

## **SESSION 1A**

### **KEYNOTE LECTURES**

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## **A reformed CAP and its impact on agriculture in an enlarged community**

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### **ABSTRACT**

The changes that have taken place in the CAP are part of a more general move towards reliance on markets to determine what is produced. The ten new member countries are joining a CAP that focuses on environmental and social concerns rather than production. This paper outlines the major characteristics of the agriculture and the pressures they experience in adapting to the policy of the EU. It then describes the changing role of agriculture within the enlarged community, noting changes in consumer perception and preference, in the structure of the agri-food sector and the importance of non-market values relating to the environment and animal welfare. In the light of this it discusses how the location of production will be affected by enlargement, first within the framework of the CAP as it is and second in the context of a further liberalisation of world trade in agricultural goods.

### **INTRODUCTION**

The CAP reforms that came into effect in January this year represent a new relationship between farming and the public. It is a relationship that reflects a shift from command economies that dominated the post war world to reliance on the market and an agricultural policy based not on anxiety about food supply but about concern about the impact of agriculture on the environment, health and the agendas of several non-farming pressure groups.

In the world of 1945 Governments, seeking to reconstruct devastated economies attempted to plan and manage economies in detail. The move away from that approach was both a response to and a necessary condition of rising real incomes that Western Europe enjoyed in the second part of the 20<sup>th</sup> century. The events of 1989 represented the culmination of this process as countries in Central and Eastern Europe liberated themselves from their command economies and sought to join fully that part Europe where living standards had risen most and individuals enjoyed a higher level of personal freedom as well as access to a huge range of choice in the goods and services.

The market economy had succeeded because of the power of competition to harness new technologies, to devise new products and to displace less efficient producers by those who could make more productive use of the same resources. It exposed European industry to international markets as protection was diminished through GATT and more recently through WTO. It resulted in radical structural change, so that some whole industries disappeared and the processes of concentration and specialisation resulted in economies unrecognisable in terms of the criteria of 1945. From telling industry what to do the role of government became regulating what it did.

The enlargement of the EU in 2004 represented for the new members a commitment to dismantle the apparatus of the command economy and to accept a system where the use of resources and the generation of employment would depend upon the ability to compete. This is an uncomfortable and stressful process. These countries had to compress changes that occurred over decades in the West into a relatively few years. Adjustment processes are often painful and sometimes wasteful. They involve not just a shift in material goods but a revolution in attitudes and in responsibilities.

Agriculture within the EU of 15 had remained outside the competitive economy. It was protected from external competition and underpinned in its internal markets by the CAP. Reluctantly this relic of a command economy has been forced to change under the pressure of surpluses that led to ever growing budget costs, as a result of international pressure from countries whose markets were undermined by export subsidies and as public opinion shifted from anxieties about food supply to concerns about the environment.

In 2003 the programme of CAP reform instituted by Commissioner Fischler marked the latest stage in the move of agricultural policy from the command structures of the past towards a fully open market economy. The process is incomplete but the logic and dynamics of the new policy are radically different from those of the CAP of the 1960's or 1990's. For farming in the EU this will involve implementing changes that existing policy has frustrated. It will imply openness to international markets, a far reaching restructuring of the industry in order to achieve lower costs and a relationship with the state more driven by public anxieties about farming practice than by any wish to support farmers. For farmers in both the EU of 15 and the new member countries, the next decade will require coming to terms with competitive markets. This will impose stress and for some disappointment but it also opens up new exciting possibilities.

This paper looks at how enlargement will impact on this process, for both the new and existing members of the EU. It starts with a brief reminder of some of the relevant numbers; it then discusses the policy framework created by the reformed CAP and the shape of a competitive agriculture within the EU.

It is worth noting a major assumption; that the EU itself will continue, in much its present form into the future. In practice, if it is to cope with the demands of 25 plus countries in 2010, changes will be needed in its decision taking processes. These were designed to meet the needs of six relatively similar countries in the 1950's, not 25 more disparate countries in the 21<sup>st</sup> Century. The proposed new constitution for the Community was intended to address these problems. The failure to ratify the changes proposed does not remove the problems so that decision taking within the EU may well become more protracted, more vulnerable to political uncertainties and less able to facilitate the changes needed if the Union is to compete within the world.

The CAP still embodies a legacy of 'command economy thinking'. Those who value most the economic and political potential of the enlarged EU recognise the need for a clear articulation of the changed role of government and the need to enable people to make their own decisions. This must respect national and regional diversity and not be frustrated by entrenched national interests that dominate the language of governments and the media. The optimistic assumption implicit here is that the Community will overcome these problems.

## The shape of an enlarged EU

In 2004 the EU became 25 members. The expectation is that Bulgaria, Romania and possibly Turkey will become members making a Community of 28 countries. Table 1 below shows some of the numbers indicating how increased membership will affect the EU of 15. The land area will rise by some 57% and the population by 46%. The countries that are joining are substantially poorer than existing members, agriculture remains a larger part of their overall economy and the share of food, drink and tobacco in personal expenditure is very much higher than among the 15.

Table 1. The dimensions of an enlarged EU

	Total area km <sup>2</sup>	Population 1000s	GDP per inhabitant	Share of Agriculture in GDP	% household spend on food, drink & tobacco*
EU 15	3234295	377787	24060	1.6	16.2
CC10	738573	73927	11320	2.4	28.7
Applicant 3	1119189	98812	5666	..	37.8

\* Data for households excludes Turkey

Source: Agricultural In the European Union, *Statistical and Economic Information 2003*, Table 2.0.1.1. ([http://www.europa.eu.int/comm/agriculture/agrista/2003/table\\_en/tab.pdf](http://www.europa.eu.int/comm/agriculture/agrista/2003/table_en/tab.pdf))

Enlargement will result in a significant increase in agricultural production. Table 2 shows the area of main crops grown in 2002. If this pattern of production continues there will be major impacts on the cereal and potato markets.

Table 2. Agricultural production in an enlarged EU

	EU15	CC10	CC10 % EU
UAA total 000's ha	129974	38130	29
Cereal total excluding rice	36529	16050	44
Rice	395	2	0.5
Sugar beet	1857	538	29
Oilseeds (total)	5845	1629	28
Potatoes	1252	1505	120
Fresh vegetables (total)	904	379	42
Citrus fruit (total)	460	5	1.0

Source: Agricultural In the European Union, *Statistical and Economic Information 2003*, Table 3.1.2.1. ([http://www.europa.eu.int/comm/agriculture/agrista/2003/table\\_en/tab.pdf](http://www.europa.eu.int/comm/agriculture/agrista/2003/table_en/tab.pdf))

A substantial proportion of the agricultural trade of the new members is with the EU of 15 but their accession will also make a significant change in EU trade with the rest of the world.

Table 3. Agricultural trade with the Rest of the World in the EU15 and the 10 new member countries (CC10)

	Agricultural Imports	Agricultural Exports
EU 15	62337	61580
Total for CC10	14,043	8,461
EU25	76380	70041
CC10 as % EU 25	18	12
Existing trade with EU as % of total trade of the 25	6	9

Source: FAO Production and Trade *Agricultural Data FAOSTAT* (<http://faostat.fao.org/collections>)

The countries that are joining vary greatly in size. Some such as Malta and Cyprus are so small as almost to disappear on charts that include all members of the 10 (Table 4).

Table 4. Farm production of wheat, pigmeat, poultry meat, milk and cattle numbers in the new member countries

	Common wheat 000t	Pigmeat 000t	Poultry meat 000t	Milk Production 000t	Cattle numbers per 000 head
Czech Republic	3918	457	219	2804	1520
Estonia	154	"	"	611	261
Cyprus	"	32	"	140	54
Latvia	520	85	9	812	385
Lithuania	1218	375	30	1765	752
Hungary	3865	"	375	2068	783
Malta	"	1919	"	43	19
Poland	9297	60	581	11873	5499
Slovenia	175	"	59	686	477
Slovak Republic	1542	243	"	1162	625

Source: Agricultural In the European Union, *Statistical and Economic Information 2003*, Tables 4.1; 4.15; 4.16; 4.18 and 4.20. ([http://www.europa.eu.int/comm/agriculture/agrista/2003/table\\_en/tab.pdf](http://www.europa.eu.int/comm/agriculture/agrista/2003/table_en/tab.pdf))

Differences in the density of population are equally marked. By comparison with most member states, the Scandinavian and Baltic countries are sparsely populated. In so far as policies concern themselves with land use, the problems facing these countries are very different from those in countries such as the Netherlands or Germany (Table 5).

Table 5. Land area per inhabitant in the EU of 25.

Member State	Area Per inhabitant/Km <sup>2</sup>	Member State	Area Per inhabitant/Km <sup>2</sup>
Malta	0.79	Hungary	9.43
Netherlands	2.2	Slovenia	10.17
Belgium	2.96	Austria	10.3
United Kingdom	4.14	Greece	12
Germany	4.33	Spain	12.49
Italy	5.29	Cyprus	13.62
Luxembourg	5.82	Ireland	18.1
Czech Republic	7.72	Lithuania	18.93
Denmark	8.03	Latvia	27.55
Poland	8.12	Estonia	33.35
Portugal	8.89	Sweden	50.39
Slovak Republic	9.11	Finland	65.09
France	9.25		

Source: Agriculture in the European Union, *Statistical and Economic Information 2003*, Tables 2.2.2.1 and 3.2.2.2. ([http://www.europa.eu.int/comm/agriculture/agrista/2003/table\\_en/tab.pdf](http://www.europa.eu.int/comm/agriculture/agrista/2003/table_en/tab.pdf))

The proportion of the labour force engaged in agriculture is much larger among the new members than in the EU15, i.e. 13.4% compared with 4% in the EU15, but there are significant differences between the new member countries (Table 6).

Almost 70% of the addition to the agricultural labour force is located in Poland. In Lithuania and Latvia as well as Poland, agriculture still accounts for between 15% and 20% of the total labour force. Elsewhere the proportion as well as the numbers of farm workers is much lower. Everywhere, apart from Poland and Slovenia, there is a tendency for the share of the labour force in farming to decline. In existing member countries the impact of the decline in the labour force has been substantial. For example in 1970 29.5% of the civilian population of Spain was in this category; by 2002 this had fallen to 5.9%. The social and political impacts of changes in farming activity are of far reaching importance.

Table 6. The agricultural population of the new member countries.

