
fresh start
project
EU IMPACT ON LIFE SCIENCES
Avoiding the global slow lane
Getting the right deal for the UK

Fresh Start Project

The EU impact on the UK Life Science sector

Fresh Start Project Inquiry

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1. Executive Summary

The 'Life Sciences' Sector (broadly defined as the appliance of science to help tackle the most pressing global societal challenges in the two key markets of food and medicine) represents a major opportunity for the UK and other advanced European economies to exploit our competitive advantage in scientific research to help create huge new inward investment and export opportunities. With the EU in urgent need of economic growth and recovery to tackle unemployment and restore shattered public finances, this is an economic opportunity we cannot afford to miss.

However, the growing hostility of the EU to 'biotech', reflected in an increasing tide of 'anti-biotech' legislation, is having a damaging effect on the EU Bioscience Economy, and risks condemning the EU – and by extension the UK – to the global slow lane in biotechnology. Just as the genomic revolution is beginning to offer untold opportunities across medicine and agriculture to help us generate huge economic, social and political dividends for mankind by helping to liberate billions from the scourge of insufficient food, medicine and energy, the EU is developing an increasingly hostile regulatory framework which risks undermining Europe as a hub of biotechnology.

This regulatory hostility to biotech is having its most serious impact in agricultural research, where the EU's hostility to GM has already led German based BASF and US major Monsanto to announce their withdrawal from Europe in Agricultural Research and Development. Unless something is done other companies such as the UK's Syngenta (which employs thousands and has a turnover of billions) will follow suit, with dire consequences for the UK and European Life Science sector.

In Medicine the story has been a much happier one, with the EU seen in the post-war years as an enlightened and progressive jurisdiction for investing in biomedical research. However, recent trends have led to growing concerns from academic researchers, companies and medical charities that the EU is in danger of becoming an increasingly unattractive territory for the new technologies and disciplines such as stem cell and regenerative tissue science, genomics and genetic epidemiology and the use of clinical data in large scale 'BigData' studies to help drive Stratified and Personalised Medicine.

Equally concerningly, in some of the most exciting emerging life science markets driven by new technologies and the convergence of different disciplines (such as 'Nutriceuticals' and 'Functional Foods') our inquiry found real cause for concern that the EU policymaking machine is in danger of adopting an increasingly biotech-hostile regulatory framework to undermine Europe's position as a global leader in this fast growing new field.

The problem appears from our inquiry to be driven by four key factors:

- The growing influence in European policymaking of Green lobbyists and political parties with an agenda that is anti-corporate and anti-capitalist, and particularly hostile to biotech.
- The structure and process of the EU policymaking process which unduly rewards early influence by professional lobbyists and political groups with a presence in Brussels and Strasbourg.

- Insufficient influence or effective representation of the individuals, charities and companies in the UK doing so much to pioneer these emerging fields.
- Inconsistent and differential implementation and imapct of EU legislation across different member states.

We conclude that the solution can only come through:

- A fundamental review and reform of the way that the EU's policies are affecting the European and UK 'Bio Economy' sector. This should include a specific requirement that all EU policies comply with the overall policy of promoting the EU as a global power in bioscience. A specific mechanism should be introduced to allow the impact of potentially damaging legislative measures to be properly assessed, monitored and if necessary, amended.
- In biomedicine, where the EU framework is well established and has had a good reputation as a largely benign influence on life science investment, more effective influence from the UK is needed to deal with potential new challenges and threats posed by the EU's response to new technologies.
- In agriculture and emerging sectors like 'Functional Foods' and 'Nutriceuticals', where the EU's hostility to the appliance of genetics in agricultural biotechnology risks directly undermining the UK Government's stated policy of attracting a growing share of the global market for GM research, serious consideration should be given to repatriating the regulation of agricultural and food research to member states. This would allow countries that support the appliance of science and innovation, like the UK, to exist happily alongside, but not be undermined by, those like France and Germany which are increasingly hostile to it.

Summary of Findings

The evidence from this inquiry was very clear: whilst the EU has until recently been a largely progressive and enlightened force for progress through the appliance of science and technology in the Life Sciences, especially in biomedicine, the rising tide of hostility to corporate biotechnology, expressed through increasingly powerful lobby groups with increasing influence in the EU legislative process, has started to have a serious impact on the EU and UK's ability to secure investment.

Unless serious steps are taken to tackle it, the EU – and by extension the UK – can expect a continued decline in life science investment and influence in this most exciting of global sectors. This would condemn the EU and its member states to a backseat of the biotechnology revolution transforming the life prospects of billions of our fellow citizens, allowing others to reap the economic dividend which could have been ours.

In particular, the inquiry heard that:

- EU membership gives UK-based Life Science companies access to the single market and a uniform regulatory system, which, when properly implemented, offers certainty and consistency. Through its presence in the EU institutions, the UK is able to exert some influence over both EU and also global rules, although it has not always done so successfully.

- The UK is a net beneficiary from the EU's scientific research funds, which also serve to facilitate cross-border, multi-disciplinary collaboration. However, it is easier for large institutions such as universities to tap into this funding while small companies can struggle with the associated bureaucratic burden.

- Through its ability to strike comprehensive free trade agreements with other countries the EU can force open new markets for UK Life Science companies. However, there is a risk that anti-biotechnology interests and protectionist attitudes in the EU more generally could restrict these opportunities, while the UK has no ability to sign its own FTAs with emerging economies.

- In the area of medicine the EU regulatory framework is generally efficient. For example, once a new medical device is approved by any national regulator, it can be marketed throughout the whole EU. However, new EU data protection rules which could damage medical research and an anti-scientific bias in ECJ rulings – exemplified by the Brüstle vs Greenpeace ruling – are a risk.

- Conversely, in the area of agricultural biotechnology, EU membership is seriously hindering the UK's world class agricultural and food research sector. Due to a combination of factors including an emphasis on precaution as opposed to risk-based regulation and a susceptibility to lobbying by hostile interests, it is very difficult, expensive and time-consuming to get EU approval for new products in this field. This stands in contrast to other global jurisdictions where the GM agriculture and biotechnology markets are booming. Many scientists and companies have already left the EU in order to pursue these growth opportunities.

- The EU also faces a challenge in the form of a new innovative range of products - so called 'nutraceuticals' or functional foods – which have both nutritional and medical properties. These products are part of a wider revolution which is delivering more tailored and personalised healthcare, but the EU's regulatory framework is struggling to adapt.

The EU's approach to Life Sciences is not an isolated issue but a microcosm of how well it can respond to the challenge of an increasingly competitive global economy. As demonstrated above, EU membership has offered many advantages for the UK's Life Science sector over the first 30 years of UK membership (1974-2004), but in the last decade the rise of institutionalised hostility to biotechnology, particularly in the field of agriculture and nutrition, combined with an increasing emphasis on the Precautionary Principle and 'risk based' rather than hazard based regulation, is seriously jeopardising the global standing of the EU and UK as a location of choice in the increasingly global markets of life science investment and research.

Tested against three of the principles outlined in David Cameron's 'Bloomberg' speech on EU reform, we conclude that the EU's regulatory framework and general policymaking approach scores 5 out of 10 for competitiveness, 6 out of 10 for flexibility and 4 out of 10 for accountability.

Recommendations

Therefore, we propose a package of ten measures to address the failings in the EU's current approach which apply both to the EU itself as well as to how the UK government and parliament engages with it:

POLICYMAKING

1. **A clear statement of the EU's policy regarding biotechnology and the bio-economy.**

2. **A shift away from the increasingly widely used risk-based 'Precautionary Principle'.**

3. **An easier way of amending flawed EU legislation and/or ECJ rulings.**

4. **Ensuring more joined-up policy making at the EU level.**

5. **More accessible and transparent early consultation processes before legislation is drafted or proposed.**

6. **Better and more active UK Government and parliament engagement in the legislative process.**

BIOMEDICAL RESEARCH

7. **Greater freedoms for member states to determine their own policies with respect to Data Protection**.

8. **Greater freedoms for member states and different public healthcare systems to determine their own policies with respect to Early Access to medical innovations.**

9. **Reforming access to EU research grants.**

AGRICULURAL BIOTECHNOLOGY AND GM

10. **Greater flexibility for member states to 'go it alone' in designing appropriate regulatory frameworks for GM crops**.

2. Background: why ‘Life Sciences’ matter

2.1 A more broadly defined ‘Life Sciences’: the global opportunity for mankind

‘Life Science’ has traditionally been used to refer to the use of biological science in helping preserve and promote life and health in the pharmaceutical and ‘biotech’ sectors of healthcare. But profound changes in the disciplines and technologies used to study disease, and in our understanding of the range of factors from genetics to diet which determine how disease takes hold in different populations are changing the boundaries and driving a broader multi-disciplinary definition of life science.

In this report we use this more broadly defined definition of ‘life science’ to span both medical and agricultural science and the wide range of biomedical and agri-nutritional research which is driving a whole new class of technologies, markets and opportunities, including for example ‘Nutri-ceuticals’ and ‘Functional foods’ (nutritional products with healthcare benefits), Genomic research and the use of large scale genomic and phenotypic data sets to drive breakthrough insights in predictive medicine.

Profound changes in the bio-pharmaceutical sector, and transformations in our understanding of the implications of a wide range of factors in how disease takes hold in different patients groups in different ways (from genetics to diet and lifestyle) are profoundly changing the boundaries of disciplines and terminology, and driving a profound convergence of disciplines and technologies into a much broader definition of ‘life science’ spanning genetics, biomarkers, diagnostics, epidemiology, devices, nutrition and lifestyle.

This convergence of different disciplines within a more broadly defined ‘life science’ sector has been driven not least by transformational advances in our knowledge and understanding of genetics, and how DNA is key to controlling the functions of life across different plant and animal species (genomics). Centres like the European BioInformatics Institute on the Hinxton Campus in Cambridge, across the road from the Wellcome Trust Sanger Centre where so much of the groundbreaking genetic science to crack the human genome was conducted, represent a global reference library for genetic information on not just human but all animal and plant species.

As well as the convergence of disciplines and technologies, the growing interest in the UK in exploiting our competitoive advantage against the rapidly emerging ‘tiger’ economies through exploiting our knowledge economy, has seen the Coaltiion Government launch a series of long term, ambitious Industrial Strategies for key economic sectors in which the UK Government see’s major opportujitied for the UK provate and public sectors to work more closely together to support long term global trade growth. The UK’s Life Sciences Strategy (2011) and Agri-Tech Strategy (2013) have set out ambitious plans for the two key sectors of Medicine and Food+Agriculture.

The growing focus in the UK (and USA with the recent publication of the US BioEconomy Strategy) on the global trading opportunities from investing in the technologies to help the fasterst growing developing economies meet the urgent need to ‘feed, fuel and heal’ their exploiding populations is also driving a wider definition of Life Science as the ‘appliance of

science to help tackle the most pressing societal challenges' in three key markets of food, medicine and energy.

2.2 A rapidly emerging new market

The combination of a growing global population and rapid societal and economic development in the developing economies is exerting significant pressure on global resources. This challenge presents a huge opportunity for the Life Science sector with its focus on providing innovate scientific solutions in the areas of medicine, agriculture and energy – although this report will focus on the interlinked sectors of food and agriculture.

The global market in pharmaceuticals and biotechnology generated total revenues in excess of $1.1 trillion in 2011 – up from €855 billion in 2007 - with strong growth expected to continue, particularly in emerging markets. Conversely, the EU-Big 5 (UK, Germany, France, Italy and Spain) is the only global region in which sales are expected to fall by 2020.

In 2012, the global market value of biotech/GM crops was $14.84bn, representing 23% of the $64.62bn global crop protection market and 35% of the $34bn global commercial seed market. These crops differ from conventional ones by possessing certain induced characteristics such as drought resistance or higher yields. As with pharmaceuticals, most of the growth is taking place in developing countries while total crop hectarage in the EU is insignificant on a global scale.

According to the UK government's Office for Life Sciences, UK life science industries generate turnover of over £50 billion and employ 167,500 people in over 4,500 companies. With its science base, the UK is therefore well placed to be a world leader in these areas and tap into these global growth opportunities in order to reap significant economic benefits.

Life Sciences can also be a key asset for the UK as it seeks to improve its competitiveness in the 'global race'. However, the UK faces stiff competition not only from established competitors such as Germany and the US but also from newcomers such as the BRIC economies and the Gulf.

Much of the legislation applying to UK-based Life Science companies is now determined at the EU level. For this reason, the Fresh Start Group decided to conduct a parliamentary inquiry into whether the EU's regulatory framework and general policymaking approach serves to facilitate or hinder this industry, and if so, in what ways.

2.3 The Challenge and the Opportunity

As the UK confronts a major generational challenge of how to develop a new sustainable economic model based on trade with the emerging markets, the Life Science sector represents a major opportunity. Defined more broadly as the appliance of science to solve some of the most pressing challenges facing human society in the three core sectors of Medicine, Food and Energy, the Life Science sector has the potential to attract major new inflows of inward investment and to unlock new export markets for Europe and the UK in particular.

The combination of a rising world population – set to exceed 10 billion by 2050 - and growing pressure on global raw materials and resources is creating huge new markets for technological innovations to help 'feed, fuel and heal' the emerging markets of tomorrow'. Today, these emerging markets need the basics of food security, affordable energy supplies and the basics of public health. But their elites already have come to demand western style diets, medicines, sophisticated energy and 'Clean-tech' solutions, and their middle classes are already following suit.

