

Technical Updates

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REACH

REACH (the Registration, Evaluation and Authorisation of Chemicals) is a draft European Regulation in the later stages of being approved as law. The European Parliament is due to debate a second reading of the draft regulation in October this year. If approved, REACH could come into force around April 2007. The BioTrade Initiative has studied the REACH proposals to better understand the potential impact on exporters in the programme. This is a summary of those findings, not a legal interpretation.



Why is REACH an important issue to BioTrade?

REACH is an important issue to BioTrade because a number of the exporters in the BioTrade Programme are trading natural ingredients to Europe that could fall within the scope of REACH. These include essential oils and possibly natural colours. The same or other exporters may also be investigating new products for export to Europe that may need to comply with REACH.

Few, if any, would disagree with the higher aims of REACH to protect the consumer and the environment. However, in cases where the costs of obtaining additional data requirements to prove safety are prohibitive or ingredients already on the market are no longer authorised by the European Union then, some substances may no longer be manufactured or imported.

Exporters of natural ingredients need to know about REACH because it might impact upon their existing business with European companies or business plans.

“REACH places responsibility for testing and risk assessment onto European manufacturers and importers who sell chemicals on the European market.”

The Aims of REACH

The aims of REACH are to improve the knowledge and information about the safety and environmental impact of chemicals manufactured in or imported to Europe. This regulation will replace the current regulations that differentiate between “existing” chemicals on the market before 1981 and “new” chemicals introduced since 1981. Furthermore, it places responsibility for testing and risk assessment onto European manufacturers and importers who sell chemicals on the European market.

Underpinning the REACH regulation is the “precautionary principle”. This is incorporated in REACH by, for example: safety assessments, that are based on the scientific evidence that gives rise to the highest concern; risk management measures such as authorisation for substances of “very high concern” and restrictions where “severe risks” are indicated.

The initial focus of REACH is to improve the knowledge and information about the safety and environmental impact of around 30,000 “existing” substances on the market as listed on EINECS (the European Inventory of Existing Commercial Chemical Substances). REACH also applies to new substances that may be brought onto the European market.

A European Chemicals Agency (ECA) will be created to manage the registration process, carry out evaluations and advise the European Commission in respect of authorisations or restrictions.

The basis of REACH is Registration and this is carried out by European manufacturers or importers or “only representatives.” The latter are suitably qualified European legal entities who could register substances specifically for non-EU companies. It must be noted that non-EU companies cannot register substances.

Exemptions from Registration

REACH registration procedures do not apply for substances used in foods and medicinal products. However, substances used in cosmetic products are, potentially, subject to the provisions of REACH. The focus of this update is the use of substances in cosmetic products.



The draft REACH regulation includes a list of categories of substance and specific substances that are exempt from registration.

Naturally occurring substances are exempt from Registration **if they are not classified as dangerous according to European legislation.**

A substance occurring in nature is defined by the REACH draft regulation as:

"A naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means"

All of the natural ingredients in the BioTrade programme are, by definition, naturally occurring substances. In the case of extracts, extracts using water are within the above definition. Extracts made using other solvents – glycol, alcohols, etc. – would be considered as Preparations or mixtures of substances. Each substance in the preparation would need to be assessed to know whether it is within the scope of REACH or not.

What is a dangerous substance?

The definition of dangerous can be found in Council Directive 92/32/EEC of 30 April 1992¹. This is the seventh amendment of Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances. This directive states that the following are "dangerous" within the meaning of this Directive:

- a) explosive substances and preparations: solid, liquid, pasty or gelatinous substances and preparations which may also react exothermically without atmospheric oxygen thereby quickly evolving gases, and which, under defined test conditions, detonate, quickly deflagrate or upon heating explode when partially confined;
- (b) oxidising substances and preparations: substances and preparations which give rise to a highly exothermic reaction in contact with other substances, particularly flammable substances;
- (c) extremely flammable substances and preparations: liquid substances and preparations having an extremely low flash-point and a low boiling-point and gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure;
- (d) highly flammable substances and preparations:
 - substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy, or
 - solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition, or
 - liquid substances and preparations having a very low flash-point, or
 - substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities;
- (e) flammable substances and preparations: liquid substances and preparations having a low flash-point;
- (f) very toxic substances and preparations: substances and preparations which in very low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;
- (g) toxic substances and preparations: substances and preparations which in low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;
- (h) harmful substances and preparations: substances and preparations which may cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;
- (i) corrosive substances and preparations: substances and preparations which may, on contact with living tissues, destroy them;
- (j) irritant substances and preparations: non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, may cause inflammation;
- (k) sensitising substances and preparations: substances and preparations which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction of hypersensitisation such that on further exposure to the substance or preparation, characteristic adverse effects are produced;
- (l) carcinogenic substances and preparations: substances or preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence;
- (m) mutagenic substances and preparations: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence;
- (n) substances and preparations which are toxic for reproduction: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may produce, or increase the incidence of, non-heritable adverse effects in the progeny and/or an impairment of male or female reproductive functions or capacity;
- (o) substances and preparations which are dangerous for the environment: substances and preparations which, were they to enter the environment, would present or may present an immediate or delayed danger for one or more components of the environment.

