



Underdetermination and evidence-based policy

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ABSTRACT

Safety assessment of technologies and interventions is often underdetermined by evidence. For example, scientists have collected evidence concerning genetically modified plants for decades. This evidence was used to ground opposing safety protocols for “stacked genetically modified” plants, in which two or more genetically modified plants are combined. Evidence based policy would thus be rendered more effective by an approach that accounts for underdetermination. Douglas (2012) proposes an explanatory approach, based on the criteria of transparency, empirical competence, internal consistency of explanations, and predictive potency. However, sometimes multiple explanations can satisfy these criteria. We propose an additional criterion based on converse abduction, where explanations are selected on the basis of ontological background assumptions as well as by evidence. We then apply our proposed scheme to the case of the regulation of stacked genetically modified plants. We discuss the implications and suggest follow-up work concerning the generalizability of the approach.

1. Introduction

A challenge when relying on science as a key element for governance is that experts interpret scientific data differently, and disagree on how to weigh evidence, even when a reasonable amount of data is collected (Douglas, 2000; Sawyer & Loja, 2015). This is not surprising, since scientific evaluation often involves diverging evidence from different disciplines. Lab model experiments, for instance, might show a toxic endpoint for a certain chemical and indicate a certain mechanism of action for the toxic effect, while population studies show the toxicity as statistically insignificant. Evaluating how to weigh evidence in such cases can be challenging, and crucially, it is not a purely empirical matter. It depends instead on a series of extra-evidential premises (Weed, 2005; Williamson, 2017). In such cases of evidential underdetermination, then, one cannot rationally counsel policy choices about risk and benefits of technologies and interventions, based on scientific evidence alone.

Here we offer a possible complement to the approach proposed by philosophers such as Heather Douglas (Douglas, 2000) and Helen Longino (Longino, 1990), who argue that decision-making can be improved by a plurality of diverging scientific advice, so long as each position is transparent about the extra-evidential premises that it adopts. Thus, different evaluations of the same evidence ought to meet some specific requirements. These include, among others, completeness,

rigor, transparency, and communicability to non-experts (Douglas, 2012). When multiple scientific evaluations meet these requirements, they can be compared in a way that emphasizes the core of the disagreement. This sets a premise for the solution of such disagreements.

As discussed in Douglas (2012), none of the conventional approaches to the evaluation of the scientific evidence fully meets the criteria listed above. As a case in point, consider the “rule-based” approaches to evidence evaluation, such as the “pyramid of evidence” found in evidence-based medicine. The pyramid indicates a hierarchy in which evidence from systematic reviews of randomized controlled trials is considered the most reliable, while evidence from case series or causal mechanisms are given low epistemic status. Although this method is rigorous and systematic, it might, on the basis of a general rule, exclude evidence that is particularly relevant for a specific case, and therefore lack completeness (Clarke 2013; Greenhalgh et al., 2014). Algorithm-based approaches, such as Bayesian networks, can be both complete and rigorous, but they hardly ever meet the requirements for transparency or communicability. This is due to the fact that basic assumptions and general reasoning are adopted by the programmer, but remain hidden to the users. Social approaches such as elicitation of expert opinions are likely to be more transparent, but less rigorous (Douglas, 2012).

In response to this, Douglas (2012) proposes an alternative, qualitative approach to evidence evaluation, based on explanations. An

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interesting aspect of this approach is that it benefits from an increasing number of possible explanations of the same evidence. It is therefore an approach that takes underdetermination seriously. Douglas' approach is, however, admittedly limited, and here we suggest a development based on our view of expert disagreement, which focuses on ontological background assumptions.

The philosophical discourse over evidential underdetermination, and its effects on scientific investigation as well as, later on, knowledge-based decision making, traditionally focuses on the works of Duhem and Quine (Kyle, 2017) or Poincaré (Worrall, 1989) at the turn of the 20th century. Duhem, for instance, argued that any scientific evidence is evaluated from a pre-existing web of knowledge and beliefs which are "beyond dispute" (Duhem, 1914, p 185). These beliefs contribute to the formation of scientific explanations and theories together with the empirical evidence at hand. A scientific explanation, accordingly, is determined not only by evidence, but also by a series of pre-existing assumptions and "impinges on experience only along the edges" (Quine, 1951, p. 42).

The relation between underdetermination, expert disagreement and pre-existing assumptions, has been a recurring issue in science since the sixteenth century. Crucially, Kepler and Galilei adopted strategies for dealing with such issues, and we wish to draw on their strategies here. Kepler and Galilei approached underdetermination by weighing evidence based on what they considered the most plausible ontological background assumptions. This strategy has been called *converse abduction* (see Andersen, 2017; Myrstad, 2004).

