Austrian Biosafety Policy—'Founded on Ignorance'?

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Abstract

This paper investigates Austria's precautionary responses to applications for the environmental release of two types of transgenic insect-resistant Bt maize in the late 1990s. In contrast to the 'deficit model' analysis implied by the title, the paper examines different concepts of 'ignorance' drawn from studies of decision-making under uncertainty. The utility of these concepts in understanding Austrian policy is tested by dissecting the scientific arguments put forward by the Austrian government in support of Article 16 bans of Bt maize under EC Directive 1990/220. The study shows that, although they were not originally formulated for this purpose, concepts of 'ignorance' have a useful, although limited, role in comparative studies of risk assessment.

Introduction

Shortly after the US filed a complaint at the WTO, the British newspaper *The Guardian* published a commentary article by Will Farish, the then US ambassador to the UK. The article read 'Europe's continued blocking of GM imports is illegal, unjustified and founded on ignorance' (Farish 2003). Reminiscent of the arguments of the US Trade Representative when announcing the WTO dispute in May of that year (USTR 2003), the article refers to a lack of any scientific basis or justification for the EU's position: 'EU member states have blocked regulatory approval of new agricultural biotechnology products since 1998, and have done so without presenting any scientific evidence demonstrating a danger to human health, as required by the WTO'. In comparison, the Austrian government has justified its decisions to ban Bt maize under Article 16 of EC Directive 1990/220 with reference to specific scientific evidence related to both human and environmental safety. This paper examines the evidence put forward by Austria as a case study to investigate the utility of various concepts of 'ignorance' found in the literature

on decision-making under conditions of uncertainty. Following a brief introduction to the case study and a review of some of the relevant theoretical literature, the specific arguments put forward by the Austrian government are subjected to review and analysis.

Bt maize in Europe and Austria

Transgenic Bt maize contains a gene from the bacteria *Bacillus thuringiensis* (Bt) that encodes a toxin specific to certain insect species. Bt toxins have been used in biopesticide sprays for decades, including in organic agriculture. In the two types of Bt maize covered in this paper—Bt176 and Mon810—the maize has been engineered to produce a toxin known as Cry1Ab, which is targeted at specific caterpillar species that are significant maize pests, especially in Southern Europe. Physical environmental risk issues most commonly cited with respect to Bt maize include potential impacts on non-target organisms, the development of resistance to Bt toxin among target insects, the 'horizontal transfer' of transgenes from Bt maize to other organisms (primarily cited in the case of Bt176, which includes an antibiotic resistance marker gene) and 'vertical transfer' of transgenes from Bt maize to other maize. This paper primarily concentrates on the first of these—the potential for Bt maize to lead to changes in populations of non-target species in the environment.

Table 1 outlines the major events in the appraisal of Bt176 and Mon810 for environmental release in Europe, and specifically in Austria. In both cases, regulatory dossiers were initially submitted to the French competent authority and circulated to other EU Member States following positive French appraisals. The regulatory dossiers themselves differed between the two products, but all in all included direct toxicity tests for a variety of species (many chosen for their suitability as indicators of ecotoxicological impacts from conventional pesticides) and data from field trials in which populations of non-target organisms were monitored over one or two growing seasons. In practice, however, assessments of ecotoxicological risk were largely made on assumptions (also supported by bioassays, molecular weight, immunoreactive and terminal amino acid sequence data in the applications) of the equivalence of the Bt toxin (more specifically its active form) produced in the plants and that produced in bacterial strains (used in biopesticide sprays). The target range of bacterially produced Bt toxins was known to be very narrow, and non-target impacts from even widespread, indiscriminate use of these sprays were insignificant. These general principles were taken as relevant to the assessment of Bt crops and the French competent authority judged that the products did not pose significant risks to non-target organisms (CGB 1995; 1997, and interviews).

