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PERSPECTIVES

Expert judgment based multi-criteria decision model to address uncertainties in risk assessment of nanotechnology-enabled food products

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Abstract Currently, risk assessment of nanotechnology-enabled food products is considered difficult due to the large number of uncertainties involved. We developed an approach which could address some of the main uncertainties through the use of expert judgment. Our approach employs a multi-criteria decision model, based on probabilistic inversion that enables capturing experts' preferences in regard to safety of nanotechnology-enabled food products, and identifying their opinions in regard to the significance of key criteria that are important in determining the safety of such products. An advantage of these sample-based techniques is that they provide out-of-sample validation and therefore a robust scientific basis. This validation in turn adds predictive power to the model developed. We achieved out-of-sample validation in two ways: (1) a portion of the expert preference data was excluded from the model's fitting and was then predicted by the model fitted on the remaining rankings and (2) a (partially) different set of experts generated new scenarios, using the same criteria employed in the model, and ranked them; their ranks were compared with ranks predicted by the model. The degree of validation in each method was less than perfect but reasonably substantial. The validated model we applied captured and modelled experts' preferences regarding safety of hypothetical nanotechnology-enabled food products. It appears therefore that such an approach can provide a promising route to explore further for assessing the risk of nanotechnology-enabled food products.

Keywords Risk assessment · Expert judgment · Multi-criteria decision models · Nanotechnology food products · Uncertainty · Governance

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Introduction

The advent of nanotechnologies has unleashed enormous prospects for the development of new products and applications for a wide range of industrial and consumer sectors. The known and projected applications of nanotechnology for the food sector, so far, fall into four main categories: (i) processing or formulating foodstuffs to form nanostructures, (ii) using nano-sized, nano-encapsulated or engineered nano-additives in food, (iii) incorporating engineered nanomaterials (ENMs) in plastic polymers to develop improved, 'active', or 'intelligent' materials for food packaging (largest market share of current applications) and (iv) using nanotechnology-based materials and devices for food safety and traceability (Chaudhry et al. 2008).

In consumer applications, ENMs may be present as free particulates or in a bound, fixed or embedded form in objects and articles. Of particular concern in this regard are those products and applications that can give rise to exposure to free nanoparticles either via inhalation (e.g. cleaning aids, spray cosmetics and coatings), skin application (cosmetics), ingestion (food and drinks) or intravenous delivery (e.g. some medicines and diagnostic aids). Other applications may not pose an immediate risk to the consumer, but may have an adverse impact on the environment after disposal.

In particular, applications for a sensitive area like food have raised a number of concerns and issues. In this regard, questions have been raised over whether the current risk assessment paradigm and regulatory frameworks, designed for conventional materials, would be applicable and adequate for the new materials and products of nanotechnologies.

Although a number of recent reviews have concluded that the existing risk assessment paradigm should in principle be applicable to engineered nanoparticles (Rocks et al. 2008; EFSA 2009; SCENIHR 2009; OECD 2009), the current knowledge gaps pose a major stumbling block to new developments in this area. These knowledge gaps also make probabilistic uncertainty analysis methods difficult to implement on assessment of nanotechnology-enabled products. Linkov et al. (2009) argued that this high level of incomplete knowledge for nanotechnology-enabled products demands integrating expert judgment with multiple other factors that are perceived as important for policy making and decision making.

Currently, risk assessment of nanotechnology-enabled food products is fraught with difficulties due to the many uncertainties and knowledge gaps (EFSA 2009; FAO/WHO 2009; OECD 2010). Concomitant to the growing industry interest in nanotechnologies and products in the food sector are concerns about safety, ethical, policy and regulatory issues. A number of NGOs have already called for a moratorium, or a ban, on nanotechnologies until they are proven to be safe to consumers and the environment (ETC Group 2004; Friends of the Earth 2008; Soil Association 2008). At present, the uncertainties are difficult to address due to the lack of knowledge of possible interactions of nanomaterials at the molecular and/or physiological levels, and their potential effects on human health either directly (i.e. ingestion of food items that may contain ingredients manufactured via nanotechnology processes) or indirectly (i.e. via environmental exposure). This level of uncertainty can only be addressed by expert judgment, but it can also be expected that experts' opinions at early stages of the new technology will vary. The issue in question then becomes:

(1) how to capture experts' current knowledge and uncertainties, and
(2) to understand how experts use their knowledge when thinking about possible risk of nanotechnology-enabled food products.

An interesting approach towards the development of a framework for informing risk analysis and risk management of nanoparticles was published in 2005 by Morgan. The author developed a set of influence diagrams based on elicited expert judgment. These influence diagrams were described by the author as preliminary, as there was no data behind the proposed relationships of the identified variables. As such, the influence diagrams developed do not have the ability to predict a level of potential risk from nanoparticles.

A classification system of nanomaterials in a number of ecological risk categories (i.e. very low, low, medium, high, or extreme risk) was produced by Tervonen et al. (2008). The authors used an outranking method implemented as stochastic multi-criteria acceptability analysis (SMAA-TRI) to assign weights in a number of pre-selected criteria with the view to classifying nanomaterials according to the possible risk they may pose in the environment. Uncertainty of stakeholders providing inputs for this analysis was introduced in categorical terms as well, i.e. low, medium and high. It was shown that data were considered too imprecise to indicate a single risk category for each of the five nanomaterials they tested as case studies. Their method enabled them to categorise nanomaterials, although the uncertainties underlying this categorization were considered as quite high, due to the limited amount of empirical data.

Linkov et al. (2006) proposed the employment of multi-criteria decision analysis methodologies coupled with structured stakeholders' involvement for robust decision making in areas where systems are complex and burdened with a high degree of uncertainties. Multi-criteria decision analysis approaches (in particular the analytical hierarchy process) have been applied in the past within the context of risk management of possible risk of nanomaterials in the environment (Linkov et al. 2007). The latter approach involved the integration of heterogeneous information (e.g. environmental, ecological, technological, economic and socio-political relevant factors) to estimate likely toxicity and risk for nanomaterials given that information on their physical and chemical properties is limited.

Recently, Canis et al. (2010) reported the employment of a multi-criteria decision making model as a framework to select the best possible synthesis process of single-wall carbon nanotubes and direction for most important relevant research direction.

Our approach employs elicitation of expert judgment on safety of hypothetical nanotechnology-enabled food products, and the application of a multi-criteria decision model (MCDM), based on probabilistic inversion (Teck et al. 2010; Flari et al. 2010; R. Neslo, R. Cooke, V. Flari, Q. Chaudhry, Probabilistic Inversion and Stakeholders' Preferences: Application to Nano-Enabled Food Products, unpublished communication) that enables us to model experts' judgments in terms of inferred scores on a number of criteria. The particular MCDM approach is novel; it employs discrete choice data and applies probabilistic inversion to quantify, with uncertainty, the weights in the model. Briefly, the technique involves the following steps:

(1) experts are assumed to be a random sample from a virtual population of experts;
(2) experts express preferences between discrete choice alternatives, described in terms of values on a fixed set of criteria;
(3) a MCDM is posited, with each experts deriving his/her preferences as a weighted combination of criteria scores, with the weights unique to each expert;
(4) a distribution over weights is found which optimally reproduces the observed pattern of preferences for the choice alternatives.