By recalling Galilean-Keplerian arguments relating to evidential underdetermination in astronomy and physics, we aim to gain insights on a current instance of the same type of problem: the evidential underdetermination in scientific safety assessment of technologies and human interventions. We use the classic case of underdetermination of theories of planetary motion for two reasons. The first is that it is a standard example of empirical equivalents (Van Fraassen, 1980): diverging theories that are equally well supported by evidence, which makes our point easier to show. The second is that underdetermination was solved through selection of the most defensible ontological background assumption, which then played the role of tie breaker. In other words, we want to offer a clear example where ontology picked up where epistemology dropped off, and show how and why such a strategy can succeed.

We recognize that the different extra-evidential components of evidence-evaluation, both epistemological, ontological and ethical/political, are essential and integrated parts of evidence-based policy. Therefore, by transposing a strategy from the historical case to the current picture, we also consider the complexities of modern evidence-based policy through a final case-study: The scientific controversy over a variety of stacked genetically modified corn. We already analyzed this case in terms of diverging background assumptions of an ontological type in Rocca & Andersen, (2017). Here, we show how converse abduction could be used to resolve the underdetermination issue.

2. Why do experts disagree about common evidence?

In the realm of evidence-based policymaking, scientific disagreement over common evidence is usually analyzed in two ways. Some analyze the issue in terms of conflicting socio-political value judgements (Hartley et al., 2016; Holman & Bruner, 2017; Wickson & Wynne, 2012). Others analyze it in terms of "epistemologically deep" disagreements, meaning that "the interlocutors have radically different ideas - not about what kinds of things exist, but rather - about what kinds of research should be carried out in order to support or undermine a claim" (Hicks, 2015, p. 2). Hicks (2015) argues that opposing parties generally agree on the basic concepts involved. For instance, scientists agree on what a crop yield is. The disagreement is about which methodology is best suited for comparing the yield of conventional and genetically modified plants (Hicks, 2015).

Contrary to Hicks we argue that expert disagreement is often ontological in nature, even when the divergence appears to be merely epistemic. As an illustration of controversies rooted in ontology, we recall the roots of modern scientific practice: the scientific revolution. The switch to the new type of inquiry - the scientific inquiry - was itself the resolution of underdetermination through a debate over which ontological background assumptions one should adopt.

Galilei (1615) describes science as a knowledge generating process that starts from what he calls "primary suppositions". In the Galilean definition, a primary supposition is a background assumption or a basic world-view that a scientist adopts prior to any empirical investigation. Since those background assumptions concern the nature of things, we call them *ontological background assumptions*.

Reichenbach (1958), Kuhn (1970) and Einstein, (1936) argued that such assumptions are prerequisites for scientific research, the idea being that any experimental set-up and interpretation of data requires theoretical justification. Ontological background assumptions are the most basic element of such justifications. In the words of Einstein, they resemble "... rules of the game in which, while the rules themselves are arbitrary, it is their rigidity alone which makes the game possible" (Einstein, 1936: 292). If ontological background assumptions set the rules of the game, they are part of the fabric of science. We adopt this idea here as a premise for our proposition on how to deal with underdetermination of expert judgements.

In Rocca & Andersen, (2017), we describe the function of background assumptions as follows:

"Background assumptions are more general than new evidence, and play a regulatory function in relation to it. This means that, whatever their origin, background assumptions co-determine how a scientist chooses methodology, analyses data, and picks out relevant evidence. In short, background assumptions are the lens through which we view new information." (Rocca & Andersen, 2017: 2)

Notice that, although we maintain that ontological, epistemological and socio-political background assumptions are components of scientific inquiry, we emphasize ontological background assumptions here. To our knowledge, these have received comparative little attention in the literature on evidence-based policy and responsible research and innovation.¹ Our claim is that different ontological background assumptions sometimes motivate different rules of scientific inquiry, such as the choice of the most reliable methods for collecting and analyzing evidence, and the overall significance of such evidence. In other words, apparent epistemic disagreement is sometimes rooted in diverging ontologies. The role of ontological background assumptions in theory building is commonly debated in certain parts of philosophy of basic sciences (Stump, 2015; Nicholson and Dupre' 2018); however, it has not been extensively discussed within the field of evidence based policy (Rocca & Andersen, 2017).

Hicks (2015), assumes that many "socially relevant" controversies do not involve diverging background assumptions of an ontological type. It is possible, however, that diverging ontological background assumption are present, but remain implicit and therefore hidden in the debates. From this perspective, there is less talk of ontological depth in socially relevant scientific controversies (such as the health risk of tobacco or the secondary effects of prescription drugs) because such controversies have not been actively analyzed in terms of ontology. We choose the latter explanation for three reasons. The first reason, which has been widely accepted in the literature, is that ontological background assumptions are part of scientific inquiry. This does not imply that all expert disagreement is due to diverging ontological background assumptions.