Table 1. Key events in the regulation of Bt maize in Europe and Austria up to 2001/18

Year	Month	Event
1990	April	Directive 1990/220 on deliberate release of GMOs passed.
1992		Parliamentary enquiry commission into genetic engineering.
1994	November	Part C notification for Bt176 maize submitted to France (C/F/94-11-03).
1995	January	Austrian Gene Technology Law (*Gentechnikgesetz*) comes into force, Austria joins EU.
	March	French competent authority approves Bt176 application in order that dossier can be passed to other EU Member States.
	December	Part C notification for Mon 810 Bt maize submitted to French competent authority (C/F/95-12-02).
1996	December	Regulatory dossier for Mon810, already approved by the French competent authority, is forwarded to other EU Member States.
1997	February	Commission Decision 97/98/CE formally approves placing on the market of Bt176.
	February	Austria bans Bt176 using Article 16 (of Directive 1990/220).
	March April May	EC Scientific Committee on Plants (SCP) replies to Austria's arguments for its Article 16 ban of Bt176, arguing that they did not add new relevant evidence to that already considered by the Committee and that none of the Committee's conclusions on the risk to the environment were affected by the Austrian arguments.
	April	Austrian people's initiative (*Volksbegehren*) gathers 1.23 million signatures, demanding no genetically modified food, no deliberate releases, no patents on life.
1998	March	European Commission Decision 98/294 formally approves Mon810.
1999	June	European de facto moratorium begins.
	June	Austria bans Mon810 using Article 16 (of Directive 1990/220).
	September	EC Scientific Committee on Plants delivers opinion providing that the justification and information submitted by the Austrian authorities did not impact on the original assessment in terms of risks to human health or the environment.
2001	March	Directive 2001/18 enacted.

The Austrian law on gene technology (*Gentechnikgesetz*), adopted shortly prior to Austria's entry to the EU, assigned responsibilities for the different institutions over questions of deliberate release. The competent authority for commercial releases of genetically modified organisms was originally the Ministry of Consumer Protection (*Bundesministerium für Gesundheit, Sport und Konsumentenschutz*), which would rely on advice from its own civil servants and co-ordinate views put forward by other ministries. The Environment Ministry, for example, has played a significant role in decision-making at the domestic level via its former technical agency, the Federal Environment Agency (*Umweltbundesamt*), and in defending these decisions at the European level through representing Austria at the EU Council of Ministers. The *Umweltbundesamt* assumed an early leadership in technical issues relating to deliberate release, commissioning much of the early official research in Austria and being present at European regulatory discussions even before the *Gentechnikgesetz*.

Science in biotechnology regulation

In a seminal paper in 1972, Alvin Weinberg differentiated between science and 'trans-science', the term he used to refer to questions which 'can be asked by science and yet which *cannot be answered by science*'. Weinberg's distinction between science and trans-science in policy-making went on to inform several analyses of 'regulatory science' that highlighted its differences with 'normal science', especially the importance of incomplete knowledge and public policy implications (see for example Rushevsky 1986).

Jasanoff's analysis of developments in US environmental, food safety and occupational health regulation (Jasanoff 1990) built on these earlier studies, taking into account three findings from the social studies of scientific knowledge: (1) that scientific 'facts' are mostly socially constructed, (2) that scientific knowledge is not established with reference to objective criteria of validity, and (3) that despite the contingency and relativistic character of scientific knowledge, science has often succeeded in maintaining its authority even in areas of significant uncertainty (13–14). Regulatory science therefore involves a mix of scientific, social and political judgements; as a result, future visions of the world in which we would prefer to live create and condition our conception and interpretation of risks. In the field of biotechnology, Jasanoff (1995) has differentiated between three cultures of risk assessment, each of which, to different extents, thematising risk as physical, social or political. In contrast to the 'product' approach favoured by the United States of America and the 'process' approach adopted in the United Kingdom, the history of Austrian biotechnology regulation seems to most closely resemble the 'programmatic' culture that Jasanoff attributes to Germany. As well as assigning technocratic responsibilities for the assessment of physical risks, Austria has adopted a social thematisation of risk by including issues such as '*Soziale Unverträglichkeit*' ('social unsustainability') (see Seifert & Torgersen 1997 for a discussion of this concept) in the *Gentechnikgesetz*, and addressed risk in the political frame through the Parliamentary Commission of Enquiry (*Enquete-Kommission*) conducted in 1992.