Its major strengths lie in the following areas:

(1) Flexibility of the models produced; the approach is not restricted to a simple MCDM model, it would work equally well with linear or non-linear models.
(2) The experts/stakeholders do not assess the weights of criteria but supply discrete choice data, therefore avoiding problematic assumptions regarding the independence of criteria weights and criteria scores.
(3) An advantage of these sample based techniques is that they provide out-of-sample validation, and therefore a robust scientific basis. This validation in turn adds predictive power to the model developed.

Most importantly, the MCDM model we developed for nanotechnology-enabled food products was discussed thoroughly and its performance was assessed externally by a (partially) different set of experts during a workshop that took place at Fera, York, UK, on the 27th and 28th May 2010.

This article describes the approach we followed to elicit expert judgment, the feasibility of the particular multi-criteria decision model for application in this emerging area of risk assessment and possible ways forward including harmonization of risk assessment approaches of nanotechnology-enabled food products.

Methods

Our work involved a number of successive, lengthy steps to collect, analyse and model information captured via elicitation of expert judgment and to validate the model we developed:

Step 1: Selection of criteria[1]

Criteria are defined as a number of attributes of ENMs that have been considered as most significant in order to evaluate potential risk considerations of

[1] The work on defining the criteria employed in the model started as an activity of the Interagency Risk Assessment Consortium working group on nanotechnology and risk assessment that was led by Dr. Villie Flari (Jan 2009–Nov 2009) with the collaboration of Dr. Qasim Chaudhry. The final selection and development of measurement units was finalised by Dr. Qasim Chaudhry (Nov 2009–Jan 2010)

nanotechnology-enabled food products (Table 1). The scientific basis for selection of criteria is based on how ENMs are likely to enter the body, and the important parameters that are likely to control their behaviour, interactions and fate. The main route of consumer exposure to ENMs via consumption of nano-foods is through the gastrointestinal (GI) tract. It is well known that a healthy digestive system only allows absorption of nutrients from the GI tract after digestion of foods. The gut wall is designed to ensure the passage of dietary nutrients, but prevent the passage of larger-sized insoluble materials. The main concern in this regard is whether nano-sized food ingredients and additives can bypass this barrier, and thus expose the body to insoluble nanoparticles consumed via food. Indeed, translocation from the GI tract has been reported to be greater for nanoparticles than the larger particles (Desai et al. 1996; Hillyer and Albrecht 2001; Hoet et al. 2004; des Rieux et al. 2006). Following oral administration, translocation and distribution of metal nanoparticles to different organs and tissues has also been reported (Hillyer and Albrecht 2001; Kim et al. 2008). Despite such concerns, there are certain aspects that will have a major bearing on the potential risk of ENMs applied to food products. For example, foodstuffs contain a variety of nano-structures, e.g. natural colloids, or processed emulsions, micelles or liposomes. The presence of such nano-structures in food, however, does not raise any special safety concern because they are composed of natural food materials which are digested in the GI tract, and the resulting nutrients are assimilated by the body. Similarly, food additives formulated in nano-carriers may be released in the GI tract as a result of the digestion of carrier system, and thus lose the nano-character. Any nano-specific risk from such applications may only arise if a nano-carrier can remain intact in the GI tract and can deliver a substance to other parts of the body via the circulatory system. The main consumer safety concerns in relation to the use of ENMs, however, relate to insoluble ENMs which are not digested in the GI tract and are biopersistent, i.e. they can remain in the body over long period (Tran and Chaudhry 2010). Thus, in addition to the smaller size, which is the main characteristic of an ENM that can enable them to cross the gut barrier, their digestibility and bio persistence form important criteria which need considering in risk assessment. Other exposure related criteria that need to be considered in risk assessment include the concentration of nanomaterials in a food product, the amount of nano-food consumed at any one time and the frequency of such consumption (Tran and Chaudhry 2010). These criteria, along with possible surface modifications of ENMs, which can alter reactivity and hence potential risk, were captured and presented to the experts for the elicitation exercise.

The range of each criterion was set in a way to facilitate expert judgment. In relation to risk assessment of nano-foods, it is also of note that acutely toxic materials are unlikely to be used knowingly in food products, and the main concerns over consumer safety relate to long term, or new/unforeseen harmful effects of ENMs. For this reason, the chemical nature of ENMs was not included in the selection of criteria presented to the experts.

Step 2: The definition of scenarios

Twenty-six hypothetical nanotechnology-enabled products were defined precisely by us according to the criteria shown in Table 1. These hypothetical products, shown in Table 2, were defined considering the current and projected applications of ENMs in food and related sectors (Chaudhry et al. 2008, 2010).

For defining the scenarios, the selected criteria were used in a manner that presented the experts with a plausible food application—without elaborating however the nature of application—whilst giving them a choice for prioritising between different criteria.

In devising these scenarios, we considered a range of hypothetical products and applications with the view to covering as much landscape of current and future applications as possible taking into account the dynamic development of nanotechnology-enabled applications in the food sector.

Step 3: Identifying and recruiting experts

We identified 53 highly recognized international experts with expertise in food related applications of nanotechnologies, whom we invited to participate in the expert elicitation exercise. The invited experts were affiliated with either academia, research institutes, non-profit organizations, regulators or governmental

Table 1 The criteria we employed to define precisely the scenarios of hypothetical nanotechnology-enabled food products are listed below

Criteria	Range	Unit	Comments
Fraction of the food	0.001–1	N/A	Criterion for exposure assessment
Fraction of the diet	0–100	(%)	Criterion for exposure assessment
Number of days consumed	0–365	Days	Criterion for exposure assessment
Primary particle size	1–1000	nm	Criterion for hazard assessment (relating to potential absorption and translocation of ENMs from the GI tract to other parts of the body)
Secondary particle size	1 > 1000	nm	Criterion for hazard assessment (relating to potential absorption and translocation of ENMs from the GI tract)
Surface area	6–200	m^2/g	Criterion for hazard assessment (metric for estimation of the level of potential interaction of ENMs with biological entities)
Solubility	0–100	(%)	Criterion for hazard and exposure assessment (relating to that fact that fully soluble materials will lose any nano-specific characteristic)
Digestibility	Binary	(digestible or non-digestible)	Criterion for hazard and exposure assessment (relating to that fact that digestible materials will lose any nano-specific characteristic)
Bio persistence	Binary	(bio-persistent or non bio-persistent)	Criterion for hazard and exposure assessment (relating to that fact that non bio-persistent materials will be metabolised or excreted)
Surface modification	0–100	(%)	Criterion for hazard assessment (relating to the fact that surface modifications may lead to an increase or decrease in reactivity and thus potential harmful interactions)

We realise that a number of criteria and characteristics for nanoparticles have been identified as important in determining the potential harmful properties (Tran and Chaudhry 2010) but we considered only those that are relevant to food applications. This means the criteria judged as important in terms of oral intake and uptake via the gastrointestinal tract (i.e. digestibility, solubility, biopersistence) in addition to primary and secondary (i.e. aggregation) sizes along with surface modifications. Finally, we employed three additional criteria to account for exposure

departments. The experts were selected from the EU countries, Japan, Australia or USA.