¹ While we agree with arguments about the inter-dependency and mutual value of these three types of background assumptions (see Longino, 1996), we maintain that it is crucial to fully understand the potential significance of each type.

Neither does it imply that whenever there are diverging ontological background assumptions, experts will disagree. For instance, Einstein and Lorentz disagreed on the nature of time and space but agreed on the formation of theories, the mathematical framework and the physical predictions (Andersen, 2017). So, diverging ontological background assumptions do not guarantee disagreement on all specifics. We do however argue that diverging ontological background assumptions might be at the root of controversies more often than generally assumed.

The second reason is that there is evidence for the existence of contrasting ontological background assumptions outside the realm of basic science. Some examples of this include: ecologists and molecular biologists who conceptualize genes differently (Carver et al., 2008; Stotz et al., 2004); big-data scientists who conceptualize space differently (Leonelli 2018); toxicologists who conceptualize the dose-response curve differently (Calabrese & Baldwin, 2003); risk researchers who conceptualize community differently (Paveglio et al., 2017); and so on. We see therefore, that there are diverging ontological views both between fields and within fields. These kinds of discrepancies are at the roots of, or at least contribute to, some expert disagreement, but this remains implicit.

A third reason is that in some case studies taken from basic and applied science, different ontological background assumptions were shown to motivate different scientific norms (Anjum & Mumford, 2018). For instance, ontological background assumptions motivated different scientific assessments of harm and benefits for technologies (Andersen et al., 2019; Anjum, 2016; Anjum & Rocca, 2018; Rocca, 2018; Rocca & Andersen, 2017; Rocca & Anjum, 2019). Many ontological background assumptions involved in applied research appear to be adopted uncritically and remain implicit. Disclosing them, and openly assessing their role in grounding risk evaluation, is therefore a crucial step in fully explicating a scientific opinion.

We here state that implicit ontological background assumptions are (i) necessary, (ii) can be divergent, and (iii) create norms of inquiry. But how does this work, in practice? We will address this question by examining a current and controversial case in evidence evaluation and risk assessment. However, prior to this we shall illustrate our point by using a textbook example, that is, the Galilean defense of the Copernican theory.

- (i) The Ptolemaic theory, which was the standard framework, was set within Aristotelian physics, cosmology and ontology. It therefore applied ontological background assumptions about teleology, natural and unnatural motions, different materials for the earth and the planets, as well as assumptions that "... celestial movements are all circular and regular, namely uniform; that heaven has a spherical shape; that the earth is at the center of the celestial sphere, is spherical, motionless, etc." (Galilei, 1615, p.85). That the earth is motionless follows directly from the Aristotelian ontology which is presupposed.² From these assumptions we get a set of meaningful questions, such as why planets appear to display retrograde motions, rather than "circular and regular" ones (the planets appear to move backwards at regular intervals, and then forward again). Without the ontological background assumptions, retrograde motions could be thought of as brute facts, rather than problems. Here we see that background assumptions determine meaningful questions.
- (ii) The Copernican theory starts from a different and unified ontology, where the earth and the other planets consist of similar materials and there is no notion of natural and unnatural

motions. The theory states that the earth can and does move. Galilei expanded the ontology into a new full alternative. In this ontological framework, earth's motion can be taken as brute fact since there is no ontological reason why it should be motionless. However, new sets of questions arise, such as why we do not experience the motion of the earth directly. Here we see how diverging ontological background assumptions motivate new research questions.

- (iii) Through the Copernican ontology, Galilei develops a new theory of motion in which relative motions can be measured, while shared motions cannot (the principle of relativity). This principle resolves a series of objections to the Copernican theory, as it shows how a set of questions are either answered or become meaningless. In effect, the norms of inquiry change when Galilei adopts a new ontology.

Note that the new Galilean theory of motion does not stem from new observations. It considers the same empirical observations that underlie the Ptolemaic theory. The new theory is a re-conceptualization that Galilei needs to introduce in order to understand the same relevant empirical evidence through the lens of the ontological assumption "movable earth".

So far, we have set the premise that ontological background assumptions are intrinsic aspects of science, that there are diverging positions, and that these positions lead to diverging scientific norms. In what follows, we show how this perspective warrants a development of the explanatory approach to evidence evaluation (Douglas, 2012). However, before we proceed, we will sketch Douglas' approach and the specific limitation that we aim to amend.

3. The explanatory approach to evidence evaluation

In parallel with the Galilean view, Douglas starts her approach from the idea that

"experts often differ in their assessments of the complex sets of evidence because they have different explanations of why the evidence looks the way it does." (Douglas, 2012: 152)

Douglas' explanatory approach is based on multiple conflicting evaluations of the same evidence. Crucially, each evaluation must be accompanied by an *explicit* explanation of why the evidence looks the way it does. Different explanations might adopt different evaluations concerning the relevance of an animal model, the importance of a chemical pathway, or the conclusiveness of an epidemiological study for the purpose of detecting causal relationships (Douglas, 2012).

