THE BITTER SWEET TASTE OF STEVIA

Commercialisation of Stevia-derived sweeteners by violating the rights of indigenous peoples, misleading marketing and controversial SynBio production

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The Department for Agricultural Engineering works since 1992 under the supervision of Professor Jungbluth on *Stevia rebaudiana* as a new crop. We started in 2005 with first efforts on Benefit Sharing for Stevia. We initiated four pan-European research projects financed by the EU Commission on Stevia where the idea of Benefit Sharing is embedded. Our Stevia information web pages are: www.stevia.uni-hohenheim.de and www.go4stevia.eu

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FOREWORD BY THE AUTHORS

The diverse and international nature of the organisations and institutions co-publishing this report reflects the breadth of problems related to the production of steviol glycosides, which are high intensity sweeteners found in many food and beverage products today.

A primary concern is that the production of steviol glycosides is based on biopiracy. It is a clear example of the inequitable appropriation of a genetic resource and its associated traditional knowledge.

Stevia's sweetening property has long been known by the Guaraní people, who live on both sides of the border region in Paraguay and Brazil. Yet neither they, as the holders of this traditional knowledge, nor Paraguay or Brazil, as the countries of origin of the plant, are receiving the fair and equitable share of the benefits due to them from the commercialisation of steviol glycosides.

Instead a few multinational commodities, food and beverage, and biotechnology corporations are using the appropriated knowledge and genetic resources to generate significant levels of profit. The multinational corporations are controlling the market with patents and are now successfully marketing steviol glycosides as *the* natural sweetener of the future. In sharp contrast, the traditional use of Stevia leaves as a sweet food is prohibited in most industrialised countries.

This state of affairs could deteriorate even further. Today it is still possible for Paraguay and other developing countries to generate at least a small share of the profits by growing Stevia plants as a raw material for the production process. However, if plans go ahead to market steviol glycosides using synthetic biology, there may no longer be a market for those Stevia leaves. In this case the entire value-added revenue will flow into the pocket of a few corporations primarily based in the North. The Guaraní and the countries of origin will go away empty-handed.

We therefore hope that this report will help to convince the producers of steviol glycosides to commit to mediated negotiations with the Guaraní people and the countries of origin about a fair and equitable sharing of benefits, in accordance with the Convention on Biological Diversity and the Nagoya Protocol. Benefit sharing does not have to be monetary, but it has to meet the needs, for instance the need for land, expressed by the Guaraní.

Furthermore we expect that governments will take further measures to implement effective legislation on Access and Benefit Sharing at the national level, and that they will introduce more stringent measures to ensure that the sellers of products containing steviol glycosides are prohibited from marketing their products as being "traditional", "from the Guaraní" or "natural" when this is clearly not the case. Steviol glycosides originating from synthetic biology, should not be produced without an independent socio-economic impact assessment with a positive outcome, as requested by the parties of the Convention on Biological Diversity.

It is time to ensure that steviol glycosides lose their bitter aftertaste, becoming an example of genuine Access and Benefit Sharing, rather than an example of biopiracy.

ABBREVIATIONS

ABS	Access and Benefit Sharing
ADI	Acceptable Daily Intake
ALS	Working Group of Food Chemistry Experts of the German provinces and of the German Federal Office for Consumer Protection and Food Safety
BACN	Library and Archive of the National Congress of Paraguay
BAG	Swiss Federal Office for Health
BMG	German Federal Office for Health
CA	Canada
CBD	United Nations Convention on Biological Diversity
CCFA	Codex Committee on Food Additives (FAO & WHO)
CIMI	Conselho Indigenista Missionário
COP	Conference of the Parties
DNA	Deoxyribonucleic acid
EC	European Commission
EFSA	European Food Safety Authority
EP	European Patent
ETC	Action group on Erosion, Technology and Concentration
EU	European Union
FAO	United Nations Food and Agriculture Organization
FDA	US Food and Drug Administration
FIAN	Food First Information and Action Network
FIFA	Fédération Internationale de Football Association
FOEN	Swiss Federal Office for the Environment
FSA	Food Standards Agency
GE	Germany
GIZ	German Association for International Co-operation
GRAS	Generally Recognized as Safe Notification by the FDA
ILA	International Law Association
IFST	Institute of Food Science and Technology
IPTA	Paraguayan Institute for Agricultural Technology
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MAG	Paraguayan Ministry of Agriculture and Livestock
MAT	Mutually Agreed Terms
MTA	Material Transfer Agreement
NZZ	New Zurich Newspaper
OECD	Organisation for Economic Co-operation and Development
OLG	Oberlandesgericht (a judicial instance in Germany)
PIC	Prior Informed Consent
REDIEX	Paraguayan Network for Investment and Export
SENAVE	Paraguayan National Service for the Quality and Health of Plants and Seeds
SMTA	Standard Material Transfer Agreement
SynBio	Synthetic Biology
TBT	Test Biotech
UK	United Kingdom
UN	United Nations
UNDRIP	United Nations Declaration on the Rights of Indigenous Peoples
UPOV	International Union for the Protection of New Varieties of Plants
US	United States
WIPO	World Intellectual Property Organization
WHO	United Nations World Health Organization
WO	Short for WIPO – World Intellectual Property Organization
WTO	World Trade Organization
ZAR	South African Rand

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1 EXECUTIVE SUMMARY

Humans have developed and shared traditional knowledge about how to breed and use plants and animals in order to produce food, cloths, medicine and other utilitarian, cultural and spiritual items for millennia. However, this knowledge is increasingly being appropriated and often monopolised by companies.

Governments have now agreed—through the Convention on Biological Diversity (CBD) and its Nagoya Protocol—that the holders of traditional knowledge have a right to benefit from the knowledge that they have developed. The United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP), which was adopted by the United Nations (UN) General Assembly in 2007, is also highly relevant, since it affirms indigenous peoples' rights with respect to their territories and traditional knowledge.

This is highly relevant to the impoverished Guaraní people in Paraguay and Brazil, who knew about the sweetening properties of *Stevia rebaudiana* leaves for centuries. Their traditional knowledge is the origin of all later commercialisation of Stevia—as steviol glycosides which are "high intensity sweeteners" used to sweeten products such as diet soda drinks. Global demand for natural and sugar-free products is expanding rapidly, as a result of increasing concern about obesity and diabetes, and Stevia plants are being grown and processed commercially in many countries outside Paraguay, especially China. However, the Guaraní people's right to benefit from its use, as established under the Convention on Biological Diversity's Nagoya Protocol, is being ignored. This is a clear case of biopiracy.

The companies producing and selling steviol glycosides are also benefitting from different rules and regulations applying to the import and use of Stevia leaves and industrial steviol glycosides, which prohibit the direct use of Stevia leaves as a sweetener. For example, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has concluded that steviol glycosides are safe to consume, but only in limited quantities, and has recommended an acceptable daily intake (ADI). This ADI is now used in both the EU and the US. In complete contrast, Stevia leaves cannot be sold on US, European or Swiss markets. This appears to be related to the fact that there is little commercial interest in pursuing expensive approval processes for Stevia leaves. In practice this means that the products of large multinational corporations are able to access markets far more easily than products based on the traditional use of whole stevia leaves.

However, even though Stevia leaves cannot be sold in the US or the EU, and steviol glycosides are substantively

Most Guaraní in Paraguay live under difficult economic conditions. © Keystone

different to Stevia leaves, large companies such as Coca Cola are misleading consumers by playing on the benefits associated with the plant in its natural state, and even the traditional knowledge of the Guaraní. For example, Pepsi and Coca Cola have both launched colas containing steviol glycosides, "Pepsi Next" and "Coca Cola Life". A lot of effort has been put into highlighting the new "natural" aspect of these drinks. Coca Cola Life is also marketed as a means of tackling obesity and helping people to balance their lifestyles, even though it still contains more than four teaspoons of sugar per can as well as the steviol glycosides.

Furthermore, as the steviol glycoside "boom" gathers pace a race is under way to patent methods to produce steviol glycosides via synthetic biology (SynBio), instead of producing them from leaves. This would mean that in the near future large companies selling or using steviol glycosides produced using synthetic biology would no longer be dependent on the cultivation of Stevia plants or the vagaries of weather, climate, and international trade.

One of the frontrunners in this research is Swiss company Evolva, in collaboration with Cargill, a US-based multinational. Cargill is one of the two global market leaders producing and selling steviol glycosides, and Coca-Cola and PepsiCo are two of its main clients. Two other companies engaged in the race to "win" the SynBio Stevia market include a small biotech company based in California, Stevia First, and multibillion-dollar chemical giant DSM based in the Netherlands. This race will not only impact manufacturers of steviol glycosides though: if SynBio steviol glycosides are commercialised there are likely to be severe negative impacts on the small holder farmers growing Stevia in Paraguay and elsewhere.

A dispute over SynBio steviol glycosides is also emerging in the JECFA Committee, which has started a new evaluation to allow the use of synthetic Rebaudioside E and M as primary steviol glycosides for use in food and beverages—even though they will never have seen a Stevia plant and cannot be considered "natural". This is being opposed by the government of Paraguay, which is requesting that an analytical methodology is developed to differentiate between natural and SynBio steviol glycosides, and approval for the use of steviol glycosides of a lower purity. Paraguay's approach could have important consequences with respect to labelling Stevia leaf-based products if successful.

In order to resolve this case of biopiracy, and to further promote rural development for smallholder farmers, a number of steps need to be taken by governments generally, and by companies producing or using steviol glycosides:

- **The producers and users of steviol glycosides should commit to mediated engagement with the Guaraní to agree how to share the benefits of the commercialisation of steviol glycosides in a fair and equitable manner.**
  This is especially important in a country like Paraguay where effective national legal obligations on ABS do not exist yet. Benefit sharing does not have to be monetary, it can also be realised through other forms of support.

- **Governments of user and provider countries—including the Paraguayan government—should implement the Nagoya Protocol optimally at national level with comprehensive and effective national laws on Access and Benefit Sharing.**
  It should be impossible to derive any profit if genetic resources and their associated traditional knowledge are accessed illegally and the benefits are not shared.

- **Governments and sellers of products containing steviol glycosides need to make sure that any advertisements which describe steviol glycosides as "traditional" or "natural" are stopped.**
  Governments and companies in consumer countries should stop the deliberate misleading of consumers by advertising chemically purified or synthetically produced steviol glycosides as "natural" and "traditional" products. Deceptive marketing is a major concern, and advertisements that focus on the "naturalness" of steviol glycosides and Guaraní heritage are deliberately misleading consumers. They should be prohibited.

- **The government of Paraguay and other governments should ensure that the production of Stevia plants supports smallholders and rural development.**
  Any rural development programme should support ecologically sustainable, small-scale production, and recognise Guaraní land and territorial rights. It should also provide support for small holders in the form of access to extension services, markets and fair credit, and farmer-to-farmer exchanges.

  The Paraguayan government, which is already developing the Stevia sector in Paraguay, should extend its support for smallholders and the nascent domestic processing industry.

- **Finally, Governments should also ensure that producers may not produce or market steviol glycosides based on synthetic biology in the absence of an independent socio-economic impact assessment with a positive outcome, as requested by the parties of the Convention on Biological Diversity.**
  The trend towards using synthetically produced steviol glycosides poses a threat to the huge potential that cultivating Stevia has in terms of rural development in countries such as Paraguay. It moves production away from smallholder farms and into corporate laboratories. However, if steviol glycosides produced via synthetic biology are placed on the market governments must ensure that companies selling the end products are obliged to clearly label them as such.

