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转基因作物在美国的发展、应用和趋势

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摘　要　2013 年，美国生物技术作物种植面积达到了 7 010 万 hm^2，占全球种植面积（1.75 亿 hm^2）的 40%，主要转基因作物平均普及率近乎达到了 90%。美国目前绝大多数被认证的生物技术作物都集中于改良农艺性状，其中尤其以抗生物逆境为主。在不远的将来，焦点仍会放在农艺性状特别是害虫的防治上，同时由于气候变化及耕地利用等一系列的外部环境压力不断增大，人们在耐非生物逆境胁迫方面也越来越有兴趣。农业生物技术不仅帮助世界范围内的农民提高农作物产量，改善土地的生态状况，同时可以提高资源的利用效率。这些技术的使用减少了耕作活动（这可以降低二氧化碳等温室气体的排放）、降低了水土流失和燃料的消耗。先进的害虫控制技术在增加现有土地的产量的同时也降低了将森林和荒地变为可耕地的压力。如果目前要求生物技术无风险的过严监管政策、有组织的造谣惑众、资源缺乏的状况得不到改变，那么不仅是不能提高环境收益，就连改善营养品质、减少采后损失和促进食物安全等方面的潜力也难以发挥。

关键词　遗传工程；转基因生物；动植物检疫局；同源转基因；异源转基因；基因组编辑
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据估计，为了满足 2050 年世界人口对粮食的需求，全世界必须用更少的土地，更少的水、能源、化肥和农药等投入来增产 70%～100%。这就需要更先进的粮食作物生产体系来应对系列的巨大变化，包括日益增长的人口、急速变化的气候、逐渐减少的资源；逐渐变化的饮食习惯以及消费者对安全、高质量、营养丰富且便利的食品的需求。鉴于这些变化，需要有创新的技术来保证人体可获得的、经济上实惠且富含营养的粮食的充足供应。从食品匮乏的市中心到贫瘠的荒地，获得健康的饮食对很多人来说仍是奢望。只有在发达国家和发展中国家都能广泛使用的技术才能消弭两者之间在食品上的不平等。与发达国家急剧增加的肥胖、心血管疾病、糖尿病、癌症以及相关的疾病形成鲜明对比的，则是欠发达国家的慢性营养不良。这类问题都需要一种改良的食品，生物技术虽然不是唯一的解决方案，但必然会起到重要的作用。可持续集约化发展将是大势所趋。

2013 年，美国的转基因作物占地 7 010 万 hm^2，占了全球总种植面积（1.75 亿 hm^2）的 40%，在主要作物中的普及率平均约 90%（图 1）[1]。其主要的作物是大豆、玉米和棉花，而主要的改良性状是耐除草剂（主要为草甘膦）和抗虫（来自苏云金芽孢杆菌，简称 Bt）。2013 年美国约一半的土地（1.69 亿英亩）种植转基因作物，包括抗虫玉米、耐除草剂油菜、耐除草剂甜菜、耐除草剂苜蓿和抗病毒的木瓜和南瓜。

基于美国农业部提供的数据，耐除草剂大豆的种植面积比例从 1997 年的 17%增长到 2001 年的 68%，2014 年达到了 94%。耐除草剂棉花的种植比例从 1997 年的 10%到 2001 年 56%，2014 年达到了 91%。而耐除草剂玉米的种植虽然在前几年增加较缓慢，但在 2014 年也达到了 89%。抗虫型 Bt 基因从 1996 年以来一直应用于玉米和棉花，抗虫玉米的种植比例从 1997 年的 8%增加到 1999 年的 26%，而在 2000 年和 2001 年的时候降到了 19%，2003 年达到了 29%，2014 年更是高达到 80%。这几年种植面积的增加很大程度上可能是因为 Bt 玉米新品种的商业引入，其同时对欧洲玉米螟、食根虫与食穗虫具有抗性，而之前的 Bt 玉米只针对欧洲玉米螟。抗虫棉花的种植面积也增加很快，从 1997 年的 15%上升到 2001 年的 37%，2014 年达到了 84%[2]。

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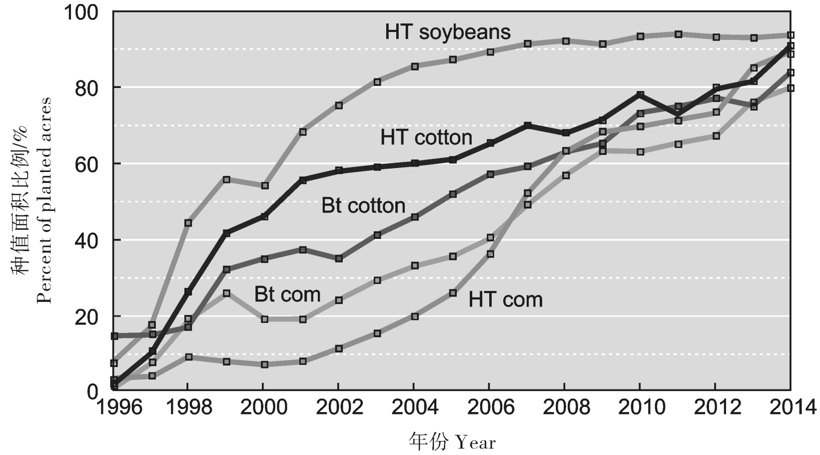
抗虫玉米还有一个间接效应:减少了害虫侵害的同时也减少了真菌的侵染,这可减少对健康有严重伤害的真菌毒素的污染。根据 Hutchisons 等的报道[3],转基因玉米使人们在过去的14年中获得了32亿到36亿美元的效益,而其中有19亿到24亿美元是来自于“光环保护效应”带给非转基因玉米种植者的。人们认为这与对害虫种群抑制的理论预测一致(转基因种植区对害虫的有效防治可以惠及周边非转基因种植区),这种经济利益可以促使种植户维持非抗虫玉米中存在的抗虫性遗传资源。随着欧洲螟虫和玉米根虫哪一个是转基因玉米的主要目标的变化,转基因玉米的种植在未来仍会有一些波动。同样,转基因抗虫棉的种植取决于它们的目标害虫到底是烟草蚜虫、棉铃虫还是棉红铃虫。抗虫的保护效应已经达到最佳并使得其种植面积趋于稳定。所有种植的转基因玉米已经占了玉米总种植面积的93%。所有的转基因棉花,包括耐除草剂和抗虫品种,达到了棉花总种植面积的96%,与之相近的是转基因大豆占94%。由于大豆不会受一些主要的害虫的侵害,所以抗虫的转基因大豆还没有研发。

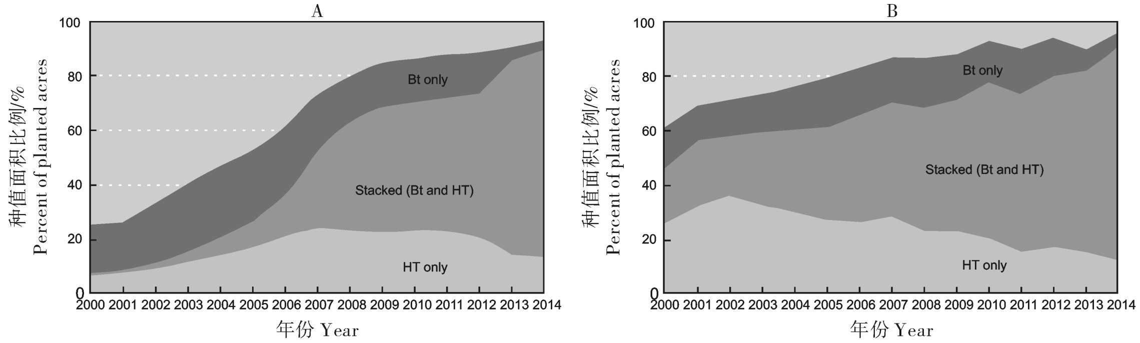
在生物耐逆境方面,人们的焦点已经转移到多性状叠加的转基因控制体系(图2A,B)[2]。理论上可以获得双重效益,提高广谱性效果同时多重高效抗逆特性可以组合,这时选择压力也较低。最近几年,人们越来越接纳多重转基因品种,2014年,多效转基因棉花占总棉花种植面积的79%。玉米则为76%。Monsanto(孟山都)公司与Dow(陶氏)公司合作研发出了八重抗逆抗虫特性的组合品种——



Data for each crop category include varieties with both HT and Bt(stacked) traits.
Sources:USDA,Economic Research Service using data from Femandez.Comejo and MoBride(2002) for the years 1996–1999 and USDA, National Agricultural Statistics Service. June Agricultural Survey for the years 2000-2014.

