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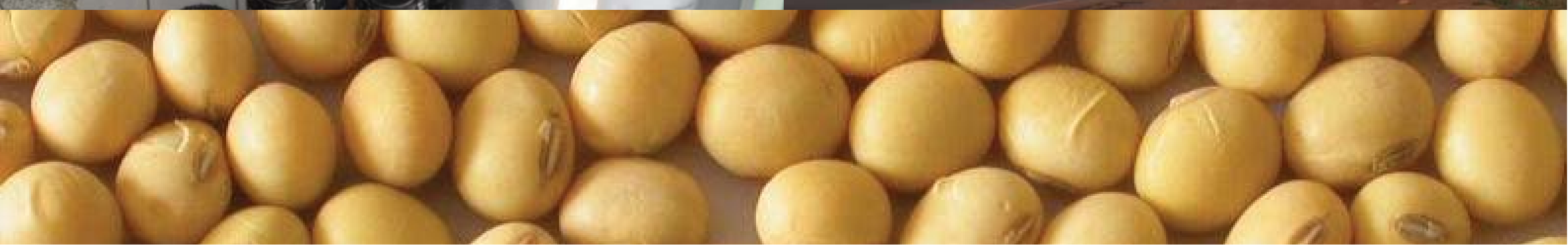

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The institutional and legal environment for GM soy in Brazil

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Foreword

This study to the institutional and legal environment of GM soy in Brazil has been commissioned by the agricultural counsellor of the Dutch Ministry of Agriculture, Nature and Food Quality (LNV) at the Dutch embassy in Brasília. The financial support received for this study from the Ministry of LNV is gratefully acknowledged. The authors also wish to acknowledge the contributions of the following Brazilian organizations that were interviewed within the framework of this project: Fundação MT, Aprosoja, IMCOPA, Abiove, CTNBio, Embrapa and SEAB. The views expressed in this report are not necessarily those of the Ministry of LNV or of the interviewees.

Summary

Soy production in Brazil has rapidly expanded in the last 15 years and Brazil has become the second largest soy producer in the world with a production 60 million ton soybean on an area of 21.6 million ha in 2007/2008. Both the EU and Brazil have a large mutual stake in the soy trade. For the EU, Brazil is the most important country of origin of soy imports and the EU livestock industry heavily depends on the import of soy proteins. For Brazil, the EU is an important market outlet for their soy industry, even thought the share of China in the Brazilian export has rapidly grown in recent years. Most soy produced in Brazil, and in the other main soy exporting countries, comes from genetically modified (GM) plants. The use of genetic modification is of importance for the soy chain, because genetic modification has an impact on the sustainability of production and raises lots of societal debate, and also because genetic modification may cause regulatory obstacles for trade. This study aims to provide an overview of the status of the GM soy chain in Brazil with an emphasis on legal and regulatory issues and the possible consequences for trade and industries in Brazil and the EU. The study is based on a review of documents, websites, scientific literature and interviews with stakeholders in the chain.

In comparison with the other main soy exporting countries, Brazil was initially rather slow with the adoption of GM crops, partly due to the unclear status of the actors responsible for the registration of GM crops. When a new biosafety law was adopted in 2005, the responsibilities in the registration process became clearer. In Brazil, the two main organizations responsible for the approval of GMOs are the National Technical Committee on Biosafety (CTNBio) and the National Biosafety Council (CNBS). CTNBio primarily deals with evaluating the safety of GMOs for humans, animals and the environment. After this technical assessment, CNBS judges whether the release of the GMO is in the broader interest of Brazil and eventually decides on the commercial release of GMOs. CTNBio has a role that is well comparable to that of EFSA's at the European level. Also the type of data that is required for the assessment of a GMO is in broad lines similar in Brazil and the EU. A difference between the approval processes is that the safety assessment by CTNBio is considered conclusive, which implies that if CTNBio considers a GMO safe for environmental or commercial release, the release cannot be halted by other actors, e.g. CNBS, based on safety arguments. In the EU safety arguments often play a role in the political decision process that follows after a GMO is considered safe for release by EFSA.

In soy, only one event (glyphosate resistant, Roundup Ready or RR soy) has so far been approved for commercial use in Brazil. RR soy is currently cultivated on an estimated 60-65% of the total soy area. Three other events leading to herbicide resistance are at this moment in the registration process for commercial release. Moreover, 32 new events or combinations of events have been authorized for testing in the field, leading to herbicide resistance, insect resistance, drought tolerance, heat tolerance, or a combination of these characteristics in soy. These events are being tested by multinational companies such as Monsanto, Pioneer Hi-bred / DuPont, Bayer and Dow Agro Science, as well as by the public research organization Embrapa. The current situation with only one commercially available event in soy owned by a single company, is thus likely to change in the near future when a variety of new events enter the market. Also the contributions of a public research institute like Embrapa, besides various multinationals, to the development of new events is likely to affect the seed sector.

In Brazil, RR soy is protected by a patent on the genetic transformation event, held by Monsanto. This patent grants its holder exclusive rights to the commercialization of soy varieties containing this event. These exclusive rights provide the basis for royalty payments. In Brazil, Monsanto agreed in 2004 with the National Association of Seed Producers and the soybean crushers that the royalty payment is implemented at two stages. Farmers are able to pay a royalty at the point of seed sale, which is verified when farmers deliver their harvested soy to the mill. Alternatively farmers could choose to pay a royalty when delivering the produce to the mill. If a farmer chooses not to declare that the soy is GM, and claims in effect that it is conventional soy, a test could be undertaken to check for the presence of RR soy. If this accounts for more than 5% of the delivery, farmers are required to pay a royalty which is 50% higher than the fee applying to the voluntary disclosure and the test costs. The possibility of paying the royalty later appears to offer farmers the benefit of a royalty charge depending on the amount of harvested soy, and thus being linked to the achieved performance. This system of royalty payments also stimulates non-GM farmers to

keep their production GM-free, as otherwise they face the risk of being penalized when delivering the produce to the mill. Local organizations receive a share in the royalties from Monsanto if the RR gene has been bred into a variety produced and owned by them, depending on the licensing agreements negotiated with Monsanto. This is an incentive for local companies to produce GM varieties, which might come at the expense of non-GM soy breeding programs. The public research organization Embrapa considers maintaining a non-GM soy breeding program a strategic priority, irrespective of the situation regarding royalties on GM crops.

Brazil is in a relatively favourable position to export non-GM soy, as adoption rates of GM soy are lower than in other exporting countries and Brazil has a functional segregation system of GM and non-GM soy which is mostly maintained by parties in the private sector. The availability of cheap and rapid strip tests to detect the presence of RR soy in samples is helpful to maintain a segregation. Brazil has no national policy in place that regulates the coexistence of GM and non-GM crops. When a GMO is authorized for commercial cultivation, it is subject to the same control procedures applied to non-GM products relating to checks for quality and phytosanitary aspects. Processors and traders are generally in favour of maintaining a non-GM soy sector in Brazil, as it allows them to capitalize on the demand for non-GM soy in the EU and Japan. The segregation of non-GM from GM during transport, storage and processing comes with higher costs and therefore traders demand a premium for non-GM produce from buyers. The poor availability of genetically pure non-GM sowing seed and of sufficient ware houses to separately store GM and non-GM soy could threaten the current segregation system.

With the anticipated arrival of new GM events patented by a variety of seed suppliers, the cultivation of GM soy probably becomes more attractive. A basket of events is more likely to offer agronomic or economic benefits to farmers than the single event that is currently available. The technology fees for GM seed may decrease when more suppliers of GM seed compete with each other. As the difference in agronomic or economic performance between GM and non-GM soy increases, farmers are likely to demand higher premiums for non-GM produce from processors and traders, leading to higher price differences for buyers of non-GM soy. Farmers mentioned they rarely receive premiums when delivering non-GM soy to traders or processors. This should eventually change if the sector wants to maintain non-GM production. As the domestic demand for non-GM soy is small, the willingness of consumers overseas to pay (increasing) premiums for non-GM soy will determine the future of the non-GM soy sector in Brazil.

The regulations for labeling and traceability of products made with the help of GMOs in Brazil are different from those in the EU. Among others, the Brazilian labeling policy is product-based (i.e. only if recombinant DNA or transgenic proteins are present in the end-product, it is subject to labeling regulations), while the EU policy is process-based (i.e. all authorized GMOs and products derived from GMO, whether or not containing detectable recombinant DNA or transgenic proteins, have to be labeled). This is not a problem for the trade of beans and meal, as the presence of GM can be easily monitored when shipments arrive in the EU. With the smaller imports of soy oil and other products derived from soy, in which the use of GMOs cannot measured in de end product, the situation is more complex. The EU requires in that case a traceability of the product to determine the use of GMOs in the production process. As this is not a legal requirement in Brazil, private initiatives should ensure this when targeting the non-GM markets in the EU.

The asynchronous approval of events in Brazil and the EU, along with a zero-tolerance policy in the EU towards the import of unauthorized events, may cause a disruption of the trade in soy products between Brazil and the EU. Given the dependency of the EU livestock sector on imported soy, the economic consequences of a disruption could be severe for the EU. The asynchronous approval of GM crops other than soy can also hinder the soy trade between Brazil and the EU, as the minute presence of other crops in soy shipments cannot be entirely avoided. Given the large number of new events that are in the registration procedure or being tested in the field, asynchronous approvals will remain an issue of importance. The presence of a strict ‘identity preserved’ system for non-GM soy or for EU-authorized GM soy is costly, but can reduce though not eliminate the risk of the adventitious presence of unregistered events. A lack of storage and transport facilities in Brazil can make the segregation of non-GM, EU-authorized GM and EU-unauthorized GM soy impossible however. When the approval of a GM event may lead to a trade disruption, CNBS could decide to postpone or cancel the release of this event, for instance based on the argument that the release is not in the socio-economic interests of Brazil. Actors in the Brazilian soy chain are well aware of the potential consequences of asynchronous approvals for the trade with the EU and are willing to undertake efforts, by targeting CNBS or in other ways, to avoid this.

Summary (in Portuguese)

A produção de soja no Brasil se expandiu rapidamente nos últimos 15 anos e o Brasil se tornou o segundo maior produtor de soja do mundo, com uma produção de 60 milhões toneladas de soja em uma área de 21,6 milhões de hectares em 2007/2008. Tanto a UE e o Brasil mutualmente, possuem grande participação no comércio de soja. Para a UE, o Brasil é a principal origem das importações de soja, sendo o setor de produção animal da EU fortemente dependente da importação de proteínas de soja. Para o Brasil, a UE é um importante mercado para a sua indústria de soja, mesmo sabendo que a participação da China nas exportações de soja brasileira tem crescido rapidamente nos últimos anos. A maior parte da soja produzida no Brasil, e nos outros principais países exportadores de soja, são oriundos de plantas geneticamente modificados (GM). O uso de modificação genética é de importância para a cadeia da soja, porque a modificação genética tem um impacto sobre a sustentabilidade da produção e gera vários debates dentro da sociedade, e também porque a modificação genética pode causar obstáculos regulamentares para o comércio. Este estudo visa fornecer uma visão geral do estado da cadeia de soja transgênica no Brasil, com ênfase nas questões legais e regulamentares e as possíveis consequências para o comércio e indústrias do Brasil e da UE. O estudo é baseado em uma revisão de documentos, websites, literatura científica e entrevistas com participantes envolvidos na cadeia.