2 THE GUARANÍ AND STEVIA

The impoverished Guaraní people in Paraguay and Brazil knew about the sweetening properties of *Stevia rebaudiana* leaves for centuries. This traditional knowledge is the origin of all later commercialisation of Stevia and Stevia-derived products. However their rights to benefit from its use, as established under the Convention on Biological Diversity's Nagoya Protocol, are being ignored.

Stevia, called Kaá he'é by indigenous Guaraní people, became known about outside Paraguay when it was obtained by Swiss botanist, Dr. Moisés Santiago Bertoni, who learned about the species and its sweetening properties from the Guaraní and Mestizos in 1887. By 1894, he had managed to acquire some leaves and he described and classified Stevia as a member of the sunflower family (*Asteraceae),* giving it its scientific name.

In 1918 Bertoni explicitly described how he was provided with information about the plant by herbalists and indigenous people in north eastern Paraguay:

"[In] 1887, during my explorations of the extensive forests of eastern Paraguay, I heard references about this plant from herbalists (yerbateros) from the northeast and Indians from the Mondaíh. The latter knew them from the nearby grasslands of Mbaeverá and Kaa Guasú"[1] (Bertoni, 1918).

He realised the benefits the plant could provide, based on its traditional use as a natural sweetener to replace artificial sweeteners like Saccharin which was already being marketed, in his lifetime, as a herbal alternative for people with diabetes. On this basis he forecast the future successful commercialisation of the Stevia plant.

Also based on traditional knowledge of the Guaraní concerning the use of the Stevia leaves as a natural sweetener, which was substantiated by studies undertaken by chemist Ovidio Rebaudi, Bertoni thought that the plant was safe to consume:

"Having no toxic effect and being, to the contrary, healthy, known by long experience and according to the study of Dr. Rebaudi"[2] (Bertoni, 1918).

Moreover, an analysis of various historical sources concerning the use of medicinal plants by the Guaraní Indians also revealed the use of *Stevia rebaudiana* as a sweetener (Noelli, 1998). Some Paraguayan studies from the 1970s supported the idea of using Stevia to treat diabetes (Soejarto *et al.,* 1983), and leaves and twigs are sold in some local drug stores and market places for this purpose in Paraguay. This traditional knowledge about Stevia as a sweetener is the origin of all later commercialisation of Stevia and Stevia-derived products. However the Guaraní people's right to benefit from their traditional knowledge, as enshrined in the Convention on Biological Diversity (CBD), is being ignored.

Just like many other indigenous peoples, the Guaraní have a long history of exploitation and discrimination.

Today, the Guaraní are living in parts of Brazil, Paraguay, Bolivia and Argentina. The Guaraní groups that have used *Stevia rebaudiana* over the centuries are the Guaraní Kaiowá in Brazil and the Pai Tavytera in Paraguay.

The Pai Tavytera in Paraguay have a population of 15.097 inhabitants, split into 61 communities. Due to the dispossession and deforestation related to the expansion of the agricultural frontier, the Pai Tavytera use only a small part of their traditional territory. Their food system, once based on hunting, fishing and gathering, now depends more and more on small scale agriculture and paid work on cattle ranches (Glauser, 2011). 14 communities have no land at all. Surrounded by cattle ranches, in an area increasingly controlled by drug lords, there are many reports of violence by ranch and plantations owners.

Data from 2010 shows that there were about 46,000 Guaraní Kaiowá living on the Brazilian side of the border,

STEVIA REBAUDIANA BERTONI

Stevia rebaudiana Bertoni is named after the chemist Ovidio Rebaudi, who analysed the plant when invited to do so by Bertoni (Rebaudi, 1900; Kienle *et al.,* 2008; MAG, 1991). The place of origin of *Stevia rebaudiana* is located between 22° and 24° latitude in the southern hemisphere and 55° to 56° western longitude. This comprises the Paraguayan highland of Amambay and the eastern parts of the Mato Grosso do Sul (Katayama *et al.,* 1976).

1 Translation from Spanish to English by the Berne Declaration.
2 Translation from Spanish to English by the Berne Declaration.

The Guaraní have lost their ancestral lands which today often contain plantations for sugar cane production. © Misereor

Stevia leaves are traditionally used as natural sweeteners for instance for Mate tea. © Keystone

in Mato Grosso do Sul. Over the course of the last century, they have lost almost all their territory in this state, most of which used to be forest. Today they live in small and often overcrowded reserves, surrounded by cattle pastures and sugar cane plantations. Many Kaiowá have no land at all and live in small tents by the sides of roads. Hence, traditional knowledge about using Stevia has been mostly lost.

In recent years, conflicts over land and violence against the Guaraní have intensified dramatically in Mato Grosso do Sul. In 2007 the Brazilian government committed itself to demarcating 36 territories for the Kaiowá, in the southern part of Mato Grosso do Sul. However, primarily because of the objections of large landowners, these land demarcations have not yet been implemented.

Legitimate indigenous land claims are coming up against increasing investments in sugarcane by joint ventures involving large-scale land owners and multinational commodity traders, especially as Mato Grosso do Sul is one of Brazil's sugar cane expansion hotspots. Between 2007 and 2012, the area of sugar cane monoculture in this state tripled from 180,000 ha to 570,000 ha (Oxfam, 2013). A well documented example is the land of Jatayvary in the region of Dourados. Although the Federal Minister of Justice had officially recognized the traditional land rights of one Guarani group, the sugar plant Monteverde of Bunge continued to buy sugarcane from five plantations located on this land and refused to cancel the contract before the term. Bunge is one of the key sugar suppliers to Coca-Cola (Oxfam, 2013; Survival International, 2013).

Although violent land conflicts have a long history in Mato Grosso do Sul, attacks on Guaraní have definitely intensified in the last few years. In 2014, 25 members of the Guaraní were murdered in this state alone (CIMI, 2015). In August 2015, the UN Special Rapporteur on the rights of indigenous peoples, Victoria Tauli-Corpuz, expressed deep concern about reports that the police are being pushed to evict Kaiowá indigenous people forcibly from their 'tekohas' (traditional lands). According to her information, some 6,000 indigenous people are refusing to leave their lands and have warned that they plan to resist the eviction 'until death'.

This loss of territories has completely impoverished the Kaiowá people. Due to the fact that there are few other livelihood opportunities, many of them now work on sugarcane plantations in extremely precarious conditions. In 2011 about 10,000 Guaraní men were working on the plantations—and between 2004 and 2010, 2,600 Guaraní Kaiowá workers were liberated from slave-like working conditions (FIAN, 2012). Other acute problems include a lack of appropriate health care facilities, leading to a high rate of childhood mortality, lack of support for school education for indigenous children, and due to their dire circumstances, a high level of alcohol consumption. The number of suicides amongst the Guaraní in Mato Grosso do Sul is far above the number in other Brazilian states. Between 2000 and 2014, 707 cases were documented (CIMI, 2015).

3 STEVIA: INDUSTRIAL DEVELOPMENT AND COMMERCIAL PROSPECTS

3.1 DISPERSAL AND USE OF STEVIA PLANTS

Although the Guaraní's use of Stevia leaves was first learned about at the end of the 19th century, Stevia was only really commercialised in the 1970s, in Japan. Now, global demand for natural and sugar-free products based on "high intensity sweeteners" such as steviol glycosides is expanding rapidly, as a result of increasing concern about obesity and diabetes.

Today, steviol glycosides, the pure sweetener derived from the Stevia plant, can be found in market places, supermarkets, shops and drug stores across the world and commercial interest in it is growing globally. Yet the wild Stevia plant is virtually extinct (MAG, 1991; Willi, 2006).

The commercial use of Stevia, mainly as steviol glycosides only began in the early 1970s (Kienle *et al.,* 2008). After sweeteners such as cyclamate and saccharin became suspected of being carcinogens, the search for a new sweetener began and Japanese scientists came across the Stevia plant. In two Japanese expeditions approximately 500,000 wild plants were excavated in the area of origin and brought to Japan. The Japanese company Morita Kagaku Kogyo Co., Ltd. subsequently became the first to produce a commercial sweetener from Stevia in 1971 (Morita Kagaku Kogyo Co., Ltd., 2007).

The almost forgotten plant from Paraguay is now becoming a major global business involving multinational corporations like Cargill, Coca Cola and PepsiCo. The various molecules that give Stevia leaves their sweet taste, collectively known as steviol glycosides, are in increasing demand in the global food market as sweeteners, sugar substitutes and dietary supplements. They are thus becoming an "alternative" of increasing importance in the still growing global sweeteners market (OECD/FAO, 2013).

Demand for steviol glycosides and other "natural" and sugar free products is clearly being driven by rising concern about the spread of obesity and diabetes and a growing awareness about healthy foods in western societies. steviol glycosides are free of calories and up to 300 times sweeter than sucrose, which makes them one of the sweetest known natural substances (Nikolova, 2015; Lemus-Mondaca *et al.,* 2012; MAG, 1991).

In 2009 the World Health Organization (WHO) estimated that steviol glycosides have the potential to replace 20–30 % of all dietary sweeteners in the coming years (WHO, 2009). The expected revenue from food and beverages containing steviol glycosides as sweeteners is expected to be US$ 8–11 billion in 2015 (IndustryARC, 2014). Mintel also gives figures for the growing market for steviol glycosides themselves, estimating that this will more than double between 2013 and 2017, jumping from US$ 110 million to US$ 275 million (Mintel, 2014).

3.2 INDUSTRIAL DEVELOPMENT ACROSS THE GLOBE

Stevia plants are also being grown commercially in many countries outside Paraguay, specifically to produce steviol glycosides.

According to company SteviaOne, by 2012 80 % of global cultivation was situated in China, 5 % in Paraguay, 3 % in Argentina, 3 % in Brazil and 3 % in Colombia. It was also being grown in India, Japan, Kenya, South Korea, Taiwan, Vietnam and the USA (SteviaOne, 2012; Gmuer, 2015). China is growing an area of some 20,000 to 25,000 ha (Kienle, 2014), and it is estimated that globally a total of 30,000 ha of Stevia plants was cultivated in 2011 for steviol glycoside production (Quelle Sante, 2011).

Today, especially following the lifting of restrictions in the US and the EU (for more detail see below), steviol glycosides can be found in hundreds of food and beverage products, including cereals, teas, juices, flavoured milks, yogurts, and carbonated soft drinks (Evolva, 2014). Coca Cola and PepsiCo have both launched a carbonated soft drink containing steviol glycosides (called Coca Cola Life and Pepsi Next respectively) (Coca Cola, 2014; PepsiCo, 2015). The biggest markets are in the US, Japan, China and the EU (Gmuer, 2015).

INTERNATIONAL STEVIA COUNCIL MEMBERS[3]

Refiners (producing according to JECFA specifications)
Cargill
Ingredion
Morita
Pure Circle
Real Stevia
SteviaOne
Verdure Science

Ingredient Users
Coca Cola Company
Nordzucker

Leaf Growers and Producers
Sweet Green Fields
(leaf production in US)

Associate Members
DSM

To represent the interest of companies involved in the commercialisation of steviol glycosides, the International Stevia Council, a global trade association, was created in 2010. Its members include companies that produce and refine industrial steviol glycosides, marketing them as naturally-sourced Stevia sweetener products.

3.3 PRODUCTION OF STEVIA IN PARAGUAY

Although China is the main country producing and exporting Stevia leaves, Paraguay still produces and exports the crop, and the government of Paraguay has been promoting the sector as a means of rural development. Stevia has tremendous potential to contribute to a viable smallholder sector in Paraguay.