Servicing these exploding new markets represents a major growth opportunity for the UK across the 'Big Three' markets of food, medicine and energy. The potential here is considerable - as Jim O'Neil documented in his recent book 'The Growth Map', the aggregate GDP of the BRIC countries almost quadrupled from around $3 trillion to around $11-$12 trillion between 2001 and 2011, while their share of world trade doubled from 10% to 20% over the same period. On current trends, it is likely that the combined GDP of the BRICs will exceed that of the US before 2020, while China alone could match the US as soon as 2027.

As the Foresight Report published in 2010 set out very starkly, by 2050 the world will have to double production using the same land area and roughly half as much water and energy. This represents new opportunities for the UK which is still a major global force in agricultural science and research. The scale of this opportunity was recognised with the launch this year of the UK £180m Industrial Strategy for Agri-Tech, to follow the internationally lauded UK Industrial Strategy for Life Sciences launched by the Prime Minister in 2011. Similarly in the medical life sciences and in 'Cleantech' (the use of bioscience to generate new ways of getting rid of waste and saving and generating energy) the UK has a world class science base.

The revolutions in genetics and computing, and the increasing sophistication of new industrial biotechnolgy tools and processes, are also creating vast new opportunities; especially where these three new markets overlap. (For example, the new Lotus High Performance car recently developed in Norfolk run on biofuel created by bacteria in a new process to convert agricultural waste into high performance fuel; the appliance of 'Life Science' - creating new technologies, products and markets.)

However, many in the sector worry that in recent years the European Union has started to adopt an increasingly hostile regulatory framework towards the bio-economy in general, and towards GM crops in particular. Since much of the regulatory framework covering UK Life Sciences is decided at the EU level, this could significantly damage efforts to unlock global growth opportunities described above and undermine the attractiveness of Europe - and by extension the UK - as a destination of choice for inward investment. The central question is whether the EU is set over the coming decades to help or hinder UK life science competitiveness and growth?

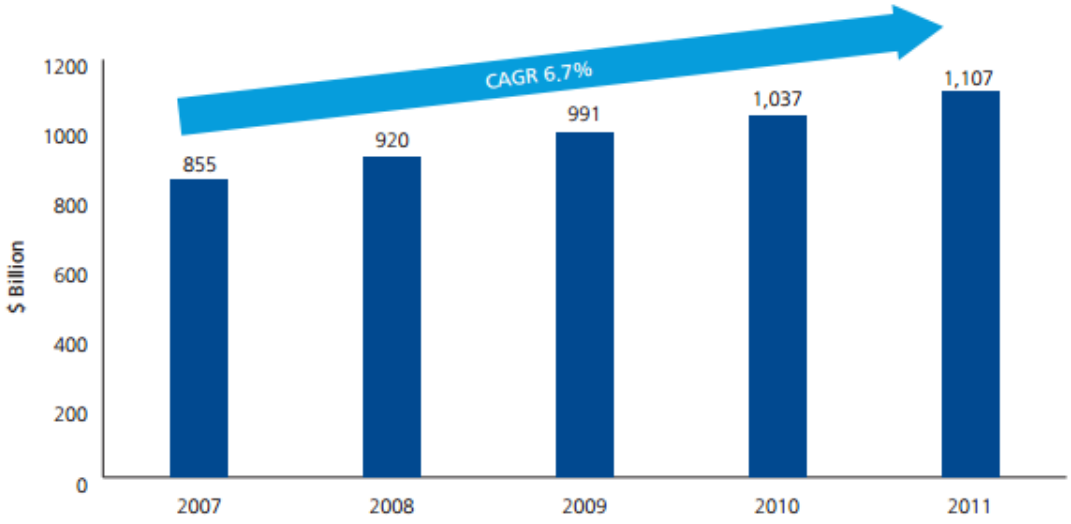
This report seeks to address this question based on evidence received during a parliamentary inquiry and call for evidence conducted between June and September 2013. The inquiry and report focus on the interlinked sectors of food and agriculture, in part because the Fresh Start Project has already proposed reforms to EU energy policy in its 'Manifesto for Change', and part because a further Parliamentary inquiry into EU energy policy is planned for 2014.

3. Life sciences: the global market

3.1. Medicines and pharmaceuticals

According to figures compiled by Deloitte, in 2011 the global market in pharmaceuticals and biotechnology generated total revenues in excess of $1.1 trillion; Compound Annual Growth Rate (CAGR) of 6.7% compared with 2007.[1]

Figure 1: Global pharma and biotech revenue, 2007-2011



Source: DTTL Global Life Sciences and Health Care Industry Group analysis of "Global pharmaceuticals, biotechnology & life sciences industry profile" Marketline, May 2012, EIU database

The Americas account for the largest share of the global pharmaceutical market representing 46% of total revenues, but life sciences companies are increasingly targeting emerging markets such as China, India, Brazil, and others; these markets accounted for 20% of global pharma sales in 2011. China and Russia are considered to be the world's priority markets in terms of growth potential – the Russian market increased from $23bn in 2011 to $30bn in 2013, while Argentina, Indonesia, India, and Ukraine are also tipped to perform strongly.[2]

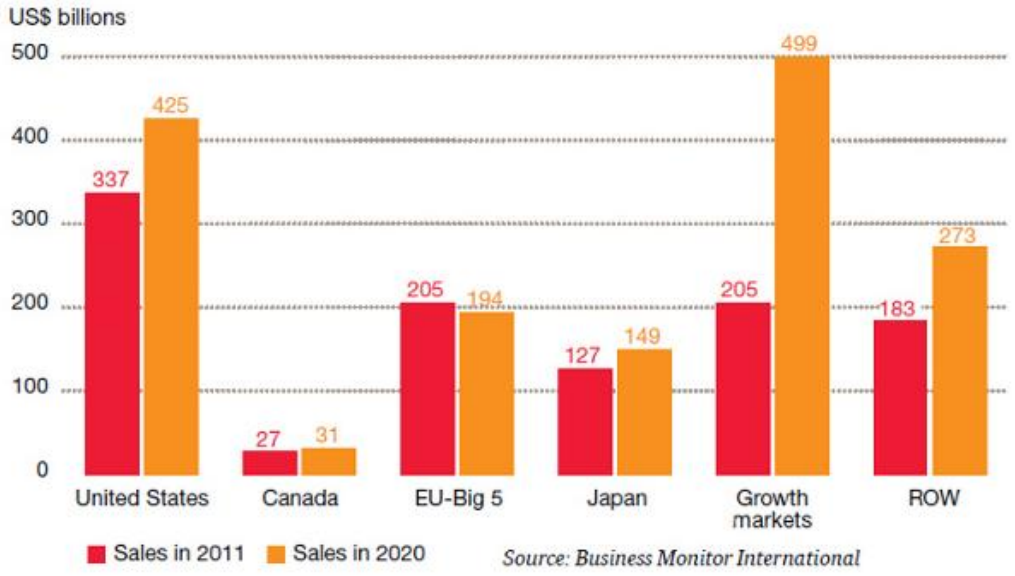
In terms of the EU market, Germany, France and the UK are the main players. France is the EU's biggest producer of medicines by volume and among the world's main global pharmaceutical exporters with yearly revenue of around €47bn. France's biopharmaceutical sector employs some 104,000 people.[3]

[1] Deloitte – 2013 Global life sciences outlook
http://www.deloitte.com/assets/DcomIreland/Local%20Assets/Documents/Life%20sciences/2013%20Global%20Life%20Sciences%20Sector%20Report.pdf
[2] Ibid.
[3] Jones Lang LaSalle – Life Sciences Cluster Report 2012
http://www.us.am.joneslanglasalle.com/ResearchLevel1/Life%20Sciences%20Cluster%20ReportGlobal2012.pdf

According to the UK government's Office for Life Sciences, UK life science industries generate turnover of over £50 billion and employ 167,500 people in over 4,500 companies.[4] The UK's medical research charities and foreign-owned companies account for around 45% of all business R&D in the UK and for 1 in 4 of the world's top 100 medicines and 45% of the product pipeline in Europe.[5]

However, despite these strengths, as PWC has documented, the core EU market is facing a period of decline compared with other global regions.[6]

Figure 2: The global pharmaceutical market in 2011 and 2020



As figure 2 shows, the EU-Big 5 (UK, Germany, France, Italy and Spain) is the only global region in which sales are expected to fall by 2020; other mature markets such as the US and Japan will continue to grow while the emerging economies are expected to more than double in size.

3.2. Bioinformatics and genetic data

Rapid developments in computing in recent years have given rise to a new field of 'informatics': the collation, storing and analysis of large scale data sets to help accelerate scientific advance. Across every sector of the Life Sciences, informatics is contributing to new discoveries, opportunities, innovations and markets. The combination of computing power and genetics is perhaps the best recognised example. The sequencing of the human genome took over a decade of focused global effort and cost over $1bn, was ultimately completed as a result of the dramatic acceleration of computer processing.

[4] Department for Business, Innovation and Skills – Life Sciences in the UK
https://www.gov.uk/government/organisations/office-for-life-sciences
[5] Lifesciences Healthcare Ltd – A UK Prespective
http://www.lifesciences-healthcare.com/index.php?option=com_content&view=article&id=53&Itemid=70
[6] PWC – Pharma 2020: Market opportunities and outlook
http://www.pwc.com/gx/en/pharma-life-sciences/pharma2020/market-opportunities-and-outlook.jhtml

The global bioinformatics market was valued at $2.9 billion in 2012 and is poised to reach $7.5 billion by 2017 at a compound annual growth rate of 20.9%. North America accounted for the largest market share of the bioinformatics market, followed by Europe, in 2012. However, Asian and Latin American countries are emerging markets in this area.[7] In terms of genetics, the Next Generation DNA Sequencing market was valued at €1.3bn on 2012 and is rapidly evolving with a large number of developments taking place to increase accuracy and speed, while reducing costs. It is the fastest-growing and most lucrative segment in the field of genomics (the study of the genomes of organisms) with an estimated growth rate of 16.3%.[8]

The European Bioinformatics Institute in Cambridge is one of the world's nominated repositories for all genetic sequencing data, and represents one of the three global libraries of genetic information on human medicine but also covers plants and the animal kingdom. It is a vast reservoir of data containing within it untold opportunities to discover new opportunities in Human and animal health and agriculture.

Computing is also allowing extraordinary breakthroughs in remote sensing and diagnostics, from satellite to personal metabolic monitors, in turn creating vast new data sets and opportunities for using data to accelerate the discovery of new technologies and markets. The application of Big Data is transforming the Life Sciences, and explains why UK Government has recently launched major initiatives in the field:

- The £100m NHS Genomic Medicine Initiative which is sequencing the genomes of 100,000 NHS patients in order to catapult the UK into the lead in the 'global race' for genetic medicines,
- The £180m UK Agri-Tech Strategy – including an Institute for Agricultural Informatics.

This rapidly expanding market creates major opportunities for Europe as a global hub of data and research, but also creates a set of challenges around the appropriate regulation of data to ensure the necessary public trust and confidence and political support that is vital to inward investment into research and exploitation.

3.3. Farming and agri-technology

As in medicine, agriculture is being transformed by breakthroughs in genetics, with rapid adoption of a range of genetic innovations in agricultural breeding. In 2012, the global market value of biotech/GM crops was $14.84bn, representing 23% of the $64.62bn global crop protection market and 35% of the $34bn global commercial seed market.[9] GM crops experienced huge growth in recent years with total global crop hectares increasing from 1.7 million in 1996 when first commercialised to 170 million in 2012.