	Agriculture as % total working population	Total Civilian Employment 000s	Implied Agricultural Labour Force 000s
Cyprus	5.4	315	17
Czech Republic	4.9	4763	233
Estonia	6.5	581	38
Hungary	6.1	3846	235
Latvia	15.3	987	151
Lithuania	18.6	1421	264
Malta	2.1	144	3
Poland	19.6	13820	2708
Slovakia	9.7	922	89
Slovenia	6.6	2111	139
New members	13.4	28910	3877
EU15	4.0	162974	6542

Source: Agriculture in the European Union, *Statistical and Economic Information 2003*, Table 2.0.1.2. ([http://www.europa.eu.int/comm/agriculture/agrista/2003/table\\_en/tab.pdf](http://www.europa.eu.int/comm/agriculture/agrista/2003/table_en/tab.pdf))

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The EU collects information about farm incomes through its Farm Accountancy Data Network (FADN). Data is not yet available for all the new member countries but for those that are shows the level of income per agricultural work unit (AWU) for recorded farms up to 100 European Size Units (ESUs) (Table 7). The data for farms in excess of 100 ESUs is excluded because in the absence of an upper size limit, that the category ranges from what are large-scale conventional farms to corporate or co-operative businesses.

Table 7. Net Value Added per Agricultural Work Unit (AWU).

	Small < 8ESU	Medium small 8 - 16 ESU	Medium large 16 - 40 ESU	Large 40 -100 ESU	Very Large > 100 ESU
EU 15	6.13	12.84	24.85	48.72	151.47
Czech Republic	2.86	6.51	8.07	26.49	345.84
Estonia	3.3	9.05	34.27	50.68	221.44
Cyprus	..	..	..	..	..
Latvia	1.81	5.94	11.61	16.19	280.53
Lithuania	4.79	11.28	24.95	60.36	116.71
Hungary	2.62	8.64	20.03	53.52	312.82
Slovak Republic	-0.6	0.42	0.32	17.71	280.67

Source: Agriculture in the European Union, *Statistical and Economic Information 2003*, Tables 3.2.3 and 3.2.1. ([http://www.europa.eu.int/comm/agriculture/agrista/2003/table\\_en/tab.pdf](http://www.europa.eu.int/comm/agriculture/agrista/2003/table_en/tab.pdf))

For most size categories net value added per AWU is higher in the EU than among the new member countries. Net value added per AWU is especially low in the Slovak republic, effectively negative for the smallest and the medium sized farms. In contrast medium size farms in Hungary, Lithuania and Estonia seem to perform as well or better than equivalent farms within the EU15.

Modern farming depends on inputs produced off the farm on which they are used. Some of these are the products of other farms but many come from the chemical, pharmaceutical and machinery industries.

Table 8 shows the amount of inputs used and their proportion to total production in the EU of 15 and among the new member countries. The farm inputs use in the new member countries is equivalent to about 13% of the amount used in the existing EU.

The pattern of input use varies considerably among the new member countries. Inputs to livestock enterprises vary from a third to over a half of all inputs. The chart below shows the use of those inputs most relevant to arable agriculture as a share of the total use of inputs. In most cases seeds, fertilisers and crop protection inputs account for around 15% of inputs (Table 9). This is not substantially different than within the EU 15. In contrast machinery and energy costs figure much more heavily.



Table 8. The use of inputs.

	Consumption of inputs Mio €	Share of input costs in value of production %
Czech Republic	2354	71.7
Estonia	277	58.3
Cyprus	n.a.	n.a.
Latvia	332	56.6
Lithuania	757	70.9
Hungary	3975	65.4
Malta	68	46.6
Poland	8324	62.9
Slovenia	568	53.5
Slovak Republic	1151	68.6
EU 15	138247	48.3

n.a.: data not available

Source: Agriculture in the European Union: *Statistical and Economic Information 2003*, Tables 3.1 and 3.2. ([http://www.europa.eu.int/comm/agriculture/agrista/2003/table\\_en/tab.pdf](http://www.europa.eu.int/comm/agriculture/agrista/2003/table_en/tab.pdf))

Table 9. The use of inputs in arable farming among the New Member Countries.

	Consumption of inputs Mio €	Share of inputs in production	Percent of total input use				Energy and Lubricants
			Seeds and reproductive material	Fertilisers and soil improvers	Crop Protection Products and Pesticides	Maintenance of machinery	
Czech Republic	2354	71.7	..	..	..	..	..
Estonia	277	58.3	1.3	5	2	5.1	16.3
Latvia	332	56.6	3.8	6.7	3	5.7	17.9
Lithuania	757	70.9	4.6	13.8	6.3	4.7	21.2
Hungary	3975	65.4	6.4	6.5	6.1	4.8	12.7
Malta	68	46.6	4	1.9	1.3	9.9	8.2
Poland	8324	62.9	1.7	6.9	4.6	7.5	21.2
Slovenia	568	53.5	4.3	6.5	3.3	4.1	11
Slovak Republic	1151	68.6	6.2	5.8	6.7	1.9	15.1
EU 15	138247	48.3	5	6.8	5.6	6.6	9.2

Source: Agriculture in the European Union, *Statistical and Economic Information 2003*, Table 3.1.3. ([http://www.europa.eu.int/comm/agriculture/agrista/2003/table\\_en/tab.pdf](http://www.europa.eu.int/comm/agriculture/agrista/2003/table_en/tab.pdf))

### **Pressures on Agricultural Policy for the new member states.**

Accession to the EU implies that the new member countries apply those policies already agreed among existing members, the '*acquis comunitaire*'. A substantial part of the negotiations involved in agreeing the terms of accession involved determining the way in which the CAP could be applied. There were at least five categories of problem.

- The new members were experiencing the transition from centrally planned to market economies. They faced the need to make rapid and radical progress in terms of farm structure, the existence of a modern economic infrastructure and a sophisticated 'food chain' – processing, distribution and retailing.
- The application of the CAP as it stood before 1992 would have involved a substantial increase in prices. This would have stimulated production and depressed consumption amongst the new member countries, adding to the surpluses of the EU 15, the pressures on its budget, having an adverse impact on international trade and reducing the real living standards of the poorest people in the new member countries.
- Some CAP policies required detailed information about the sector and an ability to administer complex product, rural development and environmental policies. There was a lack of administrative capacity, a relatively rapid rate of change in land ownership and control resulting in major problems in operating supply control policies such as quotas or set aside.
- The CAP itself was seen to be need of reform. Both internal concerns about the cost of the policy and the need to reach an accommodation with other countries if a GATT settlement were to be achieved implied significant changes from the policies in existence at the end of the 1980s.
- Opening up frontiers presented a problem of ensuring that products sold within the enlarged EU met the standards of hygiene and freedom from disease that applied elsewhere in the Community. Not only did this make heavy demands on the monitoring resources of the new members but it also raised questions about the permeability of their frontiers to imports from countries to the east and south where standards were thought to be lower.

The post-Fischler CAP sustains the concept of a Common Market and Community Preference, which is at the heart of the Treaty of Rome. For most products it relies on tariffs to provide preference and allows markets to determine EU prices. Support that used to depend upon high prices, intervention purchase and export subsidies is now provided as a single payment, unrelated to current production, linked to conditions of cross compliance and distributed according to past levels of production. Unreformed relics of past regimes include quotas for milk and sugar and the retention in some member countries of a degree of 'coupling' in the distribution of the single payment.

In principle this should be good news for new member countries. Whereas the unreformed CAP would have driven up costs as it induced investment in production that could only be sustained by protection within the Union, the reformed policy will create an environment within which farmers and other investors will have to take seriously what the market will

actually pay not what politicians would like farmers to receive. Although this may disappoint some farmer expectations it provides a platform for development that is less insecure than one which is wholly at the mercy of political forces. It also reduces the increases in price facing consumers, an issue of particular importance in economies where many people spend a relatively high proportion of their total income on food.

To consider the long run implications of operating in a competitive market within the EU it is helpful to start where the final decisions lie, with the consumer. Consumer behaviour in Europe is conditioned by a number of different and sometimes conflicting concerns.

- In much of Europe people are money rich and time poor. Food preparation, which used to occupy much of the time of the household has been minimised by convenience foods, by increased use of ready prepared meals or eating out. This responds to the increased participation of women in the labour force and to the general wish to avoid repetitive, boring and tiring manual work. It is facilitated by the mechanisation of many processes within the kitchen and through the sale of ingredients already partly prepared for use.
- Whilst routine meal preparation has been marginalised in the life of many households, there is a growing interest in the preparation of very high quality meals, partly as a craft in itself and partly as an entertainment for visitors. Many popular television programmes about food reflect and inform this preference. Within this sector of the market there is often a wish to source fresh products directly rather than rely on the conventional offerings of the super market.
- There is concern about the safety of food – suspicion that this may be compromised by cost saving techniques on the farm or elsewhere in the food chain. The BSE experience and the delayed recognition that this animal disease could affect humans undermined confidence. Outbreaks of animal diseases such as Foot and Mouth, Swine Fever or Avian flu are now greeted as cause for alarm.
- There is a growing interest in the relationship between food and health. This centres on issues such as obesity, the excessive use of salt and the consequences of sugar for dental health. This has led many commentators to refer to cheap, convenient mass produced meals as 'Junk Foods'. It has also led governments to seek to persuade the food manufacturing industry to reduce the quantity of salt and sugar it uses in its products.
- The farmer is primarily a producer of inputs for the food industry. Most products are processed, much of it manufactured and presented in forms that bear little relationship to the raw materials used. The result is a substantial asymmetry in power between the farmer and his major customers. At the same time these substantial national or multi-national businesses are in fierce competition for the consumer euro. These same consumers who insist on safety, freshness and nutritional quality, also choose to buy at the least cost possible. As a result the major suppliers seek to minimise their costs including those of raw material from farms. The prices offered within such a competitive environment will inevitably be pushed down to the minimum needed to supply the volume needed.
- For some farmers an escape from this may be offered by direct marketing. Given a suitable situation and an appropriate set of skills and attitudes sales from the farm or

through farmers markets can secure higher prices and build a continuing customer base. However, in a largely urban community in which time pressures are strongly felt it is likely that direct sales will remain a relatively small part of the industry's sales.

