DISCUSSION SESSION 3

REGULATION OF ADJUVANTS – CURRENT STATUS AND FUTURE PROSPECTS

Chairman and Session Organiser: Dr John Caseley
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Regulation of adjuvants – current status and future prospects

Tank mix adjuvants are widely used to improve the performance of pesticides. Regulations governing the sale and use of adjuvants and inerts vary between countries, but in both Europe and North America requirements for authorisation are being revised and in the future additional information will be required.

This session will start with two short presentations to stimulate discussion.

Rupert Sohm, *Syngenta Crop Protection, Muenchuilen, Switzerland* will give an overview of developments in adjuvant markets worldwide and examples of the current regulations.

Dr Jan Rosenblom, *AkzoNobel Surface Chemistry, Stenungsund, Sweden* will focus on chemical legislation changes and pressures which may affect the cost and availability of tank-mix adjuvants including the re-registration processes in Europe and the USA.

Copies of their presentations are presented in the following pages.

Market and regulatory trends affecting the use of tank mix adjuvants

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Many pesticides need to be sprayed in conjunction with inherently non-pesticidal substances in order for the full effect of the pesticide to be delivered.

The potential benefits to the grower include:

- Improved cost-effectiveness of the crop protection products applied – e.g. via the use of wetting/retention aids, bioefficacy enhancement adjuvants, etc.;
- Improved reliability of the crop protection product – e.g. via the use of rainfastness aids, water quality modifiers;
- Avoidance of adverse off-crop effects – e.g. via the use of spray drift reduction additives.

The majority of developments in the use of tank mix adjuvants have been driven by their use with herbicidal products. Of these, the single biggest source of change has resulted from the growth of glyphosate-based products. This active ingredient provides many opportunities for enhancement of product performance through the use of adjuvants.

There is a diversity of grower attitudes towards tank mix adjuvants. Growers managing large acreages tend to have the expertise to gain the maximum benefit from a wide range of tank-mix adjuvants while smallholder farmers tend to prefer products where the adjuvant is co-formulated with the active ingredient. Overall there is a gradual global trend towards 'built-in' products. The primary driver for this is the desire for simplicity in an environment that is becoming increasingly complex.

Manufacturers of crop protection products also prefer 'complete' products. This is driven primarily by the desire to ensure that the benefits of adjuvant technology are not shared with competitors. In many cases such 'built-in' products are not practical due to the wide range of application rates which may be appropriate for an active ingredient.

The regulatory environment is equally diverse. There is a broad spectrum of regulatory data requirements for tank mix adjuvants. One extreme is presented by the USA, where the Environment Protection Agency (EPA) requires little more than proof that the formulants used are exempted from tolerance (i.e. 'approved' by the EPA) and some limited toxicology data. The other extreme may be found in some European markets, where extensive data requirements linking the adjuvant to the a.i. are required. In many such cases extensive biological data needs to be generated (e.g. ecotox, environmental fate and AI residue data in the target crops). The diversity of regulatory requirements in Europe is a consequence of an absence of EU-wide legislation relating to the regulation of tank mix adjuvants. Again, the regulatory environment is not static. Setting aside the pressures upon the suppliers of the

formulants there is a trend towards more regulation of adjuvants and therefore more extensive data requirements and therefore higher costs and longer development times for new entrants.

As a consequence both the market and the regulatory environment are driving the crop protection market away from tank-mix adjuvants. This is not a rapid trend, but can be observed in most of the key markets.

A few clear exceptions are expected to emerge:

- Where commercial factors are important – e.g. where distributors/retailers wish to provide a technical service to growers.
- Where vendors of tank mix adjuvants can demonstrate unique benefits – often through novel products generating enhanced benefits.
- Where the adjuvant is required only in specific circumstances and routine use would not be cost effective (e.g. avoidance of spray drift).
- Where the active ingredient has a broad range of application rates making it difficult to build in a single robust and economic level of adjuvant.

The only clear certainty in this market is that it will remain dynamic and evolve with time.

Trends in the chemicals regulatory arena affecting tank mix adjuvant markets

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Producers of tank mix adjuvants make these products from formulants supplied by chemical manufacturers. While on the one hand there is a trend towards more regulation of adjuvants as such, the development of general chemicals legislation, especially in Europe, may affect both the availability of chemical substances for use as formulants as well as the possibility to protect proprietary formulation know-how.