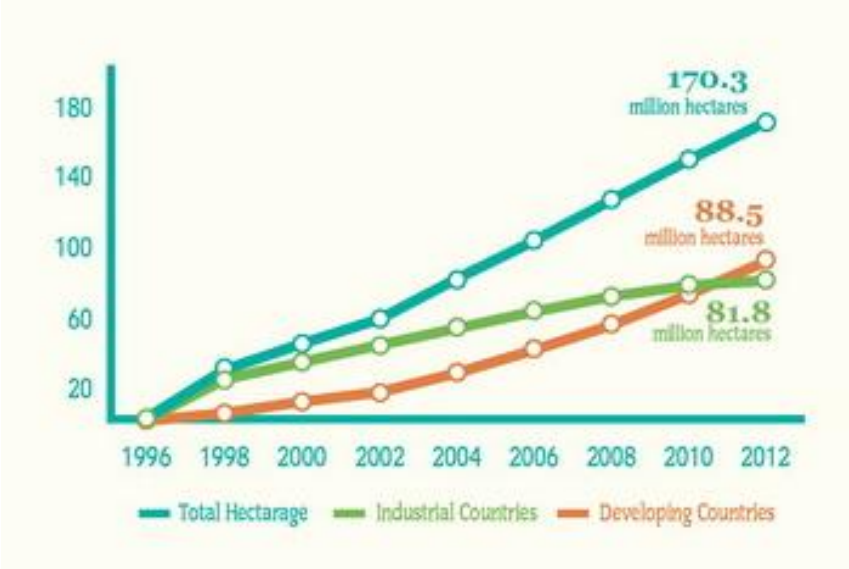
[7] Markets and Markets – Bioinformatics market – Global Forecasts to 2017 http://www.marketsandmarkets.com/Market-Reports/bioinformatics-39.html

[8] PR Newswire - The Global Next Generation Sequencing (NGS) Market is Poised to Reach $2.7 Billion by 2017, 8 August 2013 http://www.prnewswire.com/news-releases/the-global-next-generation-sequencing-ngs-market-is-poised-to-reach-27-billion-by-2017-says-latest-report-218872771.html

[9] International Service for the Acquisition of Agri-biotech Applications - Global Status of Commercialised Biotech/GM Crops in 2012 http://www.isaaa.org/resources/publications/pocketk/16/

It is striking how this adoption is being driven by emerging economies. Significantly, 2012 was also the first year in which more GM crops were grown in developing countries as opposed to industrialised countries – 52% and 48% respectively. In 2012, the growth rate for GM crops was at least three times as fast, and five times as large in developing countries, at 11% or 8.7 million hectares, versus 3% or 1.6 million hectares in industrialised countries. Of the 28 countries which planted GM crops in 2012, 20 were developing and 8 were industrialised countries.[10]

Figure 3: Total global hectarage of GM crops



Source – International Service for the Acquisition of Agri-biotech Applications[11]

Nonetheless, the US continues to be by far and away the world leader in total hectarage (69.5m hectares) followed by Brazil (36.6m hectares), Argentina (23.9m hectares), Canada (11.8m hectares) and India (10.8m hectares). Africa has also seen an expansion of GM crops with South Africa the regional leader with 2.9m hectares. Asian countries are also expected to see substantial growth in this sector in coming years. In the EU, the main GM crop is maize with a total 129,071 hectares under cultivation, of which 90% is grown in Spain.[12] Furthermore, 2012 saw a record 17.3 million farmers grow biotech crops, an increase of 600,000 million compared with 2011. Of these, over 90%, or over 15 million, were small resource-poor farmers in developing countries.

3.4 Nutriceuticals and Functional Foods

The British Nutrition Foundation describes functional foods as foods which contain ingredients that have health promoting properties over and above their nutritional value. The total UK market for functional foods was valued at £1.46bn in 2009.[13] The sector is the largest in the UK health foods market after organic foods. Fortified dairy products and cereal products

[10] International Service for the Acquisition of Agri-biotech Applications - Top Ten Facts about Biotech/GM Crops in 2012 http://www.isaaa.org/resources/publications/briefs/44/toptenfacts/default.asp
[11] International Service for the Acquisition of Agri-biotech Applications – Brief 44-2012 Infographic http://www.isaaa.org/resources/publications/briefs/44/infographic/default.asp
[12] Ibid
[13] Functional Foods Market Assessment 2010 http://www.keynote.co.uk/market-intelligence/view/product/2386/functional-foods

comprise the majority of sales and 97% of total revenues. Although the price premia of functional foods can be as high as 30%, the difficulty in promoting the health benefits is perceived to be stifling product sales. Indeed, it has led to many product failures and market withdrawals.[14]

Nonetheless, according to research by Global Industry Analysts, the global functional food and drink market is expected to exceed $130 billion by 2015.[15] Globally the nutraceutical market was estimated to be US$140.1 billion in 2010. Of this USA and Europe formed the largest markets accounting for 36% and 25% respectively. Germany, Netherlands and Sweden have emerged as the key nutraceutical innovation hubs in Europe, while Britain and Spain have emerged as key test markets for new products. Globally, the forecast compound annual growth rate from 2010 to 2015 is estimated at 14.7%.[16]

The US market - the largest in the world and the trend leader for functional food - shows total sales of health foods of $140bn in 2010/11 of which $38bn were true functional foods. This shows one of the big trends – consumers are interested in functional foods but are increasingly interested in those which are seen as naturally good for you e.g. 'superfoods' such as blueberries and enriched foods such as the new Beneforte broccoli rather than those which are seen as too processed or manufactured.[17]

Brands dominate the functional food and drink market, but are now coming under increasing pressure from own-label variants. Both branded and own-label new product development has jumped up in the last two years in relation to pre-2011 levels, although the latter is increasing at a faster rate and eroding the branded share of total functional launches. Mintel has provided sales data for selected leading brands that have traditionally established themselves as 'functional', to provide an indication of performance on a comparable basis, rather than for the market as a whole, which remains in a state of flux.

Table 1: Retail sales of selected brands currently or recently positioned as functional

	2010	2011	2012 (est)	change 2010 -12
	£m	£m	£m	%
Lucozade (GSK)	407	418	423	3.9
Activia (Danone)	257	267	264	2.7
Actimel (Danone)	118	112	112	-5.1
Benecol (McNeil)	82	88	90	9.8
Onken	48	56	57	18.8
Yakult	26	28	30	15.4
Glacéau Vitaminwater (Coca-Cola)	9	11	16	77.8
Dunn's River Nurishment (Enco Products)	10	11	12	20
Flora pro.activ (Unilever)	10	11	11	10
Total	**967**	**1,002**	**1,015**	**5**

[14] http://www.druppas.com/Publicatie%20(EVD).pdf
[15] http://www.prweb.com/releases/functional_foods/functional_drinks/prweb4688424.htm
[16] *Global Nutraceutical Industry: Investing in Healthy Living*, Frost & Sullivan, July 2011
[17] http://www.ift.org/food-technology/past-issues/2012/april/features/top-10-functional-food-trends.aspx?page=viewall

Source: Mintel/based on SymphonyIRI group InfoScan[18]

Probiotics

Probiotics are foods containing live bacteria with beneficial properties for humans. The value of the sector in 2010 was estimated to be worth $19.6bn globally, and is projected to reach $28.1bn in 2015. In 2012 the probiotic sector in the UK was valued at £200m. As European regulation of food health claims has tightened, probiotic manufacturers have to provide stronger scientific evidence to support health claims. For example, in July 2012 the European Food Safety Authority (EFSA) rejected health claims made by the probiotics industry. According to Global Industry Analysts, Europe is the largest and fastest growing probiotics market with Germany and the UK accounting for around 45% of the total EU market with annual growth rates of 10-12% quoted by various analysts. Japan, the second largest market, is seen as a maturing market.[19]

Enriched (Beneforte) Broccoli

Monsanto, as licensee, sees Beneforte as key to its growth plans. Along with other major agricultural and biotechnology businesses, Monsanto is now seeking to deliver consumer benefits directly through food rather than simply focusing on increasing yields of commodity crops for growers. This whole area has significant implications for future nutrition and healthcare. Although Beneforte sales so far are modest, market penetration for a new variety can be relatively swift if it becomes the adopted standard. Seminis, owned by Monsanto, supplies around 40% of world broccoli seed. Apio Inc, one of the largest North American grower/distributors of fresh vegetable produce, anticipates 100% replacement of conventional broccoli within five years.

The Global Bone and Joint Ingredients Market

In 2012, the market size of the bone health ingredients market in United States and Europe was $346.8 million. DSM Nutritional products, ADM, BASF, Huber Engineered Materials, and Verdure Sciences are key players in the bone health ingredients market.

In terms of market size, the joint health ingredients market is larger than the bone health ingredient in the United States and Europe earning $584.2 million in sales during 2012. The most important ingredients represented in this market segment are glucosamine and chondroitin. Companies like InterHealth Nutraceuticals and Biocell Technology are active in the collagen peptides market.[20]

[18] *'Consumer attitudes towards functional food and drink'*, Mintel, February 2013
[19] http://www.biomedtrends.com/GetDetails.asp?CatName=Probiotics
[20] *The State and the Future of the Global Bone and Joint Ingredients Market*, Frost & Sullivan, January 2013.

4. Does the EU help or hinder UK life science competitiveness and growth?

4.1. Overview

This section looks at whether the EU's regulatory framework and wider policy orientation is beneficial or detrimental to the UK interest in the bio-economy. Whilst the position in the Agricultural and Medical sectors are different (as we show below), there are a number of generic benefits to the whole bioscience sector arising from the EU which we describe here.

1. Market Access: Most obviously, EU membership is positive for UK life science companies in that it offers access to the European market, while the right of free movement within the EU allows UK companies to recruit highly educated, skilled and hard-working people from across Europe in the industry. Through its presence in the EU institutions, the UK is able to exert some influence over the rules governing that market, although as this report will demonstrate, it has a mixed record of success in this regard.

2. A uniform regulatory system: Another key benefit of EU membership for the life sciences sector – and indeed for UK business and industry more generally – is that a uniform regulatory system can offer certainty and consistency. This is particularly attractive to companies that operate across borders. However, not all member states always implement what has been agreed leading to an uneven playing field at national level, meaning that sometimes, companies in the UK that adhere to the new rules are disadvantaged relative to their EU competitors.

   When it comes to EU legislation, it is important to distinguish between directives – which have to be transposed into national law – and EU regulations, which are directly applicable across the whole EU. In theory, the latter ought to ensure uniform implementation, which is more effective in removing barriers to trade within the single market. In both cases however member states' competent authorities - the bodies that police the legal framework - can retain a degree of discretion, meaning there is still scope for differentiation even though the written law is the same.

   One example specific to life sciences are EU rules governing animal welfare in scientific research. Under the previous system, the UK companies adhered to much tougher standards, but an EU directive from 2010 should bring standards in other countries up to those already applied in the UK. Another example of where uneven implementation of EU legislation is problematic is the Clinical Trials Directive (see below).

   Overall, our evidence gathering heard that UK Life Science companies are not opposed to EU regulation, providing that this facilitates trade and investment and is implemented consistently across the EU. However, as we shall discuss below, much of the EU legislation which applies to Life Sciences increasingly does not – whether by design or effect - facilitate trade, research or innovation. Instead, political considerations often result in legislation that is restrictive in nature and damages the UK and EU's global competitiveness in this sector.

3. Access to EU funding and trans-EU research networks: A third general advantage of EU membership for the UK life science industry is the access to scientific research funds via the EU budget, of which the UK is a significant recipient over and above its share of contributions. According to evidence provided by the Russell Group of UK Universities, the UK won 16% of funding available under the FP7 programme, equal to some €3.7bn between 2007 and 2011.[21] According to EU Commission data, there are 13,541 FP7 participants in the UK ranging from universities to SMEs.[22]

   In particular, the EU Horizon 2020 Programme, which is a major source of long term funding in a range of key areas of research relevant to tackling many of the global Grand Challenges highlighted in this report, has been cited by many of our witnesses and correspondents as a hugely important source of funding and of pan-European collaborative working between companies and academic groups in different centres of research, with specific provision for involvement by smaller 'biotech' companies.

   EU research programmes also facilitate cross-border, multi-disciplinary collaboration; having partners based in other member states is often a pre-condition for accessing EU funding. In many cases, this has allowed UK scientists to build collaborative research networks with world class European counterparts which have continued even after the term of the original venture.

   However, submissions to the inquiry revealed a number of shortcomings with the current system, most notably the bureaucratic burden. While universities and large research institutions are better placed to absorb this – indeed many employ dedicated full-time staff for this purpose – small private companies and charities can struggle. The main problems they face are the time pressure that comes with having to fill out detailed forms both ahead of and during the lifetime of the project, as well as a lack of expertise in 'gaming the system'. Even where grants are awarded, there can be a significant delay before they are paid out. In the area of agriculture, the inquiry heard that there was a heavy ideological bias towards organic farming as opposed to GM crops which affects the distribution of funding (see below).

4. External Trade policy: The EU's external trade policy plays a big role when it comes to UK life sciences, given that the UK can no longer strike its own free trade agreements with other countries. The sector is therefore heavily reliant on the EU to negotiate favourable terms in agreements with other global actors – this is particularly important given the growing market and export opportunities in emerging economies as detailed in Section II.

   The recent EU-South Korean free trade agreement (FTA) has been praised for delivering new opportunities for UK life science, in particular the pharmaceutical sector (see below). Life sciences also feature prominently in the on-going negotiations with the US over the

[21] Evidence from the Russel Group to the House of Lords Inquiry into the Effectiveness of EU Research and Innovation Proposals http://www.russellgroup.ac.uk/uploads/HoL-EU-Select-inquiry-into-EU-research-and-innovation-evidence-from-the-Russell-Group-11-February.pdf

[22] European Commission, FP7 Country Profiles – United Kingdom http://ec.europa.eu/research/fp7/pdf/country-profiles/united_kingdom/country_profile_and_featured_projects.pdf#view=fit&pagemode=none

Transatlantic Trade and Investment Partnership (TTIP), with access to the EU market for US GM crops proving a contentious issue.[23]

If the EU can prove itself to be a broadly liberalising force for life science products and services in global trade talks, membership will remain an advantage. If, however, political hostility towards biotech and an overly restrictive regulatory framework – and protectionist attitudes more generally – succeed in making the EU less free trade orientated, both UK and international life science companies could conclude that they would be better off exploiting global opportunities for growth outside of the increasingly marginalised and restrictive EU market.

Case Study: UK aid and trade opportunities in East Africa

As globalisation gathers pace it is unlocking huge new market opportunities for advanced technological innovations developed by the UK Life Science sector. The fundamental importance of these markets to emerging economies creates an opportunity for the UK to develop a much deeper and more strategic relationship with these countries, not least given the UK's deep historic links with many of them.