It seems that up until 2005 the entire harvest of Stevia in Paraguay was exported to neighbouring Brazil. Since then, however, dried Stevia leaves have also been exported to other countries including the US, Japan, Germany, Argentina, Mexico, France and even to the principal current producer, China (GIZ, 2008).

Unlike sugar cane or maize (the feedstock for high fructose corn syrup), the Stevia plant is predominantly produced by smallholders, both because its production is labour intensive and because it can be cultivated in diversified systems. In Paraguay, the average smallholder producer has only 5–10 ha of arable land available, and cultivates Stevia in crop rotation with other crops such as cotton, cassava, sesame or soybean. Similarly, in China, Stevia is typically produced by contracted smallholders on plots of 1 mu, i.e. 667 m^2 (Bamber and Fernandez-Stark, 2012; Kienle, 2011).

Farmers can start harvesting in the first year, with up to four harvests per year possible in Paraguay (Nikkei Asian Review, 2015). Thus the production of Stevia in Paraguay offers benefits for smallholders, as well as potential for value-added processing for both export and domestic markets. However, farmers do still need support in terms of access to markets, extension services, and farmer to farmer information exchanges, and they are usually only successful if they collaborate with other producers and get fair access to finance (Bamber and Fernandez-Stark, 2012).

Paraguay's Ministry of Agriculture and Livestock (MAG) is promoting the Stevia sector as part of its Agricultural and Rural Development Plan (WTO, 2005; MAG, 2006). However, with burgeoning production elsewhere, including the developing use of synthetic biology ("SynBio") techniques (see section 4), the tremendous potential for smallholder development in the "birthplace" of Stevia could be blocked.

Markets for Stevia leaves and related products cultivated in and exported from Paraguay are in general uncertain. For example, in 2011, Japan stopped importing Stevia from Paraguay, because of concerns about foot and mouth disease in Paraguay. This, combined with a slump in Stevia leaves prices, reportedly caused Paraguay's exports to drop from US$ 1.2 million in 2011, to just US$ 368,000 in 2014 (Nikkei Asian Review, 2015). However, in February 2015 the Japanese government announced that it was reversing this position, announcing a deal to supposedly purchase all of Paraguay's Stevia leaves exports. The Paraguayan Network for Investment and Export, a branch of Paraguay's Ministry of Trade and Industry, also states that prices have now stabilised (REDIEX, 2015).

In general, the government of Paraguay is clearly moving to develop the Stevia sector in Paraguay. It aims to capitalise on growing consumer knowledge about the link between Stevia and Paraguay, benefiting from existing corporate marketing strategies, and to significantly increase Paraguayan exports of Stevia leaves and crude steviol glycosides. To this end it is moving to change the international standards defined by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (and by extension national standards in the US and the EU), so that they no longer discriminate in favour of chemically purified or synthetically produced steviol glycosides, which could have a significant negative impact on the production of Stevia leaves in Paraguay.

3.4 THE DIFFERENCE BETWEEN STEVIA LEAVES AND STEVIOL GLYCOSIDES

Although companies marketing steviol glycoside-based products like to confuse the two, there are important differences between Stevia leaves (the traditional sweetener) and steviol glycosides (the industrially-produced sweetener developed by commercial enterprises). These differences relate to the production processes.

The leaves of the *Stevia rebaudiana* plant contain a number of different molecules that are responsible for its sweet taste. Collectively they are referred to as steviol glycosides. The traditionally known *Stevia rebaudiana* leaves contain predominately Stevioside and Rebaudioside A, Rebaudioside C and Dulcoside A, beside Rebaudioside D and Rebaudioside E which are found only in traces. However, some of the most palatable, such as Rebaudioside D, are only present in the leaves in very small quantities (Kinghorn, 2002). Rebaudioside M can be found only in very specific varieties (Ohta *et al.,* 2010).

Genetic manipulation is being used to increase the number of detectable steviol glycosides in Stevia plants. For example, the variety *Stevia rebaudiana Morita* has been found to have 21, 10 of which are novel including Rebaudioside M (Ohta *et al.,* 2010). For one decade specific breeding has

3 International Stevia Council Membership – www.internationalsteviacouncil.org/index.php?id=7

The leaves of *Stevia rebaudiana* are traditionally used and sold as a natural sweetener in Paraguay. © getty images

Steviol glycosides are produced by a chemical/physical process from Stevia leaves. This facility is in Paraguay, however most production sites are located outside of Paraguay. © getty images

particularly concentrated on improving the content of Rebaudioside A, which has a good taste profile (some others have a bitter aftertaste) (IFST, 2015; Kuznesof, 2007).

It is important to note that steviol glycosides are not "natural" as many companies assert in their advertising. Furthermore, different chemicals may be used to purify steviol glycosides (Watson, 2012) and many of these production processes are protected by patents (see Section 5 for more information).

Steviol glycosides are produced from the leaves of *Stevia rebaudiana Bertoni* with hot water, and the resulting aqueous extract is precipitated by adding salts (e.g. $Ca(OH)_2$, $CaCO_3$, $FeCl_3$ or $AlCl_3$). The precipitated solution will be filtered with subsequent treatment with an ion-exchange resin (anionic and cationic) in order to remove salts and ionic molecules. Through the ion-exchange process some decolouring of the aqueous solution is achieved. Decolouring with adsorption resins follow the ion-exchange process step. By this means a raffinate of the steviol glycosides is achieved (FDA, 2008). Specific adsorption resins may trap the steviol glycosides. The resin is then washed with a solvent alcohol to release the steviol glycosides and the product is recrystallised from methanol or aqueous ethanol, which produces highly purified steviol glycosides. The final product will be spray-dried (JECFA, 2010; EC, 2012).

Critically, some of these production processes may not be environmentally friendly (Kienle, 2011; Watson, 2012). Purified steviol glycosides can also contain unwanted artefacts and isomers that form during the chemical/physical purification process (BAG, 2010).

3.5 APPROVALS OF STEVIOL GLYCOSIDES

In Paraguay, the consumption and sale of Stevia leaves has never been restricted (MAG, 1991), but in other countries extensive long-term toxicological studies are required for the authorisation of food products and additives, including both Stevia and steviol glycosides. However, different regulations apply in different countries. Here we briefly consider global standards, and approvals in the EU and US, specifically with respect to steviol glycosides.

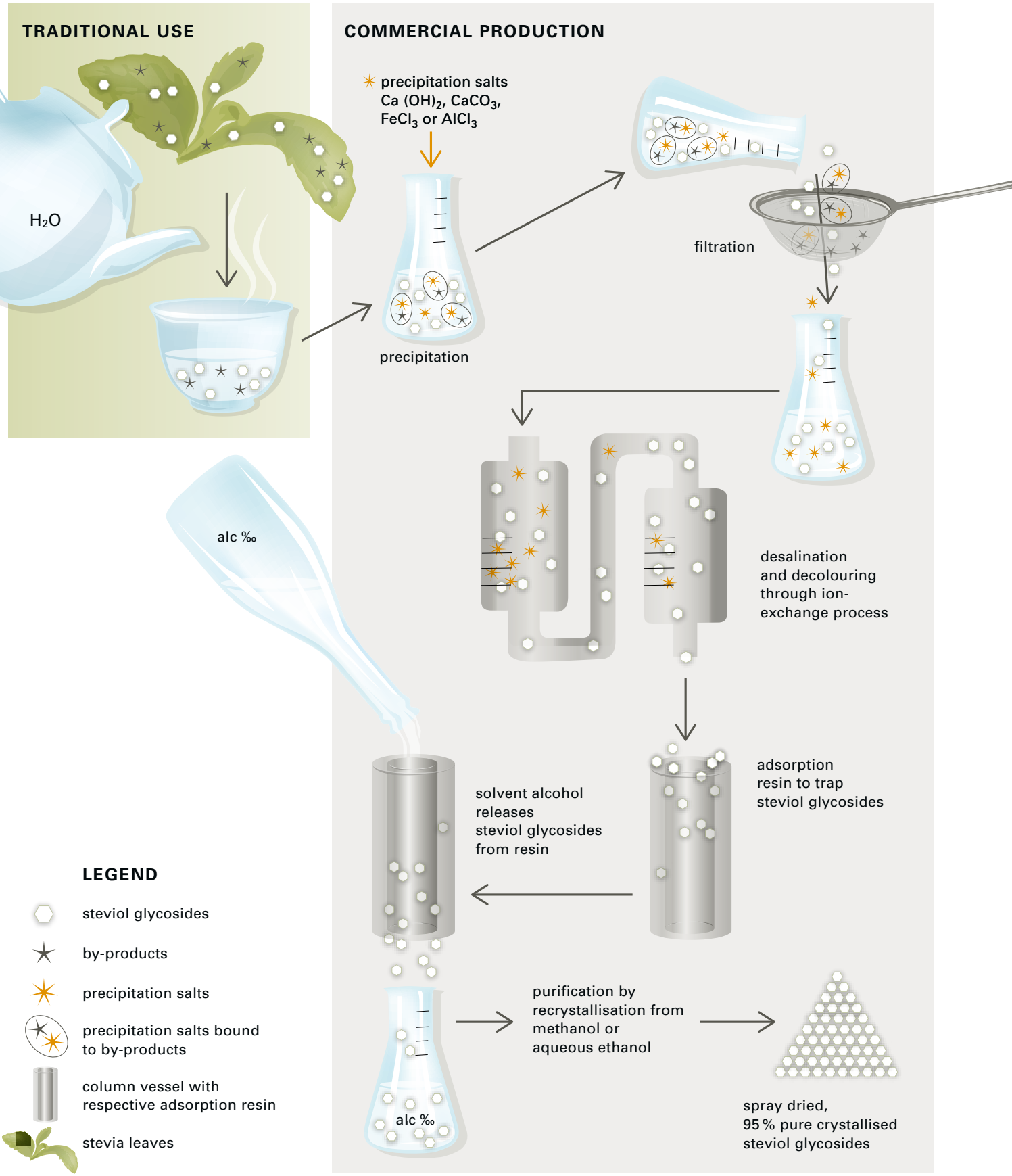
The Joint FAO/WHO Expert Committee on Food Additives (JECFA)

JECFA is an international scientific committee jointly administered by the United Nations Food and Agriculture Organization (FAO) and WHO. It is responsible for evaluating the safety of food additives, and evaluating contaminants in food (FAO & WHO, 2015).

JECFA provides standards for the production of steviol glycosides (JECFA, 2010; JECFA, 2010a). JECFA assessed research concerning the safety of steviol glycosides (primarily Stevioside and Rebaudoside A) in 2009, concluding that it was safe, but only in limited quantities, and recommended an acceptable daily intake (ADI) of 0–4 mg/kg bw expressed as steviol, and a required level of purity of more than 95 % (JECFA, 2009).[4]

However, on request of the governments of the United States and Malaysia, the JECFA Committee has now started a new evaluation to allow the use of *synthetic* Rebaudioside E and M—which will never have seen a Stevia plant and cannot be considered "natural" (see section 4 on SynBio)—as

PRODUCTION OF STEVIOL GLYCOSIDES BY A CHEMICAL/PHYSICAL PURIFICATION



primary steviol glycosides in food and beverages. A first decision is expected during the JECFA Meeting in June 2016.

