欧洲转基因作物现状

Justus Wesseler Dusan Drabik

荷兰瓦赫宁根大学农业经济和农村政策小组,海尔德兰省瓦赫宁根市 16706,荷兰

摘 要 欧盟不同国家对转基因生物的注册审批是有差异的,尤其是在转基因作物的培育上存在很大的争议。一些成员国允许培育转基因作物,而另一些成员国则禁止培育。其中一个解决方案是将审批流程国有化,这或许可以为当前的僵局提供一个解决方法(取决于它的实施情况)。随着世界上新型转基因生物的应用越来越多,进口转基因生物的注册审批流程陷入困境,导致注册审批的不同步和结构贸易破坏的发生率日益增高。当务之急就是需要可以超越目前国有化审批流程的改革措施。国际贸易中审批流程的不同步也会影响其他国家,因此,急需一个国际层面的解决方案。

关键词 转基因生物;欧盟;条例

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基因工程作物一般被称为转基因生物,一直是很多国家的农业经济政策的一大挑战。在农业领域从未有过一项新技术在相关人士之间争论得如此激烈。某些国家成群的消费者、政治家及某些非政府组织反对转基因生物的引入。他们认为转基因作物与有机农作物共存环境中会对生物多样性、人类健康、农村社区经济构成威胁,而且可能成为种子供应商之中垄断力量的来源。也有一些人因为伦理道德的原因反对它。而另一些国家,农民、政治家和科学家则很拥护转基因生物。他们认为这是改善环境和保障经济可持续发展,以及世界范围内获得更稳定的粮食安全保障的一个有效途径。

在持续的争论之中,一些国家的消费者对待转基因生物常选择谨慎的态度,而他们的政府则通过条例来控制潜在风险以及增强公信力。

转基因生物的引进、接受及国际贸易在全球化经济中持续增加,生物技术条例必须借助其一定的灵活性来掌控这样的变化。否则,食品和饲料生产和贸易会受到影响。

欧盟对于转基因生物进口和培育的注册审批是不一样的。历史上欧盟对新的转基因生物的进口相对迟缓的审批已经导致市场破坏以及贸易伙伴之间的摩擦。随着世界很多地方审批和接受新的转基因生物逐渐增加,欧盟的注册审批流程陷入困境导致注册审批的不同步发生率日益增高——例如一个新的转基因生物在某个国家批准生产而在另一个国家却不能进口和使用。欧盟对不利事件的处理以及它们在国际市场越来越大的意义只会增加国际与欧盟审批不同步出现的可能。

对于一些未经批准的转基因生物食品(可能在运向欧盟的货物中发现)的零容忍政策,将会在越来越大的程度上挑战国际商品供应链。在本文中,我们对未来转基因生物进入国际农业贸易可能对欧盟的农业所产生的潜在挑战进行了分析。文章概述了近年来欧盟对转基因生物的相关政策,并讨论了未来可能面临的一些挑战。

1 欧盟关于转基因生物的政策

1999 年 6 月,丹麦、希腊、法国、意大利、卢森堡宣布他们将会阻止新的转基因生物审批,直到欧洲委员会提出额外的法规来控制它们的风险评估、市场推广、标识和来源[1]。这导致欧盟转基因生物的培育和进口都只能暂时终止。此外,疯牛病以及类似的食品丑闻的经历导致食品和饲料的风险估计和风险管理出现分离。技术风险评估由欧盟食品安全局作出,而风险管理作为一个政治决策,则牵涉到常委会、委员会和内阁会议。欧盟转基因生物的审批流程见图 1。

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E-mail:Justus.Wesseler@wur.nl;Dusan.Drabik@wur.nl;电话:+31(0)317 482621 传真:+31(0)317 484736

