Session 1

Responsibilities and Challenges of Modern Crop Protection

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Platform Papers:	1-1 to 1-3

The future is agriculture and plant science will help

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Agriculture touches every aspect of daily life and its importance is growing dramatically. With each passing day, the demands are increasing.

Challenges facing global agriculture

A growing world population, expected to near nine billion by 2050, demands food – not just more, but better, more nutritional and more diverse food. With increasing affluence in newly industrialised and developing countries, the demand for meat-based protein is growing, thereby requiring increasing demands for grain. Fruits and vegetables, not only those familiar, but exotic options from around the world are in demand more than ever as consumers strive for healthier living.

The need for energy security and for renewable sources of energy demand solutions that agriculture can help provide. While world energy demand is expected to increase by more than half our current consumption rate by 2030, finding a solution to the threat of global warming and the end of fossil fuels becomes more urgent. While energy efficiency through wiser consumption is paramount, cleaner energy sources derived from bioenergy feedstocks can help achieve a more sustainable energy future.

In addition, a healthy environment requires new consumption options using material that have a smaller footprint on the environment, whether in manufacturing or in the management of waste after use. Biodegradable and renewable products made from fields give consumers and industries new alternatives.

So, agriculture must provide food, feed, fibre and now fuel and new material to the world – and more of it. Agriculture, in particular crop agriculture, will be fundamental in the 21st century to use the photosynthesis capacity of plants to convert solar energy more fully. But in order to be ready to cope, agriculture will have to adapt.

This is no small task. Primarily because agriculture will need to tackle these challenges with limited resources. There is a finite amount of arable land and we must treat it well. That entails managing soil fertility, avoiding soil erosion, saving habitat and withstanding the pressure of increased urbanization. There is also a limited supply of water. With 70% of available freshwater used in agriculture, farming actors must manage it with care and responsibility through methods like micro-irrigation and new technologies that minimise water use. And with the concerns about global warming, reducing carbon emissions is also a priority for us all. In short, we must do more with less. Less land, less soil, less water, less biodiversity, less CO_2 emissions. Also less farmers.

This year, the world population has reached the inflection point when, for the first time in the history of humanity, more people live in cities than in the country. And those who continue to farm the countryside are mostly among the poorest people on the planet. Whilst there is enormous potential, more than 1 billion farmers (80% of the world farmers) live in

poverty or extreme poverty and don't have the opportunity to move beyond subsistence farming. They don't have access to credit, to technology, to advanced knowledge, to markets and, in some cases, to land. They will not be in a position to tackle alone the challenges facing agriculture today. Fighting poverty and hunger are inextricably linked. Improved agriculture is a path out of rural poverty and hunger in many regions. It is the very foundation of economic security for most countries. It is equally important that those improvements ameliorate the health and well-being of the people who work in agriculture.

Addressing the challenges

Increasing production is a challenge agriculture has faced before. Farmers have, for the last 11,000 years or so, employed new techniques and agricultural methods to feed growing populations and to free resources to fuel economic growth. However, this is a critical juncture, with a dramatic and immediate jump in demand and an acute shortage of land resources to do it with. The techniques applied to addressing this challenge will need to be more innovative, more environmentally-sensitive and more sustainable than ever before. Consider that global corn demand is up by 200 million tonnes over the past ten years and is expected to reach 800 million tonnes in 2008. There is a clear and growing demand.

Agriculture has maintained a stable area of land since 1950. That land base is not expected to increase except for some nations, and only in certain areas, where there is limited opportunity to develop arable lands. Increased adoption of farming practices such as continuous cropping and multiple cropping can further increase the productive output of existing lands, but these must be achieved in a sustainable manner.

Other solutions have been offered and will continue to be offered by plant science. For example, through biotechnology plant breeders have increased the yield of corn in the Philippines by 41-60% over traditional varieties while improving net income for farmers by one-third. And these kinds of yield improvements will continue for all crops. Up to 40% of the world's crop production is lost annually because of the effects of weeds, pests and diseases; crop losses would be higher without crop protection.

Technology-based improvements and better practices must take into account conservation of natural resources. Crop protection and biotechnology have facilitated the move to conservation tillage, which has reduced soil erosion and carbon emissions. But, soil conservation practices will have to be intensified to limit further soil degradation. Methods like micro-irrigation and new technologies that minimise water use, such as rice that requires less water and corn that is tolerant to drought, will be applied increasingly.

A greener world will be fuelled by feedstocks derived from crops. The International Energy Agency predicts that farmers could supply the world with about 10% of its gasoline needs by 2025. Renewable crops can also be used for bioenergy and biodegradable packing, car parts, carpets and clothing. Vegetable-based inks, used by the printing industry, are less damaging to the environment, more easily recycled and less toxic to humans.

For agriculture to successfully meet the food, feed, fibre and fuel demands of a growing world, and to provide opportunities for farmers in the developing countries, trade policies need to be adapted. Trade-distorting policies will have to be abolished. Trade policies and approval regulations must also facilitate access to technologies. Every year the crop protection industry trades US$18 billion worth of products internationally but farmers are

still paying unnecessary duties that hamper access to technologies that are needed for plant protection and production.

Further achievements in reducing trade barriers and improving the rules of international trade in goods and intellectual property is essential. For example, eliminating tariffs on crop protection products, greater harmonisation of rules and standards and the removal of agricultural trade barriers such as subsidies will facilitate world trade and economic development. When access works, there are many examples where technology transfer to the developing world has improved lives. For example, the adoption of fungicides in Zimbabwe has allowed farmers to grow tomatoes in the rainy season when prices are ten times higher than the dry season. Growing Bt cotton in South Africa has increased the earnings of small landowners, providing money to educate their children and allowing for expansion of their farms.

These challenges cannot be addressed in isolation. Strong partnerships and multi-stakeholder solutions will be required to feed our growing demand. Through international networks with a broad range of groups including farm groups, United Nations organizations, national governments and aid agencies, the plant science industry is working to improve agriculture.