This is being opposed by the government of Paraguay, which is requesting that, "an analytical methodology be included to differentiate between glycosides from the plant and glycosides produced by enzymatic modification or synthesis by genetically modified organisms" (CCFA, 2015). Paraguay is also seeking the extension of the acceptable daily intake or ADI for steviol glycosides of a lower purity. Paraguay's request to JECFA to distinguish between the different production processes could have important consequences with respect to labelling stevia-based products, if successful.

The European Food Safety Authority (EFSA)

The European Food Safety Authority recommended the use of steviol glycosides as a food sweetening additive in 2010, in line with JECFA findings, and recommended the same ADI. Steviol glycosides were then authorised for consumption in the EU (as additive E960) in 2011 (EU, 2011).

Subsequent deliberations in the EU have focused on whether children are likely to consume more than the recommended amount (EFSA, 2011; EFSA, 2014), and on a proposed extension to the permitted uses of steviol glycosides, which was submitted by Tata Global Beverages GB Ltd. and could lead to those limits being exceeded (EFSA, 2015).

US Food and Drug Administration (FDA)

The US has three routes to approval. The FDA may either approve a food additive or list and affirm it as *generally recognized as safe* (GRAS). However, under federal law some ingredients may now be added to food under a GRAS determination made independently from the FDA (GRAS notification procedure). Overall, FDA scrutiny of food additives appears to be waning.[5]

With respect to steviol glycosides, the FDA accepted the two first GRAS notifications (number 252 and 253) on Rebaudioside A sweeteners in 2008, based on JECFA's evaluation (see above). This means that companies can now produce and sell steviol glycosides as sweeteners in the US (FDA, 2015a).

3.6 REJECTIONS OF APPLICATIONS FOR APPROVAL FOR STEVIA LEAVES

In complete contrast to the situation regarding authorisation of steviol glycosides, Stevia leaves cannot be sold on US, European or Swiss markets. This appears to be related to the fact that there is little commercial interest in pursuing expensive approval processes for Stevia leaves. In practice this means that the products of large multinational corporations are able to access markets far more easily than those from smallholder farmers.

In the US, the FDA has a current import alert mandating the detention of imports of Stevia leaves if they are to be used as food additives[6] (but not if labelled as a dietary supplement[7] or being for specific listed purposes such as research or processing). The alert says:

"With regard to use in conventional foods, Stevia leaf is not an approved food additive and has not been affirmed as GRAS in the United States due to inadequate toxicological information. Whole leaf Stevia has not been the subject of a GRAS notice. With regard to use in dietary supplements, dietary ingredients (including Stevia) are not subject to food additive regulations" (FDA, 2015b).

Similarly, Stevia leaves are not authorised for sale in the EU (they would need authorisation as a novel food) (FSA, 2015). A novel food is a food that does not have a significant history of consumption within the European Union before 15 May 1997. In the EU an application to market the living plant and dried leaves as a novel food has been refused due to lack of adequate information. In the meantime a new application has been presented but is not moving forward at the moment because the safety dossier is incomplete. In Switzerland Stevia leaves are also not authorised due to lack of substantial proof relating to health concerns (BAG, no date), except for 2 % in herbal mixtures.

Although steviol glycosides are authorised for sale in the USA, Europe, Switzerland and other countries, the sale of Stevia leaves is prohibited in those same regions. © Fotolia

4 However, according to OECD guideline 453, the ADI is only based on the results of a two-year rat study. The study establish a so called "no observed effect level" (NOEL) and the ADI is calculated by dividing this figure by 100.

5 www.washingtonpost.com/national/food-additives-on-the-rise-as-fda-scrutiny-wanes/2014/08/17/828e9bf8-1cb2-11e4-ab7b-696c295ddfd1_story.html

6 The term "food additives" in its broadest sense, refers to substances added to food. Legally they are "any substance the intended use of which results or may reasonably be expected to result—directly or indirectly—in its becoming a component or otherwise affecting the characteristics of any food" (FDA, 2014).

7 "A dietary supplement is a product taken by mouth that contains a 'dietary ingredient' intended to supplement the diet" (FDA, 2015).

4 EVOLVA, STEVIA FIRST AND DSM RACE TO COMMERCIALISE "SYNBIO" STEVIOL GLYCOSIDES

As the steviol glycoside "boom" gathers pace a race is under way to patent methods for synthesising steviol glycoside molecules, instead of producing them from leaves. This would mean that in the near future large companies selling or using steviol glycosides would no longer be dependent on the cultivation of Stevia plants or the vagaries of weather, climate, and international trade.

One of the frontrunners in this research is Swiss company Evolva, in collaboration with Cargill (Edison, 2015). Evolva aims to use synthetic biology techniques to synthesise the sweetest and least bitter tasting of the steviol glycosides, Rebaudioside M (Reb M) and Rebaudioside D (Reb D). At the moment the more abundant Rebaudioside A is blended with sugar in Coca Cola Life (Coca Cola, 2015) and high fructose corn syrup in Pepsi Next, but has a somewhat bitter aftertaste. But Rebaudioside D is only found in very small quantities in Stevia leaves (less than 1 %) as well as Rebaudioside M from the *Stevia rebaudiana Morita* variety, making it uneconomical to produce them from the leaves (Evolva, 2015).

Evolva, which focuses on producing saffron, Steviolglycosides and vanillin using SynBio processes, has developed a yeast-based SynBio fermentation process to produce these steviol glycosides, based on low-cost carbohydrate feedstocks. The proportion of each steviol glycoside produced by the host can be tailored, based on the composition of the genes which are inserted into the yeast cell, so that the desired steviol glycosides can supposedly be produced in a consistent and reproducible manner (EP 2575432 A1[8]).

Evolva has an ever-expanding intellectual property portfolio on steviol glycosides (Evolva, 2014). The first broad-ranging patent they applied for (EP 2575432 A1), in June 2011, concerned the recombinant production of steviol and steviol glycosides such as rubusoside and Rebaudioside A, by recombinant micro-organisms, plants or plant cells (Google, 2015). In August 2014 Evolva and Cargill jointly announced a World Intellectual Property Organization (WIPO) patent application (WO 2014122227)[9] on methods for improved production of Rebaudioside D and Rebaudioside M. In their communication they stated that "By producing Reb M using fermentation, Cargill and Evolva can produce the desired sweetness at a scale and cost that is not feasible through extraction of Reb M from the Stevia leaf" (Cargill, 2014).

In October 2015 Cargill presented its new SynBio and fermentation based sweetener *Eversweet,* developed by Evolva (Grundlehner, 2015). Cargill and Evolva intend to launch this new sweetener with its fermentation-derived steviol glycosides commercially by 2016 (Swissinfo, 2015; Watson, 2015) and a Cargill facility that already exists is currently being converted to a manufacturing plant in Blair, Nebraska (Swissinfo, 2015; Evolva, 2015).

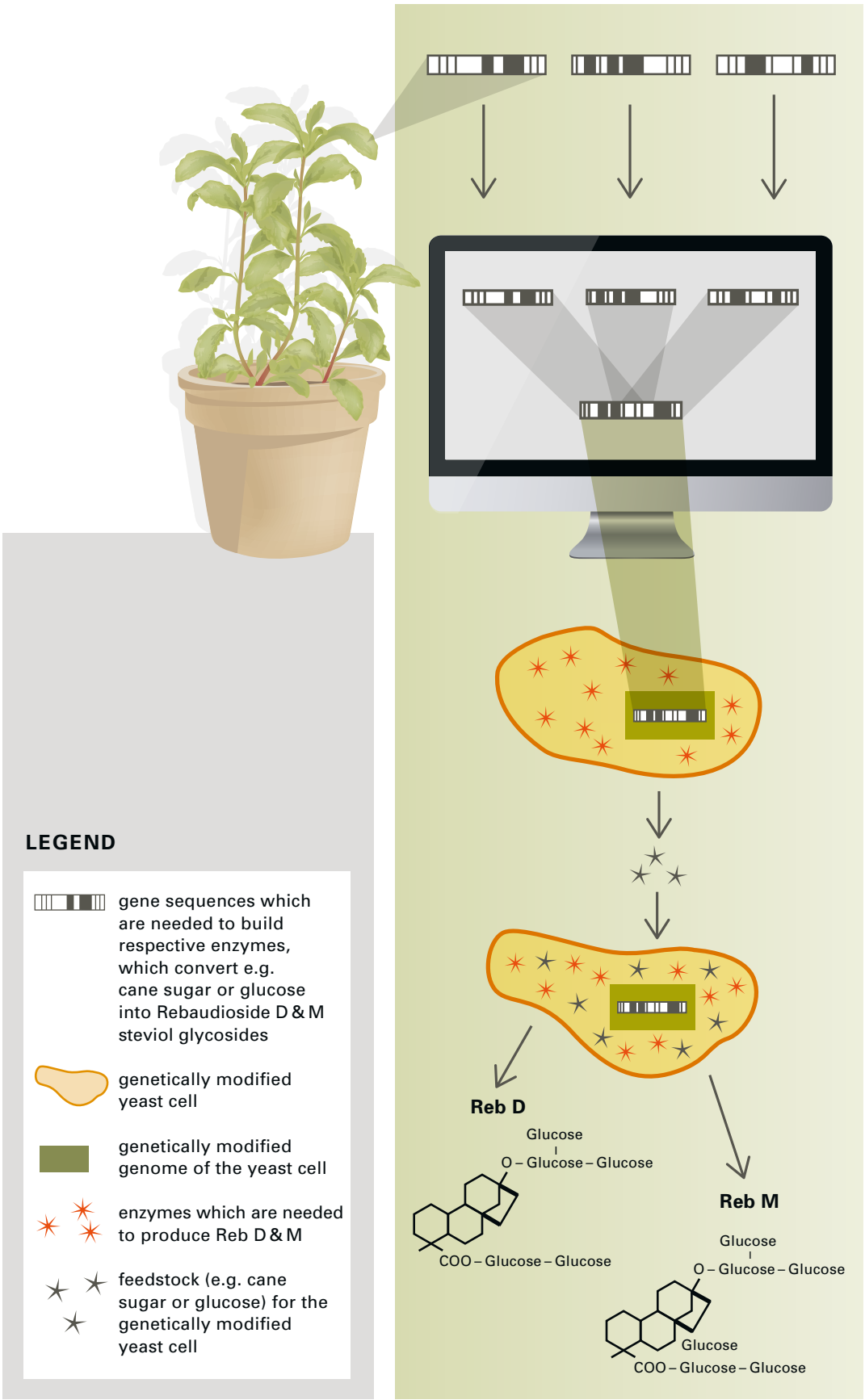
Evolva and Cargill also find themselves competing with a small biotech company based in California, Stevia First. Stevia First is also actively pursuing a fermentation-based approach to producing steviol glycosides, and already received its steviol glycoside by microbial fermentation patent in August 2012 (having filed the patent in 2007). As well as the biosynthetic route Stevia First also claims to have an enzymatic process to transform low grade Stevioside into Rebaudioside A (Watson, 2014a). Evolva and Stevia First are now racing to find the perfect combination of genes in order to produce the best tasting glycosides for the lowest costs (Savrieno, 2014).

Multibillion dollar chemical giant DSM from the Netherlands has now joined the fray, announcing the production of SynBio steviol glycosides, and has filed numerous patent applications relating to technology for the synthetic production of steviol glycosides, as well as preparing GRAS notifications to the US (see above), all with a view to launching its SynBio steviol glycosides by the end of 2015 (Daniells, 2014). However it seems that this GRAS notification has not yet been submitted (FDA, 2015c). The company also strengthened its presence in China, so far the largest steviol glycosides producing country, with a dedicated local business organisation and a new blending facility in Yixing (DSM, 2014).