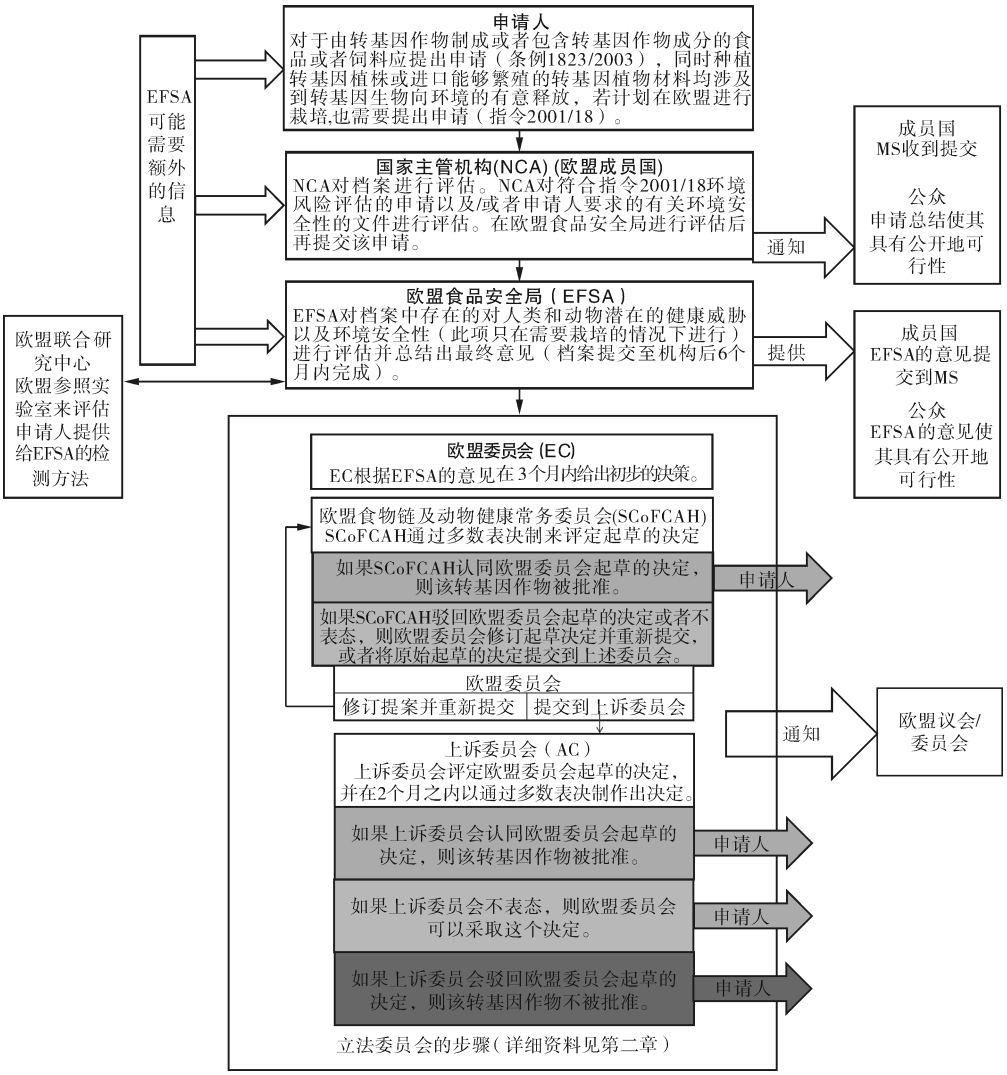

图 1　得到欧盟食品安全局正面评价以及欧盟委员会起草正面决定的转基因作物的审批流程

Fig. 1　Approval process for GMOs with a positive EFSA opinion and positive draft decision by the EC

图 1 中转基因生物在欧盟有 2 个不同级别的审批过程(转基因生物指南,2011):(a) 进口由转基因植物生产出的食品和饲料[2];(b) 在欧盟可以进行生长和繁殖,即可以释放到环境中的转基因生物[3]。为了保障欧盟消费者的选择权,含有超过 0.9% 的转基因成分的食品和饲料需要贴上标识和来源。然而,由转基因饲料喂养的动物生产的产品则不需要标识(细节见表 1)。

表 1 中,90 年代中期一部分转基因作物在进入欧盟市场时就被批准在欧盟种植。目前,有 2 种转基因作物在欧盟种植,一是由孟山都公司培育的转 Bt 玉米 MON810,另一种是由巴斯夫公司培育的转基因马铃薯 EH92-527-1(*Amflora*)。MON810 首先由 2001/18 指令批准引入,在 90 年代末期开始在市场推广。由旧的注册流程审批的转基因生物在批准之后可以在市场上推广 9 年但需要进行通知。9 年后要按照新的规定重新提交申请。关于 MON810 的继续推广种植,已经提交了新的申请,其继续在欧盟市场推广的审批流程也已经开始[5]。

虽然存在一些对于欧盟漫长的审批流程的抱怨,但实际上 2003 年以后欧盟审批的时间已经缩短了,而在美国的审批时间则变长了,因为在审批过程中受到了更广泛的公众参与以及更高要求的安全评定[6]。

尽管有了这些审批,但一部分欧盟国家仍然援用 2001/18/EC 指令的保障条款来禁止已批准的转基因生物的栽培[7]。这些条款允许成员国禁止已批准的转基因生物进行栽培,如果它对人类健康或者

表1 欧盟需要标识的转基因生物[1)]

Table 1 Labeling requirements for GMOs in the EU

转基因产品 GM product	举例 Example	是否需要标识
转基因植物、种子和食品 GM plants, seeds, and food	玉米、玉米种子、棉花种子、豆芽、番茄 Maize, maize seed, cotton seed, soybean sprouts, tomato	是 Yes
通过转基因作物生产出的食品 Food produced from GMOs	玉米粉、豆油、菜籽油 Maize flour, soybean oil, rape seed oil	是 Yes
通过转基因作物生产出的食品添加剂/调味品 Food additive/flavoring produced from GMOs	从转基因大豆中提取的高度过滤的卵磷脂 Highly filtered lecithin extracted from GM soybeans	是 Yes
转基因饲料 GM feed	玉米 Maize	是 Yes
通过转基因作物生产出的饲料 Feed produced from a GMO	玉米蛋白饲料、大豆粉 Corn gluten feed, soybean meal	是 Yes
通过转基因作物生产出的饲料添加剂 Feed additive produced from a GMO	维生素 B2 Vitamin B2	是 Yes
转基因饲料喂养的动物生产的产品 Food from animals fed on GM feed	鸡蛋、肉、牛奶 Eggs, meat, milk	否 No
转基因酶的辅助下生产的产品 Food produced with the help of a GM enzyme	淀粉酶辅助下生产的烘焙产品 Bakery products produced with the help of amylase	否 No

1)由欧盟委员会修改[4] Modified from the EU Commission[4].

环境有危害风险。如果他们提出新的科学证据证明有害,成员国可以使用保障条款。不过有时他们会因为政治因素援用一些条款,虽然转基因生物已经得到了欧盟食品安全局的正面评价,认为它们在本质上和本地的生物是相同的[8]。实际上7个欧盟成员国——奥地利、保加利亚、法国、德国、希腊、匈牙利、卢森堡和波兰——仍然在反对 MON810 的种植。这个禁令通常被认为是违反了欧盟的转基因生物审批流程(如 2001/18 指令[3]和 1829/2003 法规[2]所述)。为此,欧盟委员会在欧洲法庭状告了波兰[9](而孟山都公司起诉了法国[10]和德国[11])。

1.1 转基因生物在欧盟以及世界农业的现状

尽管 MON810 受到一些成员国的禁止,但2012年有6个成员国种植 Bt 玉米,其中包括捷克共和国(3 080 hm^2)、波兰(4 000 hm^2)、葡萄牙(9 278 hm^2)、罗马利亚(217 hm^2)、斯诺伐克(2012年未报道面积)以及西班牙(116 306 hm^2)(见表2)。2010年在捷克共和国(150 hm^2)、德国(15 hm^2)和瑞典(80 hm^2)对转基因马铃薯第一次进行了商业化规模的种植[6]。总而言之,2012年在欧盟有133 070 hm^2的土地用于种植转基因作物,占其农业耕地面积的0.06%。尽管数量很少,但转基因作物在欧盟农业方面展示出的潜力具有重要意义[12-13]。

与欧盟相比,一些粮食生产大国对转基因作物的接受较快。2010年,在29个国家的1 540万农民在1.48亿 hm^2的土地上种植了转基因作物[14]。转基因大豆、棉花、玉米、油菜分别占该作物种植面积的90%、62%、29%、23%。

表2 欧盟国家中 MON810 的培育面积[1)]