The role for plant science

Several of these solutions have come from plant science research and it is this research that holds the key to the next wave of solutions. Solutions that will make it possible to meet the challenges of a bio-economy depending on agriculture for more and more product. Our industry, involved in the CropLife network, includes over 1,000 companies around the world, serving a US$36 billion crop protection and a US$6 billion biotech seed market throughout most countries of the world.

The innovation investment is considerable. In 2005, the top ten plant science companies spent US$2.25 billion, or 7.5% of sales in crop protection and an estimated US$1.5 billion, or 25% of sales in plant genomics and biotech R&D. These figures demonstrate that the plant science industry is one of the world's most innovative sectors, comparable to pharmaceuticals, electronics, information technology, and automotive industries in terms of percent of sales re-invested in R&D. This is about one-third of all private research in agriculture. The other two-thirds are public research (see Fig. 1), although public research in agriculture has declined over the last decades. To effectively address the challenges mentioned above requires sustained R&D activities in both the public and the private sector and proper exchange mechanisms to leverage the strengths and outputs of each.

Crop protection companies have introduced an average of 12 new products a year for the last couple of decades. This is not an insignificant number given that a new crop protection product takes around eight to ten years and approximately US$150-200 million to develop. Innovation has also brought new formulations that are safer and easier to use, and new application equipment and machinery. For a new biotechnology trait, the cost of obtaining regulatory approvals in key markets is US$100 million, let alone the cost of development. The advent of biotechnology has and will continue to enable the introduction of traits that could not be expressed through traditional breeding: traits to protect against certain insects, to tolerate non-selective herbicides, to express different oil profiles, to resist abiotic stresses such as drought or salinity.

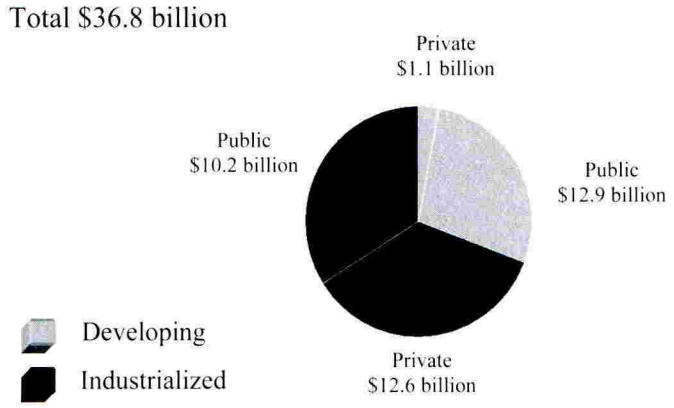

Fig. 1: Agricultural research spending (2006). Source: CGIAR

The long-standing commitment to increasing safety and productivity for agriculture is being furthered by the work now underway to create agricultural products which better fill global demand. Where once plant science was about growing healthy plants, it is now about growing healthy plants that meet unique needs. Many plant science companies are breeding vegetables with higher nutritive value, oilseeds that produce healthier cooking oils and crops that create polymers to replace plastics and man-made fabrics. These are solutions that support global goals from start to finish. Providing more of what we need with fewer resources.

Technology in itself, though, is value-neutral. Benefits only accrue and overshadow negative externalities when it is used well. The history of technology has examples of technologies that have been misused. Plant science technology is no different. This why CropLife and its members put a strong emphasis and considerable investment on the stewardship of their technologies and products. CropLife supports programs around the globe to foster the responsible use of crop protection products. Last year alone, training on the responsible use of pesticides and integrated pest management techniques was conducted with over 350,000 farmers, 5,000 extension workers as well as 75,000 other stakeholders including retailers.

This is only one of several stewardship programs we offer, on the ground, with the goal of protecting people and environment.

- CropLife programs encourage people to choose our products when they want them, use them only when needed and use only as much as needed.
- In Africa, CropLife is part of a multi-partner initiative to remove all obsolete pesticide stocks from the continent.
- CropLife conducts training on the proper ways to clean and dispose of pesticide containers. The member associations run or are engaged in schemes to collect and recycle those containers.
- Lock boxes and smaller containers are being used to minimize the opportunity for people to misuse our products to commit suicide.
- Training on buffer zones, proper spraying techniques and related methods to protect the environment is incorporated into our programs.

Based on twenty years of experience in stewardship of crop protection products, the industry has also embarked on a similar stewardship programme for biotech seeds, starting with field trial measures such refugia training and proper field isolation. Our US association BIO has also recently initiated a fully fledged quality management programme for the stewardship of biotech seeds. In both technologies, the industry embraces a concept of stewardship that spans the life cycle of plant science products and forms the basis for CropLife programming (see Fig. 2).

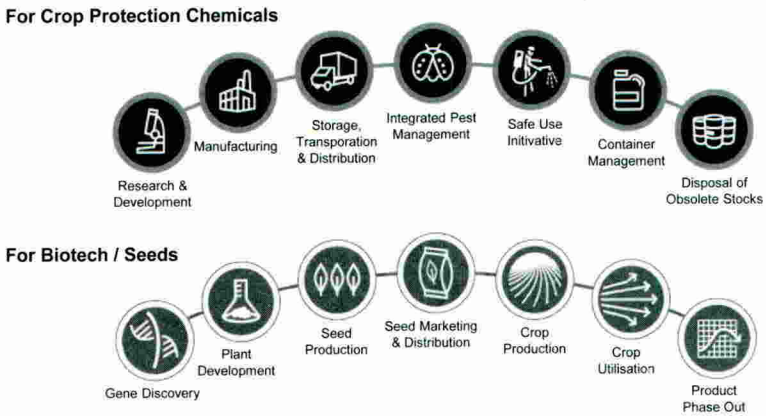

Fig. 2: The life-cycle concept of stewardship for plant science products.

The role of stewardship becomes even more important when you consider the growing demand. Agriculture is an ideal source for renewable, biodegradable resources. As the demand for agricultural products moves past the traditional needs of food, feed and fibre into the world of fuel, polymers and industrial products, we lay the path to a bio-based economy.

