- Identifying uncertainty in environmental risk assessments: the development of a novel 1 2 typology and its implications for risk characterisation. 3 Daniel JC Skinner^a, Sophie A Rocks^{b*}, Simon JT Pollard^c and Gillian H Drew^d 4 Cranfield University, Collaborative Centre of Excellence in Understanding and Managing 5 Natural and Environmental Risks, Cranfield, Bedfordshire, MK43 0AL, UK. 6 * Corresponding author 7 8 9 ^a tel: +44 1234 750111 email: d.j.skinner@cranfield.ac.uk ^b tel: +44 1234 750111 x2370 10 email: s.rocks@cranfield.ac.uk ^c tel: +44 1234 754101 11 email: s.pollard@cranfield.ac.uk ^d tel: +44 1234 750111 x2718 email: g.h.drew@cranfield.ac.uk 12 13 14 15 16 17 18 19 20 21
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ABSTRACT

Environmental risk analysts need to draw from a clear typology of uncertainties when
qualifying risk estimates and/or significance statements about risk. However, categorisations
of uncertainty within existing typologies are largely overlapping, contradictory, and
subjective, and many typologies are not designed with environmental risk assessments
(ERAs) in mind. In an attempt to rectify these issues, this research provides a new
categorisation of uncertainties based, for the first time, on the appraisal of a large subset of
ERAs, namely 171 peer-reviewed environmental weight-of-evidence assessments. Using this
dataset, a defensible typology consisting of seven types of uncertainty (data, language,
system, extrapolation, variability, model, and decision) and 20 related sub-types is developed.
Relationships between uncertainties and the techniques used to manage them are also
identified and statistically evaluated. A highly preferred uncertainty management option is to
take no action when faced with uncertainty, although where techniques are applied they are
commensurate with the uncertainty in question. Key observations are applied in the form of
guidance for dealing with uncertainty, demonstrated through ERAs of genetically modified
higher plants in the EU. The presented typology and accompanying guidance will have
positive implications for the identification, prioritisation, and management of uncertainty
during risk characterisation.

Keywords: uncertainty, typology, environmental, risk, assessment

INTRODUCTION

Uncertainties within environmental risk assessments (ERAs) need to be properly managed to enable risk estimates to be used as a sound basis for risk management actions (van der Sluijs *et al.* 2004; Refsgaard *et al.* 2007). National and international regulatory bodies stress the importance of acknowledging and dealing with uncertainty in ERAs during the risk characterisation phase (Fairman *et al.* 1998; USEPA 1998; DEFRA 2011). Implementing such guidance starts by identifying potential types of uncertainty (Morgan *et al.* 1990), at which point it is essential that environmental risk analysts are able to draw from a clear and defensible typology of uncertainties (Knol *et al.* 2009; Ramirez *et al.* 2012). Existing typologies have limitations, relating primarily to research domain transferability and content reliability (Walker *et al.* 2003; Ascough II *et al.* 2008; Knol *et al.* 2009; Troldborg 2010). In this paper, we present the development of an evidence-based typology of potential uncertainties in ERAs which, together with implementation guidance, aims to resolve the issues surrounding existing categorisations and better equip environmental risk analysts when attempting to identify and manage uncertainty.

There are a wide range of different types of evidence that can be used to formulate and evaluate risk estimates within ERAs (e.g. toxicological, biological, financial). In some situations, different lines of evidence are amalgamated and the degree to which they support or refute hypotheses about risk is evaluated (Linkov *et al.* 2009). This process, termed weight of evidence (WOE), aims to provide either a definitive course of action for decision-makers where the evidence may be contradictory, or identifies missing information needed to form a definitive conclusion (Chapman 2007). WOE can be applied to ERAs (as well as to ecological or human assessments), but is not recognised as being a specific type of ERA (Suter II and Cormier 2011) and is not consistently defined (Weed 2005). ERAs that apply WOE methods follow the same four phases (problem formulation, exposure assessment,

effects assessment, and risk characterisation; DEFRA 2011) as ERAs that do not use WOE methods, and can therefore be used to identify a useful and manageable dataset to assess how uncertainty is categorised and managed across the much larger set of available ERAs in different risk domains.

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It is largely agreed that environmental uncertainty is comprised of different aspects, commonly termed dimensions (Janssen et al. 2003; Walker et al. 2003; Knol et al. 2009). These dimensions relate to: the inherent nature of the uncertainty, either epistemic (limitations in our knowledge) or aleatory (the randomness of natural systems and their components); the severity of the uncertainty, ranging from deterministic treatment at one end of the spectrum to indeterminacy at the other; and the location of the uncertainty, which describes where, in applied situations, the uncertainty manifests. As different uncertainties must be managed differently using different techniques (van der Sluijs et al. 2004; Refsgaard et al. 2007), identifying the different types of uncertainties that exist in applied situations is an essential part of uncertainty management (Morgan et al. 1990). A typology of uncertainty can aid this process by providing comprehensive, relevant, and reliable categorisations (complete with definitions) of all potential types of uncertainty that may be encountered (van Asselt and Rotmans 2002; Knol et al. 2009). However, existing typologies are based on small-scale literature reviews, amalgamations of existing frameworks, or researcher opinion (Table 1). As a result, the typologies often contain contradictory definitions and terms, communicate varying frequencies of uncertainty, are rarely comprehensive within their intended research domains, and do not include a clear method for the collection and collation of the evidence base. Furthermore, whilst these typologies may be applicable in a wider riskcontext, they are not designed specifically for use with ERAs. Since the overall reliability of a typology relies on the legitimacy of the adopted categorisation(s), in the context of ERAs, it is crucial that this is rectified.

[TABLE 1 NEAR HERE]

This research offers a new categorisation of uncertainties based on the appraisal of a large subset of ERAs in which uncertainties have been transparently identified. As the evidence base is formed of peer-reviewed environmental ERAs that feature WOE methods, the assertions made in this article span a diverse set of interests, making the resulting typology relevant across a number of distinct risk-based research domains. The typology is combined with an analysis of the adoption of uncertainty management techniques (UMTs) used when faced with different uncertainties, and guidance for dealing with uncertainty drawn from key observations.

Uncertainty analysis should be a principal component of risk characterisation and thus ERAs. In reality, this is rarely the case. The introduction of an uncertainty typology that consults a manageable subset of the vast available ERA evidence base, coupled with prioritised guidance, will assist risk analysts in their attempts to prioritise, identify, and manage uncertainties within applied ERAs.

METHODOLOGY

Building the Evidence Base

In order to categorise uncertainty in ERAs that feature WOE methods (hereafter termed WOE-ERAs) and analyse the use of techniques in their management, an evidence base of peer-reviewed literature was established. Searches were conducted for directly labelled WOE-ERA literature, using the ISI Web of Science and Scopus academic databases, respectively, and using the terms weight, evidence, risk, and uncertainty (in the title, abstract and keywords field for Scopus, and in the topic field for ISI Web of Science). Non-labelled WOE-ERA literature was also searched for, using the terms risk, assessment, and uncertainty (in the title, abstract and keywords field for Scopus, and in the topic field for ISI Web of

Science). In-built filtering within the online databases was used to remove obviously non-relevant literature (non-English articles, book series articles, articles from the domains of social science, arts and humanities) before the remaining articles were assessed for inclusion based on the following criteria:

- the article must include (or be in its entirety) an ERA that applies either a qualitative, semi-quantitative, or quantitative WOE methodology (after Linkov *et al.* 2009);
- the assessment must make direct reference to the uncertainties to be recorded within this research, thereby minimising researcher-subjectivity when creating the typology;
- the assessment must be original research and not a review of previously published work, in order to avoid duplicate values; and
- an aspect of the environment must feature in at least one part of the source-pathway-receptor (S-P-R) paradigm, where the environment "... consists of all, or any, of the following media, namely the air, water, or land" (EPA 1990).