图1　1996—2014年转基因作物在美国的种植情况[2]

Fig.1　Adoption of genetically engineered crops in the United States,1996—2014[2]



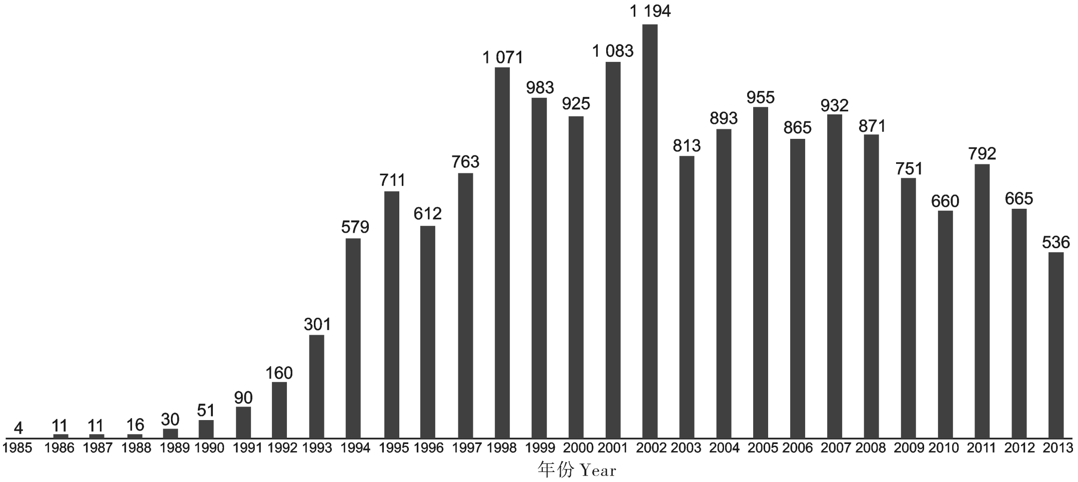
Source: USDA, Economic Research Service using data from USDA, National Agricultural Statistics Service, June Agricultural Survey.

Source: USDA, Economic Research Service using data from USDA, National Agricultural Statistics Service, June Agricultural Survey.

图2　2000—2014年美国转基因玉米(A)和转基因棉花(B)所改良的目标性状趋势[2]

Fig.2　Adoption of genetically engineered corn (A) and genetically engineered cotton (B) in the United States,by trait,2000—2014[2]

SmartStax，可以一并防治地上地下昆虫并且耐广谱除草剂，其综合利用了多种优势，包括 Yieldgard VT Triple（来自 Monsanto 公司）、HerculexXtra（属于 Dow 公司）、oundUp Ready 2（Monsanto 公司）和 Liberty Link（来自 Dow 公司）。玉米、棉花和大豆已有商业化品种，而更多的 SmartStax 作物品种正在研发中。据估计，在抗虫能力方面，这一品种只需要种植 5％的普通棉花供害虫食用，即可媲美之前 20％所达到的效果[4]。目前为止，害虫对 Bt 转基因作物产生抗性的情况极少，对经济和农业的影响甚微[5]，但有一些迹象表明害虫针对抗虫作物的抗性在某些区域正在显现。此外，由于美国对草甘膦的过度依赖，杂草的多样性降低，这已经促使 14 种杂草出现了对草甘膦除草剂的耐受[6]。



＊ 截至 2013 年 9 月 24 日。

转基因生物体（大部分是植物）被批准田间释放是指经美国农业部的动植物检疫局（APHIS）批准，技术提供者可以进行田间试验。

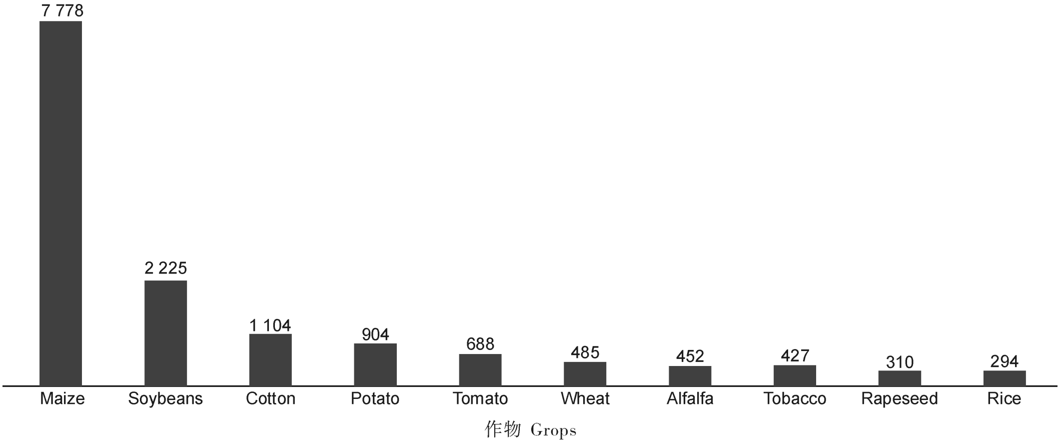
来源：生物技术信息系统（ISB，2013），美国农业部经济研究中心（ERS，2014）。[2]

＊ As of September 24，2013.

Authorizations for field releases of GE organisms (mostly plant varieties) are issued by USDA's Animal and Plant Health Inspection Service (APHIS) to allow technology providers to pursue field testing. Source：Information Systems for Biotechnology (ISB，2013) and USDA Economic Research Service (ERS，2014)[2].

图 3 1985－2013 年美国农业部的动植物检疫局通过的转基因生物品种数目

Fig. 3 Number of releases of genetically engineered (GE) organisms varieties approved by APHIS，1985－2013＊



田间释放测试是经美国农业部的动植物检疫局（APHIS）批准的。

来源：生物技术信息系统（ISB，2013），美国农业部经济研究中心（ERS，2014）。[2]

Authorizations for field releases of GE plant varieties are issued by USDA's (APHIS).

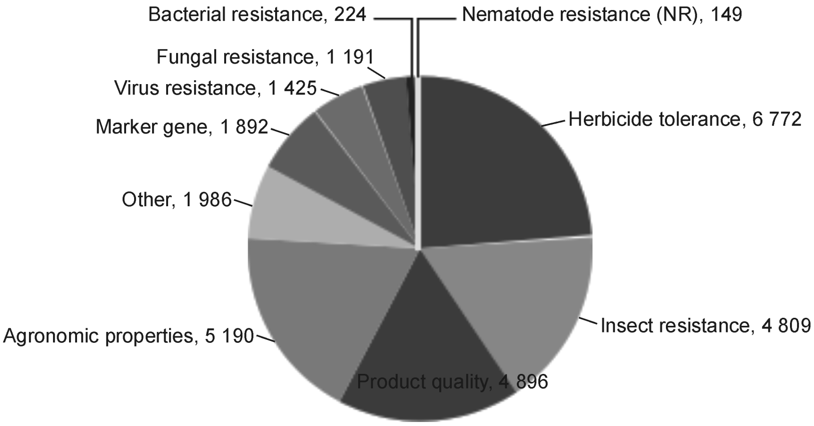
Source：Information Systems for Biotechnology (ISB，2013) and USDA Economic Research Service (ERS，2014)[2].

图 4 10 大重要作物中经美国农业部动植物检疫局（APHIS）批准的田间释放的数目

Fig. 4 Number of releases approved by APHIS：Top 10 crops

用于田间试验的转基因作物品种从1985年到2013年已经累积超过17 000例（图3）。其中大多是主要粮食作物，特别是玉米，其在2013年共有约7 800例被批准进入田间试验程序。此外，通过批准的还包括超过2 200例转基因大豆，1 100例转基因棉花，还有约900例转基因马铃薯（图4）。这些转基因品种特性包括耐除草剂（6 772例），抗虫性（4 809例），改善品质如味道或营养（4 896例），农艺特性（例如抗旱性等，共5 190例），还有抗病毒或真菌（2 616例）（图5）[6]。

农业资源管理局的调查表明，农民更愿意种植转基因玉米、棉花和大豆的原因主要是可以提高产量。其他原因还有节省管理时间、促进其他生产实践（如轮作和保护性耕作）以及减少农药成本[6]。



允许田间释放的转基因品种指经美国农业部动植物检疫局许可用于田间试验的转基因作物。数字表示每一种转基因性状的许可例数统计。http://www.aphis.usda.gov/biotechnology/status.shtml.

来源：生物技术信息系统（ISB，2013），美国农业部经济研究中心（ERS，2014）。[2]

Authorizations for field releases of GE plant varieties are issued by USDA's Animal and Plant Health Inspection Service(APHIS) to allow technology providers to pursue field testing. Counts refers to the actual number of approved release locations per phenotype category. http://www.aphis.usda.gov/biotechnology/status.shtml.

Source: Information Systems for Biotechnology (ISB, 2013) and USDA Economic Research Service (ERS, 2014).

