巴西生物安全立法与转基因作物的应用

Alexandre Lima Nepomuceno[1] Mauricio Antonio Lopes[2] Flavio Finardi-Filho[3]
Marcus Vinicius Segurado Coelho[4] Renata Fuganti-Pagliarini[1]

1. 巴西农业科学研究院大豆部；2. 巴西农业科学研究院总部；3. 巴西圣保罗大学医学部；4. 巴西农业部畜牧和食品供应处

摘 要 巴西目前有37个转基因品种获准商业化，转基因性状包括除草剂抗性、昆虫和病毒抗性。《巴西生物安全法》对科研及市场产品研发过程中如何安全运用遗传工程技术建立了指导准则，该法设立了新的机构并让高校与政府机构参与共同制定生物安全指导方针、进行风险评估和行政监督。根据该法，巴西设立了“国家生物安全理事会”(CNBS)，并重组了“国家生物安全技术委员会”(CTNBio)。CTNBio负责建立生物安全指导准则，并向所有从事转基因生物相关机构颁发“生物安全许可证”(CQB)。《生物安全法》将所有违反其准则的行为或不作为均视为违法。在注册与监督机构(OERF)确定制裁标准、规定罚金数额并提交给联邦政府后，即可对违法行为实施制裁。除此之外，巴西有关转基因生物的重要法规还有第8078号法，该条款赋予国内所有消费者知情权。依据该法律，巴西司法部建立了食品标识体系，规定人体食用或饲料用食品或食品成分若含有超过1%的转基因生物成分，必须在商品标签上注明并附转基因标志(正中间含有字母T的黄色三角形)。不可否认，在这部新的《生物安全法》颁布实施后，遗传工程技术在巴西农业中的应用呈现快速增长。毫无疑问，在各机构的协作参与下，生物安全立法框架中的法律、规定和指导准则联合作用，让投资者、科研工作者、公私营机构及其他所有巴西农业的利益相关者重拾信心。

关键词 转基因；《生物安全法》；巴西国家生物安全技术委员会(CTNBio)；注册与监督机构；生物安全政策；生物安全许可证

中图分类号 Q 785；S 5-1 **文献标识码** A **文章编号** 1000-2421(2014)06-0040-06

在过去的20年，转基因作物的种植总面积增长了1 000倍，从1996年的几千公顷增长到2013年的8 000多万 hm^2[1]。现在，世界耕地面积的10%以上种植的是转基因作物。在种植转基因作物的国家中，巴西以4 000多万 hm^2 的种植面积位居第二，而美国以7 010万 hm^2 的种植面积排名第一。2009年，巴西转基因作物的种植面积比前一年增长了35.40%，成为转基因作物种植面积占耕地总面积比例最高的国家[2]。在2012/2013收获季，巴西转基因大豆种植面积占巴西大豆种植总面积的85%以上；玉米的转基因种植面积占75%以上；转基因棉花占50%以上。

目前，巴西国家生物安全技术委员会(CTNBio)批准38个转基因作物品种商业化，包括5个大豆品种、20个玉米品种、12个棉花品种和1个菜豆品种。自1998年以来，CTNBio释放的转基因作物品种中，有31个是最近5年释放的。获准商业化的转基因作物的特性主要包括除草剂抗性、昆虫和病毒抗性。值得注意的是，在2013/2014收获季，巴西收获的转基因作物中，约63%含有除草剂抗性，约16%可以抗虫，约20%的品种同时含有2种抗性[3]。

新版的《巴西生物安全法》自2005年3月开始实施即发挥了重要作用，不仅为研发过程中遗传工程技术的安全运用建立了指导准则，而且使得巴西在农业、工业和人类/动物福利方面一直扮演重要角色。下面，我们将对这部法律及其成果的里程碑意义进行几点探讨。

1 巴西有关转基因作物的立法

《巴西生物安全法》在2005年3月24日第11105号法(http://www.ctnbio.gov.br/index.php/content/view/12847.html)由巴西国会核准通

收稿日期：2014-09-22

过，由此结束了巴西国内围绕转基因生物（GMO）的立法争议。该法根据 2005 年第 5591 号法补充，新版法是对自 1995 年以前的生物安全法的全面修订，1998 年具有草甘膦除草剂抗性的转基因大豆依据先前的生物安全法成为首个获准商业化种植的品种。除了在生物技术研究方面增加了新的一般性规定之外，第 11105 号法对宪法提出的原则进行细化，为监管涉及转基因生物及其副产品的活动建立了安全标准和机制。拟定这部法律所用的指导准则是基于对以下各领域科学进展的认知：生物安全与生物技术、生命保护、人类健康、动植物健康和对环境保护中“预防原则”[4]的遵守。依据第 11105 号法，成立了“巴西国家生物安全理事会”（CNBS），重组了 CTNBio，拟定了“巴西生物安全政策”（PNB）。该法令的目的在于为转基因生物及其副产品在以下各环节设立安全准则与监督机制：构建、培养、生产、操作、运输、转移、进出口、储存、科研、环境释放、GMO 释放和商业化等。该法令将转基因生物（GMO）定义为其遗传物质（DNA/RNA）经过分子生物学/遗传工程技术修饰的生物体。同时，将“转基因副产物”定义为由转基因生物得来的产物，并无自主复制能力，不含活体转基因成分。该法涵盖了科研活动和商业化应用，涉及产品可用于农业、人类健康、环境及水产领域。与之相似的是，该法主张任何个人若计划从事该法令涵盖的活动，亦需要获得“巴西国家生物安全技术委员会”（CTNBio）的许可，该委员会将在其决议规定的时间范围内作出回复。该法要求，国内外所有公私营组织，若要从事《巴西生物安全法》中所述的活动，在活动开始前都需要获得由 CTNBio 颁发的“生物安全许可证”（CQB）。所有从事与转基因生物相关工作的组织，若未遵守该法令或相关法规，并对人体和动物健康所造成实质伤害，或对环境造成重要影响，需对此负责[5]。