Yet, with the industry's commitment to change, there are obstacles that stand in the way of investing in and commercialising or maintaining new technologies. Public opinion towards and acceptance of these technologies is divided, resulting in enthusiasm and embrace by some and rejection or even destructive protest in others. The demands placed on companies by regulatory agencies often mean that access to new technologies by farmers is restricted, considerably delayed or prevented all together. The inefficient and asynchronous approvals of products also result in international complications and trade disruptions such as detained shipments and lost sales, or open trade disputes between major trading blocs.

Threats on the protection of intellectual property rights are also a major cause of concern for the industry. Proper enforcement of those rights is essential for an innovative sector such as the plant science industry. In contrast, the industry is facing erosion of the protection of safety and efficacy data, counterfeited products occupying between 5 and 35% of certain significant markets, and an international disagreement on the way to protect plant varieties and biotechnological inventions. The end-result is a disincentive to further innovation and potential harm to society. Better scrutiny by governments of the implementation and enforcement of intellectual property rights will help the plant science industry deliver on its commitment to innovate and deliver state-of the-art products to the world's farmers.

In a nutshell, policy-makers and stakeholders need to address these critical factors for an innovative plant science industry:

- Better recognition of the role and benefits of plant science technology for the future of sustainable agriculture,
- Science- and risk-based regulations for the approval of products that are both effective and workable,
- Protection of the innovation cycle through better enforcement of decent intellectual property rights,
- Fair and free trade rules,
- Integrity standards and commitment to stewardship and
- A willingness to engage in dialogue and in multi-stakeholder partnerships.

The future is a mandate for science and innovation. If plant science is to achieve this, expertise, funds and public-will must be mustered. By reaching out to opinion leaders and policy makers, it is possible to show a path forward to a sustainable bio-economy. And the entire agriculture sector – private and public alike – needs to speak up about the future of agriculture and the future that is agriculture.

How safe is our food? Whom do you trust?

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Abstract
Consumers may be directly exposed to pesticides that are present as residues in or on food or in drinking water. For plant protection products, the demanding regulatory framework at the EU level and in Member States has been further strengthened since 2002 to ensure food safety and the safe use of pesticides for people and the environment. Residues in food are monitored against their approved Maximum Residue Levels (MRLs), the legally permitted limits in food. Analytical surveillance results show that more residues are being detected now than a decade ago but these are generally at lower levels, reflecting increased technical ability to detect, changing patterns of pesticide use and more demanding legislative requirements.

The European Food Safety Authority (EFSA) was established under the General Food Law in 2002 to provide independent scientific risk assessment advice to European and Member State risk managers. EFSA's scientific Panel on plant protection products and their residues (PPR) deals with questions concerning the safety of pesticides for users/workers, consumers of treated products and the environment. The strengthened Rapid Alert System for Food and Feed (RASFF) provides rapid exchange of information on potential food risks amongst the European Commission and the Member States. Food safety will remain a high priority for the European crop protection sector.

Introduction
In the last 50 years, the agricultural and crop protection industry has seen the progressive development and application of technology, better plant breeding and chemical innovation which has led to dramatic increases in crop production. Driven by consumer and environmental safety concerns, the regulatory framework for risk assessment and risk management of plant protection products has been refined at the European level and increasingly harmonised across the expanding Member States. During this period, increasing sophistication of crop protection agents to guarantee economic yields and to provide the quality demanded by consumer markets has raised many challenges to food safety. In the context of crop protection, this paper will look at some of the issues around the frequently asked question – how safe is our food?

Ensuring the safe use of pesticides for people and the environment is the principal aim of the Pesticides Safety Directorate (PSD), an Executive Agency of the Department for Environment, Food and Rural Affairs (Defra). As the UK competent authority PSD is responsible for the approval and regulation of plant protection products, while the active substances are regulated centrally at the European level by the Commission. The Food Standards Agency (FSA) was set up by an Act of Parliament as an independent Government department in 2000 to protect the UK public's health and consumer interests in relation to food. It works closely with PSD to ensure a precautionary approach when approving the use of pesticides, that acceptable levels can be set for residues in food and that enough good-quality information is available on which to base these decisions.

As part of the regulatory process, the risk assessment of each plant protection product involves the critical comparison of exposure with effect or impact and forms the basis for the risk management decisions. The same principle of risk assessment applies to the consumer as to users of pesticides or to environmental compartments and non-target organisms. Harmonised data requirements specify the very extensive package of data which has to be evaluated to provide assurance of safety before market approval is given[1]. The comprehensive risk assessment process includes thorough review of the intrinsic properties of the active substance, its physical and chemical properties, its fate and environmental behaviour and extensive evaluation of its toxicology and ecotoxicology. Risk management decisions include the conditions of approval of the active substance and its formulated products, which regulate application rates, frequency of use and where appropriate the intervals before harvest and potential entry into the food chain.

Pesticide residues in food

Consumers may be directly exposed to pesticides present as residues in or on food or in drinking water. The protection of the health of consumers, users and the environment is the driving principle behind regulatory control. It is expected that residues of pesticides will find their way into food supplies but conditions are set during regulatory approval to ensure that any residues present are not at levels which may cause harm and which should be as low as practically possible, even if higher levels would still be safe. The occurrence of any residues will be influenced by the pattern of use of plant protection products on the growing crops or subsequent use during storage and may be reduced during food processing. Measured residue levels on or in food also reflect our ability to detect and quantify them.

The Maximum Residue Level (MRL) is the maximum specified amount of a pesticide legally permitted on crops or foodstuffs, showing that the pesticide was applied in accordance with the approved conditions of use (Good Agricultural Practice). MRLs are set for each approved pesticide on a wide range of fruit and vegetables, cereals and animal products as appropriate. They are not safety limits but are always set below, often far below, safety limits. Detected exceedencies of the MRL are further investigated and may lead to enforcement activity by the regulators.