Out of the 53 invited experts, 26 agreed in participating in the exercise and 21 of these completed the exercise. Our panel comprised 6 experts from academia, research institutes and non-for profit organizations, 3 regulators and 12 governmental scientists (i.e. risk assessors, molecular biologists, toxicologists and chemists). No monetary compensation was provided to the experts who agreed in participating in the exercise; they worked *pro-bono*. It was agreed that their individual inputs would remain confidential and that their anonymity would be preserved.

Step 4: The elicitation of expert judgment

Ranking preferences regarding potential safety considerations of the scenarios developed were elicited from the 21 experts remotely. The elicitation document sent to our experts is shown in Appendix of electronic supplementary material. Our approach involved elicitation of discrete choice data, i.e. individual ranking preferences. All scenarios were described in terms of values on the 10 criteria (Table 2). Experts were invited to rank (a) the five scenarios that, to their point of view, trigger the least potential human health concern (these products will be referred to as 'potentially safe' from now on) and (b) the five scenarios that, to their point of view, trigger the greatest potential human health concerns (these products will be referred to as 'potentially unsafe' from now on). At the end of the exercise, only 10 of 26 hypothetical nanotechnology-enabled food products were ranked by each expert. All data elicited from experts are assumed to be individual decisions; to our knowledge, there was only one exception of an expert whose final decisions were formed via a group discussion with his/her colleagues.

Step 5: Modelling experts' ranking preferences

Experts' preference rankings were modelled by assuming that each expert determined his/her scores per scenario as a function of weights for criteria k, and the scores c_{ik} of scenario i on criteria k:

Table 2 Experts were presented with twenty-six scenarios of hypothetical nanotechnology-enabled food products, therefore they were asked to assess products in which nanomaterials were deliberately added

Scenario	Fraction of the food (0.001–1)	Fraction of the diet (%)	Number of days consumed (1–365)	Primary particle size (nm)	Secondary particle size (Agglomeration) nm Mean	Standard deviation	Surface area (m^2/g)	Solubility in water (%)	Digestible	Bio-persistent	Increase in change of reactivity due to surface modification (%)	Your ranking preference. Please, employ the drop down menu in each cell of each scenario. Please, remember only 10 out of 26 scenarios should be tagged with your individual ranking preferences. The rest should be marked as 'non ranked''
B	0.001	3	45	30	100	30	200	10	No	Yes	25	Choose an item from the list
L	0.9	5	50	30	100	30	200	100	Yes	No	0	Choose an item from the list
F	0.001	1	10	100	250	100	60	10	No	Yes	50	Choose an item from the list
C	0.006	5	200	30	100	30	200	10	No	Yes	0	Choose an item from the list
V	0.001	25	25	1000	Non agglomerated		6	10	No	Yes	100	Choose an item from the list
H	0.9	40	10	100	250	100	60	100	Yes	No	50	Choose an item from the list
K	0.001	10	50	30	Non agglomerated		200	10	No	Yes	50	Choose an item from the list
Z	0.001	9	360	30	Non agglomerated		200	10	No	Yes	25	Choose an item from the list
Y	0.01	7	56	100	Non agglomerated		60	20	No	Yes	25	Choose an item from the list
G	0.001	8	243	100	Non agglomerated		60	10	No	Yes	75	Choose an item from the list
O	0.001	15	277	100	250	100	60	10	No	Yes	25	Choose an item from the list
R	1	3	290	30	100	30	200	100	Yes	No	0	Choose an item from the list
T	0.001	2	325	1000	Non agglomerated		6	0	Yes	No	75	Choose an item from the list
X	1	6	310	100	250	100	60	100	Yes	No	0	Choose an item from the list
M	0.007	9	1	1000	Non agglomerated		6	100	Yes	No	0	Choose an item from the list
J	0.001	10	256	1000	Non agglomerated		6	80	Yes	No	0	Choose an item from the list
A	1	14	1	30	Non agglomerated		200	100	Yes	No	50	Choose an item from the list
Q	0.001	3.5	2	100	250	100	60	0	Yes	No	100	Choose an item from the list
E	0.85	2	8	100	Non agglomerated		60	100	Yes	No	75	Choose an item from the list

Table 2 continued

Scenario	Fraction of the food (0.001–1)	Fraction of the diet (%)	Number of days consumed (1–365)	Primary particle size (nm)	Secondary particle size (Agglomeration)		Surface area (m^2/g)	Solubility in water (%)	Digestible	Bio-persistent	Increase in change of reactivity due to surface modification (%)	Your ranking preference. Please, employ the drop down menu in each cell of each scenario. Please, remember only 10 out of 26 scenarios should be tagged with your individual ranking preferences. The rest should be marked as 'non ranked''
					nm Mean	Standard deviation						
N	0.001	5	175	1000	Non agglomerated		6	10	No	Yes	100	Choose an item from the list
I	0.95	6	190	100	Non agglomerated		60	100	Yes	No	50	Choose an item from the list
P	0.001	8	280	30	100	30	200	0	Yes	No	25	Choose an item from the list
D	1	11	240	30	Non agglomerated		200	100	Yes	No	25	Choose an item from the list
U	0.001	35	300	100	250	100	60	0	Yes	No	0	Choose an item from the list
S	0.005	7.5	15	30	100	30	200	0	Yes	No	25	Choose an item from the list
W	0.005	5	5	1000	Non agglomerated		6	0	Yes	No	100	Choose an item from the list

The scenarios did not include any hypothetical nanotechnology-enabled food product in which nanosheets are included. It was considered that biopersistent materials are not metabolised or excreted; the time of bio persistence of each nanomaterial however is unknown

Score(i) = $\sum_{k=1,\ldots,10} w_k c_{ik}$. The weights w_k and thus the scores are specific to each expert. The approach assumes the following:

- safety has only a single dimension and can be used for ranking; all experts' preferences are determined by the above MCDM model, with weights specific to each expert;
- there is a population of experts (connoted as T-experts) who would be able to rank these hypothetical nanotechnology-enabled food products; the number of experts in this population is assumed as large but the actual number of these experts is unknown;
- ranking preferences of hypothetical nanotechnology-enabled products (scenarios) vary over this population of T-experts, particularly as this area of research is burdened with numerous uncertainties;
- the experts who participated in our exercise are assumed to be a representative sample of the total population of T-experts and they will be referred to as R-experts from now on.