- Consumer concerns also include some non-market values. There is anxiety about the impact of highly productive food systems on the environment. Some critics express alarm about a globalised food system that flies perishable product around the world with high levels of carbon emission. Some wish to remedy what they see as the 'raw deal' experienced by producers in some low-income countries and seek to buy products that can claim to be 'fair trade'. There is a very powerful and articulate animal welfare lobby that focuses on what they see as the unsatisfactory nature of animal production and slaughter. In terms of marketing these may represent niches that can be exploited. In political terms they are likely to generate regulatory responses that restrict the freedom of action of the farmer and the food industry.

### **How will enlargement affect the location of production within the EU?**

We start with the assumption that the EU continues to sustain a high level of protection at its frontier. This may not be the case once the Doha round is complete and the final part of this paper will consider that situation.

As the tables above demonstrate, generalisations about the agriculture of the new member countries are more likely to mislead than inform. They are diverse in terms of economic development, in their physical and climatic endowment, in their product mix and productivity. For some, such as Poland and Hungary farming remains a major industry and a potential export earner. For others such as Malta, Cyprus and Slovakia farming is a small part of their total economic activity. A detailed analysis providing an exploration of each country's potential response is beyond the scope of this paper. However, some critical issues can be identified.

New members will have to maintain the phyto-sanitary and environmental standards that the EU requires. These are extensive and there is a widespread concern that they will not be met either because of administrative incapacity or because of the lack of suitable infrastructure resources. However, the anxieties of existing member countries to minimise risks of plant, animal and human disease will ensure that the Commission will be increasingly vigilant in ensuring that standards are maintained.

The CAP will offer higher prices than many of the applicant countries have enjoyed. In its analysis of the impact on markets of enlargement the Commission anticipated some increase in the level of output of major commodities (Commission DG for Agriculture, 2002). The June 2003 reforms, which switch support from commodities to farmers, will diminish the incentive to expand production, but some increase must still be anticipated. Labour costs and land prices are relatively low, in some major producing areas climate is favourable for some key products – cereals, potatoes. In general, purchased input prices are unlikely to be higher than that elsewhere in the Union. The farming sector has had a substantial period to change its managerial structure and although this may not be complete and attitudes may still not have fully adjusted to a market economy, it has substantial opportunities both to improve productivity and to capitalise on the higher and more secure rewards now on offer. For farmers in the West, currently facing challenges resulting from limitation of scale, there may

be an incentive to move capital and skills into larger enterprises among some of the 10 new member countries. Thus whilst it is improbable that there will be any dramatic explosion of production among the new member countries, they will increasingly tend to add to the overall pressure on commodity markets within the EU.

Competition takes place when the consumer chooses one product rather than another. There is a continuing arbitration between price and value and ultimately consumers buy that which represents the best return for their money. The bundle of values incorporated will determine which product is bought. Choices may include preferences about how and where a product is produced. For equivalent products or close substitutes attention focuses on the price of the product in the shop. This must cover not just raw material costs but all the inputs involved in food preparation, storage, transport and presentation. Food, as it leaves the farm gate, accounts for only a part of total consumer spend. Value added on the farm, in the UK, captures only 5.3% of consumer expenditure on food (Agriculture in the UK, 2004a). Even for a basket of fresh products farmers share of consumers spend is only 35% and this proportion continues to fall (Agriculture in the UK, 2004b). A very low cost on the farm cannot guarantee competitiveness if it cannot find a route to the final consumer that is also efficient and low cost.

We have therefore to explore not just the ability of farmers to survive at low prices but also the competitiveness of the infrastructure of the food chain. The important difference between these elements is that at either end, production and consumption, the location of activity is fixed. In contrast processing, manufacture, storage, research and the management activity can be relocated when reinvestment takes place. Within the Community the distribution of processing and manufacturing is the outcome of past commercial and political decisions. As the market is opened up, by the admission of new members and the end of intervention purchase, locations will have to be reviewed. Businesses will necessarily look both at the costs of the raw material foods they require and at the differing costs of production and delivery within the enlarged EU. In many of the new member countries wage levels are well below those of the 15. For labour intensive operations this must be attractive. However, location will also depend on the adequacy of transport, the availability of skills in the installation and maintenance of machines, the existence of financial services, the stability of the local community and the quality and safety of the raw materials produced locally.

Enlargement brings fresh opportunities for companies already operating in the EU to use established skills and reputation to expand into the retail and distributive sector of the new member countries. A growing consumer market would also support investment in production in local farms and processing. Together such investments will create a potential to export more high quality products to consumers within the established 15 members of the EU.

The thrust of this analysis is that there will be a powerful incentive for significant parts of the food industry to relocate to the East. That process will, however, tend to generate increased costs in the new locations as wage levels rise, regulatory requirements become more stringent and land prices tend to be forced up. A new equilibrium will emerge in which the new members take a larger share of the EU market but competitive businesses in the West continue to thrive.

### **The Agriculture of an Enlarged Community in a liberalised world.**

This analysis is based on the assumption that the EU continues to impose sufficient tariff barriers to give preference to internal suppliers over those situated abroad. This is realistic in the short and even the medium term. However, the contemporary Doha negotiations within the WTO point in a very different direction. If they succeed there is likely to be a significant cut in tariffs, a substantial increase in the amount of food imported from third countries and a reduction, if not elimination, of export subsidies. This is likely to reduce the level of preference received by producers within the EU but not to end it. However, the WTO process will engage the Community in a continuing process of seeking to remove tariff barriers and to deal with environmental and social problems by decoupled payments rather than the manipulation of commodity prices.

Such a perspective suggests that within the enlarged EU, in the longer-term, production will need to be assessed in terms of the opportunities of the World rather than the Community market. On such a time scale a number of other issues will assume critical importance including for example; global rates of growth in population and real income, the development of changed dietary patterns in newly industrialised societies, the impact of climate change and the cost of energy.

A study of the long term perspectives for agriculture published by FAO in 2003 (Brusinma, 2003) suggests that despite a slow down in the rate of increase yields, supplies are capable of meeting demand at a global level in 2030. The study notes that this does not mean that supplies will be adequate in every location; developing countries will become more dependent upon imports. In many poor areas food security will not increase without substantial increases in local production. Further, whilst supply may generally be sufficient, in years when production of some products falls as a result of weather or disease there may be shortages.

This presents a relatively optimistic picture in contrast with the more gloomy perspective of some other analyses (Brown 1996). It suggests that there is little likelihood of the price of food in international trade reaching the levels received by farmers within the EU under the protection of the CAP. If the Doha round succeeds the location of production within the EU will be more influenced by world market conditions.

The pattern of activity that might then result would reflect the preferences and concerns of an affluent European market. Here diversity, quality, market segmentation to meet the demands of identified social groups, (ethnic, religious, vegetarian etc) and an overall concern with safety will shape what can be sold. The raw materials for this will be sourced where, reaching the necessary standard, they can be accessed at least cost. Some of this will be local partly because of the economics of transport and partly because 'place of origin' may become a selling point. However, the major arable and livestock products will have to compete within a lower priced market than they enjoy now. Producers will need to see themselves not as Community suppliers but as world producers. The straight forward commodity markets are unlikely to be highly rewarding, so greater attention will have to be given to adding value, through varieties that meet specific needs, through processing and through the building up of reputation for quality, safety and reliability.

Such an external dimension suggests that within Europe the industry will need to modify its existing organisational structure to gain benefits of scale, a recognisable global identity and

the ability to fund and apply research. This could well represent the greatest challenge to an industry in which member states that have strictly national objectives and farming interest groups see themselves as competitors rather than partners. Progress in this direction will not be driven by governments or pressure groups; it will depend upon entrepreneurial businesses that see themselves as world enterprises. The best the industry can hope for is that the entrenched interests of politicians and stakeholders will not prevent them moving forward.

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## **Retail perspectives on crop production**

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### **ABSTRACT**

The retail food market is dynamic and fast paced. However, this process is driven by a more rapidly changing consumer. Supply chains from farm to retailer have to become more aligned. The starting point has to be an understanding of the consumer; their needs and requirements. Some characteristics of retail consumers will be summarised. Increasingly, supply chains will consider themselves as a single entity rather than individual compartmentalised units. Finding ways of achieving this has to be an industry priority.

### **INTRODUCTION**

ASDA is a multiple retailer that operates 280 stores throughout England, Scotland and Wales and is expanding into Northern Ireland. ASDA is wholly owned by Wal-Mart, having been purchased in 1999. We are a fresh food retailer with a large range of general merchandise including clothing and electrical goods. Food is the business driver and we like to consider ourselves as understanding the food market and its trends.

ASDA and other retailers maintain very close links with customers, the consumers. Broad and specific areas of interest are regularly put to groups of consumers. This can be as basic as 'how much would you pay for this?' to more detailed assessment of preferences and attitudes. I am sure that the crop protection sector also carries out similar work with its customer base. The difference for retail is that there is no further upward chain. Retail customers directly consume the product. This means that retail has responsibility for the actions of its downstream supply chain. Supply chains that, except for a few exceptions, are fragmented and by definition not aligned to end markets. This presents a conundrum. How can retailers relate to and form a dialogue with supply chains with which they have no identification? This will change with the impact of Common Agricultural Policy (CAP) reform, likely agreements through the World Trade Organisation Doha Development round and the influence of consumer expectation. The first signs of this change are starting to become apparent.

### **CONSUMERS AND AGRICULTURE**

The consumer of the products of agriculture can be described as a well defined, if poorly understood creature. An industry has developed to categorise to taxonomic standards different sectors within various markets and their needs. An example of this is summarised in Table 1 where the Food Standards Agency (FSA) commissioned qualitative research to 'explore and understand in more depth the extent and basis of concern over the use of pesticides'. Group



discussions were undertaken with consumers who identified themselves as concerned over the use of pesticides to grow food. The sample covered broad socio-economic mix and key ethnic minorities were also included.

