

## INGSA CASE STUDIES

***TANGERIA:  
GENE-EDITING AND CLIMATE RESPONSE: SCIENCE, VALUES AND  
POLITICS***

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# TANGERIA

## GENE-EDITING AND CLIMATE RESPONSE: SCIENCE, VALUES AND POLITICS

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### Context

Tangeria is a presidential representative democratic republic that has a high literacy rate and a low corruption index. The President of Tangeria is the head of the state and the head of the government. The parliament is formed by proportional representation with a number of parties both in the government and opposition. A pro-environment party is a significant voice in the parliament but is not in government.

The government is formed from a coalition (“National Alliance”) between a business–friendly party with an urban voter base and a largely rural party. It was elected on a platform of promoting economic growth for the regions. It is three years away from the next election, which occurs every 5 years. Opinion polls suggest the public is worried about the government’s performance in sustaining economic growth. Climate change is high in the public consciousness: its importance is not debated as there is a broad consensus that Tangeria must address its emissions profile which largely comes from pastoral agriculture, transport and energy production (60% of its energy is produced from coal – much of it by trans-border importation from a neighbouring and more authoritarian country, Energeria, which has surplus energy).

But notwithstanding the broad based acceptance of climate change as a matter to be addressed, the opposition regards the actions taken by the government as timid consensus. After the Fukushima event, Tangeria shut down its only nuclear power station and doubled imports of coal derived electricity from Energeria. At the same time a prominent local celebrity has launched a high profile campaign about the state of the environment – demanding more action on climate change and greater protection of Tangeria’s national parks.

Tangeria has a significant, export-oriented agricultural component to its export economy (based on the production of beef and corn/maize which is mainly used as a cattle feed in the dry months and a significant horticultural economy – mainly of fruit and vegetables – which relies heavily on irrigation from water sourced from a large aquifer). Farming is still largely a family affair but large farming corporations are becoming more established, especially as the population generally ages and urbanises. Politically there are concerns about the declining state of the rural economy, the emptying out of provincial towns and the social consequences of rapidly increasing urbanisation. This is impacting on the governing coalition and causing tensions within it.

Modelling suggests that because of climate change, Tangeria will face increasingly wet conditions which will affect pasture growth. Indeed in four of the last five years there have been unusually severe rains affecting agricultural production due to a decline in suitable pasture, a greater dependence on maize production to feed the cattle and depressing horticultural growth rates.

About two decades ago, the country previously rejected the use of genetically modified organisms in agriculture and food production, although foods containing GM grain and soy are now imported

from Energeria, a neighbouring country that grows GM crops. GMO-containing foods are sold in most supermarkets although not explicitly labelled as such. They may also be found in animal feed. Indeed, Tangeria is a member of a free trade block in which some countries grow GM crops and some do not. The opposition to the ruling “National Alliance” is demanding the labelling of foods that contain GM products beyond trace levels, although there is no consensus as to what that means.

The debate 20 years ago was intense, with opponents of GMOs promoting scientific uncertainty and precaution as the reason to ban them. Today, however, there is growing pressure on the government from the farming sector and rural business leaders to protect the sector by addressing the impending shift to more arid conditions with a technology-based climate change mitigation strategy.

The warmer wetter conditions have also brought a greater number of pest species of weed into the Tangeria ecosystem. One weed, the Emperor Grass, has rapidly spread. It has not only invaded cropped landscapes to the point where it is interfering with machine harvesting, but it is also host to the Emperor maize weevil, which in the past was not a problem in Tangeria. Now, however, it is affecting agriculture because the weevil preferentially eats the growth buds of maize and several horticultural crops. Glyphosate appears to be the only herbicide that eliminates the Emperor Grass. Farmers want to use far more glyphosate but they have the challenge that glyphosate also will hurt their crops. They are keen to start using glyphosate-resistant maize, originally developed as a GM-modified strain and now available as a gene-edited strain. The latter was developed at Tangeria National University (TNU).

