

GMOs in the pipeline: Looking to the next five years in the crop, forestry, livestock, aquaculture and agro-industry sectors in developing countries

1. Background

The FAO international technical conference on “Agricultural biotechnologies in developing countries: Options and opportunities in crops, forestry, livestock, fisheries and agro-industry to face the challenges of food insecurity and climate change” (ABDC-10, <http://www.fao.org/biotech/abdc/>) took place in Guadalajara, Mexico in March 2010. A major objective of the conference was to take stock of the application of biotechnologies across the different food and agricultural sectors in developing countries, in order to learn from the past and to identify options for the future to face the challenges of food insecurity, climate change and natural resource degradation. It brought together about 300 policy-makers, scientists and representatives of intergovernmental and international non-governmental organizations. This included delegations from 42 FAO Member Nations.

At the end of ABDC-10, the Member Nations reached a number of key conclusions (FAO, 2011a). Among these, they acknowledged that “Agricultural biotechnologies encompass a wide-range of tools and methodologies that are being applied to an increasing extent in crops, livestock, forestry, fisheries and aquaculture, and agro-industries, to help alleviate hunger and poverty, assist in adaptation to climate change and maintain the natural resource base, in both developing and developed countries”; that “The various applications of agricultural biotechnologies have not been widely used in many developing countries, and have not sufficiently benefited smallholder farmers and producers and consumers”; and that “More research and development of agricultural biotechnologies should be focused on the needs of smallholder farmers and producers”.

ABDC-10 was dedicated to “agricultural biotechnologies”, a term representing a broad range of technologies used in crops, livestock, forestry, fisheries and aquaculture, and agro-industry [see Ruane and Sonnino (2011) for more details]. They are used for a variety of different purposes such as the improvement of plant varieties and animal populations to increase their yields or efficiency; characterization and conservation of genetic resources; plant or animal disease diagnosis; vaccine development; and production of fermented foods.

One of these biotechnologies is genetic modification and it is used to produce genetically modified organisms (GMOs), which are organisms in which one or more genes (called transgenes) have been introduced into their genetic material from another organism using recombinant DNA technology, i.e. a set of techniques for manipulating DNA, including the identification and cloning of genes; the study of the expression of cloned genes; and the production of large quantities of gene product (FAO, 2001). The genes may be from a different kingdom (e.g. a bacterial gene introduced into plant genetic material), a different species within the same kingdom or even from the same species. For example, so-called “Bt crops” are crops containing genes derived from the soil bacterium *Bacillus thuringiensis* coding for proteins that are toxic to insect pests that feed on the crops.

While there has been little controversy about any of the other biotechnologies, there has been considerable debate about the current and potential implications that genetic modification and GMOs have for food security, the environment, biodiversity, human health, farmers income, the global food system and other issues. This often-polarized debate began in the 1990s and it still continues today without showing significant signs of abating. Issues related to GMOs tend to be widely reported in the media and policy-makers often have to specifically address them at the national level and also at the international level where they have come together to draw up internationally binding agreements on the subject. For example, some 163 countries and the European Union have ratified or acceded to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, an international agreement whose objective is to contribute to ensuring the safe transfer, handling and use of GMOs that “may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements” (see

<http://bch.cbd.int/mop6/> for details of its latest meeting, held on 1-5 October 2012 and attended by some 1500 delegates from over 100 countries).

Among the many agricultural biotechnologies discussed at ABDC-10, genetic modification is therefore much more in the public spotlight and it demands far more attention from policy-makers than all the other biotechnologies. It is also an area of major R&D investment and it is predicted that the range of modified traits and species that will be commercially available to farmers in developing countries in the future will be far wider than it is today. For this reason, the FAO Biotechnology Forum is hosting this e-mail conference on “GMOs in the pipeline: Looking to the next five years in the crop, forestry, livestock, aquaculture and agro-industry sectors in developing countries” to look into the near future in order to inform the debate about GMOs in the pipeline, considering the specific kind of GMOs that are likely to be commercialized in developing countries over the next five years and to discuss their potential implications.