巴西国家生物安全技术委员会通过制定规范性决议（http://www.ctnbio.gov.br/index.php/content/view/12840.html），负责建立生物安全指导准则，并向在巴西进行转基因产品研发的所有组织颁发许可证（CQB）。第 1、2、6、8 号规范性决议规定了 CQB 许可证的获取步骤，及在封闭和大田条件下进行研究的步骤。第 5 号规范性决议，CTNBio 为在巴西进行转基因生物商业化的应用申请提出了指导准则。

《巴西生物安全法》将违反该法规定的所有行为或不作为均视为违法，对违法行为可处以下制裁：警告；罚款；查扣转基因生物及其副产品；勒令中止转基因生物相关活动；部分或全部废除已授权进行转基因相关工作的设施；中止或吊销注册、许可或授权；取消或削减政府给予的税收优惠及补助；取消或中止在官方信贷机构的信贷额度；干预其相关设施；禁止在 5 年内与公共管理机关签订任何协议。注册与监督机构（OERF）负责确定制裁标准、规定罚金数额，并提交给联邦政府。根据对人畜健康及对环境危害的严重程度，处以 1 000 美元至 75 万美元的罚金。该罚金可累积处罚，若再次违反本法，应处加倍罚金。若造成持续性侵害，处罚应以每日计算，直到该违法行为或不作为停止。

除了上述的处罚措施以外，《巴西生物安全法》还声明，若在未告知并得到 CTNBio 和 OERF 授权的情况下，转基因生物释放或排放至环境、商业化应用、在封闭环境或大田做研究、运输、进出口，或以其他方式利用，将处以 1～4 年监禁。如果环境或第三方受到损害，可增加 1/6 至 2/3 的监禁时间。

除此之外，巴西有关转基因生物商业应用的重要法规还有第 8078 号法（1990 年 9 月 11 日通过），这一法令由第 4680 号法细化，该法规赋予国内所有消费者知情权。2003 年，巴西司法部依据该条款发布了《第 2658 号行政条例》，建立了食品标识体系，规定人体食用或饲料用食品或食品成分若含有超过 1%的转基因生物或其副产品，必须在商标上注明相关信息，并附上“转基因”标志（正中间含有字母 T 的黄色三角形）。

《巴西生物安全法》使高校与政府机构（CIBio，CTNBio，CNBS，OERF）参与进来，设立了新的机构，来制定生物安全指导方针、进行风险评估和行政监督，流程图如图 1 所示，下面做简要介绍。

2　生物安全内部委员会（CIBio）

任何涉及运用遗传工程技术方法，或者无论在实验室、温室或大田利用转基因生物和/或其副产品做研究，或计划申请将转基因生物及其副产品进行商业应用的公共或私营机构，其内部必须设立“生物安全内部委员会”（CIBio），该机构须由在生物技术、遗传工程、生物安全或其他相关领域受到一定训练

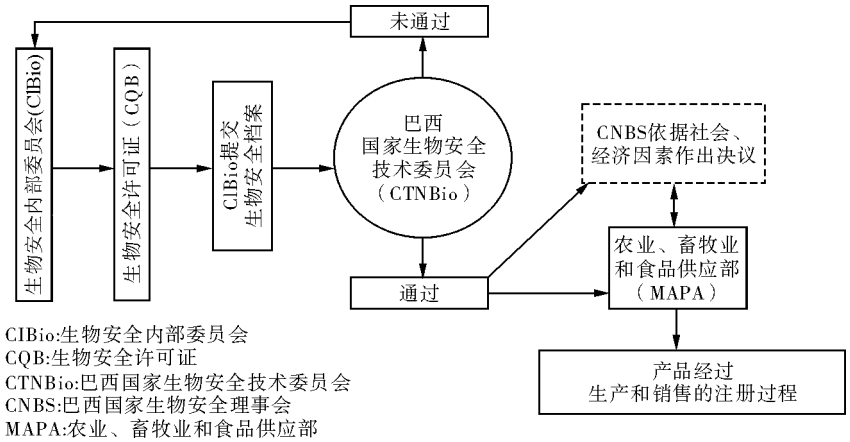

图1 转基因作物科研或商用的批准流程图,依据《巴西生物安全法》2005年第11105号法

Fig. 1 Workflow representing the approval process of a GM crop for research or commercial use according to the Brazilian Biosafety Law n° 11 105/2005

和教育的人员组成。必须指定一个首席研究员(PI)为该组织利用转基因生物的每一个项目负责。

CTNBio负责发放生物安全许可证(CQB),该许可保证CIBio在政府掌控之下开展工作。之后,CIBio将承担法律责任,保证整个设施的生物安全状况,对相关设施进行常规检查,并向CTNBio发送活动与项目年度报告。在该团体的工人与成员的健康和安全可能受到该活动的影响时,CIBio有责任告知他们。CIBio必须实行预防措施与检查计划来确保设备运行符合生物安全的标准和规范,同时需将所有记录交至CTNBio以供分析、注册或授权所用。在可行的情况下,CIBio应为每位成员对转基因生物或其副产品研究和/或开发相关的监测活动保持记录。CIBio须对与转基因材料接触的个体及可能导致生物媒介传播的事故或事件进行风险评估,并将评估结果告知CTNBio。针对发生的事故及可能与转基因生物及其副产品的使用或操作有关的疾病,CIBio须进行调查,并将结论及采取的措施通知CTNBio。若提案的项目拟使用转基因生物,必须由首席研究员提交给CIBio,再由后者对涉及到的风险进行评估,并决定是否批准该项目。批准通过后,该项目将被提交至CTNBio采用以下两种途径之一进行分析:涉及转基因生物风险组1(RG1)的项目,其相关活动在限制条件(实验室、温室等)下进行,可以由CIBio授权;项目通过后即可启动,CIBio要在年度报告中将该项目活动汇报给CTNBio。对于其他风险组和分析后用于大田的风险组1项目,CIBio须经CTNBio授权后方可启动项目。用于商业应用的提案亦须首先经CIBio分析,风险评估结果须递交给CTNBio。

3 巴西国家生物安全技术委员会(CTNBio)