In the UK the independent Pesticides Residues Committee advises Government on a nationwide surveillance programme to monitor pesticide residues in food and drink. Food samples bought by shoppers at retail and/or wholesale outlets are taken to laboratories where they are analysed. Some 4000 food samples are analysed each year for a wide range of pesticides and the number of individual pesticide/food combinations is around 180,000. In addition to the dietary staples (potatoes, bread and milk) the annual surveillance programme includes a rolling programme which monitors different fruit and vegetables, cereals and cereal products, fish and fish products and products of animal origin every few years. Between 35 and 45 foodstuffs are surveyed each year depending on their dietary importance, past findings which might indicate a historical problem, or intelligence from industry, or monitoring schemes in other countries. In recent surveys no pesticide residues were detected in 70% of the samples, residues below the appropriate MRL were detected in almost 30% and in only 2% were the statutory limits (MRLs) exceeded. Very few of these

[1] The Plant Protection Products Directive (91/414/EEC), 'The Authorisations Directive', was adopted by the Council of Ministers on 15 July 1991 and published on 19 August 1991 (OJ L230, ISSN 0378 6978). It came into force on 26 July 1993 and is implemented in the UK by the Plant Protection Products Regulations 2003

gave rise to health concerns for the consumer. The survey results are published promptly (PSD website) and are reported to the European Commission annually as required as part of food monitoring Europe-wide.

At the European level since 1976 harmonised provisions for MRLs have been progressively added to EU legislation for various pesticide/commodity combinations and currently some 250 pesticides are covered. The European Commission has a food standards programme to harmonise the remaining 650 pesticides which potentially could be present as residues on food (EC 2005). However since many pesticides are no longer used in agriculture within or outside the EU, it is appropriate to set MRLs for such essentially obsolete pesticides as low as possible. Therefore the Commission will propose that MRLs for 660 obsolete pesticides are set at the limit of determination, which is the lowest level that surveillance laboratories can achieve in monitoring analyses (0.01mg/kg). For the remaining approximately 240 pesticides, the Commission will review the temporary MRLs established nationally by the Member States and, after a comprehensive assessment of the active substances, will establish the final MRLs. In addition, the health of infants and young children are further protected by the provisions of the Baby Food Directive (EC 2006). This stipulates that, for practical purposes, there should be no pesticide residues in foodstuffs for particular nutritional uses intended for infants and young children and sets the level at 0.01mg/kg, again the limit of analytical determination.

Developments in analytical technology and methods have improved analytical capability and the sensitivity of detection which has been paralleled by more demanding legislative requirements. This combination has led to an improved ability to monitor for pesticide residues in food. Chromatographic columns have improved, detection systems have improved and we are now able to look for more pesticides in more samples with lower limits of detection and quantification, resulting in improved quality of pesticide residue data. In the mid-90s surveillance methods used gas liquid chromatography (GC) and were capable of detecting 30 to 40 compounds in multi-residue methods in several runs using selective detectors (e.g. fluorescence) with a reporting limit of 0.05 mg/kg.. With the development of liquid chromatography – mass spectrometry (LC-MS), currently the UK monitoring programme now looks for over 200 compounds in two runs with a reporting limit of 0.01 mg/kg. The wider introduction of Time of Flight mass spectroscopy (TOF-MS) will enable the collection of all screening data from a sample, with interpretation limited only by the data software and spectral libraries rather than the selective limitations of the detector.

The general trend from the analytical results of surveillance laboratories over the last decade is that even though more residues are being detected these are generally at lower levels. This reflects patterns of pesticide use and the more demanding legislative requirements regulating pesticide residues on or in food.

Pesticide usage

Pesticide residues on food will also be influenced by usage during production and storage. Systematic surveys of pesticide usage on farms in England and Wales started in 1965 on a wide range of agricultural and horticultural crops and have continued on average at 4 yearly intervals by crop type. This is the longest and best documented data set in Europe and patterns of usage have changed dramatically over this period (http://www.csl.gov.uk/newsAndResources/resourceLibrary/articles/puskm/index.cfm).

For example in arable crops, which account for more than 90% of total pesticide usage in Great Britain, between 1994 and 2004, whilst the area of crops grown increased by 3%, the area treated increased by 42% but the total pesticide weight applied fell by 4% (Garthwaite *et al.* 2005). This resulted from increases in the average number of sprays applied and in the number of products used and thus the degree of tank mixing, from an average of 7 products per crop to an average in 2004 of over 11 products per crop. . The reduction in weight of pesticides applied each year through the ten years arises from the development and introduction of newer molecules which are intrinsically more active at lower doses together with the greater use of reduced doses by farmers and growers. Thus through this period the organochlorine insecticides were withdrawn, use of organophosphorus insecticides fell by 78% and the use of the pyrethroids, with lower rates of application, had increased 3 fold by 2004. Whilst fungicide use increased by 56% and herbicides by 44%, total annual weights applied increased by only 14% and 25% respectively during the 10 years. At the European level, national estimates of use derived from commercial sales data are available for 1992 to 2003 (Eurostat 2007).

Food safety in Europe

The ultimate goal of the European Commission's policy on food safety is to ensure a high level of protection of human health and consumers' interests in relation to food, taking into account diversity, including traditional products whilst ensuring the effective functioning of the internal market. The underlying principle is an integrated approach from farm to table which includes all sectors of the food chain including primary production, feed production, storage, transport and retail sale. Prompted by the high profile and much publicised food safety scares of the '90s, including bovine spongiform encephalopathy ('mad cow' disease), dioxin-contaminated feed and adulterated olive oil, together with the realisation that a more cohesive and comprehensive approach was required, the Commission introduced its umbrella legislation which is referred to as the General Food Law (EC 2002a).

This Regulation has three main components:

a) It introduces the concept of traceability for food and feed businesses which must ensure that all foodstuffs, animal feed and feed ingredients can be traced right through the food chain from farm to table.
b) It establishes the independent European Food Safety Authority (EFSA) to bring together all food safety risk assessment activities from a range of previous scientific committees into one place and to make the processes more public.
c) It strengthens the rapid alert system that the Commission and Member States use to inform each other and act quickly in the event of a food/feed scare.