Em comparação com os outros principais países exportadores de soja, a adoção de culturas GM no Brasil foi inicialmente bastante lenta, em parte devido à situação incerta dos agentes responsáveis pelo registo das culturas GM. Quando uma nova lei de Biossegurança foi aprovada em 2005 as responsabilidades no processo de registro se tornaram mais claras. No Brasil, as duas principais organizações responsáveis pela aprovação dos OGMs são a Comissão Técnica Nacional de Biossegurança (CTNBio) e o Conselho Nacional de Biossegurança (CNBS). A CTNBio lida principalmente com avaliação da segurança dos OGMs para os seres humanos, animais e meio ambiente. Após esta avaliação técnica, os membros CNBS julgam sob os apectos da vida e oportunidades sócio-econômica se a liberação comercial do OGM está no maior interesse do Brasil, e eventualmente, avocar e decidir, em última e definitiva instância, sobre os processos relativos a atividades que envolvam o uso comercial de OGM e seus derivados. A CTNBio tem um papel que é bem comparável ao da EFSA's, a nível europeu. Os tipo de dados que são necessários para a avaliação de um OGM são, em linhas gerais, também semelhantes no Brasil e na UE. A diferença entre os processos de aprovação é que a avaliação de biossegurança executado pela CTNBio é considerado conclusivo, o que implica que, se a CTNBio considera um OGM seguro para a liberação ambiental e comercial, a liberação não pode ser interrompida por outros atores, por exemplo, CNBS, baseada em argumentos de segurança. Por outro lado, na UE os argumentos externos de segurança, muitas vezes desempenham um papel no processo de decisão política que se segue depois de um OGM é considerado seguro para a liberação pela EFSA.

Para a soja até então, apenas um evento (tolerância ao herbicida glifosato, o Roundup Ready ou soja RR), foi aprovado para uso comercial no Brasil. A soja RR é atualmente cultivada em, aproximadamente, 60-65% da área total de soja. Três outros eventos tolerantes a herbicidas estão neste momento dentro do processo de registro aguardando a decisão da comissão sobre o pedido de liberação comercial. Além disso, 32 novos eventos ou combinações de eventos relacionados à tolerancia a herbicidas, resistência a insetos, tolerância à seca, tolerância ao calor, ou uma combinação destas características na soja, foram autorizadas para testes no campo. Estes eventos estão sendo testadas por empresas multinacionais como a Monsanto, Pioneer Hi-bred / DuPont, Bayer e Dow Agroscience, bem como pela instituição pública de pesquisa Embrapa. Portanto, é provável que a situação atual com apenas um evento em soja disponível comercialmente e pertencente a uma única empresa, mude no futuro próximo, quando uma série de novos eventos no mercado. Além disso as contribuições de um instituto de pesquisa público, como Embrapa, e de várias empresas multinacionais, no desenvolvimento de novos eventos provavelmente afetará o setor de produção e comercialização de sementes.

No Brasil, a soja RR é protegida por uma patente sobre o evento de transformação genética, pertencente à Monsanto. Esta patente confere ao seu titular direitos exclusivos sobre a comercialização de variedades de soja que contêm este evento. Estes direitos exclusivos fornecem a base para a cobrança de royalties. No Brasil, em 2004, a Monsanto concordou com a Associação Nacional dos Produtores de Sementes e as indústrias

processadoras de soja das principais regiões produtoras que o pagamento de royalties poderia ser implementado de duas maneiras. Os agricultores que adquirissem sementes licensiadas poderiam pagar o royalty através de um boleto de pagamento após a compra das semenstes. Além desta opção, os agricultores poderiam optar por pagar o royalty no momento da entrega dos grãos. Se um agricultor opta por não declarar que a soja que está sendo comercializada é RR, um teste é realizado para verificar se a entrega não contém soja RR. Se o teste demonstrar a presença de soja RR superior a 5% do fornecimento, o agricultor é obrigados a pagar um royalty 50% superior à taxa aplicável no caso de divulgação voluntária mais os valores gastos com o teste. A possibilidade de pagar o royalty no momento da entrega parece oferecer aos agricultores o benefício de uma taxa de royalties, dependendo da quantidade de soja colhida, e assim estar ligada ao desempenho alcançado. Empresas de melhoramento genético público e privado recebem uma participação nos royalties pagos a Monsanto, caso o gene RR tenha sido introduzido em uma variedade desenvolvida e pertencente a tais institutos, dependendo da negociação de acordos de licenciamento com a Monsanto. Este é um incentivo para que as organizações locais desenvolvam variedades geneticamente modificadas, o que pode vir em detrimento de programas de melhoramento genético convencionais. Embrapa, por outro lado considera a manutenção de um programa convencional de melhoramento de soja uma prioridade estratégica, independentemente da situação envolvendo o pagamento de royalties sob o cultivo de OGMs.

O Brasil está em uma posição relativamente favorável para exportar soja não-transgênica, visto pelas taxas de adoção da soja transgênica inferiores aos de outros países exportadores, e o fato do Brasil possuir um sistema de separação funcional da soja GM e não-GM, que é mantida principalmente pelos representates do setor privado. A disponibilidade de testes de fitas baratos e rápidos para detectar a presença de soja RR em amostras é útil para garantir a segregação. O Brasil não tem uma política nacional em vigor que regula a coexistência de culturas GM e não GM. Quando um OGM é autorizado para cultivo comercial, ele estará sujeito aos mesmos procedimentos de controle que se aplicam aos produtos não-transgênicos em matéria de controle de qualidade e aspectos fitossanitários. Processadores e exportadores em geral são a favor da manutenção de um setor para a soja convencional no Brasil, o que lhes permitem aproveitar a demanda por soja não-transgênica na UE e Japão. A segregação de soja transgênica e convencional durante o transporte, armazenamento e processamento vem com custos mais elevados e, portanto, as indústrias e traders exigem dos compradores um prêmio pela produção de soja convencional. A baixa disponibilidade de sementes não transgênicas e da suficiente estrutura para armazenar separadamente a soja trasngênica e convencional poderiam ameaçar o sistema de segregação atual.

Com a aprovação de novos eventos GM patenteados por uma variedade de empresas, o cultivo da soja transgênica provavelmente se tornará mais atraente. Uma cesta de eventos é mais provável de oferecer mais benefícios agronômicos e econômicos para os agricultores que o único evento que está atualmente disponível. As taxas de tecnologia para as sementes GM também podem diminuir quando mais empresas fornecedoras de tecnologia transgênica competirem uns com os outros. Com o aumento na diferença do desempenho agronômico ou econômico entre a soja transgênica e não transgênica, os agricultores tendem a exigir de índútrias e traders prêmios mais elevados para produzir soja convencional, levando a diferenças de preços mais elevados para os compradores de soja não-transgênica. Os agricultores entrevistados mencionaram que raramente recebem prémios ao entregar soja não-transgênica aos comerciantes e processadores. Esta situação deve vir a alterar-se se o setor quiser manter a produção não transgênica. Como a demanda interna de soja não-transgênica é pequena, a disposição dos consumidores no exterior para pagar (crescente) prêmios de soja não-transgênica vai determinar o futuro do setor de soja convencional no Brasil.

Os regulamentos de rotulagem e de rastreabilidade dos produtos feitos com a ajuda de organismos geneticamente modificados no Brasil são diferentes das normas da UE. Entre outros, a política brasileira de rotulagem é produto orientada (ou seja, apenas se DNA recombinante ou proteínas transgênicas estão presentes no produto final, que está sujeito a regras de rotulagem), enquanto a política da UE é baseado em processo (ou seja, todos os OGM autorizados e produtos derivados de OGM, contendo ou não detectáveis de DNA recombinante ou proteínas transgênicas, têm de ser rotulados). Este não é um problema para o comércio de grãos e farelo, já que a presença da OGM pode ser facilmente monitorados quando os navios desembarcam na UE. Sobre as menores quantidades de importação de óleo de soja e outros produtos derivados da soja, em que a presença do DNA recombinante ou proteínas transgênicas não podem ser medidas ao chegarem na UE, a situação é mais complexa. A UE exige nesse caso, uma rastreabilidade do produto para determinar a utilização de OGM no processo. Como no Brasil isto não é uma exigência legal, a iniciativa privada deve assegurar isso quando estiver visando os mercados não-GM dentro da UE.

A aprovação assíncrona de eventos no Brasil e da UE, juntamente com uma política de tolerância zero na UE para a importação de eventos não autorizados, podem causar uma interrupção do comércio de produtos de soja entre o Brasil e a UE. Dada a dependência do setor pecuário da UE em relação à importação de soja, as consequências econômicas de uma interrupção poderá ser grave para a UE. A aprovação assíncrona das culturas geneticamente modificadas que não a soja também podem entravar o comércio de soja entre o Brasil e a UE, já que a mínima presença de produtos de outras culturas nos embarques de soja não podem ser totalmente evitada. Dado o grande número de novos eventos que estão no processo de registo ou que está sendo testado no campo, as aprovações assíncrona continuaram a ser uma questão de importância. A presença de um rigoroso sistema de 'preservação de identidade' para a soja não-transgênica ou para a soja transgênica autorizada na UE é caro, mas pode reduzir, mas não eliminar, o risco da presença adventícia de eventos não registrados. Além disso, a carência de infra-estrutura de armazenamento e de transporte no Brasil podem fazer a separação das variedades de soja convencional, transgênicas-autorizada pela UE e da soja transgênica não autorizada pela UE impossível. Quando houver a aprovação de um evento GM capaz de conduzir a uma perturbação do comércio, a CNBS poderá decidir pelo adiamento ou cancelamento do lançamento deste evento, por exemplo, com base no argumento de que a liberação desfavoreceria os interesses socio-econômico do Brasil. Atores da cadeia da soja brasileira estão bem cientes das potenciais consequências resultantes das aprovações assíncronas para o comércio com a UE e estão dispostos a empreender esforços, através da CNBS ou de outras formas, para evitar esta situação.

1. Introduction

Soy production in Brazil has rapidly expanded in the last 15 years and Brazil has become the second largest soy producer in the world with a production 60 million ton soybean in 2007/2008 (ISTA Mielke in MVO, 2009). The US had a production of 72.9 million ton and Argentina produced 46.2 million ton in 2007/2008. While in the early 1990s the increase of the Brazilian soy production was mainly due to an increase in productivity, the increase in 1996 -2003, when the production went from 23 million tones to almost 52 million tons, was mostly the result of a rapid increase in the soy area (Figure 1.1). The export of soybeans and soy products has become the main agricultural commodity in the trade balance of Brazil. In 2005, the Brazilian soy exports reached a value of US$ 9.5 billion (ABIOVE, 2009).

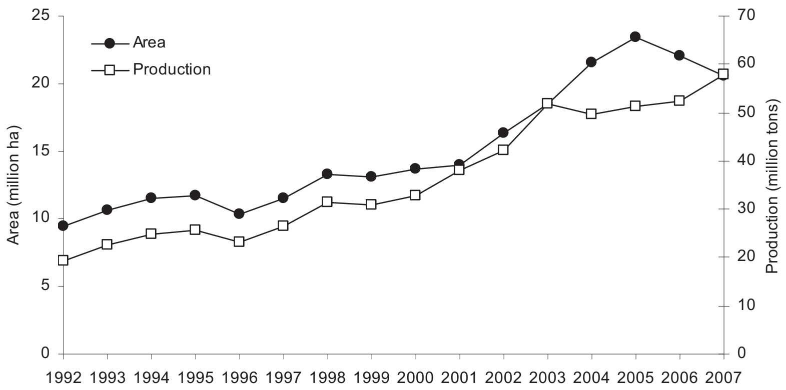

Figure 1.1. The Brazilian soy area and production in 1992-2007 (IBGE/PAM, 2009).

Soy is produced in Brazil on a wide variety of farms in all states south of the Amazon biome. Two important regions for soy production can be distinguished: the more traditional soy production area in the southern states of Brazil and the newer production area in the central west (Mato Grosso and neighbouring states). In production areas far from harbours or domestic markets, e.g. in the central west, farms tend to be large scale (> 1000 ha), which is a necessity to compensate for the poor infrastructure and high transportation costs of soy grain to market outlets. In the southern States, also smaller (< 100 ha) arable farms exist. More recently, an extension of the soy area has also occurred in south Maranhão, south Piaui and Toscantins. While the vast majority of soy in Brazil is produced on family-owned farms, some agri-businesses have emerged producing soy on very large landholdings, some owning more than 100,000 ha. These agri-businesses are usually also involved in other parts of the soy chain, such as storage, processing, transportation and trade. Although domestic soy consumption is increasing in Brazil, the vast majority of the production is exported to other countries by multinationals, which are usually also engaged in a range of other activities in the Brazilian agri-chain including storage and processing, the production of fertilizers and credit supply to farmers (Meijerink and Danse, 2009).