Table 1. Summary of consumer concern over the use of pesticides to grow Food (FSA 2004)

Category	Key features
Avoiders	<ul style="list-style-type: none"> <li>• Pesticides, an issue of negligible concern</li> <li>• Reassurance and information not required</li> </ul>
Mainstream	<ul style="list-style-type: none"> <li>• Limited understanding of pesticides</li> <li>• Low overall level of concern, and resisting a complex issue</li> <li>• When raised, seek assurance of whether safe to eat different foods</li> <li>• Lack of awareness of regulatory process</li> <li>• Reassurance provided by:               <ul style="list-style-type: none"> <li>- Presence of authorities who control use</li> <li>- Assurance schemes</li> <li>- Explanation of maximum residue levels</li> </ul> </li> <li>• Did not identify labelling as information solution</li> <li>• Potential role for Pesticides Safety Directorate as provider of information</li> </ul>
Discerners	<ul style="list-style-type: none"> <li>• Mainly ABC1</li> <li>• Want to make informed choices in terms of food</li> <li>• High level of concern for both health/safety and environmental impacts</li> <li>• Want detailed information to help them make their own decisions</li> <li>• Labelling not sufficient in short term, need broader education first</li> <li>• Not trusting of regulatory authorities, also need to see Non-Governmental Organisations activity</li> <li>• Assurance schemes helpful when known (currently low awareness)</li> <li>• Understand trade off between pesticides and alternatives when explained</li> <li>• Explanation of maximum residue levels provides reassurance</li> </ul>

However, any dispassionate observer of the relationship between agriculture and consumers would reflect that the cry is often heard that producers need to get closer to customers; to understand them. It seems that the production sector is in a race to catch up with consumers and just as you feel you have a grasp of their requirements, they change. This dynamic has serious implications at various stages on the food supply chain. The retail sector is constantly responding to, and trying to anticipate, customer preferences. There are myriad of examples of once successful organisations that have failed to respond to customer changes and conversely, once failing organisations that have changed and developed very successful operations. But what does this mean for the food supply chain below the retail sector?

## Consumer categories

The demographics of the British market are interesting and pose challenges to food supply chains. At ASDA, we have investigated our key customers and categorised them in an attempt to understand their needs and drives. The groupings encompassed eight descriptors are shown in Table 2.

Table 2. The eight descriptors of consumers

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Pester power	Younger international tastes
Pound stretchers	Weight watching
Quality first	Simple & convenient
Conservative cooks	Older & traditional tastes

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For example, 'Pester Power', these customers are dominated by the requirement for family orientated easy meal solutions. Many of their favourite products are marketed specifically for children. These customers are value driven; price is a major consideration for them. They purchase fewer than average fresh goods and basic cooking items. Their preferred reading is the Sun and News of the World. This group is 15% of national customers but 17% of those of ASDA. In terms of social grouping they are mainly C1 and C2. Younger International Tastes are a different grouping. They, as their title suggests, buy more international foods. The format of these purchases is interesting. They buy easy to prepare sauces and fresh ready meals. They also eat out more than other groups. In terms of population they are 12% of British customers and 14% of those of ASDA. Pound stretchers are totally driven by budget and price is of paramount importance. These shoppers do shop around for the best buys and, crucially, know the price of their regular items. This category makes up 17% of British customers and 18% of ASDA shoppers.

Why focus on these three particular segments? They are the fastest growing ones with Pound Stretchers growing at 6.4%, Younger International Tastes by 6.9% and Pester Power by 6.6%. These groups are growing ahead of the market in value. They are the key consumer trends at present.

### What do ASDA's Customers think about food?

The data that I have presented has resulted from a series of customer listening groups held around Great Britain during 2004. The groups were drawn from core female ASDA shoppers concentrating on mothers with children at home. Why these in particular? They represent ASDA main shoppers and have the next generation's interest to the fore; hence they have a key role in forming personal and family views on food. Both urban and rural locations were used. Those with no views at all or extremely strong views were excluded.

People shop at multiple retailers because of convenience. This is the main factor in choice followed by range of products and price. The area of convenience has to be extended to include meal preparation, as well as shopping ease and is a reflection on the desire of customers to use the limited resource of time according to their wishes.

When prompted for 'issues' the groups segmented into three areas.

- Women with very young children and babies were vigilant and exacting about the products they fed their children
- Women who had adapted their behaviour and purchasing habits with acquired knowledge to cope and secure the health of their family
- Women who had become very disillusioned with 'regular' food scares. This group abrogated responsibility for dealing with food issues to their multiple retailers. An element suspected that there was a conspiracy to encourage more expensive or organic food to be purchased.

### **How has their behaviour changed?**

The first response has been to value 'freshness'. They are using their skills as shoppers to select food that appears fresh i.e. avoiding old looking meat or blemished produce. The next step for the concerned shopper has been to focus on intervention and to get more closely to 'back to nature'. This group has the greatest concerns of Genetic Modification. Finally, shoppers are looking towards the reputation of their source. The retailer has moved to being the guardian of food standards. The trust has placed in the retailer for wholesomeness of food. As a result, retailers throughout the British market have adopted assurance schemes to secure this position and act as a promotional vehicle. Hence, there has been widespread adoption of the Little Red Tractor (LRT) scheme and logo in pack labelling and consumer communication. The Red Tractor is administered by Assured Food Standards ([www.littleredtractor.org.uk](http://www.littleredtractor.org.uk)). Assured Food Standards (AFS) is the independent organisation set up to manage the LRT scheme. AFS, through sector standard setting boards, sets for most major food products the LRT standards that must be achieved before the logo can be applied to those products. For field crops, the sector board is Assured Produce Scheme. This approach is being adopted outside the UK. Again, there is no particular hazard that is being addressed through the farm assurance schemes, rather retailers and processors are protecting their reputations and hence consumer trust.

### **How should these observations be interpreted?**

Consumer concerns over food production are strong. It is clear that customers have become slightly unnerved by the number and regularity of food scares which is in the main due to the increasing industrialization of food. There was recognition that ASDA has a tough job in hand ensuring that everything is both safe and fresh. However, this was quite clearly seen as an ASDA duty.

There has been much more emphasis laid by customers in this research compared to others about a concern that things have gone 'too far'; perfection is being pursued at the cost of natural and they want to see the balance redressed slightly in food production.

### **A Future British agriculture**

We find some of the best discussions on the challenges faced by British farming come from those who are selling through Farmers Markets. It does not matter whether you sell from a single stall or nearly 300 stores the principles are exactly the same. Incidentally, there is a major market move where producers are testing their products at Farmers Markets and using this as a springboard to build supply business with larger retailers. This is a fantastic development route.

Farmers are unique. They are described as customers both by their suppliers and by their customers; this has to change. A supplier mindset is very different. ASDA works at getting our suppliers to think like us. Only by doing so can they align their businesses to ours. There is no point in having different business directions. If your customer is not thinking in ways you can assist with – find a new customer! Working together is critical and easy to say and we spend a lot of time working on it (and we are not there yet). It is the only way to have a sustainable business.

ASDA tends to work with a few key suppliers; they understand our business and the success factors that drive it. We are value retailers. This is not about cutting suppliers prices to the point of death. We offer volumes and growth that spreads costs enabling us to meet our target prices (and offer customer value) but we also work with suppliers to take out costs. Often these are costs that by dialogue and discussion (not table thumping) have joint responsibility.

This is important; direct and clear communication requires changing attitudes on all sides. Our strategy is medium term. Short term deals are always on offer but frequently are unsustainable. We walk away from these offers. There is no value unless it's on the shelf. So we want to work with suppliers who want to work with us.

Combinable crops and other sectors now freed from the embrace of the CAP are facing serious challenges. There are key pieces of learning that can be adapted by farming from other industries to address the pressing needs for greater business improvement. ASDA has supported the value chain analysis programme of the Food Chain Centre. Sector structures focus on each part of the chain optimising its part. This can lead to the total chain being weak. Looking forward we need better information flow up and down chains and the understanding of all the aspects of production that build value to the customer. These are not small challenges but a framework of working together is the best way to build for the future. ASDA has successfully worked with some sectors in a co-operative way for nearly a decade. Potatoes and other field crops are grown under cost plus contracts. We expanded our British production. Carrots are grown from Scotland to Suffolk and we have not imported a carrot for over two years. Yes, it would be cheaper and perhaps easier to source from over the Channel and pick up French carrots. But our sales dipped when we stocked French and took several weeks to recover when the British supplies became available. Now we have steady sales/happy customers. This is true alignment and co-operation. We are working on similar initiatives with potatoes

However, we need to face into either further cost competitiveness or to seek further product quality differences. There is a particular challenge in that for many of British farms' produce – beef, lamb, milk, potatoes, the thinking has not been developed. There has been considerable focus on regionality as a differential. While there are strong regional preferences, for many the customer is looking for further gains. When we talk to customers we get two responses: one group recognise local produce for freshness and quality. Another reason is that as it has not travelled so far so it should be cheaper. I think that for most farmers the market returns are going to come from the traditional markets.

These are often described as commodity. This is not a true reflection of the market. As retailers, we always have cheaper sources of farm produce. Why are they not taken up?

- Firstly, our customers want British produce. While price is still a key issue, there are also the logistical challenges of maintaining supplies. It is not a sensible option to have to resolve problems on the other side of the world unless there is an overwhelming advantage – such as supplementing the seasonality of UK lamb with NZ.
- Secondly, if we want to build solid relationships with open free communication, and we do, you can't base this on quicksand. Short term advantages will be soon lost in the medium term.
- Thirdly, the standard that British supply offers are world leading. If you doubt this put farm assurance into an internet search engine and see the global reach of this approach. Where we import we use farm assurance schemes or equivalents.

The huge challenge in the new era is to rediscover farming objectives on quality and efficiency. We have to invest in R&D to compete and the R&D has to be refocused on markets. There has to be ways to recoup or protect this investment for all in the supply chain. The crop protection sector has a crucial role in this move. Relationships and alignment that I have described for retail, processors and farmers must involve farm input suppliers. We are seeing the dawn of a new era where supply chains start to act as their name describes, chains that are linked at each stage to be successful.

Closer alignment with sharing of information will become normal business practice. ASDA gives free (in all senses of the word) access to retail sales information. Relationships will focus on whole chain requirements. Joint business planning will increasingly incorporate downstream suppliers such as plant breeders and agrochemical organisations. Rather than optimising individual components of a chain (grower, processor or retailer), the emphasis will be on the whole chains optimal performance. The key to this will be the development of trust through communication.

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## Future developments in risk assessment for pesticides

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### ABSTRACT

Regulatory risk assessment for pesticides is continually evolving, in response both to advances in scientific knowledge, and also to changes in public perceptions and expectations. This paper describes three areas in which developments are currently occurring, and illustrates some of the challenges in ensuring that changes in regulation are based on sound science and at the same time practical to implement. The topics covered are: the assessment of health risks from mixtures of pesticides; comparative risk assessment for pesticides; and the assessment and management of indirect effects of pesticides on wildlife.

Over recent decades, regulatory risk assessment for pesticides has become progressively more precautionary. Before a product can enter the market, or retain approval following review, increasing reassurance is required that its use will not lead to unacceptable adverse effects, either on human health or on the environment.