So it seems that DSM could be ahead in terms of launching commercially, whilst Stevia First seems to be ahead in the patent race, and Evolva has made the greatest strides in terms of finding a strong commercial partner. Cargill has invested over US$ 4.5 million in the joint development and commercialisation of steviol glycosides obtained by fermentation (Evolva, 2014), and the establishment of a joint venture seems imminent (Edison, 2015). Cargill is one of the two global market leaders of steviol glycosides and counts Coca Cola and PepsiCo as two of its main clients, who would benefit from access to cheaper steviol glycosides (Palm, 2013). Clearly if Cargill does not

8 EP 257 54 32 A1: Recombinant Production of Steviol Glycosides – https://data.epo.org/gpi/ep2575432a1-recombinant-production-of-steviol-glycosides
9 WO 2014122227: Methods for improved production of rebaudioside D and rebaudioside M–https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2014122227

PRODUCTION OF STEVIOL GLYCOSIDES BY A SYNTHETIC BIOLOGY PROCESS



USING PARTS OF THE *STEVIA REBAUDIANA* GENOME AND OTHER ORGANISMS (e.g. maize, blue algae, arabidopsis thaliana etc.), gene constructs are synthesised in the lab and inserted into a yeast cell. In this way the cell is genetically modified.

THE GENETICALLY MODIFIED YEAST CELL produces the enzymes needed to convert the feedstock into Rebaudioside D & M steviol glycosides.

FEEDSTOCK (GLUCOSE) is fed to the genetically modified yeast cell.

ENZYMES TRANSFORM FEEDSTOCK into Rebaudioside D & M steviol glycosides.

LEGEND

- gene sequences which are needed to build respective enzymes, which convert e.g. cane sugar or glucose into Rebaudioside D & M steviol glycosides
- genetically modified yeast cell
- genetically modified genome of the yeast cell
- enzymes which are needed to produce Reb D & M
- feedstock (e.g. cane sugar or glucose) for the genetically modified yeast cell

A SHORT HISTORY OF SYNTHETIC BIOLOGY

Synthetic biology (also known as "SynBio") focuses on synthesising the building blocks of life, creating new and artificial "parts, devices and systems" and redesigning "existing natural biological systems for useful other purposes" (CBD, 2014).

It is often described as a form of extreme genetic engineering (Friends of the Earth, 2014; ETC, 2015). Instead of moving genes between organisms it focuses on creating new DNA sequences and designing new organisms (Friends of the Earth, 2014) that can do new things, such as produce biofuels (SynBio Project, 2015) or steviol glycosides (Transparenz Gentechnik, 2011). SynBio can include building molecules on the basis of computer-generated DNA coding, "directed evolution", and site-specific mutagenesis (making intentional changes to DNA sequences) (Friends of the Earth, 2014). SynBio is commercially attractive because it offers the potential for faster and more powerful methods than "traditional" genetic engineering (Friends of the Earth, 2014). The first organism with a completely synthetic genome able to self-replicate was developed by Craig Venter's company Synthetic Genomics in 2010 (The Guardian, 2010).

Synthetic biology can be applied in medicine, agriculture, energy production or the food additives sector. Constructed genes or gene sequences contain the information which enzymes need to produce fuels, chemicals, plastics, vitamins, flavourings or fragrances. These genes are then inserted into a host (such as yeasts or *E. coli)* by means of genetic engineering, where they direct the production of the desired output from carbohydrate feedstock such as cellulose and plant sugars.

The major funders of synthetic biology research to date have been the US government and the oil industry. So far, there are virtually no regulations or control measures applying to synthetic biology, even though it is likely to be highly unpredictable (Nature, 2010), and the impacts on human health and the environment have not been adequately assessed (Gen-ethisches Netzwerk, 2010; Friends of the Earth, 2011; TBT, 2010).

On top of this, synthetic biology enables "digital biopiracy", meaning that no material is physically removed from a community as in "traditional" biopiracy. Once sequenced the DNA of an organism can be digitised and uploaded to the internet and synthesised in a laboratory elsewhere. This sidesteps the need for a Material Transfer Agreement (MTA), which is normally used to regulate the transfer of tangible research materials between two institutions. Corporations can then patent these DNA sequences as inventions (Friends of the Earth, 2011). This approach could also be used to sidestep the need for Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT), which are used to regulate access to and the use of genetic resources and traditional knowledge under the CBD and the Nagoya Protocol.

win "the race" to produce cheaper steviol glycosides it stands to lose two of its main clients to its rival, so the company has a big incentive to partner with Evolva.

The race to "win" the SynBio steviol glycoside market will not only impact manufacturers of steviol glycosides. It is also likely to have severe negative impacts on the small holder farmers growing Stevia or being encouraged to grow Stevia in Paraguay (as part of the country's rural development programme (WTO, 2005) and other countries.

THE CBD AND SYNTHETIC BIOLOGY

At its eleventh meeting (COP 11 in 2012), parties to the CBD noted, based on the precautionary approach, the need to consider the potential positive and negative impacts of components, organisms and products resulting from synthetic biology techniques on the conservation and sustainable use of biodiversity (CBD, 2012). They followed this up at COP 12 in 2014 with the following decision, designed to avoid the possible negative effects of using synthetic biology:

"The Conference of Parties…urged Parties and invited other Governments, to take a precautionary approach… [and]… (d) To carry out scientific assessments concerning organisms, components and products resulting from synthetic biology techniques with regard to potential effects on the conservation and sustainable use of biodiversity, taking into account risks to human health and addressing, as appropriate, and according to national and/or regional legislation, other issues such as food security and socio-economic considerations with, where appropriate, the full participation of indigenous and local communities…(e) To encourage the provision of funding for research into synthetic biology risk assessment methodologies and into the positive and negative impacts of synthetic biology on the conservation and sustainable use of biodiversity, and to promote interdisciplinary research that includes related socio-economic considerations" (CBD, 2014).

Thus there is developing momentum for the implementation of the precautionary approach with respect to synthetic biology. There is also a mention of socio-economic considerations and the participation of indigenous and local communities (but, note, *where appropriate).*

5 INTELLECTUAL PROPERTY PROTECTION AND MARKETING

In many jurisdictions plant varieties can be protected by Plant Breeders' Rights (a special form of intellectual property rights for plant varieties). In addition there are many different jurisdictions in which patents can be filed in order to protect intellectual property on plants, plant varieties, products or processes.

5.1 PLANT BREEDERS' RIGHTS TO VARIETIES OF STEVIA PLANTS

The International Union for the Protection of New Varieties of Plants (UPOV) database shows that there are some 40 applications worldwide for Plant Breeders Rights (31) or Plant Patents (9) concerning Stevia (UPOV, 2015).[10]

It seems that there have been applications for Plant Breeders Rights for ten Stevia varieties in Paraguay—one from the Paraguayan Institute for Agricultural Technology (IPTA) (the former Paraguayan Ministry of Agriculture), one from the company "3com Products", one from the agricultural cooperative "Tabacalera Misiones" and seven from the Pure Circle Company. Based on oral information received by the Paraguayan National Service for the Quality and Health of Plants and Seeds (SENAVE) officials in August 2015, it can be assumed that these have been granted.

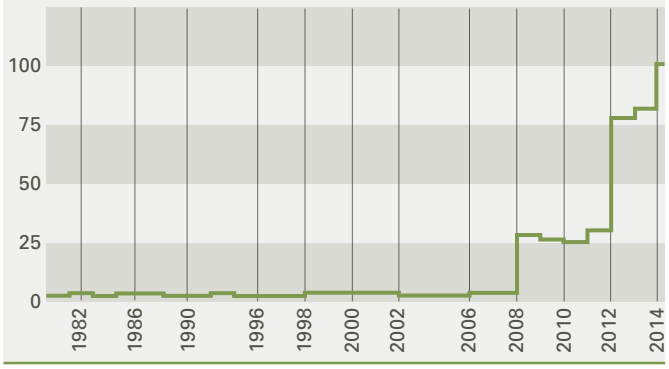
PURE CIRCLE CULTIVATING "PROPRIETARY VARIETIES" OF STEVIA IN PARAGUAY

PureCircle is a Bermuda-based company which has headquarters in Malaysia and is listed on the London stock exchange. It is second only to Cargill in terms of providing steviol glycosides to Coca Cola. The company works with growers in Paraguay, Kenya and China, ensuring that the growers use plant varieties that it has the rights to. The company says it is diversifying its Stevia leaf sources because of growing consumer demand and rising production costs in China (Nikkei Asian Review, 2015).

5.2 PATENTS ON STEVIA/STEVIOL GLYCOSIDES

Stevia rebaudiana and its sweet derivatives—the steviol glycosides—are the subject of intense patent activity. Over 1,000 patent applications concerning Stevia had been filed by the end of 2014. While most patent applications were filed in China and Japan, none were filed in Paraguay, the country of origin of the Stevia plant. Of these 1,000 around 450 patents, belonging to 158 patent families, relate specifically to steviol glycosides.[11]

NUMBER OF FILED PATENTS RELATED SPECIFICALLY TO STEVIOL GLYCOSIDES BY YEAR BETWEEN 1 JANUARY 1979 AND 31 DECEMBER 2014[12]



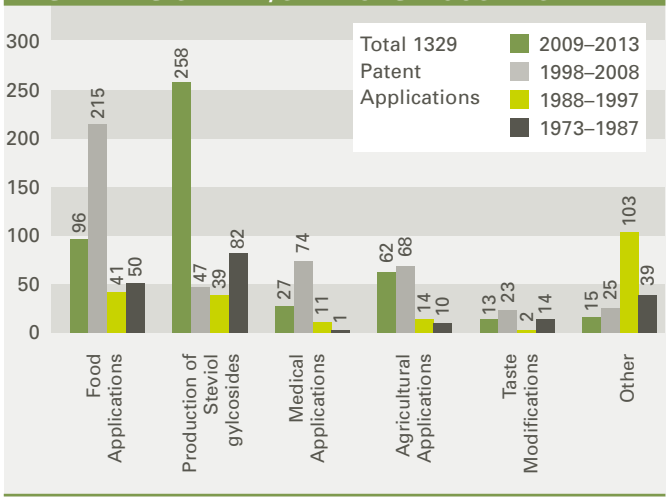
Source: Lens, 2015

The first traceable patent application was filed in 1973 in the US, for a method of producing steviosides (US 3723410 A[13]). With the start of the marketing of steviol glycosides in Japan, around 1976, an increase in published patents was recorded. In the EU and the US, the number of patent applications for steviol glycosides only began to rise after the JECFA evaluation of the safety of steviol glycosides in 2008 (see JECFA section above).

It is interesting to note that in South America only three patents in Argentina (Suntory Holdings Ltd), one in Brazil (PepsiCo) and one in Chile (Coca Cola together with Pure Circle) have been published. Surprisingly there are none listed in Paraguay.