This Background Document aims to provide information that participants will find useful for the e-mail conference. In Section 2 an overview of GMOs that are currently commercialized in food and agriculture is given. Section 3, on the GMO pipeline, briefly discusses the research-to-commercialization pathway; the choice of a 5-year time horizon for the e-mail conference; and some GMOs that are in the pipeline in the different sectors. Section 4 presents some specific guidance about the topics that are to be discussed in the conference. Section 5 provides references of articles mentioned in the document, abbreviations and acknowledgements.

2. Commercially available GMOs in food and agriculture

In this section, the kinds of GMOs that are actually released and commercially available are summarized. Note, it does not include GMOs at the research level or that are awaiting commercial approval.

2.1 GM crops

GM crops were first grown commercially in the mid 1990s. While the vast majority was grown in developed countries in the past, this is changing and almost half of the global GM crop area is now estimated to be in developing countries (James, 2011). These estimates indicate that 13 developing countries planted over 50,000 hectares of GM crops in 2011, i.e. Brazil (30.3 million hectares), Argentina (23.7), India (10.6), China (3.9), Paraguay (2.8), Pakistan (2.6), South Africa (2.3), Uruguay (1.3), Bolivia (0.9), the Philippines (0.6), Myanmar (0.3), Burkina Faso (0.3) and Mexico (0.2). For comparison, in 1997 the only developing countries reported were China (1.8 million hectares), Argentina (1.4) and Mexico (less than 0.1). Among the economically developed countries, almost all GM crops are in North America, with an estimated 69.0 and 10.4 million hectares cultivated in the United States and Canada respectively in 2011 (James, 2011).

Almost all GM crops grown commercially worldwide are genetically modified for one or both of two main traits: herbicide tolerance (an estimated 59% of GM crops planted in 2011) or insect resistance, i.e. Bt crops, (15%) while 26% have both traits. Four crops are responsible for virtually all the area cultivated worldwide with GM varieties, namely soybean (47%), maize (32%), cotton (15%) and canola (5%). It is estimated that 75% of the global soybean area is cultivated with GM varieties. For maize, cotton and canola, these proportions are 32%, 82% and 26% respectively (James, 2011). Soybean and maize, apart from human consumption, are also used in livestock and fish feeds and GM varieties are extensively traded internationally for this purpose (e.g. Nowicki et al., 2010).

2.2 GM trees

Commercial release of GM forest trees has been reported in one country, China. In 2002, approval was granted for the environmental release of two kinds of Bt trees, the European black poplar (*Populus*

nigra) and the hybrid white poplar clone GM 741, together representing about 1.4 million plants on 300-500 hectares (FAO, 2011b).

2.3 GM livestock

No GM livestock have been commercially released for agricultural purposes.

Outside the field of agriculture, GM animals have been approved to produce a small number of pharmaceutical proteins that are commercially available (EMA, 2012; Vázquez-Salat and Houdebine, 2012). These include the use of GM rabbits to produce conestat alfa, the active substance in Ruconest (a medicine used to treat attacks of hereditary angioedema in adults) and the use of GM goats to produce antithrombin alfa, the active substance in Atryn (used to treat patients who have congenital antithrombin deficiency). The pharmaceutical proteins are extracted from the animals' milk. GM animals, mainly mice, are also used extensively in biomedical research.

2.4 GM fish

No GM fish have been commercially released for food purposes.

A number of ornamental GM fluorescent fish have been commercialized in some countries, including the United States, Malaysia and Taiwan Province of China (Hallerman, 2004). These aquarium pets, of the zebrafish and tetra fish species, express fluorescent colour proteins encoded by genes from jellyfish and sea anemone so that they can glow at night.

2.5 GM micro-organisms

Micro-organisms (or microbes) are living organisms which are microscopic in size, and include bacteria, fungi and viruses. Although documentation is generally quite poor, use of genetically modified micro-organisms (GMMs) in food processing and the animal feed sector is routine in developed countries and is also a reality in many developing countries.

In the agro-industry sector, enzymes (i.e. proteins that catalyse specific chemical reactions) are commonly used in food processing and in the production of food ingredients and many of them are commonly produced using GMMs. For example, since the early 1990s, preparations containing chymosin (an enzyme used to curdle milk in the preliminary steps of cheese manufacture) derived from GM bacteria have been available commercially. Developing countries which currently produce enzymes using GM micro-organisms include Argentina, Brazil, China, Cuba and India (FAO, 2011c). Similarly, many colours, vitamins and essential amino acids used in the food industry are also from GMMs.