Based on the above assumptions, we infer the marginal distribution over the rankings of these hypothetical nanotechnology-enabled food products from our R-experts' ranking preferences. As the method does not elicit directly weights for the criteria k, these are indirectly inferred and will be computed. In particular, a distribution over the weights and product scores is obtained via a probabilistically inverting of the distribution over our R-experts' ranking preferences. Full details of the methodology and the mathematics underlying this method will be described in another paper currently in preparation (Neslo et al., unpublished communication).

The linear model was chosen for modelling R-experts' ranking preferences for the following reasons: (a) it is easy to grasp; (b) the weights assigned by the model characterize the importance of the criteria; (c) the expected score of a new product (i.e. not included or assessed in the model) can be computed using the means (over the R-experts) of the weights.

Step 6: Validation of the model developed

Out-of-sample validation

We reviewed the multi-attribute/multi-criteria literature but did not identify any method for obtaining true out-of-sample validation for such models. As mentioned above, instead of directly eliciting weights for criteria, our approach requires experts to rank a number of scenarios differing with respect to values on the criteria. Probabilistic inversion is then used to obtain a distribution over criteria weights which best reproduces the observed distribution of R-experts' ranking preferences. Out-of-sample validation is achieved by excluding a portion of the rankings from the fitting; the excluded rankings are then predicted by the model fitted on the remaining ones. This validation is fully described in Neslo et al. (unpublished communication).

External validation of the model

The model was thoroughly assessed during a workshop on risk assessment of nanotechnology-enabled food products that took place at Fera, York (27th–28th May 2010). In total, 34 participants representing academia (6), governmental research institutes (14), regulatory agencies (7) and industry (7) attended. Workshop participants represented a partially different set of experts from the set of R-experts; 10 of 34 workshop participants were R-experts.

Following general presentations and discussions, workshop participants were divided into three breakout groups; R-experts participating in the workshop were included in all breakout groups. Each breakout group devised a number of hypothetical nanotechnology-enabled food products which participants, as a group, considered either as 'potentially safe' or 'potentially unsafe'; these products were afterwards 'blindly' scored according to the multi-criteria decision model that we developed. The process allowed us to (a) validate the model externally and (b) assess its predictive value.

Step 7: External assessment of the model

We anticipated that, inevitably, most of workshop participants' opinions on the feasibility and applicability of the model would be expressed via qualitative descriptors. As a result, recording and analysing participants' thoughts and opinions became a major challenge as we wished to ensure that most expressed information was captured, and that there was no ambiguity among participant participants regarding objectives of particular questions.

Table 3 Inferred weights were computed as distributions, and in this table their means are shown for a number ($n = 6$) of model fittings

	Fittings of the multi-criteria decision model on:					
	Potentially safe ranks		Potentially unsafe ranks		All ranks	
	All potentially safe ranks employed for model fitting	*Most common (>0.1) potentially safe ranks employed*	All potentially unsafe ranks employed for model fitting	*Most common (>0.1) potentially unsafe ranks employed*	All (i.e. potentially safe and potentially unsafe) ranks employed	*Most common ranks (of both potentially safe and potentially unsafe) ranks employed (>0.1)*
Bio persistence	14	*11*	8	*12*	10	*14*
Number of days consumed	13	*11*	10	*9*	13	*10*
Fraction of diet	13	*16*	12	*10*	13	*15*
Digestibility	12	*13*	11	*10*	9	*12*
Solubility	12	*9*	11	*10*	14	*9*
Surface modification	10	*6*	10	*9*	12	*7*
Surface area	8	*10*	9	*9*	9	*8*
Fraction of the food	7	*8*	12	*9*	8	*9*
Primary particle size	6	*8*	8	*9*	5	*6*
Secondary particle size	5	*8*	9	*13*	7	*10*

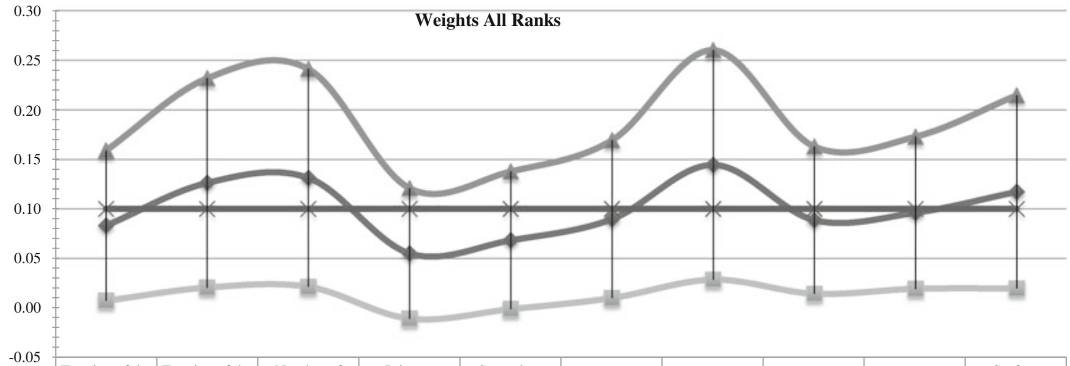
The multi-criteria decision model developed was fitted six times on six different sets of R-experts' ranking preferences. These six sets refer to three categories of ranking preferences: two model fittings employed R-experts' ranking preferences regarding products that, to their point of view, are ranked as higher in that they do not trigger a potential human health concern. These ranks were categorized as 'Potentially safe ranks'. Two other model fittings referred to R-experts' rankings regarding products that, to their point of view, are ranked as higher in that they potentially trigger human health concerns. These ranks were categorized as 'Potentially unsafe ranks'. Finally, two model fittings referred to all R-experts' ranking preferences, that is both the 'potentially safe ranks' and the 'potentially unsafe ranks'. The columns in italics refer to the model fittings that employed most common ranks (i.e. rankings that were chosen by at least 10% of the experts) irrespective of the category involved

In order to address the above challenges, we opted to follow a structured approach to record participants' opinions. In particular, we formulated our objectives in a number of pre-defined structured questions. The same pre-defined structured questions were presented to all workshop participants, and they were relevant to:

1. The value of the approach, i.e. the feasibility and applicability of the particular multi-criteria decision model for assessing the safety of nanotechnology-enabled food products.
2. Model's reliability, i.e. shortcomings of the first version of the model.
3. Possible ways to develop the model further in order to address identified shortcomings and to comply with particular requirements of risk assessment of nanotechnology-enabled food products.