Both the EU and Brazil have a large mutual stake in the soy trade. For the EU (EU-27), Brazil is the most important country of origin of soy imports. For Brazil, the EU is an important market outlet for their soy industry, even thought he share of China in the Brazilian soy export has rapidly grown (Figure 1.2). In 2008, 52% of Brazil's soy exports were shipped to the EU. As a comparison, 44% of Argentina's and 9% of the US soy exports went to the EU. In 2008, the EU imported 34.4 million tonnes of soybean meal equivalents, of which 46% came from Brazilian exports to the EU, primarily (> 95%) as beans and meal. Argentina and the US were responsible for 38% and 10%, respect-tively, of the EU imports. Brazil is the largest exporter of soybeans and oil to the EU and the second largest exporter of soy meal (after Argentina). Soybeans imported in the EU are virtually all crushed into soy meal and oil. Soy oil has a wide range of applications in the EU in the food industry and the chemical industry. Soy meal is primarily used in the livestock feed industry, as a high protein content and favourable protein composition make soy meal a popular component of poultry and pig feed. The EU livestock industry is largely dependent on the import of plant proteins from soy, as currently no agronomically and economically suitable alternatives for soy meal in feed are available (Bindraban *et al.*, 2008). Soy covered 65% of the total demand for proteins used in animal feeding in the EU in 2007 (FEFAC, 2008).

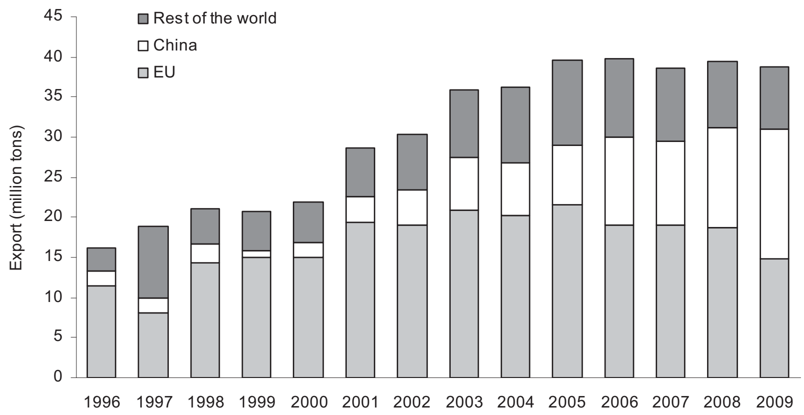

Figure 1.2. Main destinies of Brazilian soy exports in 1996-2009 (beans, meal and oil combined; 2009 data are projected exports) (SECEX, 2009).

The rapid growth of soy production in Brazil and elsewhere in Latin America in the last 15 years has raised concerns about the sustainability of the soy chain. While the expansion of the soy sector contributed to economic growth and job creation, it also entailed considerable social and environmental costs. In response to these concerns, the Round Table on Responsible Soy (RTRS) has been established by stakeholders in the soy chain, including producers, agri-businesses and civil society organizations (RTRS, 2009). Among others, the RTRS has defined principles and criteria for a responsible soy chain and is currently testing the implementation of draft principles and criteria in the field.

The majority of soy produced in Brazil and the other main soy exporting countries in the world comes from genetically modified (GM) soy plants. The use of genetic modification in soy is of importance for the soy chain, not only because genetic modification has an impact on the sustainability of soy production and raises lots of societal debate, but also because genetic modification may cause regulatory obstacles for trade. Trade may be affected, for example, by the numerous new GM events that are likely to be commercially released in Brazil in the next few years, as regulations with regard to new GM soy lines in soy importing countries or trade blocks such as the EU are unlikely to be synchronic (in time) with those of Brazil. This asynchrony may cause gaps in the supply of soybean to the European market (Aramyan *et al.*, 2009), that may in turn affect the livestock production sector in Europe (Bindraban *et al.*, 2008). Also the implementation of these regulations may differ between countries. Therefore, it is important for actors in the soy chain, including stakeholders of the RTRS, to be informed about the institutional and legal aspects of GM soy in Brazil. This will help the actors in the soy chain to deal with regulatory obstacles for trade that may be associated with the introduction of new GM soy lines in Brazil. The economic importance of the soy trade between Brazil and the EU for both trading partners highlights the need for information on the institutional and legal aspects of GM soy in Brazil and Europe.

This study aims to provide an overview of the status of GM soy in Brazil with an emphasis on legal and regulatory issues and the possible consequences for trade and industries in Brazil and the EU. The study is based on a review of documents, websites, scientific literature and interviews with stakeholders in the soy chain.

A series of interviews were held within the framework of this project by A.C. Franke and F. M. Greco in Brazil between August 24 and September 3, 2009. Most of the interviewees had limited comprehension of English and interviews were usually held in Portuguese. Since the reports of the interviews were in English, the interviewees have not checked the content of the summaries. Therefore, in this report we refer to information from the interviews as personal communication with representatives from the organizations. These interviewed organizations were:

- Fundação MT – one of the main breeding companies of Mato Grosso working with soy.
- Aprosoja – an association of soybean producers from Mato Grosso.
- IMCOPA – an exclusively non-GM soy processing and trading company.
- Abiove – the Brazilian Association of Vegetable Oil Industries.
- CTNBio – the national technical commission on Biosafety, the commission evaluates the safety of new GMOs.
- Embrapa – The Brazilian Agricultural Research Corporation, a public research organization
- SEAB – Secretariat of Agriculture and Food Stocks of Paraná State, a State of Brazil that has implemented a policy favouring the cultivation of non-GM crops.

2. GM soy in Brazil

2.1 Actors in the soy chain

Soy is produced by farmers that are usually organized through farmers' associations, and cooperatives. Some of the bigger farmer groups include APROSOJA (Mato Grosso State), COAMO, COCAMAR (Paraná State) and COMIGO (Goiás State). Some of the large agri-businesses that produce soy in Brazil include Grupo André Maggi and SLC Group that together cultivate 255,000 hectares and produce close to 793,000 tons of soybeans.

The soy varieties sold in Brazil were before the introduction of GMOs almost exclusively developed by public research institutes such as Embrapa and local companies, such as FT Sementes, Fundação Mato Grosso in the State of Mato Grosso, Coodetec in the State of Paraná and Fundacep in the State of Rio Grande do Sul. More recently, large multinational seed suppliers, such as Monsanto Company, BASF Group, Bayer CropScience, Syngenta seeds and Pioneer Hi-Bred / Dupont, have initiated activities in Brazil through the sale of sowing seed and/or the development of new (GM) soy varieties. They usually do this in partnership with local breeding and seed production companies and sometimes with agricultural research organizations, such as Embrapa, as these organizations have access to the locally adapted soy varieties.

The main overseas traders of soy are multinationals such as Cargill, ADM, Bunge, Amaggi and Louis Dreyfus. These multinationals may also take care of soy processing, transport and other aspects of the soy chain in Brazil and in soy importing countries. For instance, Cargill and ADM are the major processors of soybeans in the Netherlands (MVO, 2009). The vegetable oil industry in Brazil is represented by ABIOVE, the Brazilian Association of Vegetable Oil Industries. Some soy processors are specialized in non-GM soy. Producers and industries active in the non-GM chain (soy and other crops) are represented by ABRANGE, the Brazilian association of non-genetically modified grain producers (ABRANGE, 2009).

Research on soy is carried our by universities, including the University of São Paulo and Mato Grosso and the Matogrossense Institute of Agricultural and Livestock Farming Economics. Much of the applied agricultural research on soy as well as soy breeding is done by Embrapa, the Brazilian Agricultural Research Cooperation. Embrapa Soybean, for instance, actively contributes to the development and testing of new GM soy lines in Brazil, together with partners from the private sector. Sister institutions, like Embrapa Cerrado, support this process.

Ministries that deal with the soy chain, including biotechnology, are the Ministry for Agriculture, Livestock and Food Supply, the Ministry for Health, the Ministry of Science and Technology and the Ministry for Environment. The National Biosafety Council (CNBS) plays a role in the registration of GMOs and is composed of representatives from 10 ministries. The National Technical Committee on Biosafety (CTNBio) includes more technical experts and has the objective to provide technical support to the Brazilian Federal Government to its National Biosafety Policy. This includes advice on the registration of new GMOs.

Many Civil Society Organizations from Brazil and elsewhere deal with the Brazilian soy chain. Civil Society Organizations that are member of the RTRS include WWF, the Moore Foundation, Conservation International, Solidaridad, Instituto ETHOS and Instituto de Pesquisa Ambinetal da Amazônia (IPAM). Other Civil Society Organizations, such as Corporate Europe Observatory, Grupo de Reflexión Rural and Greenpeace, are critical on the aims or the approach of the RTRS.

2.2 Approved GM events

As per October 2009, 18 events or combinations of stacked events were approved for commercial use in crops (including cultivation) by CTNBio in Brazil (CTNBio, 2009). More detailed information on the functioning of CTNBio is given in Chapter 3 of this report. Approved GM events in Brazil include:

Soybean
- GTS40-3-2, glyphosate resistant (herbicide-resistant; Roundup Ready; approved on 29 September 1998)

Maize
- GA21, glyphosate-resistant
- NK603, glyphosate-resistant
- T25, glufosinate-resistant
- MON810, Lepidoptera-resistant
- Bt11, Lepidoptera-resistant
- TC1507, Lepidoptera-resistant
- Bt11 x GA21, insect and herbicide resistant
- MON810 x NK603, insect and glyphosate resistant
- MIR162, insect resistant
- TC 1507 x NK 603, Insect and glyphosate resistant
- Mon 89034, Insect resistant

Cotton
- MON1445, glyphosate resistant
- LLCotton25, glufosinate resistant
- 281-24-236/3006-210-23, insect resistant
- MON15985, Bollgard II, insect resistant
- MON 531 x MON 1445, insect and herbicide resistant
- 531, insect resistant

In addition, with regard to approvals for import only, CTNBio considered a request that was made by poultry producers to allow the use of maize grain imported from Argentina in 2000. Whilst the ensuing decision does not specifically mention the GMOs, it mentions the newly introduced proteins in the various GM maize lines, including mutant maize EPSPS (glyphosate resistance), PAT (glufosinate resistance), and Bt proteins Cry1Ab, Cry1Ac, and Cry9C. The decision focuses on the safety of these newly expressed proteins and poses requirements regarding the transport and handling of the imported GM maize grains, including the use of only non-viable processed products as animal feed, the destruction of discarded materials, and the reporting of any accidental environmental releases.

The current situation regarding GM soy is thus relatively simple with only one GM event (glyphosate resistance) in soy allowed for commercial cultivation and import.

2.3 Expected GM events

The following GMOs have been submitted for regulatory approval by CTNBio in Brazil (status as mentioned in the agenda of the ‘124a Reuniao ordinária da CTNBio’ (CTNBio, 2009):

Soybean
- A2704-12, glufosinate-resistant (herbicide-resistant, Liberty Link, Bayer S.A.)
- Event A5547-127 glufosinate resistant (herbicide-resistant, Bayer S.A.)
- CV127 Imidazolinone resistant (herbicide resistant, BASF S.A. / Embrapa soja)

Maize
- MON89034 (insect resistant, Monsanto)
- Insect resistant maize (Syngenta Seeds Ltd)

Rice
- LLRICE62, glufosinate-resistant (herbicide-resistant, Liberty Link, Bayer S.A.)

Cotton

- MON531xMON1445 (insect and glyphosate resistant, Monsanto)

The three GM events in soy that have been submitted to CTNBio for approval for commercial release all have traits leading to resistance to broad-spectrum herbicides. These events are likely to be commercially released in the near future.