Some of the drivers for the development of chemical regulations are:

- The current trend of globalization of businesses and information flows, supported by communication technologies like the internet
  - makes issues, perceived or real, travel faster and faster to other regions of the world
  - facilitates copying of legislation from one region to another
  - supports harmonization of regulations between regions

- Increased pressure from non-governmental organisations, consumer groups and other stakeholders
  - Political pressure for more stringent regulations on chemicals
  - Increased pressure for transparency of data and risk assessments

- Political pressure results in
  - Increased regulatory requirements in most regions of the world and in particular in Europe

In Europe the general use and classification and labelling of chemical substances is currently regulated by the Directives on Dangerous Substances, Dangerous Preparations and Safety Data Sheets (SDS). There are no special requirements for testing or registration of a substance before use in a particular application as long as the substance is listed in the inventory of existing chemicals (EINECS) and the application not subject to specific regulations. This may however change in the future according to a proposal for new European chemicals legislation called REACH. The acronym stands for Registration, Evaluation and Authorisation of Chemicals.

REACH will replace the existing European legislation on chemicals which makes a difference between new and existing substances. REACH does not make this difference and covers registration, evaluation and authorization of all substances produced or imported in one single system.

- Registration of substances manufactured in quantities above 1 tonne per year;

- Evaluation by authorities of substances manufactured above 100 tonnes per year or of very high concern;

- Authorisation of substances of very high concern.

The registration will require:

- a dossier with toxicity and ecotoxicity data the scope of which are triggered by volumes produced;
- a human health and environmental risk assessment for all intended uses;
- a chemical safety report including risk management recommendations based on the outcome of the risk assessment

While the current legislation requires authorities to do risk assessments the proposal puts the full responsibility for the safe use of chemical substances on industry including the chain of downstream uses.

While REACH may have an impact on the possibilities to use a specific chemical substance as an ingredient the other competitive strength of a formulator, the formulation know-how, will be affected by another recent regulatory requirement. The new updated European Preparations Directive require all ingredients in a formulation classified as dangerous to human health or environment to be revealed in the obligatory SDS. Since most of the key ingredients in a formulation are revealed in the SDS it will be very difficult to keep propriety technology and knowledge secret which in turn will weaken the contribution of strength in technology to competitiveness.

In the future there will be increasing regulatory burdens which will result in:

- small volume specialty products will have difficulties recovering the costs to comply with regulations;
- the number of available small volume specialty chemicals will probably decrease due to rationalization of product portfolios;
- many small and medium sized companies may have difficulties in recruiting and keeping experts needed as well as finding the financial resources;
- favours the use of global formulations;
- large companies will be favoured being able to capitalize on a larger global market.

DISCUSSION SESSION 4

DOES UK PLANT BIOTECHNOLOGY HAVE A COMMERCIAL FUTURE?

Chairman: Professor John MacLeod
RHS Professor of Plant Science, Cambridge, UK

Session Organiser: Dr Rod Morrod
Biotech2020 Organising Group Chair, Maidenhead, UK

Does UK plant biotechnology have a commercial future?

In February 2003, BCPC organised a major Forum on plant biotechnology entitled *Biotech2020: Plant Biotechnology in the World of 2020.* This brought together over 50 experts and senior representatives from government, international institutions, research, industry and commerce.

The purpose of the meeting was to identify the emergence by 2020 of new plant science and biotechnology on a global basis and to discuss its interaction with relevant aspects of the world of 2020, including geopolitics, trade, food supply, societal values and the nature of the agri-food market. By focusing on 2020 and creating cross fertilisation between very different disciplines, the Forum provided new insights to those involved in policy making, strategy setting and investment in the UK and Europe. (The Report of the Forum is available from BCPC Publications Sales price £25. Email: publications@bcpc.org).

One of the clearest messages from the Forum was that increased understanding of plants over the next two decades and beyond, will be unprecedented and will provide huge opportunities for mankind throughout the 21st century. The UK, through university groups and research institutes, is at the forefront of this exploration. However, a number of factors were identified that could seriously undermine the conversion of this research into commercial activities with the capability to participate successfully in future European and global biotechnology markets.

The Discussion Session will raise questions on three aspects of the route to market for UK plant science.

1. What relationship should the UK maintain with the international bioscience companies?

2. Do we need a new paradigm to achieve impact from UK biotechnology in outlets specific to the UK which is of no commercial interest to the multinationals?

3. What are the critical issues for the UK's successful involvement in the non-food crops sector, including renewable energy and the replacement of current petro-chemical products?