

REACH and the Malaysian Palm Oil Industry

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INTRODUCTION

In 2001, the European Union released a white paper proposing the establishment of a regulation on the registration, evaluation and authorization of chemicals (REACH). The key objective of the regulation is to increase the protection of the consumers; health and the environment from the exposure to hazardous substances. The regulation was adopted in September 2003 by the European Union (EU) Parliament and eventually, enforced on 1 June 2007. Affected parties have been advised to carry out pre-registration of phase-in substances in the period June to November 2008. Many Malaysian oleochemical manufacturers, the most affected sector in the palm oil industry, have already pre-register their products.

The important implications of reach are:

- only registered existing and new substances (except those exempted) may be manufactured, imported or used;
- not only the substances, but also the whole supply chain has to be registered, evaluated and authorized;
- manufacturers and downstream users are equally responsible for the safe handling and use of these substances; and

- there will be a tremendous increase in the cost of doing business involving affected substances because of the various requirements for the registration.

EXEMPTION FROM REGISTRATION

There are some substances that are exempted from REACH registration. This includes substances used in food, feeding stuff, medicinal products, cosmetics, veterinary products, *etc.* that are regulated by other EU legislations, as well as those listed in Annexes IV and V of the REACH Regulations. Substances exempted under Annex IV are specifically named products while Annex V contain a list of natural occurring substances, and those that have not undergone any chemical modification processes, and include amongst others, mineral materials, petroleum products, by-products, *etc.* As oils and fats are also used in non-food products, they may require registration under REACH.

Under the initial provisions of Annex IV, several oils and fats and their fatty acids were exempted from registration, but palm oil, palm kernel oil and their fatty acids were glaringly excluded from the list for unknown reasons. The Malaysian Oleochemicals Manufacturing Group (MOMG) established a technical working group comprising members of MOMG, representatives from MPOB and SIRIM to work closely with ASEAN Oleochemicals Manufactur-

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ing Group (AOMG) and relevant European trade associations such as the European Chemical Industry Council (CEFIC) and the EU Oil and Protein Meal Industry (FEDIOL) as well as MPOB, Ministry of Plantation Industries and Commodities (MPIC), and the Ministry of International Trade and Industry (MITI) in seeking for amendments in the REACH exemption list. Several petitions, with technical justifications, have been sent from 2007 to 2009 to the EC through the channel of MITI and MPIC to request for a review and clarification of the lists of exemption under Annexes IV and V.

Finally on 8 October 2008, a Directive, Commission Regulations (EC) No. 987/2008 amending the Regulation (EC) No. 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), as regards Annexes IV and V was released by the European Commission. This new document reviewed the former Annexes IV and V, and spelt out the revised lists of substances exempted from REACH Registration under the new Annexes IV and V.

Revised Annex IV

Substances are exempted under this Annex because sufficient information is known about them that they are considered to cause minimal risk because of their intrinsic properties as far as the oils and fats industry is concerned. The revised Annex IV includes substances in *Table 1* (EC, 2008).

Revised Annex V

This Annex stipulates a more general list of criteria for exemptions from REACH registration. The substances listed are generic in nature. In the case of oils and fats and their products, para 9 of the Annex V (or the new Annex II), states that (EC, 2008):

'The following substances obtained from natural sources, if they are not chemically

modified, unless they meet the criteria for classification as dangerous according to directive 67/548/EEC with the exception of those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36] or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex III or unless they were identified in accordance with Article 59(1) at least two years previously as substances given rise to an equivalent level of concern as set out in Article 57(f)'. The substances are vegetable fats, vegetable oils, vegetable waxes, animal fats, animal oils, animal waxes, fatty acids from C6 - C24 and their potassium, sodium, calcium and magnesium salts; glycerol.

As Annex IV provides specific names of substances that are exempted (thus there is no ambiguity), it is not the same in Annex V, where the substances listed are mostly generic. Thus, there could be different interpretations of the various clauses in Annex V. As a tool to help registrants, ECHA has come up with *Guidelines for Annex V* [http://guidance.echa.europa.eu/guidance4_en.htm].

With this revision, common oils and fats products, their fractions and basic fatty acids, whether as single component or in mixtures (unless those which are skin and eye irritants) and natural glycerol are exempted. However, the following matters are still unresolved:

- methyl esters of fatty acids derived from oils and fats are not listed in Annex V, and in Annex IV, only coco methyl esters is listed. This means that methyl esters from other oils and fats are not exempted;
- as substances derived from hydrogenation are not considered natural, and thus will not be exempted under this Annex. As a result, the status of fatty acids derived by hydrogenation of unsaturated acids (e.g. stearic acid from

TABLE 1.

EINECS No.	Name of substance	CAS No.
232-307-2	Lecithin	8002-43-5
232-442-7	Tallow, hydrogenated	8030-12-4
262-998-1	Fatty acids, coco, methyl esters	61788-59-8
266-948-4	Glycerides, C ₁₆₋₁₈ and C ₁₈ - unsaturated	67701-30-8
269-658-6	Glycerides, tallow mono, di and tri, hydrogenated	68308-54-3
270-312-1	Glycerides, C ₁₆₋₁₈ and C ₁₈ - unsaturated, mono and di-	68424-61-3
288-123-8	Glycerides, C ₁₀₋₁₈	85665-33-4

hydrogenation of oleic acid) as well as hydrogenated vegetable oils are still not clear; and

- it is not certain if glycerol obtained from transesterification of oils and fats (as in the production of biodiesel) is exempted under the provision of Annex V.

Thus, there are inconsistencies in the exemption of certain substances – e.g. hydrogenated tallow and coco methyl esters are specifically listed in the exemption under Annex IV. The Technical Working Group is still pursuing these items and hopefully a fair and non-discriminatory outcome can be found. If these issues are not resolved, then there will be a need to segregate (natural) stearic acid from fractional distillation of

tion is done by a consultant who acted as the ‘Only Representatives’ for the company or through the company’s branch office (which must be a legal entity) in the EU. Joint submission by several companies through a consortium can bring down the cost tremendously. An estimated breakdown cost of registration for a single high production volume product has been worked out to as in Table 2. (Surina, 2009).

CONCLUSION

REACH is a complicated regulation and Malaysian exporters to the EU countries have no other alternative but to register the phase-in products unless they are willing to forego that market. It is rather strange that despite several petitions by the Malaysian palm oil industry through the appropriate

TABLE 2.

Item	Cost factors	Amount (€)
1	Registration fee (joint submission)	23 250
2	Registration dossier, including technical data	1 582 616
3	Cost of consortia/administration fees/miscellaneous	60 000
Total		1 665 866

vegetable fatty acids from splitting that are derived from hydrogenation, and the same for glycerol from different routes!

COST IMPLICATIONS

Registration of phase-in substances under REACH Regulation can be a costly affair. The cost may vary from one manufacturer to another depending whether the registra-

channel, the inconsistencies in the exemption of palm oil products and oleochemicals, as listed in Annexes IV and V still could not be rectified. Nevertheless, the Malaysian palm oil industry, especially the oleochemical industries together with the relevant agencies are preparing themselves in a very cooperative manner to face the challenges post by complying with the REACH Regulations.