巴西国家生物安全技术委员会(CTNBio)挂靠在巴西科技创新部(MCTI)。CTNBio是一个多学科的合议机构,通过商议与审议行使职能,为联邦政府规划、更新并执行针对转基因生物及其副产品的"国家生物安全政策"提供协助与技术支持。依据从动植物检疫、人体健康及环境风险各方面的评估,CTNBio对转基因生物及其副产品的科研相关活动和商业化应用建立了安全技术规范。此外,CTNBio对科研用转基因生物的进口给予授权,并为注册与监督机构(OERF)提供技术支持,同时对生物安全、生物技术、生物伦理及相关领域取得的科技进展进行监测,旨在提升对人类、动植物健康和环境的保护能力。

CTNBio大体分为植物、动物、人体卫生和环境等4个分委员会。科技创新部部长委派部里一名成员供职CTNBio主席,任期2年,可再连任1届。CTNBio长年设有执行秘书处,为CTNBio的成员提供技术与行政协助,并负责组织每月的例会。该委员会由27位衔称委员及其替补委员组成,所有委员在收到来自其他部的提名后,由同一部长任命。所有成员任期皆为2年,可再连任2届。所有成员

必须为技术专长过硬且在科学团体中参与度得到公认的巴西公民。所有成员皆须有博士学位，且在生物安全、生物技术、生物学、人畜健康及环境或相近领域表现活跃。12 名来自科学界的成员均由科技创新部直接委派，其他成员由以下各部委派：农业、畜牧业和食品供应部（MAPA）；卫生部；环境部；农地发展部；发展、工业与外贸部；国防部；水产与渔业部；国内事务部；司法部。CTNBio 全体成员名单见网页：http://www.ctnbio.gov.br/index.php/content/view/2251.html。

CTNBio 的会议在达到法定最少参会人数 14 名（半数人员多 1 名）时可以召开，4 个分委员会中每个分委员会应至少包括 1 名代表。必要时，科学界代表、公共部门代表和民间团体可被邀请参会，但无投票权。CTNBio 的所有决议皆须经过至少 14 名成员的记名投票通过。所有决议将在联邦刊物中发表，并在 30 d 内征集公众意见。CTNBio 的所有会议均向公众开放，民众可参阅会议日程并可在 CTNBio 网站浏览委员会通过的所有文档（http://www.ctnbio.gov.br/index.php/content/view/12840.html）。一般来说，在转基因生物新品种商业许可的审议及 CTNBio 投票表决之前，应召开公开听证会。

4　巴西国家生物安全理事会（CNBS）

巴西国家生物安全理事会（CNBS）是依据新生物安全法创立的，旨在为巴西总统制定和实施国家生物安全政策（PNB）时提供更高级的咨询援助，并在建立规范与指导准则时，考虑社会经济和政治的便利与机遇，以及转基因生物的商业化应用中涉及到的国家利益。CNBS 直接向巴西总统府负责，由 11 位国务部长组成。CNBS 应该公布对一个转基因生物品种的商业化应用的最新和最终决定。关于转基因生物商业应用生物安全的技术性决议由 CTNBio 作出；然而，在 CTNBio 发布技术性观点之后，CNBS 有 30 d 的期限来驳回对该品种转基因生物商业应用的许可。如果 30 d 内 CNBS 没有驳回该许可，该产品自动获得商业化应用的授权。

5　注册与监督机构（OERF）

注册与监督机构（OERF）包括巴西国家卫生监督局（ANVISA）、巴西环境协会（IBAMA）以及转基因生物安全协调会（CBIO），这 3 个机构分别附属于卫生部、环境部以及农业、畜牧业和食品供应部。依据《巴西生物安全法》，OERF 在其职权范围内，根据 CTNBio 的技术性决议与评估，负责管理转基因生物及其副产品以实现如下目标：监督科研活动；对转基因生物的商业化应用进行注册与监督；对科研及商用进口产品给予授权；对执行相关活动和项目的机构及首席研究员的信息进行及时更新；协助 CTNBio 确定生物安全评估的参数并向公众发布，对转基因生物的商业化应用给予注册和授权；对使用转基因生物的机构及其设施与田间试验进行监督检查；在生物安全规则遭到违反或人和/或动物健康或环境受到破坏的情况下，进行执法并执行既定处罚。

6　转基因生物商业许可情况回顾

巴西是世界主要粮食和农产品生产国之一，也是在未来几十年很可能实现粮食增产的少数几个国家之一。在世界农产品生产国中，巴西有极大潜力成为重要的生物能源提供国。在多数发达国家，生物能源与食品生产相竞争，巴西可以在不损害本土原始环境、不干扰食品生产区的情况下，投入 3 000 万 hm^2 以上的土地用于生物能源作物的种植。巴西大约利用着世界 12％的淡水供饮用及农业灌溉。此外，巴西拥有世界 15％～20％的生物多样性，这使得巴西具有巨大潜能成为在农业、医药和工业新产品的重要来源。

因此，巴西农业（包括从大型农场到个体农户）以及整个涉农商业完全有条件发展至其他新兴国家的水平，并且推动巴西国内的经济和社会进步，同时帮助解决世界粮食问题。20 世纪 70 年代粮食及牲畜生产向塞拉多地区（位于巴西中部）的迁移向我们展示了农业产业如何刺激经济和社会发展。举个例子，巴西中西部城市拥有巴西全国最高的“人类发展指数”，证明农业综合产业对经济的贡献毋庸置疑。

由全球变暖导致的极端气候现象，以及日益增长的世界人口所带来的挑战使得可持续性的粮食生产成为未来几十年的关键问题。这样一来，为了保持生产率，需要对可以改变生产和消费观念、标准和模式的新技术有敏锐嗅觉、加以了解并进一步掌握，因此，将遗传工程运用到农业来面对目前的挑战不仅对巴西，对世界也是有战略意义的。

过去10年中，巴西转基因作物以4 000多万hm^2的种植面积位列世界第二。尽管1998—2005年间的法律争议造成的“非正式暂停”使得转基因作物较晚才被采用，生物科技产品在农业的应用仍然为巴西达到目前生产水平起了决定作用[6]。新的《生物安全法》的实施，使转基因作物的应用在令人信赖的法律框架下得到官方许可，而这是保证所有经济部门稳定的前提[7]。