These criteria ensured that only original (i.e. non-review-based) environmentally-focused WOE-ERAs (including ecological, environmental, and human-health risk assessments) that specifically mentioned uncertainty were included within this study, whilst the general search terms used allowed representation from a wide range of research domains.

Data Collection

The articles (conforming to the selection criteria) were examined in full and relevant information was extracted and recorded in separate spreadsheet entries. A working list of definitions was kept to ensure that observations were consistent and distinctions between uncovered uncertainties were not blurred. Importantly, no upper limit was set as to the number of UMTs that could be associated with each identified uncertainty type.

Data Organisation

The uncertainty data were organised using an iterative category clustering technique (Hartigan 1975). The different objects (i.e. the uncertainties) were categorised into distinct groups, such that the degree of association between any two objects was maximal if they belonged to the same group and minimal otherwise. In this way, the articles (from the data collection stage) were organised into groups by relevance to other similar data values. To reduce the potential for subjectivity in assigning objects to groups, the process was performed iteratively, with definitions and categorisations continually refined.

Data Analysis

The frequencies with which the different locations and sub-locations of uncertainties were associated with the UMTs were recorded. These were converted to percentage values of total occurrences in order to identify the most commonly occurring relationships. A separate bivariate analysis was performed using SPSS v18 (SPSS Inc., Chicago IL) to quantify the relationships between all two-variable combinations ($P \le 0.01$).

RESULTS

Data Frequencies and Organisation

Uncertainty typology

Analysis of the collected WOE-ERA literature (n=171 assessments), in conjunction with iterative clustering of the extracted data (Figure 1), revealed 20 separate types of uncertainty (Table 2), with a total of 385 individual occurrences. The data uncertainty (n=125 out of 385; 32.5%) and extrapolation uncertainty (n=110; 28.6%) locations were the most

frequently occurring, with the decision uncertainty (n=6; 1.6%) and language uncertainty (n=16; 4.2%) categories the least frequent.

[FIGURE 1 NEAR HERE] [TABLE 2 NEAR HERE]

Uncertainty management techniques

Data extracted from the sources highlighted the use of a variety of UMTs (n=27), with a total of 453 separate applications. Occurrence proportions of the most frequently occurring mechanisms are shown in Table 3, along with brief descriptions and associated uncertainties. Monte-Carlo simulation was adopted most frequently (n=100 out of 453; 22.1%), followed by uncertainty factors (n=75; 16.6%), sensitivity analysis (n=38; 8.4%), and 'taking no action' (n=35; 7.7%).

[TABLE 3 NEAR HERE]

Relationships Between Uncertainties and Uncertainty Management Techniques

Frequency relationships

The highest frequency relationships between the uncertainty locations and UMTs employed (Figure 2) occurred between data uncertainties and Monte-Carlo simulation (n=56 out of 453 relationships), between extrapolation uncertainties and uncertainty factors (n=40), and between extrapolation uncertainties and Monte-Carlo simulation (n=18). On a proportional basis, the highest dependencies were seen between language uncertainties and fuzzy logic (68.8%; i.e. language uncertainties were managed with fuzzy logic in 68.8% of cases), model uncertainties and sensitivity analysis (35.1%), and data uncertainties and Monte-Carlo simulation (34.4%). Overall, uncertainties were associated with at least one UMT in 92.3% of cases, and were therefore unmanaged 7.7% of the time.

[FIGURE 2 NEAR HERE]

Statistical relationships

The strongest correlations between the uncertainty types and UMTs (Figure 3) occurred between decision uncertainty and adaptive management (ρ =0.57), spatial (extrapolation) uncertainty and interpolation (ρ =0.46), and cause (system) uncertainty and causal influence (ρ =0.40). A similar strength correlation occurred between the portion of data uncertainties used as parameter values in computational and/or numerical models (and therefore consist of repeated values from within the data location; marked *model input* in Figure 3) and Monte-Carlo simulation (ρ =0.32).

Positive correlations were also observed between several uncertainty-location/UMT combinations, where all individual uncertainty types within the location shared a positive correlation with the respective UMT. The strongest of these relationships were language uncertainties with fuzzy logic (ρ =0.45) and fuzzy-stochastic systems (ρ =0.24), and model uncertainty with sensitivity analysis (ρ =0.29).

[FIGURE 3 NEAR HERE]

DISCUSSION

An Improved (Evidence-Based) Uncertainty Typology

The existing uncertainty typologies (Table 1) are predominantly based within specific research areas, using categorisations that are primarily relevant to those fields. They communicate varying frequencies of uncertainties, often in a contradictory fashion, and use a number of different approaches in their construction, including small-scale literature reviews (e.g. Regan *et al.* 2002) and amalgamations of existing frameworks (e.g. Ascough II *et al.* 2008). This has led to overlapping and contradictory sets of categorisations. The uncertainty typology presented in Table 2 addresses the following issues:

- The set of articles analysed included ecological, environmental, and human-health risk assessments. Although the specific requirements of these assessments differ, they do contain the same four phases and many of the same processes (US EPA 1998; Zhang et al. 2010; DEFRA 2011). Therefore, the developed typology does not restrict observations to narrowly-defined research domains (e.g. conservation biology) but instead extends the focus to all concerns of an environmental nature, enabling the typology to be more transferrable and relevant to a larger number of risk analysts.
- Using WOE-ERAs, which contain a variety of ERA techniques as well as distinct forms
 of evidence, increases the potential for a larger spectrum of uncertainties to exist. This is
 reflected in the typology which, containing 20 distinct forms of location-based
 uncertainties arranged according to their natures, is the most extensive to date.
- By constructing and interrogating a large supporting evidence base of peer-reviewed articles (n=171) all uncertainty categorisations within the typology are supported and defensible.

- It is also pertinent to address the potential limitations associated with the method used to construct the typology and its resulting categorisations:
 - Dependence on existing assessments to contain reliable information. This limitation may have been realised where incorrect information was presented within the sourced materials, though the peer-review process was expected to resolve these errors. Perhaps of more concern was the potential omission (rather than incorrect inclusion) of important uncertainties; key uncertainties that went unidentified in the source materials could not feature in the typology. However, the evidence base of 171 assessments was believed to be extensive enough to account for all potential uncertainties.

- Subjectivity in the information clustering process. The clustering process used to form categorisations within and between the different types of uncertainty, whilst efficient and effective, did require an element of subjectivity on the part of the researcher. This type of qualitative clustering has the potential to blur definitions, thereby reducing the clarity of the clustered output. This potential limitation was managed as far as possible by making the clustering process transparent (see Figure 1).
- Representativeness of the typology for application to ERAs. Limiting the included studies to WOE-ERAs may have led to biases within the evidence base, which would have been transferred into the typology. One potential bias was a focus on risk domains in which WOE-ERAs are commonly used. This potential limitation may result in a lack of representativeness when applying the typology to non-WOE-ERA scenarios. However, when weighed against other viable alternatives, such as building an evidence base of ERAs based in specific risk domains, the WOE-ERA approach was deemed to be the most representative for future application of the typology.
- The outlined advantages together with the management of potential limitations ensures that the presented typology addresses the issues associated with existing categorisations.