Austrian cultural perceptions of agriculture regard it as a multifunctional sector, preserving both traditional country life and an intact natural landscape (Torgersen 2002). Levidow (1999) has put forward convincing cultural differences, for example over what 'environment' should be protected, what future vision of agriculture should be sought, and what uncertainties matter for risk assessment, to explain trans-Atlantic differences in the regulation of Bt maize. Focussing primarily

on the interplay between these differences and the issues of non-target impacts and target insect resistance, Levidow argues that 'at issue is the interpretation of scientific data and even the questions that research should address. As a result, the precautionary principle is necessarily redefined anew in each context'. Later studies by Levidow (2001) and Levidow and Murphy (2003) have shown how conflicting social values have amplified the implications of emerging scientific evidence, serving to reframe questions of risk in both the US and the EU. Levidow (2001) argues that 'such value conflicts made scientific uncertainty more important —rather than *vice versa*. When risk research methods were challenged, fact/value boundaries were blurred, thus increasing 'uncertainty'—rather than *vice versa*'.

Decision-making under uncertainty

Conventional risk assessment aims to apply scientific knowledge to the quantitative estimation of probabilities and consequences of potential events. Incomplete scientific knowledge means these assessments are subject to various types of uncertainty. Since Weinberg (1972) scholars have developed a multitude of devices for differentiating between different forms of risk and uncertainty such as that derived from trans-science.

An informative European research project (ESTO 1999) highlighted problems seemingly intractable to conventional risk assessment, such as 'ignorance' ('we don't know what we don't know') and 'incommensurability' ('we have to compare apples and pears'). Stirling has proposed a category scheme of states of knowledge that incorporates these problems (Stirling 1999; Stirling 2004), see Figure 1. Under Stirling's scheme, which borrows heavily from other authors, incertitude is the term for the overarching condition that subsumes four different categories: risk, uncertainty, ambiguity and ignorance. Risk is defined so as to describe states where outcomes are well defined and knowledge is sufficient to assign a probability to each of them (if outcomes are discrete) or a probability density function (if outcomes lie on a scale).

Figure 1. Dimensions of Incertitude: an emerging scheme due to social science (taken from Stirling 2004)

<table>
<tr><th rowspan="2">KNOWLEDGE ABOUT LIKELIHOODS</th><th colspan="3">KNOWLEDGE ABOUT OUTCOMES</th></tr>
<tr><th>continuum of outcomes</th><th>set of discrete outcomes</th><th>outcomes poorly defined</th></tr>
<tr><td rowspan="2"></td><td colspan="3">INCERTITUDE</td></tr>
<tr><td colspan="2">RISK
apply:</td><td>AMBIGUITY
apply:</td></tr>
<tr><td>firm basis for probabilities</td><td>frequentist distribution functions</td><td>discrete frequentist probabilities</td><td rowspan="2">fuzzy logic
scenario analysis
sensitivity analysis</td></tr>
<tr><td>shaky basis for probabilities</td><td>Bayesian distribution functions</td><td>discrete Bayesian probabilities</td></tr>
<tr><td rowspan="2">no basis for probabilities</td><td colspan="2">UNCERTAINTY
apply:</td><td>IGNORANCE
apply:</td></tr>
<tr><td colspan="2">scenario analysis
sensitivity analysis</td><td>precaution
resilience
flexibility
diversity</td></tr>
</table>

The scheme also uses the terms ambiguity and ignorance, where the nature of the outcome itself is in question. Ambiguity describes states of knowledge in which it is not the likelihood, but the nature (and significance) of the outcomes that is contested. Ignorance, lastly, describes areas in which 'it is possible neither to resolve a discrete set of probabilities (or a density function) along a scale of outcomes (…) nor even to define a comprehensive set of outcomes' (Stirling 1999). This state may come as a result of 'incomplete knowledge, contradictory information, conceptual imprecision, divergent frames of reference and the intrinsic complexity or indeterminacy of many natural and social processes' (Stirling 1999).

In his 1986 chapter 'Usable knowledge, usable ignorance', Ravetz has drawn on common findings from the history and philosophy of science to highlight the pervasiveness of technical ignorance and to propose measures for dealing with it. According to Ravetz (1987) 'a decision problem involves ignorance when some components which are real and significant are unknown to the decider at the crucial moment'. This definition implies that the identification of areas of ignorance is only possible with the benefit of hindsight, and the only honest advice from scientists to policy-makers is 'we don't know' or indeed 'we *won't* know' (Ravetz 1986).