图5 经美国农业部动植物检疫局许可的转基因性状

Fig.5 Number of releases approved by APHIS by GE trait

除了抗生物胁迫，批准的转基因作物还包括改良的抗非生物胁迫和良好的农艺特性（耐寒冷、干旱、霜冻和高盐，提高氮利用效率，增加产量）；增强的品质，如延迟成熟、更美味，以及纹理色泽（水果和蔬菜）；增加蛋白质或碳水化合物、脂肪酸及微量元素的含量；改良淀粉、颜色（棉花和花等）、纤维品质（棉花）或谷蛋白含量（小麦）；去咖啡因（咖啡）；保健物质（如添加维生素、铁、抗氧化剂如β-胡萝卜素等）乃至药品等（表1）[6]。

除了大规模商品，遗传工程也为一些特种作物提供帮助，如抗病毒的“Rainbow”木瓜，利用转录后病毒基因沉默——RNA干扰（RNAi）技术的一种——顾名思义“Rainbow”拯救了夏威夷的这个行业，因为在木瓜栽培种中根本没有自然的抗木瓜环斑病毒的能力[7]。Rainbow木瓜通过减少岛上的病毒总量也帮助了有机种植者。因为存在着引起柑橘绿化的细菌（*C. liberibacter*）[8]，佛罗里达柑橘产业也面临类似问题。而对于这个毁灭性的病原体，没有已知的有效且可持续的控制体系，目前方法主要是砍伐掉整个果园，这不仅激进，而且并非有效。对于这种病原体，从其他植物中获得抗性基因的生物技术解决方案已经有了进展。同样需要拯救的还有加州葡萄酒行业，其面临一种难治的细菌病害，而没有可行的有效且可持续的控制方法。苹果生产中主要利用抗生素喷洒以控制火疫病，即便有机苹果也是如此，然而在20世纪90年代末就通过生物技术研发出一个抗性品种Gala苹果，由于解除管制的过程成本太过高昂，该品种只能困于实验室中。

但总体上来说，这些特种作物的缺乏应该引起注意。这并非由于对它们需求不够，而是通过解除限制过程的高昂成本使人望而却步。目前很多得到许可的作物也支持上述观点，即解除限制过程只有资本充足的大公司才有实力涉足，而这些大公司主要针对上述大型商品化粮食作物。特种作物监管问

表 1 目前已经可以获得及正在研发中的转基因作物

Table 1 Biotech crops currently available and in development

Crop	Input traits				Output traits	
	Herbicide tolerance	Insect resistance	Virus/fungi, resistance	Agronomic properties[11]	Product quality[14]	Pharmaceuticals/ nutraceuticals[17]
Corn	C	C[5+]	D	C[12]D	D	D
Soybeans	C	D		D	C[15]D	
Cotton	C	C[6]		D	D	
Potatoes		W[7]	D	D	D	D
Wheat	C[2]		D			
Other field crops[1]	C[3]D[4]	D	D	D	D	D
Tomato, squash,melon, sweetcorn		C[8]	C[9]D	D	C[16]D	D
Other vegetables	D				D	
Papaya			C[10]			
Fruit trees			D		D	
Other trees				D[13]	D	
Flowers					D	

[1] Includes barley, canola, peanuts, tobacco, rice, sugar beet, alfalfa, etc.

[2] Monsanto discontinued breeding and field level research on its GE Roundup Ready wheat in 2004.

[3] Canola, sugar beet, alfalfa.

[4] Barley, rice.

[5] Bt corn to control the corn borer commercially available since1996; Bt corn for corn rootworm control commercially available since 2003; Bt corn to control the corn earworm commercially available since 2010; stacked versions of them also available.

[6] Bt cotton to control the tobacco budworm, the bollworm, and the pink bollworm, commercially available since 1996.

[7] Bt potatoes, engineered to be resistant to the Colorado potato beetle were commercially introduced in 1996 and withdrawn in 1999 due to push back by McDonalds.

[8] Sweet corn with insect resistance (to the corn earworm and European corn borer) was planted in about 20 000 acres and sold in the fresh market in 2008[5].

[9] Cucumber virus resistance squash accounted for about 12 percent of the squash produced in 2005[5].

[10] In response to papaya ringspot virus (PRSV) epidemic, researchers at Cornell University and at the University of Hawaii developed two virus-resistant varieties of GE papaya. First commercial plantings were made in 1998.

The new varieties were successful in resisting a PRSV epidemic and were planted on more than 30 percent of Hawaii's papaya acreage in 1999.

[11] Such as resistance to drought, frost, salinity; more efficient use of nitrogen.

[12] Drought tolerant maize approved for commercial use in 2011.

[13] Modified lignin content.

[14] Includes delayed ripening (fruits and vegetables with longer shelf life); protein content, carbohydrate content, fatty acid content, micronutrient content, oil content, modified starch content, flavor and texture (fruits and vegetables), color (cot-ton, flowers), fiber properties (cotton), gluten content (wheat), naturally decaffeinated (coffee), and low phytase.

[15] High oleic soybeans.

[16] FlavrSavr tomato genetically engineered to inhibit enzymatic breakdown of the cell wall was removed from the market because of production and marketing problems.

[17] Includes increased vitamin, iron, beta-carotene, lycopene, amino acid content; substitute sugar; hypoallergenic crops; antibodies, vaccines. Industrial uses (high amylopectin potato).

Sources: ISB (2013); National Research Council (2010)[5]; USDA Animal and Plant Health In section Service, ERS, 2014[2]. (Modified from Fernandez-Cornejo, J. 2014)[6].

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[8] Pharmaceutical plant compounds produced are intended for pharmaceutical use and must be approved from at least one of the following agencies prior to commercialization: U. S. Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (human biologics), FDA Center for Drug Evaluation and Research (human drugs), FDA Center for Veterinary Medicine (animal drugs), and USDA Center for Veterinary Biologics (animal biologics).

None of the plants currently under permit produce pharmacologically active compounds.

讯处(SCRA)的创建就是来解决这样的问题，他们在 2011 年 12 月举行了一个研讨会，对转基因特种作物如何提交相应机构进行管理的具体细节进行了讨论。对农业生物技术有司法权的美国三大管理机构(USDA-APHIS，美国农业部动植物检疫局；EPA，美国环保署；FDA，美国食品和药物管理局)都参与了这次研讨会并展开合作[9]，然而这之后，基本没有太多的进展。

全世界的监管体系存在不对称性并缺乏共识。基于无假设的评估已经成为了全世界的标准，并且这些已经收录在卡塔赫纳议定书的路线图(Cartagena Protocol’s Roadmap)中，这导致了安全评估成本直线上升，在安全性方面却没有明显增强。鉴于当前的监管情况，很难想象改良的特种作物，特别是品质性状得以改善的作物得以投入市场。这无形阻碍了大宗粮食作物和一般性状之外的各种创新性研究。

一些产品已经在技术层面成功地走了监管过程的捷径。这是通过一个称作“询问信”(letter of inquiry)的机制，当开发者们不确定他们产品的监管情况时可以寻求美国农业部动植物检疫局的生物技术监管服务中心(BRS)的意见[10]。通过提交一份包含以下信息的署名询问信，包括(i)目标表型/性状，(ii)遗传修饰的成分和来源，(iii)指定的接受者/受体，美国农业部动植物检疫局会给开发者提供一个关于他们指定技术或产品的监管状况的评估回复。目前已经有 26 封这样的信件提交上去(表 2)，前面已经提到，这 26 封信中许多来自小型生物技术公司或公共研究所，得到的回复是依旧没有进入监管流程，说明更小的实体机构若通过这项监管可能需要更多考虑[11]。基于他们最后的产品的性质、转化过程或近期发展的转基因技术的利用，这 26 封询问信可以大致分为 4 种类型，包括无效分离(例如 cre-lox 特异性位点基因重组研发的早花且持续开花)、基因转移体系(biolostics 微粒转移造就的柳枝稷)、同源/异源转基因(例如 RNA 干扰研发的花青素改良葡萄)和定向位点核酸酶切精确育种(一般指基因组编辑)，未归入以上分类的都算作第 5 类(表 2)。