Defining Uncertainty

The nature of uncertainty

Interrogation and analysis of the WOE-ERAs (n=171) identified a total of three types of nature-based uncertainty, which are discussed in detail here.

Aleatory uncertainty

Aleatory uncertainty represents the inherent randomness displayed in human and natural systems (Bedford and Cook 2001; Ascough II *et al.* 2008). Aleatory uncertainty

cannot be reduced, although additional research may help to better understand the complexities of the system(s) of interest. Whilst such systems may in actuality be chaotic rather than random (and are therefore in principle understandable; Regan *et al.* 2002), risk analysts find it useful to treat the associated uncertainties from the latter position. For example, stochastic numerical techniques (such as Monte-Carlo simulation and Latin Hypercube sampling) act as realistic representations of real-world processes, which are either viewed as being too complex for deterministic interpretation (e.g. seismic activity) or as inherently random (e.g. weather systems). However, in mimicking nature, stochastic models can produce results that are consistently more representative than their deterministic counterparts (Hromkovic 2005).

Epistemic uncertainty

Epistemic uncertainty (Bedford and Cooke 2001; Walker *et al.* 2003; Petersen 2006; Ascough II *et al.* 2008; Knol *et al.* 2009) represents the imperfection of knowledge concerning a system of interest. Epistemic uncertainty can be quantified, reduced, and possibly eliminated, depending on the specific situation. However, whilst epistemic uncertainty is in principle reducible by increasing relevant knowledge, this new information can reveal the true depths of our ignorance, only serving to increase the associated uncertainty (Janssen *et al.* 2003; van der Keur 2008).

Combined uncertainty

This research introduces a combined epistemic and aleatory category, reflecting the potential for the location-based uncertainties contained within it to incorporate both epistemic and aleatory aspects, and forcing a separation from those sets. For example, model uncertainty may incorporate system uncertainty, which can reduce confidence in the structure

of a model, as well as variability uncertainty, which may cast doubt over the validity of the model's output. For this combined category, reducing secondary uncertainties associated with incorporated groups is just as important as managing the primary failings.

The location of uncertainty

Interrogation and analysis of the WOE-ERAs (n=171) identified a total of 7 main types of location-based uncertainty and 20 related sub-types, which are discussed in detail here.

Data uncertainty

Data are used extensively in risk assessments, not least environmental WOE-ERAs. For example, data may be used to draw attention to a source of environmental danger, to assess the degree of harm imposed upon a valued asset, or to support or refute damaging claims made against an individual, organisation, or even nation. Whether empirical or experimental, all data carries a level of inherent confidence associated with its truth and correctness. Identifying potential sources of uncertainty within data can help to distinguish between the reliable and the unreliable.

Data uncertainties can be further arranged into three groups: availability, referring to the incompleteness, scarcity, or absence of data (i.e. data is not available); precision, concerning the lack of accuracy in obtained data (i.e. data is not precise); and reliability, reflecting its trustworthiness (i.e. data is unreliable, possibly due to errors associated with its processing, statistical analysis, or presentation). The data reliability sub-location, which accounts for 20.8% of all uncertainties within the WOE-ERA evidence base, primarily reflects the measurement and systematic sub-categories seen within existing typologies (Table 1).

Language uncertainty

Language is used both in conjunction with and separately to data. The uncertainties associated with language arise for a number of reasons, but stem primarily from a lack of clarity. Language can be used to express ideas and commands or to communicate the final results of assessments; its use is unavoidable and necessary.

Linguistic uncertainties are comprised of three types: *ambiguity*, where multiple meanings are possible; *underspecificity*, where meanings are not exact; and *vagueness*, where meanings are not clear and understandable. The use of a single field-specific term can carry all three linguistic uncertainties: it may not be clearly defined and therefore have many meanings throughout the community (ambiguous); its use may be superseded by a more relevant and accurate term (underspecific), and certain members, especially those from outside the field, may have heard of the term, but have a limited understanding of its true meaning (vague; Acosta *et al.* 2010).

In previous typologies, language uncertainties (if included at all) were typically separated into their own category (e.g. Morgan *et al.* 1990; Regan *et al.* 2002; Ascough II *et al.* 2008), but are here deemed to be epistemic. The uncertainties associated with language arise for a number of reasons, but stem primarily from a lack of clarity (Morgan *et al.* 1990). However, the definitions, contexts, and applications associated with language can be controlled (Regan *et al.* 2002). Theoretically, language uncertainties can be quantified, reduced or even removed – techniques such as fuzzy logic are testament to this – equating them with the other uncertainties (data and system) within the epistemic set. Despite their relatively low levels of occurrence within the WOE evidence base (of just 4.7%; Figure 4.2), communicating the epistemic quality of language uncertainties allows analysts to approach them with reduction and elimination in mind, which may previously not have been the case.

System uncertainty

System uncertainty tallies closely to scientific understanding; if the understanding is low the uncertainty will be high, and vice-versa. However, a field which develops rapidly, such as biotechnology, will contain high levels of knowledge as well as some system uncertainty, due largely to the unknowns that progress brings.

System uncertainties can be more clearly defined according to the source-pathway-receptor relationship, which constitutes the three main phases of system understanding: *cause*, which concerns a lack of clarity regarding the source(s) of harm; *effect*, relating to the influence a particular stressor (source) has upon the receptor(s); and *process*, which concerns either not understanding the risks or not identifying something vital to a successful assessment.

Process uncertainty correlates with the pathway stage of the relationship, which can be anything between the source(s) of harm and asset(s) of value. It can contain a variety of uncertainties, such as not identifying the critical dose needed for an adverse effect to result (Meek and Hughes 1995). The risks associated with certain nanotechnologies, a rapidly developing field, are unclear because of a lack of process understanding, which in some cases may be coupled with high effect uncertainty. For example, the contribution of physical structure to a nanoparticle's toxicity may not be fully understood (Gottschalk *et al.* 2010), whilst its effects upon different receptors may simply be unknown (Zalk *et al.* 2009).

Variability uncertainty

Also described as random and stochastic, variability uncertainty is the inherent unpredictability of any human or natural system. *Human* variability in ERAs results primarily from intentionally biased and subjective actions (Khan *et al.* 2002), but extends to all

qualities of humans which are, either literally or from the viewpoint of the risk analyst, stochastic in nature. Irrespective of their position or seniority, humans involved in the assessment process may display bias when they have something to gain, or subjectivity when they believe their own views to be more correct than those of others (Chen *et al.* 2007). Human variability can be exhibited by those with close links to a project, such as decision-makers, stakeholders, and scientists, as well as those with no vested interest, such as hired laboratory technicians or computer modellers (Croke *et al.* 2007).

The *natural* element may be considered unexpected and free from intentional bias (Jørgensen *et al.* 2009). It pertains to the chaotic traits of natural systems. Natural variability is also the primary cause of uncertainties associated with extrapolation; a process that becomes necessary when faced with limited knowledge (e.g. limited data or limited process understanding).