As per September 2009, 32 new GM events in soy have been authorized by CTNBio for testing in the field. Of these 32 events, 15 lead to herbicide resistance, 14 to insect resistance, 2 to both insect and herbicide resistance and one to both drought and heat tolerance. These events are being tested by Monsanto (14 events), Embrapa (6 events), Pioneer Hi-bred / DuPont (3 events), Bayer (3 events) and Dow AgroScience (2 events). National research institutions besides Embrapa, such as The Fundação Centro de Experimentação e Pesquisa Fecotrigo and The Cooperativa Central de Pesquisa Agrícola – Coodetec, are also involved in the testing of new GM events. These institutions obtained access to the transgenic technology through licensing agreements with Monsanto or Embrapa.

The current situation in Brazil with only one GM event in soy commercially available owned by a single company, is thus likely to change in the near future when a variety of new events patented by different parties enter the market.

2.4 Adoption of GM soy

Before regulatory approval of RR soy in Brazil in 2003, it was likely that GM seeds were smuggled into Brazil and planted, primarily in the southern part of the country (Rhodes, 2007). When GM cultivation was officially permitted in 2003, the share of GM soy in the total soy area rose rapidly, up to an estimated adoption fraction of 66% in 2007 (USDA/FAS, 2009). The rapid growth in the adoption of RR soy came to a halt in 2008 when 65% of the area planted with soy was GM. Based on the interviews held in Brazil, the authors estimate that the adoption rate of RR soy in 2009 (season 2008/2009) has remained 60-65% of the total soy area. The lack of economic incentives to grow RR soy was frequently mentioned by farmers as the main reason for the stagnation of the growth in the adoption rate of RR soy. The adoption rate of GM soy varies between regions. According to the farmers' association Aprosoja, GM soy was grown on 50% of the soy area of Mato Grosso, while this was reported by SEAB to be only 40% in Paraná State.

With a total soy acreage of 21.6 million ha in 2008 (USDA/FAS, 2009), the area of GM soy in Brazil in 2008 was estimated to be 13.0 - 14.0 million ha and the area of non-GM soy to be 7.6 - 8.6 million ha. With an average soy yield in 2008 of 2.8 ton / ha, the GM soy production is estimated to equal 36.4 - 39.2 million tons and the non-GM soy production to be 21.3 – 24.1 million tons.

3. The registration process of GM crops in Brazil

3.1 The establishment of a legal framework for GMOs

In comparison with the other main agricultural producers in the Americas - Argentina, the US and Canada - Brazil was rather slow with the approval of the first GM crops. In Argentina RR soy was already released in 1996 and the financial crisis in the late 1990s gave a stimulus to Argentinean policy makers and farmers to support the RR soy technology because of the export potential of soy (not specifically GM soy). To understand why the creation of a legal framework for GM crops has taken more time in Brazil than in Argentina or the US, one has to understand the drivers and constraints in the politics of agricultural biotechnology in Brazil.

The debate on agricultural biotechnology in Brazil was an extension of two other policy debates: the debate on land reform and the debate on the 'green revolution' in agriculture. The political alliances in these debates had a clear overlap with the alliances in the debate on agricultural biotechnology. Furthermore the debate on agricultural biotechnology was highly influenced by the emergence of consumer and environmental legislation and lobbies. Together with the Brazilian system of federalism, this made the debate relatively pluralistic in nature (Rhodes, 2007).

In the late 1990s and early 2000s Brazil was the most important agricultural exporter that had objections against the revolution of biotechnology in agriculture. The creation of the National Biosafety Technical Commission (CTNBio) (see also section 3.2) in 1996 was controversial, since the Commission had the power to overrule objections of the health and environmental ministries. From the start, therefore, there was a divide in the government between the Ministry of Agriculture, Livestock and Food Supply, and the Ministry of Science and Technology on the one hand, and the Ministry for Health, and the Ministry for Environment on the other hand.

CTNBio approved Monsanto's RR soy varieties in 1998. A conspicuous feature of the approval was that, in addition to granting a five-year approval period, CTNBio also demanded that monitoring potential environmental impacts in the field should be done. This monitoring had to focus on weed biodiversity in soy fields, transfer of the transgenes to weed species (providing a selective advantage for escape), periodic analysis of indicator organisms (insects, pathogens, nitrogen-fixing and phosphate-solubilizing soil micro-organisms). The company had to provide annual reports to CTNBio, whilst CTNBio experts should also be able to inspect the monitoring areas themselves (Mendonca Hagler *et al.*, 2008).

When the CTNBio gave permission to Monsanto to conduct field tests of RR soy in Brazil, the consumer protection NGO Instituto Brasileiro de Defesa do Consumidor (IDEC), together with other consumer protection and environmental NGOs (including Greenpeace) and the Landless Rural Workers' Movement (MST) started a campaign for a transgenic-free Brazil. These organizations were engaged in battles against the cultivation and commercialization of GM soy and other GM crops in Brazilian courts, the national and state legislatures, and public opinion. They focused on the important group of urban, middle-class consumers in the major cities and succeeded to capture much media attention with protests at supermarkets where GM food products were sold and (legal) actions to prevent shipping of GM products from the US to Brazil (Rhodes, 2007; Scoones, 2008).

When CTNBio approved RR soy varieties in 1998, IDEC immediately responded by filing a lawsuit to prevent the commercial release of the new varieties, which resulted in a legal ban against commercial release in December 1998 (Scoones, 2008). The most important objection of the opponents was that the approval was given without a formal environmental impact assessment, which was required by law. In 1999 protests against GMOs increased and activists tried to stimulate state-level governments to prevent the expansion of biotechnology in agriculture. The governments of three southern states (Paraná, Santa Catarina and Rio Grande do Sul) responded positively and introduced legislation that was stricter than the federal legislation (such as more detailed environmental impact assessments) with the ultimate aim to keep their states GM-free. The reaction of the agribusiness sector differed however. In Paraná State, the main agribusiness representative groups supported the anti-GM stance of the government, as they feared loss of exports to the EU, which is Paraná's most important export market. In Rio Grande do Sul, soy producers opposed the anti-GM policy of their government, as they feared a loss of competitiveness to Argentina and the US (Pelaez and Albergoni, 2004). Later, federal courts decided that the states had no power to declare their states GM-free.

The government of President Cardoso, which was initially slow to embrace agricultural biotechnology, tried to turn the tide by empowering CTNBio in 2000, but this did not have much impact on the authorization of RR soy. After a new president (Lula) was elected in 2002, the new Minister of Agriculture, Roberto Rodrigues, expressed his support of GM crops. RR soy was probably already widely adopted by this time in Brazil, as RR seeds were increasingly being smuggled into Brazil and planted by farmers. Especially in the southern states of Brazil, nearby Argentinean soy production areas, many farmers were already growing RR soy. It is estimated that in 2001, already 30% of the soy acreage in Brazil was GM (USDA/FAS, 2009). Therefore, the Lula government was faced with a major dilemma – either continue to uphold the ban and enforce the destruction of the planted GM soybean which could result in major claims for compensation, or allow its sale. The Brazilian president decided to allow the sale of RR soy through a series of presidential decrees, despite the fact that GM soy had not been officially approved for planting.

Subsequently, the Biosafety Law was revised in March 2005 and the government passed a bill that recognized the full powers of CTNBio. Hence, after a period of ten years (1995-2005), Brazil succeeded in creating a clear legal framework governing GMOs with clear positions and responsibilities for the regulatory institutions (see also Mendonca Hagler *et al.*, 2008). Table 3.1 provides an overview of the most relevant legislation on biotechnology in Brazil. In addition, CTNBio has published twenty 'Normative Instructions' and two 'Normative Resolutions' for among others GMO risk evaluation and authorization.

Table 3.1. Chronologic overview of most important Brazilian legislation on biotechnology.

Date	Legislation	Description
1981	Law 6.938	Referenced with regard to obligatory environmental impact assessments
1991	Law	Consumer Protection Code: basis for GM labeling requirement
1995	Law 8.974	Requires environmental impact assessments to be completed before GM crops may be commercialized
1995	Decree 1.752	Establishes regulatory norms for Law 8.974; creation of CTNBio
2001	Decree 3.871	Requires labeling of foods with more than 4% GM content
2003	Decree 4.680	Requires labeling of foods with more than 1% GM content
2003	Decree 10.688	Decree permitting commercialization of GM soy for one year
January 2005	Law 11.092	Liberates GM soy harvest of 2004/05 (as has happened with 2002/03 and 2003/04 harvests)
24 March 2005	Law 11.105	Streamlines approval process for scientific research; approval of requests by Ibama, Anvisa and Ministry of Agriculture not required anymore; creation of CNBS; strengthening of position of CTNBio
22 November 2005	Decree 5.591	Implements Law No. 11.105
21 March 2007	Law 11.460	Change of Law 11.105: simple majority of votes (instead of two third) is needed to approve new GM events
18 June 2008		CNBS decides to not to evaluate technical decisions on GM events that are approved by CTNBio (i.e. strengthening of position of CTNBio and further streamlining of approval process)

3.2 The current registration process

The two main organizations involved in the approval of GMOs are CTNBio and CNBS. CTNBio primarily deals with evaluating the safety of GMOs for humans, animals and the environment. After the technical safety assessment by CTNBio, CNBS judges whether the release of the GMO is in the broader interest of Brazil.

CTNBio is designated a multidisciplinary institution, whose objective is to provide technical support to the Brazilian Federal Government, through consultations and assessments, with its National Biosafety Policy. The topics covered by these activities include the technical standards of safety, the protection of human and environmental health of GMOs and derived products used for research, experimentation, transport, cultivation and other forms of environmental release, marketing, and consumption. CTNBio was legally restructured by Law #11,105 of 24 March 2005 as part of/under the Ministry of Science and Technology.

CTNBio committee has 27 positions (and their deputies) available for experts, which are subdivided into four groups of three experts specialized in the field of human health, plant sciences, animals sciences, and environmental sciences (nominated by the Minister of Science and Technology), and, additionally, six experts specialized in consumer protection, health, environment, biotechnology, household agriculture, and labourers' health (each one nominated by the ministry responsible for the pertinent topic) (Table 3.2). In addition, positions have been reserved for one representative of each of the various ministries that take part in the CTNBio, including the Ministry of Science and Technology; the Ministry of Agriculture, Livestock, and Supply; the Ministry of Health; the Ministry of the Environment; the Ministry of Rural Development; the Ministry of Development, Industry and Foreign Trade; the Ministry of Defence; the Ministry of Foreign Affairs; and the special presidential secretariat on aquaculture and fisheries. Law # 11.640 of March 21 2007 changed the approval process in CNTBio, and the two-third majority required to approve a GMO under article 11 of Law #11,105 was changed into a the majority of votes (GAIN Report Number BR 7626, 7/17/2007).

Table 3.2. The composition of CTNBio.