Table 2 Cultivation of MON810 in the EU in hectares hm^2

国家 Country	2005	2006	2007	2008	2009	2010	2011	2012
西班牙 Spain	53 225	53 667	75 148	79 269	76 057	76 575	97 325	116 306
法国 France	492	5 000	21 147	/	/	/	/	/
捷克共和国 Czech Republic	150	1 290	5 000	8 380	6 480	4 868	5 090	3 080
葡萄牙 Portugal	750	1 250	4 500	4 851	5 094	5 500	7 723	9 278
德国 Germany	342	947	2 685	3 171	/	/	/	/
斯洛伐克 Slovakia	/	30	900	1 900	875	1 740	761	/
罗马尼亚 Romania	110 000*	90 000*	350	7 146	3 344	823	588	217
波兰 Poland	/	100	320	3 000	3 000	3 500	3 900	4 000
转基因作物总计 Total GM Crops	54 959	62 284	110 050	107 717	94 750	91 193	115 386	133 070

1)转基因生物指南(2013)包含转基因大豆的培育,从2007年罗马尼亚加入欧盟后被禁止。* GMO-Compass (2013). Cultivation of GM soybeans included. Banned since 2007, when Romania joined the EU.

今后的10年,全球对转基因作物的接受有望变得更快,因为巴西和中国等国家对新型转基因事件的研究已经大幅度增加。随着基因改良前沿技术的持续发展,产品和方法的创新也在同时进步。根据 Stein and Rodriguez-Cerezo[15],经过批准的转基因事件有望从2008年的39个增加到2015年的142

个。这将使欧盟和主要产粮国家在接受转基因作物之间的差距越来越大，同时也增加了欧盟在竞争力和国际贸易上的不确定因素。

1.2　共存政策

在欧盟，经过批准的转基因作物的培育受到共存政策的管理。成员国可以制定他们自己的共存政策，然后欧盟委员会提出一个通用的指导方针，并成立了共存局这样的机构，制定针对特定作物的指导方针，为成员国制定政策时提供帮助。欧洲共存局指出："共存是对转基因生物、食品、饲料按照相关规定进行标识，农民对转基因和非转基因作物有选择的权利"。在不同国家，共存条例对接受转基因作物的影响是完全不同的。比如，西班牙使用共存条例来管理转基因作物的生产，而其他国家，如保加利亚使用共存条例来禁止转基因作物的生产。人们会认为对于转基因作物的生产，额外的管理条例会增加生产成本，从而会降低接受度[16]。但如果管理条例具有一定的灵活性，就未必会出现这样的情况[13]。

环境保护政策对转基因作物的生产所产生的潜在影响是近来引起大家关注的一个问题。在很多自然保护区，如 1992 年 5 月 21 日的理事会指令 92/43/EEC[16]建立的自然 2000 保护地区中，转基因作物禁止培育。在一些国家规定了转基因作物和保护区的最小距离。密集分布的这类区域（包括缓冲带）很大程度上减少了转基因作物的种植面积。

通过共存和环保政策来禁止培育转基因作物，为国有化的转基因作物审批的僵持局面提供了法律对策（下面进行了更详细的讨论）。

1.3　消费者问题

第一代转基因生物主要是培育抗除草剂和抗虫的作物，以此提高其种植效率[17]。这样消费者可以从中享受到更低的食品价格，但是这样的利益很难被消费者认识到。在没有健康和其他直接利益保障的情况下，而且还会感知可能存在风险的情况下，一些消费者对于转基因生物一直持有谨慎的态度。通常欧洲消费者并不反对生物技术并且支持将其应用于医疗卫生领域，而大多数人都反对将生物技术应用于食品生产中（详见文献[18]中的综合分析），但是这种反对也并不一定反映在购物行为中[19]。

在欧洲有大量的非政府组织（NGOs）利用消费者对于转基因生物的态度成功地反对了转基因食品。同样，欧盟已经落实了标识管理条例，以便消费者可以在转基因和非转基因食品之间自行挑选。许多零售商和食品制造商也推出了非转基因产品流水线并要求他们的供应商也遵守这些禁令[20]。对转基因生物持消极态度的消费者增大了推广转基因食品的社会成本。对转基因食品进行标识旨在通过告知消费者从而减少社会成本。然而，消费者通常对于转基因和非转基因食品的有关政策并不了解[19]。因此，最终消费者的否定态度能在该区域、国家和欧盟选举会议上产生重大影响，进而影响了欧盟的政策。

1.4　贸易问题

欧盟对进口转基因产品的审批程序太过缓慢，2003 年阿根廷、加拿大和美国就此向世贸组织提出申诉。2006 年，世贸组织裁定欧盟在 1984－2004 年期间禁止进口转基因产品的做法违反了国际贸易规则。随后加拿大和阿根廷分别于 2009 年和 2010 年与欧盟达成协议，结束了这场纠纷。2008 年 10 月，欧盟和美国就转基因进口问题进行了商讨，尽管美国保留有还击的权利但依然为进一步会谈宽限了时间。2004 年以后，虽然有更多的转基因产品被批准进口欧盟，但美国、加拿大和阿根廷依然持续关注着市场准入[20]的情况。在任何情况下，由于欧盟政策引起的国际贸易间的冲突都能导致饲料进口产生临时或持续的中断，而饲养禽畜的农民以及其消费者则成为了最大的受害者[21]。

欧盟面临的另一个与转基因生物有关的问题是与美国正在进行的跨大西洋贸易投资协议（TTIP）的谈判。尽管多数人都认为由于 TTIP 的监管趋同会导致欧盟在美国的施压下降低食品安全标准（包括对转基因生物的限制）以消除任何贸易屏障，但是预计双方的监管决策过程并不会由于 TTIP 的影响而改变[22]。因此，目前并不确定 TTIP 的监管趋同会对欧盟转基因政策带来何种程度的影响。欧盟贸易委员 Karel de Gucht 近期的声明则表明了欧盟的态度，他表示："我们不会因为此项协议而改变本国的食品安全法规，对于转基因食品和含激素牛肉等产品的态度同样如此。这些问题是不需要讨论的。"

2　未来的挑战

在过去的 10 年里，曾在欧盟陷入僵局的转基因作物培育已取得了进展：在欧盟食品安全局对其进行了科学评估后，欧盟食品安全局和欧盟委员会均支持授权转基因作物的培育，但常务委员会和部长理事会依然不支持科学评估的结果。即便对转基因