表 2 对监管状态的询问信

Table 2 Letters of inquiry on regulated status

Category	Inquiry Date	Applicant	Host Organism	Genetic Modification/Phenotype	Transformation Method	Status
I Null Segregants	01/18/11	USDA Agricultural Reseach Service	Plum	Accelerated Breeding (***Null Segregant***)	N/A	--
	01/22/11	North Carolina State University	Tobacco	Accelerated Breeding (***Null Segregant***)	N/A	--
	12/10/11	Univeristy of Nebraska	Sorghum	Decreased MSH1 Expression (***Null Segregant***)	Agrobacterium tumefaciens	--
	01/27/11	New Zealand Institute for Plant and Food Research	N/A	Genome Editing (Production of Double Haploids)	***Centromere-Mediated Chromosome Elimination*** (*CCE*)	--
II Gene Delivery Systems	03/08/95	(none listed)	Carnation	(none listed)	***Agrobacterium tumefaciens***	--
	09/01/09	Noble Foundation	Barrel Medic	*Tnt1* Retrotransponson Expression (Knockout Library)	***Agrobacterium tumefaciens***	Regulated
	07/30/12	Del Monte Fresh Produce Company	Pineapple	Altered Fruit Tissue Color/Anthocyanin Content	***Agrobacterium tumefaciens***	--
	12/11/07	New Zealand Crop and Food Limited	Petunia	Altered Vegitative Pigmentation	***Biolistics***	--
	09/13/10	Scotts Company	Kentucky Bluegrass	Glyphosate Tolerant	***Biolistics***	--
	01/20/12	Ceres, Inc.	Switchgrass	Improved Biofuel Yield Potential	***Biolistics***	--
	01/31/12	Scotts Company	Kentucky Bluegrass	Glyphosate Tolerant, Enhanced turfgrass quality	***Biolistics***	--
	02/01/12	Scotts Company	St. Augustinegrass	Glyphosate Tolerant, Enhanced turfgrass quality	***Biolistics***	--
	07/23/12	Ceres, Inc.	Switchgrass	Enhanced Water-use Effificency	***Biolistics***	--
	07/23/12	Ceres, Inc.	Switchgrass	Biomass more easily converted to fermentable sugars	***Biolistics***	--
	07/23/12	Ceres, Inc.	Switchgrass	Biomass more easily converted to fermentable sugars	***Biolistics***	--
	07/23/12	Ceres, Inc.	Switchgrass	Biomass more easily converted to fermentable sugars	***Biolistics***	--
III Cisgenics	02/23/12	Wageningen University	Apple	Scab (Disease) Resistant (***Cisgenic***)	Agrobacterium tumefaciens	Regulated
	02/08/12	University of Florida	Grape	Increased Anthocyanin Production (***Cisgenic***)	Biolistics	--
IV Precision Breeding	03/01/10	Dow	Corn	Suppressed Phytate Biosynthesis	***Zinc-Finger Nuclease*** *(EXZACT™)*	Regulated*
	09/09/11	Cellectis	N/A	Genome Editing (Targeted Indels)	***Meganuclease*** *(I-Cre1)*	Regulated*
V Other	03/07/94	Washington State University	Rhizobium leguminosarum	Insect Tolerance	(none listed)	--
	02/16/05	V.P. Technology Development	*Chlamydomonas reinhardtii* HSV8	Expression of Antibodies for Human Therapeutics	(none listed)	--
	04/06/08	Coastal Biomarine	Algae strains	Expression of Glucose Transporter from *Chlorella*	(none listed)	--
	02/21/11	Danziger	Baby's Breath	Altered Flower Color	(none listed)	--
	06/15/12	BioGlow LLC	[CBI]	[CBI]	[CBI]	--
	10/23/12	BioGlow LLC	[CBI]	[CBI]	[CBI]	--

*Transgenic crops genetically modified by targeted deletions, during which no plant pest genetic informaion is incorporated into the host genome, were determined to fall outside of the scope of 37 CFR Part 340; Transgenic crops genetically modified by targeted insertions would have to be reviewed on a case-by-case basis to determine regulatory status.

表中粗斜体代表特定的分类，红色字体代表监管状态的可能原因。此表来自 Chi-Ham et al，2014 [11]，略有修改。Bold，italicized texts indicate the criteria that were used to assign queries to particular *ad hoc* categories. Red text indicates the understood reason for a ‘regulated’ status determination. Modified from Chi-Ham et al，2014[11].

2 个有意义的品质性状正在借助 RNA 干扰技术得到改良。第 1 个是 Artic 苹果已经得到改良可以抗氧化，因为切开的苹果其切面由于接触氧气会激活多元酚氧化酶(PPO)而氧化变黄，为了达到抗氧化的目的，Okangan 共表达了 PPO 基因并通过沉默内源性的 PPO 有效获得了低氧化的效应[12]。第 2 个是 Simplot J R 研发的低丙烯酰胺马铃薯 ，这一款品种有 3 个提高品质的修饰，研究人员将此

命名为“Innate”(固有的)技术，基本是通过 RNA 干扰技术沉默马铃薯中调控黑斑、天门冬酰胺和还原糖的基因的表达来实现。

这种非理性的管理措施在转基因动物万面达到了更匪夷所思的地步，其将转基因动物定义为“旨在影响人体或其它动物的结构或功能的物品(而不是食品)”，而把转基因的动物食品当做药物来管理，这明显忽略了一个事实，即所有类型的传统育种食品都有着相似的定义！因此，转基因动物食品必须通过美国食品与药品管理局的新动物药品准许过程。这意味着转基因动物产品必须证明其安全、有效，同时需要按照《国家环境政策法》的要求，提供一份对环境影响的评估。Van Eenennaam 等[13]指出，与转基因植物面临境况一样，将传统育种和转基因动物置于完全不同的监管标准之下，这不仅与科学观点不一致，也对发展遗传工程技术强加了过多的负担。他们同时指出，只强调评估转基因动物食品的潜在风险而忽略其带来的受益是相当不公平的。即便存在，也少有技术可以在只强调风险的评估中继续发展。他们以鲑鱼为例，野生捕获耗尽了海洋中的鲑鱼，已经找不到长期的、生态可持续的办法满足全球鲑鱼需求。而发展转基因鲑鱼的益处之一就是面临耗尽海洋资源的时候帮助缓解这一压力。

最后需要指出的是，转基因产品的商业化仅仅是历史长河中人类为满足社会需求而与自然互动的又一阶段，因此，应当与传统食品安全评价的标准一致。借助遗传修饰来辅助育种已经有了长久且安全的历史，生物技术不过是以更加精确的方法延续了它的优势而已。最核心的一点就是监管体系应该在充分保护消费者和环境的同时，不能阻碍有益的科技创新[14-15]。含有 2 个野生种基因的抗晚疫病的 Fortuna 马铃薯就是这样一个例子，这解决了喷洒包括有机许可的硫酸铜在内的各种杀菌剂的问题，可以带来 50 亿美元的效益，然而，尽管其对种植者和环境都有潜在的巨大效益，由于获得欧盟监管通过的可能微乎其微，它的研发者正准备放弃。当然，欧盟国家的农民经济上可以承担继续使用杀菌剂的成本，但是没有其他可替代选择的低收入农民却可以从这些改良的抗病品种中获得较大收益。类似的，转细菌性斑点抗性基因品种已经在胡椒和番茄中被应用，其可以大幅增加产量并消除含铜农药的使用[16]。

显然，在发展、使用新的资源优化型科技过程中会遇到一系列挑战，包括需要解决的科技本身和科技转化等复杂问题，才能更好地改良性状。针对性状改良的技术不断发展，包括基因组编辑方面的诸多新方法将利用优良表型的快速基因渗入达到精细改良性状的目的。此外，合适的机制也需要落实到位以促进下游开发、部署乃至商业化。我们都知道没有投资就鲜有创新，但公众对种子科技领域知识产权的所属以及法人权限认识的提高抱有负面态度，这会对企业雇佣带来负面影响，特别是小农场。降低知识产权关卡、改进商业化策略以及促进有利科技转化的机制必须到位。对于生物科技产品真实风险的过度的担心将导致全球市场的过度监管和过度反应。传统与新兴两个生产体系的共存需要合理的容忍和适当的切实可行的界定。全球不同国家针对作物科技的监管方法并不一致，并且很大程度上并不科学。规章制度需要在确保对于消费者和环境足够安全的同时，不得妨碍有益的科技创新，并且不能默许对过时的、低效且非可持续的方法依赖。目前的选择往往并不是可持续性最佳或者伤害最小化的。围绕新兴生物科技的不实宣传不断扩张，讨论议程也已经被种种不良动机的言论所侵占[17]。

一系列科学证据表明转基因食品并不会对人类健康带来所谓新的不同寻常的危害。绝大多数的科学研究者、医药专家、美国医学会及美国食品与药品管理局都持有一致意见：转基因食品是安全的。世界卫生组织已经正式声明“在已经允许转基因商业化国家中已经证明，人们食用安全认证的转基因产品没有任何副作用”。据估计，过去的 16 年全世界共食用了 2 万亿份含有转基因成分的膳食，没有一例被证明对健康有害。美国科学院重复性研究也证明如此。大约 700 到 1 000 份经过同行评议的科学研究也表明利用现代生物科技生产的农产品是安全的。加州大学戴维斯分校近期的一项研究考察了引入转基因食品前后长达 29 年来自动物的上千亿生物学数据，发现转基因食品的引入对家畜健康和生育率没有任何影响。假设获得的转基因食品的 70%～90%被用于饲养为人类提供肉食品的家畜，那每年高达 90 亿头家畜中的 95%所吃的饲料中含有转基因成分，因此，我们就有理由相信转基因食品对动物健康没有任何副作用[17]。即便在欧盟中存在反对声音，欧盟委员会在 2011 年的一项总结报告