Extrapolation uncertainty

Extrapolation can occur across a variety of means, and is usually present wherever there is missing information or knowledge (Luttik *et al.* 2005), but is not necessarily associated with numeric data. In the developed typology, extrapolation uncertainty is a subcategory of the aleatory category, where previously it has either been grouped with model uncertainties (Walker *et al.* 2003; Regan *et al.* 2002; Finkel 1990), treated as a branch of variability (Huijbregts 2001), or more commonly ignored altogether. Extrapolation can be considered an attempt at rectifying availability issues: if information were readily available, extrapolation would not be necessary. However, when it is required, the process is deemed uncertain due to the natural variability involved (e.g. spatially and temporally extrapolating meteorological data beyond the physical limits of an existing network of measuring stations to a study site). Extrapolation can therefore be considered the result of epistemic failings,

with the connected uncertainties driven through aleatory means. Whilst an increase in relevant epistemic knowledge may prevent the need for extrapolation (thereby providing a distinction from variability uncertainty, which can be neither eliminated nor reduced), when it is required it is the aleatory-based failings that must be addressed. These observations confirm extrapolation uncertainties to be aleatory in nature, and indicate that they should be considered separately from the variability location.

Extrapolation is identified in six forms: *intraspecies*, where information specific to members of a species is used to represent other members of the same species; *interspecies*, where information specific to members of a species is used to represent members of a different species; *laboratory*, where information specific to laboratory conditions is used to represent real-world scenarios; *quantity*, where information specific to one quantity is used to represent another; *spatial*, where information specific to one spatial scale is used to represent another; and *temporal*, where information specific to one timescale is used to represent another.

Model uncertainty

With regard to a system of interest, modelling is an attempt to understand processes, predict responses, evaluate management alternatives, and support the policy and decision-making process (Arhonditsis *et al.* 2007). Modelling procedures vary according to the system of study and desired outcomes, though they invariably involve an initial conceptualisation stage, which is then developed into a numerical and/or computational representation (Stephens *et al.* 1993). Simplifications and assumptions are usually necessary features of the structural process, since natural features and dependencies are complex and numerous. The initial conceptualisation stage is arguably the most important. Any uncertainties that exist here will likely be propagated throughout the rest of the modelling procedure. The conceptual

representation also needs to be fit for purpose: an oversimplification may result in a failure to capture essential features, leading in turn to inadequate numerical or computational simulations. Conversely, an undersimplification may yield a model that is too complex, and therefore time-intensive, or even prohibitive, to build and execute (El-Ghonemy *et al.* 2005).

Model uncertainties relate to the different stages of the process: *structure*, which concerns the representation of real-world processes in model form; and *output*, which reflects the level of confidence in the results. The model structure sub-location, which accounts for 3.9% of all uncertainties within the WOE-ERA evidence base, primarily reflects the structural and technical sub-categories seen within existing typologies (Table 3.1).

Decision uncertainty

Decision uncertainty exists when doubt surrounds an optimal course of action, often in the face of differing objectives. There may be multiple options which satisfy at least a part of the criteria for the decision, but also possible is the existence of no such alternatives. For example, management of ecological and environmental resources requires decision-makers to evaluate multiple and often conflicting strategies, whilst balancing objectives of productivity and sustainability (Ducey and Larson 1999). Decision uncertainty is potentially comprised of all uncertainties identified up to and including this stage of the WOE-ERA process.

The level of uncertainty

Every identified uncertainty with a defined nature- and location-type must also be considered in terms of its level (i.e. severity; Janssen *et al.* 2003; Walker *et al.* 2003; Refsgaard *et al.* 2007). The level of an identified uncertainty is highly context-dependant and cannot, at present, be ascribed *a priori* along with its nature and location. Due to this, there is a reduced need (compared with the nature and location) for an uncertainty typology to make

specific reference to potential levels within its main structure. It may simply be more appropriate to do it in an accompanying narrative, as is the case here.

Humans exhibit a variety of distinct levels of knowledge, ranging from determinism (perfect knowledge) to indeterminacy (lack of knowledge; Wynne 1992). The further we move from a deterministic understanding of a system, the more severe the uncertainty becomes (Walker et al. 2003). The level of uncertainty is described according to two factors, namely the degree of confidence attached to the likelihood of an event occurring, and the degree of confidence attached to the severity of outcomes should that event occur (Wynne 1992; Stirling 1999). These metrics are used to convey the level of understanding, and therefore the level of the associated uncertainty. Recognised levels of uncertainty include: deterministic uncertainty, in which we are confident about the likelihoods and outcomes; statistical uncertainty, where we can confidently assign probabilities to events but have little understanding of the ramifications of the events; scenario uncertainty, where there is confidence about the outcomes but not likelihoods of an event (i.e. the reverse of statistical uncertainty); recognised ignorance, where it is not possible to define probabilities or a complete set of outcomes; and total ignorance, which is the uncertainty of which we know nothing and to which we are ignorant (i.e. the inverse of deterministic uncertainty).

When the focus shifts from uncertainty identification (i.e. the purpose of the typology presented here) to uncertainty management, an effective typology should also aim to communicate methods for quantification and/or reduction. In that instance, communicating the uncertainty levels is essential as a change in level can cause a change in the optimal UMT. In terms of data uncertainties, for example, when there is a level of statistical uncertainty the associated data uncertainty can be tackled through sensitivity analysis. However, if we were in the range of scenario uncertainty, scenario analysis, for example,

would be more appropriate (Refsgaard *et al.* 2007). Ultimately, selection of a suitable UMT is dependent on the mix of all three uncertainty dimensions: location, nature and level.

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Dealing with Uncertainty

The appropriateness of UMTs employed

UMTs should be used in concert with specific types of uncertainty (Refsgaard et al. 2007). The correct adoption of any one UMT is therefore dependent upon the uncertainties present (Stirling 2012). The occurrence frequency analysis and statistical analysis conducted between the uncertainty types and UMTs highlighted several relationships, the vast majority of which show the UMTs being used to tackle appropriate uncertainties. This observation extends to frequently occurring uncertainty and UMT combinations (e.g. Monte-Carlo simulation being used to tackle data reliability uncertainty; Figure 3) as well as those combinations which occur less frequently, but are no less appropriate (e.g. MCDA being used to tackle decision uncertainty; Figure 3; Linkov and Moberg 2011). This is a positive finding, since the incorrect utilisation of a UMT may be considered just as important as choosing not to use one at all, which was the fourth most-adopted option in the studied data set. We have defined taking 'no action' as the publication author(s) recognising uncertainties but not taking action, with or without offering justification (e.g. Wright-Walters et al. 2011). As well as indicating the inappropriate use of this technique with reference to specific uncertainties (primarily model and variability), the occurrence frequency analysis and resulting dependency model (Figure 2) convey a more important point: dealing with uncertainties should be a major priority within these assessments. The fact that the 'no action' mechanism appears so often suggests that this is not currently the case.

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Separating uncertainty and variability

The categorisation of uncertainties as being either epistemic, aleatory, or a combination of the two, might imply that each of the identified UMTs can equally be assigned to one of these groups. This is not the case, nor is there a single mechanism that offers comprehensive solutions to all of the identified uncertainties.

Whilst uncertainties appear to fall easily into the aforementioned groupings, the boundary can be less well defined in applied situations (Merz and Thieken 2009). The most pertinent example of this is the use of Monte-Carlo Simulation in an attempt to cope with both forms of uncertainty. Since epistemic and aleatory uncertainties can both be described by probability distributions, many assessments involving a first-order Monte-Carlo procedure claim to successfully handle both (Wu and Tsang 2004). However, the ensuing single distribution (which may combine data reliability uncertainty with inherent natural variability) incorrectly implies that uncertainty and variability are the same, and that they can be dealt with as one (Wu and Tsang 2004). Problems may still exist even when a distinction is made: incorrectly treating variability as if it were uncertainty may yield a meaningless distribution when a single figure is required (Vose 2000). Effectively, the techniques that are employed to manage uncertainty can, if executed incorrectly, introduce further errors.

