

# FAQ-Sheet

## >>> Impact of REACH on Ajinomoto OmniChem's Natural Specialities.

### >>> WHAT IS THE HISTORICAL BACKGROUND OF REACH?

As a consequence of EU directive 67/548/EEC (27 June 1967) EINECS (European Inventory of Existing Chemical Substances) was established. It lists all chemicals commercially available within the EU between 1 January 1971 and 18 September 1981. The EINECS inventory comprises roughly 100000 entries.

As of 1981 EINECS was replaced by the ELINCS system and new chemical substances put on the market in the EU had to be registered under this new system. Based on a number of criteria safety information must be provided in order to allow regulatory authorities to conduct a risk assessment of the new product. Currently the ELINCS system comprises roughly 3800 entries.

As of June 1<sup>st</sup> 2007 both EINECS and ELINCS have become obsolete and are replaced by the unified REACH (Registration, Evaluation and Authorisation of Chemicals) system.

### >>> WHAT IS THE PURPOSE OF REACH?

The distinction between "existing" and "new" chemicals under EINECS/ELINCS resulted in a situation in which "new" chemical substances were submitted to a safety assessment prior to marketing while the bulk of the chemicals used in Europe – the "existing" EINECS registered substances – in most instances were never properly assessed.

REACH is designed as a unified platform for the risk assessment - according to a well-defined methodology - of all chemicals within the EU. It no longer differentiates between existing and new chemicals and the scope of the system is also considerably wider than that of the preceding systems. Not only is information required regarding the material itself but also on the downstream uses/processing of the chemical and the potential risks associated with the direct or indirect exposure of humans and the environment to the substance.

### >>> MUST ALL CHEMICALS BE REGISTERED UNDER REACH?

No, a number of chemicals remain exempted from REACH registration, primarily because they are regulated by some other part of the European regulatory framework. Major exemptions include:

- Active pharmaceutical ingredients (API's)
- Polymers
- Food ingredients (e.g. food additives, colorants, sweeteners,...)

However the use of the same chemical in an application different from the food application will require the registration under REACH. Thus phosphoric acid used in the manufacture of soft drinks is exempted but use of the same chemical as part of a rust converter will require registration.

Furthermore chemicals produced for experimental purposes are also under certain well defined conditions completely or partially exempted.

Registration is also not required if total production per year does not exceed 1 ton material averaged over the last 3 years period.

And finally a limited number of products considered as safe, listed in Annexes IV and V of EU Regulation EC 1907/2006 are also exempted.

### >>> ARE CHEMICALS OBTAINED FROM NATURAL SOURCES EXEMPTED?

Generally speaking: no, they are not. Only products obtained by manual, mechanical, gravitational means or by means of water dissolution, flotation, extraction, distillation or by heating solely to remove water of materials occurring in nature are exempted, provided they are not chemically modified. The result of a “chemical modification” is a substance of which the chemical structure has changed during the applied process.

A substance retrieved by water extraction, and afterwards purified by a solvent extraction is not chemically modified and thus is exempted from registration. However, the same substance retrieved by a solvent extraction is today not exempted from registration, due to the different extraction medium.

### >>> WHO NEEDS TO REGISTER?

Generally speaking the (European) producer or the first (legal) European owner of a (new) imported chemical requiring REACH registration must register.

Ajinomoto OmniChem already started preparing for REACH in 2006. Since then we have evaluated our options and established a list of actions we need to take in order to continue the marketing of our existing and future products.

### >>> WHAT ARE THE CONSEQUENCES OF NOT REGISTERING?

If a chemical is not properly registered production and use will no longer be allowed in the EU.

If a chemical is registered under REACH but one of its applications is not properly documented, the use in that particular application will no longer be allowed.

### >>> MUST CHEMICALS ALREADY ON THE EU MARKET BE REGISTERED?

Yes, but their REACH registration will depend whether they are already part of the EINECS or ELINCS registry system.

Chemicals registered under ELINCS already have an extensive safety dossier and have already undergone a risk assessment. Therefore these products will automatically receive a REACH registry number.

Chemicals part of EINECS often lack, or only have an incomplete, safety assessment. These products will be phased-in the REACH system by an initial pre-registration, followed by a final registration step.

### >>> WHAT IS THE PURPOSE OF PRE-REGISTRATION?

Pre-registration provides an opportunity to extend the registration deadline for existing chemicals. Depending upon volume and initial hazard assessments this extension period can be postponed from 2010 up to 2018.

If an EINECS registered chemical is not pre-registered before December 1<sup>st</sup> 2008 it is considered as a new chemical entity and must go through the normal REACH registration procedure, i.e. a full dossier must be submitted to the authorities prior to the (re)introduction of the product on the market.

### >>> WHAT IS THE TIMEFRAME FOR IMPLEMENTING REACH?

REACH has come in force as of June 1<sup>st</sup> 2007, but the first consequences of REACH will only become clearly visible from June 1<sup>st</sup> 2008 onwards.

From June 1<sup>st</sup> 2008 until November 30<sup>th</sup> 2008 phase-in chemicals can be pre-registered at the European Chemicals Bureau (ECHA) in Helsinki.

By end November 2010 all pre-registered high volume (> 1000 ton/year) and/or high hazard chemicals must be fully registered and before 1 June 2013 all pre-registered products produced in quantities in between 100 and 1000 ton/year.

By end May 2018 pre-registered chemicals produced in quantities in between 1 and 100 ton/year must also be fully registered.