Twelve members are specialists of recognized technical and scientific knowledge, who are currently active professionals	Three Human Health Specialists Three Animal Specialists Three Plant Specialists Three Environment Specialists
One member representing one of the following bodies	Ministry of Science and Technology Ministry of Health Ministry of Environment Ministry of Agriculture and Supply Ministry of Agrarian Development Ministry of Development, Industry and Foreign Trade Ministry of Defence Ministry of Foreign Relations Office of the Special Secretary for Aquiculture and Fisheries
One consumer rights specialist, appointed by the Minister of State of Justice	
One health specialist, appointed by the Minister of State of Health	
One environment specialist, appointed by the Minister of State of Environment	
One biotechnology specialist, appointed by the Ministry of State of Agriculture and Supply	
One family agriculture specialist, appointed by the Minister of State of Agrarian Development	
One specialist in occupational health, appointed by the Minister of State of Labour and Employment	

CTNBio requires the following detailed information from the applicant before a biosafety analysis can be performed by CTNBio (FVO, 2007):

- Details of the transformation event, and detailed account of the method of production and manufacturing
- Copies of studies which have been carried out demonstrating the safety of the product relating to human and animal health and any impacts on the environment
- Methods for detection, including the DNA sequencing of the genes and primers to be used in the PCR technique to specifically identify the GMO

Following an analysis by CTNBio, a technical opinion is issued covering (FVO, 2007):

- A description of the GMO
- Expressed proteins
- Agronomic factors
- Environmental safety
- Aspects related to human and animal health
- Conclusions
- Decisions including any detailed requirements for the cultivation of the GMOs

CTNBio, in its technical opinions, has to consider the particular circumstance of the local Brazilian environments (article 14, paragraph 4). This is particularly exemplified in CTNBio's opinions on GM cotton, in which the occurrence of biologically important varieties of cotton and its relatives in particular geographical areas is considered. An noticeable point in this regard is that, besides the occurrence of the indigenous wild relative *Gossypium mustelinium*, also traditional cotton, either grown for medicinal purposes or in abandoned agricultural areas, are included in the considerations of preservation of biodiversity. GM cotton is therefore not allowed to be grown within various geographical areas spread over the nation, including Amazonia, Pantanal, Serido, and North Bahia, which have been identified by Embrapa, the Brazilian Agricultural Research Cooperation. Transport of seeds of GM cotton through these areas should be done in a way that prevents spillage of seeds (Barroso *et al.*, 2005; CTNBio, 2008). For GM soy GTS40-3-2 (RR soy), CTNBio considered that it is an exotic, highly domesticated species without compatible wild relatives in Brazil. It also considered the unlikelihood of survival of soy outside its agricultural habitat, the possible selective advantage of glyphosate resistance in the wild, and the occurrence of glyphosate resistance in weeds (CTNBio, 1998).

Besides risk assessments of GMOs that have been notified for commercial release, CTNBio has a mandate regarding other activities with GMOs, including research, development, and experimentation. Institutions of governmental or industrial background that develop and/or use GMOs for non-commercial purposes, such as research and experimentation, as well as companies that use GMOs in contained production facilities have to acquire a biosafety quality certificate and CTNBio's positive opinion on research activities. In addition, the institution should install an institutional biosafety committee (CIBIO), as well as a biosafety officer that is responsible for the institution's biosafety policy. CTNBio provides technical support to these institutions, including annual visitations and exchanges of information (e.g. LAW #11,105; Fontes *et al.* 2003). CTNBio also provides technical support to the other governmental agencies (e.g. inspection agencies) that are involved in GMO activities. At a more general level, CTNBio also develops norms and guidance for research and other activities with GMOs, as well as requirements and procedures for biosafety within the institutions (Law 11.105, Chapter III).

The National Biosafety Council (CNBS) was legally established through Law # 11,105 of 24 March 2005, under the Office of the President. Chapter II of this Law specifies that this council gives opinions with regard to the commercial use of GMOs in Brazil. It will do so based on the opinion of CTNBio following the latter's scientific risk assessment of a given GMO but may also consider social-economic issues, opportunities and other matters of national interest. CNBS also has to establish guidelines and principles for other governmental institutions dealing with GMOs. CNBS counts eleven members, including ten ministries and one federal secretary. The CNBS members represent:

- The Minister of State Chief of the Civil House, who is the CNBS chair person;
- Ministry of State of Science and Technology;
- Ministry of State of Agrarian Development;
- Ministry of State of Agriculture and Supply;

- Ministry of State of Justice;
- Ministry of State of Health;
- Ministry of State of Environment;
- Ministry of State of Development, Industry and Foreign Trade;
- Ministry of State of Foreign Relations;
- Ministry of State of Defence;
- Special Secretary for Aquaculture and Fisheries.

Other representatives besides the abovementioned members can, in exceptional cases, be invited to take part in a CNBS meeting. For the meetings to be held, at least six members should participate, whilst decisions will be taken by majority voting. Moreover, the CNBS chair person has the power to veto a decision made by CTNBio.

CTNBio provides risk assessments, based upon which CNBS will decide whether or not the GM crop will be approved. On June 18, 2008 CNBS decided that it will only review appeals that are of national interest (involving social and economic issues). This means that CNBS will not evaluate technical decisions on GM events approved by CTNBio, but considers all approvals on the technical aspects of GM events by CTNBio as final (USDA-FAS, 2008).

Approval for import of commercial GMOs is granted by the inspection and registration agencies of the ministries of Agriculture, Livestock, and Supply; of Health; and of Environment, as well as of the Secretariat for Aquaculture and Fisheries. Approval for the use of GMOs is granted by the various ministries and secretariats based upon the opinions received from CTNBio and CNBS. It depends on the scope of the application as to which institution will grant the approval, inspect and monitor the use of the pertinent GMOs, as follows (Law # 11,105, Chapter IV):

- The Ministry of Agriculture, Livestock and Supply for use in agriculture and livestock husbandry
- The Ministry of Health for human applications of GMOs including food, pharmaceutical and other non-food applications
- The Ministry of the Environment for GMOs released into natural ecosystems
- The Secretariat for Aquaculture and Fisheries for the use of GMOs in aquaculture and fisheries.

4. GM soy and Intellectual Property Rights (IPR)

4.1 IPR agreements surrounding Roundup Ready soy in Brazil

In considering intellectual property rights (IPRs) over GM soybeans and associated contractual obligations for farmers, it is helpful to understand some of the basic legal instruments and associated terminology. Newly-bred plant varieties are normally only protectable with a special IPR, known as a plant breeder's right (PBR), which is also referred to as plant variety protection (PVP), provided they meet the necessary criteria. Under the TRIPS Agreement, all WTO member countries are obliged to offer either PVP or patent protection for new agricultural plant varieties, or both. Patent protection is generally broader than PVP, as the latter allows for breeders to continue to use each other's varieties in subsequent breeding without explicit permission (breeder's exemption). PVP may also still allow farmers to save seed under a farmer's privilege, depending on the specific legislation. In Brazil, plant varieties are protectable by PVP, but not by patent protection (as is the case in the EU).

The TRIPS Agreement also requires members to offer patent protection for biotechnological inventions, such as genetic transformation events incorporated into agricultural plants. Thus, GM plants are typically covered by patent protection and this implies that the plant variety in question is also effectively covered by patent protection. Generally under most jurisdictions, this implies that the use of the plant (variety) in subsequent breeding, or the saving of seed can only be undertaken with the permission of the patent holder. It is relevant to point out that such restrictions might also, separately, be included in biosafety legislation and regulations.

In Brazil, RR soybeans are protected by a patent on the genetic transformation event, held by Monsanto. This patent would normally grant its holder exclusive rights to the commercialization varieties of soybean containing this event. These exclusive rights, which mean that the patent holder can pursue legal action against suspected infringers who reproduce or sell seed without the patent holder's authorization (including legal requirements to desist, and also an obligation to pay damages for lost sales) provide the basis for royalty payments. The royalty charged by Monsanto on the seed in most countries (e.g. US, Canada, Argentina) has often been labeled a 'technology fee'. As explained above, RR soy was first brought into Brazil from neighbouring countries and disseminated through informal means, outside of official regulatory frameworks with respect to either biosafety or IPRs. This situation presented additional challenges to enforcing IPR protection once RR soy was approved, as there was already considerable unofficial, or black market, multiplication and sale of the seeds.

Pursuing legal action against suspected infringers can be relatively costly and the effectiveness of such a strategy can be reduced depending on the reliability and efficiency of a country's legal system. The costs of enforcement can be high particularly where monitoring of smallholder farmers practices with respect to seed saving and exchange is undertaken. There do not seem to be any analyses of the specific situation in Brazil, although one article by academic researchers has suggested that the costs and in particular uncertainty, associated with judicial enforcement in the country may be quite high (Cardwell and Kerr, 2008). In reaction to such circumstances, Monsanto has sought other solutions elsewhere to be able to enforce its patent on a GM crop (as for example with Bt cotton in Mexico, or earlier in South Africa) (Tripp *et al.*, 2007).

In Brazil, Monsanto reached an agreement in 2004 with both the National Association of Seed Producers and also the (limited number of) soybean crushers present in the relevant growing regions (Reuters, 2003; 2005). Under the agreement, the payment of the royalty, or technology fee, is implemented at two stages. Farmers are able to pay a royalty at the point of seed sale, which is verified when the farmers deliver their harvested soy to the mill. According to the farmers' association Aprosoja, this royalty equalled R$ 0.43 per kg of seed. Alternatively farmers could choose to pay a royalty when delivering the produce to the mill. According to Aprosoja, the royalty equalled 2% of the yield in 2009. If a farmer does not choose to declare that the soy is RR, and claims in effect that it is conventional soy, an on-the-spot (quick strip) test could be undertaken to check whether the delivery does contain RR soy. If this accounts for more than 5 percent of the delivery, farmers are then required to pay a royalty which is 50% higher than the fee applying to the voluntary disclosure (3% of the yield) and the test costs. Moreover, according to Aprosoja, if farmers pay royalties at the point of seed purchase and obtain more than 74 kg of grain for every kg of seed purchased, they will have to pay additional royalties (2% of the yield) over this surplus production. Farmers reckon that this arrangement has the effect of penalizing more efficient farmers who achieve higher yields. With very limited numbers of mills to which to sell their crop, it appears that the possibilities for farmers to evade the royalty are limited, though there does not seem to be an objective analysis of this situation. The possibility of paying the royalty later appears to offer farmers the benefit of the royalty charge depending on the amount of harvested soybeans, and thus being linked to the achieved performance, as opposed to the upfront payments. This system of royalty payments also stimulates non-GM farmers to keep their production GM-free, as otherwise they face the risk of being penalized when delivering the produce to the mill.

Soy traders and processors that collect royalties on RR soy on behalf of Monsanto receive a small share in the royalties to cover their costs of collection, according to ABIOVE. Moreover, local seed breeders and Embrapa also receive a share in the royalties if the RR gene was bred into a variety produced by them, depending on the contractual agreements negotiated with Monsanto. Since the approval of RR soy in Brazil, Monsanto has set up licensing agreements with four Brazilian parties for the use of the RR gene. With regard to the use of the RR gene for breeding, Monsanto opted for the adoption of an ‘open source’ system. This ‘open source’ system means that any company could obtain a license to introduce the RR gene into their varieties after meeting a few points determined by Monsanto, such as the commitment to follow all requirements of the biosafety law during the testing stages and the procedures established by the CTNBio and CNBS.

In terms of IPR protection, the situation in Brazil is somewhat different from Argentina. The application for patent protection for RR soybean was never approved in that country, and Monsanto’s varieties were covered only by PVP (Kesan and Gallo, 2007). The company has claimed that the possibilities for enforcement have been insufficient. This need not imply that enforcement is not legally possible. Instead, this can be interpreted in an economic sense as meaning that the costs, both financial and in terms of the company’s own resources, of pursuing suspected infringers, coupled with uncertainty and delays concerning outcomes of litigation, are too high relative to the benefits achieved. The benefits, in this case, consist of the damages awarded, or even of the possible discouraging effect on other potential infringers. Monsanto has attempted to reach an agreement with Argentine farmers and seed producers similar to that in use in Brazil, but this has not materialized. The company claims that due to the difficulties in royalty collection, it has elected not to market its new RR2 soybean, or other new GM crop varieties, in the country (Reuters, 2004). Monsanto has sought enforcement in European countries where Argentine soybean shipments have been delivered, under the patent protection offered for RR soy.

Other contractual arrangements for soybean cultivation in Brazil that have received attention concern the contracts between farmers and mills, specifying a sale price in advance for the farmer’s harvest. Such contracts are intended to reduce the uncertainty that both parties may face, due in particular to unpredictable weather and pest risks. In practice, there is some evidence that a considerable number of farmers have broken their delivery contracts when the spot price has risen above the price agreed in the contract. Mills are then faced with the option of trying to collect the penalty agreed through resort to legal channels.

