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EDITORIAL

How agri-biotech contributes to the EU bioeconomy

Beat Späth, Director Green Biotechnology, EuropaBio, Brussels



Beat Späth studied European affairs and languages in the UK, France and Belgium. He began his career in 2001 at the European Parliament, where he worked as an assistant to a German MEP, before moving on to join the Brussels office of the German Retail Federation as an advisor with a focus on the environment, social affairs and corporate social responsibility. At EuropaBio, Späth currently manages the political aspects of agricultural biotechnology at the EU level. He interacts with representatives from member companies to facilitate industry positions on political developments, and communicates with EU decisionmakers on behalf of the association.

In October 2012, the European Commission issued a communication on its new Industrial policy identifying biotechnology as one of six Key Enabling Technologies. Biotech will be an important tool in helping Europe deliver on its Europe 2020 strategy of creating an innovative, resource-efficient, smart, sustainable and inclusive economy.

Due to the many challenges facing Europe and the world today – among them the threat of climate change, a decreasing amount of arable land and a growing population worldwide – we will need to use every available tool to optimise the use of land and resources and enable those in developing countries to improve their quality of life. Innovation in plant breeding is essential to feed the world's growing numbers and help reduce poverty by improving food security. Global demand for food is expected to increase by 70% by 2050. To meet this demand, we will need to produce the same amount of food in the next 40 years as we did in the past 8,000.

However, land is the limiting factor in producing sufficient food, feed and fuel to meet global demands. Biomass should therefore always be produced with land and resource efficiency in mind, and should ultimately be used in a smart and sustainable way. To make this possible, farmers need the right to choose what they plant and grow. That will allow them to make the best use of the available resources and enable them to preserve other land for biodiversity purposes. In biobased industries, there should be a level playing field when it comes to biomass used for energy purposes and that used for high value chemicals and biobased plastics produc-

tion. The production of the latter two provides greater economic benefits in terms of economic growth and jobs, and uses far smaller amounts of biomass. In addition, helping to create new markets for biobased products through incentives and public procurement would help increase the value of agricultural residues, thereby bringing greater benefits to farmers.

According to the latest global biotech crop acreage report published by the International Service for the Acquisition of Agri-biotech Applications (ISAAA), more than 18 million farmers are currently planting biotech crops on 175 million hectares. Of those farmers, more than 90% – or 16.5 million of them – are small-scale and resource-poor. The benefits of agricultural biotechnology are clear in countries that have adopted it. A recent study has shown that the adoption of Bt maize allowed Spain to reduce its imports of the crop by over 853,000 tonnes between 1998 and 2013, with consequent savings of €156m. It is time that we begin to view agricultural biotechnology as what it is: a technique that is an integrated part of the European transition to a lower-carbon, more resource-efficient bioeconomy. ◀

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COVER STORY



GM crops and the protected EU market

6

A ministerial vote on whether or not to allow a strain of transgenic maize to be planted in the EU has brought the debate on GM crops in the bloc to a head. Although 19 out of 28 Member States came down against Pioneer’s 1507 strain, that wasn’t enough to reject it outright. The European Commission now has the thankless task of approving the crop by default in the face of massive adversity from both national governments and environmental groups – unless an emergency compromise can save the day.

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EUROPEAN COMMISSION

Biosimilars: what's in a name?

► **Brussels** – EU Member States are unhappy with World Health Organisation plans to give biosimilars a unique international non-proprietary name (INN) that would clearly distinguish them from their originators. According to the summary of a meeting held by the European Commission's pharmaceutical committee, various Member States voiced concerns that different INNs "could undermine the trust of healthcare professionals and the public in biosimilar medicinal products." The WHO will hold a conference to discuss its new naming policy in October.

Australia is pushing in a different direction for naming biosimilars. Last August, its regulatory authority (TGA) published guidelines adopting the naming scheme of the WHO, because studies only provide data on comparability – but not bioequivalence – of a biosimilar with its originator (see EUROBIOTECHNEWS 9/2013). To be able to trace safety data for individual biosimilars, the TGA proposed tagging generic biosimilar names with a specific identifier and additional three-letter code. The US Food and Drug Administration (FDA), which is expecting the first marketing authorisation application for a biosimilar this year, has not officially decided on its naming policy. However, FDA officials have been vocal about the need for robust pharmacovigilance for biosimilar drugs.

Increasingly under cost pressure, healthcare systems are promoting policies aimed at establishing a low-cost market for interchangeable biologics and biosimilars. This year, France became the first country to promote biosimilars by allowing pharmacists to substitute a biosimilar with an identical INN for an original biologic drug (see EUROBIOTECHNEWS 1-2/2104). Industry opinion is divided. In contrast to companies like Sandoz or Hospira, Amgen has argued that different INNs are essential to ensure adequate pharmacovigilance, and claims they would not affect market adoption. ◀

Heard in Brussels

■ Careful what you do – or don't – vote for

Brussels – Shhhhh, is that the sound of a chicken coming home to roost in Switzerland? Worried? If you are a scientist working internationally, you should be – and not just because you want a job in Switzerland. The result of the recent referendum on quotas for immigrants to the alpine country sounded a lot like the usual grumblings of discontent about how Brussels ruins your life by letting foreigners steal your jobs. Usually things like this have little real fall-out. This time however, there was a potentially disastrous impact for science in Switzerland almost immediately. The failure of the Swiss government to sign a free movement deal with Croatia – a direct result of the referendum – suspended talks for Swiss access to Horizon 2020.