BioTrade Ingredients within the scope of REACH

In the case of natural ingredients supported by the BioTrade initiative, the most obvious group of substances that are "dangerous" within the above definition is essential oils. Other natural substances may also be included, such as natural colours and, possibly, some vegetable oils, although generally the latter are not considered to be dangerous. Substances that appear on the EINECS register will need to be pre-registered by EU importers, manufacturers or "only representatives" within 18 months of REACH coming into force if the substance is listed on the EINECS register and quantities imported exceed 1 tonne per year per importer. Importers or other potential registrants working with smaller import volumes can also pre-register if they wish to be part of Substance Information Exchange Fora (see below).

¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992L0032:EN:HTML>

Registration deadlines and information required - "no data, no market²."

All substances that fall within the scope of REACH and which are manufactured or imported in quantities of one tonne or more per year per manufacturer or importer need to be registered with the European Chemicals Agency (ECA).

The information required and the deadlines for registration are related to the volumes imported or manufactured and the risks. As mentioned above, registration is carried out by European manufacturers or importers or "only representatives" of non EU manufacturers.

High volume (+1,000 tonnes) and substances of very high concern need to be registered within 3 years of REACH coming into force. For volumes exceeding 100 tonnes per year the deadline is 6 years and, for volumes of more than 1 tonne, 11 years after REACH enters into force.

The information requirements are proportional to the volumes and risks. The highest volume or highest risk chemicals require the most detailed information about safety and effect on the environment. The draft regulation includes Annexes detailing all the information requirements.³

As mentioned above, there is a Pre-Registration deadline for existing substances, 18 months after REACH comes into force and the European Chemicals Agency will publish the list of pre-registered substances. Clarification is being sought from the European Commission on what procedures exist to amend or update this list should, for example, an exporter find out that one of their existing substances has not been pre-registered by an importer.

As with the existing legislation, suppliers are required to provide Safety Data Sheets to their "downstream" recipients, regardless of the volumes imported or manufactured.

"REACH is encouraging a One Substance-One Registration approach to avoid duplication of tests."

REACH steps after registration

Dossiers received by the ECA are checked for completeness. For low volume chemicals (1-10 tonnes) registrants only have to submit already available data, unless those substances are identified as of potential concern. In other cases, dossiers can include proposals for obtaining the required test data, according to the specified requirements for that particular volume/risk, rather than having to submit all the test data.

The ECA advises the European Commission in cases where authorisations or restrictions are considered necessary for certain hazardous substances. Such decisions may be taken by the European Commission if the risks cannot be adequately controlled, or the socio-economic benefits do not outweigh the risks to human health or the environment, or if there are suitable alternatives. There are routes to appeal such decisions.

In the case of new substances that require registration the regulations detail exactly what tests are required. They also specify that the laboratories that carry out the tests need to meet the standards expected of the European Commission.

A study published by KPMG has estimated the costs of testing and registration at the different volume levels.⁴

Costs per substance - single registrant

The costs detailed above are for a single registrant. The European Commission has proposed a number of ways to reduce the cost and testing burden on registrants (see below). The costs of registration are costs that have to be incurred by the importer, manufacturer or "only-representative". How these costs are recovered is left to the "market."

Volume	Test Cost (€)	Registration Cost (€)	Total Cost (€)
1-10 tonnes	8,702	5,900	14,602
10-100 tonnes	151,573	11,150	162,723
100-1000 tonnes	243,467	38,630	282,097
+1000 tonnes	278,213	44,950	323,163

Steps to reduce the burden of registration

"It is likely that for the vast majority of BioTrade ingredients volumes will be less than 100 tonnes per year."