European Food Safety Authority

EFSA was established by the adoption of the Regulation in February 2002 and is an independent Community organisation with responsibility for a) risk assessment and b) risk communication. It is not a regulatory body since the risk management role and decision making remains in the European Commission (with DG SANCO, the Directorate General for Health and Consumer Affairs) and with the European Parliament and the Council. Initially located in Brussels, EFSA moved to Parma in northern Italy after a political decision in 2003 by the Member States. EFSA is a separate legal Community body, funded by the Community budget but operating independently of the Community institutions and is managed by its Executive Director, who is answerable to a Management Board and not to the Commission.

EFSA is the keystone of the EU system of risk assessment of food and feed safety right across the food chain and its independent scientific advice underpins the decisions of policy makers and risk managers in the European institutions and Member States. It is also committed to openness and transparency in all its work, is opening up its meetings, organises consultations with stakeholders and the public and publishes its documents rapidly on the internet.

EFSA consists of four bodies: the Management Board, the Executive Director and staff, the Advisory Forum, and the Scientific Committee and risk assessment Panels. Made up of 14 members who are appointed from across the EU, together with a representative of the Commission, the Management Board is responsible for the direction, policies and efficient functioning of EFSA. The Executive Director is then responsible for the day to day management of EFSA and its 250 administrative and scientific staff. The Advisory Forum is a consultative network which importantly links EFSA to the equivalent national food safety organisations in the Member States. This body advises the executive Director on scientific matters, priorities and the work programme and exchanges information on risk assessment and food and feed safety issues, including the identification of emerging issues.

EFSA's scientific staff

EFSA's scientific staff responsibilities include providing the secretariat support for the independent risk assessment Panels, contributing specialist scientific expertise on food and feed safety matters including emerging risks, gathering scientific data and information, and assisting the EU institutions in crisis management. In relation to pesticides, EFSA's Pesticide Risk Assessment Peer Review Unit (PRAPeR) is responsible for the peer review of assessments on new or existing active substances used in plant protection products carried out initially by the rapporteur Member States.

PRAPeR is also responsible for providing reports on the evaluation of these pesticides to the European Commission. This review programme for EFSA, specified by Commission Regulations EC 2000, EC 2002b and EC 2004 covers the remaining 449 substances (52 under stage 2, 144 under stage 3 and 249 under stage 4). Those in stage 1 were initiated before EFSA was established and are being finalised by the Commission. As a result of this extensive review programme, including the lack of continued support by industry for particular active substances, the number of plant protection products available on the market may be reduced by as much as 50%.

As part of the harmonisation programme of maximum residue levels EFSA was also asked by the Commission in September 2006 to contribute to the review of the temporary EU MRLs and to provide a reasoned opinion on their potential chronic and acute risks to consumers' health. In order to assess the safety of these proposed future MRLs with respect to the food consumption patterns of all European consumers, the PRAPeR Unit developed a model for this risk assessment based on all the appropriate European consumption data available. In a major piece of work the Unit then carried out the chronic and acute risk assessment for 236 active substances and reviewed a total of 62,068 proposed temporary MRLs (TMRLs). For 92 substances, no consumer health risk was identified. However for the remaining substances, potential acute and/or chronic health risks could not be excluded. Of these, the PRAPer Unit identified 110 substances that have to be reconsidered with regard to potential chronic risk to consumers. In the acute risk assessments, 109 active substances and a total of 2570 individual TMRLs were identified to give concern for consumer safety and these will require lowering or further refinement by the Commission.

EFSA's Scientific Committee and Risk Assessment Panels

Approximately 190 independent scientific experts from round Europe were appointed to EFSA's nine risk assessment Panels and cross-cutting Scientific Committee, drawn from academia and public institutes across the Member States. These Panels, each made up of approximately 21 members, cover all the sectors of the food chain (Table 1) and provide risk assessment advice and opinions to the European Commission, the European Parliament and the Member States. The EFSA Panels respond to general requests for scientific opinions, and provide advice, undertake assessment of regulated substances and products, monitor and assess specific biological risk factors for human health and animal diseases and strive to improve European risk assessment approaches and methodology. A register of requested opinions is also available on the website (http://www.efsa.europa.eu/en.html) and internet public consultations are held in relation to major opinions. First set up in 2003, the Panels are in their second mandate and to date more than 450 scientific opinions have been published on the internet in EFSA's electronic Journal. The Scientific Committee, consisting of the chairs of the Panels and six other independent scientists, provides advice on multi-sectoral issues that fall within the competence of more than two Panels or not falling within the remit of any of the Panels. It is also responsible for the general co-ordination of EFSA's scientific work and consistency in the scientific opinions of the different Panels.

Table 1. EFSA's Risk Assessment Panels and their remits

	Risk assessment panel	Mandate
AFC	The Panel on food additives, flavourings, processing aids and materials in contact with food	questions of safety in the use of food additives, flavourings, processing aids and materials in contact with food; with associated subjects concerning the safety of other deliberately added substances to food and with questions related to the safety of processes
AHAW	The Panel on animal health and welfare	questions on all aspects of animal health and animal welfare, primarily relating to food producing animals including fish
BIOHAZ	The Panel on biological hazards	questions on biological hazards relating to food safety and food-borne disease, including food-borne zoonoses and transmissible spongiform encephalopathies, microbiology, food hygiene and associated waste management
CONTAM	The Panel on contaminants in the food chain	questions on contaminants in food and feed, associated areas and undesirable substances such as natural toxicants, mycotoxins and residues on non authorised substances not covered by another Panel
FEEDAP	The Panel on additives and products or substances used in animal feed	questions on safety for the animal, the user/worker, the consumer of products of animal origin, the environment and with the efficacy of biological and chemical products/substances intended for deliberate addition/use in animal feed
GMO	The Panel on genetically modified organisms	questions on genetically modified organisms as defined in Directive 2001/18/EC, such as micro-organisms, plants and animals, relating to deliberate release into the environment and genetically modified food and feed including their derived products
PPR	The Panel on plant protection products and their residues	questions concerning the safety of pesticides for users/workers, consumers of treated products and the environment
NDA	The Panel on dietetic products, nutrition and allergies	questions related to dietetic products, human nutrition and food allergy as well as associated subjects such as novel foods
PLH	The Panel on plant health	newly created in 2006 and deals with questions related to the scientific assessment of plant health risks in order to help secure the safety of the food chain