From June 1<sup>st</sup> 2008 all new chemicals entering the European market must be REACH registered prior to their start-up production.

### >>> WHAT KIND OF INFORMATION WILL BE NEEDED TO COMPLY WITH REACH?

Basically 3 sets of information are required:

- (1) identification of the substance (chemical characterization, purity, assaying,...)
- (2) biological data (e.g. toxicological/eco-toxicological information)
- (3) information on the different uses of the product and the possible risks associated with this use (e.g. possible exposure risks of factory workers working with the product but also the risks for consumers using items containing the chemical)

The information listed under (1) and (2) must be generated by the applicant, thus Ajinomoto OmniChem, but to comply with the requirements listed under (3) Ajinomoto OmniChem will request for assistance from its customer base.

Failing to generate sufficient data to support a particular application could result in the authorities revoking the continued use of a product in such an application. It therefore is in the interest of both customers and Ajinomoto OmniChem to provide as much information as possible on the final applications of our products. It is clear that such information will be treated as confidential and will not be exchanged with third (non-regulatory) parties.

## >>> WHAT ARE THE CONSEQUENCES FOR THE OMNICHEM NATURAL SPECIALITIES PRODUCTS?

### >> Hydrolysable tannins.

Depending on the raw material source used for the extraction of hydrolysable tannins these products can be described as complex mixtures of polygalloylglucoses or polygalloyl quinic acid derivatives<sup>(4)(5)</sup>.

Considering the definitions in REACH regarding polymers<sup>(3)</sup>, hydrolysable tannins can be defined as polymers and consequently are exempted of REACH registration. This affects all the ALSOK, Brewtan, Floctan, Tanal, Tanex and Textan grades. Tanal WG is not a hydrolysable tannin and will be discussed under the grape seed extracts. Although polymers are exempted the un-reacted monomers present as part of the polymer matrix must be registered under REACH if they are present in excess of 2 %. This is not the case for most of the Ajinomoto OmniChem tannin grades and thus no registration of any of the monomers is required.

Notwithstanding this exempted status Ajinomoto OmniChem has already pre-registered its tannic acid (pre-registration number 05-2116385613-40-0000) in order to monitor and participate in the upcoming SIEF (Substance Information Exchange Forum).

### >> Condensed tannins.

#### Grape Seed Extracts – Tanal WG, OmniVin grades.

Grape seed extract is already an EINECS listed substance, and thus REACH pre-registration is required. Ajinomoto OmniChem has pre-registered its grape seed extracts under pre-registration number 05-2117171852-40-0000 and is preparing itself to participate in the upcoming SIEF (Substance Information Exchange Forum) negotiations.

Considering current production volumes and the low hazard profile of this product we expect that full registration will have to be completed in the 2013 – 2018 timeframe.

#### Cocoa Extract – OmniCoa 55

Cocoa extract is also already listed under EINECS, and thus also requires REACH pre-registration. Ajinomoto OmniChem cocoa extract is pre-registered under number 05-2117171862-39-0000.

Considering current production volumes and the low hazard profile of this product we also expect that full registration will have to be completed in the 2013 – 2018 timeframe.

#### Oak Extract – Oaktan grades

Although Oak extracts have been on the market in Europe for some time they are not registered under EINECS/ELINCS and consequently must be considered as new chemicals entities and would require registration.

However considering that these products are water based extracts, Oaktan extracts would be exempted from registration.

#### Blended tannin grades.

Blended materials are not subject to REACH registration but the ingredients are.

Consequently Ajinomoto OmniChem will rely on its own registration dossiers for the ingredients it manufactures itself or it will contact its suppliers in order to be assured that the raw materials we use will continue to be available in the future.

Currently this involves the following products: QCT, QCTN and Tanal QW2.

### **Pentagalloylglucose - PGG**

PGG is one of the major constituents of tannic acid but unlike tannic acid it can not be considered as a polymer due to the fact that it is a mono-component.

However considering today's small production volumes PGG currently does not require registration.

### **>> Other products.**

#### **Phosphatidyl serine - Ultraserine**

Considering that Ultraserine is a soy-lecithin enriched in phosphatidyl serine registration is not necessary because lecithins are part of the exempted substances listed in Annex IV of EU Regulation EC 1907/2006.

#### **Rosmarinic acid**

Rosmarinic acid is a new substance under EINECS/ELINCS and therefore will require registration under REACH.

However considering today's small production volumes rosmarinic acid currently does not require registration.

### **>>> REFERENCES.**

- (1) REACH in brief. European Commission, Enterprises & Industries Directorate General – Environmental directorate General; Dec 2006
- (2) EU Regulation EC 1907/2006
- (3) EChA Guidance for monomers and polymers; June 2007
- (4) Technical Leaflet G01: "An introduction to OmniChem's tannic acid."
- (5) Technical Leaflet G02: "OmniChem's hydrolysable tannins: origin and manufacture"

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The information in this paper is compiled to the best of our abilities and is based on the present state of our knowledge. Due to the continuous evolution of this legislation we can not guarantee that this leaflet is in agreement with the latest versions of this legislation but we do try to keep this information up-to-date to the best of our abilities. Ajinomoto OmniChem will not accept any liabilities or damages due to non-conformity or miss-interpretation from our part off the current legal framework in the EU. The information provided in this document does not constitute legal advice.

The information provided in this leaflet is only applicable to the Ajinomoto OmniChem Natural Specialities products. The status of competing products can be different.