Unintended consequences

I'll bet my last euro that this was not a topic of conversation when Swiss citizens were weighing up how to vote, and it is a massive wake-up call for all of us. The Swiss debate reflects arguments going on in our own countries, and the frankly disgracefully low turn-outs in elections. Voter apathy leaves the floor clear for people with 'interesting' views to shout loudly, and as they also tend to be keen voters, they often win. The Brits reading this will recognise the booming call of the swivel-eyed loon as it stalks the marshes of the south, and know the danger out there in the mist.

If you are a scientist anywhere in Europe, you need to stand up and fight for the amazing scientific platform that it brings, and do some shouting of your own on why it is essential to vote to protect it. Switzerland has in fact done us a favour before the impending European elections by providing an example of what happens when you can't be bothered to vote, think that a sensible



Claire Skentelbery,
Secretary General of the European
Biotechnology Network

result must come anyway, or that results won't affect you.

European science has already been hit by the repercussions of the Swiss referendum, years before the idiots that drove the yes campaign manage to implement quotas of any description. I want you to promise me now that you will start telling people how the science they need to save their lives, reduce pollution, grow their food and drive their economies (and cars) is delivered by international partnerships – a benefit that greatly outweighs a perceived blight upon their lives from people with different accents who might need to go to the doctor once in a while.

Every voice of reason counts

I also want you to promise that you will cast your vote in the European elections in May. It is time for scientists to rule the world, we can't trust anybody else to do it. As the great popular music combo Faithless would say, "inaction is a weapon of mass destruction". So head for the polls, my fearless warriors, and let the world hear our voice. ◀

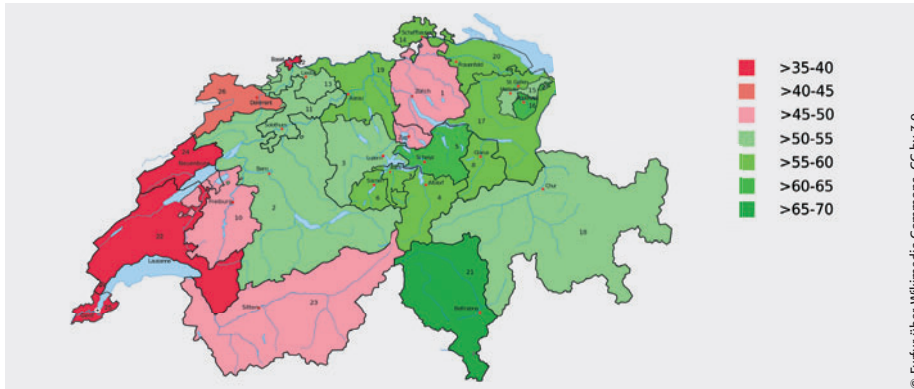
REFERENDUM

The penalties of implementation

The Swiss federal popular initiative “Gegen Masseneinwanderung” (Against mass immigration) was narrowly accepted by Swiss voters (50.34%). Driven by the conservative Swiss People’s Party (SVP) the referendum on 9 February targeted a fundamental pillar of the European idea – the right of citizens to move and reside freely (Directive 2004/38/EC). The initiative suggests limiting immigration through quotas. Although Switzerland is not part of the EU, it is interlinked with its neighbours through various treaties like the seven-part Bilateral I agreement, which includes the now questioned free movement of people.

The Swiss government now has three years to react to the vote. Swiss Biotech Association head Nic Alexakis is contemplating the situation: “For the time being, nothing will change regarding the free movement of personnel.” He is concerned, however, that the referendum result is causing a lot of insecurity, both for foreigners planning to work in Switzerland and Swiss companies that

the Bilateral packages as a whole, since they come with a “guillotine clause”. If a single part of the treaty is declared void, then all the others are as well. That would mean, for example, that biotech companies exporting products to the EU would have to check conformity to GMP standards anew. Until now, the agreements have ensured seamless trade. Cancelling Bilateral I would have an additional impact on the academic life sciences scene, as Switzerland has taken part in European research and development programmes since 2004. The referendum has also tied the hands of the Swiss Federal Assembly to wave through the addition of Croatia to the free-movement-of-persons zone. The EU has in response made this a prerequisite for Switzerland to take part in Horizon 2020 and other pan-EU sponsoring programmes. What’s being called a “mini-guillotine” has now taken the country’s science industry hostage. “The timing of the start of Horizon 2020 in January 2014 and the suspension hit our academic world



Results of the referendum in individual cantons: High acceptance green, low acceptance red

rely on a steady influx of motivated staff. About a quarter of the country’s population are not Swiss citizens – which some claim is a key factor in why Switzerland is one of the most economically competitive countries in the world. Natives of Switzerland, however, appear to have developed fears of being overwhelmed by foreigners.

Major industry associations have warned that the successful initiative could threaten

hard,” comments Alexakis. “In the life sciences – and especially in biotech – the industry works closely with academic centres and technology transfer agencies.” In the current situation, Swiss institutions will not be eligible to coordinate EU research programmes. Unifying the conflicting interests will take plenty of diplomacy. At least that’s something the Swiss have had a lot of experience with in the past.



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Achim Raschka

+49 (0)2233 4814-51
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