As one of the fastest growing regional markets in the world, East Africa is a good example. Dramatic population growth is fuelling extraordinary economic advances and a growing demand for Western style 'infrastructure' across the region, research and innovation in food, medicine and energy, and also investment in banking, construction, professional services, tourism, and a host of other markets in which the UK - and Europe – are highly specialised. Kenya's capital city Nairobi is rapidly becoming a global city and hub of this exploding regional market which also includes Uganda and to a slightly lesser extent Tanzania – all countries with historic and cultural links with the UK.

Some in the UK are asking whether these ties create an opportunity for the UK to develop a much more strategic relationship with these countries with an integrated aid and trade mission: using the UK's aid budget to help accelerate the development of a more sustainable model of growth through education, agriculture, nutrition and food security and renewable energy, and using UKTI's budget help promote inward investment and trade between emerging African countries and established UK businesses, be it in agriculture, tourism, healthcare, and other sectors.

This in turn raises interesting and important questions about the extent to which the UK has ceded sovereignty over its ability to enter onto these sorts of strategic bilateral trade agreements with emerging nations, and if so, the extent to which Europe can, and is actively looking to, embrace such opportunities.

If the UK is to prosper in the 'global race', we need an EU framework for trade agreements with emerging economies which is conducive to more strategic engagement by the EU, and member states, in supporting technology transfer.

[23] Global Trade Magazine – White House calls EU GM rules "unnecessary"
http://globaltrademag.com/white-house-calls-eu-gm-crop-rules-unnecessary/

4.2. Medicines and pharmaceuticals

Our enquiry found that the benefits of EU membership are more tangible in this area of Life Sciences than in others with a regulatory framework that has broadly served to liberalise trade within the single market while also maintaining high product standards. The UK has been able to utilise the benefits of EU membership such as free movement and access to funding streams to further build up its already formidable strength in these sectors. Nonetheless, there are also a several daunting challenges on the horizon where the EU could not only hold back further expansion but also threaten existing progress, not least via new data protection rules.

Benefits

1. Easier to bring products to market: The key benefit of EU membership for companies involved with medicines and medical devices in addition to market access is scalability: rather than having to seek product approval in each of the 28 member states, companies are assured of the same requirements across the territory of the EU. This avoids vast and prohibitive costs and delays, making for a much more dynamic economy.

   The inquiry heard that in the area of medical devices, the current EU regulatory framework worked well and had successfully lowered barriers to trade. Currently, there are around 80 bodies in the EU which are accredited by the 28 national regulators to certify medical devices for public use. Once a product has been certified by any one of these bodies, it was in effect certified for use across the whole EU, although the Commission is proceeding to further simplify the system by broadening the definition of a "device" and having fewer notified bodies.

   The EU system is therefore able to deliver products to market faster than the US by up to three years, as the US only has one body qualified to issue approvals – the FDA – which results in a regulatory bottleneck. Overall, the European system is well regarded internationally, and while there had been some problems with uniform implementation by some of the newer EU member states, national authorities from other member states, including the UK, had stepped in to help.

2. The UK as an international Life Sciences hub: As with financial services, the UK and London in particular is a gateway for international companies to the EU market. London is a hub for medical and pharmaceutical companies and the location of the EU's medicines regulator, the European Medicines Agency (EMA). One of the EU's three planned unitary patent courts, specifically the one which will deal with pharmaceuticals and life sciences, will also be based in London.

   The EMA was generally well regarded, although the inquiry heard differing views on how easy it was to deal with. John Martin, Professor of Cardiovascular Medicine at UCL, noted that the US' Food and Drug Administration (FDA) was more responsive when it came to the issue of licensing, whereas the EMA adopted a more formal attitude. However, Professor Derek Hill, founder and CEO of IXICO Ltd, argued that when it came to the approval of imaging biomarkers aimed at improving the efficiency of Alzheimer's trials, the EMA process was "much more rapid and less formal than the FDA", with the biomarker qualified within a matter of months rather than still on-going after a couple of years as with

the FDA, illustrating the importance of regulatory process, speed and efficiency in attracting investment.

3. 'Critical mass' in the study of rare diseases: The EU is also able to provide 'critical mass' in the study and treatment of rare diseases (defined as diseases with less than one case in 2,000). By the very nature of such diseases, the number of patients is very low – often too low for a single member state to make significant progress on their own – whereas the EU framework facilitates cross-border collaboration. Likewise, the UK's membership of the EU's Tissue and Cells regulatory system increases the potential donor pool for UK patients to undergo haemopoietic stem cell transplantation - one of very few effective treatments for genetic conditions.

4. Trans-EU medical infrastructure: The Innovative Medicines Initiative (IMI) is a joint undertaking between the EU and the pharmaceutical industry and is Europe's largest public-private initiative which the aim of speeding up the development of better and safer medicines for patients. The IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe such as the European Medicines Research Training Network (EMTRAIN) which aims to provide support to scientists working across the entire medicines pipeline by integrating education and training programmes across the EU into a single framework and improving researcher mobility.

5. Better access to global markets: As mentioned above, the EU's ability to strike free trade deals with other global actors has been particularly beneficial for the UK's pharmaceutical sector. Under the terms of the EU-South Korean FTA, Seoul has committed to abolishing its tariff rate on pharmaceutical products from 8% by July 2014. The European Commission estimates that there has been a 50% reduction in the cost of non-tariff barriers in pharmaceuticals following the implementation of the FTA. According to Foreign and Commonwealth Office figures, pharmaceuticals represent 5% of all UK exports to South Korea and saw a 21% increase in value between January and March 2013 compared with the same period last year.

Obstacles

1. New EU data protection rules: In order to understand why issues around personal data are so important in the context of life sciences, it is necessary to appreciate the major shift taking place in medicine from the traditional 'one size fits all' model of 'blockbuster' drug discovery and development which has dominated the pharmaceutical sector in the post-war period to an increasing focus on 'stratified', 'targeted' and 'personalised' treatments. This development has been driven by breakthroughs in genetics and computing and the resulting potential for much more 'bespoke' medicines. Not all issues around data sharing in the EU are necessarily detrimental to UK life sciences, there are some positive examples such as PHACTS – an easily accessible integrated platform which brings together publicly available pharmacological and physiochemical data from multiple sources. SMEs in particular stand to benefit from this initiative.

   However, the EU Commission last year announced a comprehensive reform of the EU's existing data protection legislation which dates from 1995 in order to both "strengthen

online privacy rights and boost Europe's digital economy".[24] The inquiry heard from a number of sources that the proposed changes could be very damaging not only to business in general, but to life science companies and medical research charities in particular as it would hinder their ability to collect, store and share patient data.

Of particular concern are amendments tabled by German Green MEP Jan Philipp Albrecht which would remove the current provisions and derogations that facilitate scientific research, making it impossible for researchers to access identifiable data without "specific, informed and explicit consent". Both the UK's Association of Medical Research Charities (AMRC) and Science Europe, an umbrella organisation of 51 national research institutions, have warned that too rigid a focus on data protection will damage medical research in the EU, and that therefore it is essential to reject the amendments.

The data protection issue is particularly relevant to the UK from a life sciences perspective, more so than to other member states. Due to the unique unitary nature of the NHS compared with continental healthcare systems, it has a huge pool of patient data on which to draw, with a potentially transformational impact on healthcare costs and outcomes in the UK, as well as the UK Life Science economy. The UK Government has recently announced a series of groundbreaking initiatives in the field of medical data, including the £100m Genomic Medicine project to sequence the genome of 100,000 NHS patients and combine with NHS medical records, announced by the Prime Minister in December 2012. GPs are currently in the process of sending NHS patient records to a central database for the first time under the new General Practice Extraction Service (GPES), which the Government intends to be exploited commercially by universities and private companies for the purpose of medical research.[25] The new EU rules could pose a serious threat to these ambitions.

[24] EU Commission, DG Justice - Commission proposes a comprehensive reform of the data protection rules, 25 January 2012 http://ec.europa.eu/justice/newsroom/data-protection/news/120125_en.htm
[25] Daily Mail, Your confidential medical records for sale... at just £1: Hunt insists plan to sell details to private firms is vital to combat epidemics - but critics fear 'unprecedented' privacy threat, 18 August 2013 http://www.dailymail.co.uk/news/article-2396362/Your-confidential-medical-records-sale--just-1-Hunt-insists-plan-sell-details-private-firms-vital-combat-epidemics--critics-fear-unprecedented-privacy-threat.html#ixzz2fALiVZDu

Case Study: The Data Protection Regulation (2012/0011(COD))

The original proposal from the European Commission set out a proportionate mechanism for protecting privacy, while enabling health research to continue. This was widely supported by research organisations, but the European Parliament's amendments undermine this and will make vital research with personal data at worst illegal and at best unworkable.

For example:

- The Collaborative Oncological Gene-environment Study, involving 140 research groups and 200,000 individual participants, aims to improve prevention and treatment strategies for cancer. This important collaboration could become unworkable if the Parliament's amendments become law.
- European Medical Information Framework is a €56 million project to link together existing health data from sources across Europe to make this wealth of information available to researchers for studies on obesity and Alzheimer's disease. The development and use of this valuable research resource would be seriously threatened if the Parliament's amendments were adopted.

Individual patient records provide a vital resource for health research. This research greatly benefits society, for example by improving our understanding of the factors underpinning health and disease. Access to patient records also enables researchers to identify and invite suitable participants to take part in research studies. Under the Parliament's proposed amendments this potentially life-saving research would be severely limited.

The Parliament's amendments would affect the work of individual researchers and research organisations across Europe.

Background

In January 2012 the European Commission published a proposal for a General Data Protection Regulation to replace the current Data Protection Directive. This represents a major reform of the EU legal framework on the protection of personal data. As a Regulation, the DPR will be directly binding throughout all 28 Member States and does not need to be transposed into national law.

The DPR covers the use of personal data in research and aims to harmonise data protection law within the EU. It will strengthen individual rights and tackle the challenges of globalisation and new technologies. It has a very broad scope, including the use of personal data in research.

The draft Regulation published by the Commission in January 2012 included important articles that would provide a proportionate mechanism for protecting privacy, while enabling health research to continue. These proposals were welcomed across the research community. The Commission's proposal (Article 83.1) enables personal data to be processed for historical, statistical and scientific research without the need for consent, provided that it fulfils the following requirements; personal data should not be used if

anonymous data would be sufficient, and if possible, any identifying information should be kept separately from other information.

While the Commission's proposal sets out a positive position for research, it would still benefit from amendments to clarify and strengthen the text.

The proposal is currently going through the legislative process, which involves the European Parliament and Member State governments through the Council of Ministers.

Position of Parliament

The Civil Liberties and Home Affairs (LIBE) committee has led the scrutiny of the Regulation within European Parliament, which includes proposing amendments to the text. In January 2013, the rapporteur of the LIBE committee proposed amendments that would have devastating consequences for health research, if adopted. Many members of the European Parliament (MEPs) tabled positive amendments that would strengthen and clarify the text. However, in the committee's discussions on the DPR they developed amendments on research that were very similar to the rapporteur's damaging proposals. The committee voted on a package of compromise amendments on 21 October 2013. In total, the committee adopted 91 amendments, 85 of which were voted on in a single block. Consequently, MEPs were not able to separately oppose the amendments to the articles around health research.

The Parliament's amendments undermine provisions for research in the Commission's draft that proposed a proportionate mechanism for protecting privacy, while enabling important health research to continue. The amendments would:

- Make the use of pseudonymised health data in research without specific consent very difficult, if not impossible. This would include data from many cohort studies, biobanks and routine healthcare data.
- Prevent the use of any identifiable data in research without specific consent.

Impact

The draft amendments proposed would prevent the use of data concerning health without specific consent in research. The amendments would also make it very difficult to use pseudonymised data concerning health without specific consent.

These amendments will make much of health research involving personal data at worst illegal, and at best unworkable. This will put at risk significant European investments in genetics, cohort studies and the use of routinely collected healthcare data, including:

- The European Prospective Investigation into Cancer and Nutrition, the largest study of diet and health ever undertaken, involving over half a million European citizens.
- The European Medical Information Framework, a €56 million project to link together existing health data from sources across Europe to make this wealth of information available to researchers for studies on obesity and Alzheimer's disease.
- The Collaborative Oncological Gene-environment Study, which aims to improve

prevention and treatment strategies for cancer, involving 140 research groups and 200,000 individual participants across many European countries.

In many studies that will be affected, individuals have voluntarily given broad consent for their data to be used in health research to further our understanding of health and disease. Their valuable contributions will risk being wasted if the amendments become law.

Why this so damaging

The requirement for specific, explicit consent would render broad and generic approaches to consent for use of personal data in most research at best often unworkable and at worst illegal. It does not recognise that individual privacy can be protected through strong data governance and other approaches, as well as or in place of consent.

The amendments will put at risk significant European investments in genetics, cohort studies and biobanks, cancer registries and the use of routinely collected healthcare data. Personal data, such as individual patient records, provide a vital resource for health research for the benefit of society. For example, such data is critical for observational studies which have led to breakthroughs such as identifying the association between smoking and lung cancer and informing treatment of infection in unborn babies.

Research is already subject to strict ethical controls which could be strengthened if necessary. Health research using personal data takes place within a robust ethical framework to ensure that an individual's personal data are only used in research when this is proportionate to the potential benefits for society as a whole. Project approval by an ethics committee is a particularly important safeguard and the Regulation could be strengthened to clarify this.