Results and discussion

In this article, we focus our analysis and discussion on the application of the developed multi-criteria decision model on risk assessment of nanotechnology-enabled products. Details of the theoretical background of the mathematical approaches and description of all analyses we performed will be provided by Neslo et al. (unpublished communication).



	Fraction of the food	Fraction of the diet	Number of days consumed	Primary particle size	Secondary particle size	Surface area	Solubility	Digestibility	Biopersistence	Surface modification
Mean Weight	0.083099428	0.126226991	0.131296331	0.055037128	0.068272695	0.08964307	0.144442924	0.088671388	0.096106449	0.117203598
Mean-SD	0.007239981	0.020583046	0.021352915	-0.010836016	-0.001241167	0.009989824	0.028561736	0.014371492	0.019334925	0.019746068
Mean+SD	0.158958875	0.231870936	0.241239747	0.120910271	0.137786557	0.169296316	0.260324112	0.162971284	0.172877972	0.214661127
Equal Weights	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1

Fig. 1 Mean and standard variation of weights for criteria as inferred from fitting a multi-criteria decision model on all ranking preferences elicited by R-experts. A line assuming equal weight (=0.1) for all criteria is included for comparison reasons

Fitting a multi-criteria decision model on R-experts' ranking preferences: a brief synopsis

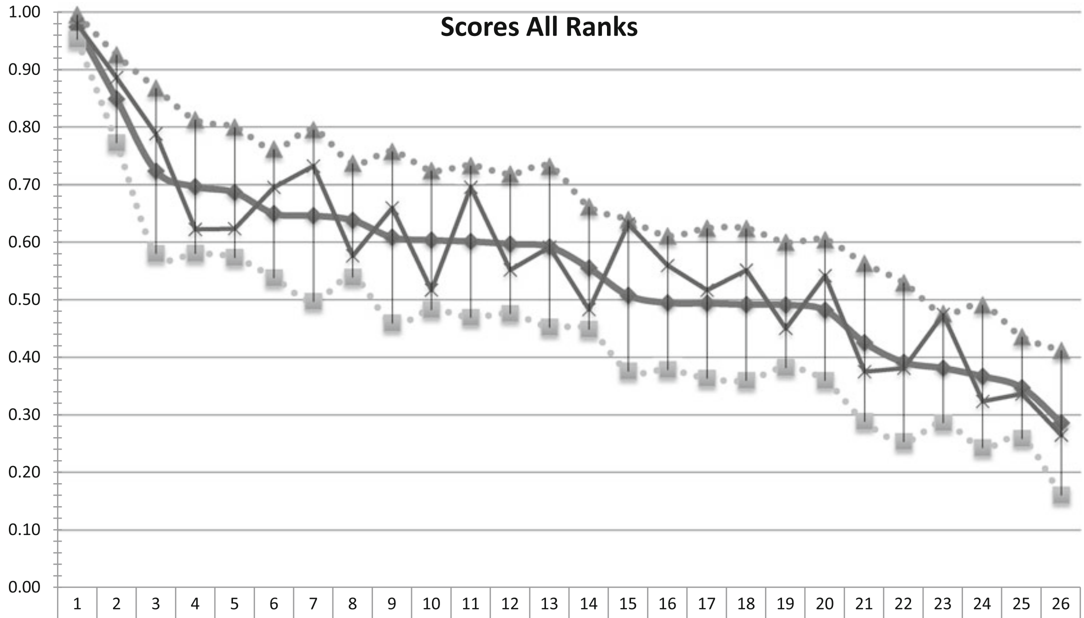
Overall, we performed six fittings of the model on ranking preferences of R-experts'; different sets of R-experts' ranking preferences were taken into account for each model fitting (Table 3).

The distributions of inferred weights for the criteria varied according to the particular set of R-experts' ranking preferences taken into account, although a number of criteria (e.g. solubility, digestibility, fraction of diet) bore high mean weights irrespective of the particular data set used (Table 3). Mean weights (taken over the R-experts) fluctuate above and below the line assuming equal weights (Fig. 1); the latter indicates clearly that there is no reason to assume that criteria included in this analysis would be weighted equally by all experts. Nevertheless, a large variation was recorded around the mean weights, a fact that implies that R-experts' opinions differed considerably (Fig. 1).

Consequently, total scores, calculated as a linear function of mean weights and criteria per product, differed according to the particular set of R-experts' ranking preferences taken into account. Measurement units of criteria were normalized before introducing them in the calculation of scores. For most criteria, higher values would be expected to indicate less possible harm, therefore it could be inferred that products with higher scores were thought of not triggering a consumer safety concern (Fig. 2). High variation around a mean score indicates variation in R-experts' judgment about the safety of the particular product; therefore higher uncertainty is implied. Mean scores fluctuate above and below the scores calculated on an 'equal weights' basis as expected, since weights of criteria would fluctuate above and below the equal weights line.

A view on R-experts' ranking preferences of the 26 hypothetical nanotechnology-enabled food products they evaluated is shown in Table 4. The ranking order of the three top products considered as 'potentially safe' was the same irrespective of the particular model fitting, and the same five products were chosen as 'potentially unsafe' in all model fittings apart from one (i.e. model fitting on the most common R-experts' ranking preferences of 'potentially unsafe' products). Products that were ranked as 'potentially safe' from R-experts were very rarely ranked as 'potentially unsafe'.

Last but not least, any strong positive correlations between weights of criteria can facilitate drawing a picture of R-experts' thought processes regarding the criteria when assessing the safety of the hypothetical nanotechnology-enabled food products (Table 5). It appears that R-experts who thought that secondary particle size is quite important considered fraction of the food quite important as well. Similarly, R-experts



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
Score	0.97	0.84	0.72	0.69	0.68	0.65	0.64	0.63	0.60	0.60	0.60	0.59	0.59	0.55	0.50	0.49	0.49	0.49	0.49	0.48	0.42	0.39	0.38	0.36	0.34	0.28
Mean-SD	0.95	0.77	0.58	0.58	0.57	0.53	0.49	0.53	0.45	0.48	0.46	0.47	0.45	0.44	0.37	0.37	0.36	0.35	0.38	0.35	0.28	0.25	0.28	0.24	0.25	0.16
Mean+SD	0.99	0.92	0.86	0.81	0.80	0.76	0.79	0.73	0.75	0.72	0.73	0.71	0.73	0.66	0.63	0.61	0.62	0.62	0.60	0.60	0.56	0.52	0.47	0.49	0.43	0.41
Equal Weights	0.97	0.88	0.78	0.62	0.62	0.69	0.73	0.57	0.66	0.51	0.69	0.55	0.59	0.48	0.63	0.56	0.51	0.55	0.45	0.54	0.37	0.38	0.47	0.32	0.33	0.26

Fig. 2 Mean and standard deviation of scores calculated per hypothetical nanotechnology-enabled food products via fitting a multi-criteria decision model on all R-experts' ranking preferences. Higher scores indicate products considered by R-experts as most safe. Variability in R-experts' opinion concerning the products considered as most safe is less compared with the rest hypothetical nanotechnology-enabled food products they assessed. A line indicating scores assuming equal weights for all criteria is introduced in the graph for comparison reason

who thought solubility was quite important also thought number of days that the product would be consumed and increase of change of reactivity due to surface modification were quite important as well.