Wynne (1992) has described ignorance as a result of taking policy decisions based on scientific knowledge, rather than a characteristic of knowledge itself (or a state of knowledge, as per Stirling). For Wynne, ignorance 'by definition escapes recognition' and describes the predicament when we 'don't know what we don't know'. Wynne also describes ignorance as a pervasive state in which causal chains (both societal and natural) and networks are open, but certain possible outcomes and pertinent variables are excluded from the predictive advisory process. This form of ignorance is seen as an inherent characteristic of normal science—a tendency to give 'prominence to *a restricted agenda of defined uncertainties*—ones that are tractable—leaving invisible a range of other uncertainties'. Hoffmann-Riem and Wynne (2002) cite our complete lack of awareness of the effects of diphenyl-trichloroethane (DDT) on eggshell thickness, or of chlorofluorocarbons on stratospheric ozone at the time of development of CFCs in the 1930s as examples of ignorance. I refer to both Ravetz and Wynne's concepts as 'epistemological ignorance'.

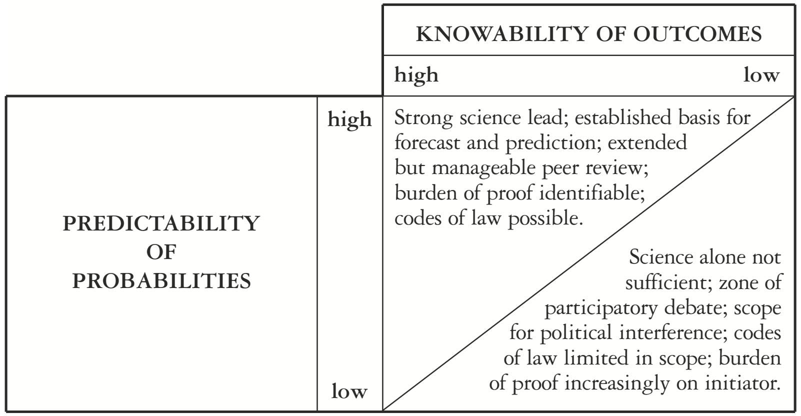
In effect, Stirling's ignorance as a state of knowledge is a result of the ignorance referred to by Ravetz and Wynne, but in contrast to theirs may also be identifiable in principle at the time of a decision (for example if scientists acknowledge insufficient knowledge of probabilities or outcomes to support advice). As we will see from the examples given later, it is often difficult to separate risk issues and arguments discretely into one or other category.

Ignorance and precaution

The precautionary principle is referred to in the *Gentechnikgesetz* and in Directive 1990/220 (by reference to the principle of preventive action in the European Treaty), however without the inclusion of a strict definition over how, or when, it is to be applied. The European Commission in 2000 suggested that the principle is to be used after 'a scientific evaluation of the risk which because of the insufficiency of the data, their inconclusive or imprecise nature, makes it impossible to determine with sufficient certainty the risk in question', however it has also stressed that 'recourse to the precautionary principle presupposes identification of potentially negative effects resulting from a phenomenon, product or process' (European Commission 2000). As such it does not explicitly refer to concepts of ignorance as defined by the authors above.

O'Riordan et al. (2001) have used Stirling's scheme to describe 'two faces' of the precautionary principle (269). 'One looks towards legal rules and flexible, but traditional, interpretations of scientific uncertainty. The other recognises that the legal process struggles to encompass highly complex themes that are both interactive and indeterminate'. They then borrow from the format of Stirling's diagram (above) to descriptively (as opposed to normatively) represent situations in which precaution can be applied (Figure 2).

Figure 2. Applications of precaution and the precautionary principle (from O'Riordan, Jordan & Cameron 2001)



Analysing Austria's scientific reasons for banning Bt maize

The Austrian government provided scientific reasons for its bans on Bt176 (14 February 1997) (Government of Austria 1997) and Mon810 (10 June 1999) (Government of Austria 1999). Here I run through the various arguments put forward with respect to impacts on non-target species from the maize, examining their links with the concepts of ignorance described above.

Bt176

In support of its decision to ban Bt176 maize Austria questioned the previous positive assessments around non-target effects by referring to qualitative and quantitative differences between the Bt toxin produced in bacteria and the Bt toxin produced in the plant. Austria pointed out that the protoxin (as produced in bacteria) rather than the truncated Bt toxin (as produced in the plant) was used in ecotoxicological studies, drawing into question the 'no-effect' conclusions of such studies, which rested on the assumption of equivalence of these two types of toxin. This argument highlights the potential for epistemological ignorance in the earlier assessments—the possibility that an unknown difference in the action of the two types of toxin could lead to effects that were neglected in the risk assessment paradigm adopted in the regulatory dossier. As a result of this ignorance, both probabilities and outcomes of non-target effects were unknown (as in Stirling's concept).