2. Flawed Clinical Trials legislation: The most commonly cited example of damaging EU legislation in this area was the 2001 Clinical Trials Directive, which has contributed to a 25% decline in the number of new trials undertaken in the EU between 2007 and 2011. Other negative results include increased costs for conducting clinical trials; staff needs for industry sponsors to handle the authorisation process have more than doubled, while non-commercial sponsors have seen a 98% increase in administrative costs. In addition, insurance fees have increased by a staggering 800% for industry sponsors, while the average delay for launching a clinical trial has increased by 90% to 152 days. These problems have been acknowledged by the Commission which has put forward plans to replace the directive with a new regulation, which should also address the issue of uneven implementation.

   Another example cited by Parkinson's UK was the 2003 Health Tissue Act – incorporating the EU's Tissue and Cells Directive – which delayed a Huntingdon's trail by between eight and nine years while the university lab in which it was taking place had to be upgraded. The EU directive is flawed because it adopts a blanket approach to studies using tissue for human use and does not take into account the considerable variability that comes with stem cell research.

3. In Vitro Diagnostic Medical Devices Regulation: The Commission's proposal for a single regulation to replace the In Vitro Diagnostic Medical Devices Directive was broadly welcomed by European industry including in the UK. However, the European Peoples' Party in the European Parliament lobbied for an amendment giving the EU the competence to use the proposed Regulation to regulate, not just devices, but also their use. The effect of this amendment, which is now before the Council of Ministers, would be to make it illegal for anyone other than a qualified medical practitioner to use any device that happens to identify characteristics that are genetic even if there is no intention of obtaining health-related information. (Even then, there is an obligation to provide counselling). This provision would impede the use of a wide class of devices, including software. It is therefore particularly inimical to the development of genomic medicines and bioinformatics in Europe and the UK.

   Because the EU does not in fact have the legal competence under the Treaties to legislate in this manner, serious consequences will follow if the Council of Ministers accepts the EPP amendments. Aside from the disastrous effects upon industry and medicine, it would set a constitutional precedent: that the competence of the Union is now greater than the Treaties provided. As this new competence would include a power to intervene in biomedical regulation, this would be a hugely worrying and potentially damaging development. This pattern is repeated in the well chronicled story of *Brüstle v Greenpeace* (see below) in which the Court of Justice has (so far successfully) extended its competence beyond that prescribed by the Treaties.

   These two examples illustrate one of the key problems of European regulation in recent years: the creeping extension of jurisdiction of different parts of the EU, and the often inadvertent effect of confusing and contradictory measures sending mixed signals about the state of the European market, undermining investor confidence and market development.

4. Flawed ECJ rulings: The ECJ plays a crucial role in interpreting EU legislation and recent rulings have started to have a very real impact in undermining confidence in the EU's commitment to appropriate regulation to promote research. Particular attention was drawn to the Brüstle vs. Greenpeace ruling involving the EU's Biotechnology Directive. The case hinged on the question of "what is a human embryo?" a question with significant implications for patentability. The judges ruled that an embryo ought to be defined as "anything capable of commencing human life" or as anything that could be traced back to such an invention; an extremely broad interpretation. This ruling was necessary because the original directive had referred to an embryo but had not defined it, even though this was a key consideration.

   Although the Court's Advocate General – whose advice is usually followed by the judges – said he would be guided by law and science rather than by ethical considerations, the Court did not hear any specialist evidence from scientists. While the practical effect of the ruling has not been as disastrous as has been perceived, it has nonetheless led many scientists to conclude that the EU – and therefore also the UK – is no longer a favourable environment in which to conduct research in the field of embryonic stem cells, while investors have similarly been discouraged from investing.

Furthermore, a series of ECJ decisions in the area of Supplementary Protection Certificates – a document granting an additional term of protection, after an underlying patent has expired – has provided a huge amount of uncertainty as to when these commercially important rights may or may not be obtained. Looking ahead, concerns were also raised that if the ECJ decides it has jurisdiction over infringement and validity matters relating to the new EU unitary patent, the result could be an unnecessarily expensive and ambiguous legal framework instead of the cheap, simple system envisaged.

4.3 Agriculture and biotechnology

In stark contrast to the medical sector, the inquiry was unable to ascertain any unique benefit to UK GM agriculture or biotechnology flowing from EU membership beyond the general benefits – market access, cross-border collaboration or access to research funding – outlined at the beginning of this section. Indeed, as this section will demonstrate, the opposite is the case – the evidence is that EU membership is now significantly curtailing the UK's scope to exploit the global growth opportunities in this sector outlined in Section 2.

Challenges

1. The dominance of precaution over risk-based regulation: The inquiry heard from a number of participants that, in the past decade, in the agricultural biotechnology field in particular, the EU has witnessed the creep of the 'precautionary principle' over risk-based regulation. The precautionary principle prohibits undertaking any action in the absence of "all relevant information", while risk based regulation acknowledges the existence of certain risks and takes due precautions to mitigate them. However, as argued by the Royal Chemistry Society, "regulation that is based solely on the avoidance of risk… is inimical to innovation". The result of such an approach has been to leave Europe as virtually the only continent where cultivation of GM crops is neither expanding, nor likely to expand in the near future, as shown in Section 2.

   The precautionary principle is however not limited only to food crops but also to other products, with the recent bans on neonectinoid pesticides and some fungicides cited as examples. There are also fears that this approach could be expanded to all chemicals in the future. The result of this shift is not only that new innovative products which could be globally successful are not being developed in the UK or EU, but also that some existing products are being removed from the market following the application of bad scientific practice, where political and societal considerations are paramount. For example, the Swiss agrochemical company Syngenta has recently taken the Commission to the ECJ over the neonectinoid decision, claiming amongst other things that that it was based on an "inaccurate and incomplete assessment" by the European Food Safety Authority (EFSA).[26] These concerns are shared by, and clearly set out by, Sense about Science, the UK lobbying organisation set up to help promote public understanding of, and trust in, science and scientific data, in public discourse[27].

[26] European Voice - Syngenta challenges EU pesticide ban, 27th August 2013 http://www.europeanvoice.com/article/2013/august/syngenta-challenges-eu-pesticide-ban/78075.aspx
[27] http://www.senseaboutscience.org/news.php/290/are-gm-crops-bad-for-the-environment-and-us

2. Societal and political factors trumping scientific evidence: The UK Government's balance of competences review in the area of animal health and welfare and food safety, noted that "there were concerns that some risk management decisions on animal health, welfare and food law had been disproportionate... where broader societal concerns and other factors had been influential in decision making." GM crops were specifically cited as an area where "some respondents argued the EU applies a political overlay that disrupts trade and stifles innovation, putting all EU countries at a competitive disadvantage."[28]

   This is despite the Commission itself concluding in 2010 that "there is, as of today, no scientific evidence associating GMOs with higher risks for the environment or for food and feed safety than conventional plants and organisms".[29] The inquiry was told that, when it came to GM crop approvals, some member states have voted against the EU's scientific advice in this area, put forward by the EFSA, more often than in support of it, with 10 member states having voted against EFSA's advice 63% of the time.

3. Susceptibility to anti-biotechnology lobbying: The precautionary principle and the general anti-scientific bias in the area of GM agriculture and biotechnology are the result of a wider climate of political hostility which has seeped through into the EU decision making process increasingly in recent years. Lobbying, in particular from green groups and NGOs, was raised as a specific factor in allowing political considerations to trump scientific evidence - for example the recent EU ban on neonicotinoids went through on the basis of a successful public campaign warning they were harmful to bees, even though there was not scientific evidence to substantiate this claim.

   The EU institutions – the Commission but above all the European Parliament – are particularly susceptible to being swayed by lobbying on science policy without any basis of scientific evidence. This is above all detrimental to small UK life science companies that do not have either the resources or the expertise to 'play the game' in the way that large NGOs can; many of these organisations have a permanent or semi-permanent presence in Brussels. The inquiry heard that these companies therefore need the UK government to stand up for their interests at the EU institutions, but that its record here is patchy.

   Livestock cloning was cited as another area where the European Parliament adopted a much stricter position than national governments or the European Commission. MEPs demanded that any foods containing meat or milk (or derivatives) from livestock clones, their progeny, grand progeny and so on in perpetuity were either banned or labelled as Novel Foods, whereas the Commission and the UK's Department for Food and Rural Affairs argued that such rules should only apply to the meat and milk derived from clones themselves.

4. Unpredictable, expensive and time-consuming approvals process: Another area of concern identified during the inquiry was that of predictability, which is vital for companies' decision

[28] HM Government - Review of the Balance of Competences between the United Kingdom and the European Union: Animal Health and Welfare and Food Safety Report https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/227367/DEF-PB13979-BalOfComp-HMG-WEB.PDF

[29] European Commission Press Release - Commission publishes compendium of results of EU-funded research on genetically modified crops, 9th December 2010 http://europa.eu/rapid/press-release_IP-10-1688_en.htm

making processes. The EU's regulatory process for plant protection and GM innovations is proving to be far from predictable and subject to unacceptable delays. This is despite EU legislation which states that member states must vote within three months of receiving a scientific risk assessment from the EFSA, and again within two months if no qualified majority is reached the first time. However, these deadlines are not being met, the result of which is a growing backlog of products waiting for approval. According to EuropaBio, Europe's bio-industry association, there are 74 GM products waiting in the approvals queue, and that even if no further applications were submitted, it would take 15 years to clear the backlog based on 2012 approval rates. EuropaBio cited the Commission's own figures estimating the total cost to the wider economy of such disruptions at €9.6bn.[30]

Furthermore, predominantly due to the large number of studies which applicant companies have to present to EFSA, EuropaBio has estimated that the average cost for having GMOs approved in Europe has been estimated at between €7m and €10m per event.[31] The combined effect of such an expensive and drawn out approvals process is to limit opportunities for the commercialisation and export of innovative agricultural products by UK companies. A further side effect is higher than necessary food prices for consumers.

The combined effect of all the problems detailed above has been to put the EU's, and therefore also the UK's, agri-tech sector at a significant competitive disadvantage compared with the US, Japan and the emerging economies, with fewer opportunities for innovation and commercialisation. The Agricultural Biotechnology Council, an umbrella group representing the six largest global agri-tech companies including BASF, Bayer and Monsanto, described the barriers presented to UK businesses in this field as a result of having to implement EU regulations as "significant and highly-restrictive".

The National Farmers' Union, concluding that the "EU legislative process for key agricultural technologies and innovations is broken", while a recent report by the Advisory Committee on Releases to the Environment (ACRE), the UK Government's science advisory committee, described the EU's decision-making process for GM as "outdated and not fit for purpose", and called for it to be replaced.[32] The European Academies Science Advisory Council (EASAC), composed of the national science academies of EU member states, has warned that the current EU policy towards GM crops is leading to the EU "falling behind international competitors in agricultural innovation, with implications for EU goals for science and innovation, and for the environment as well as for agriculture."[33]

Unsurprisingly, the inquiry heard of several cases where companies and individual scientists had decided to re-locate outside the EU in order to benefit from a more permissive regulatory environment and/or to take up funding opportunities not available in

[30] EuropaBio – 44 years of delays in the EU's approval of GM products, 5th November 2011
http://www.europabio.org/agricultural/positions/44-years-delays-eu-approval-gm-products
[31] EuropaBio - GM Crops: Reaping the benefits, but not in Europe, May 2011
http://www.europabio.org/sites/default/files/position/europabio_socioeconomics_may_2011.pdf
[32] The Times, Farmers 'left behind' by EU's block on GM crops, 16 September 2013
http://www.thetimes.co.uk/tto/business/industries/article3869854.ece
[33] European Academies Science Advisory Council - Planting the future: opportunities and challenges for using crop genetic improvement technologies for sustainable agriculture, June 2013
http://www.easac.eu/fileadmin/Reports/Planting_the_Future/EASAC_Planting_the_Future_FULL_REPORT.pdf

the EU. Examples included BASF closing its R&D HQ in Europe, while biotech giant Monsanto likewise announced recently it would drop plans to seek approval to produce new GM crops in the EU due to the hostile political climate and a regulatory system based increasingly on the precautionary principle. The UK's leading agricultural technology company, Syngenta, has also signalled that unless progress is made it will not be able to avoid reviewing its commitment to the UK and EU market.

Such actions are likely to be repeated by others if the current approach continues, with a clear impact on jobs and investment. The inquiry also heard that the number of new GM trials taking place in Europe has fallen drastically, with more now being conducted in Africa than in the whole EU28, a trend which will be difficult to reverse. In the UK, one field trial was held in 2012 compared with 37 in 1995. Meanwhile, the planting of GM crops in other countries has been increasing substantially as detailed in Section 2 earlier.

5. Misalignment of policy making and policy impact: Another flaw in the current EU legislative process is the misalignment between where policy proposals originate and where decisions are made, and where the impact of these is felt most acutely. For example, in the area of agriculture and biotechnology, it is the Commission's Environmental DG and the corresponding European Parliamentary Committee that draw up and decide much of the legislation – as opposed to their counterparts in the fields of agriculture and/or science– despite the fact that they may lack the relevant expertise and tend not to view the advancement of technology or innovation in life sciences as a key priority.