This trend has been driven in part by advances in scientific knowledge. A good example is the discovery that even with good agricultural practice, pesticide residues can vary importantly between individual fruit or vegetables from the same crop. This is a potential concern where a residue is acutely toxic and the crop is one from which a single item might constitute all or a large part of a person's total intake of the food in one day (e.g. an apple or a carrot). In these circumstances, if an individual was unlucky, and happened to consume a fruit or vegetable with an unusually high residue, there was a possibility that standard margins of safety could be eroded, even though calculations based on average residues across the crop did not indicate that the ADI would be exceeded. The dietary risk assessment was therefore refined to take account of within-crop variation in residues that might impact on risks of acute toxicity.

In other cases, developments in risk assessment have occurred in response to changes in public perceptions and expectations. In Britain, as in many other countries, public concern about environmental threats to health has increased over the past 50 years. Interestingly, this has occurred at a time when overall mortality has been falling, and it is possible that because people now have a greater expectation of health and longevity, risks that in the past were considered negligible are now regarded as important. At the same time, there has been a growing emphasis on the rights and interests of the individual relative to those of society more generally. Thus, people are much less accepting of adverse impacts on their lives when they perceive no compensatory personal benefit. In addition, regular and often misleading media publicity has heightened awareness of environmental health hazards. For these reasons, the public nowadays expects a higher level of precaution in the regulation of pesticides, and regulatory authorities, as servants of the public, have rightly responded.

In this paper, I will discuss three aspects of pesticide regulation in which new developments are currently in progress.

## 1. HEALTH RISKS FROM MIXTURES OF PESTICIDES

The first of these areas of development concerns risks from exposure to combinations of pesticides, either at the same time, or cumulatively over a period. Simultaneous exposure to mixtures of pesticides occurs most obviously when two or more active substances are co-formulated in a single product or applied together in a tank mix. In these circumstances, the combined exposure may apply not only to operators, but also "bystanders", workers who subsequently enter the treated crop, and people who eat food derived from the crop. Mixed exposures may also occur, however, through consumption of food from a crop that has been treated with a variety of pesticides at different times, or from simultaneous consumption of two or more foods containing different residues. In addition, over longer periods, people can be exposed to multiple pesticides from a range of sources (Table 1).

Table 1. Sources of exposure to pesticides

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- Mixing, loading or applying pesticides occupationally
  - Bystander exposure to aerosols and vapour during and after professional application of pesticides
  - Contact with pesticide residues on treated and non-target surfaces (including work with treated crops)
  - Non-occupational use of pesticides in the home or garden
  - Consumption of food derived from crops treated with pesticides or grown on land previously treated with pesticides
  - Consumption of drinking water contaminated with pesticide residues
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The potential for two toxins to act together other than by simple addition of their effects has long been recognised, and can be important, for example, in patients treated with combinations of drugs. Such interactions can take various forms (Table 2). In general, however, it has been assumed in the past that important toxic interactions between pesticides were unlikely to occur in practice because of the relatively low doses to which people are exposed. This is in contrast to medicines, which often are administered at doses close to or above their threshold for toxicity. A bigger concern has been the possibility of interaction between pesticides and other chemicals (in particular drugs) encountered at higher doses, and this has been addressed within the 10-fold assessment factor that is normally applied to allow for possible differences in sensitivity between individuals within a single species.

Table 2. Circumstances in which the combined effect of two toxins may be other than simply additive

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**Toxico-kinetic**

One toxin may affect the absorption, distribution, metabolic activation, metabolic inactivation, or excretion of the other

**Toxico-dynamic**

Both toxins may act on the same target by a similar mechanism (e.g. two cholinesterase inhibitors)

Both toxins may cause the same adverse effect, but acting through different mechanisms (e.g. one may inhibit production of a hormone, and the other enhance its degradation)

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Because of growing public concern about possible “cocktail effects”, however, we have now reached a point where stronger reassurance is needed that important toxic interactions between pesticides will not occur in practice. To address the problem, therefore, the Department of Health’s Committee on Toxicity (COT) was asked to review the science underpinning risk assessment for mixtures of pesticides, and their findings were published in 2002 (Committee on Toxicity, 2002).

The COT concluded that there was a clear potential for interaction where two or more pesticides affected the same target organ by the same mode of action. In general, this would be expected to take the form of “additivity of dose”, the impact on the toxic end-point depending on where exposures lay on the dose-response curve (Figure 1). Where pesticides have different toxic actions, the default assumption would be simple additivity of effects, although in specific instances the possibility of potentiation might have to be considered. They also recommended that a systematic scientific framework be established to decide when it is appropriate to carry out combined risk assessments for more than one pesticide.



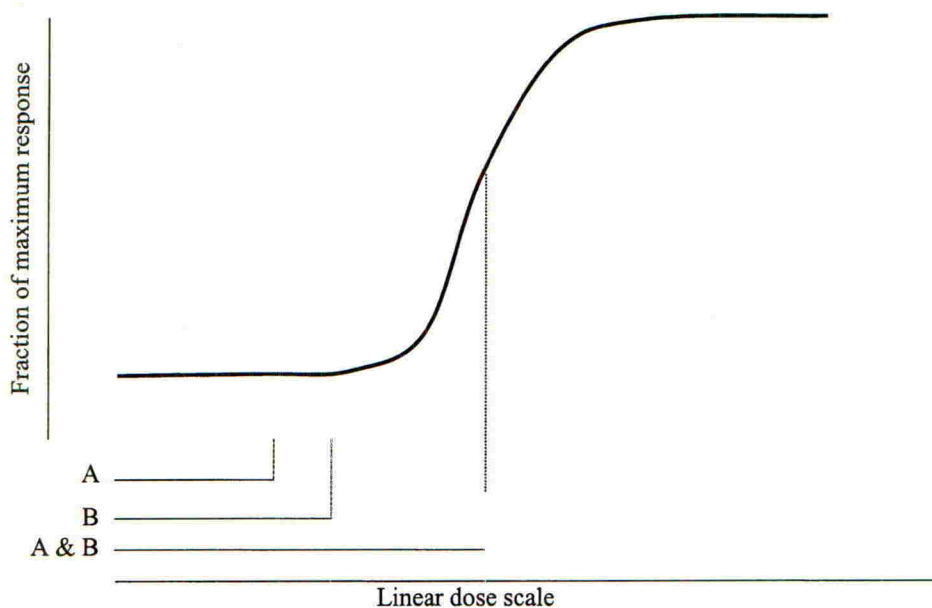


Figure 1. Dose additivity for two pesticides, A and B. In this case, neither pesticide would produce an effect on its own, but an effect occurs with combined exposure

Following on from the COT report, various changes have been introduced in the regulatory assessment of pesticides overseen by the Advisory Committee on Pesticides (ACP). We now routinely consider potential toxic interactions when more than one active substance is present in the same product – usually adequate reassurance can be derived from arguments based on the standard toxicity data package, but occasionally there may be a need for additional empirical data to address outstanding uncertainties. Using a similar approach, we have also reviewed the tank mixes that are most often applied. In addition, the Pesticides Safety Directorate (PSD) is preparing a risk assessment for combined exposures to cholinesterase inhibitors, these having been identified as an important group of pesticides acting through a common mechanism, which could be used to develop test methods for combined risk assessment when there is potential for additivity of dose. An added advantage of starting with the cholinesterase inhibitors is that those approved for use in the UK have all recently been subject to regulatory review, and therefore have up-to-date toxicological data bases.

This combined risk assessment, which is still in progress, has thrown up a number of challenges. One is the method for characterising the relative toxicity of different active substances. This must be achieved in the face of several practical constraints. At least in the first place, we are obliged to use toxicological data that are already available. However, the nature and quality of these data vary from one compound to another. Thus, for some substances information about cholinesterase inhibition is available from studies in humans, whereas others have been investigated only in animals. And even where two pesticides have been studied in the same species, comparisons may be hampered by differences in the method

of administration or dose-spacing. Also, it is important that the method that is adopted for combined risk assessment should give outcomes that are consistent with regulatory decisions for individual products. It would be anomalous, for example, if the chosen method indicated an unacceptable risk when it was applied to a single pesticide that currently was approved according to standard criteria.

Having thought through these problems carefully, the ACP has recommended to PSD that the risk assessment should be based on exposures normalised to the relevant reference dose for each pesticide (i.e. one that would be derived in relation to its effects on cholinesterase). With exposures to each individual pesticide normalised in this way, the aim would be that a person's total exposure to all of the pesticides did not exceed a value of one.

Another challenge lies in the assessment of potential exposures. In the standard risk assessment for an individual pesticide, we derive realistic worst case exposures using a deterministic model, and then compare these with relevant reference doses. However, a deterministic approach is not practical when multiple pesticides are being considered, and it will therefore be necessary to apply probabilistic modelling, which will require appropriate underpinning data. In some cases, the task may be facilitated by reasonable simplifications. For example, one potential source of exposure may so dominate another that the latter can be ignored. But difficulties will remain. In particular, allowance must be made for the fact that the levels of different residues in a single dietary portion are unlikely to be statistically independent. If a crop has been treated with one cholinesterase inhibitor, it will often be less likely that it has been treated with another.

A further difficulty will lie in deciding what an acceptable outcome is when a probabilistic risk assessment is applied. What theoretical prevalence of exposures above the agreed reference dose would be considered tolerable? Such decisions entail value judgements and are not scientific. However, they cannot be made without an appreciation of the scientific limitations of the method, particularly at the upper extremes of the projected exposure distribution. My view is that it will be better to air this problem in public before the first combined risk assessment is completed, and it will be the main topic for discussion at the ACP's open meeting this year.

## **2. COMPARATIVE RISK ASSESSMENT**

Another challenge with which the ACP has been grappling in the last few years is comparative risk assessment for pesticides. Where use of a pesticide is deemed necessary, how do we ensure that the product chosen for the job offers the best balance of benefits to risks? Currently, regulatory procedures go some way towards achieving this in that products are not allowed onto the market if they are not effective, or if there is inadequate reassurance of their safety. However, among the pesticides that are available to the farmer, some may be better than others. Various regulatory approaches might be adopted to improve the selection of pesticides by farmers, each with its advantages and disadvantages.