4.2 Expected changes in IPR agreements with the arrival of new events

The contractual arrangements described above between seed producers, farmers and millers or traders are relatively easy, in theory, to maintain as long as there is little competition in the supply of GM soybeans. With more suppliers competing for farmers’ purchases, there might be some downward pressure on seed prices and/or royalty fees, but other suppliers will also presumably need to enter into similar contractual arrangements. Unless supply chains for each different type/variety of GM soy are segregated, then some collaborative agreements may be necessary between competing seed suppliers, seed producers, and mills and traders.

If such competition were to come from a public sector organization, e.g. Embrapa, this might be expected in general to put downward pressure on seed prices and/or royalty fees, if such an organization was not oriented towards maximizing profits. During the interview with Embrapa, it was mentioned that the income from royalties had no influence on Embrapa's research strategies with regard to biotechnology and soy breeding. These research priorities were rather based on societal demands. Embrapa has entered into a collaborative agreement with Monsanto in which the Brazilian organization has a license to use Monsanto's RR event in Brazilian soybean varieties. In 2006 and 2007 together, Embrapa received R$ 3.2 million (US$ 1.9 million) from the royalties on RR seeds collected by Monsanto. Also the new CV soy with resistance to imidazolinones (herbicide) has been developed by Embrapa in collaboration with the multinational BASF.

4.3 IPR and the herbicides used in conjunction with GM soy

Glyphosate is the main herbicide used in conjunction with RR soy. Monsanto Company developed and patented the herbicide glyphosate in the 1970s. The US patent on glyphosate ended in 2000. Since then, Monsanto Company has maintained a dominant market share in the sales of glyphosate in North and Latin America. However, alternative producers of glyphosate have emerged and as a consequence the price of glyphosate has dropped in recent years. Herbicides used in conjunction with the new herbicide-resistant GM soy lines that may be launched in Brazil in the next years are in some cases patented by the owner of the event. Other herbicides used in conjunction with the expected new GM herbicide-tolerant soy lines are not patented.

5. Segregation and labeling of GM and non-GM soy

5.1 Testing methods and responsibilities

To measure the level of admixture between GM and non-GM plants, PCR (Polymerase Chain Reaction) methods are used as official methods in Brazil (and the EU) for the detection of GMOs. Various Brazilian scientists have developed relatively low-cost methods for identification of RR soy seed within seed lots. This method relies upon imbibing the seeds in glyphosate-containing solutions and subsequently following the developed of the young seedling plant (analysis within 6 days; Cunha *et al.*, 2005; Tillmann and West, 2004) or its peroxidase activity (analysis within 3 days; Menezes *et al.*, 2004). Quick commercially available strip-tests are also used, among others by seed producers and soy processors. A strip-test detects the transgenic protein, for each transgenic protein a different test has to be developed (although detection of different transgenic proteins may be combined in one test)

The Brazilian Ministry of Agriculture, Livestock & Food Supply is responsible for the enforcement of the national legislation concerning GMO biosafety in agriculture and livestock products and activities, including legislation on segregation and labeling. State governments may develop initiatives to monitor and enable the segregation of GM and non-GM chains, as is for example done by the government of Paraná State. State governments cannot enforce a legislation on segregation that is stricter than the federal legislation. Furthermore, private parties that aim to capitalize on the demand for non-GM products in Europe and Japan have set up systems to monitor the segregation of GM and non-GM soy in the chain in Brazil, as discussed in more detail in section 5.4.

Brazil has no national policy in place regarding the coexistence of GM and non-GM crops in the field (USDA FAS, 2008). For maize however Normative Resolution No. 4 of August 16, 2007 states minimal distances between GM and non-GM commercially grown maize varieties. When a GMO is authorized for commercial cultivation, it is subject to the same control procedures applied to non-GM products relating to checks for quality and phytosanitary aspects. In areas with wild cotton varieties where the cultivation of transgenic cotton is legally prohibited, legal inspections are carried out. However, this is not the case for GM soy. Soy farmers themselves are thus responsible for the coexistence of GM and non-GM soy in the field.

Also seed producers themselves are responsible for the segregation of GM and non-GM during seed production. A company visited by the Food and Veterinary Office (FVO) of the EU in 2007 carried out a range of tests including a strip-test on seeds from trucks arriving at the seed company and it applied ‘fail safe’ systems to prevent the inadvertent mixing of varieties during the process of cleaning, sizing and packing (FVO, 2007). Moreover, GM and non-GM crops are harvested separately, which greatly reduces the chance of admixture.

Official controls of seed production are carried out by the SFA (Federal Agricultural Superintendence), a decentralized unit of the Ministry of Agriculture, Livestock and Food Supply. The SFA carries out five visits per season for certifying sowing seeds, which consists of sampling each batch of finished products and contains ‘some element of GMO testing’ (FVO, 2007). These controls are reduced when a company receives a self-certification status. Thereafter, the SFA takes samples from certified seeds at random from the company’s stores. As far as we are aware, no threshold levels have been set that define a maximum allowance of GM in non-GM sowing seed in Brazil. Such thresholds have not been defined in the EU either.

Official controls of soy storage and processing facilities do not include GMO testing. Neither are there any official controls on the export of GMOs. Only compliance to the phytosanitary requirements of the importing country is verified (FVO, 2007).

5.2 Coexistence in the field

Coexistence of GM and non-GM soy in the field can be achieved relatively easily. Soy plants are to a great extent self-pollinators with outcrossing levels on average in the order of 1%. Experiments showed outcrossing levels between fields of 0.6 and 0.2% with a 1 and 5 m isolation border, respectively in the state of Paraná (Schuster *et al.*, 2007). Outcrossing of 0.5 and 0% with a 1 and 10 m border, respectively was reported in the Cerrado biome (Abud *et al.*, 2007). While the actual percentage of soy fertilized with GM pollen in a non-GM field will vary, e.g. depending on the size of the fields and the distance from a GM field, this percentage is likely to stay well below the threshold levels for labeling produce as GM in Brazil (1%) and the EU (0.9%) with ordinary agricultural practices. If non-GM soy is grown for seed (by farmers or by seed companies), and not for grain, stricter measurements should be required to avoid the cross pollination between GM and non-GM seed to ensure the purity of the seed.

5.3 Labeling GM produce

Regulations to label produce containing GM products only apply to the domestic market. For international trade, no regulations exist for labeling GM products. The Brazilian Decree No. 4680, 2003 requires labeling of domestic products if the fraction of a GMO product exceeds 1% of the final product (food or feed). Previously a legal threshold of 4% was in place (Decree No. 3871, 2001). This limit was considered too high by consumer groups and environmentalists in Brazil. No labeling is required if the product does not contain any detectable recombinant DNA or protein, such as refined soy oil and soy lecithin. According to Brod and Arisi (2008) the Brazilian 1% threshold applies to the whole product. For example, if a whole product contains 10% soy protein of which 5% is from GM origin, the whole product does not have to be labeled in Brazil, as the whole product then contains 0.5% GM.

Greiner and Konietzny (2008) also showed that, in 2005, 36% of the tested soy-containing food products (e.g. soy flour, bakery products, pasta, desserts, tofu, soy-based drinks, instant soup) contained more than 1% GM soy, i.e. above the labeling threshold. However, none of the products were correctly labeled as a GM product. Also Marcelino *et al.* (2007) observed that, in 2005 (their latest year of measurement), approximately 25% of foods tested for the presence of GM soy or maize contained GMO levels higher than 1% while they were not labeled as a GM product. Mendonca Hagler *et al.* (2008) mention that the labeling decree is not enforced by the legal authorities. This information suggests the compliance of labeling with the domestic regulations to be poor in Brazil. The Brazilian rules for labeling products containing GMOs is different from those in the EU, as further discussed in section 6.3.

5.4 Private initiatives to serve non-GM markets

Brazil, with an estimated GM adoption rate of 60-65%, is in a relatively favourable position to serve non-GM soy markets, as the other two main soy exporting nations Argentina and the US have GM adoption rates exceeding 90%. China and India also produce large quantities of non-GM soy, but the Asian production is mainly destined for the regional market. In section 2.4 we estimated the non-GM soy production in 2008 in Brazil to equal 39.2 million tons. It is likely that some of the non-GM produce is mixed with GM soy during transport, processing or storage in Brazil and as a result, cannot be traded as non-GM soy. Thus, the actual amount of certified non-GM soy exports leaving Brazil is likely to be smaller than the non-GM field production. Non-GM soy is traded by large traders dealing with both GM and non-GM soy, e.g. AMaggi and Cargill, and also by smaller companies that are specialized in the non-GM sector, e.g. IMCOPA. Many of these traders are member of ABRANGE, the Brazilian Association of non-GMO producers.

The segregation of GM and non-GM soy is facilitated by the fact that some export harbours in Brazil only handle GM-free soy. From Mato Grosso, Brazil's largest soy producing state, two roads can be used by trucks carrying soy leads to the exporting harbour of Santarém along the Amazon river and Porto Velho in Rondônia located at a side river Madeira of the Amazon. Soy from Porto Velho can be shipped to the harbour of Itacoatiara along the Amazon river, from where the soy is carried overseas. Soy loads that enter Santarém or Itacoatiara are tested for the presence of GM soy seeds. Soy loads that contain GM soy are simply refused by the traders Cargill and AMaggi operating from the harbours of Santarém and Itacoatiara, respectively. This system for segregating GM from non-GM soy is operated and maintained by the soy traders and appears to function satisfactorily. Other harbours, for example the harbour in Paranaguá in the south, have separate terminals for GM and non-GM soy. The government of Paraná state implements and controls the segregation in this harbour. This geographical segregation of soy export corridors in the Amazon has an impact on farmers' decision to grow GM or non-GM soy, unrelated to the agronomical aspects of GM and non-GM soy. For instance, soy farmers in northern Mato Grosso face higher transportation costs when growing GM soy, as this soy cannot be exported through the relatively nearby harbours in the Amazon, but needs to be exported overland to one of the harbours in southern Brazil over a distance of more than 2000 kilometres.

During the interviews with actors in the Brazilian soy chain, it was often mentioned that non-GM soy farmers themselves are responsible for the purchase of non-GM seed, and the prevention of admixture during field operations and harvest, and thereafter up to the delivery of the produce to a soy processor or trader. Some non-GM soy processors (e.g. IMCOPA) sign contractual agreements on the delivery of non-GM soy with farmers before the start of the growing season and support farmers with keeping their produce GM-free through the supply of GM-free seed and monitoring the segregation in the field. Also the royalty payment system encourages farmers to segregate GM from non-GM soy, as royalties need to paid when farmers deliver their produce to the mills without a proof of payments of royalties at the beginning of the season, if the produce contains more than 5% GM soy. Thus, in case a farmer delivers a load of supposedly non-GM soy that contains more than 5% GM, e.g. as a result of unintended admixtures, the farmer will have to pay the full amount royalties over this load, equal to the royalties paid over a load containing 100% GM.

According to the Secretariat of Agriculture and Food Stocks (SEAB) of Paraná State, large-scale farmers are better capable of segregating GM from non-GM soy than small-scale farmers, as large-scale farmers have more control over the infrastructure necessary for segregation. Small-scale farmers, for instance, have smaller fields (more influence from outside), and may need to share machinery or warehouses with other (GM) farmers. Non-GM soy buyers therefore prefer to purchase from large-scale farmers or their cooperatives, also because these can provide larger volumes of soy. Thus, large-scale farmers might be better able to capitalize on the overseas demand for non-GM soy than small-scale farmers.

Traders receive higher prices for non-GM soy, compared to GM soy, in the export markets of the EU and Japan. According to ABIOVE, these higher prices are necessary to cover the costs for segregating GM from non-GM soy in the chain. Non-GM soy requires separate transport, processing and storage, while turn-over rates of non-GM soy are lower than those of GM soy. According to the farmers' association Aprosoja, farmers in Mato Grosso barely receive any premiums for the delivery of non-GM soy. Apparently, the supply of non-GM soy in Brazil is currently sufficient to satisfy the demand of processors and at least some traders do not see the need to transfer premiums for non-GM soy on to farmers.