6. Alleged ideological bias in awarding of EU research grants: Questions were also raised about the neutrality of draft funding calls under Horizon 2020, in particular in the area of agriculture. Professor Maurice Maloney, Director of Rothamsted Research, has argued that only one-third of draft calls are science based, whereas two-thirds are "ideologically framed" as they require the data to support a previously-held position; an "unethical" approach which inhibits objective scientific discovery and innovation. There is allegedly a "heavy predisposition" towards uncovering the positive attributes of organic agriculture as the Commission appears to have concluded that it is less carbon intensive than conventional agriculture, even if other scientific studies have shown this is unlikely to be true. Professor Maloney described this approach as 'policy-based evidence' rather than 'evidence-based policy', and warned that billions of euros could be wasted in the pursuit of 'pseudo-science' intended to support predetermined ideological positions.

7. Impact of EU hostility on emerging democracies: There is growing concern in some quarters that the cultural hostility of EU institutions to agricultural biotechnology may be encouraging Governments in less developed countries to adopt similarly hostile regulatory regimes. This is especially alarming in areas where the need for the benefits of genomic science across the wider life sciences - in medicine, food and energy – is especially urgent. For example, the Kenyan Government implemented a ban on GMO's in 2012, with potentially very damaging consequences for that country's – and that region's - agricultural and economic development.

   The Kenyan decision flies in the face of the striking adoption of GM by some agriculturalists in the region: the UK Parliament's All Party Parliamentary Group on Science and Technology in Agriculture recently received a presentation from a pioneering Ugandan GM

banana farmer, highlighting the benefits of Genetically Modifed Banana plants in reducing the use of toxic pesticides and maximising the economic value of the banana crop to local growers.

In the government gazette of Oct 11, the Kenya government appointed a task force under the Minister of Health to review matters relating to genetically modified foods and food safety. In late 2012 the Kenyan government introduced the unofficial “GMO ban.

Global momentum on GM Crops and Agricultural Biotechnology

The overall impact of the EU’s growing hostility to GM and Ag Biotech is all the more striking when viewed in the context of the extra-ordinarily rapid adoption and development of agriculutural biotechnology around the world. The review of recent news headlines from the agricultural biotechnology sector below illustrates the point: while in Europe the growing influence of biotech hostile Green politics (and local/nationalist political parties like the SNP and Plaid Cymru, despite Scotland and Wales’s world class agricultural science research centres) has seen the very slow adoption of GMOs and with drawl of international inward investment, in the fastest growing emerging economies – the ‘BRIC’ nations of Brazil, Russia, India, China, and a number of other fast emerging countries, GM adoption is taking off apace. A review of recent news headlines in the ag-biotech space from December 13 illustrates the pattern of worldwide adoption of agricultural genetics in the face of EU obstruction.

EU court overturns approval of BASF’s Amflora GM potato

Europe's second-highest court today annulled a decision by the European Commission in 2010 to permit the cultivation and sale of a GM potato developed by BASF. Following a legal challenge by the Hungarian government, the EU’s General Court said the Commission had failed to fulfil its procedural obligations when approving the industrial Amflora potato, which is genetically modified to produce extra starch for use in the paper industry.

The Commission first proposed the cultivation and sale of Amflora in 2007, after a positive scientific assessment by the European Food Safety Authority (EFSA). Following the failure of EU governments to approve or reject the proposal, the Commission exercised its power to grant approval in 2010. But in its judgment, the General Court said that following the publication of an updated scientific opinion by EFSA in 2009, the Commission should have submitted new proposals for approval by EU governments rather than simply adopting its 2007 version.

While Amflora is no longer grown in Europe - BASF withdrew the product in 2012 citing opposition to the technology - the ruling reinforces concerns about the EU's complex and much-criticised approval system for GM crops. It is the second time in a matter of months that the European Commission has been found at fault in its handling of the GM approvals process.

Campaign groups Greenpeace and Friends of the Earth welcomed the judgement, and called on the Commission to halt the approval process for other GM crops.

Fierce GM debate in China stirred by anti-US concerns

In the latest of a series of articles focusing on global GM crop developments, *The Economist* reports that public debate over GM food in China is escalating, as anti-GM campaigners and hardline Communists claim the spread of the technology is part of a US plot to gain domination over the world's food supply. China already grows GM cotton and imports GM soybeans, but the widely anticipated move to cultivate varieties of GM rice and maize already granted safety certificates by the Chinese authorities back in 2009 appears to have been put on hold until the public debate has died down.

Russia to permit GM crop cultivation

All About Feed reports that the Russian government has approved a decree, due to take effect from 1 July 2014, permitting the commercial cultivation of GM crops. Currently only experimental GM crops can be grown in Russia. Agribusiness sources suggest that after two years of official seed registration this decision could see the first GM soybeans grown commercially in Russia from 2016-17.

Global GMO standards needed says U.S. Fed official

Reuters reports that a top U.S. Federal Reserve official has called for a move towards internationally accepted standards for GM crops, following recent rejections of U.S. corn shipments by China. Since mid-November, China has turned away several cargoes of corn testing positive for the GM corn variety MIR 162, which has been approved for import by all other major buyers, including Japan, South Korea, Russia and even the EU, but not China. Approval by China has been pending for more than two years.

New Minister expected to signal a positive shift on GMOs in India

Last week's appointment of Veerappa Moily as India's new Environment Minister is widely tipped to herald a more favourable government position on GMOs, paving the way for a lifting of the *de facto* moratorium on field trials of GM food crops which has been in place since 2009. Responding to reports that the government may soon approve GM food crops in India, shares in Monsanto India and Bayer CropScience rose by 17% and 8% respectively in trading late last week.

Brazil GM crop area up 6.8%

Brazilian farmers have increased plantings of GM soybean, corn and cotton by 6.8% this season, according to the latest economic forecasts. About 91% of Brazil's current soybean crop - expected to be the largest in the world at 87.2m tonnes - is GM, up from 89% a year earlier. The most significant increase is in cotton, where cultivation of GM varieties is up by 35.7% over 2012/13.

Welsh MEP calls for EU freeze on GMOs

Plaid Cymru MEP Jill Evans has called for a freeze on all potential or pending GMO authorisations after the European Parliament's environment and public health committee voted to reject the Commission's proposal to authorise a new insect-resistant GM maize for EU-wide cultivation. Ms Evans, who has long campaigned against the growing of GM crops in Wales, described the committee's vote as a setback for the European Commission, adding that the recent European Court ruling which overturned a previous authorisation by the Commission (Amflora), raised wider concerns about the EU's GMO approvals process.

Crop Protection Products

The introduction of functional food and nutraceuticals will require effective crop protection if EU farmers are going to compete in their cultivation and marketing.

The change in pesticide regulations to a risk based assessment is reducing the number of pesticides both currently approved and developed in Europe when compared with the rest of the world.

European science led businesses have managed technical, commercial and regulatory risk, but when confronted by uncertain risk-based regulation and political intervention (insecurity) the evidence is that R&D expenditure is being reallocated away from the EU. In all probability new genetics based technologies will also be subject to that same (or harsher) challenges.
In the case of neonicotinoids we see a difference between the UK view[34] and that from EFSA.[35] Clearly this is a complex area, but is interesting to note that neonicotinoids are widely used in Australia. Colony collapse disorder is not an issue with Australian bees – indeed they are exported to the US. It should also be noted that the bee parasite the Varroa mite is not yet present in Australia.
As **Dr Gordon Jamieson,** Knowledge Exchange and Commercialisation Director at the John Innes Centre put it:

"A consequence of increased risk based regulation for crop protection products is that the EU will increasingly rely on agricultural imports to make up our self-inflicted food shortfalls caused by the failure to adopt new technologies.

"When the UK exported its manufacturing activity, the Chinese had a willing and educated workforce and for a period, at least, the UK made good by growing the service economy. This contrasts with a situation where the acreage of agricultural land is declining and demand from food and feed on a global level is projected to increase dramatically. The public has to become aware that EU policy on GM and pesticides is not risk free. At best it results in exporting the use of pesticides to countries where their application is less well regulated and at worst it will increase food prices and jeopardise food security.

"This is not a plea for the removal of regulation. Thoughtful regulation stimulates innovation and improves our lives.

"At the moment the EU retains a formidable group of scientists in public and private sectors involved in food and agri-tech.

"If the Commission's obsession with risk continues, rather than engaging the public in discussing balancing risk and reward from various new technology options, our research base will decline in the same manner as the UK's historic expertise in civil nuclear-engineering has, in essence, disappeared."

[34] https://www.gov.uk/government/policies/making-the-food-and-farming-industry-more-competitive-while-protecting-the-environment/supporting-pages/neonicotinoid-insecticides
[35] http://www.efsa.europa.eu/en/press/news/130116.htm

4.4 Next generation products: “Nutraceuticals” and Functional Foods

A new class of products

One of the most interesting and rapidly emerging fields in Life Sciences is in the convergence of food and medicine in a new class of products called ‘Nutraceuticals’. The more that we learn from the study of genetics and disease histories using modern medical informatics, tissue 'biobanking' and genetic epidemiology the more we know that different diseases affect different people differently, and that lifestyle and especially diet are critical to long term health and, along with genetics, shaping people’s predisposition to disease.

For many years the pharmaceutical industry has sought to develop high value ‘NCE’ medicines which can be taken orally, as a pill, and delivered to the body through the digestive tract. But not all drugs are well suited to that delivery route and we have also seen a broadening of delivery routes from patches to nasal to IV to sophisticated infra-cellular delivery using biochemical or photo-therapies. As the industry seeks to grapple with the prohibitive cost of developing safe, effective and cost efficient 'blockbuster' oral drugs, and societies and insurers start to take more interest in preventing rather than simply treating disease, there is growing interest in the 'easier' markets of 'functional foods' and ‘nutraceuticals’: products which are classified not as medicines but as foods, but which have health benefits for healthy consumers, and which must be approved by EFSA. Companies like Danone, Unilever, and other global majors have major investment programmes in this fast emerging new field (See Section 3).

Another very important area is that of dietary Foods for Special Medical Purposes (FSMPs), which are available in the UK and EU for the dietary management of a wide range of diseases and conditions including cancer cachexia, COPD, epilepsy, metabolic conditions and early Alzheimer’s disease. These products are specifically designed and formulated for the dietary management of a disease/disorder or medical condition and are used under medical supervision as part of a patients overall care.

Developments in genetics and nutrition are driving a range of new product categories emerging over the next decade such as genetically modified vegetables with particular health enhancing properties, disease resistant crops like the blight-resistant potato recently developed at the UK John Innes Centre, and healthier versions of popular western foodstuffs associated with western diseases, such as cheese without damaging saturated fats, bread without gluten, or cholesterol reducing milk.

As we seek to shift the burden of healthcare costs from the treatment of late stage diseases – which is expensive and where the majority of the NHS budget is currently spent - to earlier diagnosis and prevention which is hugely valuable to society, then the role of genetics, diagnostics, dietary FSMPs, new 'lifestyle' medicines and other non-medicinal ways of managing diseases is likely to make 'nutriceuticals' an increasingly active and attractive space for investment and innovation in the Life Sciences.

This in turn raises a raft of important questions about how to develop or use the right regulatory framework for this new class of products, and may well demand some fresh thinking about the risks and appropriate level of protections required. There are already real

issues around food labelling, and at what point an advertised health benefit moves from being a marketing message to a health 'claim' which needs to be clinically validated.

At both a deep science and consumer marketing level, the deeper integration of food and medicine is here to stay, and the UK and EU will need to react appropriately with a regulatory framework which is conducive to investment and public confidence. If the right balance is struck, the UK and the EU will have an opportunity to be a world leading hub of the new 'nutraceuticals' sector for decades to come. Otherwise, the risk is that the market will be dominated by the EU's international competitors, with the EU and UK once again, as with GM, being in the slow lane and missing out on the chance to shape and benefit from some hugely exciting progress for mankind from science and innovation.

Many in the industry fear that unless something is done, an increasingly fundamentalist objection to any form of 'modification' of food, especially genetic, and a cultural and political hostility to the global Food and Pharma companies investing in this space risks leaving Europe, and the UK, a backwater in an increasingly globalised market for investment and research. The EU's record in this area has so far failed to inspire confidence. For example, a recent epilepsy remedy failed to secure a medical classification as it came in the form of a food supplement.

Nutraceuticals – the regulatory dilemma

The core challenge in this field is where to draw the line between a 'food' and a 'medicine' and the appropriate regulatory hurdle required to allow health 'claims' to be made alongside food products. The central problem is that, owing to the complexity of identifying and measuring specific effects in a complex dietary intake across a large enough population to be able to provide the sort of statistical guarantees demanded in the approval of medicines would mean very large and expensive trials to demonstrate benefits in humans, but general consumers will not pay pharmaceutical prices for food. It is consequently frequently difficult to generate the business case to support appropriate trials.

This represents a dilemma for the policy makers: should major trials with potential major health benefits be publicly funded – recognising market failure – or should the hurdles to make regulatory claims be reduced through using data from surrogate endpoints (more limited tests in animal models or humans) or underpowered trials? Those who work in the area told us that whilst a case by case justification would seem commercially logical, it would be a bureaucratic nightmare for the EU. How do you balance the trials expenses and allowable claims for a nutraceutical that is generally regarded as safe but will give only a marginal benefit – albeit to millions against an existing un-patentable dietary supplement that has a dramatic benefit for 50 people but has vocal celebrity or media advocacy?!