巴西从事转基因作物研发的有公共机构、私营机构、国内企业、外国公司，他们开发出的转基因作物因农艺性状优良，使得该农产品的价值有所提升。巴西种植的转基因作物大多是大豆、玉米和棉花，都属于第一代转基因作物，即具有抗虫和/或抗除草剂的特点。

与其他国家相似的是，巴西转基因作物的商业生产中占份额最大的是孟山都、杜邦先锋、拜尔、陶氏之类的私营企业。然而，本土研究团体知道怎样挖掘感兴趣的基因和新型遗传工程策略中的“观念论证”，在密闭条件和大田条件下进行检验，然后将研发产品推入市场。我们的研究所、大学和巴西农业研究公司(EMBRAPA)已经开发出了多种具有不同性状的转基因作物。EMBRAPA开发并发布了巴西第一个具有金色花叶病毒抗性的转基因菜豆(*Phaseolus vulgaris*)品种，随后投入商业化生产；此外，EMBRAPA与德国BASF公司合资，培育和释放了抗除草剂大豆新品种。该品种具有咪唑啉酮类除草剂抗性，将在2014/2015种植季投入销售，商品名为“Cultivance”。

除了大豆、玉米和棉花之外，在巴西还有许多其他转基因作物进入研发后期，正在进行田间试验。水稻、西番莲、桉树、豇豆和甘蔗等都是进入大田试验阶段的物种，它们被测试的性状分别是高产、抗旱、抗真菌、油品质量和木材密度。在2014年底之前，CTNBio很可能会投票授权首个转基因树木品种商业化，即生长特点有所改良的桉树。

上文已经提到，CTNBio已经批准了37个转基因品种的商业应用。1998年，商品名为“Roundup Ready”(“终结者”)的抗草甘膦大豆成为第一个获批的品种。1998年至2005年，在新《生物安全法》实施之前，只有“BollGard”(“宝嘉德”)Bt抗虫棉品种释放。依据新的法规，2007年首批3个转基因玉米品种得到许可。2008年，5个转基因品种获准释放，包括3个玉米品种和2个棉花品种。2009年，9个转基因作物品种获授权商业应用，包括1个大豆品种、5个玉米品种和3个棉花品种。2010年，8个新品种获批，包括3个大豆品种、4个玉米品种和1个棉花品种。在接下来的2年(2011和2012)里，9个转基因作物新品种获批，包括3个玉米品种和5个棉花品种及1个大豆品种。1998年以来，CTNBio释放的37个转基因作物品种中，有32个是近7年释放的。巴西所有获得商业应用授权的转基因品种可参见http://www.ctnbio.gov.br/upd_blob/0001/1873.pdf。

毋庸置疑，在新的《生物安全法》颁布实施后，遗传工程技术在巴西农业的应用呈现快速增长。毫无疑问，在各机构的协作参与下，生物安全立法框架中的法律、规定和指导准则联合作用，使得投资者、科研工作者、公私营机构及其他所有巴西农业的利益相关者重拾信心。如果我们想要提高食品产量、改善食品质量，并应对未来的挑战，生物技术在农业的应用只能勇往直前。

参 考 文 献

[1] CLIVES J. Global status of commercialized biotech/GM crops: 2013[G]. ISAAA Briefs 46. Ithaca, NY: ISAAA, 2014.

[2] CLIVES J. Global status of commercialized biotech/GM crops: 2009[G]. ISAAA Briefs 41. Ithaca, NY: ISAAA, 2009.

[3] CÉLERES. Benefícios socioambientais da biotecnologia no Brasil: 1996/97 a 2011/12 [R/OL]. http://celeres.com.br/wordpress/wp-content/uploads/2013/01/PressRelease2012_Ambiental.pdf. 2013.

[4] BODANSKY, D. Precautionary principle, oxford reference[R/OL]. http://www.oxfordreference.com/view/10.1093/acref/9780195324884.001.0001/acref-9780195324884-e-191. 2009

[5] CTNBio-Comissão Técnica Nacional de Biossegurança[R/OL]. http://www.ctnbio.gov.br. 2014.

[6] CÉLERES. Relatório de Biotecnologia[R/OL]. http://celeres.com.br/wordpress/wp-content/uploads/2012/12/RelBiotecBrasil_1201_vf.pdf. 2012.

[7] SOUZA L. Brazilian virus-resistant beans[R/OL]. http://www.biofortified.org/2011/10/brazilian-virus-resistant-beans/. 2011.

Biosafety legislation and the use of GM crops in Brazil

Alexandre Lima Nepomuceno[1]　Mauricio Antonio Lopes[2]　Flavio Finardi-Filho[3]
Marcus Vinicius Segurado Coelho[4]　Renata Fuganti-Pagliarini[1]

1. *Embrapa Soybean*, *Carlos João Strass Road*, *Warta-PR*, *Brazil*;
2. *Embrapa Headquarter*, *Parque Estação Biológica s/n*,
PqEB, *W3 Norte-Asa Norte*, *Brasília-DF*, *Brazil*;
3. *Pharm*, *São Paulo University*, *Cubatãostreet*, 86, *cj* 909,
Vila Mariana. *São Paulo- SP*, *Brazil*;
4. *Mapa-Ministry of Agriculture*, *Livestock and Food Supply*,
Esplanada dos Ministérios-Bloco D-Brasília/DF, *Brazil*