In animal nutrition, feed additives such as amino acids and enzymes are widely used in developing countries. The greatest use is in pig and poultry production where, over the last decade, intensification has increased, further accelerating the demand for feed additives. For example, most grain-based livestock feeds are deficient in essential amino acids such as lysine, methionine and tryptophan and for high producing monogastric animals (pigs and poultry) these amino acids are added to diets to increase productivity. The use of enzymes such as phytase in pig and poultry feeds in intensive production systems in developing countries is also significant. Phytase addition can reduce phosphorus excretion and increase profitability (by decreasing the amount of phosphorus that needs to be added to the diet). These amino acids and enzymes are produced in some cases by GMMs (FAO, 2011d).

Metabolic modifiers are a group of compounds that alter the physiology and metabolism of animals to improve efficiency of meat and milk production. One of these is somatotropin (also known as growth hormone) and GM bacteria are used to produce recombinant bovine somatotropin (rBST), to increase feed conversion efficiency and milk yield and decrease milk fat in dairy cows, and recombinant porcine somatotropin (rpST), to increase muscle growth, reduce body fat and improve carcass

composition in pigs. The hormone is administered by injection and has been approved since the 1990s in several developed and developing countries (FAO, 2011d).

Poor animal health is a major factor that impacts negatively on productivity in developing countries. Animal disease control can be improved through vaccination, where a host organism is exposed (usually by injection) to biological material (antigen) that allows it to mount a specific immune reaction giving it better capability to fight subsequent infections of a specific pathogen. Recombinant DNA technology is now used to develop different kinds of vaccines to manage diseases in livestock and fish. Some of these vaccines offer advantages over conventional vaccines, such as safe and cheaper production; earlier administration and immunity of the animal; more protective immunity; and the possibility to differentiate vaccinated from infected animals. These include gene-deleted vaccines, where pathogens (bacteria or viruses) with deletions in genes associated with virulence or involved in key metabolic pathways are used as live vaccines; recombinant vaccines based on vectors, where avirulent viruses or bacteria containing foreign genes coding for antigens are used for delivery of these antigens to the host animal; subunit vaccines, composed of semi-pure or purified pathogen proteins produced by recombinant DNA technology; or DNA vaccines, where bacterial plasmids (i.e. self-replicating non-chromosomal DNA molecules found in many bacteria) encode protein(s) of an infectious agent (OIE, 2012).

Several of these new kinds of vaccines are commercially available, such as a gene-deleted bovine herpesvirus 1 (BoHV-1) for cattle or viral vector vaccines against poultry diseases such as Marek's Disease, Fowl Pox and Gumboro or against West Nile virus (WNV) in horses. Several influenza vaccines for poultry (and humans) are produced from reverse genetic systems (which make it possible to introduce designed mutations, insertions and deletions into the viral genome of live viruses) and are produced and applied in developing countries against H5N1 (the highly pathogenic avian influenza virus currently circulating in a number of countries) in poultry. For DNA vaccines, the main commercialized product is a WNV vaccine for horses, which contains genes for two WNV proteins and does not contain any whole WNV, live or killed. DNA vaccines are also commercially available against infectious haematopoietic necrosis virus for salmon. Further details about these kinds of vaccines, including examples of their commercial application, are provided in OIE (2012).

3. GMOs in the near pipeline

The pathway leading from research to the eventual commercial release of GMOs is typically long and complex. For example, in crops this process has been recently described by Phillips McDougall (2011), who break it into seven 'activity stages', some of which overlap in time. The first stage is 'early discovery', involving preliminary screening and identification of genetic sequences with the potential to deliver the trait of interest. The second is 'late discovery', where the candidate genetic sequences are evaluated in model plant systems (such as the much-studied *Arabidopsis thaliana*). The third is 'construct optimization', where the candidate genetic sequences are combined with different promoter sequences to develop the most suitable genetic construct. The fourth is 'commercial event production and selection', where the optimized genetic constructs are introduced into the target crop species for subsequent evaluation under greenhouse and/or field conditions. The fifth is 'introgression, breeding and wide-area testing', where a number of genetic events are identified or selected on the basis of their biological activity for introgression into the most elite germplasm. The sixth is 'regulatory science', which involves conducting regulatory science studies and generating data in the field, greenhouse, growth chambers and laboratories. The seventh and final stage is 'registration and regulatory affairs', where results of the regulatory studies are submitted to the relevant regulatory bodies to seek approval for cultivation or for import. If approval is granted, commercialization can then begin. Phillips McDougall (2011) analyzed the experiences of six major multinational companies and reported that, for a single GM event, it took them on average 11.7, 12.0, 12.7 and 16.3 years to go from early discovery of the new trait to commercial sale in canola, maize, cotton and soybean respectively.