10 Some varieties might be the same but protected in different countries.
11 Certain patents within this search might not include the production process of steviol glycosides but the mere utilisation of steviol glycosides. Data based on appearance of the term "steviol glycosides" in the patent abstracts on Lens.org (as accessed on 22 July 2015).
12 Search term: "steviol glycosides" in abstract.
13 US 3723410 A: Method of producing Stevioside – www.google.com/patents/US3723410

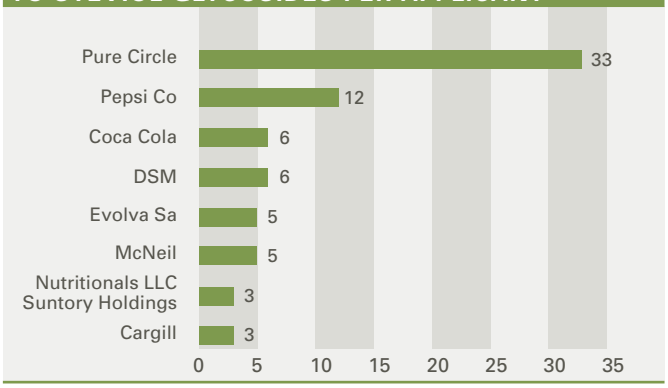
FIELD OF USAGE OF THE PATENT APPLICATIONS REGARDING STEVIA/STEVIOLGLYCOSIDES



Source: Espacenet, 2013 – European Patent Office

The analysis of the information, which is based on Espacenet data, also shows that there are an increasing number of patents focusing on ways of producing steviol glycosides, as opposed to using them; and within those there is an increase in the percentage that are claimed to produce steviol glycosides either by genetic modification or synthetic biology. It seems as if this may well become the major production technique within a few years.

NUMBER OF PATENT FAMILIES RELATED TO STEVIOL GLYCOSIDES PER APPLICANT[14]



Source: Lens, 2015

The analysis also shows that the eight companies that have made the most patent applications applied for 46 % of the 158 patent families. These companies are Pure Circle, Pepsi Co, Coca Cola, DSM, Evolva Sa, McNeil Nutritionals LLC, Suntory Holdings and Cargill (Lens, 2015). With their patents these companies will be able to control the market for steviol glycosides. The other 54 % were applied for by various smaller companies, especially from Asian countries such as Japan, China and South Korea. Most of the patent applications from the big multinational corporations focused on production methods rather than use. The fact that Evolva and DSM appear in this list is not surprising since they are expected to be launching their synthetically produced steviol glycosides shortly (see section on Synthetic Biology).

PepsiCo, McNeil Nutritionals and Cargill applied for the most use based patents, although the rate of applications has been declining since 2008. It can be assumed that Cargill is awaiting the launch of Evolva's synthetic steviol glycosides, which will be used for Cargill's *Eversweet* sweetener and could involve further use based patent applications.

5.3 MARKETING STEVIOL GLYCOSIDES AS "NATURAL" AND "BASED ON TRADITIONAL KNOWLEDGE"

Even though Stevia leaves cannot be sold in the US or the EU, and steviol glycosides are substantively different to Stevia leaves, large companies such as Coca Cola are increasingly playing on the benefits associated with the plant in its natural state, and even the traditional knowledge of the Guaraní.

Paraguay and the indigenous Guaraní people, as home to and bearers of the traditional knowledge about the sweetening effects of the Stevia plant respectively, are not benefiting from their knowledge or receiving the fair and equitable share of the profits that should be due to them under the Convention on Biological Diversity and its Nagoya Protocol.

Pepsi and Coca Cola have both launched colas containing steviol glycosides, "Pepsi Next" and "Coca Cola Life". "Pepsi Next" was launched in 2012 in the US and Australia (Herbison, 2015). "Coca Cola Life" was launched as a pilot product by the Coca Cola Company, first in Argentina and Chile in 2013, then in the US and the UK in 2014, and then in other European countries including Switzerland and Germany in 2015.

The industry likes to suggest that Stevia leaves and steviol glycosides are the same thing, because food additives generally have a negative image, while the Stevia plant and the concept of using plants in their natural state is popular with health-conscious consumers. "Pepsi Next" has even used the phrase "Stevia Leaf Extract" which is highly misleading, given the differences between the plant Stevia, and the chemically purified steviol glycosides.

The new drinks are promoted with slogans such as "natural flavours", "sweetened from natural sources", "the

14 Includes patents on the production process of steviol glycosides as well as on their use.

COCA COLA AND STEVIA

Coca Cola UK says of Stevia, "It's been grown, harvested and used in recipes by indigenous people for centuries" (Davies, 2015).

Coca Cola Germany even put an "interview" with a Stevia plant on their website (see page 22): "The Guaraní are using my leaves for their Mate tea and as a drug, for instance against stomach ache and digestion problems, skin rashes and tooth inflammation or to lower blood pressure. Also today I am being used in Paraguay to sweeten tea and for the production of sweets. Because we Paraguayans love it sweet! We live in accord with nature and we do not have to hide. Maybe this is why we consider ourselves in surveys as the happiest people in the world" (Coca Cola GE, 2015; advertisement for Coca Cola Life, translated from German).

The Coca Cola Company and the International Football Federation (FIFA) also used images of Guaraní to promote Coca Cola beverages during the 2014 World Cup in Brazil (see page 22).

It is especially tragic to note such cynical marketing campaigns when, according to other sources, the Guaraní face the highest suicide rate in the world, often living in squalor following the loss of their livelihoods, villages and land to soy, cattle ranching and sugar cane plantations. Absurd, but probably not unique, is the case of Jatyavary: The land had been grabbed from the Guarani, later sugarcane was grown for the commodity giant Bunge, which is an important sugar supplier to Coca-Cola Company. The complete workforce in the sugar sector in Mato Grosso do Sul consists of Guarani. Working conditions are extremely precarious, there have been several reports of slave-like working conditions over the last years (see chapter 2).

MARKETING STEVIOL GLYCOSIDES IN AUSTRIA, GERMANY AND SWITZERLAND

During the summer of 2013, the University of Hohenheim in Germany undertook a market survey to examine how companies launched and generally marketed products containing steviol glycosides in Austria, Germany and Switzerland.

The survey identified a total of 82 companies manufacturing products containing steviol glycosides and selling them in supermarkets (the survey did not include any company selling exclusively via the internet). All of those companies use the term "Stevia" to promote the sweetening effect of the food additive steviol glycoside (E960) and about half linked the products to traditional knowledge in their labels or advertisements.

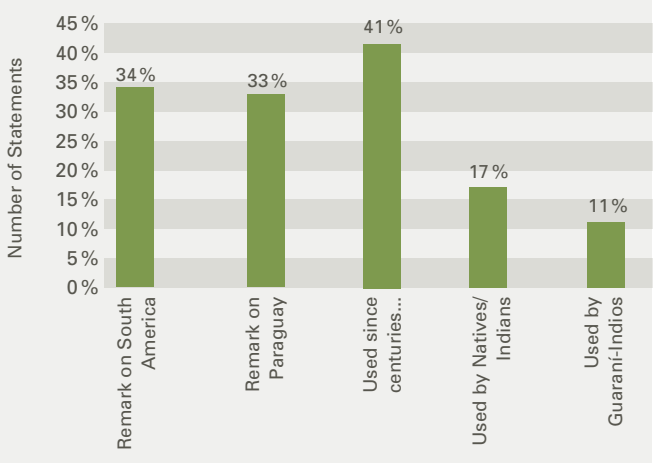
About 41% of the companies use the term "Used for centuries..." to raise consumer confidence in the safety of the product. Around 34% mentioned that Stevia originally comes from South America, and 33% mentioned that it comes from Paraguay. Approximately 17% mentioned that Stevia was used by "natives" or "Indians" and 11% linked Stevia with the Guaraní communities as the original bearers of the know-how relating to *Stevia rebaudiana* and its sweetening property. Sometimes erroneous statements were made, such as "used/known by Amazonian Indians".

In a further market analysis undertaken in Germany in July 2015, misleading labelling can still be found on 88% of products offered to consumers. Another 7% of products do not comply at all with EU food laws. Only 5% of the products were correctly labelled. It seems that companies using steviol gylcosides are not willing to apply EU food laws correctly.

extract comes from a natural source" or "naturally sweetened" (Coca Cola GB, 2014; PepsiCo CA, 2014). Thus, a lot of effort has been put into highlighting the new "natural" aspect of these drinks. In addition the colour and design of the packaging for both suggests that they are healthy and environmentally friendly.

Coca Cola Life is also marketed as a means of tackling obesity and helping people to balance their lifestyles. In the UK for example, Coca Cola signed the government's controversial Responsibility Deal, which aims to improve public health, promising to lower its average calorie count (The Guardian, 2014). But even though Coca Cola Life does have 36% less calories and sugar than standard Coca Cola, it still has more than four teaspoons (22g) of sugar per 330ml can, which accounts for 25% of the maximum daily intake of a child (The Guardian, 2014; Daily Mail, 2014). Pepsi Next, which has substituted 30% of the sugar content with steviol glycosides, has an even higher sugar content (26g per 335 ml can) (PepsiCo CA, 2014).

MARKETING ARGUMENTS FOR FOOD AND BEVERAGES SWEETENED WITH STEVIOL GLYCOSIDES RELATED TO ORIGIN AND TRADITIONAL KNOWLEDGE



Source: Breitenstein *et al.*, 2013

Examples include Belgian chocolate, Cavelier, which has the words "with sweeteners from Stevia-a natural source" on a green background. In reality, this chocolate is sweetened with the food additives steviol glycoside and erythritol as well as with oligofructose (Cavelier, 2014).

Another example is Assugrin Stevia Sweet Crystal which has illustrations of Stevia leaves on its packaging and in its advertising, even though it is also sweetened with a combination of steviol glycosides and erythritol. The ratio of steviol glycosides to erythritol is 1:50 however, and erythritol is a sugar substitute which is produced through fermentation by yeast cells and cannot be metabolised by the human body. The marketing of this product is thus deliberately misleading. Swiss chocolate company Stella Bernrain even sells a "Stevia chocolate", with packaging depicting Stevia leaves and in large letters the term "Stevia extracts". Again, it is sweetened with steviol glycosides.

On 2 July 2015 the Berne Declaration questioned Coca Cola and PepsiCo about whether they intend to use synthetic steviol glycosides in their food and beverages in the future, and if yes, whether they would change their labelling and advertisements as well as their communication strategy accordingly. No answer was received from PepsiCo. Coca Cola responded as follows:

"Due to commercial and proprietary reasons our company does not comment on (either to confirm or deny) questions such as the above."

"As with the answer above, no comment, other than the Coca Cola Company complies with all relevant local labelling requirements."

After the presentation of the new SynBio and fermentation based sweetener *Eversweet* by Cargill in October 2015, Evolva CEO Neil Goldsmith also declined to respond to the question of whether Cargill is intending to use Cargill's (i.e. Evolva's) SynBio steviol glycosides in their beverages in the future (Grundlehner, 2015).

5.4 ADVERTISING RESTRICTIONS

This misleading advertising has already been noted in a number of countries, and several governments have established regulations intended to prevent such deception.

In Switzerland for example, steviol glycoside is not allowed to be declared as "natural" or to be illustrated with Stevia leaves. Expressions like "containing stevia-extract",

Products are frequently green in colour, implying that they contain „natural" Stevia ingredients. However, all products include chemically/physically purified steviol glycosides. Some (Cavalier chocolate and Assugrin) even use additional artificial sweeteners such as erythritol. © K. Hutter

"sweetened with stevia" or "steviol glycosides are naturally contained in Stevia leaves" are also prohibited. The word "Stevia" may only be used in advertisements that clearly state something akin to: "Steviol glycosides are produced from Stevia leaves". It is also not permitted to say "known about by indigenous peoples for centuries", since they used the Stevia plant, not purified steviol glycosides (BAG, 2010).