Negative correlations between weights of criteria, however, need to be examined more carefully. The model applied is linear and the weights are constrained to sum up to 1, therefore modest negative correlations could be introduced to fulfil the latter constrain. With that in mind, the negative correlations between the following pairs of weights of criteria may be of interest:

- Solubility—fraction of the food, solubility—secondary particle size and solubility—primary size: one can infer that experts who think solubility is very important to safety also think that fraction of the food, secondary particle size and primary size are less important.
- Digestibility—number of days consumed and bio persistence—number of days consumed: one can infer that experts who think digestibility or bio persistence is important to safety, think number of days consumed is less important.
- Fraction of the food—number of days consumed: in this case, both criteria consist part of the exposure element of the model and they are strongly interrelated. However, if fraction of food is driving exposure, then number of days consumed would be less important.

Main messages inferred by analysing R-experts' ranking preferences

Elicited ranking preferences from R-experts indicated that engineered nanomaterials are preferred not to be used in food applications in the first place, whilst the use of micro-particles is considered to carry relatively less risk. It can be inferred, therefore, that the use of engineered nanomaterials is associated with a possible risk, although the latter should be seen under the

Table 4 Top 5 products considered by R-experts as 'potentially safe' and top 5 products considered by R-experts as potentially triggering human health concerns

	Rank	Scenarios	Scores	Fraction of the food	Fraction of the diet	Number of days consumed	Primary particle size	Secondary particle size (Agglomeration)	Surface area	Solubility	Digestible	Bio-persistent	Surface modification
Potentially safe	1	M	0.974	0.007	9	1	1000	Non agglomerated	6	100	Yes	No	0
	2	J	0.849	0.001	10	256	1000	Non agglomerated	6	80	Yes	No	0
	3	W	0.724	0.005	5	5	1000	Non agglomerated	6	0	Yes	No	100
	4	E	0.696	0.85	2	8	100	Non agglomerated	60	100	Yes	No	75
	5	L	0.686	0.9	5	50	30	100 30	200	Yes	Yes	No	0
Potentially unsafe	22	C	0.391	0.006	5	200	30	100 30	200	10	No	Yes	0
	23	O	0.381	0.001	15	277	100	250 100	60	10	No	Yes	25
	24	K	0.367	0.001	10	50	30	Non agglomerated	200	10	No	Yes	50
	25	G	0.347	0.001	8	243	100	Non agglomerated	60	10	No	Yes	75
	26	Z	0.286	0.001	9	360	30	Non agglomerated	200	10	No	Yes	25

The scores shown in the table are calculated from fitting a model on all ranks of R-experts

Table 5 Correlations between weights of criteria were calculated

Correlation	Fraction of the food	Fraction of the diet	Number of days consumed	Primary particle size	Secondary particle size	Surface area	Solubility	Digestibility	Bio persistence	Surface modification
Fraction of the food	1.00	−0.14	**−0.52**	0.02	**0.45**	−0.10	**−0.60**	0.04	0.19	−0.24
Fraction of the diet	−0.14	1.00	−0.01	0.05	**−0.31**	0.04	0.08	-0.18	-0.20	−0.08
Number of days consumed	**−0.52**	−0.01	1.00	0.04	**−0.44**	0.15	**0.31**	−0.25	**−0.37**	−0.01
Primary particle size	0.02	0.05	0.04	1.00	−0.12	0.25	**−0.32**	−0.07	−0.13	**−0.42**
Secondary particle size	**0.45**	**−0.31**	**−0.44**	−0.12	1.00	−0.31	**−0.53**	0.14	0.20	−0.13
Surface area	−0.10	0.04	0.15	0.25	−0.31	1.00	−0.12	−0.18	−0.18	**−0.38**
Solubility	**−0.60**	0.08	**0.31**	**−0.32**	**−0.53**	−0.12	1.00	−0.15	−0.19	**0.36**
Digestibility	0.04	−0.18	−0.25	−0.07	0.14	−0.18	−0.15	1.00	−0.02	−0.08
Bio persistence	0.19	−0.20	**−0.37**	−0.13	0.20	−0.18	−0.19	−0.02	1.00	−0.02
Surface modification	−0.24	−0.08	−0.01	**−0.42**	−0.13	**−0.38**	**0.36**	−0.08	−0.02	1.00

Strong positive correlations (indicated in *bold*) are of particular interest as these indicate correlations in R-experts' thought processes regarding the criteria assessing the safety of the hypothetical nanotechnology-enabled food products caveat that it is almost impossible to test for potential biases routed from the framing of the task. Examples of high-risk category will be products containing engineered nanomaterials in high concentrations, e.g. fortified food or health-food products. Alternatively, products may contain a low concentration of engineered nanomaterials (e.g. migrating from food packaging, or resulting from a carryover of residues from agriculture) but could be consumed every day, e.g. water, bread, dairy products.

R-experts thought that physicochemical properties, e.g. digestibility, solubility, bio persistence and particle size as important factors in relation to the safety of particulate materials in food products. From the elicited ranking preferences, it can be inferred that soluble, digestible and non bio-persistent engineered nanomaterials with large particle sizes are considered as 'potentially safest' (Table 4). Whereas, insoluble, non-digestible and bio-persistent engineered nanomaterials with small particle sizes have been considered as 'potentially unsafe' (Table 4). Exposure descriptors, e.g. fraction of engineered nanomaterials in food intake, frequency of nano-food consumption, have also been considered as major factors in the safety of nano-applications in food products (Table 5).

External validation of the linear multi-criteria decision model we developed

Challenges encountered when defining products according to the model's criteria

Workshop participants in all ($n = 3$) breakout groups designed a number of hypothetical nanotechnology-enabled food products using the same criteria we took into account to develop our model (Table 6). All breakout groups followed a bottom-up approach to design the products, e.g. they considered 'potentially safe' or 'potentially unsafe' hypothetical nanotechnology-enabled food products which they then defined precisely according to the criteria of our model.