The REACH system encourages (a) a One Substance-One Registration approach to avoid duplication of tests, (b) the formation of Consortia and (c) all Registrants to become members of Substance Information Exchange Fora (SIEF). These aspects of REACH create an expectation that European importers and manufacturers will work together to submit the majority of dossiers for existing substances, with a view to ensuring a future market for those existing substances that have a market now.

Implications for exporters in the BioTrade Initiative

The first critical decision point is related to the volumes exported. If more than 1 tonne per year of a substance (that is not exempt from registration) is exported to a single importer, that substance will require **registration by the importer** – if the importer wants to continue to supply that substance in the EU market.

² Article 5 of REACH Common Position.

³ <http://register.consilium.europa.eu/pdf/en/06/st07/st07524.en06.pdf>

⁴ http://www.cefic.org/files/Publications/KPMG_study.pdf

An importer might purchase the entire quantity from one non-EU manufacturer or the same substance may be supplied to one EU importer by more than one non-EU manufacturer. For example, one EU importer might buy, on an annual basis, 750kg of a substance from exporter A and 750kg of the same substance from exporter B. As the total exceeds 1,000 kg per year the EU importer will need to register that substance. A different EU importer who buys 750kg of the same substance from Exporter A is not required to register that substance.

If the annual volume imported is greater than 1 tonne but less than 100 tonnes and the substance is not carcinogenic, mutagenic, toxic to reproduction or very toxic to aquatic organisms, then the registration deadline is 11 years after REACH enters into force, notwithstanding the need to pre-register. If the volume is between 1 and 10 tonnes, manufacturers and importers only have to submit **already available data**, unless those substances are identified as of potential concern.

If the annual volume imported is greater than 1 tonne and the substance is categorised as carcinogenic, mutagenic, toxic to reproduction or very toxic to aquatic organisms, then the deadline for registration is 3 years after REACH comes into force, notwithstanding the need for pre-registration.

It is likely that, for BioTrade ingredients within the scope of REACH, the other volume related deadlines for registration will not be relevant. The imported volumes are envisaged to be less than 100 tonnes per year per importer per ingredient.

To put this into context, figures from the European essential oils industry suggest that 97% of the essential oils imported to Europe fit into the category of less than 100 tonnes per importer per year. Of the 97%, around 57% are imported at less than 1 tonne per importer and so will not require registration and 40% are expected to require registration within 11 years of REACH coming into force, as between 1 and 100 tonnes are imported or manufactured. 3% of essential oils are expected to require registration within 6 years (100-1000 tonnes imported/manufactured).

Existing Ingredients

In the case of existing ingredients that require registration, as indicated above, it is likely that the European importers will work together to share the costs and workload of preparing dossiers. With the existing market for these ingredients, it is expected (but not guaranteed) that the burden for the information requirements will remain primarily amongst the importer community in the European Union. However this should not be relied upon and so exporters need to be prepared to provide data and they should monitor developments with their importers.

An example of non-EU **exporters** working together to prepare a more complete dossier is the Australian Tea Tree Oil industry. In December 2004 the (European) Scientific Committee on Consumer Products published an opinion on tea tree oil in which they concluded that the dossier on tea tree oil was incomplete. As a consequence the Australian tea tree industry is now engaged in preparing a more complete dossier of safety information to present to this committee.

New Ingredients to the Europe Market

Under REACH, the threshold for registration of new substances has been raised from 10kg to 1 tonne. This is to encourage innovation. However, as with existing ingredients, suppliers are required to provide Safety Data Sheets to recipients of the dangerous substance (or at the request of the downstream user even if the substance is not dangerous) regardless of the volumes imported.

A new substance will require registration once the volume imported exceeds 1 tonne per year and, for new substances, it is likely that the non-EU manufacturer/exporter will need to obtain the test data as part of their offer to the importer (rather than expecting the importer to do this). Specific negotiations between the exporter and importer or "downstream users" **might** result in agreements where both sides contribute to the costs of preparing the data, if this is necessary. In such negotiations it will be essential to clarify the owner(s) of the data/information and to establish measures so that the owners can protect that data/information.

There might be a situation where more than one non-EU manufacturer supplies the same new substance to the same EU importer and that total annual volume might exceed 1 tonne. In these circumstances it would be beneficial for those non-EU companies to collaborate on data collection, where necessary, and also, if appropriate, work together with the importer. It should be borne in mind that registration documents for substances imported between 1-10 tonnes can initially include only the test data that is already available unless the substance is of concern.