6. GM soy in the international setting

6.1 Approval procedures in Brazil and the EU

Many issues that are regulated by separate regulations in the EU have been brought together in Brazil under the heading of law 11,105 of 24 March 2005. CTNBio appears to have a role that is well comparable to that of EFSA's at the European level. Also EFSA takes up the role of assessing the safety of GMO's for humans, animals and the environment. The type of data that is required for the assessment of a GMO is in broad lines similar in Brazil and the EU. Detailed information by the applicant is required concerning methods of detection, including DNA sequences of the genes and primers to be used in the PCR technique to specifically identify the GMO. A difference with CTNBio however is that the European GMO panel does not contain representatives from institutions, but consists of experts selected based on their expertise.

An important difference between the approval procedures in Brazil and the EU is that the safety assessment by CTNBio is considered conclusive, which implies that if CTNBio considers a GMO safe for environmental or commercial release, the release of the GMO cannot be halted by other actors, e.g. CNBS, based on safety arguments. In the EU on the other hand, safety arguments often play a role in the political decision process that follows after a GMO is considered safe for release by the EFSA. This makes the outcome of the authorization procedure in the EU relatively uncertain. These days, national governments of the EU also have the power to ban the cultivation of an already authorized GM crop if new data give occasion for concerns regarding the safety of the GMO. The Brazilian decision making (CNBS and ministries) is different from that in the EU. The European Commission drafts decisions on GMO approvals, which subsequently has to be voted on by member states' representatives (in the Standing Committee on Food Chain and Animal Health, and, possibly, the Council of Ministers), before the Commission can finalize the decision on the pertinent GMO.

6.2 Asynchronous approvals of events

The European import of GM crops from Brazil is not problematic in case these GM crops are authorized for import and processing in the EU. However, if Brazil approves the cultivation of a GM crop before the EU approves the crop for import and processing, the import of Brazilian agricultural produce in the EU could be disrupted, as specified by recent reports (Backus *et al.*, 2008; Aramyan *et al.*, 2009; Stein & Rodríguez-Cerezo, 2009). These so-called 'asynchronous approvals' of GM crops, coupled with the operation of a zero tolerance threshold for the presence of GMOs unauthorized in the EU, already led and may continue to lead to difficulties with the EU import of food and feedstuffs from major exporting countries. GMOs that are not approved for cultivation or use in food or feed in the EU are not allowed in the EU (zero tolerance threshold) and should be taken from the market, even when the presence of unauthorized GMOs is minute. Impurities or contaminations in traded commodities are however difficult to avoid.

The asynchronous approval of GM crops other than soy can equally hinder the soy trade between Brazil and the EU, as the minute presence of products of other crops grown in the vicinity of or in rotation with soy in soy export loads cannot be entirely avoided. The situation in 2009 where US farmers were growing GM maize that was not registered in the EU led to the refusal of US soy shipments in the EU due to the minute presence of non-registered GM maize. The presence of a strict Identity Preserved (IP) system for non-GM soy or EU-authorized GM soy can reduce the risk of the adventitious presence of unregistered GM crops, but cannot eliminate the risk (Defra/FSA, 2009).

As a consequence of asynchronous approvals, European livestock producers face the risk of being cut off from especially high-quality, protein rich feedstuffs that are essential to feed their animals. Soy covered 65% of the total demand for proteins used in animal feeding in the EU in 2007 (FEFAC, 2008). The asynchronous approval combined with the zero tolerance threshold may also cause problems for the food industry with respect to the sourcing of conventional raw materials.

Given the large number of new events that have been released in Brazil recently or are likely to be released in the near future, it is well possible that asynchronous approvals will cause a disruption in the soy trade between Brazil and the EU. The situation is complex because GM events in crops other than soy, as well as the asynchronous approval of GM crops in countries neighbouring Brazil followed by illegal seed imports into Brazil, could also disrupt the soy trade between Brazil and the EU. A comparison between events recently approved in Brazil and the state of the relevant authorization procedure in the EU reveals that a number of events in maize and cotton approved in Brazil have not received authorization in the EU yet (Table 6.1). Other recently approved events in Brazil were authorized in the EU long time ago and are already in the procedure of renewing the authorization. The average duration of the registration procedure of the events in Table 6.1 was longer in the EU (44 months) than in Brazil (28 months). Moreover, the length of the registration procedure in Brazil appears to decline rapidly, while this is not the case in the EU. Some recently approved events in Brazil were authorized in a period of 5 months. It may still take several years after an event has been approved for commercial release until seed of locally adapted varieties containing this event are available to Brazilian farmers. The current asynchronous approvals have no resulted in an immediate disruption of the trade, but they have the potential to do so in the future.

6.3 Non-authorized sowing seed entering Brazil

The illegal import of GM seeds from neighbouring countries into Brazil may also cause disruptions in the trade between Brazil and the EU, especially if these GM events are not registered in the EU either. This issue is therefore related to the potential problems with asynchronous approvals. Problems with illegal imports of GM soy sowing seed from Argentina in Brazil occurred before Brazil's presidential decrees legalized the cultivation of RR soy in 2003. Before 2003, the Brazilian government was clearly unable to halt the at that time illegal RR soy seed imports from Argentina. These seed imports did not hinder the soy trade with the EU, as RR soy was already approved for import and processing in the EU at that time. The only GM soy line currently (September, 2009) approved in neighbouring countries has also been approved in Brazil. Therefore, the risk of unauthorized soy entering Brazil is low at the moment, and official testing by the SFA on unauthorized GMOs focuses on crops other than soy. Brazil is currently probably better equipped to monitor the influx of illegal GM seed than before 2003, because of its recent experiences with GMOs, including the segregation and testing of GMOs.

In the coming years, the risk of illegal GM seed entering Brazil could remain low, as according to the national agricultural research institute Embrapa, governments and companies in neighbouring countries invest less resources in the development and testing of new GM crops than Brazil. Actually, a reverse situation may occur whereby GM seeds that are legally cultivated in Brazil are smuggled into neighbouring countries where these seeds are illegal. Embrapa as well as several multinational and local seed companies have created a relatively favourable environment for the development and field testing of new GM soy events, as shown by the large number of GM events that are currently being tested or have been submitted for regulatory approval. In neighbouring Argentina, seed companies are less eager to invest in the development and registration of new GM soy events, among others because of the weak intellectual property protection that RR seed received in the past.

Table 6.1. Date of approval of events by CTNBio and duration of the registration process in Brazil (for commercial cultivation) in comparison with the state of the registration process in the EU (import and processing only) (October 2009).

Event	Brazil [1]		EU [2]	
	Date of approval	Duration of the registration process (months)	State of approval	Duration of the registration process (months)
Maize, insect and herbicide resistant (TC 1507 x NK 603)	15/10/2009	5	Approved 24/10/2007	37
Maize, insect resistant (MON 89034)	15/10/2009	13	Approved 30/10/2009	33
Cotton, insect and herbicide resistant (MON 531 x MON 1445)	15/10/2009	5	Application for renewal of authorization submitted [3]	No information
Maize, insect resistant (MIR 162)	17/09/2009	22	Application submitted only in combination with Bt11 and GA2, February 2009	
Maize, insect and herbicide resistant (MON810 x NK603)	17/09/2009	5	Approved 24/10/2007	40
Maize, insect and herbicide resistant (Bt11 x GA21)	17/09/2009	5	Application submitted, November 2007	Proceedings suspended, additional information required
Cotton, insect resistant (Mon 15985)	21/05/2009	23	Application for renewal of authorization submitted [3]	No information.
Cotton, insect and herbicide resistant (281-24-236/3006-210-23)	19/03/2009	30	Application submitted August 3, 2005	Proceedings suspended, additional information required
Maize, insect resistant (TC1507)	11/12/2008	24	Approved 03/03/2006	48
Cotton, herbicide resistant (MON 1445)	18/09/2008	47	Application for renewal of authorization submitted [3]	No information
Maize, herbicide resistant (GA21)	18/09/2008	31	Approved 28/03/2003	33
Maize, herbicide resistant (NK 603)	18/09/2008	51	Approved 03/03/2005	46
Cotton, herbicide resistant (LLCotton25)	21/08/2008	51	Approved 29/10/2008	55
Maize, insect resistant (Bt11)	20/09/2007	86	Approved 19/05/2004	63

[1] *CTNBio (2009)*
[2] *GMO Compass (2009)*
[3] *These products remain marketable in the EU if an application for renewal has been submitted*

6.4 Detection, labeling and traceability of GMOs in Brazil and the EU

No specific laws exist on the traceability of GMOs and derived products in Brazil. In the EU on the other hand, traceability is obligatory in general according to the General Food Law (EC Regulation No. 178/2002). Each member state of the EU is obliged to check their food and feed supply for compliance with EU food and feed law, including GMO legislation (Control Regulation EC/882/2004 and amendments). Regulation EC/882/2004 outlines the general approach to be taken and the principles for the official control by the competent authorities of EU member states. The regulation encompasses the official control at all stages of production, processing and distribution, and also the control of feed and food produced outside the EU. Regulation EC/1830/2003 on the traceability and labeling of GMO food and feed products in the EU only stipulates that countries should ensure that inspections and other control measures are carried to ensure compliance with EC/1830/2003 (art. 9, paragraphs 1-3). To help the member states, a central register has been put in place that contains sequencing information and reference materials for GMOs (including non-authorized GMOs). In the course of the registration procedure, EFSA forwards to the Community reference laboratory the method of analysis proposed by the applicant. The Community reference laboratory tests and validates the method of detection and identification (EC/1829/2003, art 18-3d) and forwards it to the National reference laboratories. For authorized GMOs, a detection method is thus available. For unauthorized GMOs, however, this is not always the case. Technical guidance for sampling and detection of GMOs in the context of EC/1830/2003 are given in the Commission Recommendation 2004/787/EC. For GMO control in the Netherlands in 2009, 300 feed samples (mainly imported from third countries) are investigated for the presence of GMOs, including non-authorized GMOs (Nationaal Plan Diervoeder, 2009). For this purpose for 8 GM crop species (including 54 varieties), methods of detection, and in most cases also of quantification, have been validated (7 GM varieties of soy can be detected) (E.J. Kok, project leader GMO detection methods for official use, The Netherlands, personal communication).

The Brazilian labeling requirements for products containing GMOs differ from those in the EU. In the EU, the labeling policy is 'process-based', which implies that all authorized GMOs and products derived from GMO, whether or not containing detectable recombinant DNA or transgenic proteins, have to be labeled. Conventional food and feed products contaminated unintentionally by authorized GMOs during harvesting, storage, transport or processing are not subject to traceability or labeling requirements if they contain authorized GMO traces below a 0.9% threshold level per ingredient, and provided the presence of authorized GM material is adventitious or technically unavoidable. This latter is considered to be the case where it can be show to the competent authorities that appropriate measures have been taken to avoid the presence of authorized GM material. The 0.9% threshold also applies to once authorized GMOs that are withdrawn from the EU market by the applicants, for the duration of 5 years after withdrawal. During a transitional period (a period due to a change in legislation) for non-authorized GMOs for which a positive opinion had been issued by EFSA but which were not authorized yet, a 0.5% threshold level has been applied. Nowadays however, GMOs not (yet) authorized in the EU should be completely absent from food and feed (EC Regulation No. 1829/2003 and No. 1830/2003 and amendments thereof). All thresholds in the EU are per ingredient, as to check analytically for compliance with whole (mixed) product thresholds is very hard if not impossible (E.J. Kok, project leader GMO detection, the Netherlands, personal communication). In Brazil, the labeling policy is 'product-based', which implies that only if recombinant DNA or transgenic proteins are present in the end-product, it is subject to labeling regulations. Hence, the 1% threshold for labeling refers to the whole end product, whereas the 0.9% threshold in the EU counts for each ingredient. However it is not clear if the 1% threshold for labeling in Brazil (or in Portuguese: 'com presence acima do limite de um por cento do produto' (Decreto 4680 de abril de 2003)) is in fact used by the Brazilian official control bodies per whole food product or per ingredient.