TNU scientists claim that new breeding techniques based on gene editing show promise for developing drought-resistant crops and plants. In general, such new molecular techniques do not involve the insertion of foreign genetic material into the plant. Rather, they work through the targeted manipulation of one DNA nucleotide in the gene that regulates certain pathways, expressed as drought resistant characteristics in the plant. TNU scientists report that they have successfully crossed the construct used for drought resistance with that that confers glyphosate resistance to create the “ideal” maize crop for Tangeria: indeed they are calling it ‘super-maize’

The technology’s proponents claim that this gene-edited maize is no different to traditionally bred varieties. They also argue that gene editing is safer and more targeted than many of the current, less targeted crop-development techniques, through radiation or chemical toxins. They furthermore state that there is no scientific evidence to think that these methods should be considered risky.

Others, including some scientists, have publicly invoked one version of the precautionary principle, suggesting that these techniques should not be introduced unless proven absolutely safe. They raise the potential risk of microRNAs in the foodstuffs, originating with this technique. They also claim that the new strain would lead to the excessive use of glyphosate. Indeed, as they sense some growing sympathy for the use of new technologies/ they have started to claim that the risks with glyphosate make the introduction of this super-maize downright dangerous. Although Tangeria is not part of the EU, the environmentalists are pointing to the WHO’s and EUs rulings on glyphosate (see below) as reasons for banning extensive use of glyphosate in crop framing.

Organic (and many conventional) farmers suggest the super-maize will hurt their markets. There is yet to be any structured political or public debate over the acceptability of these new techniques. At the same time, the farming community is pushing hard for progress: they have even started to suggest that they would increase the area of land used in cropping so as to make synthetic meat rather than expand the number of cattle – this would help reduce greenhouse gas emissions, water and energy use (they claim). A farmers business cooperative (Tangeria Advanced Agriculture Cooperative Incorporated, TAACI), chaired by a previous minister of business and innovation and former leader of the rural party and coalition partner, has licensed from a Californian company the rights to make synthetic hamburger meat from cropped plants. Their goal is to produce meat for the mass market at a price that competes with ground beef. They have funded TNU to undertake some necessary scale-up research to make this a realistic possibility

Officials in Tangeria's Treasury estimate the net value of moving to weather resistant crops as a climate change adaptation measure is in the order of 2% of GDP. They see a similar massive upside from suppressing the Emperor weed by extensive use of glyphosate. There is also an argument put forward that these crops would allow for farming systems with less dependence on livestock and thus reduce agricultural greenhouse gases.

## Dilemma

The National Agricultural Research Institute of Tangeria (NARIT) wishes to test the new varieties of super-maize and pasture grass produced by gene-editing. The institute has been promised strong financial support from TAACI who are prepared to meet 75% of the development costs. There is also interest from UN organisations that are promoting better responses to the International Sustainable Development Goals. NARIT is well positioned to become a world leading research and innovation hub in agricultural gene editing technology and indeed this is part of the institution's stated strategic plan.

Leading scientists from both TNU and NARIT maintain that gene-editing techniques do not produce GMOs in the conventional sense and therefore are not subject to the country's regulations that currently limit the release of GMOs. The proponents point out that there has been expert opinion in several other countries regarding this point with the consensus that these methods are fundamentally no different to standard forms of plant breeding. But those who are opposed point to other countries that do consider that gene-editing techniques should be regulated in the same way as GM.

The Science Advisory Council to TAACI has produced a report on the safety and advantages of glyphosate, which points out the deficiencies in the EU-WHO analysis. This report is rejected by a group called Doctors for the Sustainable Environment who argue that the evidence shows that glyphosate causes cancer.

A regulatory change would be needed before the field trials would be possible. The government is under growing pressure from the farmers' lobby, TAACI and from the minority party in the coalition. Editorials are split with environmental arguments being put both to allow the super-maize and extensive use of glyphosate and others to continue to ban it.