Austria also noted that plant-produced Bt toxin would not be inactivated by UV light in the same way as Bt used in biopesticides and that the toxin would be produced constantly throughout the plant, rather than only used occasionally as in sprays. In addition, a study showing binding of Bt toxin to clay particles (Tapp & Stotzky 1995) was cited to demonstrate the possibility of higher concentrations/longer persistence of Bt in the environment than previously believed. These arguments suggested different (increased) levels of exposure to the toxin with Bt plants than with Bt sprays. As they do not introduce new variables into the question at hand, but merely suggest that recognised variables (exposure levels) were assessed as lower than they should have been, these arguments in themselves do not invoke concepts of epistemological ignorance. Neither does the argument that 'data concerning the toxicity of maize expressing cry1A(b) for a species of collembola (*Folsomia candida*)' were absent. This argument was also used by Austria and referred to a difference between the regulatory dossier submitted in the USA and that submitted in Europe.

Mon810

The two years between the Article 16 bans imposed by Austria produced a great deal of scientific evidence around non-target effects of Bt crops, some of which was cited in the reasons for Austria's ban of Mon810 Bt maize.

Austria drew on a laboratory study on the effects of Bt maize pollen on the monarch butterfly (Losey, Raynor & Carter 1999) to highlight the possibility of unexpected effects on non-target Lepidoptera. To some extent, the study inferred the possibility of a new route of exposure (consumption of maize pollen blown onto milkweeds) and thus demonstrated an area of epistemological ignorance in the French assessments. However, pollen had been mentioned as an exposure route in the Bt176 application, and it was already recognised that non-target Lepidoptera could be affected by the Bt toxin. Austria's citation of the monarch study, therefore, did not show true epistemological ignorance in the earlier assessments or represent the state of knowledge around non-target Lepidoptera as ignorance, but rather a situation of uncertainty, amenable to further empirical investigation. The following sentence in the document, however, reads 'further effects on the food chain are possible and should be clarified' (Government of Austria 1999). This seems to open up the question of non-target risk to include wider effects across trophic levels, raising a more significant issue than that inferred by the monarch study taken alone.

Austria cited an influential study that reported an effect from Bt maize acting across three trophic levels (plant/herbivore/carnivore; Hilbeck et al. 1998). The findings of this study suggested the possibility of a less obvious exposure route (through prey organisms) and a novel mode through

which the toxin could act (the possibility that the toxin went through/led to some sort of change in the prey organism that increased its target range), prospects that had not been studied (beyond field studies) in the regulatory dossiers. Citing another tritrophic study that used a Bt spray preparation (Hafez et al. 1997), Austria argued that parasites of pests could also be affected through cultivation of transgenic Bt plants. The citation of multi-trophic effects appears to be a post-hoc recognition of epistemological ignorance in France's original assessments. Although multi-trophic effects had not been studied in the regulatory dossiers or by the French competent authority, exposure across trophic levels had been mentioned in the Bt176 application, and as the risk could be conceived of this was not an area of true epistemological ignorance.

In common with the earlier reference to Losey et al. (1999), the Austrian arguments were careful to point out that such multi-trophic effects were amenable to further empirical study. In this way, although the exact outcome (in terms of effects on a particular species) was not specified, the broad category of impacts (multi-trophic effects on non-target organisms), and the causal pathway (as presented in Hilbeck's studies), are clear. Under Stirling's scheme, this may be thought of as a state of uncertainty. Nevertheless, the implications of the Hilbeck et al. (1998) findings in addition meant that there was further scope for the surprise appearance of ecological interactions of the 'egg-shell thickness' sort (see above). They also meant that neither probabilities nor outcomes (in terms of effects on particular species) could be reliably predicted, so, in Stirling's sense, ignorance was the operative state of knowledge according to Austria.