Although all breakout groups were able to define a number of products, the participants indicated that they encountered a number of challenges whilst applying this process:

- *Digestibility*: definition of digestibility criterion was considered as inadequate as it was not clear whether absorption was meant to be included in this criterion as well, or how digestibility was meant to relate with uptake.
- *Exposure*: workshop participants had to make assumptions regarding the population of exposure for their products, as the model did not accommodate for variability in susceptibility of individuals, due to age, ethnic groups, particular medical conditions, etc.
- *Primary particle size*: workshop participants noted that a linear change in the primary size of the particle is implied. Nevertheless, this is true only when considering materials in isolation, i.e. an artificial environment and is uncertain whether such a pattern is followed when a product is consumed.
- *Secondary particle size*: as agglomeration is dependent upon many variables (e.g. pH) when nanomaterials are present in the food matrix and in different regions of the gut, high uncertainties regarding the actual degree of aggregation of nanomaterials in vivo exist.
- *Solubility*: workshop participants assumed that the solubility criterion refers only to water solubility and does not relate to fat solubility.
- *Surface modification of a nanomaterial*: workshop participants needed to make assumptions for this criterion, as they thought that:
    - The surface modification of a nanomaterial could bear either beneficial or negative effects for the consumer.
    - Surface reactivity of a nanomaterial is not only always due to surface modification.

Predictive power of the model

The hypothetically designed products were scored by our model, and the ranks predicted by the model via scoring were compared with the ranking order of the products as thought by the workshop participants in each breakout group (Table 6).

The degree of external validation was less than perfect, but very substantial, although it varied according to the particular model fitting taken into account (Table 6). The model fitting assuming equal weights predicts correctly 6/12 of the rankings, whereas the highest level of agreement (rank order of 9/12 products correctly predicted) was achieved

Table 6 The table includes the hypothetical food products designed by workshop participants

	Description of the product	Score calculated by fitting the model on:							Ranking of products in terms of their safety by experts in breakout groups
		Potentially safe rankings		Potentially unsafe rankings		All rankings (potentially safe + potentially unsafe)		All ranks assuming equal weights for criteria	
		All	Most common (> 0.1)	All	Most common (> 0.1)	All	Most common (> 0.1)		
Group 1									
P1	Nano salt applied as a surface seasoning on crisps.	1	1	1	1	1	1	1	1
P2	ZnO in low-fat spreads as an antimicrobial agent.	2	2	2	2	2	2	2	2
P3	Food colouring; Al_2O_3 to provide blue colour in children's shakes.	3	3	4	4	4	3	4	3
P4	Nanopesticide as a residue on cereals.	4	4	3	3	3	4	3	4
Group 2									
P1	Milk processed to cause a fraction of the protein content to encapsulate the lactose, forming non-digestible nano-encapsulates that render the lactose non-bioavailable and so makes the milk suitable for lactose-intolerant individuals. The milk is unchanged in all other aspects.	2	2	2	2	2	2	2	3
P2	Skimmed (low-fat) milk processed in a way to change the fat droplets to become nano-sized and so make the milk have a more full-fat creamy mouth feel. The milk is unchanged in all other aspects.	1	1	1	1	1	1	1	1
P3	Vitamin D encapsulated in protein that is extracted from milk, and dispersed into soft drinks. The encapsulation makes the vitamin compatible with the drink but it is readily digested to liberate the vitamin in vivo.	4	5	5	4	5	5	5	2
P4	A nano form of iron that resists digestion but can be taken-up and then enter cells directly and then liberate iron, thus giving greater bioavailability. The application would aim to fortify breakfast cereals.	3	3	3	3	3	3	3	4
P5	Nano gold used to coat an ice cream and so colour it.	5	4	4	5	4	4	4	5

Table 6 continued

Description of the product	Score calculated by fitting the model on:							Ranking of products in terms of their safety by experts in breakout groups
	Potentially safe rankings		Potentially unsafe rankings		All rankings (potentially safe + potentially unsafe)		All ranks assuming equal weights for criteria	
	All	Most common (> 0.1)	All	Most common (> 0.1)	All	Most common (> 0.1)		
Group 3								
P1 Non-digestible nanolipid in sausage to suppress appetite; the application is non water soluble, non-digestible, and non bio-persistent.	2	2	2	2	2	2	2	2
P2 Nano TiO2 in cake icing and sweets. The application is non water soluble, non-digestible.	3	3	3	3	3	3	3	3
P3 Nano carotene in margarine.	1	1	1	1	1	1	1	1

Experts in each breakout group defined precisely the products according to the criteria employed to develop our multi-criteria decision model and decided the products' rank in terms of their safety (*shown in the last column*). Highlighted cells in the table indicate agreement of the rank order predicted by the model with the one decided by experts

when the model was fitted on the R-experts ranking preferences of products they considered as 'potentially safe'.

Regardless of the model fitting and the level of agreement though, the actual scores of the newly designed products from workshop participants were 'clumped' within a particular scoring range. As a result, the scores did not reflect fully the degree of safety as implanted in the designed products by participants. Most probably this happened because the model does not accommodate for particular aspects of the designed products that workshop participants took into account when designing 'potentially safe' and 'potentially unsafe' hypothetical products, for example, nano-pesticides and nano-applications for food for children.

Value of the approach

Overall, workshop participants agreed that the approach carries significant value for aiding the assessment of safety of nanotechnology-enabled food products. The particular multi-criteria decision model could serve as a screening or a first tier tool to distinguish products that could be considered as 'potentially safe' from the ones for which far more detailed risk assessment may be needed, provided that (i) avoidance of possible misuse or misapplication of the tool could be assured, and (ii) its predictive power refined and increased. This approach will be very helpful for the industry (especially small and medium enterprises) in making initial judgments about their future products which they intend to bring in the market.

On the other hand, workshop participants acknowledged that the approach is very novel, and they identified a number of shortcomings of the current version of the model that could be addressed when developing the model further:

- Participants thought that the criteria taken into account in our model signify a rather simplified picture of risk assessment of nanotechnology-enabled food products; these criteria need further refinement to address possible interactions with biological systems when nanomaterials remain insoluble, non-digested and are translocated out of the GI system.

- At the moment, the criteria do not include a link with the intrinsic hazard (e.g. toxicological profile, distinction between organic and inorganic nanomaterials and/or composite nanomaterials) or to the biological activity of the nanomaterial (i.e. purpose and mode of action of the nanomaterial); workshop participants agreed that both aspects should be addressed by further developed versions of the model. Once more, these questions would arise only for particular products, i.e. non-digestible, insoluble engineered nanomaterials that could be translocated out of the GI system.
- Exposure was thought to be best included as a single criterion, instead of the current three (i.e. fraction of diet, fraction of food, number of days consumed). Suggestions included (i) the replacement of fraction of diet and fraction of food with a criterion of intake (mg/kg/kg BW) and (ii) the removal of the criterion of the number of days consumed as one would not expect acutely toxic substances to be used in food products.
- The current version of the model does not accommodate for any dependencies and interrelationships among criteria. Nevertheless, the method has the ability to produce a number of model fittings that could take into account possible interrelationships, although the latter comes with the understanding that if a non-linear model is employed its value as a predictive tool would be substantially reduced.
- The need for building one or more decision making trees that would enable end users to re-weight criteria was highlighted (for example, to identify soluble, fully digestible products that would not translocate from the GI system in nano-form; the risk assessment of such products would be no different from the one followed if the products were conventionally produced).
- Accumulated risk due to cumulative consumption of a number of nanotechnology-enabled food products is not addressed in the current version of the model.