It is increasingly recognised that uncertainty and variability need to be treated separately (Kelly and Campbell 2000; Li *et al.* 2008; Kumar *et al.* 2009; Qin and Huang 2009; Helton *et al.* 2011). Once separated, both aleatory variability and epistemic uncertainty can be quantified, and steps can be taken to reduce and potentially remove epistemic uncertainty. Techniques such as second-order Monte-Carlo (Griffin *et al.* 1999; Wu and Tsang 2004) and integrated fuzzy-stochastic systems (Li *et al.* 2007; Kumar *et al.* 2009; Qin and Huang 2009) have emerged that can manage both aleatory and epistemic uncertainties. Moreover, through correct uncertainty management, they attempt to eliminate the inferred,

and potentially unjustifiable, level of confidence that can incorrectly be assigned to risk estimates.

Guidance for practitioners

In order to help practitioners better prioritise, identify, and manage uncertainties in assessments, we propose combining the uncertainty typology (Table 2) with the uncertainty-based frequency and dependency (Figure 2) data. The resulting list of potential uncertainties (Table 4), which is organised by uncertainty location and sub-location, is ranked according to the frequency with which the uncertainties appear in the evidence base (of 171 WOE-ERAs). These rankings correspond to the order in which practitioners may wish to consider uncertainties in their assessments. The individual uncertainties are further categorised according to their nature. In addition, several options for managing each uncertainty are presented, ordered according to the strength of the dependencies between an uncertainty sub-location and its respective UMTs within the evidence base (where one is the optimal UMT and three is the least optimal).

536 [TABLE 4 NEAR HERE]

Applying the guidance: the case of genetically modified higher plants

In the European Union (EU) the introduction of Genetically Modified Organisms (GMOs) for experimental purposes and for placing on the market for cultivation, importation or processing is regulated by European Commission Directive 2001/18/EC (EC 2001). In order to obtain consent for purposes of deliberate release into the environment, applicants must submit a comprehensive dossier containing relevant information about the GMO, including an ERA. However, submitted ERAs rarely consider uncertainties, and where uncertainty is acknowledged it is primarily handled by adopting (favourable) worst-case estimates (Hart *et al.* 2007).

A well-researched example of GMOs in the environment is the potential risk of *Bacillus thuringiensis* (Bt) modified maize to non-target Monarch butterflies, with research in USA investigating levels of risk under differing exposure scenarios. For the purposes of this research, this specific case can reasonably be expanded to a more generalised relationship of potential Genetically Modified Higher Plant (GMHP) risk to Lepidoptera. Whilst 81 examples of this scenario exist within the publically available dossiers submitted by applicants under Directive 2001/18/EC, the dossiers do not include evidence to support attempts to identify or manage uncertainties within their respective ERAs, which seems to contradict the instruction in the enforcing regulation to do so.

Directive 2001/18/EC promotes a six-step ERA procedure for applicants to follow, where the first four steps correspond to the ERA and the final two to risk management options beyond the assessment. The first four steps are commonly known as problem formulation, effects assessment, exposure assessment, and risk characterisation (DEFRA 2011). An ERA carried out by an applicant can be expected to consist of these four phases, which, on the basis of information contained within relevant governmental guidance documents (Fairman et al. 1998; USEPA 1998; DEFRA 2011), and in the context of potential GMHP risk to Lepidoptera, could contain most or all of the major elements listed in Table 5. The presented uncertainty typology (Table 2) and guidance (Table 4) can be applied to this standard ERA structure to determine potential locations of uncertainty and relevant options for their management (Table 6). For example, problems may exist when attempting to determine aspects of the dose of the GMHP stressor (e.g. modified protein) received by the Lepidoptera receptor during the effects assessment phase of the ERA. Such issues could feasibly correspond to: uncertainty in applying relevant data about the duration, frequency, or intensity of the dose (leading to data reliability, availability, and/or precision uncertainty); variability about the situation (natural variability); forced extrapolations from the available

data to other points of interest (interspecies, spatial, intraspecies, temporal, laboratory, and/or quantity extrapolation uncertainty), or; defining parameters in models that reflect the data utilised (model structure uncertainty) and using those models to quantify the dose received (model output uncertainty).

[TABLE 5 NEAR HERE] [TABLE 6 NEAR HERE]

By applying the uncertainty typology (Table 2) and guidance (Table 4) to the rest of the ERA structure in Table 5, we formulated a list of 43 potential uncertainties. These uncertainties are categorised according to the four phases of the ERA and the main locations in which uncertainty can exist (e.g. data, variability), which are in turn organised in order of their highest ranked uncertainty sub-location (e.g. data reliability, natural variability). System uncertainties are likely to dominate the problem formulation phase, with data, variability, extrapolation, and model uncertainties the focus in the middle analysis phase (effects and exposure assessments), and language and decision uncertainties playing more of a role at the final risk characterisation step. The responsibility for determining whether the potential uncertainties exist, and at what level of severity, will rest with the relevant applicant(s). Prioritised techniques for the management of each uncertainty sub-location (brought forward from Table 4) are also included. When implementing these UMTs applicants should ensure that epistemic and aleatory uncertainties are approached in the correct way.

This simple example demonstrates how potential uncertainties can be identified using the presented uncertainty typology and guidance. This may allow for more considered uncertainty analyses in both established risk domains and highly regulated emerging fields, such as GMHPs, leading to more robust ERAs. Environmental decision-making at some of the highest strategic levels (e.g. the European Union) may ultimately benefit. However, the researchers recognise that application of the presented typology will inevitably require some end-user subjectivity, and that consistent reproduction of results may be hard to achieve. To

that end, the researchers are currently investigating, applying and validating methods to improve the uncertainty identification process within ERAs, which build on the presented typology and reduce the reliance on the skill, experience and ability of the end-user.

CONCLUSION

Uncertainty typologies aim to foster understanding, further acting as tools to aid uncertainty identification during risk characterisation. The categorisations and definitions presented within uncertainty typologies must be comprehensive and reliable, but existing typologies have been found to be lacking in a number of ways, especially in an ERA context.

This research presented a typology of uncertainties based, for the first time, on the analysis of a large evidence base, namely 171 peer-reviewed environmental WOE-ERAs. In creating the typology, which consists of 7 main types of location-based uncertainty (data, language, system, extrapolation, variability, model, and decision) and 20 related sub-types, several key issues surrounding existing typologies, including research domain transferability and content reliability issues, have been resolved. In addition, whilst the techniques used by analysts to manage these uncertainties were implemented appropriately, we have shown that in some cases the validity of a risk estimate is negatively impacted as uncertainty management is excluded. The practical guidance that we have introduced here will help resolve this issue by providing a robust method for dealing with uncertainty, as demonstrated through an applied case study focussing on ERAs of genetically modified higher plants in the EU. This case study also highlights the relationships between different uncertainties and the various phases and tasks within ERAs. Moving forward, we are currently exploring these relationships in more detail, with the aim of adding value to the uncertainty identification process.

The typology presented here and accompanying guidance, which should be utilised by risk analysts during the formative stages of uncertainty analyses, will have positive implications for the identification, prioritisation, and management of uncertainty during risk characterisation.