玉米 MON810 的审查结果为安全的，某些成员国依然维持对转基因作物的禁令使得欧盟理事会内部不能就此达成共识。

2009 年底，欧盟委员会主席 Barroso 提出一项议案，该议案尝试将转基因作物培育的授权转移到各个成员国内部，这样就可以避免安理会不能达成共识的矛盾[23]。一些成员国拒绝了这项议案，因为这涉及到遵守 WTO 规章以及欧洲单一市场原则(EESC，2010)等方面的法律问题[7]。本着创建灵活管理的精神，欧盟委员会提出了另一项议案，该议案允许成员国因为各自的原因申报无转基因生物区域，前提是符合欧洲单一市场原则。但是以何种原因申请该禁令则是一个需要考虑的问题。已批准的转基因生物对环境以及人类健康经过验证是安全的，不仅能带来环境效益，还能至少在短期和中期增加农民的收入[17,24-25]。因此，也许很难找到一个能经受严格审查并被多数人接受的合适的理由。出于伦理层面的原因禁止种植转基因作物也是不妥的。如果接受了因为伦理原因而禁止转基因生物，今后将很难对其他伦理上存在争议的农产品提出禁令，比如农畜产品甚至是非农产品[7]，这就好比打开了欧盟内外贸易歧视的潘多拉魔盒。一个比较切实的解决方法是通过共存发挥间接禁止培育，但是这似乎难以被成员国所接受。

近期，希腊总统再次将批准国有化的议案提出，目前来看似乎在各个成员国中有着较高的支持率。新一届欧盟委员会主席 Jean-Claude Juncker 已将建立解决方案作为他的首要任务之一。在他写给新一届卫生和食品安全委员们的信中强调了工作重点："在任期最初的 6 个月里，对现有的与转基因生物有关的决策进行审查。"[26]

随着国际上越来越多的转基因作物被批准，以及各国进口审批不同步的事件愈加频繁的出现，贸易问题将逐渐凸显得更加严峻。对复合性状转基因作物的引进和当前审批单一性状转基因的政策以及这两种状况并存的问题都在挑战着欧盟食品安全局的能力。未来可能会出现两种情况。第一种就是公司可能会申请单一或者复合性状转基因作物的审批。这会导致成员国面临大量难以处理的审批请求。成员国可以接受这些提议并将其提交给欧盟食品安全局，将压力转移到欧盟食品安全局；或者直接拒绝这些申请。不论采取哪一种方式，审批进度估计都会很缓慢。第二种情况是由于申请复合性状转基因作物的审批需要准备大量的提案，考虑到本来已经很昂贵的审批流程之外又需要增加庞大的额外费用，公司可能会决定不提交所需的提案[14]。不论发生以上哪一种情况，由于零容忍条例，欧盟都会将自身独立于有关转基因生物的国际贸易之外，从而增加欧盟内部农业生产的相对成本。

委员会法规 619/2011 规定，允许进口转基因成分低于 0.1%的转基因饲料和食品，但这并不能解决固有的贸易问题。即使在严格的隔离程序下，非转基因食品和饲料中也不可能完全不含有微量的转基因物质。转基因成分可能不只在同一作物如玉米中存在，也可能在玉米和大豆之间传播。比如 Starlink 事件表明，很难将已批准的用于饲料的转基因作物和用于食品的转基因作物完全分开，若是发生共同混合市场的瓦解则会给有关公司和国家带来巨大的损失[27]。同样，对贸易中的大宗农业商品进行检测发现转基因微量存在的结果已经引起了巨大的市场混乱[28]。如果在贸易商品中检测到未经批准的转基因成分，那么国家可能会从法律层面要求该商品撤出市场。

如果欧盟对未批准的转基因食品施行零容忍条例，也许部分欧盟进口的食品和饲料将不复存在。这项政策最先将影响到食品和饲料的经销商，他们将被禁止发货，随后将迅速影响到农业部门，饲料价格的提升将增加农畜产品、加工产品的成本进而反映到食品价格的上涨，这样又会加大改革的压力。毫无疑问必须对审批程序进行改革，但重点是怎样实施这些改革。

考虑一些消费者和非政府组织对转基因的反对，审批程序的改革并不容易。因此，欧盟委员会的当务之急是确保能得到消费者游说团体对改革的支持[29]。

此外，欧盟当前的转基因政策不仅影响到农业生产部门和消费者，还对欧洲科研部门有影响。该政策使得一些大的生物技术公司对于在欧盟的投资失去了兴趣，这其中的一个主要原因是田间试验数量的大幅减少。减少监管障碍将会重新燃起人们对科研和开发投资的兴趣。

上述的审批过程不同步的问题并不只是欧盟存在的问题。随着巴西和中国对转基因新品种的研发日益增加，一些国家如加拿大和美国等将制定对这些国家新研发产品的审批流程。事实上，很难讲清这些国家是否会在其他国家寻求放松转基因管制的

机会。如果一个国家一方面禁止进口未批准的转基因作物，另一方面利用审批程序作为一种贸易保护策略，这就很容易成为国际农业贸易中的主要摩擦。不论怎样，WTO 都需要解决这个问题；也许成立一个专门管辖国际贸易中转基因产品审批的国际机构不失为一个明智的解决方法。

3 结　论

欧盟成员国在批准转基因作物的培育上存在分歧。对于决策的国有化可能会提供一个解决方法，但它是否能成功则取决于执行情况。通过共存政策间接禁止转基因作物的培育可能是一个可行的方法，也符合 WTO 的政策，而直接禁止转基因作物的培育存在更大的争议。

总的来说，欧盟目前的生物技术政策威胁着它的国际竞争力，不仅是对农业部门，也包括整个生物经济。当务之急就是需要可以超越目前国有化审批流程的改革措施。但是，只要游说团体还能够造成对科技的公众反对力量，这将会非常艰难。随着生产流水线化的程度增加，各个国家致力于自身的发展，新型转基因生物如何进入全球贸易市场是当前迫在眉睫的一个挑战。考虑到在一些国家如中国和巴西等对新型转基因作物的开发，国际贸易中不同步的审批流程也会影响其他国家，因此，急需一个国际层面的解决方案。

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The situation for genetically modified crops in Europe

Justus Wesseler Dusan Drabik

Agricultural Economics and Rural Policy Group, Wageningen University, De Leeuwenborch 2017, Hollandseweg, 16706 KN Wageningen, The Netherlands

Abstract Regulatory approvals for genetically modified organisms (GMOs) in the European Union differentiate between alternative uses and remain particularly controversial in the case of cultivation. While some Member States cultivate GM crops others have banned them. One of the suggested solutions includes nationalizing the approval process, which—depending on its implementation—might offer a solution over the current deadlock situation. Irrespectively, the increased use of new GMOs in many parts of the world, along with a mired regulatory approval process for imports of GMOs in the European Union, promise an increasing incidence of regulatory asynchronicity and structural trade disruptions. Reforms are needed that go beyond the current debate of nationalizing the approval process. The implications of asynchronous approval processes for international trade may also affect other countries and could require a solution at an international level.