Apart from the particular target species used, the length of time required for commercialization is also affected by the sector involved (e.g. field trials of GM trees will take longer than those involving annual crops), and the strictness and requirements of the national regulatory framework.

While looking to the future will always involve a certain degree of speculation, a short time period has deliberately been chosen in this e-mail conference to try and keep the discussion firmly anchored on those products that already are at an advanced stage of development and thus are real candidates to be commercially released in developing countries within the next five years, i.e. before the end of 2017.

Choice of a short time period is also supported by the report of a session on GM crops in the pipeline held during a workshop organized in November 2011 by the European Commission Joint Research Centre, Institute for Prospective Technological Studies (JRC-IPTS) and FAO (Lusser et al., 2012). In discussing the accuracy of the commercial pipeline of GM crops, experts noted big discrepancies in the past between the announced and actual dates of release for certain GM events and concluded that commercial pipelines are not very reliable when dealing with the longer term, and should instead be focused on events in the later stages of R&D.

This was the approach used by JRC-IPTS recently when they brought together national regulators, industry representatives, experts from national and international research institutes and actors from the global food and feed supply chain to a workshop in November 2008 and, building on this, they predicted what GM crops might be commercially available by 2015 (Stein and Rodríguez-Cerezo, 2009). Compared to 2008, they predicted that the total number of commercial GM varieties cultivated worldwide by 2015 would be far higher for those species where GMOs were already approved (such as soybean, maize and cotton) and would also include those from species that were not yet approved, such as potatoes and rice. They also predicted that a wider range of traits would be commercially available by 2015, with herbicide tolerance and insect resistance continuing to dominate but with new traits such as crop composition (mostly type/proportion of oil and starch content), virus resistance, abiotic stress tolerance and disease resistance featuring prominently among the new approvals. They also predicted that substantial numbers of the new GM crops commercialized by 2015 would be developed in Asia (mostly India and China). For some of the crops, it seems now that the number of new approvals may be lower than predicted (Emilio Rodríguez-Cerezo, personal communication).

Comparable comprehensive and detailed studies of the GMO pipeline are not available for the other food and agricultural sectors. Nevertheless, we know that, compared to crops, investments in development of GMOs are modest in livestock and fish (Vázquez-Salat and Houdebine, 2012) and in trees (Kanowski, 2012), but that there is substantial research ongoing worldwide in these areas. For example, for forestry, Kanowski (2012) reported that over 700 field trials with GM trees of 30 genera have been carried out, most of them in the United States, of which over 70% involved *Populus*, *Pinus* and *Eucalyptus* species; 84 field trials have been approved in China, most with *Populus* and *Robinia*; and 18 trials of GM eucalyptus have been approved in Brazil.

In livestock, Vázquez-Salat and Houdebine (2012) reported that a small number of countries, particularly Argentina and China, have invested heavily in GM animals for food production while more have focused on GM animals for medical purposes. In China, it is reported that nearly 800 million US dollars were invested in GM pigs, cattle, sheep and crops between 2008 and 2012 and that over 20 GM food animals are being developed, including a fast-growing carp (Maxmen, 2012). Another fast-growing GM fish, the AquAdvantage Atlantic salmon, which has been modified by the addition of a Chinook salmon growth hormone gene under an ocean pout antifreeze protein promoter, is currently awaiting commercial approval in the United States (FDA, 2010; Maxmen, 2012).

For micro-organisms, there is active ongoing research involving GMMs in all the areas described in Section 2.5 as well as in a wide range of other areas where micro-organisms are useful in food and agriculture, such as the use of GMMs to modify rumen function in livestock (McSweeney and Mackie, 2012) or to convert biomass to biofuels (Ruane, Sonnino and Agostini, 2010).