The approach consists of three main steps:

"The first step is to gather and develop the competing explanatory accounts. The second step is to assess which of the competitors is adequate [...]. The third step is to assess which of the remaining competitors is best." (Douglas, 2012: 152)

Adequacy is further operationalized into three criteria: internal consistency, empirical competency, and predictive potential. However, these criteria are not always stringent; it is often the case that two or more scientifically defensible explanations apparently meet all three criteria.

Consider, for instance, the scientific assessment of long-term health effects on the Ecuadorian communities that are exposed to pollutants resulting from oil extraction. Environmental epidemiologists gave split opinions about the risk of such exposure based on the same available evidence, and they explained such opinions with equally defensible stances. Some experts valued the evidence for a mechanism of harmful oil contaminants, with the high levels of oil contamination in drinking water and heavy metals in the resident's blood as sufficient reason to infer a high risk for long-term exposure. They explained the lack of

² Aristotelian ontology states that the "heavier" materials, earth and water, seek the centre of the universe by their natural motion. The earth, whose surface consists of earth and water, is assumed to be at the centre of the universe and must therefore be motionless. If the earth moved, it would move away from its natural place, which would be an unnatural motion.

evidence for harm in any of the available epidemiological studies by citing the limited quality of these studies and the presence of multiple confounders and diverse sources of harm, pollution and vulnerability in the interested area (Hurtig & San Sebastian, 2005, Terracini, 2005). However, other experts in the same field argued that no risk could be inferred from existent evidence, due to an absence of statistically sound correlation data. Although the quality of the population study is poor, they explain, it is still far more relevant than mechanistic evidence, given that such evidence is obtained in models with low biological relevance for humans (Siemiatycki, 2002). One could add here that mechanistic understanding is unreliable because it is based on our current understanding of biological patterns of toxicity, which is at any time incomplete (Howick, 2011).

These explanations are internally consistent, and consistent with the available evidence. They produce testable predictions (for instance, with the production of better population data), thus the explanatory account cannot rule any of them out. Interestingly, as in the case of Galilei, part of the argumentation for each explanation relies on attacking the “norms of inquiry” adopted in the opposing view. This is a debate over “norms of inquiry” which, in the case of Galilei, was resolved through the selection of ontological background assumptions. Douglas’ framework does not consider this route, but rather calls for an institutional response in cases like this (Douglas, 2012, p. 158).

This is the point where we wish to develop Douglas’ framework. Before calling for an institutional response, there is a possible way to further limit the number of acceptable explanations. Our suggested route is to follow Galilei in making use of the relation between ontology and norms of inquiry. In cases of diverging norms of inquiry, we can investigate whether there are diverging ontological assumptions motivating these norms. In cases where there are diverging ontologies, we will argue for a strategy that determines which of the ontologies is more suitable. In order to see how this fits into Douglas’ overall approach, we must first go into more detail concerning what Douglas takes to be an acceptable explanation.

4. Consistency, unification and converse abduction

Douglas demands that an explanation must be internally consistent and writes about three types of consistencies. One concerns consistent and rigorous applications of selection criteria for evidence: “It would not be acceptable to exclude a study for a methodological flaw, and then to include other studies even though they have the same flaw, merely because they support the desired conclusion” (Douglas, 2012, p. 153). We take this type of methodological consistency to be uncontroversial.

A second type of consistency discussed by Douglas is of a logical form: “If we could derive any random empirical consequence from [explanations], they are unaccountable to the evidence” (Ibid). I.e., the explanation can neither be tautological nor self-contradictory. This version of consistency also plays to Douglas’ general understanding of explanations as tightly connected to predictions (see Douglas, 2009). The logical type of consistency ensures that a specific explanation is not self-contradictory, from which any empirical result would follow. As such, we take it to be uncontroversial as well.

A third type of consistency relates to unification. Douglas (2009) deals explicitly with the unification model of explanation. Here she points out that such an account of explanation is limited, with which we concur.