Abstract　Thirty-eight GM crop events are currently approved for commercial use in Brazil, where their intrinsic characteristics include herbicide, insect and virus resistance. The Brazilian Biosafety Law establishes guidelines for the safe use of genetic engineering technologies in research and product development for the market. The Law created a structure with collegiate and governmental agencies for the establishment of biosafety guidelines, risk assessment, official inspections. It created the National Biosafety Council (CNBS), and restructured the National Biosafety Technical Commission (CTNBio). The CTNBio is responsible for establishing the biosafety guidelines and to issue the Biosafety Quality Certificate (CQB) for all institutions working with GMO. The Brazilian Biosafety Law considers an infringement of the legislation any action or omission that violates the norms provided by it. Many sanctions can be applied where the Registration and Inspection agencies (OERF) define criteria, fine amounts, and collect it for the federal government. Other important Brazilian legislation regarding GMO use in Brazil is the Law n° 8 078 which establishes the right to information for all consumers in the country. Through thisLaw, Brazilian Ministry of Justice defined a labeling system whereby foods and food ingredients for human consumption or animal feed containing or produced with more than 1% GMO must contain information on its label and a symbol (a yellow triangle with a T in the middle) indicating it. It is undeniable that there was a rapid increase in the utilization of genetic engineering technologies in the Brazilian agriculture after the new Biosafety Law. The unification of laws, rules and guidelines by all agencies involved in the Biosafety legislation framework allowed, undoubtedly, the rescue of the confidence by investors, researchers, private/public institutions, and by all other stakeholders involved in the Brazilian agribusiness.

Key words　transgenic; biosafety law; CTNBio; registration and inspection agencies; biosafety policy; biosafety quality certificate

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

Biosafety legislation and the use of GM crops in Brazil

Alexandre Lima Nepomuceno[1], Mauricio Antonio Lopes[2], Flavio Finardi-Filho[3],
Marcus Vinicius Segurado Coelho[4], Renata Fuganti-Pagliarini[1]
1. *Embrapa Soybean, Carlos João Strass Road,Warta-PR, Brazil;*
2. *Embrapa Headquarter. Parque Estaação Biol-gica s/n, PqEB,W3 Norte-Asa Norte, Brasília-DF, Brazil;*
3. *Pharm., São Paulo University, Cubatãostreet,* 86*, cj.* 909*. Vila Mariana.São Paulo-SP, Brazil;*
4. *Mapa-Ministry of Agriculture, Livestock and Food Supply. Esplanada dosMinistérios-Bloco D-Brasília/DF, Brazil*

Abstract Thirty-eight GM crop events are currently approved for commercial use in Brazil, where their intrinsic characteristics include herbicide, insect and virus resistance. The Brazilian Biosafety Law establishes guidelines for the safe use of genetic engineering technologies in research and product development for the market. The Law created a structure with collegiate and governmental agencies for the establishment of biosafety guidelines, risk assessment and official inspections. It created the National Biosafety Council (CNBS) and restructured the National Biosafety Technical Commission (CTNBio). The CTNBio is responsible for establishing the biosafety guidelines and to issue the Biosafety Quality Certificate (CQB) for all institutions working with GMO. The Brazilian Biosafety Law considers an infringement of the legislation any action or omission that violates the norms provided by it. Many sanctions can be applied where the Registration and Inspection agencies (OERF) define criteria, fine amounts and collect it for the federal government. Other important Brazilian legislation regarding GMO use in Brazil is the Law n° 8 078 which establishes the right to information for all consumers in the country. Through this Law, Brazilian Ministry of Justice defined a labeling system whereby foods and food ingredients for human consumption or animal feed containing or produced with more than 1% GMO must contain information on its label and a symbol (a yellow triangle with a T in the middle) indicating it. It is undeniable that there was a rapid increase in the utilization of genetic engineering technologies in the Brazilian agriculture after the new Biosafety Law. The unification of laws, rules and guidelines by all agencies involved in the Biosafety legislation framework allowed, undoubtedly, the rescue of the confidence by investors, researchers, private/public institutions and by all other stakeholders involved in the Brazilian agribusiness.

Keywords transgenic; biosafety law; CTNBio; registration and inspection agencies; biosafety policy; biosafety quality certificate

1 Introduction

The total area of land cultivated with Genetically Modified (GM) crops has increased by a factor of 1 000x in the last two decades, from a few thousand hectares (ha)in 1996 to more than 80 million ha in 2013[1]. Today, more than 10% of the world's crop lands are planted with GM crops. Among the countries producing GM plants, Brazil has the second largest crop area, with more than 40 million hectares, surpassed only by the U. S. with 70.1 million hectares. In 2009, Brazil experienced a 35.40% increase in the amount of cropland using GM plants, thus becoming the country with the highest rate of adoption[2]. In the 2012/2013 harvest season, Brazil had more than 85% of its soybean fields planted with GM soybeans; for corn, the value was >75% (first and second harvests), and for cotton it reached >50% of the total area[3].

Thirty-eight GM crop events are currently approved for commercial use by the National Biosafety Technical Commission (CTNBio):5 soybeans, 20 maize, 12 cotton and one bean event. Among the GM crops released by CTNBio since 1998, 31 were released in the past five years. The intrinsic characteristics of the GM plants approved for commercialization in Brazil primarily include herbicide, insect and virus resistant. It should be noted that among the transgenic crops for the 2013/2014 harvest season in Brazil, ~63% of GM plants had herbicide resistance, ~16% insect resistance, and~20% had both features in the same variety[3].

The new Brazilian Biosafety Law, implemented in March 2005, played an important role in establishing the guidelines for the safe use of genetic engineering technologies in research and development, keeping Brazil as major player in the areas of agriculture, industry and human/animal welfare. Below, we discuss some of the landmarks of this legislation and its outputs.