涵盖了过去25年共有130个研究项目及500个研究团体得到的一致结论：“没有任何科学证据表明转基因食品对环境及食品安全比传统食品有更高风险”。这个报告进一步概括到：“同样没有任何证据表明转基因食品存在多世代的长期潜在风险”。

为了应对种种误导性的信息，基于科学证据的更加有效的交流机制必须建立起来，同时新兴科技与传统实践间的潜在风险与收益也需要真实的、恰当地进行比较。生物科技提供了高效且低廉的途径来获得更高质量的食品、饲料、纤维以及其他更多创新性的高附加值产品。过分的监管负担将使得人们强制性维持过时、低效且不可持续的体系，这对粮食安全来说注定是有害的。

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Future directions, development and application of GM crops in the USA

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Abstract In 2013, the US led production of biotech crops globally with 70.1 million hectares which amounts to about 40% of total global acreage (175 million hectares), with an average adoption rate of approximately 90% across its principal biotech crops. The vast majority of biotech products approved to date in the US are in the area of agronomic traits, most specifically biotic stress management. The principal focus in the immediate future will remain on agronomic traits especially the area of pest control but with an increasing interest in abiotic stress tolerance which is gaining prominence as external pressures from climate change to land use change. Agricultural biotechnology already has helped farmers around the world boost their productivity and grow crops in more ecologically healthy fields while allowing much more efficient use of resources. This technology allows reduced tillage, which cuts down on greenhouse gas emissions, water runoff, soil erosion and fuel consumption. Improved pest control increases yields on existing acreage and reduces the pressure to convert forests and wildlands into farmland. In addition to environmental benefits the potential for improved nutrition, reduced postharvest losses and increased food safety may remain unfulfilled if barriers such as disproportionate and non-risk-based regulatory regimens; effective disinformation campaigns and lack of resources prevail.

Key words genetic engineering; genetically modified organism; animal plant health inspection service; cisgenics; intragenics; genome editing

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To meet the world needs by 2050, it is estimated that 70%-100% more food must be produced from less land and fewer inputs, using less water, energy, fertilizer and chemical pest controls. This will require significantly enhancing food and agricultural production systems in order to respond to a number of transformative changes, such as a growing world population, changing climate, diminishing resources, shifting diets, rising consumer demands for improved food quality, safety, nutritional content, and convenience. In light of those changes, new and innovative techniques will be required to ensure an ample supply of physically and economically accessible nutritious food. From the food deserts of inner cities to the barren wastelands of many regions, access to a healthy diet remains elusive for many. The inequities between the affluent and developing countries must be addressed using technologies that are scalable across these economic imbalances. Dramatic increases in the occurrence of obesity, cardiovascular disease, diabetes, cancer and related ailments in developed countries are in sharp contrast to the chronic malnutrition in many Less Developed Countries (LDCs). Both problems require a modified food supply, and the tools of biotechnology, while not the sole solution, do have a significant role to play. Sustainable intensification is the future.

In 2013, the US still led production of biotech crops globally with 70.1 million hectares which amounts to about 40% of total global acreage (175 million hectares), corresponding to an average adoption rate of approximately 90% across its principal biotech crops (Fig.1)[1].

The principal crops are soybean, maize and cotton and the principal traits are Herbicide-tolerance (HT) primarily glyphosate and insect resistance (*Bacillus thuringiensis*- Bt). U.S. farmers planted about 169 million acres of these genetically engineered (GE) crops in 2013, or about half of total land used to grow crops. The minor crops are Bt sweet corn, HT canola, HT sugar beets, HT alfalfa and virus resistant papaya and squash.

Based on USDA survey data, HT soybeans went from 17 percent of U.S. soybean acreage in 1997 to 68 percent in 2001 and 94 percent in 2014. Plantings of HT cotton expanded from about 10 percent of U.S. acreage in 1997 to 56 percent in 2001 and 91 percent

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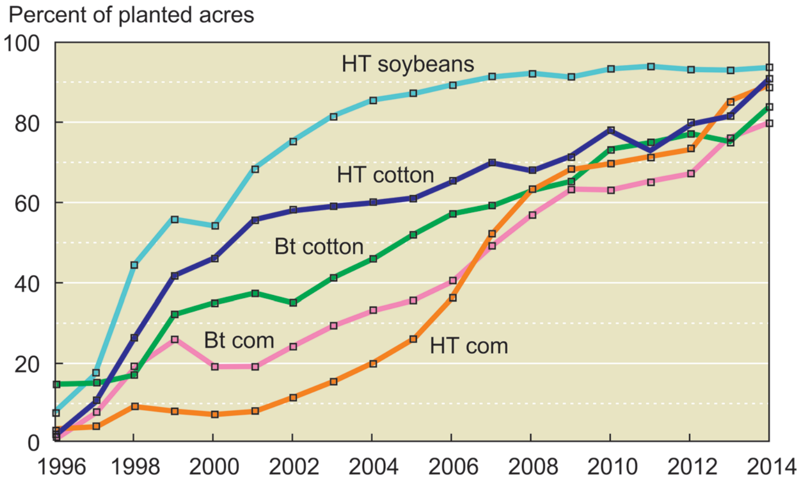


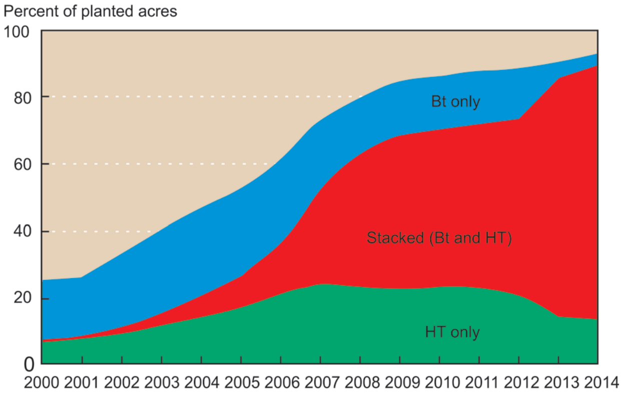
Data for each crop category include varieties with both HT and Bt(stacked) traits.
Sources:USDA,Economic Research Service using data from Femandez.Comejo and MoBride(2002) for the years 1996-99 and USDA, National Agricultural Statistics Service. June Agricultural Survey for the years 2000-2014.

Fig.1 Adoption of genetically engineered crops in the United States,1996-2014[2]

in 2014. The adoption of HT maize, which had been slower in previous years, has accelerated, reaching 89 percent of U.S. maize acreage in 2014.Insect-resistant Bt traits have been available for maize and cotton since 1996. Plantings of Bt maize grew from about 8 percent of U.S. maize acreage in 1997 to 26 percent in 1999, then fell to 19 percent in 2000 and 2001, before climbing to 29 percent in 2003 and 80 percent in 2014. The increases in acreage share in recent years may be largely due to the commercial introduction of new Bt maize varieties resistant to the maize rootworm and the maize earworm, in addition to the European maize borer, which was previously the only pest targeted by Bt maize. Plantings of Bt cotton also expanded rapidly, from 15 percent of U.S. cotton acreage in 1997 to 37 percent in 2001 and 84 percent in 2014[2].

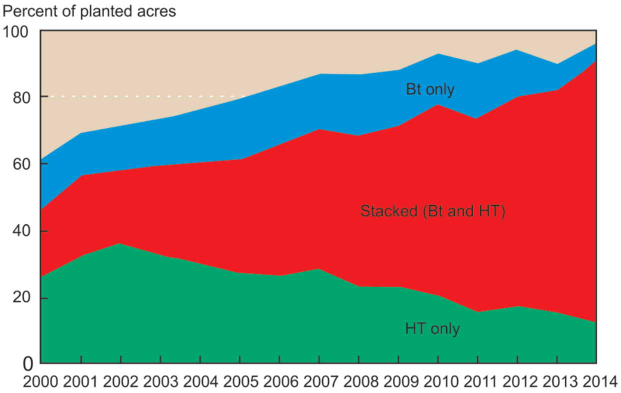
Insect-resistant maize also has a collateral effect: less insect damage results in much less infection by fungal molds which reduces mycotoxin contamination, a serious health hazard. Likewise, Hutchison et al[3] has demonstrated that insect-resistant Bt maize has led to cumulative benefits over 14 years of between \$3.2 and \$3.6 billion with \$1.9 to \$2.4 billion of this total accruing to non-Bt maize growers through a "halo" protective effect. They postulate that these results affirm theoretical predictions of pest population suppression and highlight economic incentives for growers to maintain non-Bt maize refugia for sustainable insect resistance management. Use of Bt maize will likely continue to fluctuate over time, based on expected infestation levels of European corn borer (ECB), and the maize rootworm which are the main pests targeted by Bt maize. Similarly, adoption of Bt cotton depends on the expected infestation of Bt target pests, such as the tobacco budworm, the bollworm, and the pink bollworm. Adoption appears to have plateaued, as adoption has already occurred on acreage where Bt protection is optimum. Adoption of all biotech maize accounted for 93 percent of maize acreage in 2014. Adoption of all GE cotton, taking into account the acreage with either or both HT and Bt traits, reached 96 percent of cotton acreage in 2014, versus 94 percent for soybeans. Soybeans are not susceptible to any major insect predation, so insect-resistant varieties have not been developed.