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Table 1 Uncertainty categorisations offered by existing typologies within the published environmental risk-based literature.

Source reference	Uncertainties included within source			
Vesely and Rasmuson 1984	Data; Model (understanding, approximation); Completeness; Physical variability			
Henrion and Fischoff 1986	Random; Systematic			
Alcamo and Bartnicki 1987	Model (structure, parameters, forcing, initial state, operation)			
Beck 1987	Model (aggregation, structure, numerical, parameter); Variability; Errors;			
Morgan and Henrion 1990	Statistical variation; Systematic error; Linguistic; Variability; Inherent randomness; Disagreement; Model (approximation, form)			
Finkel 1990	Model; Parameter; Decision; Natural variability			
Funtowicz and Ravetz 1990	Inexactness; Unreliability; Border with ignorance			
Wynne 1992	Risk; Uncertainty; Ignorance; Indeterminacy;			
Helton 1994	Stochastic; Subjective			
Hoffman and Hammonds 1994	Lack of knowledge; Variability			
Rowe 1994	Temporal; Structural; Metrical; Translational			
Faucheux and Froger 1995	Ignorance; Strong uncertainty; Uncertainty; Certainty			
van der Sluijs 1997	Inexactness; Unreliability; Ignorance; Model (input data, conceptual model structure, technical model structure, bugs, model completeness)			
Stirling 1999	Risk; Uncertainty; Ambiguity; Ignorance			
Bedford and Cooke 2001	Aleatory; Epistemic; Parameter; Data; Model; Ambiguity; Volitional			
Huijbregts et al. 2001	Parameter; Model; Choices; Variability (spatial, temporal, between source and object)			
Bevington and Robinson 2002	Systematic errors; Random errors			

	Epistemic (measurement error, systematic error, natural variation, inherent randomness, model, subjective				
Regan et al. 2002	judgement); Linguistic (vagueness, context dependence, ambiguity, underspecificity, indeterminacy of				
	theoretical terms)				
van Asselt and Rotmans 2002	Variability (nature, cognitive, behavioural, societal, technological); Knowledge (inexactness, lack of				
van Asseit and Rotmans 2002	measurements, practically immeasurable, conflicting evidence, ignorance, indeterminacy)				
Janssen et al. 2003	Statistical; Scenario; Recognised ignorance; Knowledge-based; Variability-based; Context; Expert				
Janssen et at. 2005	judgement; Model (structure, technical, parameters, input); Data; Outputs				
Walker et al. 2003	Statistical; Scenario; Recognised ignorance; Total ignorance; Epistemic; Variability; Context; Model				
walkel et al. 2005	(structure, technical, parameters, input, outputs)				
Brown 2004	Bounded uncertainty; Unbounded uncertainty; Indeterminacy; Ignorance				
Dewulf et al. 2005	Inherent nature of phenomena; Lack of knowledge; Ambiguity in system understanding				
Beer 2006	Probabilistic; Ambiguity; Incertitude; Ignorance; Indeterminacy				
Petersen 2006	Location; Nature; Range; Recognised ignorance; Methodological unreliability; Value diversity				
Hayes et al. 2006	Linguistic; Variability; Incertitude				
Maier et al. 2008	Data (measurement error, type of data, length of record, analysis); Model (method, record quality, calibration,				
Walet et al. 2008	validation, experience); Human (stakeholder, politics)				
Ascough II et al. 2008	Knowledge; Variability; Linguistic; Process; Model; Variability; Linguistic; Decision				
Brouwer and Blois 2008	Statistical; Scenario; Qualitative; Recognised ignorance				
Vnol et al. 2000	Statistical; Scenario; Recognised ignorance; Epistemic; Ontic (process, normative); Model (structure,				
Knol et al. 2009	parameters, input data); Methodological; Analyst uncertainty				

Table 2 Novel typology of uncertainties (including definitions) resulting from the analysis and iterative clustering of data obtained from 171 ERAs that applied WOE methods.

Nature	Location	Sub-location	Definition
Epistemic	Data	Availability	referring to the incompleteness, scarcity, or absence of data
		Precision	concerning the lack of accuracy or precision in obtained data
		Reliability	reflecting its trustworthiness i.e. data is erroneous for some specified reason
	Language	Ambiguity	where multiple meanings are possible
		Underspecificity	where meanings are not exact
		Vagueness	where meanings are not clear and understandable
	System	Cause	concerning a lack of clarity regarding the source(s) of harm
		Effect	relating to the influence a particular stressor (source) has upon the receptor(s)
		Process	where the risks are not understood or a process vital to a successful assessment is not identified
Aleatory	Variability	Human	results primarily from intentionally biased and subjective actions, but extends to all qualities of
			humans which are, either literally or from the viewpoint of the risk analyst, stochastic in nature
		Natural	pertains to the stochastic traits of natural systems
	Extrapolation	Intraspecies	where information specific to members of a species is used to represent other members of the
			same species
		Interspecies	where information specific to members of a species is used to represent members of a different
			species
		Laboratory	where information specific to laboratory conditions is used to represent real-world scenarios

		Quantity	where information specific to one quantity is used to represent another
		Spatial	where information specific to one spatial scale is used to represent another
Temporal where information specific to one timescale is used to represent another		where information specific to one timescale is used to represent another	
Combined Model Structure con		Structure	concerning the representation of real-world processes in model form
		Output	reflecting the level of confidence in the produced results
	Decision	Decision	where doubt surrounds an optimal course of action, often in the face of differing objectives.

Table 3 Descriptions of the most frequently occurring uncertainty management techniques, organised according to the percentage rates with which they occur in the evidence base of 171 ERAs that applied WOE methods, along with their associated uncertainties.

Uncertainty management	Description	Associated uncertainty	Referenced in:
technique		locations	
Monte-Carlo simulation	Utilises repeated executions of numerical models to	Data, Extrapolation,	Ma 2002
(22.1%)	simulate stochastic processes.	Variability, Model, System	Qin and Huang 2009
Uncertainty factor	Attaches a factor-based correction to the data being used	Extrapolation, System,	Calabrese 1994
(16.6%)	which reflects the level of uncertainty within it.	Data, Variability	Phillips et al. 2008
Sensitivity analysis	Tests the sensitivity of a chosen output variable to	Data, Model, Extrapolation,	Huysmans et al. 2006
(8.4%)	variations in quantities relating to input variables.	System	Oughton et al. 2008
No action	Not attempting to quantify, reduce, or manage	Data, Extrapolation,	Cesar et al. 2009
(7.7%)	uncertainties, whether recognised by the publication	System, Variability, Model	
	author(s) or identified through this research.		
Further data collection	The collection of increased quantities of data.	Extrapolation, Data,	Avagliano and Parella
(7.3%)		Variability	2009
Fuzzy logic	A form of multi-valued logic that allows its components to	Data, Language, Model,	Zadeh 1965
(6.8%)	be approximate rather than precise.	Variability	Acosta et al. 2010
Expert elicitation	Seeks to capture the knowledge of one or more experts in a	Data, System , Variability	Kandlikar et al. 2007
(4.6%)	field with regard to a specific matter.		
Probability density function ¹	Describes the frequency of occurrence for different	Data, Variability	Oughton et al. 2008