6.5 International agreements

6.5.1 Codex alimentarius on food safety

Brazil has had an active role within the Codex alimentarius ad-hoc Intergovernmental Task Force on Foods derived from Biotechnology (see, for example, http://www.anbio.org.br/codex/codex2.htm). During this Task Force's six-year mandate (2000-2006), it prepared guidelines on the assessment of the safety of foods derived from biotechnology, including GM crops, microorganisms, and animals, as well as the safety of nutritionally improved GM crops. The safety assessment approach recommended by Codex alimentarius is based on the 'comparative approach,' in which the genetically modified food is compared to a conventional counterpart with a history of safe use (e.g. GM soy with non-GM soy). Based on the differences that are thus identified in this comparison, it can be decided which tests will further be needed to assess the safety of these differences. Whilst the details of these safety assessment guidelines may not have been inscribed into regulations, based on the data that are summarized in the opinions by CTNBio, such as in the recent opinions on GM maize and cotton lines, one can deduce that the Brazilian CTNBio follows the internationally harmonized approach of Codex.

6.5.2 Cartagena protocol on biodiversity

Brazil signed the Cartagena protocol in November 2003 and it entered into force for the country on February 22, 2004 (Contini *et al.*, 2005). It is considered that Regulation 5,591/2005, Law 11,105/2005, and various normative resolutions and communications, regulate all issues on 'living modified organisms' pursuant to the Cartagena protocol. These issues include, for example, activities such as regulatory approval of GMOs; environmental release, storage, and transport of GMOs; and the maintenance of a national biosafety information system. It has also assigned, for example, two national focal points and deposited information about national regulations, approvals, risk assessments, and biosafety experts on the Biosafety Clearing-House website (Biosafety Clearing-House, 2009)). In a more general sense, Brazil strives towards implementation of the Cartagena protocol, also for other issues besides living modified organisms, such as through a national biodiversity strategy and action plan (CDB, 2009).

6.5.3 TRIPS on IPR

As a member of the WTO, Brazil is also bound by the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) which requires members to provide for minimum protection of innovations. The most relevant requirement of TRIPS for plant breeding, including genetic modification strategies, is Article 27(3)b. This requires members to provide protection for new plant varieties, through either patents, or plant variety protection (referred to as a sui generis form of protection), or both. Thus, countries are allowed to exclude plants from patentability, provided that plant variety protection is offered. In practice, the United States and Japan are the only major economies that have made patent protection available for plant varieties, in addition to plant variety protection, or plant breeder's rights, as it is sometimes known. Essentially all other countries offer only plant variety protection and this is the case in the EU, which also has a community-level form of protection, supplementing earlier national-level frameworks. Plant variety protection has been harmonized through the Union for the Protection of New Varieties of Plants (UPOV). Brazil has also chosen to make plant variety protection available, and became a member of UPOV in 1999. Importantly, Brazil has instituted plant variety protection consistent with the 1978 version of the UPOV treaty, which allows broadly for farm saving of seed. However, this practice can still be restricted through contractual agreements between seed providers and farmers. In addition, to providing protection for plant varieties, TRIPS Article 27(3)b also requires members to offer (utility) patent protection for biotechnological inventions, such as genetic transformation events, or some of the newly developed technologies used in genomic and breeding research (e.g. molecular markers). In general, a patent application must provide one or more useful purposes of subject matter. For example, a claim related to a patented gene for herbicide tolerance could be the control of weeds in field crops. Brazil's patent system does also allow for such patents. This means that a plant variety such as RR soy can come under the scope of the patent held over the genetic transformation event contained in it, as can be the case for a specific example of such a plant, even though the plant itself is not the subject matter of a patent. This does also provide a legal basis for a patent holder to restrict acts such as seed saving, which would not be possible under plant variety protection alone.

7. Discussion and outlook

The adoption rate of RR soy in Brazil has remained 60-65% of the total soy acreage in the last two years. Actors in the soy chain do not expect that the adoption of RR soy in Brazil will reach similar levels as in Argentina and the US (> 90% adoption) in the near future. According to farmers from Mato Grosso (Aprosoja), the adoption rate of RR soy does not increase anymore, as the net benefits for farmers from growing GM soy and non-GM soy are approximately equal. Whereas RR soy provides some additional flexibility in weed management, non-GM soy can be easier to sell to processors and traders, even though premiums paid to farmers for non-GM soy produce are rare or non-existent according to farmers.

Many processors and traders of soy are in favour of maintaining a non-GM soy sector in Brazil, as it allows them to capitalize on the demand for non-GM soy in the EU and Japan. Some smaller soy processors and traders have specialized in the non-GM soy sector, while the larger traders deal with both GM and non-GM soy. Brazil has a functional segregation system of GM and non-GM soy which is mostly maintained by parties in the private sector. The segregation is facilitated by the availability of rapid and cheap tests to detect the presence of the RR gene in samples. The segregation of non-GM from GM soy during transport, storage and processing comes with higher costs and therefore traders demand a premium for non-GM soy from buyers. The poor availability of genetically pure non-GM sowing seed and of sufficient ware houses to separately store GM and non-GM soy have been mentioned by stakeholders as threats to the current segregation system. Also the long distances from certain production areas to export harbours, covered with the help of different modes of transport (trains, trucks, river ships), increase the risk of admixtures.

Whereas currently only one event in soy is commercially available, this is likely to change drastically in the near future. Three new events in soy have been submitted to CTNBio for approval for commercial release and 32 new events in soy have been approved for field testing in Brazil. The events in soy that are being tested in Brazil could lead to herbicide resistance, insect resistance, drought tolerance or heat tolerance. Events are also being stacked. While at present one company (Monsanto) is the owner of the only commercially available GM event, the testing and commercialization of new GM events in soy is conducted by several multinational companies such as Monsanto, Pioneer Hi-Bred / DuPont, Bayer CropScience, Dow Agroscience and the BASF Group, and also by the public research institute Embrapa which is currently involved in the commercialization of one event and the testing of six events. Since a legal framework for the testing and commercial release of new GM events was established in 2005, Brazil has become a frontrunner in Latin America with regard to the testing of new GM events, according to Embrapa.

With the expected arrival of new GM events owned by a variety of seed suppliers, the cultivation of GM soy probably becomes more attractive to farmers. A basket of GM events in soy is more likely to offer agronomic or economic benefits to farmers than the single RR event that is currently available. The technology fee farmers pay for GM seed may decrease when more suppliers of GM seed compete with each other. For instance, in the near future, several companies are likely to offer GM soy seed with resistance to different broad-spectrum herbicides. Moreover, the public research institute Embrapa, which embraces broader societal goals than commercial companies, are also involved in the commercialization of GM events, possibly putting a downward pressure on the technology fee on events. As the difference in agronomic or economic performance between GM and non-GM soy increases, farmers are likely to demand higher premiums for non-GM produce from processors and traders, which will lead to higher price differences for buyers of non-GM soy. The interviewed stakeholders in the Brazilian soy chain agreed that a non-GM soy sector is likely to be maintained in Brazil provided that buyers are willing to pay premiums that cover the cost difference with GM soy. As the domestic market for non-GM soy in Brazil is small, the willingness of consumers overseas (i.e. the EU and Japan) to pay for non-GM soy is an important factor determining the future of the non-GM soy sector in Brazil.

The commercial launch of new events in soy is not necessarily a threat to the system segregating GM from non-GM soy. If quick low-cost methods can be developed to detect the presence of GM events in soy loads, admixture of GM and non-GM soy can be monitored throughout the chain, as is currently done with RR soy, and measures could be taken when admixtures occur. Only when asynchronous approvals lead to a situation where different types of GM soy must be handled separately, the segregation between GM and non-GM soy can also come under pressure, among others due to a lack of storage capacity, as confirmed by government officials from Paraná State.

A poor availability of sufficient, high-quality non-GM soy seed could become a threat to non-GM soy production, as mentioned by farmers (Aprosoja), government officials (Paraná State) and processors (IMCOPA). While cross-pollination between GM and non-GM soy in seed producers' fields can be largely avoided if appropriate measures are taken, a more fundamental problem could become the lack of investments in non-GM soy breeding. An increasing grip of large multinationals on the Brazilian seed sector through the purchase of local breeding and seed producing companies has been mentioned by farmers as a threat to the non-GM soy production, as large multinationals are also primarily interested in promoting the sale of GM seed. This has not been confirmed through other data gathered for this report. Also local seed companies are primarily investing in breeding GM varieties. The breeding company Fundação MT from Mato Grosso currently devotes 90% of its research activities to the incorporation of GM events in its existing variety base and only 10% to non-GM soy breeding. Breeding companies such as Fundação MT receive part of the royalties collected on the sale of GM seed produced by their companies from the owner of the gene (e.g. Monsanto) and this could make the development of GM varieties more profitable than non-GM varieties. A lack of investments in non-GM soy breeding may contribute to a widening gap in the performance of GM and non-GM soy. The public research organization Embrapa has a mandate to work on non-GM soy breeding, besides their biotechnology program, and Embrapa's research priorities are not driven by the opportunity to collect royalties on GM seed, according to Embrapa. When private companies primarily focus on GM breeding, Embrapa's role in maintaining a non-GM breeding program may grow in importance.

The regulations for labeling products that are made with the help of GMOs in Brazil are rather different from those in the EU. One of the differences is that the Brazilian labeling policy is product-based (i.e. only if recombinant DNA or transgenic proteins are present in the end-product, it is subject to labeling regulations), while the EU policy is process-based (i.e. all authorized GMOs and products derived from GMO, whether or not containing detectable recombinant DNA or transgenic proteins, have to be labeled). However, this difference is unlikely to cause any problems for the EU trade of beans and meal in which the presence of GM can be relatively easily monitored when shipments arrive in the EU. The situation with the relatively small imports of soy oil and other products derived from GM soy, in which the presence of recombinant DNA or transgenic proteins cannot measured upon arrival in the EU, is more complex. The EU requires a traceability of the product to establish whether GMOs have been used in the process. As in Brazil, the traceability of products is not a legal requirement, private initiatives should ensure a traceability of these products if the products are to be sold as non-GM in the EU.

The asynchronous approval of events in Brazil and the EU has the potential to cause a major disruption of the trade in soy products between Brazil and the EU. Given the dependency of the EU farming sector, especially the livestock sector, on imported soy, a disruption of the soy trade could have severe economic consequences. The asynchronous approval of GM crops other than soy can also severely hinder the soy trade between Brazil and the EU, as the minute presence of products of other crops (e.g. grown in the vicinity of or in rotation with soy) in soy export loads cannot be entirely avoided. Given the large number of new GM events that are in the registration procedure or tested in the field, asynchronous approvals are likely to occur more frequent in the future. The presence of a strict Identity Preserved (IP) system for non-GM soy, or for EU-authorized GM soy, is costly but can reduce the risk of the adventitious presence of unregistered GM crops. However, such system cannot eliminate the risk. In addition, a lack of storage and transport facilities in Brazil can make the segregation of non-GM, EU-authorized GM and EU-unauthorized GM soy impossible.

Actors in the Brazilian soy chain (farmers, government, processors, traders) are all well aware of the potential consequences of asynchronous approvals for the trade with the EU and are willing to undertake efforts to avoid a disruption of the trade. Despite the growing importance of China as a buyer of Brazilian soy, the EU is still an important market for Brazilian soy products. When the approval of a GM event can lead to an asynchronous approval relative to the EU and a potential disruption of the trade, it is the National Biosafety Council (CNBS) in Brazil that is authorized to postpone or cancel the release of this event. CNBS can do this for instance if the release is not in the socio-economic interests of Brazil.

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