Reliability of the model

It should be noted that the data feeding into the model are of subjective nature, i.e. R-experts' ranking preferences. As the model is highly dependent on the elicited ranking preferences, predictably, any weaknesses of the method followed to elicit those would be reflected in the model's outputs and its feasibility as a decision making support tool. Workshop participants voiced particular questions, e.g. 'How reliable is the underlying data set?'; 'How reliable and knowledgeable were the R-experts involved?'; 'Were there any biases stemming from the selections of the R-experts?', 'Are the data obtained R-experts' preferences, opinions or prejudices?', 'Were all experts conservative thinkers?'.

The decisive factors for recruiting R-experts were: (i) experts' scientific excellence via their current research profile and publications in the field of nanotechnology in the food sector and (ii) experts' professional affiliation. We focused on inviting people from academia, regulatory agencies, not-for profit organizations and governmental research institutes to avoid possible conflicts of interest.

The issue of choosing reliable experts to provide answers to the questions in hand has been addressed numerous times in the past. Historically, processes to obtain expert judgement have been ad-hoc and hard to reproduce, particularly when consensus was reached by means of group discussions. In cases requiring expert opinion, high levels of uncertainty are typical, so the elicitation process should be transparent and must allow experts to state their true opinions without being (i) influenced by other participants and/or stakeholders and (ii) pre-judged by the risk analyst/assessor (Cooke 1991; Cooke and Goossens 2000).

Cooke (1991) has developed a structured expert opinion elicitation method that allows for expert calibration against a set of variables, i.e. quantities they should know something about therefore they lie within their expertise (namely, seed variables); whether this calibration method is applicable in our case or not remains an open question. The multi-criteria decision method we followed in this study allows testing for consistency in the experts' ranking preferences, therefore identifying the ones whose answers are random. We have not tested R-experts' consistency in this study, but if further versions of the model will be developed we plan to do so. However, for the moment, the method does not provide an option for either assessing rigorously experts' knowledge or ability to convey uncertainty.

Currently, it is recognized that existing knowledge on toxicity and exposure aspects of nanotechnology-enabled food products is extremely limited, and that inevitably, experts are extrapolating from a very small set of toxicity and/or exposure data. Workshop participants took into account the fact that the criteria involved in our study span over a wide range of expertise and voiced questions regarding the equal ability of R-experts in weighing all criteria included. A possible way to address this issue in future versions of the model would be to allow experts to declare primary areas of expertise and provide a number of model fittings per expertise. The latter, however, would require the participation of high number of experts per expertise.

Conclusions and a possible way forward

Nanotechnology-enabled products are being developed already, and most probably this development will expand exponentially in the coming years. Currently, a lot of work is undertaken internationally on methods to determine a maximum daily intake of engineered nanomaterials in food products (for a list of organizations and efforts related to nanotechnology see Tsytsikova 2009); however, results of these efforts are not due until quite later. In the meantime, it has been widely accepted and disseminated that the problem in hand, i.e. risk assessment of nanotechnology-enabled food products, appears to be currently difficult due to lack of appropriate data to assess potential hazard and exposure.

The application of a precautionary principle as a political and/or a legal framework for controlling the introduction of new nanotechnologies applications in the market is a possibility. The precautionary principle is always appropriate as one option of risk management; the question is how precautionary or non-precautionary one should be. One should be careful when setting these limits as an over precautionary approach could halt the development of potentially beneficial applications, and it would not provide any direction towards further needed research (Davis 2007).

It is our view that, although many applications can be considered as nano-applications in the food sector, they can be very different in many aspects of their development, and consequently it is expected that their risk assessment should be different. Our work demonstrated that it has the potential to (i) distinguish among different nano-applications for the food sector in terms of their safety and risk assessment and (ii) predict reliably in which category experts in the field would place a newly developed product.

We think that the model we developed is a coherent and transparent way to capture and demonstrate current expert knowledge about the relative safety of different hypothetical nanotechnology-enabled food products. The uncertainty of experts regarding the safety of the hypothetical products is inevitably embedded in the individual rankings; the lower the ranking of a product the higher the uncertainty about its safety. The value of employing a structured approach to elicit and capture expert judgment including experts' uncertainty was considered by workshop participants as high, provided that any model developed would be reliable, and that end users would be appropriately trained to understand the requirements, limitations and constraints of the model. The development of nanotechnology-enabled food products is recognized as a rapidly changing area of science; as more data accumulate experts' knowledge is expected to be enriched, and their uncertainties are expected to be reduced. Consequently, it would be expected that experts' ranking preferences would change to incorporate newly gained information; workshop participants proposed that for the foreseen future, such a model should be updated periodically in order to be considered reliable.

That taken into account, workshop participants thought that the ultimate validation of this model would be realized via real-life examples; e.g. will the rankings produced by the model agree with the rankings from risk evaluations of products? As real-life examples surface they could be applied as well to update the model. Workshop participants agreed that a feasible way to minimize uncertainties regarding 'nano-specific' risks would be in vivo animal testing.

Our model is developed on 10 criteria which were thought of as the most important to take into account when assessing the risk of nanotechnology-enabled food products. Since our model is linear, any interrelations and interdependencies between the criteria were not taken into account. In this sense, one needs to be quite careful when interpreting the results. Further steps regarding the development of the model would involve (i) refining criteria in order to ameliorate the model's performance when predicting the safety of products and (ii) the development of non-linear modelling with the view to capturing such interdependencies and/or building decision making trees.

The report from House of Lords Scientific Committee on nanotechnologies and food (2010) highlights the need for transparency and effective public communication to ensure that consumers and policy makers are able to make informed decisions regarding the use of nanotechnologies in the food sector. Hopefully our work will assist in raising awareness on the applicability of structured expert opinion elicitation methodologies to capture experts' current knowledge and uncertainties, and in encouraging further interdisciplinary collaboration for developing scientifically robust risk assessment schemes in areas governed by large gaps of knowledge and high uncertainties.

This exercise has shown that application of a multi-criteria decision model is useful to capture expert judgment on this issue and can be developed further to be used as a decision support tool. Furthermore, it is anticipated that the development of robust decision support tools will help in promoting the harmonization of risk assessment approaches of nanotechnology-enabled food products at a global scale, and facilitating the implementation of life-cycle risk analyses when developing nanomaterial based or nanotechnology-enabled products.

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