Key words genetically modified organisms; European Union; regulations

翻 译:王 睿 **校 正**:练兴明 华中农业大学作物遗传改良国家重点实验室

The situation for genetically modified crops in Europe

Justus Wesseler, Dusan Drabik
Agricultural Economics and Rural Policy Group,Wageningen University,
De Leeuwenborch 2017*, Hollandseweg* 1, 6706 *KN Wageningen, The Netherlands*

Abstract Regulatory approvals for genetically modified organisms (GMOs) in the European Union differentiate between alternative uses and remain particularly controversial in the case of cultivation. While some Member States cultivate GM crops others have banned them. One of the suggested solutions includes nationalizing the approval process,Which—depending on its implementation—might offer a solution over the current deadlock situation. Irrespectively, the increased use of new GMOs in many parts of the world, along with a mired regulatory approval process for imports of GMOs in the European Union, promise an increasing incidence of regulatory asynchronicity and structural trade disruptions. Reforms are needed that go beyond the current debate of nationalizing the approval process. The implications of asynchronous approval processes for international trade may also affect other countries and could require a solution at an international level.

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1 Introduction

Genetically engineered crops, popularly known as genetically modified organisms (GMOs), have continued to challenge the political economy of agriculture in many countries. Never before has a new technology in the field of agriculture been so emotionally debated among stakeholders. In some countries, groups of consumers, politicians and certain non-government organizations (NGOs) have opposed the introduction of GMOs, which they see as a threat to biodiversity, human health, the economy of rural communities, especially in the context of coexistence with organic crops, and as a source of monopolistic power among seed suppliers. Some also oppose GMOs for ethical reasons. Yet in other countries, farmers, politicians, and scientists have embraced GMOs because they see them as a means to improved environmental and economic sustainability and more stable food security around the world.

Amid the ongoing disagreements, consumers in some countries have often adopted a cautious stance towards GMOs while their governments have sought to manage potential risks and strengthen public confidence through regulations.

In a global economy in which the introduction, adoption and international trade of GMOs continue to expand, biotechnology regulations must be able to handle such changes with a certain degree of flexibility. Otherwise, distortions in food and feed production and in international trade may arise, reducing social welfare.

GMO regulation in the European Union differentiates between approvals for import and approvals for cultivation. Historically, relatively slow rates of approvals of new GMOs for imports into the European Union have caused market disruptions and frictions with trading partners. An increase in the approval and adoption of new GMOs in many parts of the world along with a mired EU regulatory process promise an increasing incidence of regulatory asynchronicity—i.e., a situation when a new GMO has been approved for production in one country but not for import and use in another country. The regulatory treatment of stacked events in the European Union and their increasing significance in international markets will only add to the chance of asynchronicity of international and EU approvals. ①

Received date:September 22, 2014
E-mail:Justus. Wesseler@wur. nl; Dusan. Drabik@wur. nl, Tel and fax: +31(0)317482621; +31(0)317484736
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The zero-tolerance policy for the low-level presence (LLP) of such unapproved GMOs for food, which may be found in shipments to the European Union, will increasingly challenge international commodity supply chains and segregation systems for GMO-free food and feed products. In this contribution, we examine the potential future challenges in EU agriculture which may result from an increase in the GMOs entering international agricultural trade. We begin with a brief overview of the recent EU GMO policies, and then discuss some future challenges that lie ahead.

2 EU policy with respect to GMOs

In June 1999, Denmark, Greece, France, Italy and Luxembourg declared that they would block new approvals of GMOs until the European Commission proposed additional legislation governing their risk assessment, market introduction, labeling and traceability[1]. This gave rise to a temporary *de facto* moratorium on regulatory approvals of GMOs in the European Union both for cultivation and imports. In addition, the experience with "mad cow" disease and similar food scandals resulted in the separation of risk assessment and risk management for food and feed products. Technical risk assessment is performed by the European Food Safety Authority (EFSA), while risk management, a political decision, involves standing committees, the Commission, and the Council of Ministers. The approval process for GMOs in the European Union is summarized in Figure 1.

GMOs can be approved in the European Union at two different levels (GMO Compass, 2011): (a) as food or feed that is made from or contains GM plants[2]; this pertains to imports but not to cultivation; and (b) for deliberate release into the environment, which may involve growing the plant within the European Union or importing plant material that is able to reproduce[3]. In order to provide EU consumers with a choice, food and feed products derived from or containing more than 0.9 percent of authorized GMOs need to be labeled and traceable②. However, products derived from animals fed with GMOs need not be labeled (see Table 1 for details).

Table 1 Labeling requirements for GMOs in the EU

GM product	Example	Labeling requirement
GM plants, seeds, and food	Maize, maize seed, cotton seed, soybean sprouts, tomato	Yes
Food produced from GMOs	Maize flour, soybean oil, rape seed oil	Yes
Food additive/flavoring produced from GMOs	Highly filtered lecithin extracted from GM soybeans	Yes
GM feed	Maize	Yes
Feed produced from a GMO	Corn gluten feed, soybean meal	Yes
Feed additive produced from a GMO	Vitamin B2	Yes
Food from animals fed on GM feed	Eggs, meat, milk	No
Food produced with the help of a GM enzyme	Bakery products produced with the help of amylase	No

Source:modified fromthe EU Commission[4].