Austria has also published a guideline on how to correctly label products containing steviol glycosides. The guideline is more general than the regulation in Switzerland. Expressions such as "steviol gylcosides from a plant-based source", "steviol glycosides derived from Stevia/Stevia plant components" or "steviol glycosides derived from a natural source" are allowed, but not expressions like "sweetness from a natural source". Also "naturally sweetened", "Stevia extract" and visual representations or symbols of Stevia plants are considered a deception. Pictures are only allowed if a notification about the food additive steviol glycoside E960 is positioned in close proximity and with a similar degree of visibility (BMG, 2012).

In Germany any labelling that stresses the natural character of steviol glycosides is prohibited. The reason is that the additive may contain residues of ion-exchange resins used in the manufacturing process. In addition new steviol glycosides, which do not occur in the Stevia plant on a natural basis, are also formed as by-products (ALS, 2013; EU, 2012).

In Germany, the discussion about the correct advertisement of steviol glycosides actually started in 2013 with a court case. In April 2013 the regional court in Constance decided that labelling a drink containing steviol glycosides with the words "steevia-fluid" and "Stevia leaves" and illustrating it with a Stevia leaf was misleading (Az: 7 O 32/12 KfH). However in October 2013 the higher regional court in Karlsruhe decided that many of the cease and desist orders pronounced by the regional court in Constance were invalid. Such declarations were then considered valid if there was also an indication that the product contains steviol glycosides or the food additive E960. The expression "Stevia leaves" was also accepted on the basis that steviol glycosides are produced from Stevia leaves. Only the expression "Stevia extract" was ruled to be invalid. Hereinafter, the defendant signed a declaration to cease and desist (OLG Karlsruhe, 2013).

In 2013 the Committee of the Food Chemists of the German Provinces (ALS) published a ruling which states that figural presentations of either the Stevia plant or the Stevia leaves are considered to be deceptive if the labelling is not accompanied by a statement that the sweetening effect is obtained from the food additive steviol glycoside. Such a statement must be placed near the illustration in the same eye-catching manner (ALS, 2013).

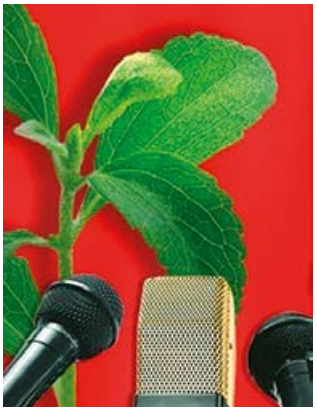
Similarly a civil suit in the US, against Cargill, argued that the tabletop sweetener Truvia was deceptively marketed as "natural" although it contains highly chemically processed steviol glycosides:

"According to plaintiff Denise Howerton, while the Reb-A is derived from a natural source (the Stevia leaf), the extraction and processing methods mean a reasonable consumer would no longer consider it to be 'natural'. […] A reasonable consumer she argued, understands a natural product to be one that does not contain man-made synthetic ingredients, is not subject to harsh chemical processes and is only minimally processed" (Watson, 2014).

By the end of 2014 Cargill agreed on a settlement, and granted a settlement fund of US$ 6.1 million for cash refunds or vouchers for consumers who had bought Truvia. They also agreed to change the product's labelling and marketing (Gmuer, 2015; Watson, 2014). Cargill's new Syn-Bio based sweetener *Eversweet,* which will be launched by 2016, will not be allowed to use the word "natural" on its packaging either (Grundlehner, 2015).

A complaint to the UK's Advertising Standards Authority also resulted in British Sugar withdrawing an advertisement for Truvia in the UK (Michail, 2015).

Misleading advertisements: a Stevia plant giving an interview on its sweetening properties on the Coca Cola Germany website, a VW mini-bus covered with leaves suggesting the "naturalness" of Coca Cola Life, and a Guaraní used to promote Coca Cola beverages at the FIFA world cup in Brazil in 2014. © Coca Cola Deutschland | K. Steiner | Survival International



6 STEVIA AND THE RULES ON ACCESS AND BENEFIT SHARING

6.1 STEVIA, THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE NAGOYA PROTOCOL ON ACCESS AND BENEFIT SHARING

Genetic resources are crucial to guarantee our survival and humans have developed and shared traditional knowledge about how to breed and use plants and animals to produce food, textiles, medicines and other utilitarian, cultural and spiritual items for millennia. But this knowledge is increasingly being appropriated by companies hoping to commercialise and profit from it. Governments have now agreed—through the Convention of Biological Diversity's Nagoya Protocol—that the holders of this traditional knowledge have a right to benefit from the knowledge that they have developed, often over centuries.

THE CONVENTION ON BIOLOGICAL DIVERSITY (CBD) AND THE NAGOYA PROTOCOL ON ACCESS AND BENEFIT SHARING (ABS)[15]

In 1993, the CBD entered into force. The CBD accords sovereign rights to each state over their genetic resources and aims to put a stop to biopiracy. Most states (195 countries and the European Union) are parties to the CBD, but the United States, the Holy See and North Korea are not. Moreover the CBD included clear obligations for its parties to implement laws on ABS: indeed, ensuring ABS is one of the three main objectives of the CBD. However, as its implementation was poor, negotiations for an additional instrument under the CBD have been ongoing for many years.

These have now culminated in the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (the Nagoya Protocol for short), which was adopted in 2010, and came into force in October 2014.

The Nagoya Protocol is supposed to address the vexed question of how to ensure the fair and equitable sharing of the benefits arising from the utilisation of genetic resources and the associated traditional knowledge. That is to say, it was hoped by many that it would prevent biopiracy—the use of genetic resources and related traditional knowledge for commercial purposes without the prior informed consent of the peoples and countries that are the legitimate guardians of that biodiversity.

In spite of the fact that the Nagoya Protocol aims to establish a clear and transparent legally binding framework (Europa, 2015) the end result is actually much vaguer than originally intended. Firstly, because the Nagoya Protocol itself has some ambiguities (which have been described as intentional [Union for Ethical Biotrade, 2010]) and secondly because the Nagoya Protocol is interpreted in a variety of ways by the various parties (Berne Declaration, 2013; Berne Declaration, 2013a). "In practice, the international patent system, and specifically the protection of plant varieties, has a much stronger bearing on the way genetic resources are handled than the CBD, and effectively decides their fate" (GIZ, 2008). Therefore the implementation of effective and comprehensive national legislation to implement ABS, as intended with the development of the Nagoya Protocol, remains a high priority:

"In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established" (Nagoya Protocol, Article 7).

"Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms" (Nagoya Protocol, Article 5.5).

It is also important to note that the Nagoya Protocol defines the "Utilization of genetic resources" in its Article 2 as "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention[16] **[…]"**. This seems to exclude the direct use of Stevia leaves for sweetening, but include steviol glycosides produced by extraction processes or synthetic biology.

15 Sources: An Activists' Guide to the Convention on Biological Diversity (Hall, 2014) and Nagoya Protocol Text (CBD, 2015).

16 Article 2 of the CBD defines biotechnology as follows: "Biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

This report, which analyses one specific ABS issue – that of access and benefit sharing in relation to traditional knowledge about Stevia – demonstrates that there is a pressing need for governments to combat biopiracy effectively by implementing the Nagoya Protocol optimally at national level. It should be impossible to derive any profit if genetic resources or traditional knowledge are accessed illegally and the benefits are not shared.

To start with, it has so far been signed by just 92 states and has only 62 parties (compared with the full convention's 196 parties). This creates a complex situation, as we will see with Stevia, because it means there are different legal situations in different countries, including countries of origin.

There are also different opinions about what the Nagoya Protocol actually covers. For many developing countries it covers every new[17] utilisation of a genetic resource. But most developed countries only include those genetic resources which were accessed after the entry into force of the protocol in the country of origin. This significantly narrows the scope of the protocol in practice.[18]

How the current ABS mechanism applies to the specific use of *Stevia rebaudiana* (Bertoni) is also a complex question. To start off with there is more than one country of origin and many user countries but the legal situation in each differs (CBD, 2015a; CBD, 2015b):

- Paraguay has both signed and ratified the CBD, but not yet integrated it into national law. However it has neither signed nor ratified the Nagoya Protocol.
- Brazil, another country of origin, has signed and ratified the CBD and has clear regulations on Access and Benefit Sharing in place nationally. It has also signed the Nagoya Protocol but has not yet ratified it.
- The US, as a main user of steviol glycosides, has signed but not ratified the CBD, and has neither signed nor ratified the Nagoya Protocol.
- The European Union and Switzerland have signed and ratified both the CBD and the Nagoya Protocol.

STATUS OF ACCESS AND BENEFIT SHARING REGULATIONS IN VARIOUS COUNTRIES

	Paraguay	Brazil	USA	EU	Switzerland
Ratified CBD	×	×		×	×
ABS law in place		×		×	×
Signed Nagoya		×		×	×
Ratified Nagoya				×	×

The spirit of the CBD and of the Nagoya Protocol is clear. The Guaraní have a right to define access to their traditional knowledge and to share in the benefits from any commercialisation. But given the watered down and narrow interpretations of the Nagoya Protocol and its differing degrees of implementation at national level, it currently seems to be a challenge to legally enforce any request for benefit sharing with respect to Stevia in the user countries—especially when the countries of origin have not ratified the Nagoya Protocol themselves.

However, it is important to note that resolving this issue would not be unprecedented, as demonstrated by a case from South Africa, which includes Cargill, a key player in the Stevia sector. Two Limpopo communities are set to receive 2.6 mio ZAR (about 187,000 Euro) for helping with the development of a non-carbohydrate sweetener based on a local plant known as Molomo monate *(Schlerochiton ilicifolius).* The South African Council for Scientific and Industrial Research signed a license agreement with the multinational Cargill in 2004 and received milestone payments in 2004, 2006 and 2013, which can now be shared with the identified communities (News24, 2015). In the case of Stevia a similar process could support the holders of the traditional knowledge. However, benefit sharing could take different forms depending on the demands and needs of the Guaraní. It seems obvious that in such a case the Guaraní living in the region of origin (the highlands of Amambay in north-eastern Paraguay and the border region of Brazil) should be the first contact. Furthermore, it is crucial that these Guaraní need to have a leading role in any negotiations on access and benefit-sharing in relation to Stevia.

6.2 OTHER INTERGOVERNMENTAL AGREEMENTS AND GUIDANCE

There are other intergovernmental agreements and guidance that are also relevant to the case of access and benefit sharing with respect to Stevia.

The United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP)

UNDRIP, which was adopted by the UN General Assembly in 2007, is also highly relevant, since it addresses indigenous peoples' rights with respect to their territories and traditional knowledge.

UNDRIP unequivocally states that "Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including hu-

17 "New" means beginning at the time when national ABS laws entered into force

18 For a more detailed analysis of the European Regulation and differences in the laws of developing countries see: Natural Justice and Berne Declaration, 2013.

SPECIFIC ABS MEASURES IMPLEMENTED TO PROTECT GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN GENERAL OR *STEVIA REBAUDIANA* IN PARTICULAR

PARAGUAY: In October 2006 the government of Paraguay issued a decree (Decreto Nr. 8392) (MAG, 2006a), recognising *Stevia rebaudiana* (Bertoni)/Bertoni Ka'a He'e as being native to Paraguay. It also declared an agricultural interest in *Stevia rebaudiana,* with a view to diversifying agricultural production. In its explanatory text it claims that *Stevia rebaudiana* has been included in the taxonomic list of endemic flora of Paraguay and that on the global level *Stevia rebaudiana* is always linked to Paraguay. It also mentions that *Stevia rebaudiana* has been listed in the category of critically endangered species in Paraguay. In February 2013 the content of the decree was transposed into law (BACN, 2013). Although this law cannot be seen as an Access and Benefit Sharing law in the narrow sense, it is clear that Paraguay is claiming ownership over the plant. It is very problematic though that the Guaraní, the indigenous holders of the traditional knowledge associated with *Stevia rebaudiana,* are not mentioned a single time in the decree or in the law—showing a lack of recognition of the rights of indigenous peoples by the national government.