The President of Tanageria and the Cabinet feel the need to clarify their existing policy in light of more precise techniques and to seek advice from their science advisory system about their perspectives on NARITs proposal to field-release the super-maize.

## Notes for the mentor

*What are the issues/questions that a science advisor or advisory system need to consider when preparing a response?*

Points to consider:

What are the scientific issues (as opposed to political ones)?

What is known, what is not known?

Precaution and risk

Communication

1. Communication of complex science to politicians
2. Language/ communication/media – how can to get to the various groups
3. It's going to be fraught – must therefore be careful to be an honest broker
  -  What we know
  -  What we do not know
  -  Risks of moving
  -  Risks of not moving
  -  Alternate approaches, credible
4. Who are all the stake-holders?
  - Broader implications- beyond the science or its communication
5. No social consensus
  -  What are the options?
  -  Dealing with the extremists/lobbyist on both sides of the debate
  -  How can science support debate?
6. Is the economics safe? Is that a question for science advisors?
7. Is the export market safe? Is that a question for science advisors?
8. Alternate solutions for the agricultural sector?
9. Tanageria's global reputation? Does it matter?

## Additional material: Review on glyphosate

### Summary

Glyphosate (N-(phosphonomethyl) glycine) is a leading herbicide, most notably sold as the compound Roundup, which is used in conjunction with crops genetically engineered to be resistant to its effects. This combination has been introduced to reduce pesticide use and increase yields. Glyphosate is used in hundreds of products, making it difficult to fully test in combination with all the other chemicals with which it might be used. In light of this, its exact toxicity to humans, bees and the environment in general has been difficult to determine. Recently, the license for glyphosate has come up for renewal in the European Union, opening up the debate about a blanket ban once again. This debate has been recently complicated by the WHO's reclassification of glyphosate as a probable carcinogen, a conclusion that was subsequently challenged by the renewal process, during which the report on acceptable risk issued by EFSA concluded.

### Introduction

In 1974, the multinational biotechnology corporation Monsanto launched a new broad-spectrum herbicide based on the active substance glyphosate. Marketed under the trade name Roundup, this herbicide was part of the corporation's large scale involvement in the "green revolution", a global project supported by the World Bank that aimed to increase food production in developing countries through the industrialization of agriculture and extensive use of fertilizers and pesticides. At its introduction Roundup could help clear land for cultivation, but it could not be used on arable crops because crop species as well as weeds succumbed.

In the early 1980s Monsanto scientists began working on genetically modified plants engineered for resistance to Roundup, thus allowing use of the compound to remove invasive weed species without damaging the crops. In 1994, the corporation released the first transgenic glyphosate-resistant crops—soybeans and canola, followed rapidly by cotton, maize and sugar beets. The uptake of these transgenic crops was spectacularly fast and wide, first in North and South America then globally. Monsanto claimed this combination of herbicide and GM seed modified to resist the herbicide enabled food producers to reduce the use of other weed-control tools (chemical or mechanical). Furthermore, glyphosate was claimed to be relatively harmless because it bound tightly to soil constituents with little movement through either soil or groundwater, and had a short environmental half-life with no atmospheric contamination because it is not volatile.

Initially, the WHO classified glyphosate as "probably not carcinogenic to humans". Multiple studies found it was not retained in animal tissue, while reports of potential toxicity in humans were generally blamed on surfactants (chemical additives to the Roundup compound), not on the glyphosate molecule itself, which was deemed non-carcinogenic and not developmentally toxic. However, many of the studies reviewed at that time were carried out by Monsanto, and the structure of risk evaluation studies could leave questions about longer-term exposure unanswered.

In 2012, the French scientist with a history of anti-GM claims published a highly controversial paper. To immense and controversial publicity, the paper suggested that Roundup caused tumours in rats when studied over a longer period. This paper was withdrawn by the publisher a year later after

vigorous criticism of its statistical and scientific validity by the scientific community. It was eventually republished without any further peer review in a different journal along with the raw data.