A handful of GM crops have been approved for cultivation in the European Union since the mid-1990s when they started to enter the market. Currently, two GM crops are cultivated in the European Union, the Bt maize event MON810 developed by Monsanto and the starch potato event EH92-527-1 (*Amflora*) developed by BASF. MON810 was approved prior to the introduction of Directive 2001/18 and has been marketed since the late 1990s. GMOs authorized under the old regulatory process can stay in the market for up to nine years after their initial approval but a notification is required. Before the end of the nine-year period, a new application has to be submitted that complies with the new regulations. A new application has been submitted for MON810 and the approval process has been initiated. The initiation of the approval process provides for the continuation of marketing within the European Union[5].

While there have been several complaints against the lengthy approval process in the EU, actually the approval time length has decreased since 2003 in the EU, while the time length in the US has increased caused among others by stronger public involvement during the approval process and more demanding safety assessment requirements in the US and the EU[6].

Despite these approvals, a number of EU countries have banned the cultivation of authorized GMOs by invoking the safeguard clause of Directive 2001/18/EC (Article 23)[7]. This clause permits Member States to ban the cultivation of an approved GMO if it poses a risk to human health or to the environment. Member States can use the safeguard clause if they believe new scientific evidence provides support for claims of harm, but at times they have also invoked the clause

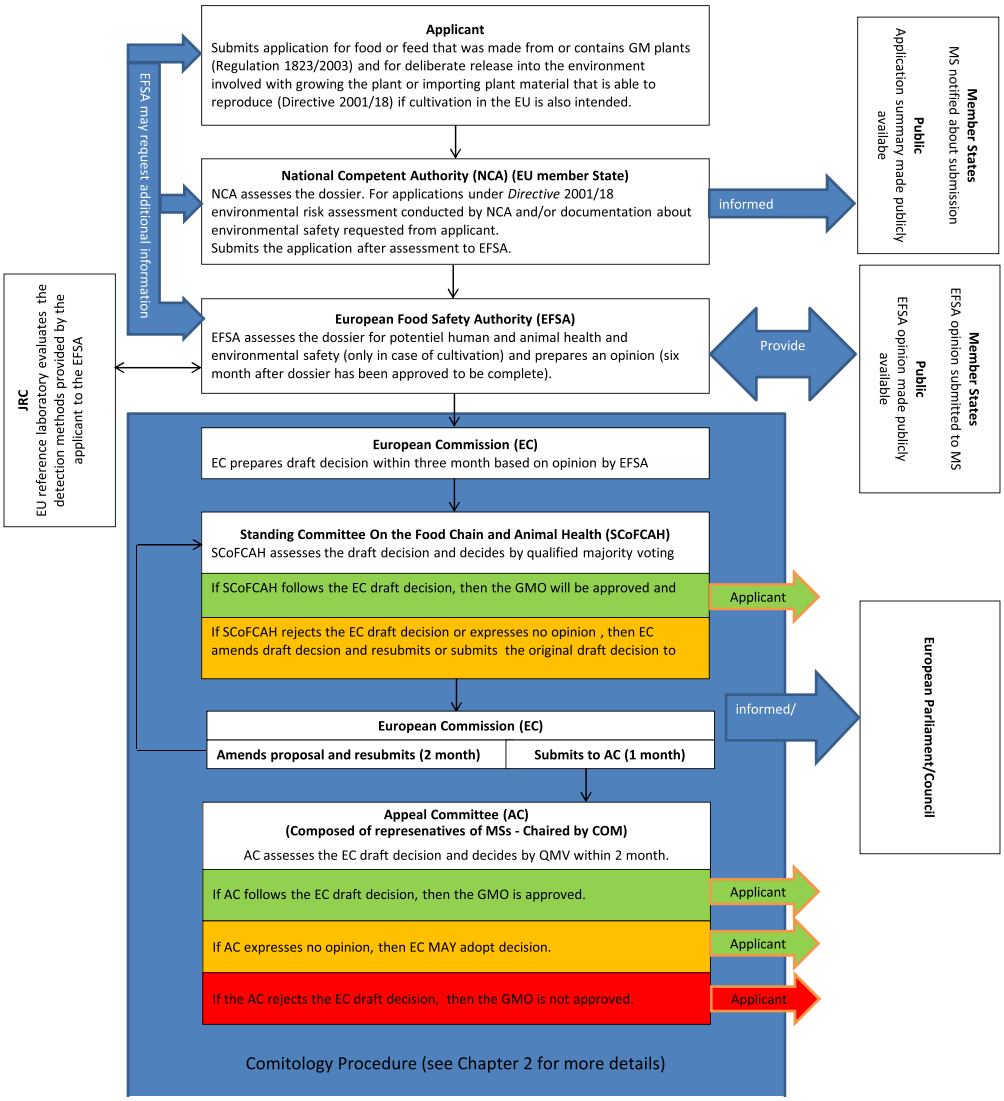

Fig.1 Approval process for GMOs with a positive EFSA opinion and a positive draft decision by the EC

for political reasons, even though GMOs that have received a positive assessment by the EFSA have been shown to be substantially equivalent to their conventional counterparts[8]. Indeed, seven EU Member States—Austria, Bulgaria, France, Germany, Greece, Hungary, Luxembourg and Poland—continue to ban the cultivation of MON810. The bans are often considered to be in violation of the EU approval process for GMOs as mentioned under Directive 2001/18[3] and Regulation 1829/2003[2]. The European Commission sued Poland at the European Court[9] (while Monsanto took legal action against France[10] and Germany[11]).

2.1 GMOs in the European Union and world agriculture

Despite the ban of MON810 in some Member States, six Member States cultivated Bt maize in 2012:the Czech Republic (3 080 ha), Poland (4 000 ha)③, Portugal (9 278 ha), Romania (217 ha), Slovakia (not reported for 2012 ha) and Spain (116 306 ha) (see Table 2).

The *Amflora* potato was cultivated for the first time on a commercial scale in 2010 in the Czech Republic (150 ha), Germany (15 ha) and Sweden (80 ha)[6]. In total, 133 070 ha were planted with GMOs in 2012 in the European Union, or about 0. 06 percent of the agricultural land. While this is a small amount, the agronomic potential for GM crops in the European Union is significant[12-13].

The limited EU adoption is in stark contrast to the rapid adoption of GM crops in major crop-producing countries. In 2010, about 148 million hectares of GM crops were cultivated by approxi mately 15.4 million farmers in 29 countries[14]. GM soybeans, cotton, maize, and rapeseed represented 90, 62, 29 and 23 percent of their global area, respectively.

