

## Rapid risk assessment: what is the risk to consumers from consumption of the seven edible insects' products currently available in the UK market?

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## 1. Executive Summary

This rapid risk assessment considers the risk in terms of allergy and microbial and heavy metal contamination to UK consumers by exposure to edible insects.

Based on the cross-reactivity between edible insects' protein with shellfish (particularly crustaceans) and mites, the exposure assessments of EFSA, and assuming that the correct labelling methods are in place to account for this cross reactivity as well as potential traces of other known food allergens (e.g. soya, wheat) from insect feed, we estimate:

- the frequency of allergic reactions to edible insects in the general population to be very low (very rare but cannot be excluded) as long as products are correctly labelled
- the severity of illness reported by consumers in relation to allergic reactions to edible insects is generally low (mild illness, not usually life-threatening, normally short duration, symptoms are self-limiting).
- however, a smaller subset of individuals with strong allergic reactions to shellfish (particularly crustaceans) and mites, the severity of illness has the potential of being high (may cause anaphylactic shock). Consumers with high reactivity to shellfish crustaceans are expected to minimise their exposure to food if appropriate labelling is in place.
- the level of uncertainty for cross-reactivity between insect and shellfish/mite allergens is low (strong evidence is provided in multiple references)
- the level of uncertainty for de-novo sensitisation to edible insect protein is medium (there are some but no complete data available)

Based on data from the literature and on the exposure assessments made by EFSA, and assuming that the measures for control are in place for the insect feed, rearing, and edible insect product, we estimate that:

• the frequency of exposure to harmful microorganisms or heavy metals to be very low (very rare but cannot be excluded).

- the severity of illness from exposure to edible insects contaminated with harmful microorganisms or heavy metals to be low (mild illness, not usually life-threatening, normally short duration, symptoms are self-limiting). Severity of illness from acute exposure to Salmonella and other highly pathogenic microorganisms can vary from asymptomatic to requiring hospitalisation in severe cases.
- the level of uncertainty for exposure to edible insects contaminated with harmful microorganisms or heavy metals to be low (strong evidence is provided in multiple references).

## 2. Statement of purpose

This rapid risk assessment focuses on defining the level of risk to UK consumers from consumption of edible insects currently placed in the market.

A full exposure assessment has not been carried out, as currently there is not enough consumption data of edible insects in the UK. The estimated risk levels assume that the appropriate methods to control exposure and to reduce microbial and chemical contaminants have been applied to the foods (e.g. heat treatment, rearing substrate screening, labelling).

The rapid risk assessment is largely based on a previous risk profile produced by the FSA, continuing the risk profile of EFSA from 2015 on edible insects, as well as recent EFSA opinions published for Acheta domesticus (house cricket), Tenebrio molitor (yellow mealworm) and Locusta migratoria (migratory locust) as a novel food.

## 3. Background

The complex picture on the status of edible insects in Great Britain resulting from retained EU law has led to industry uncertainty, as a consequence of which FSA has reviewed its policy options and identified a preferred solution.

Currently, it is probable that a variety of products (whole and processed) from seven insect species remain in scope of the transitional measures. These measures allowed a product which had been placed lawfully on the market by 1 January 2018, where the product fell within the scope of 2015/2283, to continue to be marketed until an authorisation decision was made by the EC, provided a submission for authorisation was made by the deadline of the 2nd of January 2020 (later moved back to the 1st of January 2019). The seven insect species are:

- Alphitobius diaperinus (lesser mealworm)
- Acheta domesticus (house cricket)
- Tenebrio molitor (yellow mealworm)
- Gryllodes sigillatus (banded cricket)
- Schistocerca gregaria (desert locust)
- Locusta migratoria (migratory locust)
- Hermetia illucens (black soldier fly)

In order to inform proposed policy options, the FSA has been asked to provide an assessment on what is the likely level of risk to UK consumers from the presence of edible insect products from these seven species in the market for a temporary period.

## 4. Hazard identification

Several hazards were considered for the risk assessment of edible insects as a novel food, including potential physical hazards, metabolisation and toxicity of the food, nutritional

considerations, presence of undesirable substances and allergenic potential of the food. These form the basis of all novel food regulated products' safety assessments. To inform the focus of this risk assessment, previous risk profiles carried out by EFSA and FSA, as well as recent EFSA opinions on four edible insect products were consulted.