Received date:September 22, 2014

2 Brazilian legislation on genetically modified plants

Brazil's Biosafety Law n°11 105 of March 24, 2005 (http://www.ctnbio.gov.br/index.php/content/view/12847.html), approved by the National Congress, put an end to the legislative controversy surrounding genetically modified organisms (GMOs) in the country. The law was de-regulated by the Decree n° 5 591/2005, which was a comprehensive review of a prior biosafety law from 1995 that allowed the first commercial planting of GM soybeans resistant to the herbicide glyphosate in 1998. In addition to creating general rules on biotechnology research, Law n° 11 105 regulated constitutional principles and established safety standards and mechanisms for monitoring activities involving GMOs and their by-products. The guidelines used for writing this law were the recognition of scientific advances in the areas of biosafety and biotechnology, the protection of life, human health, the health of animals and plants and the observance of the "Precautionary Principle" for the protection of the environment[4]. Law n° 11 105 also implemented the National Biosafety Council (CNBS), restructured the CTNBio and proposed the Brazilian Biosafety Policy (PNB). Its purpose and scope were to provide safety norms and inspection mechanisms for the construction, culture, production, manipulation, transportation, transfer, importation, exportation, storage, research, environmental release, discharge and commercialization of GMOs and their by-products. The Law defines a GMO as an organism whose genetic material (DNA/RNA) has been modified by any molecular biology/genetic engineering technique. It also defines a "GM by-product" as a product obtained from a GMO that has no autonomous replication capacity or that does not contain a viable GM form. It covers research activities and commercial uses for products developed for use in agriculture, human health, environment and fisheries. Likewise, this law advocates that any individual who is interested in carrying out an activity covered by this law shall request permission from the National Biosafety Technical Commission (CTNBio), which shall reply within a time frame provided by in CTNBio resolutions. The legislation requests that all public and private organizations, national or foreign, that conduct activities or projects in Brazil under the description of the Brazilian Biosafety Law, require a Biosafety Quality Certificate (CQB) issued by CTNBio prior to starting any activity. All organizations working with GMOs will be subject to liability for any eventual damage caused to human and animal health, or considerable impact to the environment by non-complying with this law or its regulation[5].

The National Biosafety Technical Commission through its Normative Resolutions (http://www.ctnbio.gov.br/index.php/content/view/12840. html) is responsible for establishing the biosafety guidelines and to issue permits (CQB) for all institutions conducting research or developing GM products in Brazil. Normative Resolutions n° 1, 2, 6 and 8 establish the procedures for obtaining a CQB and for conducting research under contained and field conditions. In its Normative Resolution n° 5, CTNBio presents guidelines for proposal applications for commercial use of GMOs in Brazil.

The Brazilian Biosafety Law considers an infringement of the legislation any action or omission that violates the norms provided by this Law. The sanctions that can be applied include the following:admonishment; fines; seizure of GMOs and their by-products; suspension of the authorization for commercial use of GMOs and their by-products; suspension of activities with GMO; partial or full disability of facilities authorized to work OGM; suspension or cancellation of registration, license or authorization; loss or restriction of tax incentives and benefit granted by the government; loss or suspension of credit line with an official credit institution; intervention at the facilities; and prohibition of signing any agreement with the public administration for up to 5 (five) years. The Registration and Inspection agencies (OERF) are responsible for defining criteria and fine amounts, as well for collecting them for the federal government. The fine ranges from US$1 000. 00 up to US$750 000. 00 and are equivalent to the seriousness of the damaged caused to human and animal health and to the environment. These fines can be applied on a cumulative basis and, in cases of re-incidence, shall be doubled every time. In cases of continuous infringement, characterized by the perpetuity of the action and omission of the punishment, the penalty shall be applied on a daily basis until the problem is stopped.

In addition to the fines and measures described above, the Brazilian Biosafety Law also preconizes punishment by confinement from one to four years if GMOs are released/discharged into the environment, used commercially, researched in confinement or in the field, transported, imported, etc., used in any way without the notification and authorization by CTNBio and OERF. The sentence can be increased by 1/6 to 2/3

if a third party or the environment is damaged.

Other important Brazilian legislation regardingthe commercial use of GMO in Brazil was Law n° 8 078 (September 11th, 1990), regulated by Decree n° 4 680, which established the right to information for all consumers in the country. Based on this law, in 2003 the Brazilian Ministry of Justice issued the Administrative Act n° 2 658, defining a labeling system whereby foods and food ingredients for human consumption or animal feed containing or produced with more than 1% GMOs or their by-products must contain information on its label and a symbol (a yellow triangle with a T in the middle) indicating this.

The Brazilian Biosafety Law created a structure with collegiate and governmental agencies (CIBio, CTNBio, CNBS, OERF) for the establishment of biosafety guidelines, risk assessment and official inspections whose workflow is presented in Figure 1 and is briefly described below.

3 Biosafety Internal Commission (CIBio)

Any public or private institution that uses genetic engineering techniques and methods, or that conducts research using GMOs and/or their by-products, whether in laboratories, greenhouses or under field conditions, or plans to apply for commercial use of GMOs and their by-products must have an Internal Biosafety Commission (CIBio), composed of individuals with proper training and education in the areas of biotechnology, genetic engineering, biosafety or other related fields. A Principal Investigator (PI) must be indicated as responsible for each specific project using a GMO at the institution.

CTNBio will issue a Certificate of Quality in Biosafety (CQB), an essential document requiredfor CIBio to work under governmental control. Afterwards, each CIBio becomes legally responsible for ensuring the biosafety conditions of the entity facilities, performing regular audits on its facilities and sending an annual report of its activities and projects to the CTNBio. It is also responsible for keeping workers and members of that community informed whenever their health and safety are liable of being affected by the activity. It must implement preventative and inspection programs to ensure the operation of facilities are within biosafety standards and norms and must forward to CTNBio all documents for analysis, registration or authorization purposes. When applicable, CIBio should maintain a record of each individual, monitoring activities related to research and/or development of GMOs or their by-products. The CIBio must notify CTNBio of the results of the risk assessment for individuals who become exposed as well as any accident or incident that may cause the dissemination of a biological agent. It must investigate accidental occurrences and diseases possibly related to the use or manipulation of GMOs and their by-products, informing CTNBio of their conclusions and measures taken. Any proposed project that uses GMOs must be submitted by the PI to CIBio,Who will assess the risks in volved and determine whether the project will be approved. Once approved, it will be submitted for CTNBio analysis in one of two ways: projects involving GMOs of risk group 1 (RG1), where activities are conducted under containment (laboratories, greenhouses, etc.), can be authorized by CIBio; once approved, the project can start and CIBio will report the activities of the project to CTNBio in its annual report. For all other risk groups and for RG1 used in field conditions after its analysis, CIBio must seek authorization from CTNBio to start the project. Proposals for commercial use must also be analyzed first by CIBio, and then the results on risk assessment must be sent to CTNBio.