On the biotic stress tolerance side the focus has moved to multi-tiered "stacked" control systems (Fig. 2a, 2b)[2]. This in theory serves a double advantage, primarily expanding the effectiveness of the broad based resistance events but also allowing more effective management of the resistance trait since there is less selective pressure when genes are stacked. Adoption of stacked varieties has accelerated in recent years. Stacked cotton reached 79 percent of cotton plantings in 2014. Plantings of stacked maize made up 76 percent of maize acres in 2014. SmartStax an eight trait event developed through collaboration between Monsanto and Dow takes advantage of multiple modes of insect protection and herbicide tolerance against above and below ground insects and provides broad herbicide tolerance including Yieldgard VT Triple (Monsanto), HerculexXtra (Dow), RoundUp Ready 2 (Monsanto), and Liberty Link (Dow). It is available for maize, cotton and soybean, and specialty crop variations are in the pipeline. It is estimated that this should require only 5% refuge acres as opposed to the 20% required of older technologies to mitigate against the development of pest tolerance[4]. So far, the emergence of insect



Source: USDA, Economic Research Service using data from USDA, National Agricultural Statistics Service, June Agricultural Survey.

Fig.2a Adoption of genetically engineered corn in the United States, by trait,2000-2014[2]



Source: USDA, Economic Research Service using data from USDA, National Agricultural Statistics Service, June Agricultural Survey.

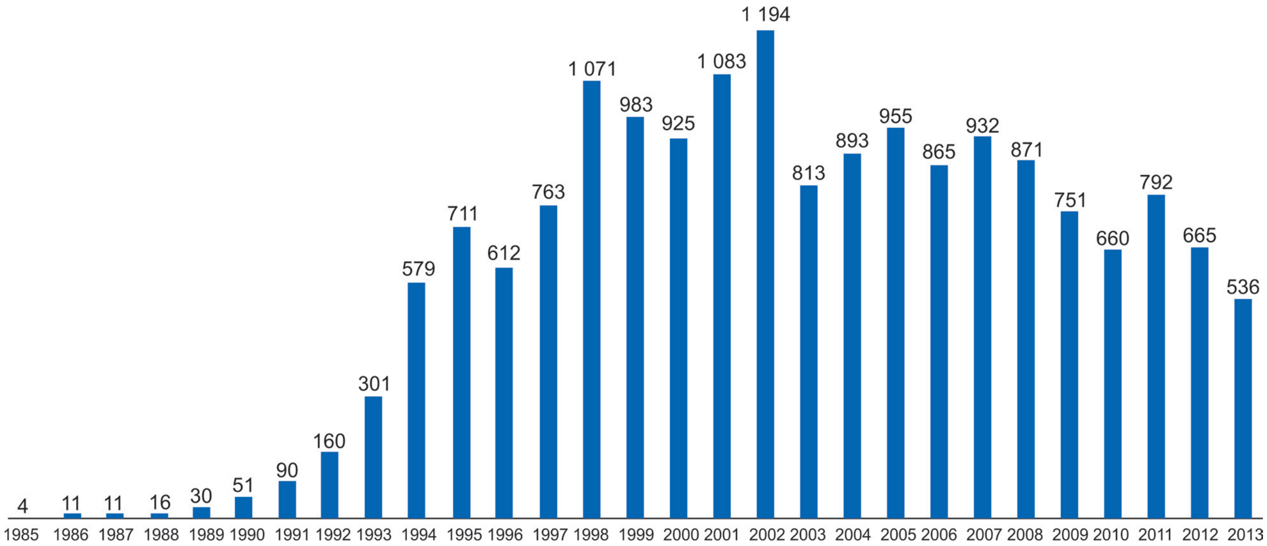
Fig.2b Adoption of genetically engineered cotton in the United States, by trait,2000-2014[2]

resistance to Bt crops has been low and of “little economic and agronomic significance”[5], but there are some indications that insect resistance is developing to some Bt traits in some areas. However, overreliance on glyphosate and a reduction in the diversity of weed management practices adopted by crop producers have contributed to the evolution of glyphosate resistance in 14 weed species and biotypes in the United States[6].

The cumulative number of releases for field testing since 1985 amounted to over 17 000 by 2013 (Fig.3). Most field releases have involved major crops, particularly maize, which had about 7 800 field releases approved as of 2013. More than 2 200 field releases were approved for GE soybeans, more than 1 100 for GE cotton, and about 900 for GE potatoes (Fig.4). Releases approved included GE varieties with traits including herbicide tolerance (6 772), insect resistance (4 809), product quality such as flavor or nutrition (4 896), agronomic properties (e.g. drought resistance) (5 190), and virus/fungal resistance (2 616) (Fig.5)[6].

Based on the Agricultural Resource Management Survey farmers indicate that they adopted GE maize, cotton, and soybeans primarily to increase yields. Other reasons given for adopting GE crops were to save management time, to facilitate other production practices (such as crop rotation and conservation tillage), and to reduce pesticide costs[6].

In addition to crops with biotic stress protection, approvals include crops with traits that improve abiotic stress tolerance and favorable agronomic properties (resistance to cold, drought, frost, salinity, more efficient use of nitrogen, increased yield); enhanced product quality such as delayed ripening, flavor, and texture (fruits and vegetables); increased

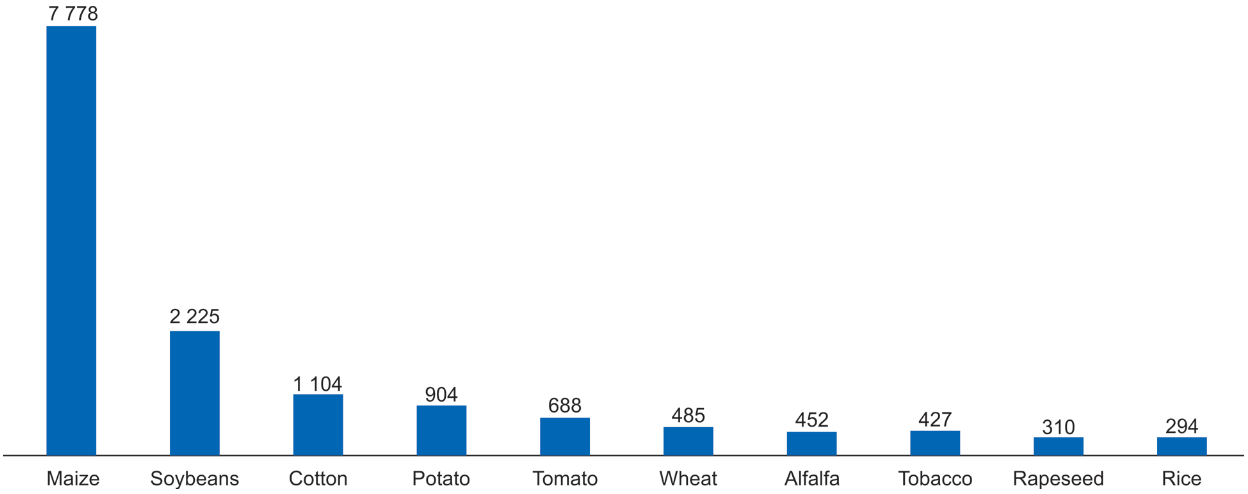


*As of September 24, 2013.

Authorizations for field releases of GE organisms (mostly plant varieties) are issued by USDA’s Animal and Plant Health Inspection Service (APHIS) to allow technology providers to pursue field testing.

Source: Information Systems for Biotechnology (ISB, 2013) and USDA Economic Research Service (ERS, 2014)[2].

