

Why should a REACH Consortium be created?

The creation of a REACH Consortium is not obligatory, but is highly recommendable. All producers and importers of a substance are obliged to register it individually. However, since the registration costs are expected to be very expensive in most cases (a toxicological study – i.e. just a part of a registration for one substance may be worth millions €), **it is obvious that the industry has to form a Consortium, logically at European level, in order to share and minimise the individual costs.** This is the main purpose of the **EBB Biodiesel REACH Consortium.**

Timetables for REACH pre-registration and registration

Registration is structured in two steps:

- 1. Pre-registration:**
by **December 1st, 2008** at the latest
- 2. Registration:**
by **November 30th, 2010** at the latest



INFORMATION DAY
1ST EBB
REACH CONSORTIUM
ASSEMBLY
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EBB European Biodiesel Board

REACH AND THE EU BIODIESEL SECTOR

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What is "REACH"?



REACH is the EU Regulation for the Registration, Evaluation and Authorisation of **CH**emicals (REACH)

Background and objectives

The overall objective of the new REACH Regulation is to register all the chemical products which are or will be produced or imported in the EU in order to ensure high level health and environmental protection.

It creates a harmonised legal system of registration and authorisation, based on the idea that the industry is the best actor for assessing and ensuring that the chemicals within the EU do not adversely affect human health and environment. The registration costs are meant to be born by the industry.

An obligation for all producers and importers

For this reason, **ALL** producers and importers of chemicals within EU are **OBLIGED to REGISTER**, i.e. to carry out an evaluation and an authorisation for each substance manufactured or imported within a specific and complex procedure.

In the absence of a full registration, importers and manufactures are no longer allowed to manufacture and/or import Biodiesel and its related products anymore. In addition, the European Chemicals Agency (ECHA), which is in charge of the executive and technical aspects of REACH, does not accept incomplete registration dossiers.



REACH and the biodiesel industry

Biodiesel under all its different compositions (ex: FAME, RME, SME, etc) as well as glycerine and any possible co-products or intermediate products produced and used by our industry **fall under the scope of the Regulation**, specifically under:

- TITLE II (Registration),
- TITLE V (Duty to identify, apply and recommend risk reduction measures of downstream users)
- TITLE VI (Evaluation procedure)



The authorisation requirement (Title VII) applies to substances contained in Annex XIV (i.e. classified as carcinogenic and mutagenic category 1 or 2, toxic for reproduction, persistent and bio-accumulative, having endocrine disrupting properties). **Biodiesel sofar does not fall under that list of substances**

More in detail the two steps of REACH detailed above will have implications for our industry:

- **Pre-registration:** identification and grouping of substances
- **Registration process:** involves a technical dossier about uses, properties of the substance and guidance for a safe use as well as a chemical safety report unless the product is produced in small quantities (less than 10 tonnes or 1000 tonnes a year, but this is not likely to apply to our industries).

NEXT STEPS

Given the **strict deadline** of the Pre-registration (1st December 2008), EBB fixed the following schedule:

InformationDay

- Organisation of an **Information Day the September 4th**, during which the legal, technical and operational aspects of REACH will be explained to all EBB members of the Consortium as well as to all potential members (biodiesel producers not yet members of the EBB, importers, Associations who may become observers, etc.). The explanation and debate will also include costs and benefits of the Consortium, and future steps. On the same occasion, the **1st Assembly meeting of the EBB REACH Consortium will be held.**

- The running operations of the Consortium will start immediately upon signature of the Consortium Agreement, with EBB acting as Secretariat to the Consortium.

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DAY
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Role of EBB under REACH

EBB is assisted by a Brussels-based consultancy specialised both on the legal and technical aspects of REACH. In order to anticipate, to explain and to suggest the next steps to EU Biodiesel industries, EBB carried out several activities regarding REACH issues, namely:

- Role of EBB under REACH**
- creation of an Ad Hoc Working Group on REACH providing strategic and technical suggestions within the overall REACH process
 - follow up of political and regulatory developments for REACH
 - encouraging the exchange of views among EBB REACH experts and check list of Annex IV and V for a broad recognition under the Annex IV (list of exemptions)
 - preparation and submission of exemption requests for various biodiesels under Annex IV
 - liaison activities with other Associations (European and US) and other companies also concerning glycerine status
 - creation and management as Secretariat of the **EBB Biodiesel REACH Consortium**

EBB Biodiesel REACH Consortium

As indicated above **The identification, analysis and evaluation process of a substance is normally very expensive.**

In order to reduce costs, REACH allows submitting the dossiers on chemical substances, by carrying out joint studies. In this context, **EBB set up a consortium framework**, in which duties, costs and benefits have been identified and **shared** between all participants. The main objectives of the consortium are to:

- share costs, information and risks
- maximise benefits, resulting from the proper use of chemicals and incentive for innovation
- reduce the number of substances to be tested and classified