There is an underlying policy question about the appropriate balance between EU and national government jurisdiction. How far should the remit of EFSA extend? Should it simply be ensuring that products are safe or should it ensure that nutraceuticals and functional foods are also efficacious? Should efficacy be assessed on a national basis? Diets in Tuscany and Govan differ somewhat. More seriously, healthcare costs are incurred by tax payers within nations – perhaps their representative are best placed to judge trial funding, health economic benefits and efficacy. Naturally, this would not preclude nations working together.

Classification of Functional Foods: food or medicine?

The potential classification Functional Foods by the EU as a medicine rather than a food is a source of real concern to leading academics, researchers, and investors in this field. Professor Tim Brocklehurst, Head of the IFR International and Business Office at the Institute of Food Research in Norwich, has highlighted the very real risk if the EU changes the designation from 'food' to 'medicine':

> *"It is imperative that UK, European and wider markets can be exploited by UK developers of functional foods that have a beneficial effect on health. (We should be careful to focus on foods, and not be side-tracked by "supplements".) These foods remain part of the diet of the individual and hence must continue to be regarded as foods. Marketing the foods with an associated health claim in Europe requires EFSA approval.Collecting evidence for health claims can be an expensive and time-consuming process, but IFR is currently coordinating a European-funded project called BACCHUS, where we are developing tools and resources that will facilitate the generation of robust and exploitable scientific evidence that can be used to support claims of a cause and effect relationship.This should make the approvals process clearer for companies to pursue, but the process could be completely undermined should Europe change the designation of these foods from "food" to "medicine".*

In a positive step, the BACCHUS project is a new project bringing together SMEs directly involved in developing food products and pursuing health claims, experts in health claims legislation and the EFSA review process, and academic and industry partners who provide high quality food and health research that can underpin health claims. Focused on the consumption of bioactive peptides and polyphenols, and beneficial physiological effects related to cardiovascular health in humans, existing SME-developed products that have clear potential for obtaining favourable opinions for health claims have been selected as test cases for study.

These have been aligned with a series of work-packages each of which addresses key aspects of the EFSA health claim evaluation process (legislation and dossiers; product/bioactive characterisation; habitual intakes; bioavailability; mechanisms and biomarkers; clinical trials evidence of health benefit) that will deliver tools, processes and high quality original science. Scientific results and best practice guidelines will be made publically available and thus support future claims for industry.

Genetics for the delivery of nutraceuticals and functional foods

A logical consequence of the development of nutraceuticals and functional foods is the use of breeding and genetic modification (GM) to improve crops. In practice, it is impossible to get new genetically modified plants registered and marketed in the EU. The departure of BASF and Monsanto R&D in this area from Europe provide clear indicators of the negative regulatory environment. R&D budgets are moving to markets that reward innovation.

In addition, the EU Commission has started deliberation on regulation of new breeding techniques that accelerate breeding rather than lead to the introduction of genes from radically different species.[36] The EFSA scientific opinion:

"The EFSA GMO Panel considers that the Guidance for risk assessment of food and feed from genetically modified plants (EFSA, 2011) and the Guidance on the environmental risk assessment of genetically modified plants (EFSA, 2010) are applicable for the evaluation of food and feed products derived from cisgenic and intragenic plants and for performing an environmental risk assessment and do not need to be developed further. It can be envisaged that on a case-by-case basis lesser amounts of event-specific data are needed for the risk assessment."[37]

This may become a significant risk to new technologies and the development of nutraceutical and functional food rich plants. Whilst the final sentence provides some hope, in terms of assessment of the level of data required, it will become very hard for consumers to differentiate products with genes from radically different species from plants derived from acceleration of breeding. (Of course this problem would disappear if/when GM becomes accepted by the EU and consumers.)

Overall, the European system for such products tends to be faster but more unpredictable, while the US system is the opposite – slower but more predictable.

The emergence of new technologies underlines the need for changes to both the UK and EU regulatory frameworks, and this is an area where the UK needs to take leadership within the EU and globally.

With 'Nutriceuticals' and Functional Foods poised to be an increasingly fast growing and important market over the coming decades, there are a number of examples of cutting-edge research in the UK:

1. Plant-made pharmaceuticals: Dr Frances Downey, Public Liaison at Sense About Science, informed the inquiry that 'growing' insulin in GM safflower plants was a cheaper and more efficient process compared with current methods. Although these plant-made pharmaceuticals are never likely to enter the food-chain, they nonetheless fall under the same EU regulations as GM crops that are grown as food, and therefore have to go through the same lengthy and costly approvals process, making this cheaper plant-made alternative production method prohibitively expensive.

2. Prof Cathie Martin at the John Innes Centre in Norwich has developed a purple tomato strain, engineered to contain high levels of anti-oxidants, with potentially significant health benefits, as recently reported in *The Times*. Prof Cathie Martin, of the John Innes Centre, Norwich, said that small innovative projects were hit hardest by the burden of European regulations. "It costs so much money that only the multinationals can afford it," she said. "It's disappointing, because I would like to see society benefiting from something that I've

[36] http://www.epsoweb.org/file/1096
[37] http://www.efsa.europa.eu/en/efsajournal/pub/2561.htm

done." Despite developing the technology here, it is being grown in Canada because applying for a European licence was prohibitively expensive.

3. Jonathan Napier is also conducting GM research at Rothamsted to develop Omega-3 long-chain PUFA enriched oilseeds (Camelina sativa) as a sustainable source of the healthy oils currently sourced only from oily fish.[38] Jonathan Napier and colleagues at Rothamsted Research in Harpenden, have genetically modified a biofuel crop related to cabbages, called camelina, to produce components of fish oils beneficial for cardiovascular health. The approach could relieve some of the pressure on the oceans. The flesh of oily fish such as mackerel and salmon, plus the livers of white fish such as cod, are good sources of omega-3 fatty acids. The most important ones are eicosapentaenoic acid (EPA) – known to reduce the risk of heart disease – and docosahexaenoic acid (DHA) – a lack of which has been linked to visual and cognitive problems. Breast milk is a good source of both, and our bodies can make small amounts of EPA from another omega-3 called alpha-linolenic acid (ALA) found in nuts and vegetable oil, which is then converted into DHA.

   The richest source of these fatty acids is fish. However, they do not produce the acids themselves. In the wild, they get them from eating smaller fish that have eaten algae, the only organisms that can make appreciable amounts of EPA and DHA. Farmed fish are fed fishmeal enriched with fish oil containing these fatty acids. Every year, around a million tonnes of oil is extracted from ground-up fish. A tenth of this goes to make fish-oil capsules and the rest is given to farmed fish. But supplies are limited and unsustainable, says Douglas Tocher of the Institute of Aquaculture at the University of Stirling, UK.

   Jonathan Napier and colleagues at Rothamsted Research in Harpenden, UK, have created an alternative, sustainable source of EPA and DHA. They took seven genes that algae use to produce these fatty acids and inserted them into the genome of *Camelina sativa*, a plant chosen because its seeds are already rich in ALA. The seeds of the modified plant yielded oil that, when purified, contained around 12 per cent EPA and 14 per cent DHA – the same proportions as in fish oil.[39]

   Napier says that if all goes to plan, the plant oil could be available commercially within 10 years. It could then help replace the fish oil used in capsules or fed to farmed fish. "We're never going to replace that 1 million tonnes a year from the sea, but if we could supply even 10 per cent, we would significantly take the pressure off fish stocks," he says.

   Tocher says that modified camelina should make it possible for people to consume the World Health Organization's recommended daily intake of 400 to 1000 milligrams of EPA and DHA. Without the plants, "if everyone ate that much, there would only be enough to supply about half the population, through capsules, fish or both", he says.

[38] http://www.rothamsted.ac.uk/projects/S5175

[39] http://onlinelibrary.wiley.com/doi/10.1111/tpj.12378/abstract;jsessionid=FFED50DF8D6F0318AAE5073C4D56AAFA.f02t03

4. Scientists in novel and non-food crops team at the National Institute for Agricultural Botany (NIAB) in Cambridge are working on a range of projects including:
    - the development of *Buglossoides arvensis* (Corn Gromwell) as a new oil crop for UK farmers, containing stearidonic acid (SDA), an omega-3 fatty acid from plants with the health benefits of fish oils.
    - adapting rosemary as a crop to provide the raw materials for a new generation of Bio-based antioxidants
    - investigating the potential to cultivate *Artemisia annua* for the extraction of Artemisinin to treat multi-drug resistant malaria

5. Scientists at the Centre for Novel Agricultural Products in York are also involved in a project with GlaxoSmithKline in Australia targeted at improving the productivity of useful opiate products including morphine, codeine and thebaine as well as noscapine, which is a non-opiate, by developing high yielding noscapine poppy varieties.[40]

All of this illustrates the speed at which the 'Functional Food' or 'Nutriceutical' sector is developing, the extent to which UK Scientists are in the vanguard of the discoveries driving this vast new sector, and the importance of the EU adopting a regulatory framework which is conducive to continued inward investment into the EU and UK science base. However, it is hard to envisage Europe being a leader in the development of these new products if the EU is not open as a market to their adoption and use.

4.5. The EU and Life Sciences: help or hindering?

It would be easy to conclude from the list of legislation and the analysis above that the UK Life Science sector views the EU as hostile to Biotechnology and Life Sciences and would support a call to simply exit the EU Life Sciences framework. That is not, however, accurate. The vast majority of academic researchers, charities, investors and companies all made the point that the EU is a major sponsor of science and research through its various Funding Programmes, and in many areas since its formation, for example in medical devices, has been instrumental in many of its policies in support of the Common and then Single Market in helping to make Europe a world class location of choice for much bio-science research.

Much of the frustration we heard was about the risk of the increasingly politicised and non-evidence based biotech-hostility in policymaking , and the increasing legal and bureaucratic complexities of EU law was in danger of undermining one of the great USP's of Europe – politically and economoically – as a major progressive global force.

Many made the point that it's important to avoid the all-too-easy 'better off out' sentiments so often and easily expressed by those who are not engaged in developing the scientific solutions to the global challenges which those at the front line of Life Sciences are. Rather than denigrate the whole idea of the EU, many of our consultees focused instead on the failings of individual institutions (i.e. the Commission, Parliament, Council and Court) in terms of their legal competence. Many pointed out that you can get a good Commission proposal, such as the proposed Medical Devices and IVD Regulations, to which Parliament

[40] https://www.york.ac.uk/biology/centrefornovelagriculturalproducts/research/health/

adds unworkable and obstructive amendments. Or you can get a misguided Commission proposal (ban electronic cigarettes) opposed by Parliament. Similarly, you can get some excellent judgments from the Court, including a recent decision in which it castigated the Commission for putting policy before law; only to hear a case such as Brüstle that shakes faith in its impartiality.

Overall we found a broad consensus in support of the EU as a potential global force for good in investing in world class science and creating a framework for its development and application for the good of mankind in a range of areas of innovation, but with considerable irritation as to how its business is run, the growing influence of unaccountable lobbyists and fringe political groups with little or no public support or legitimacy, often pushing science regulations on the basis of emotional fears based on ignorance rather than evidence, and concern that institutions may be pushing out beyond the envelope of their competence.

A number of witnesses highlighted the difficulty for the UK now of withdrawing altogether from legislation such as the Data Protection Directive, because of the reliance of many research organisations and projects on EU wide collaborations and the difficulties of the UK not being subject to the regulations, which other collaborating countries would be.

We found a number of specific problems with the process of EU legislation repeated throughout the evidence we received:

Decisions

A number of our witnesses highlighted that EU law is not solely the product of the Commission, Parliament and Council of Ministers. The ECJ is a key player. In the life science arena, the Court of Justice of the European Union recently purported, in the case of *Brüstle v Greenpeace* to oblige Member States, including the UK, to breach their obligations under the World Trade Organisation Agreement, exposing them to expensive proceedings before the WTO and to retaliatory tariffs. The court is not empowered to make such rulings, yet Member States are obliged to follow them.

Constitutional Laws

Life science technologies often invoke ethical or doctrinal concerns. These are reflected at the level of international, non-EU conventions such as the Helsinki Declaration and the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (the "*Oviedo Convention*") and its protocols on cloning, transplantation, biomedical research and genetic testing for health purposes. The UK and other EU states are not signatories to the Oviedo Convention, which the UK would find overly restrictive. However, many other Member States have ratified it and endeavour to translate its principles into the domain of EU, and thus UK, law.

The UK has negotiated its position carefully, so as to ensure a broadly permissive regime with responsible oversight of life science practices. Importantly, the UK does not subscribe to the "precautionary principle", under which innovations are presumed to be harmful, and thus regulated, unless the contrary is proved. The precautionary principle is not an element of EU

law: it appears at the level of the *Rio Declaration on Biodiversity* and the related *Cartagena Protocol*. However, the idea has gained traction among European law makers and now threatens EU and UK innovation.

The element of EU law with the greatest potential impact is the *Charter of Fundamental Rights*, which, since the Lisbon Treaty, has had the same legal value as the EU Treaties. By a Protocol to the Lisbon Treaty, the UK and Poland (and by inference other Member States) are assured that the Charter creates no new rights: it merely restates the existing position. However, the Charter has been successfully invoked by MEPs when arguing for EU-wide restrictions on the use of genetic testing and in other areas.