Panel on Plant Protection Products and their Residues (PPR Panel)
In addition to responding to questions on pesticides from the European Commission, the European Parliament or the Member States, the PPR Panel may also deal with self-tasking questions. These may either arise from the scientific services within EFSA, e.g. the PRAPeR Unit who may raise a specific question or generic issue arising from the peer review of initial risk assessments of new or existing substances, or relate to a particular self-chosen priority issue that EFSA agrees it should deal with.

Expertise across the Panel members covers toxicology (8), residues (4), environmental fate and behaviour (4) and ecotoxicology (5). The answer to an accepted question, i.e. the opinion, is adopted at a plenary meeting but most of the preparatory work is undertaken by working groups of the Panel supplemented by independent *ad hoc* experts invited to join for a particular question. Adopted opinions are rapidly published on the website (http://www.efsa.europa.eu/en/science/ppr/ppr_opinions.html).

Up to July 2006, the PPR Panel has published 32 opinions. Questions arising from specific dossiers (13) have covered a very wide range of risk assessment issues: animal toxicology issues, the interpretation and extrapolation to human exposure for both consumers and operators, specific guidance on risk assessment principles; various issues of environmental fate and behaviour, dispersion and degradation; ecotoxicology issues of exposure in non-target wildlife including the interpretation of mesocosm data from aquatic studies. These opinions, though addressing the risk assessment of particular active substances, are written to provide wider guidance and to be of more generic use. The Panel published two review opinions to summarise the main outcomes and broader principles of its risk assessment guidance at the end of its first 3-year mandate. These separately summarise the questions in the field of human toxicology (EFSA 2006a) and those in the area of environmental fate, exposure, ecotoxicology and residues (EFSA 2006b).

Two opinions have been published on the importance of acute dietary risk assessment of pesticide residues on food for the consumer. As already discussed above this is a principal factor used by the Member States and the European Commission to set EU-wide Maximum Residue Levels (MRLs), the highest concentrations of pesticide residues that are legally allowed in foods. The measure of acute dietary exposure that is used in MRL-setting is the International Estimate of Short Term Intake (IESTI). The IESTI is calculated using one of four standard equations, depending on the type of commodity involved. An MRL above the limit of detection is set for a commodity only if its IESTI does not exceed the Acute Reference Dose (ARfD) of the pesticide concerned. To inform international discussions about whether to change the way that IESTI equations are calculated, the Commission asked EFSA (the PPR Panel) for advice on how conservative the equation is in relation to the protection of the European consumer from intakes above the ARfD and how this might change if the IESTI was calculated differently. Working with a large team of experts from the Member States, using data on food consumption, body weight and residues to analyse a range of scenarios for different countries, age groups and pesticides, the PPR Panel estimated that in all scenarios over 99% of each national population is within safe levels and in most cases over 99.9%.

The results suggest that the IESTI equation is a good tool to assess the safety of individual consumers exposed to maximum legal residue levels through foods, as originally intended, while the equation would need to be modified on the basis of substantial research to reliably

assess the level of protection for the entire European population. Risk managers will now decide on any possible changes to the IESTI calculation as a basis for estimating acute exposure to pesticide residues.

In the framework of the Directive 91/414/EEC, methodologies and approaches are required to carry out appropriate exposure assessments and to evaluate the risks involved in the use of pesticides. To further develop environmental risk assessments, the FOCUS (FOrum for the Coordination of pesticide fate models and their USe) was established under the auspices of DG SANCO. Its aim was to develop standardised methods for the evaluation of different aspects concerning risk assessment of pesticides with regard to ground water, surface water, degradation kinetics, air, etc.

The PPR Panel has now published five opinions on the final guidance documents of different FOCUS Working Groups. These cover the comparability of the FOCUS groundwater models and their consistency in risk assessment of groundwater contamination; the FOCUS surface water scenarios; the FOCUS estimation of persistence and degradation kinetics of pesticides in soil; FOCUS landscape and mitigation factors in ecological risk assessment; FOCUS guidance on the movement of pesticides in air and exposure assessment.

European consultations are currently under way to revise the Plant Protection Products Directive (91/414/EEC). EFSA was asked by the Commission to review the latest draft Annexes II and III which specify the data that are required to assess the safety of an active substance and its products respectively. Six expert working groups of the PPR Panel considered the revised Annexes which had been prepared by a rapporteur Member State including extensive consultation round Europe. The PPR Panel has published six separate opinions on physical and chemical properties, analytical methods, residues, toxicological and metabolism studies, fate and behaviour in the environment and ecotoxicological studies which are now being considered further by the Member States and the Commission.

EU-level guidance on conducting risk assessments on pesticides has historically been the responsibility of the European Commission and DG SANCO including the production, revision and updating of the approximately 20 guidance documents in this pesticide area. Such guidance is used by the Member States when carrying out safety evaluations and by notifying companies applying for market authorisations under 91/414/EEC. However in 2006 this responsibility passed to EFSA and the PPR Panel has started a rolling work programme to revise existing or produce new guidance documents with priority agreed with the Member States. The first is a major revision of the Guidance Document on Risk Assessment for Birds and Mammals (SANCO 2000) which the Panel is carrying out using public consultation on the website and as a precedent, involving experts from both Member States and industry. The final draft should go for public consultation on the website by the end of 2007 before final adoption by the Panel in early 2008.

Future priorities will be the development of new guidance documents on operator and worker exposure, environmental exposure in greenhouses and the updating of guidance documents on exposure in soil. It is important that guidance documents both reflect the advances of the underpinning science as well as involve stakeholders, the risk managers and assessors in the Member States and in industry.