“[...] the unification model works best for laws explaining other sufficiently disparate laws and seems to provide no account for explanation of single instances, where we often appeal to specific causes rather than a unifying law.” (Douglas, 2009: 425)

Furthermore

“ [...] in some cases, merely unifying various instances (e.g. of particular metals expanding when heated) under a general law (metals expand when heated) is hardly explanatory at all.” (ibid)

Douglas’ argument relates to the (lack of) utility that results from using the unification of a set of phenomena as a form of explanation. In this sense, we agree with Douglas that *unifying* explanations are limited. Nevertheless, there is a further relation between unification and consistency that Douglas does not consider. In cases of multiple defensible explanations, be it law-like, causal or other, one can define the most consistent as the one that is most *unified*, in the sense that it coheres better in the wider context. In other words, an explanation of a set of phenomena studied in molecular biology is preferable if it coheres with established biological knowledge. As different sub-fields of biology often deal with different phenomena, one could ask how such coherence can be established. One way, we suggest, is to look directly at ontology. What are the common ontological claims of biology in general? How do they fit with the ontological assumptions underlying this specific explanation? In total, this implies that when faced with multiple explanations of a set of phenomena, we choose the better explanation, and thus the norms of inquiry, based on the dominant ontology of the field. This is a version of what Myrstad (2004) calls *converse abduction*,³ which is in contrast the inference to best explanation (IBE) approach of the type we see in Douglas (2012).

When applying an IBE description, evidence is gathered and explained, and we adopt the best available explanation on the basis of a set of criteria. In other words, the theories follow the evidence. Douglas’ approach is to adopt IBE and add restrictions. With a converse abduction approach, instead, there is no strict motion from evidence to explanation, but rather a dynamical relationship between explanations, evidence and ontological background assumptions. The layer of ontological background assumptions is the foundation of this relationship. The central issue is to demand that any specific explanation is consistent with this foundational level. As in all scientific thinking, explanations are constrained by evidence. In Douglas’ explanatory approach, explanations are further constrained by adequacy criteria. In the converse abduction approach, adequate interpretations of data are also constrained by the ontological background assumptions. It must be possible to express the entire explanation in accordance with the same set of ontological background assumptions, and the explanation that does this best is preferable.

We suggest that in cases where there are multiple adequate explanations, one should apply a *criterion of ontological unity*. Rather than seek the consistency of the single explanation, which is already guaranteed through Douglas’ (2012) criterion of internal consistency, we now seek *consistency between the ontological background assumptions of a specific explanation and the ontological background assumptions of current general scientific knowledge in the field*. For instance, in the case of oil contamination described earlier, the already established ontological background assumptions in biology and environmental studies should play a regulatory role. Notice that, for the criterion to work as a problem solver, it must be possible to identify a dominant ontological framework in a rather clear and uncontroversial way. In the following case study, we provide one example where this can be done. One of us made similar identifications in relation to basic science (Andersen, 2017; Andersen et al., 2018). Whether and how this approach can be generalized, how one can identify cases where it is useful, and who should be in charge of this analysis within the process of decision making are matters for future research. The aim of this paper is simply to show that this approach is

³ Myrstad (2004) argues convincingly that the converse abduction approach was the approach Kepler used to establish his three laws of planetary motion. This implies that the standard use of Kepler as an authority for IBE approaches, as is done for instance in Hanson (1958), is confusing rather than explaining the history of science.

possible and worth pursuing.

The criterion of ontological unity does not, in and of itself, perform any additional explanatory work. Rather, it helps fend off ad-hoc explanations in relation to specific cases. This would work by having scientists develop explanations and predictions of specific topics according to Douglas' (2012) description. Explanations would then be tested for adequacy according to Douglas' criteria of internal consistency, empirical competence, and predictive potential. If, at this point, there are still multiple explanations available, we apply the criterion of ontological unity. First, implicit assumptions must be made explicit. This is in line with Douglas' notion of objectivity, as expressed in Douglas (2000), and adds to the much needed transparency of evidence-based policies.

We recognize that our approach makes evidence-based policies somewhat conservative, and that newer, less established assumptions will be downgraded. We think, however, that this is acceptable and even laudable in evidence-based policy making. Indeed, a major motivation behind evidence-based policies is that policy should be built on established science. Furthermore, the criterion of ontological unity appeals to the unified views of not just a single scientist, but rather the majority of scientists in a set of fields, thereby increasing the level of consistency or unity between basic science and evidence-based policies. In the following, we provide an example of how this can be put into practice.

5. The criterion of ontological unity in practice: The case of stacked genetically modified plants

5.1. The scientific disagreement over the safety of stacked genetically modified plants

As described above, in order to be able to apply the criterion of ontological unity, it is necessary to first identify and explicate the different ontological background assumptions underlying different explanations of the same evidence. This can be an intricate and time-consuming process. Here we will use a case where the ontological background assumptions were previously explicated through a qualitative analysis of scientific argumentations (Rocca & Andersen, 2017).

In the case at hand, experts disagree over the evidence for the molecular stability and food safety of a particular type of genetically modified (GM) plants called "stacked" GM.

