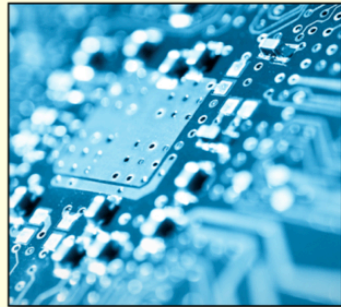




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Economic and Trade Impacts of the EU's Regulatory Changes



Dr. Caroline A. Harris

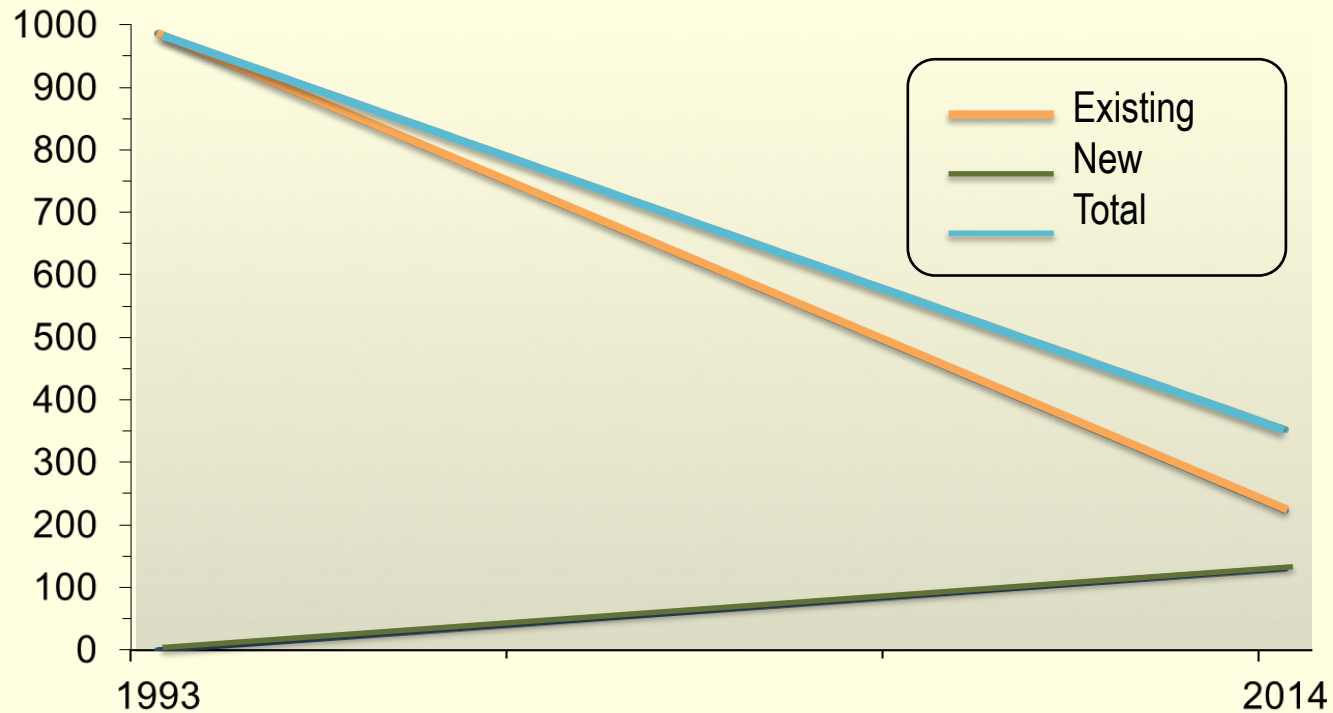
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Pesticides in Europe Today