As time went on, it was noted that resistance to glyphosate was beginning to increase in both GM crops and in related weeds through exchange of genetic material, causing farmers to apply other herbicides along with glyphosate-derived products and thus increasing rather than lowering the total volume of herbicide use.<sup>1</sup>

Although there has been widespread uptake of GM crops by farmers in the USA and South America, this increase in use has been countered by widespread public resistance in Europe and other regions. In 2015, the EU voted to allow countries to block GM. To date, 19 of the 28 member states have enacted bans.<sup>2</sup>

At the same time, the active ingredient in Roundup, glyphosate, was coming to the end of its approved licensing period in Europe, having been authorised in 2002. While Roundup accounts for a significant share of the agro-industrial market, including use by home gardeners, glyphosate is also used in a number of other products - more than 750 in the US alone (IARC 2012). It is therefore impossible to test each and every compound, particularly as new products continue to enter the market.

In Europe glyphosate must first be approved at EU level before member states can authorise its use in products for their own markets, and expiry of the approval would require all member states to withdraw authorisation for the sale of products containing it.<sup>3</sup> Periodic renewal of this approval is required, and in this instance began in 2012. Although any person can submit information during preparation of the draft assessment report which is prepared by the Rapporteur Member State (in this case, Germany), EFSA is expected to make an active assessment only of the technical evidence it receives.

In March 2015, the International Agency for Research on Cancer (IARC), the cancer-research arm of the WHO,<sup>4</sup> released a report that assessed the carcinogenicity of five major herbicides, including glyphosate. The commission used evidence from human, animal, and mechanistic studies, i.e. those seeking to explain causative processes. The IARC concluded that there was “limited evidence” from human epidemiological studies to suggest a positive association between exposure to glyphosate and increased risk of non-Hodgkin lymphoma (NHL), as well as increased risk of childhood cancers associated with application of the herbicide by their parents, but other factors could not be

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<sup>1</sup> A report by respected consultants PG Economics concludes that pesticide use has in fact decreased by 8.2% due to adoption of GM. However, this company has also been flagged by Lobbywatch.org for having undeclared interests, and its research is often funded by industry lobby groups which include Bayer, Dow, DuPont, Monsanto and Syngenta (see <http://www.lobbywatch.org/profile1.asp?PrId=308>).

<sup>2</sup> However, many EU countries which ban cultivation do allow import of GM products.

<sup>3</sup> See European Commission—Fact Sheet. FAQs Glyphosate. Brussels, 29 June 2016. [http://europa.eu/rapid/press-release\\_MEMO-16-2012\\_en.htm](http://europa.eu/rapid/press-release_MEMO-16-2012_en.htm)

<sup>4</sup> From <http://www.iarc.fr/en/about>: ‘The main objective of the IARC is to promote international collaboration in cancer research...[and] identify the causes of cancer so that preventive measures may be adopted ... The IARC Monographs Programme is a core element of the Agency's portfolio of activities, with international expert working groups evaluating the evidence of the carcinogenicity of specific exposures.’

confidently ruled out. Indeed, a large cohort Agricultural Health Study that follows thousands of agricultural workers found no significant increase of NHL. Animal studies (in mice) showed an increase in the incidence of a rare kidney cancer, and of connective tissue as well as skin cancer. “Mechanistic evidence” referred to the increase of blood markers of chromosomal damage in people after spraying of glyphosate, and evidence of glyphosate, glyphosate-formulations and oxidative stress induced by AMPA, a glyphosate metabolite in rodent and in vitro studies. While accepting that other factors could not be completely ruled out in the association with NHL, the report did conclude that there was sufficient evidence of carcinogenicity from experimental animals and from human in vitro mechanistic data to warrant reclassifying glyphosate from possibly to “probably carcinogenic to humans (category 2A<sup>5</sup>)”.

