Legislative Controls over Adjuvants

Adjuvants are authorised under European legislation Regulation (EC) No 1107/2009, which came into force on 14 June 2011 states:

“Adjuvants may be used to increase the efficacy of a plant protection product. Their placing on the market or use should be forbidden where they contain a co-formulant which has been prohibited. The technical rules necessary for the authorisation should be established.”

Article 58 ‘Placing on the market and use of adjuvants’ states:

1. An adjuvant shall not be placed on the market or used unless it has been authorised in the Member State concerned in accordance with the conditions established in the Regulation referred to in paragraph 2.
2. Detailed rules for the authorisation of adjuvants, including data requirements, notification, evaluation, assessment and decision making procedures shall be set out in a Regulation to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

However, under Article 81(3) of 1107/2009 there is a derogation stating that Member States may apply national provisions for authorisation of adjuvants until the adoption of detailed rules referred to in Article 58(2).

This new provision is implemented by Schedule 2 of the Plant Protection Products Regulations 2011.

The Regulations enable Ministers to:

1. Set certain data requirements which have to be met in order for an adjuvant to appear on the Official List. These data requirements form the basis of the application evaluated by HSE to determine the safe conditions of use of the adjuvant with an authorised plant protection product.
2. Determine the conditions to which the use of the adjuvant with a plant protection product are subject i.e. specify the conditions of use published on the List Entry for each adjuvant product. These may be amended for safety reasons or at the request of the applicant.
3. Set further requirements which may be amended in the light of available information relating to the use of the adjuvant with authorised plant protection products. This may result from a review of an individual or group of adjuvants. A listing cannot be given subject to further confirmatory data requirements being set. If an adjuvant fails to pass a review, the product may be removed from the Official List.
4. Remove an adjuvant from the Official List for a variety of reasons:
   - if the applicant fails to comply with any data requirements (as part of an application for Official Listing, or review)
   - if any relevant product literature is not in accordance with the published conditions of use of the adjuvant, (relevant literature includes the product labelling, any accompanying leaflet, or any other literature describing the product produced by the Applicant);
for safety reasons;
at the request of the applicant company.

The Regulation does not control the advertisement, sale, supply, or storage of adjuvant products but other legislation may apply (see below).

**Controls on Sale, Supply and Advertisement of Adjuvants**

There are no legal controls over the marketing and advertisement of adjuvants. Therefore there is no direct control over the content of product labels, other literature or the containers in which the product is marketed. However, an adjuvant may be removed from the List if the label or any other relevant literature promotes the use of an adjuvant with a plant protection product in a way that would either contravene the conditions of use of the adjuvant as detailed on the List, or the plant protection product authorisation(s).

HSE may, in the letter accompanying the List Entry, provide advice on label text referring to the use of the adjuvant.

Adjuvant products come under the definition of general preparations and hence these products should be classified and labelled in accordance with CLP (see below).

**Controls on Storage of Adjuvants**

There are no legal controls over the storage of adjuvant products and as HSE does not control the container in which the product is marketed, HSE does not consider the effect of packaging on the storage properties of the product.

**Controls on Use of Adjuvants**

Control over the use of the adjuvant with the plant protection product is interpreted by HSE as being at the point when the adjuvant is in physical contact with the plant protection product.

The List Entry will include specific conditions of use relating to controls over use. Any change to these conditions require an application to amend the List Entry.

**Other relevant legislation**

The aspects that are not controlled under the Regulations (e.g. storage, operator protection prior to use, environmental and toxicological classification) are controlled by other legislation:

- The Health and Safety at Work Act, 1974; and,
- The Control of Substances Hazardous to Health Regulations (COSHH) 1999; and,
- European Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. It is known by its abbreviated form: ‘the CLP Regulation’ or ‘CLP’.
Twin Packs

When an adjuvant is to be supplied and marketed together with the plant protection product for mixing before use (e.g. as a ‘twin-pack’), it is considered to be part of the authorised plant protection product. Whether or not that particular adjuvant is on the Official List, the plant protection product/adjuvant combination must be considered by HSE for safety and efficacy as part of an application for an authorisation of the plant protection product.