quality and monitor the contracted studies.
- *Dossier preparation*
We prepare Technical Dossiers for submission and Chemical Safety Reports.
- *Reviewing test reports*
We have extensive experience in reviewing test reports and check for adequacy and compliance with current test guidelines.
- *Collecting other relevant test data*
We find relevant data on your substance or close chemical analogues from the many available sources of information. We also use knowledge-based and computerized structure-activity analysis (SAR) to predict various properties.
- *Reviewing and revising classification and labelling*
We have wide experience in applying EC criteria for classification and labelling and preparing EU-format safety data sheets.
- *Preparing/updating risk assessments*
We prepare EU-format risk assessments on a regular basis and always ensure that possible future implications of risk assessment conclusions are addressed.

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