BRAZIL: As *Stevia rebaudiana* originates from the border region between Paraguay and Brazil and because the Guaraní, as the holders of the traditional knowledge, also have a strong presence in Brazil, it is also relevant to consider how Access and Benefit Sharing is regulated in Brazil.

On 20 May 2015, the Brazilian president Dilma Roussef signed the new Brazilian Biodiversity Law (Planalto, 2015). Under this law, any company which utilises genetic resources or associated traditional knowledge or exploits a product derived from them (as of 30 June 2000) has to comply with its requirements (Article 37). Benefits arising from economic exploitation of a final product or reproductive material based on access to the genetic resources of species found in *in situ* conditions, or associated traditional knowledge, have to be shared in a fair and equitable manner, even if the plant has been grown and the product produced outside the country (Article 17). The benefit sharing could be monetary or non-monetary. If the former it should be 1% of the net annual revenue generated by the economic exploitation of the final product. This percentage could be reduced to 0.1% in specific cases (Article 20). Furthermore when the final product or the reproductive material is derived from access to traditional knowledge that is of identifiable origin, the provider of that traditional knowledge is entitled to receive benefits, which are negotiated bilaterally between the community (the holder of the traditional knowledge) and the company (the user) (Article 24). In addition to the benefit sharing agreed with the community the user will have to pay 0.5% of the net annual revenue into the national benefit sharing fund.

In the Brazilian law the term "genetic resources" is not used, but instead the term "genetic heritage". This definition is a little broader than just genetic resources. Genetic heritage is any kind of information originating from genetic resources. This would also include the use of genetic data without having access to the genetic resource itself. One trigger for this definition was to prevent the circumvention of ABS obligations through the use of synthetic biology.

The new Brazilian law is a powerful tool to claim benefit sharing with respect to the use of genetic resources and traditional knowledge after 30 June 2000 (even if the resource was accessed many years before). If *Stevia rebaudiana* or at least the associated traditional knowledge is seen as also originating from Brazil, the Brazilian law could be used in this case.

EUROPEAN UNION: Although the EU has signed and ratified the Nagoya Protocol it is doubtful whether the rights of countries of origin and the holders of traditional knowledge relating to *Stevia rebaudiana* could be enforced in Europe, even though it is a key market for steviol products. This is because the way in which the European regulation interprets the Nagoya Protocol (EU, 2014) is clearly inadequate: it only applies to genetic resources and related traditional knowledge that has been accessed after its entry into force. Furthermore, "access" is defined as the acquisition of genetic resources or traditional knowledge from a party to the Nagoya Protocol—which discounts both Paraguay and Brazil in this case. It seems unlikely that the Nagoya Protocol can be used to enforce rights related to Stevia in the EU.

SWITZERLAND: The scope of the Swiss law (which could be of relevance since Evolva is based in Switzerland and steviol glycosides are also marketed there) is similar to that in the European Union. However, in the draft ordinance there is a clause which could be of importance for ABS in the Stevia case: The Federal Office for the Environment (FOEN) encourages users to share benefits arising from the utilisation of genetic resources on a voluntary basis, even in the absence of a legal obligation, in a balanced and equitable manner.

man and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions" (Article 31.1).

It is important to note that the International Law Association has the following to say about the legal status of UNDRIP: "What is really significant…is that the adoption

Cheering after the adoption of the Nagoya Protocol in 2010. © CBD/M. Bański

of UNDRIP after more than twenty years of negotiations, confirms that the international community has come to a consensus that indigenous peoples are a concern of international law, which translates into the existence of customary rules of binding force for all States irrespective of whether or not they have ratified the relevant treaties (which, on their part, taken together bind virtually all countries in the world)" (ILA, 2010). This clearly supports the case for ABS with respect to the Guaraní people and Stevia.

The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

ITPGRFA also deals with biodiversity, in the sense that it focuses on agrobiodiversity, the rights of small farmers and indigenous peoples as custodians, and access and benefit sharing (GIZ, 2008). Farmers' rights have to be implemented through national laws, which is done in various ways by the different parties. On the other hand, questions related to Access and Benefit Sharing are dealt with separately under the Treaty's articles concerning the multilateral system (which take effect through the Treaty's Standard Material Transfer Agreement.)

Stevia rebaudiana is not currently included in the list of crops that defines the scope of the treaty's multilateral system of Access and Benefit Sharing.[19] As long as this remains the same, Access and Benefit Sharing for *Stevia rebaudiana* has to be handled under the CBD and its Nagoya Protocol.

FAO-OECD Guidance for Responsible Agricultural Supply Chains (in draft)

Although not yet adopted, the Guidance for Responsible Agricultural Supply Chains is being developed by the FAO and the Organisation for Economic Cooperation and Development (OECD) (OECD, 2015). It is intended to help enterprises observe responsible business conduct standards and undertake due diligence along agricultural supply chains, especially in "frontier markets with weak governance and insecure land rights" (OECD, 2015). It targets upstream and downstream sectors from input supply to production, post-harvest handling, processing, transportation, marketing, distribution and retailing. It is thus relevant to actors in the Stevia supply chain, such as Evolva, Cargill and Coca Cola. It is due to be finalised in 2015.

With respect to Access and Benefit Sharing the draft guidance currently states "We will ensure that our operations contribute to sustainable and inclusive rural development, including, as appropriate, through promoting fair and equitable sharing of benefits with affected communities, e.g. when using genetic resources for food and agriculture"[20] (OECD, 2015).

This has a definite bearing on benefit sharing as a part of responsible business conduct, even or especially in the absence of legal obligations.

19 This list can be found here: www.planttreaty.org/content/article-xiv

20 The FAO-OECD Guidance refers to several other guidance documents in which benefit sharing principles have also been enshrined, including the Principles for Responsible Investment in Agriculture and Food Systems (CFS-RAI Principles) 2.iv-vii and 7.i & iii; the Principles for Responsible Agricultural Investment that Respects Rights, Livelihoods and Resources (PRAI Principles) 5-6; the CBD Akwé: Kon Guidelines, 46; and the IFC Performance Standard 7, paras 14 and 17-20 and Standard 8, para 16.

7 CONCLUSIONS AND RECOMMENDATIONS

It is clear that the production of steviol glycosides is a booming sector that is based on the traditional knowledge of the Guaraní people living in Paraguay and Brazil. It is also clear that as things stand the Guaraní are not likely to share in the significant financial benefits being generated—even though their traditional knowledge about Stevia and the "naturalness" of the plant-based sweetener are at the heart of corporate Stevia marketing strategies across the world. Hence, the production of steviol glycosides from Stevia leaves is a clear case of biopiracy.

In order to resolve this case of biopiracy, and to further promote rural development for smallholder farmers, a number of steps need to be taken by governments generally, and by companies producing or using steviol glycosides:

- **Producers and users of steviol glycosides should commit to mediated engagement with the Guaraní to agree how to share the benefits of the commercialisation of steviol glycosides in a fair and equitable manner.**
  Users of traditional knowledge about *Stevia rebaudiana*—the producers of steviol glycosides and multinational food and beverage companies who are generating and/or anticipating significant profits from Stevia-based products—should engage in practical discussions about implementing ABS in the case of Stevia, together with the Guaraní and governments of the countries of origin, in order to agree terms for the use of and benefits accrued from the Guaraní's traditional knowledge. This is especially important in a country like Paraguay where effective national legal obligations on ABS do not exist yet. Benefit sharing does not have to be monetary, it can also be realised through other forms of support. For instance, the key concern for the Guaraní Kaiowa in Mato Grosso Do Sul, Brazil, is access to land and territories.

- **Governments of user and provider countries—including the Paraguayan government—should implement the Nagoya Protocol optimally at the national level with comprehensive and effective national laws on Access and Benefit Sharing**
  It should be impossible to derive any profit if genetic resources and their associated traditional knowledge are accessed illegally and the benefits are not shared. The Guaraní are fully entitled to be rewarded for their contribution to the Stevia "boom", under principles already agreed by governments in intergovernmental agreements in particular the CBD and UNDRIP. Indeed, Stevia offers an opportunity for the world's governments to demonstrate how their fine words can actually be put into practice, with a view to transforming the situation of an indigenous people who have been discriminated against and marginalised.

  The key question is to how to ensure that this actually happens in practice, given (1) corporate interest in maximising profits from steviol glycosides, and (2) the rather complex legal situation that exists in relation to the CBD's Nagoya Protocol on ABS. But in essence, the key issue is that the billion dollar carbonated soft drinks sector (the main purchaser of high intensity sweeteners) and other producers and users of these sweeteners are not likely to share their profits unless they are forced to do so under national or international law or as a result of public pressure.

  Benefit sharing can take non-monetary forms. These forms should be adopted to the interests and needs of the relevant Guaraní groups. Governments need to take action to make sure the Guaraní share in the benefits deriving from Stevia commercialisation, primarily under the auspices of the Nagoya Protocol. Most importantly they need to acknowledge there is an urgent need to improve the implementation of the Nagoya Protocol by ensuring that comprehensive and effective national legislation on Access and Benefit Sharing is implemented.

- **Governments and sellers of products containing steviol glycosides need to make sure that any advertisements which describe steviol glycosides as "traditional" or "natural" are stopped.**
  Governments and companies in consumer countries must stop deceiving consumers by advertising chemically purified or synthetically produced steviol glycosides as "natural" and "traditional" products. Deceptive marketing is a major concern, and advertisements that focus on the "naturalness" of steviol glycosides and Guaraní heritage are deliberately misleading consumers. They should be prohibited.

- **The government of Paraguay and other governments should ensure that the production of Stevia plants supports smallholders and rural development.**
  Any rural development programme should support ecologically sustainable, small-scale production, and ensure

that the Guaraní land and territorial rights as well as their rights to benefit sharing are explicitly recognised. It should also provide support in the form of access to extension services, markets and fair credit, and farmer-to-farmer exchanges. Natural Stevia products could also be protected with a "geographical indication" (used to protect products like Darjeeling tea).

The Paraguayan government, which is developing the Stevia sector in Paraguay, should focus on benefits for the Guaraní people as well as for smallholders and the nascent domestic processing industry.

- **Governments should ensure that producers may not produce or market steviol glycosides based on synthetic biology in the absence of an independent socio-economic impact assessment with a positive outcome, as requested by the parties of the Convention on Biological Diversity.**

The trend towards using synthetically produced steviol glycosides poses a threat to the huge potential that cultivating Stevia has in terms of rural development in countries such as Paraguay. It moves production away from smallholder farms and into corporate laboratories. However, if steviol glycosides produced via synthetic biology are placed on the market governments must ensure that companies selling the end products are obliged to clearly label them as such.

With respect to products based on SynBio, risk assessments should be based on the precautionary principle and should include considerations of socioeconomic effects, especially for steviol glycosides produced by synthetic biology.

Rights of the Guaraní are violated through the commercialisation of Stevia-derived sweeteners by northern multinational companies. © Misereor

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