In this brief Section, it has not been our intention to provide a systematic summary of the current status of GM crops, trees, livestock, fish and micro-organisms that may soon be commercialized in developing countries. Indeed, one of the goals of this e-mail conference is to allow a full and open exchange of information from stakeholders all around the world about the topic so that a good picture can emerge of what is likely to happen soon at the commercial level regarding GMOs in these different sectors in developing countries.

4. Specific points about this e-mail conference

This is the 18th e-mail conference to be hosted by the FAO Biotechnology Forum (<http://www.fao.org/biotech/biotech-forum/en/>) since it was launched in the year 2000. As with each conference hosted by the Forum, the focus is on applications in developing countries.

There are two main topics that people are asked to address in the conference:

4.1 What new GMOs are likely to be commercialized in developing countries within the next five years (i.e. before the end of 2017) in the crop, forestry, livestock, aquaculture and agro-industry sectors?

Specific questions that can be addressed regarding these new GMOs include:

4.1.1 Which species will they be?

4.1.2 Which traits will they have?

4.1.3 Will they be developed by the public sector, the private sector or through public-private partnerships?

4.1.4 Will they be produced in the developing countries themselves or, alternatively, will they be developed elsewhere (and then imported by developing countries for commercialization purposes)?

4.1.5 What kind of intellectual property management options will be exercised by the bodies commercializing these new GMOs?

4.2 What are the likely implications of these new GMOs for developing countries?

Specific questions that can be addressed regarding this topic include:

4.2.1 What are the likely implications of these new GMOs on food security and nutrition in developing countries?

4.2.2 What are the likely implications of these new GMOs on socio-economic conditions in developing countries?

4.2.3 What are the likely implications of these new GMOs on sustainable management of natural resources in developing countries?

4.2.4 What are the likely implications of these new GMOs on adaptation to climate change in developing countries?

4.3 Topics not covered by the conference

Each conference of the FAO Biotechnology Forum takes one particular theme that is relevant to agricultural biotechnologies in developing countries and opens it up for debate for a limited amount of time. This conference focuses on GMOs in the pipeline - those that are not yet released but which may be commercially available in developing countries within the next 5 years.

This conference does **not** include discussions on:

i) whether GMOs should or should not be used *per se* or the general attributes, positive or negative, of GMOs *per se*.

(Instead, the goal is to discuss the specific kinds of GMOs that are in the near pipeline – which ones are likely to be commercialized in developing countries within the next 5 years and what their implications may be for developing countries).

ii) GMOs which are already commercially available in developing countries

(If they are already commercially available, they are not in the pipeline).

iii) GMOs that are imported to developing countries just for consumption, i.e. for food, feed and processing.

(Instead, the conference focuses on the commercial release of the GMOs for use (cultivation/production) in the crop, forestry, livestock, aquaculture and agro-industry sectors in developing countries).

iv) The kinds of GMOs that are likely to be commercialized in developed countries within the next 5 years and what their implications may be for developed countries.

(The focus of the FAO Biotechnology Forum, and each of its conferences, is on applications in developing countries).

4.4 Instructions for sending a message

Before submitting a message to the e-mail conference, participants are requested to:

- a) ensure that it addresses the topics mentioned in Sections 4.1 and 4.2 above
- b) limit its length to a maximum of 600 words
- c) follow the ‘Guidelines for Sending Messages’ contained at the end of the Welcome Text that participants receive when they subscribe to the conference. Among other things, the Guidelines note that participants: are assumed to be speaking on their own behalf and not on behalf of their employers (unless they indicate otherwise); should introduce themselves briefly in their first posting to the conference, providing also their full work address at the end of the message; and may not post libellous, insulting or defamatory messages or materials, or links to such materials and should exercise tolerance and respect toward other participants whose views may differ from your own.

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ABBREVIATIONS: ABDC-10 = FAO conference on ‘Agricultural Biotechnologies in Developing Countries’; Bt = *Bacillus thuringiensis*; FAO = UN Food and Agriculture Organization; GMMs = Genetically modified micro-organisms; GMOs = Genetically modified organisms; JRC-IPTS = European Commission Joint Research Centre, Institute for Prospective Technological Studies.

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