One option, which has been applied in Sweden (and also by at least one supermarket chain in the UK), is to prohibit the use of certain active substances that are considered to be more hazardous than alternatives. This has the merit of being easy to enforce. Moreover, the comparison between active substances can be made centrally by people with the relevant

scientific knowledge and expertise. Against this, however, the comparison is made on the basis of hazard rather than risk, and does not take account of differences in the ways in which active substances might be used (e.g. type of formulation, dose rate). Also, a given active substance may be one of several that are available for one pest problem, but the only option for another.

Another possibility would be again to carry out the comparative risk assessment centrally, but at the level of product and indication rather than active substance. With this approach, account could be taken (at least to some extent) of risk rather than simply of hazard. For example, allowing for the way in which it would be used, a given product might be acceptable for one purpose, but not for another for which lower risk alternatives were available. However, the method would be much more complex to administer (large numbers of comparative risk assessments would be required). Furthermore, it could render farmers vulnerable if resistance emerged to the lower risk products or they were withdrawn from the market. Another weakness is that no account would be taken of local circumstances at the point of application, which could alter the balance of risks between one product and another. For example, one product might be superior to another in most situations, but not where there was a possibility of spray drift onto water courses.

A third approach would be to maintain the current system for approval of products with the choice between alternatives being made at farm level, but to improve the information supporting decisions, and encourage optimal choices more actively. For example, at the time a product is approved, information in the standard data package could be used to classify it on the basis of its safety profile as a first-, second- or third-line choice in relation to each of its indications for use. This grading could then be incorporated in the product information sheet, perhaps using a "traffic light" system and adding briefly the reasons for any grading other than first-line (e.g. higher risk of toxicity in operators if mishandled, toxicity to aquatic wildlife). A farmer could then choose from any of the pesticides approved for a job, but if he wished to use a product that was not first-line, he would need to record the justification (e.g. no alternative first-line product available, no water course adjacent to treated crop). This record would have to be retained and made available to the enforcing authority for inspection if requested. The method would increase the administrative burden for farmers somewhat, but it would provide an incentive to use first-line products (less administration), and also to manufacturers to develop them (since they would have a marketing edge). The European Commission is currently considering centralised regulatory approaches to comparative risk assessment and substitution, but I believe that this third option is an idea which deserves further exploration.

### 3. INDIRECT EFFECTS OF PESTICIDES ON WILDLIFE

Ever since the first publication of "Silent Spring" in 1963 (Carson, 2000), the adverse impact of pesticides on wildlife has been a continuing public concern. As a consequence, scientific methods have been developed to evaluate the potential effects of pesticides on a wide range of wildlife species, and specified ecotoxicological criteria must be satisfied before a product can be approved. Up to now, however, the ecotoxicological risk assessment for pesticides has been limited to their potential for direct toxicity to non-target organisms. This is in contrast to the regulatory position on genetically modified crops, where risk assessment must also consider indirect effects on wildlife.

Indirect effects could arise in various ways. Use of a pesticide might deplete plants or insects that are an important source of food for other species (trophic effects). Or it could lead to a change in agricultural practice (e.g. a shift to more autumn-sown crops and earlier cultivation) with knock-on effects on habitats and food sources. Ideally, risk management for pesticides would take account of all effects on wildlife, both direct and indirect, and the ACP through its Environmental Panel has recently been exploring the scope for extending risk assessment, at least to address trophic effects.

Evaluation of indirect effects is not straightforward, not least because of the large number of factors that can impact on wildlife populations, making it difficult sometimes to distinguish the exact contribution from use of pesticides. In some ways the problem is similar to that which we frequently encounter in chronic disease epidemiology, with complex causal chains and a need to take account of multiple "confounding factors" when interpreting statistical associations. Moreover, the assessment and management of indirect impacts will often need to extend beyond what happens in one field during a single season, looking at outcomes in the context of farming systems at a landscape level over a period of years.

Despite these challenges, however, the ACP believes that useful advances can be made. For example, the risk of trophic effects on birds from use of an insecticide might be assessed through its impact on a chick food index. Where this indicated a higher probability of adverse outcomes, it might then be possible to require compensatory mitigating actions at a field or farm level such as unsprayed headlands, beetle banks, or management of set-aside for wildlife. Before this can be taken forward, however, there is a need for more robust underpinning scientific evidence, and we have recommended that PSD commission appropriately targeted research.

### CONCLUSION

There is always a danger that tighter regulation of pesticides will be perceived by manufacturers and users as an unreasonable burden. On the other hand, the public rightly expect high standards of safety in the use of toxic chemicals, particularly when they are applied in an open environment and to food sources. The aim of regulators is to ensure that controls on the sale and use of pesticides appropriately reflect societal values and at the same time are based on sound scientific evidence. Ongoing developments in risk assessment of the sort that have been described in this paper exemplify how this process continually evolves.

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**World horticulture in crisis**

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**ABSTRACT**

European Union Directive 91/414, the US Food Quality Protection Act, and Japan's Food Sanitation Law have all placed more strict regulatory requirements for maintaining registrations of existing agrochemicals and new standards on the registration of new products. These regulations, along with others, have placed severe restrictions on the availability of pest control products for minor uses on specialty, low acreage/high value crops in many countries. In the USA, the US Department of Agriculture, the land-grant university system and crop protection industry provide resources for the IR-4 Project to assist in the data development to support registration of chemical and biological crop protection products for specialty crops. Agriculture and Agri-Food Canada has recently started a program, Pest Management Centre (PMC), which is similar to IR-4 in structure and function. IR-4 works with the PMC to develop data to support NAFTA registrations. The key to IR-4's success has been a high degree of co-operation between IR-4 and the regulatory agencies, US Environmental Protection Agency, California's Department of Pesticide Regulation and Health Canada's Pest Management Regulatory Agency. The IR-4 model will be discussed and possible global solutions such as data sharing, crop grouping, representative crops, geographic zones for residue studies and standardizing of MRL's will be proposed.

Horticulture crops are grown throughout the world for food and enrichment of life. Commercial growers of these specialty crops face many obstacles including availability of adequate land, water and work force to grow the crops. Destructive pests (insects, nematodes, plant diseases, weeds) further challenge the successful production of these high value crops. Crop rotation, pest resistant varieties, mechanical weed control and other cultural practices are useful tools in an integrated approach to pest management. Crop protection products are useful and necessary tools in the integrated "war" against destructive pests. Most chemical based crop protection products are developed for large markets on the major crops such as maize, rice, soybean, and cotton where the cost of discovery, development, registration and marketing can be offset by significant sales of the product. The cost of bringing a new chemical crop protection product to market is very expensive. In the USA, the cost is in excess of \$100 million dollars. Costs (i.e. registration) rapidly escalate when the registrant of crop protection products targets market expansion to other countries.

In most countries, there are laws and regulations that govern the use of crop protection products. These laws and regulations often require specific registration for the crop and the pest before a crop protection product can be used. Growers of horticulture crops often do not have legal access to the crop protection products because the potential return on investment from sales in the relatively small specialty crop markets does not justify the incremental increase in the cost of data development by the crop protection industry to register the uses on

specialty crops and provide stewardship in marketing it to growers. Further complicating the issue is the potential for crop damage on high value, specialty crops. If a crop protection product were to injure a horticulture crop, the liability to the manufacturer would be significant and far outweigh any potential profits from such a use. This results in the proverbial "Minor Use Problem". The purpose of this paper is to examine the minor use problem and offer some options to eliminate or at least minimize its impact on the availability of crop protection products for specialty horticulture crops.

### **Current Status of the Minor Use Problem**

Directive 91/414/ European Economic Community (EEC) provides the legal basis for the placement of crop protection products on the European Union (EU) markets. The Directive places the safety of human health and the environment above the needs of agricultural production. Evaluations are comprehensive and detailed. Data requirements in the EU for crop protection products now exceed any other class of substances, including pharmaceuticals. Over 500 older crop protection products have been removed from markets due to the new costs of data development in order to maintain registration under Directive 91/414. Since the Directive was put into place, crop protection companies have only defended the highest volume products that could meet the new human health and environment safely standards. Introduction of new products with lower risk profiles has been delayed and has further complicated the minor use problem.

Directive 91/414 has given Member States two tools to reduce the impact of the minor use problem. The Voluntary Mutual Recognition of Minor Use Authorizations refers to the recognition and acceptance of data supporting a specialty crop use from one country to another. For example, Maximum Residue Limit (MRL) data for a specialty use in the UK could be used to support registration in the Netherlands. The ideal cases are those where production conditions are similar in each country. There are some obstacles that can cause difficulty with this process. In the UK for example, some growers may develop data for a use in the UK and maybe reluctant to share these data with other countries that may compete in their markets. In addition, the recognizing country may not accept the data or feel the data are not adequate to support authorization in their country.

The other tool is "off-label uses". With off-label uses, the user accepts the product risk, such as crop damage, thereby protecting the registrant from liability. The off-label uses are supported by the same data standards that would be required for on-label approvals. Off label uses must not increase the risk to operators, consumers, or the environment. With this in mind, there must be certain criteria met and data available. For example, the product must already be labelled in the Member State for another crop and a Maximum Residue Limit (MRL) established for the off label crop with residue data available. These off-label uses, however, would allow growers to legally use the product even though it was not listed on the label. However, the legal application of off-label uses may still vary within each country. Germany recently determined that they would no longer allow the "Off Label Uses". Although the MRLs can still be used to support uses, they must now be formalized with a special registration. This process now places product liability back on the registrants. Although this has caused a great deal of work for those involved in specialty crop uses, the German BBA efforts have helped to retain (maintain) many of the off-label uses for growers.

In the United States, the use of chemical and biological crop protection products is authorized under the oversight of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). This law has been amended numerous times in response to advances in science and modifications of public policy. The last two major revisions occurred in 1988 (FIFRA 88) and in 1996 with the Food Quality Protection Act (FQPA). The 1988 amendments required companies to update the data supporting the product to current standards. Many low volume, low sale products were not supported and taken off the market, similar to EU Directive 91/414. The FQPA modernised the safety standards to account for cumulative and aggregate risk. These stricter safety standards resulted in some chemicals being removed from the market on both major and specialty crops or use patterns (GAPS) being modified to reduce exposure to workers. The US Environmental Protection Agency (EPA) has encouraged companies to develop new products that are deemed lower risk alternatives. Almost all of the new chemicals and biologicals registered since 1996 have reduced human health and environmental risk characteristics. This has allowed growers the opportunity to transition away from older pest management technologies.