4 National Biosafety Technical Commission (CTNBio)

The National Biosafety Technical Commission (CTNBio) is linked to the Ministry of Science Technology and Innovation (MCTI). It is a consultative and deliberative multidisciplinary collegiate that provides assistance and technical support to the federal government to formulate, update and implement the National Biosafety Policy for GMOs and their by-products. It also establishes safety technical norms regarding the authorization of research-related activities and the commercial use of GMOs and their by-products based on the evaluation of their zoo-phytosanitary, human health and environmental risk. CTNBio also authorizes the importation of GMOs for research, provides technical assistance to the registration and inspection agencies (OERF) and monitors the development and technical-scientific progress attained in biosafety, biotechnology, bioethics and related areas, aiming to increase their capacity of protecting human, animal and plant health and the environment.

CTNBio is basically organized into four subcommissions: plant, animal, human health and environmental commissions. The Minister of MCTI appoints one of its members to serve as CTNBio's

president for a two-year term of office, extendable for the same period. It also has a permanent executive secretariat who provides technical and administrative assistance to CTNBio's members and organizes the monthly meetings. This commission is composed of 27 titular members and their substitutes, who are appointed by the same minister after receiving nominations from others ministries. All members serve a two-year term, which is extendable for two additional consecutive periods. They must be Brazilian citizens with acknowledged technical competence and recognized for distinguished participation in the scientific community. All members must have a PhD degree and be professionally active in the areas of bio safety, biotechnology, biology, human/animal health and environment or in closely related areas. Twelve members from the scientific community are directly indicated by the MCTI, while the others are indicated by one of the following:Ministry of Agriculture, Livestock and Supply (MAPA); Ministry of Health; Ministry of Environment; Ministry of Agrarian Development; Ministry of Development, Industry and Foreign Trade; Ministry of Defense; Ministry of Aquiculture and Fisheries; Ministry of International Affairs; and Minister of Justice. The full list of CTNBio members can be found at http://www.ctnbio.gov.br/index.php/content/view/2251.html.

CTNBio meetings can be held with the minimum quorum of 14 members (half plus one), including at least one representative from each of the four sub commissions. If necessary, representatives from the scientific community, the public sector and civil society entities can be invited to attend meetings but do not have voting rights. Any decisions made by CTNBio must have approval by nominal vote of at least 14 members. All decisions are published in the federal journal for comments from the public within 30 days. All CTNBio meetings are open to the general population, who can consult the meeting agendas and all documents produced by the commission on the CTNBio website (http://www.ctnbio.gov.br/index.php/content/view/12840.html). Generally, public hearings are held prior to the deliberation on commercial approval of new GMO groups and CTNBio's vote.

5 The National Biosafety Council (CNBS)

The National Biosafety Council (CNBS) was created under the new biosafety law to provide higher advisory assistance to the Brazilian Republic president in formulating and implementing the National Biosafety Policy (PNB), establishing principles and guidelines that consider socioeconomic and political convenience and opportunities related to the national interest involved in commercial use of GMOs. The CNBS is linked directly to the Brazilian Presidency and is composed of 11 state ministers. The CNBS will be requested to present the last and final decision on the release of a GMO for commercial use. The technical decision on the biosafety of a commercially used GMO is made by CTNBio; however, the CNBS has 30 days to refute the commercial approval of that GMO after CTNBio has released their technical opinion. If refutation does not occur in 30 days, the product is automatically authorized for commercialization.

6 Registration and Inspection Agencies (OERF)

The Registration and Inspection agencies (OERF) are the National Agency of Sanitary Surveillance(ANVISA), the Brazilian Environmental

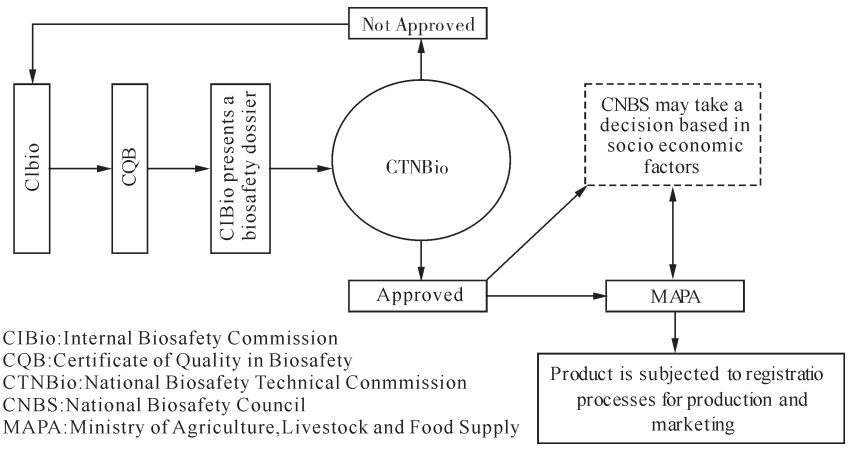

Fig.1 Workflow representing the approval process of a GM crop for research or commercial use according to the Brazilian Biosafety Law n° 11, 105/2005

Institute (IBAMA), and the GMO Biosafety Coordination (CBIO), connected to the Ministry of Health, the Ministry of Environment and the Ministry of Agriculture, Livestock and Supply, respectively. Under the Brazilian Biosafety Law and within their field of competence, in compliance with CTNBio's technical resolutions and assessments, the OERF are responsible for controlling GMOs and their by-products to achieve the following: inspect research activities; register and inspect the commercial use of GMOs; grant authorization for importing products for research and commercial use; keep updated information regarding institutions and PIs that carry out activities and projects; assist CTNBio in defining biosafety assessment parameters to disclose to the public, grant registrations and authorizations for the commercial use of GMOs; inspect institutions and their facilities and field experiments using GMOs; as well as enforce the law and implement established penalties when noncompliance with the biosafety rules or damage occurs to human and/or animal health or the environment.