The IARC report provoked strong response. The agricultural industry and the farming sector were highly critical, with Monsanto accusing the IARC of bias. But a number of other stakeholders—environmental groups, opponents of GM crops, anti-globalization advocates—used the IARC report in new campaigns to mobilize public opinion, particularly in the European Union where there has been longstanding hostility towards GMO. In the face of rising media attention, with retail outlets removing Roundup and similar products entirely (Levitt 2015), the European Commission pushed for faster completion of the regular regulatory review of glyphosate that it had begun in 2012.

In November 2015, the relevant regulator, the European Food Safety Authority (EFSA), released a report that - in contrast to the IARC report - concluded that glyphosate was “unlikely to be carcinogenic”. However, EFSA used a risk based approach, taking into account likely exposure, rather than general potential for harm (i.e. a hazard based approach). Thus it set for the first time safety thresholds for exposure, at 0.5mg per kg of body weight for consumers and 0.1 mg/kg for agricultural operators. The US Environmental Protection Agency has also recently concluded that glyphosate is not carcinogenic.

These differences in approach can largely be explained by the hazard versus risk approaches of different agencies. In other words, the underlying questions asked are different, with the IARC assessing the likelihood that the chemical might cause cancer in humans, while EFSA studies “whether there is sufficient confidence that a pesticide, when used according to the conditions of its approval (i.e. exposure patterns), will not pose an unacceptable risk to human health or the environment.” In other words, while the IARC determines whether there is sufficient evidence to link a particular substance to a higher incidence of cancer, EFSA’s brief is to determine the definition of “acceptable risk” rather than seeking definitive proof of safety (which is scientifically impossible).<sup>6</sup>

Following release of the EFSA report, a group of 96 leading scientists sent a letter to the European Commissioner for Health and Food Safety, objecting to the EFSA decision on the grounds that the IARC had assessed evidence that was in the public domain and available to independent scientists to review, while the renewal assessment report provided to EFSA by the German Federal Institute for Risk Assessment (BfR) was partially based upon confidential studies conducted by industry groups which were not available to IARC to review. EFSA was also accused of using inappropriate criteria to

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<sup>5</sup> A category that also includes eating red meat, shift work, ingested nitrates and nitrites and many chemicals.

<sup>6</sup> The sheer number of products on the market using glyphosate is beyond the capacity of any single agency to test, particularly as compounds such as Roundup can also include toxic additives, such as the surfactant POEA, or produce unexpected effects due to interactions between chemicals.

dismiss positively correlative data. The letter further argued that while IARC had carefully evaluated the strength and weakness of each study assessed, weighted findings according to quality of the data, and clearly identified all studies considered; the BfR study provided no justification for their findings, all citations having been redacted from their report. Moreover, the determination of “no unequivocal evidence” was misleading, as IARC’s determination of “sufficient evidence” in the animal and mechanical data indicates that a causal relationship has been definitively established.<sup>7</sup> The letter concluded that EFSA’s evaluation did not, therefore, “reflect the available science” and should be disregarded.

Although EFSA did not categorize glyphosate as a possible or probable carcinogen, it still recommended restricting its use. Sweden, France and the Netherlands requested that the licence not be renewed. Several meetings of the EU member states failed to reach a qualified majority to either renew or refuse approval by the deadline of 30th of June, and the EU commission instead extended the current license for a further 18 months to allow another EU agency, the European Chemicals Agency (ECHA), to complete its own review.



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<sup>7</sup> The letter points out that in terms of public health evaluations, ‘limited evidence’ in the human data does not mean that the risk is negligible, but rather that causality is, while not unequivocal, credible enough to warrant concern.



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INGSA's primary focus is on the place of science in public policy formation, rather than advice on the structure and governance of public science and innovation systems. It operates through:

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- Collaborating with other organisations where there are common or overlapping interests;
- Assisting the development of advisory systems through capacity-building workshops;
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