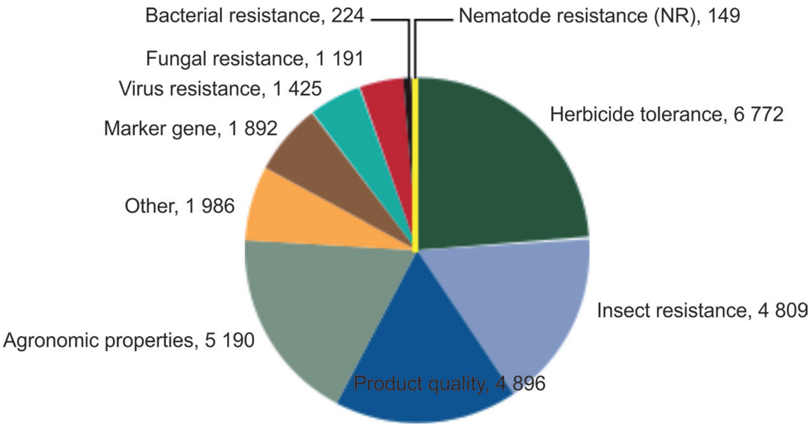
Fig.3 Number of releases of genetically engineered (GE) organisms varieties approved by APHIS, 1985-2013*



Authorizations for field releases of GE plant varieties are issued by USDA’s (APHIS)

Source:Information Systems for Biotechnology (ISB, 2013) and USDA Economic Research Service (ERS, 2014)[2].

Fig.4 Number of releases approved by APHIS: Top 10 crops



Authorizations for field releases of GE plant varieties are issued by USDA’s Animal and Plant Health Inspection Service(APHIS) to allow technology providers to pursue field testing. Counts refers to the actual number of approved release locations per phenotype category. http://www.aphis.usda.gov/biotechnology/status.shtml

Source: Information Systems for Biotechnology (ISB, 2013) and USDA Economic Research Service (ERS, 2014).

Fig.5 Number of releases approved by APHIS by GE trait

protein or carbohydrate content, fatty acid content or micronutrient content; modified starch, color (cotton, flowers), fiber properties (cotton) or gluten content (wheat); decaffeinated (coffee); nutraceuticals (added vitamins, iron, antioxidants such as beta-carotene); and pharmaceuticals Table 1[6].

In addition to the large-scale commodities, the technology has also helped some specialty crops. Virus-resistant “Rainbow” papaya, which exploited post transcriptional viral gene silencing, a form of RNA interference (RNAi), literally saved the industry in Hawaii as no natural resistance exists in the cultivated plant to the papaya ringspot virus[7]. The Rainbow papaya has also helped organic growers by reducing the viral reservoir on the island. A similar scenario may be needed to save the Florida citrus industry from the bacteria (*C. liberibacter*) which causes citrus greening[8].As there are no known effective and sustainable control systems for this devastating pathogen, current radical and largely ineffective control methods resort to cutting down whole orchards. Biotech solutions in the form of resistance genes from other plant species have been developed for this pernicious pathogen. A similar scenario may be needed to save the California wine industry from a refractory bacterial pathogen for which there are no known effective and sustainable control systems. Likewise, antibiotic spraying to control fireblight disease in apples is utilized, even in organic production, while a resistant variety of Gala apple that was developed using biotechnology in the late nineties lies languishing in the lab as the cost of taking it through the deregulation process is unnecessarily prohibitive.

However, on the whole, specialty crops are notable by their absence. This is not reflective of lack of need but rather the disincentive costs of going through the labyrinthine deregulation process. Most of the crops approved to date support that notion that the deregulation process is prohibitive for any but well financed companies whose focus is primarily the large commodity crops as just discussed. Some effort was made to redress this issue through the development of The Specialty Crop Regulatory Assistance (SCRA) initiative. They held a workshop in December 2011 on the nuts and bolts of developing dossiers on genetically engineered specialty crops for submission to US regulatory agencies. The workshop was held with the cooperation and full participation of the three US

Table 1 Biotech crops currently available and in development

Crop	Input traits				Output traits	
	Herbicide tolerance	Insect resistance	Virus/fungi, resistance	Agronomic properties[11]	Product quality[14]	Pharmaceuticals/ nutraceuticals[17]
Corn	C	C[5+]	D	C[12]D	D	D
Soybeans	C	D		D	C[15]D	
Cotton	C	C[6]		D	D	
Potatoes		W[7]	D	D	D	D
Wheat	C[2]		D			
Other field crops[1]	C[3]D[4]	D	D	D	D	D
Tomato, squash,melon, sweetcorn		C[8]	C[9]D	D	C[16]D	D
Other vegetables	D				D	
Papaya			C[10]			
Fruit trees			D		D	
Other trees				D[13]	D	
Flowers					D	

[1] Includes barley, canola, peanuts, tobacco, rice, sugar beet, alfalfa, etc.

[2] Monsanto discontinued breeding and field level research on its GE Roundup Ready wheat in 2004.

[3] Canola, sugar beet, alfalfa.

[4] Barley, rice.

[5] Bt corn to control the corn borer commercially available since1996;Bt corn for corn rootworm control commercially available since 2003;Bt corn to control the corn earworm commercially available since 2010;stacked versions of them also available.

[6] Bt cotton to control the tobacco budworm, the bollworm, and the pink bollworm, commercially available since 1996.

[7] Bt potatoes, engineered to be resistant to the Colorado potato beetle were commercially introduced in 1996 and withdrawn in 1999 due to push back by McDonalds.

[8] Sweet corn with insect resistance (to the corn earworm and European corn borer) was planted in about 20 000 acres and sold in the fresh market in 2008[5].

[9] Cucumber virus resistance squash accounted for about 12 percent of the squash produced in 2005[5].

[10] In response to papaya ringspot virus (PRSV) epidemic, researchers at Cornell University and at the University of Hawaii developed two virus-resistant varieties of GE papaya. First commercial plantings were made in 1998.

The new varieties were successful in resisting a PRSV epidemic and were planted on more than 30 percent of Hawaii's papaya acreage in 1999.

[11] Such as resistance to drought, frost, salinity; more efficient use of nitrogen.

[12] Drought tolerant maize approved for commercial use in 2011.

[13] Modified lignin content.

[14] Includes delayed ripening (fruits and vegetables with longer shelf life); protein content, carbohydrate content,fatty acid content, micronutrient content,oil content, modified starch content, flavor and texture (fruits and vegetables),color (cot-ton, flowers),fiber properties (cotton),gluten content (wheat), naturally decaffeinated (coffee),and low phytase.

[15] High oleic soybeans.

[16] FlavrSavr tomato genetically engineered to inhibit enzymatic breakdown of the cell wall was removed from the market because of production and marketing problems.

[17] Includes increased vitamin, iron, beta-carotene, lycopene, amino acid content; substitute sugar; hypoallergenic crops; antibodies, vaccines. Industrial uses (high amylopectin potato).

Sources: ISB (2013); National Research Council (2010)[5]; USDA Animal and Plant Health In section Service, ERS, 2014[2]. (Modified from Fernandez-Cornejo, J. 2014) [6].

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[8] Pharmaceutical plant compounds produced are intended for pharmaceutical use and must be approved from at least one of the following agencies prior to commercialization: U.S. Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (human biologics), FDA Center for Drug Evaluation and Research (human drugs), FDA Center for Veterinary Medicine (animal drugs), and USDA Center for Veterinary Biologics (animal biologics).

None of the plants currently under permit produce pharmacologically active compounds.

regulatory agencies with jurisdiction over agricultural biotechnology (USDA-APHIS, EPA, and FDA)[9]. However, little progress has been made beyond this initial effort.

Worldwide there is clear asymmetry and lack of consensus in regulatory systems. Non-hypothesis based evaluations have become the standard around the world, and these are being enshrined in the Cartagena Protocol's Roadmap, with the result that cost of safety assessment has sky rocketed without any discernible gain in safety. Given the current regulatory climate, it is difficult to imagine many modified specialty crops and especially quality traits ever reaching the marketplace. This discourages research on anything but the most mundane of crops and traits and is a real disincentive to creative research.

Some products have succeeded in circumnavigating this regulatory process on a technicality. Through a mechanism known as a 'letter of inquiry', developers uncertain of their product's regulatory status may seek a determination by APHIS's Biotechnology Regulatory Services (BRS)[10].Upon submission of a signed inquiry detailing (i) intended phenotype/trait, (ii) components and source(s) genetic construct(s) and, (iii) recipient/donor phylogenetic designation, APHIS will provide developers with an assessment of the regulatory status of their specific technology or product(s). Twenty six such letters have been submitted (Table 1). To the previous point, many of the 26 letters of inquiry to receive non-regulated status came from smaller biotechnology companies or from public sector research institutions, suggesting that this may be a deliberate strategy for smaller entities to navigate the regulatory[11]. The basis of the 26 letters of inquiry can be grouped into four categories based on the properties of the final plant product, transformation processes or the use of recently developed genetic modification technologies. These categories are null (negative) segregants (egcre/lox, early continuing flowering), gene delivery systems (biolostics, switchgrass), cisgenics/intragenics (RNAi, anthocyanin modification in grapes), and precision breeding via site-directed nucleases (commonly referred to as genome editing) with a fifth category included to capture those products that did not fit neatly into the above (Table 2)[11].