In the next decade, global adoption is expected to grow even faster as the research pipeline for new events has substantially increased in a number of countries, including Brazil and China. Innovation with new products and processes is growing as the frontiers of genetic modification continue to expand. According to Stein and Rodriguez-Cerezo[15], the number of approved

Table 2 Cultivation of MON810 in the EU in hectares

	2005	2006	2007	2008	2009	2010	2011	2012
Spain	53 225	53 667	75 148	79 269	76 057	76 575	97 325	116 306
France	492	5 000	21 147	–	–	–	–	–
Czech Republic	150	1 290	5 000	8 380	6 480	4 868	5 090	3 080
Portugal	750	1 250	4 500	4 851	5 094	5 500	7 723	9 278
Germany	342	947	2 685	3 171	–	–	–	
Slovakia	–	30	900	1 900	875	1 740	761	–
Romania	110 000*	90 000*	350	7 146	3 344	823	588	217
Poland	–	100	320	3 000	3 000	3 500	3 900	4 000
Total GM Crops	54 959	62 284	110 050	107 717	94 750	91 193	115 386	133 070

Source:GMO-Compass (2013). *Cultivation of GM soybeans included. Banned since 2007, when Romania joined the EU.

events is expected to increase from 39 events in 2008 to 142 by 2015. This widening gap in the adoption of GMOs between the European Union and key producing countries creates uncertainties for Europe in terms of competitiveness and international trade.

2.2 Coexistence

The cultivation of approved GM crops within the European Union is regulated by coexistence policies. Member States can design their own coexistence policies, while the European Commission provides general guidelines and has established a Coexistence Bureau which develops crop-specific guidelines and supports member states in their policy design. According to the European Coexistence Bureau:"*Coexistence refers to the ability of farmers to choose between the cultivation of genetically modified (GM) and non-GM crops, in compliance with the relevant legislation on labelling rules for GM organisms (GMOs), food and feed and/or purity standards.* " National coexistence regulations and their impacts on adoption of GM crops are quite diverse. For example, while Spain uses existing regulations to govern the production of GM crops, other countries, such as Bulgaria, use coexistence regulations which effectively ban GM crop production. One might expect that additional regulations increase production costs, in particular those of GM crop production, and reduce adoption[16]. But this may not necessary be the case if regulations offer flexibility[13].

An issue that has only recently attracted attention is the potential impact of environmental conservation policies on GM crop production. In many nature protection areas, such as the Natura 2000 network established as part of Council Directive 92/43/EEC of 21 May 1992[16], the cultivation of GM crops is banned, and in some countries a minimum distance between GM crops and a protected area is required. A dense network of such areas, including the required buffers, can substantially reduce the area available for GM crop production, or even result in a *de facto* ban on cultivation.

Banning the cultivation of GMOs via coexistence and/or environmental policies offers a legal solution to the deadlocked situation as regards the nationalization of approvals (discussed in more detail below).

2.3 Consumer issues

The first generation of GMOs were herbicide-tolerant and insect-resistant crops which improved farm efficiency[17]. As such, they have benefited consumers through lower food prices but such benefits are difficult for consumers to discern. In the absence of health and other direct benefits and in the presence of perceived risks, some consumers have maintained their cautious attitudes towards GMOs. European consumers are, generally, not opposed to biotechnology and support applications in the health sector; but its use in food production is opposed by the majority (see e.g.[18] for a meta-analysis) but not necessarily reflected in purchasing behavior[19].

Consumer attitudes towards GMOs have been used by a number of NGOs to campaign successfully against GM food products in Europe. Similarly, the European Union has implemented labeling regulations to provide consumers with the opportunity to choose between GM and non-GM food products. Many retailers and food manufacturers have also launched GM-free product lines and have demanded that their suppliers comply with such bans[20]. Negative consumer attitudes towards GMOs increase the social costs of introducing GM food products. Labeling requirements for GM food try to reduce these social costs, by informing consumers. Nevertheless, consumers often feel ill-informed about GM food and GM food policies[19]. Finally, negative consumer attitudes can play an important role in regional, national and the EU Parliamentary elections and, without doubt, influence EU policies.

2.4 Trade issues

The slow EU approval process for the importation

of new GMOs prompted separate World Trade Organization (WTO) complaints by Argentina, Canada and the United States in 2003. In 2006, the WTO ruled that the EU's GMO policies from 1984 to 2004 were effectively a ban on GMO products and illegal under the trade agreement. In 2009, Canada and the European Union and in 2010 Argentina and the European Union signed agreements ending their disputes. The European Union and the United States discussed the dispute in October 2008 and allowed time for further talks although the United States has retained the right to retaliate. All three countries continue to be concerned with market access[20] despite the fact that many more GMOs have been approved for import since 2004④. In any case, the EU policies cause frictions in international trade and can result in temporary or sustained disruptions in feed imports, in particular, harming EU livestock farmers and consumers[21].

Another issue related to the use of GMOs in the European Union is the implications of the on-going negotiations on the Transatlantic Trade and Investment Partnership (TTIP) between the United States and the European Union. Although many believe that the regulatory convergence objective of the TTIP might result in watering down of EU food safety standards (and hence the use of GMOs) under the US pressure to remove any barriers to trade, it is also expected that the TTIP will not alter the regulatory decision-making process on either side of the Atlantic[22]. So it is not sure at this moment to which extent the process of regulatory convergence under the TTIP will affect the existing EU GMO regulations. The recent statement of the EU trade Commissioner, Karel de Gucht, does however, indicate the direction[12]:"…we will not be changing our food safety laws as a result of this agreement. That goes for genetically modified food and hormone-treated beef as much as other products. These issues are just not on the table. "

3 Future challenges

Over the last decade, a deadlock in approving GMOs for cultivation in the European Union has developed:The EFSA and the EU Commission, following the scientific assessment by the EFSA, have supported authorization, while the standing committees and the Council of Ministers do not follow the scientific assessment. Even for the Bt maize event MON810 that has received a positive review and is regarded safe, the Council has been unable to reach agreement as certain Member States have maintained their bans.