5. Conclusions and recommendations

5.1. Wider lessons for the EU and UK-EU relationship

In many ways, the debate over the benefits and drawbacks of EU membership for the UK life sciences sector are a microcosm of the wider debate over EU membership for the UK economy as a whole. On one hand, the UK life sciences benefit from market access and have a seat at the table when the rules are drawn up, while one the other they have to shoulder the burden of sometimes excessive and badly designed EU regulation.

Where the EU facilitates collaboration, for example by helping to establish cross-border research networks, it allows member states to achieve better results than if they were acting in isolation. Likewise, a proportionate and consistently applied legal framework, such as in the area of medical devices, is also a huge advantage to UK life science companies. However, as this inquiry has revealed, parts of the EU legislative process in the area of life sciences are fundamentally not fit for purpose due to a combination of a lack of expertise, too much emphasis on precaution rather than managing risk and a political climate that is hostile to large swathes of life science disciplines. This is particularly true for GM crops, where Europe has completely lost out on the potential economic benefits of developing crops which could deliver both higher yields and environmental benefits.

Life science is a particularly interesting prism through which to assess the EU's wider economic and political challenges. Given the increasingly competitive global economy, and the relative decline of the Europe within it, can the EU forge a comparative advantage in this up-and-coming area and take advantage of its massive global trade and investment opportunities? Can the UK succeed in shaping the global rules on life sciences via its EU membership? Or will the UK be held back from making the most of these opportunities through overly risk-averse and burdensome regulation stemming from an ideological prejudice against GM crops or stem cells?

Tested against three of the principles outlined in David Cameron's 'Bloomberg' speech on the EU, we asked how does the EU framework for life science fare?

- **Competitiveness:** It is clear that the EU's approach to data protection (as applied to medicine) and GM crops in particular risks hamstringing UK and European firms in what are increasingly lucrative and competitive global markets. [Score: 5/10]

- **Flexibility:** In the area of medical devices, the EU framework offers multiple and different routes to market – a model that arguably provides greater flexibility than in the US. However, in the area of GM crops, for example, a one-size-fits-all approach across the EU has the effect of stifling member states that wish to develop the technology. EU data protection rules also threaten to clash with the UK's evolving model of using patient data to further medical research. [Score: 6/10]

- **Accountability**: It is clear from our inquiry the impact that individual EU institutions can have on industry and commerce. Regulation often lacks a sufficient evidence or science base and MEPs, in particular can be captured by lobbies or special interest

groups. This presents a two-level governance problem, whereby EU institutions regulate with a view to the 'precautionary principle' but it is primarily the member states that lose out in terms of lost growth opportunities. [Score: 4/10]

Therefore, we propose a package of 10 measures to address the failings in the EU's current approach which apply both to the EU itself as well as to how the UK government and parliament engages with it.

5.2 Ten steps to boost UK and EU life science innovation and competitiveness

POLICYMAKING

1. **A clear statement of the EU's policy regarding biotechnology and the bio-economy.** The EU needs to make clear that it aims to be a global player in this fast growing and increasingly global field, with policies to support inward investment into research in the EU, and that all legislation should be designed so as to conform to that bigger principle, and measured against it.

2. **A shift away from the increasingly widely used risk-based 'Precautionary Principle'.** The EU needs to move to a Hazard Based framework of regulation based on the Principles of 'Reasonable Risk' and Subsidiarity: ie. Within a general framework requiring all members states to make adequate provision for regulation to prevent unethical research, allowing different members states to compete within that jurisdiction through different interpretations to suit local circumstances.

3. **An easier way of amending flawed EU legislation and/or ECJ rulings.** Notwithstanding the need for better regulation in the area of Biotechnology going forward, a formal mechanism to amend or scrap existing legislation and/or review ECJ rulings would also be highly desirable. One way could be to give national parliaments greater agenda-setting powers, and indeed this issue is already under discussion. Likewise, the Dutch government recently proposed an override mechanism in cases where the ECJ had issued a ruling which obviously contravened the intention behind the underlying legislation, something exemplified in the Brüstle ruling.

4. **Ensuring more joined-up policy making at the EU level.** One of the problems with the EU legislative process is that policy proposals in one area can have a significant, but not immediately obvious, impact on another. For example, the new data protection proposals which could have a dramatic impact on medical research if access to patient data is unduly restrictive, were set out by the Commission's Justice Directorate, and are being negotiated by national justice ministers and MEPs on the European Parliament's Justice Committee. In general, the EU should be more mindful of the economic impact of any proposals it makes. One idea could be to appoint a dedicated 'EU Commissioner for Innovation' who could work with colleagues in other Commission posts.

5. **More accessible and transparent early consultation processes before legislation is drafted or proposed.** As the inquiry showed, UK life science companies, in particular SMEs, struggle to make their voices heard during the consultation stages of

the EU legislative process. This contrasts with many well-funded and well organised green NGOs and unrepresentative minority political groupings who often pursue an agenda that is hostile to some of the life sciences. More accessible, well-publicised and transparent consultations would facilitate greater stakeholder participation.

6. **Better and more active UK Government and parliament engagement in the legislative process.** The inquiry heard that the UK Government can sometimes take too much of a hands-off approach. For example, it delegated negotiations over the proposed In Vitro Diagnostics Directive to the MHRA – an executive agency of the Department of Health. While the MHRA is well regarded, its remit is too narrow for such a task, it is not a natural promoter of enterprise, and the arrangement lacks sufficient transparency and accountability. One possible solution could be for the government to appoint a dedicated EU-based 'Life Science Tsar', but this is really a role that should perhaps fall more appropriately to the UK's Chief Scientific Officer or EU Chief Scientific Officer (who happens at the moment to be Anne Glover, a strong supporter of UK Life Sciences). Likewise, notwithstanding the proposals above for more official powers for national parliaments, UK MPs should also liaise with their counterparts on a more informal basis to ensure UK interests in this area are presented coherently and consistently.

BIOMEDICAL RESEARCH

7. **Greater freedoms for member states to determine their own policies with respect to Data Protection**. Given the diversity of heathcare systems throughout the EU, Member States should be free to set their own policies for the use of clinical and patient data to reflect the rapidly emerging and increasingly prevalent 'Translational' (patient centred) models of Research sweeping global biomedicine.

8. **Greater freedoms for member states and different public healthcare systems to determine their own policies with respect to Early Access to medical innovations.** Member states and their public healthcare partners need to be free to develop their own arrangements for 'Translational' (patient centred) Research and Clinical Trials and Early Access to innovation.. As detailed earlier, the EU Clinical Trials Directive has imposed significant administrative burdens, leading to a substantial drop in new trials undertaken in the UK. While the revision of the directive by the Commission is welcome, there is an argument to be made that trials that only involve national subjects and practitioners could be made exempt from EU legislation altogether, as was proposed by several respondents to the inquiry.

9. **Reforming access to EU research grants,** As set out earlier, UK universities and companies broadly do well out EU research grants however there is clearly scope for reducing the bureaucratic burden associated with applying for them. Likewise, safeguards must be put in place to determine that they are not allocated according to pre-determined ideological position – this undermines the very point of scientific research. Finally, as a couple of respondents suggested – and as argued by Open Europe in its report on CAP reform, some of the funding available under Pillar II of the CAP (the rural development subsidies) could be earmarked explicitly for agricultural science R&D.

AGRICULURAL BIOTECHNOLOGY AND GM

10. **Greater flexibility for member states to 'go it alone' in the area of GM crops**. The EU needs to consider a rebalancing of competencies so that individual nation states can set their own regulatory framework regarding Agricultural Biotechnology and Nutriceuticals. A number of respondents to our inquiry suggested that this would be attractive to the UK agricultural and biotech industry and could also attract other member states who wish to go further than allowed under current EU rules while allowing those states strictly opposed to GM to maintain this stance. However, it would inevitably put back the opportunity of a single EU market in ag-biotech products, and implementing a system of checks across the single market to prevent GM crops/seeds from crossing from participating and non-participating states could be challenging and bureaucratic.

Annexes

I The Fresh Start Inquiry methodology and timing

This Inquiry was carried out by Open Europe and the UK Parliament Fresh Start Group for European Reform led by Andrea Leadsom MP and George Freeman MP, UK Government Adviser on Life Sciences 2011-2013 and Chairman, All Party Group on Science and Technology in Agriculture.
This Report has been written by Open Europe and George Freeman MP, following an extensive period of evidence gathering including 4 oral evidence sessions in Parliament Between June and July to look into specific aspects of EU policy making where experts, practitioners and stakeholders were invited to submit evidence. The details of the sessions are as follows:

- Session One: Has UK Life Science endeavour been subject to European Parliamentary abuse? What can be done to prevent this?

- Session Two: Is EU Life Science law implemented in a uniform way by competent authorities?

- Session Three: Is the European Court of Justice exceeding its powers? If so, what can a member state do?

- Session Four: How effective is the UK's involvement in the development of EU Life Science policy and Law?

The findings of the four sessions were then written up and circulated around the UK Life Science community more widely as a means of soliciting further contributions and feedback, along with an invitation to also include any policy recommendations.

This resulted in over 50 further submissions ranging from short responses to lengthy and detailed policy documents, from broad overviews of the situation to responses which highlighted specific and niche issues, which were then collated integrated together with the evidence garnered during the parliamentary sessions in this report.

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- Daniel Pearsall (APPG for Science and Technology in Agriculture)

George Freeman
(Westminster, 2013)

III Summary of EU Life Science Legislation

(Note that where legislation is proposed, it would repeal the existing laws. We have also added a note on impending legislation (NB: the trend within the EU from use of directives to regulations) and on the decisions of the Court and on Constitutional laws.

Biotechnology patents

Directive 98/44 on the legal protection of biotechnological inventions (the "*Biotechnology Directive*").

Medicines

Directive 2001/82 on the Community code relating to veterinary medicinal products ("*Veterinary Medicinal Products Directive*")

Directive 2001/83 on the Community code relating to medicinal products for medical use ("*Medicinal Products Directive*")

Regulation 726/2004 laying down Community procedures for the authorisation and supervision of medicinal pr*oducts for human and veterinary use and establishing a European Medicines Agency ("*Medicinal Products Regulation")

Regulation 469/2009 concerning the supplementary protection certificate for medicinal products ("*SPC Regulation*").

Regulation 847/2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts ‘similar medicinal product’ and ‘clinical superiority’ ("*Orphan Drugs Regulation*")

Regulation 1901/2006 on medicinal products for paediatric use ("*Paediatric Medicines Regulation*").

Directive 89/342 on vaccines, toxins, serums and allergens ("*Vaccines Directive*").

Directive 2005/28 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products ("*GCP Directive*").

Directive 2003/94 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use ("*GMP Directive*")

Directive 2004/10 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances ("*GLP Directive*").

Blood, Cells & Tissues

Directive 2002/98 setting standards of quality and safety for the collection, testing, processing, storage and distribu- tion of human blood and blood components ("*Blood Quality & Safety Directive*").

Directive 2004/33 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components.

Directive 2004/23 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (the "*European Tissue & Cells Directive*").

Directive 2006/17 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells

Directive 2006/86 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells

Regulation 1394/2007 on advanced therapy medicinal products ("*ATMP Regulation*").

Clinical Trials

Directive 2001/20 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use ("*Clinical Trials Directive*")

Cross Border Healthcare

Directive 2011/24 on the application of patients' rights in cross-border healthcare.

Medical Devices & IVDs

Directive 90/385 on the approximation of the laws of the Member States relating to active implantable medical devices ("*Active Implantable Medical Devices Directive*")

Directive 93/42 concerning medical devices ("*Medical Devices Directive*").

Directive 98/79 on *in vitro* medical devices ("*IVD Directive*").

Product Liability

Directive 85/375 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products ("*Product Liability Directive*").

Data Protection/ Biomedical information/E-Commerce

Directive 95/46 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ("*Data Protection Directive*")

Directive 97/66 concerning the processing of personal data and the protection of privacy in the telecommunications sector.

Directive 2000/31 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ("*E-Commerce Directive*")

GM and chemicals

Directive 2001/18 on the deliberate release into the environment of genetically modified organisms ("*GM Release Directive*")

Directive 2009/41 on the contained use of genetically modified micro-organisms ("*GM Contained use Directive*")

Directive 2000/54 on the protection of workers from risks related to exposure to biological agents at work

Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency ("*REACH Regulation*")

Food & Supplements

Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ("*Food Safety Regulation*").

Directive 2002/46 on the approximation of the laws of the Member States relating to food supplements ("*Food Supplements Directive*").

Impending legislation

European Parliament legislative resolution of 21 November 2013 on the proposal for a regulation of the European Parliament and of the Council establishing Horizon 2020 - The

Framework Programme for Research and Innovation (2014-2020) ("Horizon 2020 Regulation").
Proposal for a Regulation on medical devices ("*Medical Devices Regulation*")
Proposal for a Regulation on *in vitro* diagnostic medical devices ("*IVD Devices Regulation*")
Proposal for a Regulation on clinical trials on medicinal products for human use ("*Clinical Trials Regulation*")
Proposal for a Regulation on the protection of individuals with regard to the processing of personal data and on the free movement of such data ("*Data Protection Regulation*")