Two further "quality" traits are under consideration using RNAi suppression, the Artic apple which has been modified to resist oxidation when the apple is cut and the injured cells are exposed to oxygen activating the polyphenol oxidase (PPO) gene. To achieve this effect Okangan co-expressed PPO genes and effectively achieved reduced oxidation by silencing the endogenous PPO gene[12].The second is JR Simplot's reduced acrylamide potato. The JR Simplot potato that has three specific modifications for quality improvement. They use what they term "Innate" technology, basically utilizing RNAi to silence genes related to expression of black spot bruise, asparagine, and reducing sugars in tubers.

And transgenic animals take this irrationality to another level since GE food animals are regulated as drugs based on the notion that a transgene meets the

Table 2 Letters of inquiry on regulated status

Category	Inquiry Date	Applicant	Host Organism	Genetic Modification/Phenotype	Transformation Method	Status
I Null Segregants	01/18/11	USDA Agricultural Reseach Service	Plum	Accelerated Breeding (***Null Segregant***)	N/A	--
	01/22/11	North Carolina State University	Tobacco	Accelerated Breeding (***Null Segregant***)	N/A	--
	12/10/11	Univeristy of Nebraska	Sorghum	Decreased MSH1 Expression (***Null Segregant***)	Agrobacterium tumefaciens	--
	01/27/11	New Zealand Institute for Plant and Food Research	N/A	Genome Editing (Production of Double Haploids)	***Centromere-Mediated Chromosome Elimination*** *(CCE)*	--
II Gene Delivery Systems	03/08/95	(none listed)	Carnation	(none listed)	***Agrobacterium tumefaciens***	--
	09/01/09	Noble Foundation	Barrel Medic	*Tnt1* Retrotransponson Expression (Knockout Library)	***Agrobacterium tumefaciens***	Regulated
	07/30/12	Del Monte Fresh Produce Company	Pineapple	Altered Fruit Tissue Color/Anthocyanin Content	***Agrobacterium tumefaciens***	--
	12/11/07	New Zealand Crop and Food Limited	Petunia	Altered Vegitative Pigmentation	***Biolistics***	--
	09/13/10	Scotts Company	Kentucky Bluegrass	Glyphosate Tolerant	***Biolistics***	--
	01/20/12	Ceres, Inc.	Switchgrass	Improved Biofuel Yield Potential	***Biolistics***	--
	01/31/12	Scotts Company	Kentucky Bluegrass	Glyphosate Tolerant, Enhanced turfgrass quality	***Biolistics***	--
	02/01/12	Scotts Company	St. Augustinegrass	Glyphosate Tolerant, Enhanced turfgrass quality	***Biolistics***	--
	07/23/12	Ceres, Inc.	Switchgrass	Enhanced Water-use Effificency	***Biolistics***	--
	07/23/12	Ceres, Inc.	Switchgrass	Biomass more easily converted to fermentable sugars	***Biolistics***	--
	07/23/12	Ceres, Inc.	Switchgrass	Biomass more easily converted to fermentable sugars	***Biolistics***	--
	07/23/12	Ceres, Inc.	Switchgrass	Biomass more easily converted to fermentable sugars	***Biolistics***	--
III Cisgenics	02/23/12	Wageningen University	Apple	Scab (Disease) Resistant (***Cisgenic***)	Agrobacterium tumefaciens	Regulated
	02/08/12	University of Florida	Grape	Increased Anthocyanin Production (***Cisgenic***)	Biolistics	--
IV Precision Breeding	03/01/10	Dow	Corn	Suppressed Phytate Biosynthesis	***Zinc-Finger Nuclease*** *(EXZACT™)*	Regulated*
	09/09/11	Cellectis	N/A	Genome Editing (Targeted Indels)	***Meganuclease*** *(I-Cre1)*	Regulated*
V Other	03/07/94	Washington State University	Rhizobium leguminosarum	Insect Tolerance	(none listed)	--
	02/16/05	V.P. Technology Development	*Chlamydomonas reinhardtii* HSV8	Expression of Antibodies for Human Therapeutics	(none listed)	--
	04/06/08	Coastal Biomarine	Algae strains	Expression of Glucose Transporter from *Chlorella*	(none listed)	--
	02/21/11	Danziger	Baby's Breath	Altered Flower Color	(none listed)	--
	06/15/12	BioGlow LLC	[CBI]	[CBI]	[CBI]	--
	10/23/12	BioGlow LLC	[CBI]	[CBI]	[CBI]	--

*Transgenic crops genetically modified by targeted deletions, during which no plant pest genetic informaion is incorporated into the host genome, were determined to fall outside of the scope of 37 CFR Part 340; Transgenic crops genetically modified by targeted insertions would have to be reviewed on a case-by-case basis to determine regulatory status.

Bold, *italicized texts* indicate the criteria that were used to assign queries to particular ad hoc categories. Red text indicates the understood reason for a 'regulated' status determination. Modified from Chi-Ham et al, 2014[11].

requirement of “articles (other than food) intended to affect the structure or any function of the body of man or other animals” blithely ignoring the fact the all forms of traditional breeding could be captured by a similar stretch of the definition! As such they must go through the USFDA new animal drug approval process. This means that products must be proven to be safe and effective as well as provide an assessment of its environmental impacts, under the requirements of the National Environmental Policy Act (NEPA). As Van Eeneenam and Muir[13] note, similar to the situation with plants, subjecting conventionally bred and GE animals to different regulatory standards is inconsistent from a scientific perspective and places an excessive regulatory burden on the development of GE technologies. They add that assessing potential risks in the absence of considering concomitant benefits and those risks associated with alternative food production systems gives disproportionate emphasis to the risk side of the GE food animal equation. Few, if any, technologies could survive a risk-only analysis. Specifically with respect to the GE salmon they note that wild-caught fish deplete the oceanic stocks and do not present a long-term, ecologically sustainable solution to rising global fish demand. One of the benefits associated with the development of GE fish for aquaculture may well be in helping to reduce recognized pressure on wild fish populations as we threaten to deplete our marine resources.

Ultimately, commercialization of the products of this technology should be just another step in a long history of human interaction with nature to meet societal needs and, as such, the same parameters of risk-based assessment should apply. Genetic modification through breeding has a long history of safe utilization for crop improvement, and biotechnology simply extends those benefits through more precise methods. Most essential is a regulatory framework that ensures adequate protection of the consumer and the environment while not stymieing innovations that enable beneficial consequences[14-15].Biotech offers efficient and cost-effective means to produce high quality food, feed and fiber and a diverse array of novel, value-added products. Disproportionate regulatory burdens will force reliance on older, less effective and unsustainable systems that will inevitably have a negative impact on food security. A case in point is the Fortuna potato that contains two genes from a wild relative that confer robust resistance against late blight disease, a $5 billion problem, obviating the need to spray with fungicides, including the organic-approved copper sulfate. Yet its developer is abandoning the EU as it sees little hope of winning regulatory approval despite the potential benefits to growers and the environment. While farmers in the EU can afford to continue to utilize fungicides, low-input farmers with few other alternatives could greatly benefit from such genetically delivered disease resistances. Similarly, transfer of a bacterial spot resistance gene currently present in pepper varieties to tomatoes could increase yields and eliminate applications of copper pesticides[16].

Clearly, there are a number of challenges inhibiting development and deployment of novel resource-enhancing technologies, including technical and translational complexities that must be resolved to enable development of desirable traits. The ever-evolving toolbox for trait modification includes new tools for genome editing that will enable subtle modifications to facilitate the rapid introgression of desirable traits. In addition, mechanisms should be put in place to facilitate the downstream development, deployment, and commercialization requirements. While innovation cannot occur without recoupment of investment, there is a negative public attitude toward ownership of intellectual property in seed technologies and perceived enhancement of corporate power with possible negative impacts on employment, especially on small farms. Mechanisms must be in place to reduce intellectual property barriers, improve commercialization strategies, and facilitate the transfer of advantageous technologies. Unreasonable concerns about very low level presence of the products of biotechnology are not proportionate to actual risk and lead to over-regulation and over-reaction in global markets. Coexistence between different production systems requires reasonable tolerances and proportionate and workable thresholds. Worldwide regulatory regimens for crop biotechnology are not harmonized among countries and are largely not science-based. Regulatory frameworks should ensure adequate protection of the consumer and the environment while not stymieing innovations that enable deployment of beneficial technologies and do not, by default, force reliance on older, less effective and less sustainable systems. The status quo is often not the most sustainable or least harmful option. An effective misinformation campaign has grown up around this technology and the agenda has been ceded to those with questionable motives[17].More effective communication strategies must be developed using evidence-based science and appropriate context to realistically compare potential risks and benefits of new technologies versus defaulting to existing practices.

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