Traditionally, farmers have been changing the genetic makeup of crops by breeding them and selecting for the desired trait(s). This process is called *conventional plant breeding*, and its products are *conventional hybrids*. These are generally considered safe and do not need to be risk assessed before commercialization. Currently, however, more technologies are available for this same purpose of genetic improvement. In particular, *transgenic plant transformation* is the introduction of DNA material from a different species (plant, bacterium or other) into the plant's genome, with the purpose of introducing a new trait. When successful, this results in *single genetically modified (GM) plants*. It is globally agreed that single GM plants need to be assessed for safety in connection with food consumption and environmental impact before they are introduced in the market.

It is often desirable to have more than one transgenic trait in the same plant. Say, for instance, that one wants to accumulate the transgenic traits R1 and R2, which confer resistance to two different types of parasites. This can be done through the conventional breeding of two single GM plants, one containing R1 and the other containing R2, and the subsequent selection of the desired offspring (containing both R1 and R2). This process is called *stacking of GM traits*, and its products are designated as *stacked GM plants (GM Stacks)*. The risk assessment protocol of GM Stacks is the object of our case of disagreement. Some governmental agencies handle GM Stacks as new genetically modified organisms and require a new and full process of risk assessment before approving them for commercialization. Other countries consider GM Stacks as products of conventional breeding and therefore impose minimal regulatory requirements.

Central to this regulatory disagreement is the issue of whether it is possible to infer knowledge concerning the molecular and toxicological properties of a GM Stack from knowledge concerning the molecular and toxicological properties of its parental GM (single) plants. The American regime, for instance, assumes inference as the default starting point. Additional testing is required only in cases where one can reasonably expect that the transgenes and their products will interact (Pilacinski et al., 2011).

Scientists offered arguments both in favor of and against the simplification of GM stacks regulation following the American model (Agapito-Tenzen et al., 2014; Ben Ali et al., 2014; Kok et al., 2014; Kramer et al., 2016; Londo et al., 2011; Mesnage et al., 2013; Steiner et al., 2013; Weber et al., 2012). Based on the same scientific evidence, experts provide different explanations and reach two opposite conclusions.

Conclusion 1: information about the risk from GM Stacks can be inferred from the evidence provided during the risk assessment of the parental GM (single) plants.

Conclusion 2: GM stacks are new GM plants. Some issues cannot be inferred from the risk assessment of single GM parental plants and require generation of new evidence.

In Rocca & Andersen, (2017), we hypothesized that this scientific debate could be explored in light of the diverging ontological background assumptions that underlie the different explanations of common evidence. We corroborated the hypothesis by reviewing and analyzing experts' arguments in the scientific literature. Specifically, we found that each argumentation relies on a set of necessary, implicit, and unstated premises, which we diagnosed as "biological background assumptions". For brevity, we here consider only two such diverging assumptions: "equivalence of entity behavior" and "variability of entity behavior".

Briefly, "equivalence of entity behavior" is the assumption that genes and their products behave equivalently in parental GM (single) and GM Stacks. Explanation of the evidence that leads to conclusion 1 adopt such assumptions. On the contrary, conclusion 2 assumes "variability of entity behavior," which is the assumption that genes and their products might behave dissimilarly in parental GM (single) and GM Stacks. This implies that the same biological entities might behave differently across contexts.

5.2. Equivalence and Variability of Entity Behavior

As made plain in Rocca & Andersen, (2017), Equivalence and Variability of Entity Behavior are two different background assumptions about context sensitivity in biological systems.

Scientists arguing for conclusion 1 (the safety of GM Stacks can be inferred from the safety of the parental, single GM plants) maintain that the only difference between conventional hybrids, parental single GM plants and GM Stacks is the presence of none, one or two transgenic inserts. The interactions between each of the transgenic traits with all the other traits of the plants have, therefore, already been considered in each of the parental single GM risk assessments. The only remaining issue is whether the two transgenic proteins will interact with each other. This can be predicted with a sufficient degree of confidence from knowledge of the intrinsic properties of such proteins and how they behave in other contexts.

In this view, context sensitivity is understood as a pool of interactions that are *external* to the entities involved (genes and proteins). Genes and proteins behave differently in different contexts, but these different sets of behaviors are still made possible by the entities' intrinsic properties, which are maintained across contexts. The interactions are not constitutive of entities: they are external to them (compare Guttinger, 2018).

Scientists arguing for conclusion 2 (some information about GM Stacks might not be directly inferred from the safety of the parental

single GM plants) conceptualize a GM Stack as a new, different whole rather than the addition of two transgenic traits to a common genetic background. Accordingly, they are not satisfied by the targeted comparison of some components of single parental GM and GM Stacks. Rather, they argue that *the totality* of such plant components should be compared with untargeted comparison methodologies, such as proteomics, metabolomics et cetera. By requiring specific evidence for GM Stacks, one adopts the premise that the process of GM stacking confers new interacting properties to all the entities involved (and not only to the transgenic traits). In this view, what entities (DNA and proteins) can do is not strictly determined by their intrinsic nature. Rather, it is also determined by the kind of interactions in which they are involved. In other words, context and interactions are *an integral part* of the entities' properties, and not only external to them. Therefore, properties and behavior of entities cannot be inferred directly across contexts.