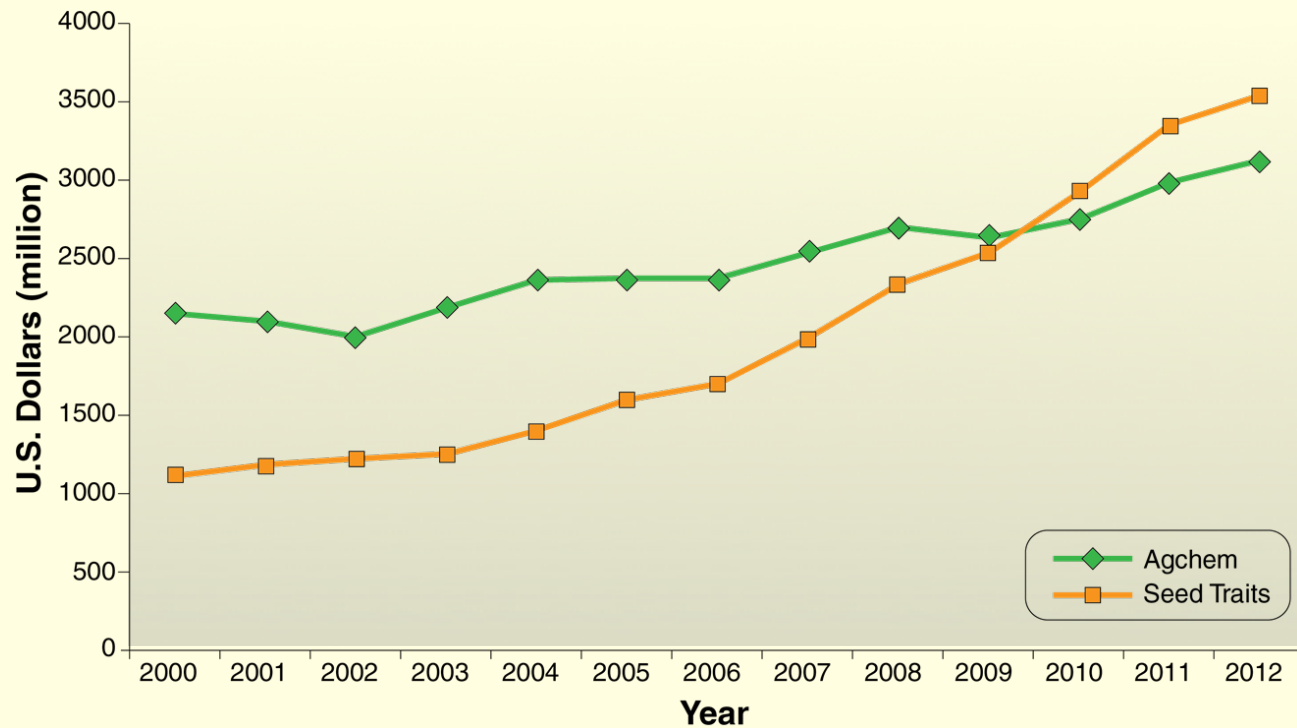
- Europe continues to be a place of regulatory challenge and change
- Goal posts moving
 - What will EFSA do next?
 - Sustainable Use Directive
 - Use reduction and risk reduction strategies
- All aimed at
 - Using fewer pesticides in Europe
 - Having lower residues in food



Number of Pesticide Active Substances in the EU



Impact of Additional Regulation on Research



Cut-off criteria (1)

- **Hazard based assessment that may (will) be used to decide whether a pesticide can be authorised for use in Europe**
 - No experience—no decisions have yet been taken not to renew a substance on the basis of hazard
 - No approval on the basis of hazard to humans, so should also prohibit imports of produce containing residues of that substance

Cut-off criteria (2)

- Fails the environmental criteria (PBT etc.) it is not necessary to prohibit imports because the 'problematic' characteristics will be expressed in the 3rd country and not the EU
 - However this will depend on what stance the Commission take on MRLs when a non-approval decision is made
- Endocrine disruption
 - How will these criteria will sit (i.e. how many substances might be affected)



Endocrine Disruptors

- Finally starting to make progress on a definition
- Regulation on hazard rather than risk
- Some member states are starting to get cold feet
- Enormous NGO pressure to ban!