Rather than citing the Losey et al. and Hilbeck et al. studies for their direct relevance to monarch butterflies or lacewings, Austria uses them to widen the scope of the risk assessment to include effects acting across trophic levels. 'Both mentioned groups work at the examination of indirect and long-term effects of Bt plants with test systems' (Government of Austria 1999). The authors' opinions on the irrelevance of experiences with Bt sprays to risk assessment of Bt maize are also cited. This greatly reduces the evidence base on which non-target effects can be predicted.

The Cry1Ab Bt toxin is only thought to be toxic to certain species of Lepidopteran (butterfly and moth) larvae. This specificity is thought to be mediated by receptor molecules on Lepidopteran gut walls to which Bt toxins bind. In relation to this, Austrian arguments against Mon810 cited a study allegedly showing Bt toxin receptors on the gut wall of the bumblebee, however the study actually referred to the silkmoth (Hua et al. 1998). A US study (EPA 1995) was cited as showing 'enhanced mortality of soil collemboles, *Folsomia candida*'. In addition, a study suggesting effects of Bt toxin on the sheep louse (Hill & Pinnock 1998) was cited to question the specificity of Bt toxins to Lepidoptera, however, the study did not refer explicitly to Cry1Ab toxin. With these arguments the Austrian government was questioning received assumptions surrounding the specificity of Bt toxins, and in this way meant to draw attention to a possible area of epistemological ignorance in the earlier assessments.

Austrian assessments of Bt maize—constructing ignorance?

The Austrian government has not explicitly used concepts of 'ignorance' in its biotechnology policy nor in its arguments against Bt maize. Implicitly, Austrian bans on Bt maize can be understood to be founded on concepts of 'ignorance' in that they have highlighted the epistemological ignorance to some extent inherent in previous assessments, and because they question the scientific basis for understanding and predicting probabilities and outcomes of non-target risks.

Specific reference to risks which fall within the 'epistemological ignorance' category is impossible, as such risks are, by definition, unknown. The reasons for Austria's bans on Bt176 and Mon810 suggested that certain important risk issues were not examined in the initial assessment by France (multi-trophic effects, for example). To some extent these represent areas which were previously characterised by epistemological ignorance—where the initial assessments did not conceive these types of risk and therefore did not examine them prior to approval. As mentioned above, however, such issues had been raised briefly (and then dismissed) in earlier documents, and thus the epistemological ignorance involved was not on a comparable level to, for example, that of ozone-depleting effects of CFCs. Instances of true epistemological ignorance, therefore, do not seem to be identifiable in this case. There seems to be more of a role for Stirling's concepts of uncertainty and ignorance. To the extent that Austria specified the category of impacts (non-target effects) that new evidence referred to, and insisted on further empirical investigation of these impacts, its assessment can be understood as highlighting uncertainty. In the sense that the new evidence and arguments put forward by Austria can be seen as questioning the basis for France's assessments of both probability and outcome of non-target effects, they can be seen as highlighting ignorance.

Although epistemological ignorance is only possible to identify post hoc, might it be possible to judge if it is more or less likely to emerge? This would be the equivalent of navigating between the top-left and bottom-right corners of figures 1 and 2. According to Stirling (1999), 'no matter how well informed, judgements concerning the extent to which 'we don't know what we don't know' are intrinsically subjective and value laden'. In the case in hand these judgements have translated into differences over what evidence and assumptions regulatory institutions accepted as valid. According to the Austrian government's reasons for banning Bt176, 'the qualitative and quantitative differences of the use of genetically modified plants expressing 'B.t. toxins' in comparison with the conventional use of microbial 'B.t. substances' were not considered sufficiently in the application'. Through questioning the assumption of equivalence between these types of Bt, the evidence provided in the regulatory dossier's ecotoxicological studies and the experience of decades of use of Bt sprays were declined as unacceptable. In the Mon810 case, Austrian authorities also drew into question the specificity of Bt toxins. 'Recent findings indicate possible differences and problems in specificity with Bt plants. Exact arguments therefore are still unknown and need further investigations'. Rejecting or questioning the acceptability of these studies, principles and assumptions left Austria with no valid scientific basis on which the non-target risks of Bt maize could be assessed.

Just as other competent authorities had constructed a state of knowledge characterised by 'risk' through accepting the assumptions and evidence put forward or implicit in the regulatory dossiers, Austria's arguments constructed a state of uncertainty and ignorance. In terms of figures 1 and 2, Austria has placed itself at the bottom (especially in the lower right-hand corner) of the diagrams, and responded accordingly.

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