The discrepancy between these two ontological background assumptions recalls previous discourses in philosophy and biology. The same dichotomy, for instance, was described in terms of a *"machine view"* versus *"ecological model"* of the world (Birch & Cobb, 1981) or in terms of *"complicatedness"* versus *"complexity"* (Kvaløy, 1992). Similarly, biological systems have been categorized into *component systems* - systems in which the behavior of the parts and the way they interact with the environment is mainly "intrinsically determined" (Bechtel & Richardson, 2010, p. 26) - and *integrated systems*, in which the parts lose their original identity, and their behavior is mainly determined through interactions with the context (ibid).

5.3. Applying the criterion of ontological unity

Which of the two ontological background assumptions identified is the most scientifically justifiable? This is difficult to determine, when only considering the specific evidence about the molecular and toxicological stability of conventional hybrids such as single GM and GM Stacks.

However, it is possible to expand our analysis by testing the validity of such assumptions against current biological knowledge. This is what is posited by the criterion of ontological unity.

Here, we will apply the criterion and argue that the accumulating knowledge in the general field of biology motivates a move *toward*, rather than away from, a description of life compatible with Variability of Entity Behavior. Based on what we described above, this implies showing a move toward an ecological or integrated view of living systems. Note that this is not trivial, in so far as it is not only about the knowledge that living entities (and their parts) change behavior in different contexts (external relations). Rather, it is about a move toward the notion that properties and behavior of living entities (and their parts) are induced, to the greatest extent, by their contextual interactions (constitutive relations). Given such premise, an argument in favor of Variability of Entity Behavior could run as follows.

- (1) In recent decades, accumulating evidence has provoked a number of paradigm changes in numerous fields of biology.
- (2) A common feature of such changes is that they confer an increased role of relations and context in shaping the properties of living systems.
- (3) The general field of biology seems united by a move away from the assumption of Equivalence of Entity Behavior and toward an assumption of Variability of Entity Behavior.
- (4) If we want unity with the current best theories in the field of biology, evaluations of the evidence of safety of GM Stacks ought to include explanations that are based on Variability of Entity Behavior.

Clearly, it is critical that statement (2) is thoroughly motivated. Which are the paradigm changes that support this argument? For a start, let us look in detail at one of them: the change of paradigm in the way

proteins are understood (Dunker et al., 2001; Tompa, 2012; Uversky, 2011).

Proteins are chains of amino acids, each serving one or multiple functions within the cell. For the last century, the "structure-function" paradigm, stating that the function of a protein is determined by its three-dimensional structure, has been central to understanding proteins. Biochemistry textbooks explain, using the classic "key-and-keyhole" metaphor, that because of its three-dimensional structure each protein interacts only with specific complementary structures. The way a protein interacts with the surrounding molecules is, therefore, determined by its properties, which remain unchanged across contexts. Predictions about proteins' behavior in different environments can in this way be inferred from one context to another. The "structure-function" paradigm is in perfect line with the ontological background assumption Equivalence of Entity Behavior.

This view has changed since the discovery that many proteins contain the so-called intrinsically disordered domains (IDP), whose function does not depend on a pre-determined three-dimensional structure (Dunker et al., 2001). IDP do not acquire a unique and stable shape, but rather they shift between multiple structural organizations. Crucially, IDP's function is not performed solely by each of the spatial structures, but also by the process of de-folding and re-folding itself. In turn, such a process is induced by complementary proteins, as well as by interactions with the solvent's aqueous environment. This new paradigm, the "binding-folding", shifts the focus toward the dynamic nature of many protein functions. Proteins' behaviors are no longer seen as exclusively dependent on pre-existent properties but as co-determined by the dynamic interactions with the environment. This interaction can be seen as synergistic, since IDP and their surroundings modify each other's properties (Guttinger, 2018; Stein, 2004; Tompa, 2012).

This paradigm shift, in which context sensitivity is not entirely an intrinsic capacity of the protein, but it is determined by the context itself, can be seen as a move toward an understanding of the world in line with the assumption Variability of Entity Behavior.