Another option, if registration is required, is for the non-EU manufacturer/s to work with an "only-representative" who carries out the registration obligations on behalf of those non EU companies. "Only representatives" need to be suitably qualified EU companies.

In all cases the level of information in the dossier is determined by the volumes to be imported. Full details of the information requirements are given in the draft regulation. The registrant submits the dossier and other required information to the European Chemicals Agency for Registration.

If, in the future, another importer is required to register the same ingredient from a different exporter then that new importer will also need to submit a dossier to the European Chemicals Agency. However if an "only-representative" was involved then, for the same substance from the same non-EU manufacturer, it would not be necessary for a new importer to register the substance because it would be covered by the existing registration, unless the volumes reached the next threshold level.

Under the OSOR and SIEF procedures there is information sharing but also cost sharing and fair compensation guidelines. It is obligatory to share animal test data within guidelines of fair compensation. Other data required may be obtained under a sharing mechanism or by separate testing. For new substances the default cost sharing mechanism is equal sharing of costs if industry cannot agree on a voluntary cost sharing agreement.

The European Chemicals Agency informs the new registrant about which registrants have the available test data and the ECA similarly contacts the existing registrant to inform them of the new registrant.

If requested by another registrant, existing registrants who own a test must share it. Therefore it needs to be clear who owns the data. As a reminder, the registrant can only be an EU manufacturer, importer or "only representative" (of a non-EU manufacturer).

REACH refers to concerns about "free-riders." The proposal includes mechanisms to ensure that all registrants pay a fair share of the costs of the test data needed for registration of a substance, starting at manufacture or import greater than 1 tonne per year.

Safety Data Sheets for New and Existing Substances Regardless of Volume

Suppliers will still have to provide Safety Data Sheets (SDS) to recipients of the substances regardless of the annual volumes sold. The SDS is required for transmitting information on safe transportation, safe handling and proper labelling of chemicals. Data on registered substances will enable the preparation of a more complete Safety Data Sheet. Substances that have not been registered might not have as much test data as the registered substances which might mean that safety data sheets from suppliers of non registered substances have more gaps in them.

Recipients can request Safety Data Sheets even if the substance is not classified as dangerous (as in the case of the cosmetics industry) and the information in the Safety Data Sheet in such cases can be proportional to the risk. In some cases "...information on certain properties is of no significance or technically impossible to provide..." (to quote from the draft REACH regulation) and in such circumstances reasons need to be given on the Safety Data Sheet under each heading. The compiler of the SDS is required to state whether the information is not available or whether the test results are negative (no significance). Ultimately, it is critical to understand the risks and dangers of particular substances prior to handling, processing or using the substance and to know the steps to take to manage the risks following the precautionary principle.

For BioTrade ingredients that are generally not known in Europe, the Safety Data Sheet requirement may cause particular challenges to exporters. It is necessary to work with competent people who can advise the exporters on compiling safety data sheets and then to be able to obtain the required information.

The Chemical Safety Report

When annual volumes exceed 10 tonnes per importer or manufacturer, in addition to the Safety Data Sheet the importer or manufacturer will also need to provide a Chemical Safety Report. These documents provide downstream users with more detailed information about the safe use of the substance.

Commercial Viability

The costs of REACH registration should also be included as part of the assessment of commercial viability.

Testing Facilities

It is not only the data and information itself but also the collection and preparation of that data and information. Laboratories will be expected to meet the standards of the European Union and be certified with Good Laboratory Practice. Exporters will need to be able to access such accredited services and other services that can provide the necessary technical expertise. In some cases it may be necessary to consider establishing "only-representatives" in Europe who can act as Registrants for exporters from non-EU countries. Within the REACH regulation, all the testing requirements are clearly described for each volume threshold that is imported or manufactured.

More Information

Further details about REACH can be obtained from the web sites below:

Overview of REACH:

http://ec.europa.eu/enterprise/reach/index_en.htm

REACH Draft Regulation:

<http://register.consilium.europa.eu/pdf/en/06/st07/st07524.en06.pdf>

KPMG Study on testing and registration:

http://www.cefic.org/files/Publications/KPMG_study.pdf

Opinions from selected NGOs can be obtained from:

<http://www.chemsec.org/>

http://www.env-health.org/IMG/pdf/NGOs_key_priorities_2nd_Reading.pdf