7 Overview of the status of commercial GMOs approvals

Brazil is one of the major food and agriculture related goods producers in the world and one of the few countries that could considerably increase its production in the next decades. Amongst the world producers, Brazil also has great potential to become the leading bio-fuels supplier. Unlike most developed countries where agro-energy production could compete with food production, Brazil can incorporate more than 30 million hectares without destroying native and preserved environments or invading food production areas. Brazil uses approximately 12% of the world's fresh water for drinking and for agriculture. Additionally, Brazil contains between 15% and 20% of the world's biodiversity, which has a huge potential as a source of new products for agriculture, medicine and industry.

Therefore, Brazilian agriculture (from large to small farmers) and the entire agribusiness related to it has all the conditions to urge development to similar levels occurring in other emergent countries and, consequently, to help improve economic and social progress in the country and at the same time help to feed the world. The movement of crop and livestock production to the Cerrado areas in the 1970's showed how agribusiness can stimulate economic and social development. For example, some cities in the Midwest have the highest Human Development Indexes in Brazil, making the importance of agribusiness to the economy undeniable.

The challenges arising from global warming, the consequent climatic extremes and an increasing world population make sustainable food production a key issue for the next decades. Thus, to maintain productivity, it is crucial to be alert, informed and acquainted with new technologies that could change production and consumption concepts, standards and paradigms.

Consequently, using genetic engineering in agriculture to confront the challenges ahead is strategic not only for Brazil, but for the world.

In the last 10 years, Brazil has become the second largest user of GM crops with an area greater than 40 million hectares. The adoption of biotechnology products in agriculture definitively helped the country to reach this production level[6], even with the late adoption of genetically modified (GM) crops, due to a "Non Official Moratorium" caused by legal disputes from 1998 to 2005. Only after the implementation of the new Biosafety Law was the use of GM plants officially endorsed in a trustable legal framework, essential for the stability of any economic sector[7].

Several public and private, national and foreign institutions conduct research and development in Brazil to produce GM plants with several agronomic traits and/or characteristics that add value to the agriculture product. The majority of GM crops being grown in Brazil are soybeans, corn and cotton, all belonging to the first generation of transgenic plants, which are insect and/or herbicide tolerant.

As is the case in the rest of the world, the biggest share of GM crops being produced commercially in Brazil were developed by private companies such as Monsanto, DuPont Pioneer, Syngenta, Bayer and Dow, among others. However, the local research community has the know how to prospect genes of interest, "proof concept" of novel genetic engineering strategies, test it in controlled and real field conditions and take the developed product to the market. Our research institutes, our universities and the Brazilian Agricultural Research Corporation (EMBRAPA) have been developing various GM plants with different traits of interest for our agribusiness. EMBRAPA developed and deregulated the first GM bean (*Phaseolus vulgaris*) with resistance to the golden mosaic virus to be produced commercially in Brazil, and, in a joint venture with the German company BASF, developed

and deregulated an herbicide-resistant soybean. The new variety, which has resistance to imidazolinone herbicides,Will be sold in Brazil in the 2014/15 growing season under the trade name "Cultivance".

In addition to soybean, corn and cotton, various other GM crops are being tested in advanced development stages in field conditions in Brazil. Rice, passion flower, eucalyptus, "caupi" bean and sugarcane are examples of species being tested in actual field conditions for different traits such as yield improvement, drought tolerance, fungus resistance, oil quality and wood density. Before the end of 2014, CTNBio will most likely be voting for the authorization of the first GM tree to be commercialized, a Eucalyptus variety with improved growth characteristics.

As mentioned above, CTNBio had already approved 38 GM crop events for commercial use. The first approval occurred in 1998 for the "Roundup Ready" soybeans with glyphosate resistance. From 1998 to 2005, only the "BollGard" Bt cotton was deregulated before the implementation of the new Biosafety Law. Under the scope of the new legislation, the first three GM corn varieties were approved in 2007. In 2008, five releases occurred, including three for corn and two for cotton. In 2009, nine GM crop events were authorized for commercial use: one for soybean, five for corn and three for cotton. In 2010, eight new events were approved:three for soybean, four for corn and one for cotton. Over the subsequent two years (2011 and 2012), nine new GM crop events were released:three for corn, five for cotton and one for beans. Of the 38 GM Crop releases by CTNBio since 1998, 31 occurred in the last 7 years. All GM crops authorized for commercial use in Brazil can be seen at http://www.ctnbio.gov.br/upd_blob/0001/1873.pdf.

It is undeniable that there was a rapid increase in the utilization of genetic engineering technologies in the Brazilian agriculture after the new Biosafety Law. The unification of laws, rules and guidelines by all agencies involved in the Biosafety legislation framework described above allowed, undoubtedly, the rescue of the confidence by investors, researchers, private/public institutions, and by all other stakeholders involved in the Brazilian agribusiness. There is no way back in the use of biotechnology in agriculture if we want to improve food production and food quality and address the challenges ahead.

References

[1] CLIVES J. Global status of commercialized biotech/GM crops:2013. ISAAA Brief No. 46. ISAAA:Ithaca, NY. 2013

[2] CLIVES J. Global status of commercialized biotech/GM Crops:2009. ISAAA Brief No. 41. Ithaca, NY:ISAAA, 2009

[3] CÉLERES. Benefícios socioambientais da biotecnologia no Brasil:1996/97. (2011-12). http://celeres.com.br/wordpress/wp-content/uploads/2013/01/PressRelease2012_Ambiental. pdf. 2013

[4] BODANSKY D. Precautionary pinciple, Oxford Reference. (2009-10). http://www.oxfordreference.com/view/10. 1093/acref/9780195324884.001.0001/acref-9780195324884-e-191.2009

[5] CTNBio-Comiss-o Técnica Nacional de Bioseguranca. www. ctnbio. gov. br. 2014

[6] CÉLERES. Relatório de Biotecnologia. (2011-12). http:// celeres. com. br/wordpress/wp-content/uploads/2012/12/ RelBiotecBrasil_1201_vf. pdf. 2012

[7] SOUZA L. Brazilian virus-resistant beans. (2011-10). http:// www. biofortified. org/2011/10/brazilian-virus-resistant-beans/. 2011