EFSA organises scientific colloquia aimed to achieve a better understanding of some of the fundamental scientific issues related to risk assessment on food and feed. In November 2006, the 7th colloquium was held in Parma to discuss the Cumulative Risk Assessment (CRA) of Pesticides to Human Health. This well-attended international meeting agreed that it was important to get started with CRA in a stepwise approach. Substances that share a common mode of action (dose-addition), for which data are already available in the US, will be the first priority for which good models already exist. Pesticides that were prioritized for work on CRA (dose-addition) are: oligophosphates, carbamates, conazoles, pyrethroids, dicarboxyamides, phalimide, spindle inhibitors, and dithiocarbamates. Whilst methodologies are not yet defined and may vary regarding compound and type of exposure (acute, chronic) guidelines will be needed eventually for probabilistic modelling and cumulative exposure assessment. Cooperation between the Member States, other bodies and EFSA will be needed to establish these guidelines. This colloquium is an important input to the current development of a PPR opinion on cumulative risk assessment at the request of the European Commission.

Rapid Alert System for Food and Feed (RASFF)

A rapid alert system for food has been operating within the European Commission since 1979 but it was greatly strengthened by the adoption of the General Food Law (EC 2002a) which provided the legal basis. The Rapid Alert System for Food and Feed (RASFF) provides for the exchange of information around the 32-partner network of the Member States (and the European Economic Area countries – Norway, Liechtenstein and Iceland), the Commission and EFSA. If a member of the network has any information to indicate that there is a serious direct or indirect risk to human health, this information is immediately notified to the Commission under RASFF who then notifies all other network members. A weekly summary is published on DG SANCO's website (http://ec.europa.eu/comm/food/food/rapidalert/index_en.htm) and since 2002 an annual report of results has been published. There are two categories of notifications: *alert notifications*, where a problem has been identified and the Member State detecting the problem has initiated relevant measures e.g. withdrawal or recall; *information notifications*, where a food or feed risk is identified but no rapid action is necessary because it hasn't got onto the market, mostly concerning food and feed consignments that have been tested and rejected at EU external borders. In the first case consumers can be reassured that such products have been withdrawn or are in the process of being withdrawn from the market and in the second case consumers can be reassured that such products have not reached the market or that all necessary actions have already been taken.

Annual reports summarise the number and origin of notifications, the countries involved, the products and the risks identified. In 2006, there were 938 alert notifications with fish, crustacean and mollusc products the largest category (20%), and the largest risk category was pathogenic microorganisms (16%). A total of 2009 information notifications were reported with the largest product category being nuts and nut products (33%) while the largest risk category was mycotoxins (40%). Reported risks from pesticide residues are way down the list at 2% of alert notifications and 4% of information notifications. The widening of the RASFF to become a more global international network is under active consideration by the Commission. Interested third countries are being encouraged to set up their own regional schemes to improve the protection of their consumers and consumers in the EU via their exported products (e.g. Thailand, Argentina and China). Once established these regional alert networks could be interconnected to become a global RASFF.

Conclusion

Food safety is a top priority both in Europe and at our national level. The demanding rules to protect the European consumer have been further strengthened since 2002 to ensure food safety. An integrated approach enables the better tracking of food from farm to table through the supply chain. The establishment of the European Food Safety Authority, separate from the European risk managers, provides a source of independent and rigorous scientific advice on risk assessment across all sectors of the food chain. EFSA, now five years old, is committed to openness and transparency in all its activities and is working as priority through its Advisory Forum to strengthen its links with the Member States and their national food safety organisations and networks. Consumers should be encouraged to see such developments which should increase confidence that food safety and the health of the consumer are very important. Ongoing review of available pesticide products, tighter EU legislative controls on use and more sensitive detection technology are continuing challenges for the crop protection industry leading in general to lower pesticide residues on food. Other challenges include increased globalisation, consumer demands and the balancing of environmental impact with food production. Food safety will remain a high priority for the crop protection sector.

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Farming at the sharp end with a blunt instrument

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Introduction

This is not an academic paper, mainly because I am no academic, and would not know how to deliver one. It is an opinion paper and one that I hope will challenge all parts of the industry to re-think how we approach the consumer, address their concerns and create a future for the food industry that is both different and more importantly connected.

Whether we like it or not, in the eyes of many, pesticides are second only to terrorists as the scourge of the modern world. Yet how can this be when pesticides help to deliver consistent quantities of good value food that is by virtually any definition, safe?

I think to understand this we have to examine where we have come from, in order to determine where we want to go.

History

Farming in the developed world has had a pretty rough time over the last 10 years with consistently low commodity prices, often below the cost of production, an increasing regulatory burden and the emergence of food safety issues not previously perceived as a problem by the consuming public.

I myself, over the last two years gave serious consideration to selling up and investing in something else that would at least give me some sort of return on the hard work and capital invested and most farmers have had to find alternative sources of income to supplement the diminishing return from their farming operation.

It is not only in the developed world that changes have occurred. In China there has been an exodus from the land to the city of approximately 10 million people per year over the last 20 years or more, driven by the poor returns from farming and the incentive of higher income in the urban environment.

However, it appears that things may be changing as we move from a period of surplus to one of potential shortage as the balance of supply and demand shifts.

There seems little doubt that climate change is impacting on the production of mainstream crops in the major production areas and as the market in commodities becomes less protected, the volatility of price becomes greater. Coupled with this is the increased demand from the emerging economies for higher-grade food, often meat, which uses seven times as much grain to produce as using the grain itself as food. Similarly the climate change scenario has led to a demand for the production of 'Green' fuels, which could eliminate the surplus production of grains and oilseeds in western agriculture.

So the pundits are declaring that the era of cheap food is over and we can anticipate 15 or more years of good returns and the opportunity to invest that has been lacking for so long.