A proposal introduced by the EU Commission's President Barroso at the end of 2009 attempted to circumvent the rules of the qualified majority by shifting the authority of cultivation approval to the national level[23]. This proposal was rejected by a number of Member States. Legal issues were invoked, including compliance with the WTO rules and the Single European Market principle[7]. In the same spirit of creating regulatory flexibility, the European Commission has prepared another proposal that would allow Member States to declare GMO-free areas for different reasons but in line with the principle of the Single European Market. The question is what kind of reasons might be invoked for such bans. Approved GMOs are considered safe for the environment and human health and typically provide environmental benefits, while they increase farm income at least in the short and medium-term[17, 24-25]. It may, therefore, be difficult to find reasons that will withstand a critical review and be supported by a qualified majority. Banning the cultivation of GM crops for ethical reasons may also be problematic. If ethical reasons could be accepted for banning GMOs, it would be difficult to reject ethical arguments for banning other agricultural goods, such as animal products and, perhaps, even non-agricultural products[7] and open a Pandora's box for trade discrimination within and outside the European Union. A practical solution is the indirect banning of cultivation via coexistence regulations. But this also seems to lack acceptance among Member States.

Recently, the nationalization of approval has been placed back again on the agenda under the Greek presidency and now the proposal seems to get a higher support from member states. The new president of the commission under Jean-Claude Juncker has made establishing a solution one of his priorities. In his letter to the proposed new commissioner for Health and Food Safety he asks to focus among others on:"Within the first six months of the mandate, reviewing the existing decision-making process applied to genetically modified organisms (GMOs), in line with the Political Guidelines. "[26]

Trade issues can also be expected to increase in the near future, with more GM crops being approved internationally and instances of asynchronous approvals for import occurring more frequently. The introduction of stacked events and the current policy to approve single events as well as their combinations challenges the capacity of the EFSA. Two future scenarios are possible. First, companies may apply for approval of single and stacked events. This will result in a large

number of approval requests that Member States will find difficult to handle. Member States will have the option either to accept the proposals for approval and forward them to the EFSA, thereby placing the burden on the EFSA, or to reject the proposals outright. In either case, the approval process can be expected to be slow. In the other scenario, due to a high number of proposals that need to be prepared for stacked varieties, companies may decide not to submit dossiers because of the substantial additional costs of the already costly approval process[14]. In either scenario, and in the presence of zero-tolerance policies, the European Union could effectively exclude itself from international trade in GMOs, thus increasing the relative costs of agricultural production within its borders.

The Commission Regulation 619/2011 on low level presence to allow a 0.1 percent tolerance level for unauthorized GM feed imports to the European Union and to maintain a zero-tolerance level for unauthorized GM food imports does not solve the inherent trade problem. Minute traces of GMOs in non-GM food and feed products cannot be avoided even under strict segregation procedures. Adventitious presence of GMOs is not only possible within one crop such as maize but also between crops such as between maize and soybeans. As the Starlink case (over Bt corn in the United States) showed, the separation of GMOs approved for feed and GMOs approved for food is difficult to maintain, and in cases of co-mingling market disruptions can result in significant costs for the companies and countries involved[27]. Similarly, the low level presence (LLP) of research events in traded agricultural commodities has caused already substantial market disruptions[28]. If unapproved events are detected in traded goods countries may legally be required to remove the good from the market.

It is very likely that certain EU imports of food and feed products will not be possible if a zero-tolerance policy for EU unauthorized GM food is maintained. This policy will at first affect food and feed traders, whose shipments will be rejected, but the effects will soon spread to the agricultural sector, as an increase in feed prices will increase production costs for livestock products, processed products, and, in the end, food prices. The increase in food and feed prices will increase the pressure for reforms. There is no doubt that reforms of the approval process will be necessary; the major question is the way these reforms will be implemented.

Reforming the approval process will not be an easy task considering the existing consumer and NGO resistance. One of the major challenges of the European Commission will therefore be to secure support from consumer lobby groups for the reforms needed[29].

Further, the current EU GMO policy not only affects the agricultural production sector and consumers but also the European research sector. This policy has left the biotechnology industry with few good reasons for investments in the European Union. One indicator of the deteriorating interest in research is the number of field trials, which have substantially dropped over the past years. Reducing the regulatory hurdles will do much to encourage a renewed interest in research and development investments.

The aforementioned asynchronous approval process is not singularly an EU problem. With Brazil and China increasingly active in the development of new GMOs, other countries, such as Canada and the United States, will have to decide how they will approve new events developed in those countries. Indeed, it is not clear at this time whether these countries will always seek deregulation of their GMOs outside their national boundaries. One can easily imagine that this could result in major frictions in international agricultural trade if countries on one hand ban imports of not-yet-approved GMOs and on the other hand use the approval process as a trade protection policy. In one way or another, the WTO will need to address the problem; a supranational institution that approves GMOs for international trade among WTO members may be a sensible solution.

4 Conclusions

The EU member states are divided about the approval of GMOs for cultivation. Nationalizing the decision for cultivation might offer a solution, but its success will depend on the implementation. An indirect ban of cultivation via coexistence regulation seems to be a feasible solution and in line with WTO policies, while direct national cultivation bans are more controversial.

Taken together, the current biotech policies in the European Union threaten the international competitiveness not only of its agricultural sector but of its bioeconomy as a whole. Reforms are needed that go beyond the current debate of nationalizing the approval process. This will be difficult as long as lobby groups are able to generate public resistance towards the technology. The most immediate challenge will be the pace of introduction of new GMOs in the global market place, as the pipeline continues to expand and additional countries become more engaged in their

development and use. Considering the development of new GMOs in countries such as China and Brazil, the implications of asynchronous approval processes on international trade may also affect other countries and could require a solution at an international level.

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Notes

① GM crops with stacked events are developed by combining multiple individual biotech events (e.g., specific insect resistant and herbicide tolerant GMOs). As the number of new GMO events increases, the number of potential combinations increases non-linearly. In the European Union, stacks of approved single events must be reviewed and approved separately. By contrast, in other countries, such as the United States, once individual GMO events have been approved, their combinations do not require a separate regulatory approval

② Such regulatory allowances recognize that perfect segregation of GMOs and conventional crops in the agri-food supply chain is impossible, and hence foods with accidental presence of traces of authorized GMOs need not be labeled

③ The case of Poland is interesting as according to [32] about 3 000 hectares of the *Bt* maize event MON810 have been planted while at the same time the Polish government banned the cultivation. We are not aware of any legal actions by the government of Poland against those farmers

④ The EU market access for GM seeds, however, remains restricted