The US EPA has been very supportive of efforts to reduce the minor use problem. There is a provision of FIFRA directing the EPA Administrator when establishing data requirements for specialty crops that they be made to commensurate with the anticipated extent of use, pattern of use and the agriculture need. The EPA has encouraged the use of reasonable crop groupings based on science as discussed in a later section. The FQPA also contains a provision providing an incentive to add specialty crop uses to registrations. Companies are given an opportunity to extend the exclusive use of data protection for up to an additional three years by adding nine specialty crops to their crop protection products. This incentive will allow the companies to protect their major markets from generic competition for a longer period and allow them to recoup some of their expenses.

In 2002, the Canadian Parliament re-worked their crop protection product law and promulgated the Pest Control Products Act. This new law and associated regulations essentially allowed Canada to harmonise their regulations with those of the United States. Today, the only major difference between the two country's data requirements is the requirement for efficacy data to support crop uses. The harmonized guidelines have supported enhanced regulatory efficiency through work share and joint review of data with the US and other countries.

Due to resource issues, Mexico has followed the regulatory lead of the USA and Canada. Mexico will allow use of a crop protection product if the chemical is registered in the USA or Canada. This allows the Government to spend its resources to evaluate if the crop protection product is efficacious under local conditions.

The government of Japan revised the Food Sanitation Law in May 2003. The revision, which goes into effect in May 2006, implements a "positive list system" prohibiting the distribution of foods that contain chemical crop protection products above certain levels unless MRLs for the chemicals on the food are established. The three-year transition period was designed to allow the government to set MRLs for existing products and add MRLs for new products currently being registered.

The Japan Ministry of Agriculture, Forestry and Fisheries (MAFF) defines a minor crop as one with a total country yield of less than 30,000 metric tons/year production. Under this



classification, there are 60 major crops in Japan. Because of this definition, a number of crops considered minor in the United States like azuki bean, taro, sweet potato, yam, Chinese radish, turnip, cabbage, cauliflower, broccoli, lettuce, onion, chive, carrot, celery, cherry tomatoes, sweet peppers, eggplant, cucumber, pumpkin, watermelon, other melons, spinach, ginger, green bean, mandarin oranges, apricot, persimmon and kiwi fruit are considered major crops in Japan. This classification poses significant challenges to the crop protection industry under the new Pest Control Act and Food Sanitation Law because new efficacy and residue data will be required to be submitted by 2006 on an estimated 3900 pest/crop/chemical combinations. The agrochemical companies are required to submit residue data requirements from two locations. The samples from each location have to be split with one portion going to a Japanese government residue lab and the other to the company's lab. In addition, efficacy studies must be run over a two year period with positive results from 6 trials. Herbicide and Plant Growth Regulatory efficacy studies are conducted by the Japan Association for Advancement of Phyto Regulators while fungicide and insecticide efficacy trials are conducted by the Japan Plant Protection Association. Efficacy data are required for each agrochemical/pest/crop combination which is the reason behind the estimated 3900 studies. The efficacy work costs the crop protection industry about \$30,000/study bringing the total study cost (residue plus efficacy) to over \$55,000. This amount is expected to be too large a financial burden for many companies.

Though the 2006 deadline associated with the Japan Pest Control Act is rapidly approaching, there has been some regulatory relief for Japan's specialty crop growers. First, specialty crop growers can obtain temporary agrochemical minor use crop permissions after approval by the Prefectural Governor and the Minister of Japan's MAFF. In addition, crop groupings have been approved by MAFF. Unfortunately, crop groupings only represent about 20% of the minor crops grown in Japan. However, MAFF has indicated that when developing the provisional MRL's they will attempt to ensure that crop groupings are consistent with those used in the USA and Europe. The regulations note that "Individual limits should be harmonised among crops in the same food category". Japan seems very interested in embracing crop groupings and the government has volunteered to serve as one of two lead countries in the modification and expansion of the CODEX international crop groupings.

The minor use problem affects growers in almost all countries of the world. However, the specialty crop growers in the USA are extremely fortunate to have a useful tool to provide significant relief; through USDA funded IR-4 Program.

### **The IR-4 Model and How It Works in the USA**

The IR-4 Program started rather modestly in 1963 with a grant from the land grant university agriculture experiment station directors to address the concerns of minor crop growers about the lack of pesticides to control their pest problems. There were two employees hired by 1964 who set up and organized the program in cooperation with state extension researchers and laboratories under registration requirements overseen by the US Department of Agriculture (USDA). When the EPA took over the registration of pesticides in the early 1970's, the regulatory requirements were increased and additional USDA funding was provided by the Cooperative States Research, Extension and Education Service (CSREES) in 1975 and the Agriculture Research Service (ARS) in 1976. This funding support partnership between the state land grant university system and the USDA has flourished in the past 30 years and has become a model for intergovernmental cooperation. The other key partners in this process are

obviously the growers, the crop protection industry and the regulating agencies (mainly the EPA although California's Department of Pesticide Regulation (CDPR) has become an important component in recent years). The regulatory partnerships have extended beyond U.S. borders to NAFTA countries, especially the Canadian Pest Management Regulatory Agency (PMRA).

IR-4 has had a positive relationship with the EPA for its 30 plus years of existence and worked with the Agency to pioneer crop groupings and representative crops which are discussed in the solution section of this paper. However, after the passage of the FQPA, it was apparent that IR-4 and the EPA needed to work much more closely together to address the concerns about older product losses and registration of newer technologies to serve as lower risk replacements. Jim Jones, then Director of the Registration Division of EPA and now Director of EPA's Office of Pesticide Programs (OPP), and the senior author organized a meeting of the two organizations under the banner of the EPA/IR-4 Technical Working Group (TWG) in January 1999. Over time the EPA/IR-4 TWG Meetings went from limited agendas to more detailed topics and more innovative regulatory initiatives. One initiative has resulted in a significant number of specialty crop clearances on Reduced Risk products spinosad and azoxystrobin with savings of over \$1 million in field and laboratory GLP research expenses. IR-4 proposed a reduced data set program for these two products based on their EPA classification and very safe dietary risk assessments. The end result was 165 spinosad clearances in 2000 and 168 azoxystrobin clearances on minor crops in 2001. In addition, 206 glyphosate clearances in 2000 were obtained as part of this innovative regulatory approach.

One of the keys to the partnership between IR-4 and the EPA has been the development of close working relationships fostered by personnel exchange and sabbaticals. In 2000 and 2001, Dr. Willis Wheeler (retired from the University of Florida and on USDA special assignment) was provided an office in the EPA and served as the IR-4 Liaison to the EPA's OPP working with Pat Cimino, EPA Minor Use Team Leader, and other EPA staff members to keep them informed of minor crop issues and alert IR-4 on key areas of Agency interest. In 2000, Sidney Jackson, EPA's Registration Division, spend time at IR-4 Headquarters and the regional laboratories to learn more about IR-4 procedures and discussing the petition review process in the Agency. This led to a sabbatical by Dr. Dan Kunkel with the EPA in 2001 to develop more innovative ways to process and improve IR-4 petitions. Earlier, IR-4 had discovered that the EPA was sending out its petitions after submission to a contract reviewer to put them in a standardized summary format. This led to IR-4 working with the Agency to develop a standardized petition submission format saving the EPA at least two months in review time and considerable out-of-pocket contract review expenses. While on sabbatical at the Agency, Dr. Kunkel learned more about the internal petition review procedures in the Registration and Health Effects Divisions so that improvements and review efficiencies could be implemented including electronic petition submissions. An annual Workplan was developed with IR-4 petitions to maximize the number of IR-4 petitions for Agency review by grouping as many as possible around key active ingredients, especially lower risk active ingredients, and combining IR-4 with registrant petitions to maximize the FQPA risk assessment process. Since IR-4 has focused between 70 to 80% of its research program on lower risk, safer chemistries since 1999, it made it much easier for the EPA to work on the registration of these products for minor crops. The end result was an increase from 25% of IR-4 petitions in the 2000 EPA Workplan to 46% on the 2001 Workplan. Since 2001, IR-4 has maintained nearly half of the new uses for existing active ingredients petition review commitment by the EPA. More recently, IR-4 has been utilizing electronic petition

submission as a means to gain additional review efficiencies in the EPA and plans to have all of its petitions submitted electronically by 2006. Other notable sabbaticals by IR-4 staff include Dr. Michael Braverman, Biopesticide Program Manager, with the Agency's Biopesticide and Pollution Prevention Division (BPPD) which registers biochemical and microbial products in 2002. This led to recommendations to improve IR-4's biopesticide petition submissions and a much better understanding about BPPD's internal petition review process. IR-4 started an IR-4/BPPD TWG in 2001 to explore ways to improve petition quality and registration efficiencies which continues to the present time. The other major sabbatical by an IR-4 staff member was Dr. Hong Chen in 2003/2004 to work on the Crop Grouping Project as a follow-up to the 2002 USDA/IR-4 International Crop Grouping Symposium. This initiative has resulted in IR-4 committing Dr. Chen full time to this important strategic objective which is described in greater detail in the solution section of this paper. The IR-4 partnership initiatives with the EPA, CDPR and PMRA led to the four groups receiving the EPA/OPP Honor Award for Excellence in Teamwork in 2001.

As noted previously, CDPR has been a highly important component of the regulatory partnership since 2000. CDPR conducted one IR-4 petition joint review with the EPA in that year and expanded this partnership dramatically in 2001 with 30 IR-4 petitions which was 10% of the entire EPA workload and 20% of IR-4 submissions. This workshare program was the major factor in IR-4 doubling its contribution to the EPA's Workplan from 2000 to 2002. The CDPR management and scientists kept up this commitment from 2002 to 2004 in spite of severe state budget restrictions. In 2005, CDPR increased its review to over 50 IR-4 petitions which was a significant increase and now accounts for nearly half of the petitions submitted by IR-4 annually.