Farmers have actually continued to invest, but not in shiny machinery as in the days of plenty, but in the new technology developed by the plant breeder and the agrochemical manufacturer. We have continued to strive to grow our crops as cheaply and efficiently as possible to deliver to the market the quality and quantity needed on a consistent basis.

In our privileged and affluent society, the scarcity of food has not been an issue for 50 years and that post war era spawned, for good or bad, the Common Agricultural Policy. We need to question as an industry, whether the prospect of further Government interference in the market is of benefit or whether there are things that we can do that might pre-empt such interference.

The subsidy system that evolved from the Common Agricultural Policy has itself become the target of much vitriol and distrust. Food mountains, corruption, inefficiency and distorted markets are all perceived to be matters that are unacceptable in this age of the Doha Round of the World Trade Organizsation (WTO).

There is no doubt that the scandal around the use of DDT in the sixties created suspicion in the minds of consumer, environmentalist and politician. There is now a presumption among many that the use of all pesticides is wrong and the presence of any amount in our food or water is a problem and of course as detection of minute traces is now possible, we have an issue to persuade consumers that even these minute amounts are safe and actually contribute to the production of wholesome food.

Today and tomorrow

In the post war era, we have moved from a situation where food was either available or not and tasted good or not, to one where the choice is limitless regardless of season and available permanently at low cost. If production protocols are deemed desirable, it is still readily available, albeit at a higher price, for those who can afford it. The supply to the shelves of the supermarket is only at risk if fuel for the lorries delivering is at risk.

So if, as the pundits predict, we are heading for an age when supplies of the major commodities are less guaranteed and governments of whatever hue are less able to manage the market because of WTO regulation, what will be the outcome?

The first lesson of economics tells us that price volatility is a certainty and we are already witnessing this in the grain markets. In 12 months, the price I have been able to sell wheat produced on my farm has altered by a factor of 100%, happily in the right direction, but could easily move in the opposite direction just as fast.

The debate has begun about the morality of growing crops for fuel when huge numbers in the world are starving and food security, a term not heard of since the end of rationing in this country is now being debated, as the concerns about lack of supply become a reality.

Charles Aslet of *The Daily Telegraph* wrote on 11 August 2007: "In five years time, public attitudes to farming could be very different. The cost of food will rise and farmers may be held responsible but people will be worrying more about supply. Food security will regain the importance it was given in the decades after the Second World War by people who remember rationing and, in parts of Europe, starvation."

How will the consumer react?
No one likes having choice removed and certainly those generations who have only ever known times of plenty will be unhappy. Nor are consumers particularly keen on higher prices and if as predicted above, farmers get the blame for this, we are likely to be as popular as Osama Bin Laden at a White House dinner.

If these matters are cyclical, we can assume that times of plenty will re-emerge at some time and with them public disquiet about production methods etc.

So what then, can we do to break the mould and re-engage with the consumer?

The future
Agriculture has for too long been a weak seller of an undervalued commodity. To improve on this situation we need to add value to our product, but it is this perception of value that particularly needs to change.

The concept of value has many elements, but too often we have concentrated on price alone. It has been understood that agriculture also fulfils a role as custodian of the land and this has had it's value recognised to some degree with the creation of a vast array of environmental schemes which reward the farmer financially for maintaining or improving a habitat.

But such a value is far removed from the consumer buying a loaf of bread, though he may be aware that some of his taxes have been used to pay for such schemes. He has no idea whether the loaf came from wheat produced on a farm engaged in such schemes or from a wildlife desert. Nor does he know whether every effort is made to minimise any risk to his health from the production of such wheat, including global warming. There is of course an assumption that the government, through its agencies, is monitoring the production of food and its safety. But is that enough? Or could we do more ourselves?

The vast success of the supermarkets in this country and elsewhere is based on delivering what the consumer wants in the manner that they want it, sometimes even before they actually know they want it!

We believe, quite rightly in my opinion, that food from our land is both safe and wholesome. We are familiar with the production methods used and that pesticides and fertilisers are used efficiently and every technology available is employed to minimise the already tiny risk to the consumer. That however, does not differentiate our production in any way from any other grown in the developed world and does not in itself add any value to the basic specification of the commodity.

We need to have an understanding of both what the consumer deems to be desirable in a product and what the manufacturer also deems to be desirable in the ingredient or commodity used to manufacture the desired product. In other words we need to know what values (other than price) should be attached to the product on the shelf.

To all intents and purposes we have to re-learn how to market and hence identify who our customers really are.

What does this have to do with the pesticide industry?
Unless I am very stupid or blind, I have seen little evidence that the pesticide industry has done anything to engage with the people who ultimately buy the end result of their products…….food.

Marketing and PR budgets should only in part be directed at the farmer. A much bigger slice should be re-directed at the consumer, first to gain an understanding of how they think and second to begin to gain their confidence again from the disastrously low point at which we stand now.

When we know what the consumer wants and what will give him confidence in a product, then we can tailor the production and supply to suit those requirements and potentially add value along the entire chain. In the process we also severely limit the opportunity for competitors to take that market share if we are able to close the supply chain loop.

We have so little understanding of what the consumer values and those who do know have a vested interest in keeping us at arm's length.

From 1990 to 2004 the spend on food in the UK rose from £64 billion to £111 billion, but agricultural turnover remained static at £15 billion. Thus in 14 years, the spend on food in this country increased by three times our annual turnover and as an industry we captured none of it.

I do believe that we have a unique opportunity to change the way our industry is perceived and more importantly valued by the 98% of the population not involved in agriculture.

We can engage with them, give them confidence, make them care about our methods, but we can also make a profit by delivering what they want. The growth of the major retailers bears witness to the fact that it is the correct approach.

So when you are planning your budgets on the back of improved commodity prices and expecting the farmer to pay a little more for the fantastic array of products at his disposal, please could you take some of that increase in margin and use it in the manner I have outlined. I do not think your shareholders will object and the returns could be excellent.

If the industry as a whole can develop an understanding of the consumer and his values, we may stand a chance of taking their opinion with us as circumstances change. If we fail we have only ourselves to blame.