(4.0%)	parameter values over a given range.				
Latin hypercube sampling	Splits a distribution into distinct intervals for sampling and	Data, Variability	Klier et al. 2008		
(3.5%)	use as inputs to a numerical model.		Kumar et al. 2009		
Bayesian belief network	A graphical representation of a system, in which	Variability, Data, System	Aspinall et al. 2003		
(3.1%)	relationships between uncertain characteristics are				
	expressed through probability values.				
Fuzzy-stochastic system	A hybrid approach for incorporating epistemic and	Data, Extrapolation,	Li et al. 2007		
(3.1%)	stochastic uncertainties separately.	Language	Kumar et al. 2009		
Precautionary management	Management based upon the application of the	Extrapolation, System	Godduhn and Duffy		
(1.8%)	Precautionary Principle.		2003		
Multi-criteria decision analysis	Brings together criteria and performance scores to provide	Decision	Linkov et al. 2007		
(1.1%)	a basis for integrating risk and uncertainty levels.		Critto et al. 2007		
Adaptive management	Incorporate the needs of many into an iterative system	Decision	Dey et al. 2000		
(0.4%)	where differing alternatives and objectives are present.		Williams et al. 2009		

¹Refers to probability density functions that are applied independently of the Monte-Carlo simulation and Latin-hypercube sampling techniques.

Table 4 Ranked potential uncertainties (according to the percentage proportion with which they occur in the evidence base of 171 ERAs that applied WOE methods) for risk analysts to consider, detailing uncertainty locations, sub-locations, and natures, along with related uncertainty management techniques in order of decreasing appropriateness. Row shadings correspond to the uncertainties that can be quantified, reduced and potentially removed (epistemic), quantified at best (aleatory), and those that must be considered on a case-by-case basis (combined).

Rank	Location of	Sub-location of	Nature of	Uncertainty management	Uncertainty management	Uncertainty management
	uncertainty	uncertainty	uncertainty	technique #1	technique #2	technique #3
1 (20.8%)	Data	Reliability	Epistemic	Monte-Carlo simulation	Sensitivity analysis	Uncertainty factors
2 (10.1%)	Data	Availability	Epistemic	Monte-Carlo simulation	Sensitivity analysis	Uncertainty factors
3 (9.9%)	Variability	Natural	Aleatory	Monte-Carlo simulation	Further data collection	Uncertainty factors
4 (7.8%)	Extrapolation	Interspecies	Aleatory	Uncertainty factors	Monte-Carlo simulation	Further data collection
=5 (6.0%)	Extrapolation	Spatial	Aleatory	Interpolation	Monte-Carlo simulation	Uncertainty factors
=5 (6.0%)	System	Process	Epistemic	Uncertainty factors	Monte-Carlo simulation	Expert elicitation
7 (5.2%)	Extrapolation	Intraspecies	Aleatory	Uncertainty factors	Monte-Carlo simulation	Further data collection
=8 (4.2%)	Extrapolation	Temporal	Aleatory	Further data collection	Uncertainty factors	Monte-Carlo simulation
=8 (4.2%)	Model	Output	Combined	Sensitivity analysis	Monte-Carlo simulation	Fuzzy logic
=10 (3.9%)	Model	Structure	Combined	Sensitivity analysis	Monte-Carlo simulation	Fuzzy logic
=10 (3.9%)	System	Effect	Epistemic	Uncertainty factors	Expert elicitation	Monte-Carlo simulation
=12 (3.1%)	Extrapolation	Laboratory	Aleatory	Uncertainty factors	Further data collection	Monte-Carlo simulation
=12 (3.1%)	System	Cause	Epistemic	Uncertainty factors	Further data collection	Monte-Carlo simulation
=14 (2.3%)	Extrapolation	Quantity	Aleatory	Uncertainty factors	Further data collection	Monte-Carlo simulation
=14 (2.3%)	Variability	Human	Aleatory	Bayesian belief networks	Expert elicitation	Sensitivity analysis

=16 (1.6%)	Data	Precision	Epistemic	Fuzzy logic	Expert elicitation	Monte-Carlo simulation
=16 (1.6%)	Decision	Decision	Combined	Adaptive management	MCDA	Bayesian belief networks
=16 (1.6%)	Language	Ambiguity	Epistemic	Fuzzy logic	Fuzzy-stochastic	N/A
=16 (1.6%)	Language	Vagueness	Epistemic	Fuzzy logic	Fuzzy-stochastic	N/A
20 (1.0%)	Language	Underspecificity	Epistemic	Fuzzy logic	Fuzzy-stochastic	N/A

Table 5 Major elements of an environmental risk assessment, derived from government guidance documents (Fairman *et al.* 1998; USEPA 1998; DEFRA 2011).

a conceptual model work/analysis plan	Define risk relationships e.g. source-pathway-receptor paradigm Select assessment endpoints e.g. development; behaviour; survival; fecundity; abundance Consider appropriateness of assessment endpoints e.g. to other endpoints; to receptor Factors affecting fate and transport of stressor e.g. physical; chemical; atmospheric; biotic
work/analysis plan	fecundity; abundance Consider appropriateness of assessment endpoints e.g. to other endpoints; to receptor Factors affecting fate and transport of stressor e.g. physical; chemical; atmospheric; biotic
work/analysis plan	Consider appropriateness of assessment endpoints e.g. to other endpoints; to receptor Factors affecting fate and transport of stressor e.g. physical; chemical; atmospheric; biotic
work/analysis plan	endpoints; to receptor Factors affecting fate and transport of stressor e.g. physical; chemical; atmospheric; biotic
work/analysis plan	Factors affecting fate and transport of stressor e.g. physical; chemical; atmospheric; biotic
work/analysis plan	atmospheric; biotic
work/anaiysis pian	
	Determined in the second of th
	Data considerations/requirements e.g. gaps; collection; synthesis;
	analysis
se the stressor-response relationship	Determine the dose received e.g. duration, intensity
	Examine assessment endpoints e.g. development; behaviour; survival;
	fecundity; abundance
stressor-response (effects) profile(s) e.g.	
point; distribution	
t data/information relating to:	The stressor e.g. composition; distribution; release
	The fate and transport of the stressor (i.e. pathways) e.g. biological;
	chemical; physical; receiving media
	The receptor e.g. composition; distribution
ate stressor-receptor contact	Co-occurrence e.g. frequency; duration; intensity
	stressor-response (effects) profile(s) e.g. point; distribution t data/information relating to:

		Nature of contact e.g. ingestion; inhalation; dermal
	Create exposure profile(s) e.g. worst-case;	
	conservative; probabilistic	
Risk characterisation	Select relevant effects/exposure profiles	
	Estimate risk e.g. single-point comparison;	
	cumulative distribution	
	Aggregate risk e.g. combine stressor-based risk	
	estimates; combine endpoint-based risk estimates	
	Evaluate risk	Confidence in risk estimate(s; i.e. uncertainty analysis) e.g. qualitative;
	Evaluate risk	semi-quantitative; quantitative
		Significance of risk estimate(s) using e.g. regulation; stakeholders;
		receptor recovery potential
	Communicate risk e.g. to risk professionals; to	
	laypersons; to stakeholders; to regulators	

Table 6 Potential uncertainties for the ERA scenario of GMHP risk to Lepidoptera, organised according to the four phases of ERAs in which they will occur: problem formulation, effects assessment, exposure assessment, and risk characterisation. Analyst(s) should consider each listed potential uncertainty against all corresponding sub-locations (which are ranked according to the frequency with which they occur within the evidence base of 171 ERAs that applied WOE methods). Prioritised uncertainty management techniques are also displayed for each uncertainty sub-location, should a related uncertainty be deemed to exist. The potential level of uncertainty must be assessed by the analyst on a case-by-case basis.