Overview of Data Requirements and Principles of Regulation in EU Legislation Addressing Endocrine Disruptors – inconsistent regulatory consequences

Plant Protection Products (EC1107/2009)	Pharmaceuticals	Food additives (EC 1333/2008)	REACH (EC 1907/2006)	Plastics with food contact (EU 10/2011)	Cosmetics (EC 1223/2009)	Food and others
Biocides (EU 528/2012)						
Are data requested under the regulation sufficient for identification?						
✓	✓	✓	(✓) depending on production volume	(✓) depending on migration from material	(✓) depending on intended use	usually no product specific tox data
What are the principle(s) of regulation?						
Approval procedure	Approval procedure	Approval (EU lists of approved additives: AII/III)	Registration, authorisation	Risk assessment + authorisation (EU list of authorised substances)	Risk assessment + inclusion in a list of restricted or allowed substances	Risk assessments General provisions
What are regulatory consequences for substances identified as endocrine disruptors?						
Ban			Authorisation required		Assessment if criteria approved	

Trade Rules are Built around Risk

- **Could bring the EU system into direct conflict with these if there is acceptable risk but 'unacceptable' hazard**
- **All these issues were raised when hazard criteria were proposed and negotiated and were put to one side by those pushing the hazard approach (who prevailed in the negotiation)**

Residues Definitions

- **Adding more metabolites into residues definitions**
- **Reason—for consumer protection**
- **Industry often need to repeat residues trials**
- **Monitoring labs have increase in cost**
 - Fewer samples for the same budget
 - Does this improve consumer protection?
- **Lack of harmonisation of MRLs**
 - Not just an EU problem



International Estimate of Short Term Intake

- **Method for estimating acute dietary exposure**
- **Based on the highest likely residue**
 - Will be based on the MRL in the future
 - Difficult for consumers to understand the use of the HR
- **Uses a factor to take account of the difference in residues between individual units**
 - Codex uses 3, EU uses 7
 - Difficulties in accepting JMPR MRLs into EU legislations



Impact?

- **Presentations by agchem industry and EFSA at recent Codex meeting**
- **Both concluded 5% of MRLs would be lost**
- **These will mostly be pome fruit, stone fruit, citrus and stored grains**
- **EU intake models conservative and don't allow use of factors to take account of losses on processing**

Apple Example (German child, 1-6 years, chronic)

- Apple as RAC = 195 g/day (6.9 oz/day)
- Apple as fresh apple = 38g/day (1.3 oz/day)
- Apple as juice = 150g/day (5.3 oz/day)
- Apple as processed = 7g/day (0.2 oz/day)





Secondary Standards

- **Standards imposed by supermarkets under consumer pressure and NGO lobby**
- **More stringent than regulatory standards**
 - Often set 'bans' on certain chemicals
 - Restrict number of residues that can occur
 - Set lower standards than MRLs
- **European Commission haven't been prepared to challenge even though devalues their system**
 - "What's wrong if supermarkets want to give consumers lower residues in their food?"
 - "They are the buyer, they can agree their own standards"



Glyphosate (1)

- **IARC (WHO), March 2015 - “probably carcinogenic to humans”**
- **JMPR (WHO), May 2016 - not carcinogenic in rats but could not exclude the possibility that it is carcinogenic in mice at very high doses**
- **EFSA conclusion, May 2016 - Unlikely to pose a carcinogenic risk to humans from exposure through the diet**
 - Acknowledged that they did not review the same data sets
- **ECHA to review classification**
- **Hazard versus risk conclusions**



Glyphosate (2)

- **EU review under Regulation 1107/2005**
- **Vote delayed**
 - No vote as no qualified majority
 - 19 MS in favour of renewal
 - 6 uncertain
 - France and Italy against
- **If no decision taken, approval will expire on 30 June 2016**
 - Extension being considered
- **The world is watching!**



Brexit!



Impact on economy?

- **Can Europe be self sufficient in food?**
 - Not based on current import statistics
- **Will food cost more?**
 - Inevitably if there is less competition
 - Diminishing household spend on food in Europe
 - “Current food price not a reflection of true cost”
- **Will there be trade barriers?**
 - Yes and confusion for food producers
- **Will food be safer?**
 - Pesticides highly regulated and tested
 - Other chemicals in food other than pesticides
 - Consumers likely to be more confused than ever

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