Canada has cooperated with IR-4 in a joint residue program since 1996 through funding provided by the Canadian Horticultural Council (CHC). PMRA staff have also been actively involved in IR-4 priority setting workshops and the National Planning Meetings. This collaboration resulted in over 90 joint field research trials based on U.S. grower driven priorities until 2003. Canadian participation was also driven by stakeholder requests conveyed through the CHC and the Canadian Provincial Minor Use Coordinators. In May 2002, the Canadian government announced joint Agriculture and Agri-Food Canada (AAFC) and PMRA programs: Pesticide Risk Reduction and Minor Use Program. A June 2002 directive set up the AAFC Minor Use Program and Pest Management Centre (PMC) along with the financial support for both AAFC and PMRA. The PMC was patterned after IR-4 which spent considerable time with AAFC staff, to discuss the organization and functioning of IR-4. The financial commitment by the Canadian government was a major one and dedicated \$63 million CN over a six year period (\$42.2 million CN to AAFC and \$20.8 million CN to PMRA were devoted to minor uses). The PMC now has a staff of 25 who oversee nine test sites or field research centres across Canada where the efficacy (Canadian submission requirement) and field GLP residue studies are conducted. Since 2003, there have been 47 joint IR-4/PMC projects (42 residue and 5 efficacy) involving 154 residue trials and 190 efficacy trials. The partnership between IR-4 and PMRA resulted in a joint PMRA/EPA workshare of an IR-4 petition submission in 2001 that resulted in the first NAFTA approval in 2002. Subsequently, the PMRA/EPA partnership in IR-4 workshare petitions has expanded with the support of the NAFTA TWG on Pesticides Executive Committee to four petitions in 2004 with two approvals anticipated in 2005. A list of potential workshare petitions has been developed for the 2006 joint review and it is expected that this program will continue to

expand into many additional submissions in the next few years as the 42 residue projects from the 2003 to 2005 period are ready for review.

The EPA/IR-4 TWG has served as a useful model for partnership building and inter-governmental efficiency. CDPR joined the TWG in 2000 and AAFC and PMRA joined in 2003. The group is now called the EPA/IR-4/CDPR/PMRA/AAFC TWG to reflect the partnership organization and continues to hold three to four meetings a year leading to a total of 26 since 1999. Regulatory initiatives proposed by IR-4 are taken to the Health Effects Division ChemSAC Committee for review and approval or rejection. Minutes are published after the meetings to keep participants abreast of the topics discussed, their status, and follow-up issues. In addition, IR-4 has sponsored nine tours for EPA staff since 1999 as an educational opportunity for the scientists and reviewers to get a close-up look at how specialty crops are grown, what pest problems growers are dealing with and how the regulatory decisions made by the Agency impact how specialty crops are grown in the USA. IR-4 has found open, transparent communication to provide the best basis for sound, long term partnerships with regulatory agencies as well as its other partners in the crop protection industry, USDA, land grant university system and specialty crop growers and the commodity groups that represent them.

### **Reaching Across Borders to Find Solutions**

The rate at which products are being labelled in one country compared to another causes a number of complications. Although one country may have access to newer products that have lower risk characteristics, it may also preclude growers and exporters from using them if the produce is going to be shipped to countries that do not have MRLs established for these new products. In the end, the growers would likely resort to using the older, riskier products for produce being shipped abroad. Therefore, if a product could be registered globally, rather than segmented country by country, there will be no clear advantage for one country over another and the new safer products could be integrated more rapidly into production systems providing even greater protection of the applicators, consumers and the environment. Jim Jones, Director of EPA's OPP, noted in his opening remarks at the December 2004 NAFTA Technical Working Group (TWG) on Pesticides Public Meeting in Merida, Mexico that "we need to find a way to harness the global regulatory resources" to work smarter in registering pest control products. There are a number of regulatory areas that are being focused on within the NAFTA countries as well as internationally by CODEX, the EU, Australia and other countries. These include: work sharing, harmonized guidelines and templates, crop zones, data requirements, risk assessment, and crop grouping.

Over the past several years, regulators from Canada, Mexico and the USA have moved to make work sharing a way of doing business. Growers, scientists, industry representatives, researchers, and other concerned stakeholders regularly have open meetings to set priorities, co-ordinate work projects, and gain an understanding of one another's concerns. As a result, the governments have developed processes for sharing resources regarding the review of pesticides, and have implemented efforts to streamline registration procedures, and eliminated a number of repetitive regulatory requirements across borders. Many of these new processes have been successful because of support from registrants and other stakeholders and the openness to work together because they are compelled by a growing North American outlook for free trade in food products, and to maintain a high level of health and environmental protection. Not only does such cooperation improve working relationships among Canada,

Mexico and the USA, but it also helps to facilitate the free flow of trade in pesticides and agricultural goods across borders by allowing for quick, coordinated efforts to make decisions on pesticides and minimize trade barriers, while ensuring the sound and sustainable management of new and older pesticides.

Guidelines and report formats have also been harmonized to make them more consistent and easier to share among reviewers not only within a given agency, but also when sharing reviews across the boarder. The NAFTA TWG continues to refine the North American Crop Zones and data requirements both for domestic requirements and for studies that will be conducted on a NAFTA basis seeking registration in all three countries. Much effort has also been put into harmonizing risk assessment and a method has been developed to statistically determine MRLs based on field data (MRL calculator).

Canada and the United States now have a process in place where data for stakeholder needs are generated by the Canadian AAFC Minor Use Program and USDA's IR-4 Program. These data are submitted to the respective agencies simultaneously. The EPA and PMRA have the framework in place to make assignments as to which agency will conduct the review for a given project (submission). One of the countries will conduct the complete chemistry, dietary and other required reviews. Then once those reviews are complete, the reports will be peer reviewed by the companion country and the registration will be approved in both countries at approximately the same time with harmonized tolerances/MRLs. The review and approval process is expected to take as little as eight months for these joint review minor use requests.

Building from past workshops and discussions, the OECD sponsored a workshop in early 2005 to advance work sharing on an international basis. The workshop examined national reviews to identify specific barriers to work sharing, to develop recommendations to eliminate or reduce such barriers, and to promote work savings. The workshop also wanted to increase the experience and confidence of government evaluators and registrants in using dossiers and monographs and to identify to what extent current procedures and processes in countries can be improved to facilitate work sharing. Some of the main points resulting from the workshop were to have the production of common data requirements and guidelines, and to standardize MRLs on a global basis. It was pointed out that problems result from the use of different methodologies in different countries and from differences in hazard and risk assessment. Finally, it was noted that there is a need for adoption of common data review format by the various national governments (common templates) and harmonized residue guidelines. Thus, the development of harmonized guidelines and terminology by the OECD is critical to the advancement of work sharing on the international level.

Significant discussion and resources have been placed into determining the feasibility of developing global zones for generating field residue data to determine pesticide levels in agricultural crops. After a long review process, the US implemented crop field trial zones in the mid 1990's that detail the productions zones for various crops and data requirements (number of field trials) for individual crops across these zones. NAFTA zone maps extending through all three countries, based on agronomic geographic regions that overlap from one country to the other, and were approved by the NAFTA TWG on Pesticides in September of 2001. As a result, requirements for residue crop studies on a NAFTA basis are significantly reduced compared to conducting studies in individual countries. In order to further promote NAFTA registrations, the NAFTA TWG has also approved further data reductions when studies are conducted on a NAFTA basis in order to promote NAFTA registrations. For a

number of crops, the NAFTA requirements are essentially equal to the maximum number of trials required by an individual country.

The OECD conducted a comprehensive review of residue data to determine if global zones could be considered to facilitate international cooperation. After their review, the team could not discern zones because of high variability in residues from comparable trials. In many cases, the data reviewed showed just as much variability within a zone as compared to across zones. The data also showed that the pre-harvest climate may not have had as strong of an influence on the residue levels as would have been expected. This indicated that the zone effects may not be a major factor in determining residues. Unfortunately, neither final zone recommendations, nor data requirements for international registrations could be suggested based on the review.

The EU is also considering a more flexible approach to pesticide registration and using geographical zones rather than country zones. The current proposal considers three zones across all of the member states and these include a north, a central, and a south region for residue studies. The scheme in the EU is to also consider having zonal evaluations that could be shared by other member states within the same regions. There are a number of pilot projects evaluating these new zonal and review schemes to see if they are feasible. The results should be available for evaluation by the spring of 2006.

Considering that zones are established for all of North America extending from the tropical southern states of Mexico, throughout the USA, including the state of Hawaii and into the Northern most regions of Canada, it could be speculated that essentially all of the regions of the world would be represented by these 21 zones. As well, zones exist for Europe and the OECD zoning project indicated that zones may not be a major factor in residue variability. The establishment of international zones could greatly facilitate the development of residue data for both major and minor crops, as well as prevent duplication of trials in various countries, thereby reducing the overall cost for industry to develop data globally. With all of this in mind, this certainly is an area that needs further discussion to make it possible for industry to pursue global registrations as they set out to register new products.

The US EPA crop grouping scheme enables the establishment of MRLs and exemptions for groups of crops based on residue data from a certain number of representative crops. The current US crop grouping has 19 groups that represent 508 commodities. The US is currently in the process of updating the crop grouping scheme to add even more crops and provided greater flexibility to extrapolate the data to a broader number of crops. Crop grouping has greatly assisted the US to rapidly expand registration of new, reduced risk products in situations where the criteria for establishing crop group MRLs were met.

As part of the US update to the crop grouping scheme, an International Crop Grouping Consulting Committee was formed made up of 30 countries including a number of EU members and the members from the leading countries for the Codex revision (the Netherlands and Japan). Currently, there are no representative commodities in the Codex system which makes it less practical to use. The CODEX system was developed to provide a complete listing of food and feed commodities and to track which commodities are in trade. Therefore, even if commodities had a MRL in one country, that MRL could not be extended to CODEX if the commodity is not currently listed in the crop grouping tables. The CODEX system needs to expand its utility to allow for representative commodity MRLs to cover a broader

range of other crops, especially those minor crops where it would be too costly to generate data for registration. As the US crop grouping system develops and has representative commodities with a larger scope, it may serve as a good model for future updates to the Codex system and other systems to consider or to adapt. If such a system were considered, it would allow for a more rapid integration of new, safer products.

In closing, IR-4 is proud of the many accomplishments that it has been able to make over the past forty years. These accomplishments are due in a large part to the great number of partnerships that IR-4 has been able to forge and maintain. These partnerships include the US EPA, crop protection industry, USDA plus the many commodity stakeholders and, more recently with international partners such as Canada, Mexico and the EU. It should also be noted that most of these accomplishments for specialty crops would not have been possible without the foresight of the early IR-4 founders who set up a program that was funded through public support to find pest management solutions for growers. Although the protection of our horticultural crops may currently be in crisis, there is still hope that as the many partnerships that have been built and are in progress will all help to assist in resolving this crisis by providing growers with the tools needed to grow these important crops.

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