Importantly for the criterion of ontological unity, this example does not represent an isolated case. Instead, a similar shift is happening simultaneously in the so-called "post-genomic" era of biology. After the big effort in clarifying the structures of genes and proteins, the scientific community is striving to understand how such entities work in systems. It is becoming increasingly clear that knowing the properties of the parts sheds only limited light on the function of living systems. Biologist Denis Noble, one of the pioneers of system biology, expresses it as follows:

"Each system has its own logic. It is not possible to understand that logic merely by investigating the properties of the system's components. [...] at this stage of our exploration of life, we must be ready for a basic re-think. [...] System biology [...] requires that we develop ways of thinking about integration that are as rigorous as our reductionist procedures, but different. This is a major change. It has implications beyond the pure scientific. It means changing our philosophy, in the full sense of the term." (Noble, 2006: x-xi)

By a "change of philosophy," Noble means that "reduction alone is far from sufficient" (ibid). Similarly, another manifesto of process biology states:

"The reductionist approach has successfully identified most of the components and many of the interactions but, unfortunately, offers no convincing concepts or methods to understand how system properties emerge [...] the pluralism of causes and effects in biological networks is better addressed by observing [...] multiple components simultaneously." (Sauer et al., 2007: 550).

In line with this, some biological disciplines are heading toward an increased "ecological" attitude, which allows the context to have an important, active, and constitutive role in living systems. As a well-established example, ecological developmental biology acknowledges

that “The regulators of gene expression need not all reside within the embryo.” (Gilbert, 2001, p. 1).

With the steady accumulation of this type of evidence, it is possible to argue that the basic ontological assumptions of Equivalence of Entity Behavior - which sees the context sensitivity of genes and proteins as an intrinsic property that is largely determined by the entities themselves, allowing for confident predictions of component behavior across contexts - is increasingly obsolete in the general field of biology.

6. Implications and future directions

Disagreement in science has led not only to an impasse for decision makers but also to a decreasing trust in science by the general public. Douglas (2012) urges us to improve the situation by demanding argumentative adequacy: it does not suffice to account for the data. The data must be explained, and the explanations must be empirically competent, internally consistent and show predictive potency.

We have taken Douglas’ approach as our starting point, whilst adding that Douglas’ Inference to Best Explanation account is impotent in cases where there are multiple adequate explanations (underdetermination). We have also argued that such cases are prevalent and that they illustrate the role of ontological background assumptions in scientific explanation.

The Inference to Best Explanation account is often the go-to description of scientific reasoning. In contrast to IBE, others have argued that a complete account of scientific reasoning must include Converse Abduction strategies. This has implications not only for the understanding of how modern science was originally formulated, but also for how we should approach evidence evaluation in cases of evidential underdetermination. We propose to apply converse abduction to the cases where multiple adequate explanations persist, by favoring the explanation whose ontological background assumptions unify better with the current ontological background assumptions of the relevant scientific fields. This has implications for the way science should advise decision-making.

Currently, expert panel reviews consist of technocratic evaluations, judging the quality of the experimental design by focusing on experimental set-up, sample sizes, statistical analyses, model choices et cetera (Giorgi Rossi, 2016). If we are to appeal to the criterion of ontological unity, we must include a wide variety of experts who can identify the ontological background assumptions of not only specific explanations, but also trends and mainstream knowledge in the field. Importantly, this is a timely implication for our account, since it echoes critical voices coming from some of the participants on expert panels. In response to perennial controversies about the significance of evidence from medical research for the purposes of clinical recommendations, some of the experts urge that the discussion should be directed to a level that is deeper than the mere evaluation of experimental design. In order to deepen the discussion, we need to involve a multiplicity of expertise:

“ [...] as we assess evidence, we need to select or formulate conjectures that explain most of the evidence available. In order to decide on such conjectures, we require individuals who are familiar with the epidemiology and the etiology of the disease, as well as with the rationale behind the technologies or interventions proposed. Finally, we need individuals who know the strengths and the weaknesses of alternative conjectures; in other words, we also require content experts.” (Giorgi Rossi, 2016: 22)

We take these exhortations to be completely in line with our stance. We suggest that if this is done, evidence-based policy making will increase in both efficiency and precision.

Finally, our analysis indicates the complex interaction between different types of non-empirical assumptions in evidence-based policy. Indeed, the presented case suggests that socio-political and ontological assumptions have a mutual valence. For example, the “equivalence”

assumption is connected to deregulatory interests, since it entails no need for additional testing and presents no new barriers to market availability. Thus, if yield increases from stacked events, one might also increase food production and economic growth without additional delay. In contrast, the “variability” assumption is linked to regulation motivated by public health and environmental protection, since it requires additional testing that puts up barriers to stacked GMs quickly moving to market. Whether or not scientists and policy makers are aware of such a socio-political connection, the social stakes and possible ethical consequences of their ontological background assumptions remain. Douglas’ inductive risk argument couples the norms of inquiry chosen by scientists with the consequences that norms can have at the societal level and calls for an increased awareness and responsibility of the scientists in this respect (Douglas, 2000). Since we argued here that ontological background assumptions are strictly inter-related with norms of inquiry and epistemic choices of scientists and decision makers, we urge that such ontological assumptions should be included in the discourse of responsibility and values in science.

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