Uncertainty location/ sub- location	Problem formulation	Effects assessment	Exposure assessment	Risk characterisation
Data (epistemic)	 Factors affecting fate and transport of stressor e.g. can we get the required data? Data considerations and requirements e.g. identifying data collection, synthesis, and analysis techniques; 	 Determine the dose received by receptor e.g. data about the duration, frequency, or intensity of dose; Examine assessment endpoints e.g. data about receptor development, behaviour, survival, fecundity, abundance; Create exposure profile(s) e.g. distributions (of stressor intensity Vs. response magnitude) using analysed data 	 Stressor info e.g. data about its composition, distribution, or release; Fate/transport info e.g. data about the dispersion or deposition of the receptor; about atmospheric, terrestrial, or biotic conditions; Receptor info e.g. data about dietary, breeding, migratory, or predatory patterns; Create exposure profile(s) e.g. using direct monitoring data; 	Assessing the significance of the risk e.g. using data regarding regulatory-enforced or stakeholder-derived acceptability levels;

Reliability (1)	Monte Carlo Simulation; Sensitivity analysis; Uncertainty factors;			
Availability (2)	Monte Carlo Simulation; Sensitivity analysis; Uncertainty factors;			
Precision (=16)	Fuzzy logic; Expert elicitation; Monte Carlo Simulation;			
Variability (aleatory)	Factors affecting fate and transport of stressor e.g. variability in/between identified processes;	 Determine the dose received by receptor e.g. variability in the duration, frequency, or intensity of dose; Examine assessment endpoints e.g. variability in receptor development, behaviour, survival, fecundity, abundance; Create exposure profile(s) e.g. variability in single point (e.g. LC₅₀, EC₅₀) estimates; 	 Stressor info e.g. variability in spatial/temporal distribution; variability in intensity or quantity of release; Fate/transport info e.g. variability in dispersion or deposition of the receptor; variability in atmospheric, terrestrial, or biotic conditions; Receptor info e.g. variability in dietary, breeding, migratory, or predatory patterns; Stressor-receptor contact e.g. variability in spatial, temporal or intensity of overlap; 	 Risk estimation e.g. variability in single-point comparisons of PEC Vs. LC₅₀/EC₅₀; variability in cumulative distributions of stressor intensity Vs. response magnitude; Assessing the significance of the risk e.g. variability in regulatory-enforced or stakeholder-derived acceptability levels; variability in receptor recovery potential;
Natural (3)	Monte Carlo Simulation; Further data collection; Uncertainty factors;			
Human (=14)	Bayesian belief networks; Expert elicitation; Sensitivity analysis;			
Extrapolation (aleatory)	Consider appropriateness of assessment endpoints e.g. extrapolating generic endpoints for use with this receptor;	Determine the dose received by receptor e.g. extrapolating knowledge for the duration, frequency, or intensity of dose;	 Stressor info e.g. forced extrapolation of release intensity or quantity information; Create exposure profile(s) e.g. 	• Risk estimation e.g. extrapolating from single- point comparisons of PEC Vs. LC ₅₀ /EC ₅₀ ; extrapolating from cumulative

	extrapolating to create conservative estimates; extrapolating to create worst- case estimates; extrapolating to create worst- case estimates; • Assessing the significance of the risk e.g. extrapolating from regulatory-enforced or stakeholder-derived acceptability levels;		
Interspecies (4)	Uncertainty factors; Monte Carlo Simulation; Further data collection; Intermoletion: Monte Carlo Simulation: Uncertainty factors:		
Spatial (=5) Intraspecies (7)	Interpolation; Monte Carlo Simulation; Uncertainty factors; Uncertainty factors; Monte Carlo Simulation; Further data collection;		
Temporal (=8)	Further data collection; Uncertainty factors; Monte Carlo Simulation;		
Lab. (=12)	Uncertainty factors; Further data collection; Monte Carlo Simulation;		
Quantity (=14)	Uncertainty factors; Further data collection; Monte Carlo Simulation; Uncertainty factors; Further data collection; Monte Carlo Simulation;		
System (epistemic)	 Define risk relationships e.g. missing a stressor, pathway, or receptor; Select assessment endpoints e.g. missing an endpoint; Consider appropriateness of assessment endpoints e.g. relevance to other endpoints; relevance to receptor; Identifying fate/transport factors e.g. are there any 		

	missing?			
Process (=5)	Uncertainty factors; Monte Carlo Simulation; Expert elicitation;			
Effect (=10)	Uncertainty factors; Expert elicitation; Monte Carlo Simulation;			
Cause (=12)	Uncertainty factors; Further data collection; Monte Carlo Simulation;			
Model (combined)		e.g. model parameters for receptor development,	 Stressor info e.g. model parameters for the composition, distribution, or release; Fate/transport info e.g. model parameters for the dispersion or deposition of the receptor; Receptor info e.g. model parameters for the dietary, breeding, migratory, or predatory patterns; Stressor-receptor contact e.g. model parameters for the 	
Output (=8)	Sensitivity analysis; Monte Carlo Sin	nulation; Fuzzy logic;	 spatial, temporal or intensity of overlap; Create exposure profile(s) e.g. using dispersion models; using probabilistic models; 	
Structure (=10)	Sensitivity analysis; Monte Carlo Sin	nulation; Fuzzy logic;		
Decision				Selecting relevant

(combined)		effects/exposure profiles; Risk aggregation e.g. combining selected estimates to form one overall risk estimate;	
Decision (=16)	Adaptive management; Multi-criteria decision analysis;	Bayesian belief networks;	
Language (epistemic)	Defining the scope of the ERA e.g. communicating with stakeholders	 Assessing the significance of the risk e.g. with regulators or stakeholders; Communicating the risk e.g. to risk professionals; to laypersons; to stakeholders; to regulators; 	
Ambiguity (=16)	Fuzzy logic; Fuzzy-stochastic system;		
Vagueness (=16)	Fuzzy logic; Fuzzy-stochastic system;		
Underspec. (20)	Fuzzy logic; Fuzzy-stochastic system;		

Figure Captions

Figure 1 Overview of the clustering process applied to the uncertainty data extracted from the collected evidence base (n=171 ERAs that applied WOE methods), showing: a) all 36 recorded location-based uncertainty types organised according to their nature; and c) final 20 location-based uncertainty types organised according to their nature. The superscript Greek letters in b) are matched to the superscript Greek letters in c), representing clustering into like groups. For example, model structure, model parameters, computer software/hardware, model calibration, and model simplification uncertainties, denoted by the Greek letter Kappa (κ), in b) are clustered into model structure uncertainty, also denoted by κ , in c).

Figure 2 Model showing the occurrence frequencies of the individual location-based uncertainty types identified (light grey squares; n=20), management techniques utilised (dark grey circles; n=10), and the relationships between them (black lines) within the collected evidence base (n=171 ERAs that applied WOE methods). The areas of the squares and circles (which depict the respective occurrence frequencies) are relative to each other, as are the widths of the dependency lines, where an increasing (square or circle) area and (line) width indicates an increasing frequency.

Figure 3 Matrix plot showing the correlation values (ρ) between the uncertainties and their respective management techniques within the collected evidence base (n=171 ERAs that applied WOE methods), where a higher value indicates a stronger correlation.