Physical hazards relate to particularly hard or large parts of the insect's body, which can be managed through direct removal of these parts. Metabolic and toxicological considerations from the insect as food (rather than cross contamination with other contaminants) was evaluated in the 2021 EFSA opinions, in which no cause for concern was raised by the Panel (EFSA NDA Panel 2021a,b,c,d). In these opinions, only three out of the seven species listed above were evaluated (yellow mealworm, migratory locust and house cricket).

The FSA risk profile of 2020 evaluated the potential risks to consumers from a nutritional standpoint (FSA 2020). Edible insects (particularly larvae) can show composition variability depending on the insect species and the nutritional profile of the feed they are reared on. However, this was not considered to be a cause for concern by the ACNFP in their evaluation of the risk profile.

The presence of undesirable substances in edible insects' products has been extensively reported, and considered a cause for concern by EFSA and FSA, if the risk is not managed appropriately. The EFSA and FSA risk profiles concluded that the risk of pesticide accumulation, and the presence of parasites, viruses and prions, are not a main cause for concern. While some cross-contamination may occur, the literature has not consistently shown bioaccumulation of pesticides by edible insects from the feed. The scientific literature concluded that parasites, viruses and prions that may affect the insects do not have the potential to infect humans, unless cross-contamination occurs. The literature showed that edible insects have a low capability of accumulating mycotoxins, however there is a knowledge gap regarding the metabolism of mycotoxins in the insect, or the potential for mycotoxin-producing organisms to proliferate and contaminate the final product. The EFSA and FSA risk profiles identified microbial contamination and heavy metal contamination as the main causes for concern when evaluating the safety of edible insects, as they have a high capability of accumulating these contaminants from the feed.

In both risk profiles, the literature proved conclusive on the allergenic potential of edible insects, as well as the cross-reactivity with allergy to crustaceans and mites.

Based on the existing evidence, this risk assessment focused on evaluating the risk to consumers of allergenicity, microbial and heavy metal contamination of edible insects' products.

#### 4.1 Allergenicity to edible insects

Food allergy involves an adverse immune reaction triggered by normally harmless protein antigens in food. In the UK there are 14 main types of food or food groups that are recognised as allergenic foods of public health importance and therefore regulated (celery, cereals containing gluten, crustaceans, eggs, fish, lupin, milk, molluscs, mustard, nuts, peanuts, sesame seeds, soya and sulphur dioxide). These 14 must be labelled on food and they make up the majority of foods that people may experience an allergic reaction to. Edible insects are not included in the list of 14 allergens. One of the main characteristics of typical insect-based food is their high content in protein, and hence, there is a risk that some of these proteins act as allergens for the consumer.

There are two components to the allergenicity hazard of edible insects to consumers:

- cross-reactivity between shellfish (crustaceans and molluscs) or mites and edible insects
- de-novo sensitisation to insect protein.

Cross reactivity between shellfish (crustaceans and molluscs) and mites, and edible insects has been extensively reported in the literature (FSA 2020, EFSA 2015, EFSA NDA Panel 2021a,b,c,d), identifying tropomyosin, arginine kinase, larval cuticle proteins and paramyosin, acting as the major cross-reacting allergenic proteins (Ribeiro et al., 2018, Zhao et al., 2015, Broekman et al., 2017, Barre et al., 2019). The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) in their risk assessments of three edible insect species flagged that the substrate used to rear the insects could impact the allergenicity profile of the novel food, exemplifying how a substrate containing known allergens could signify the final insect product containing traces of said allergen (EFSA NDA Panel 2021a,b,c,d).

#### 4.2 Microbial and heavy metal contamination of edible insects

The presence of microorganisms in ingredients, their introduction via cross- contamination during harvesting or preparation, post-process contamination, inadequate cooking of the food and/or the improper treatment and storage of products, affect the number and type of microorganisms present in food products at the point of purchase. Such microorganisms may themselves be pathogenic to consumers (FSA, 2020).

The most common indicators of microbiological contamination of food include, amongst others, counts of mesophilic aerobes, Enterobacteriaceae, Escherichia coli (including pathogenic E. coli or STEC), Salmonella and Listeria monocytogenes (HPA, 2009). Maximum microorganism count levels for different types of insect product have not been yet specified in legislation. In edible insects' products classified as ready to eat food, established maximum count levels would apply as established in Regulation (EC) No 2073/2005.

The FSA and EFSA risk profiles of 2020 and 2015 respectively identified large variability in microbial profile between different insect species, companies and even batches of products. Parasites, virus and prions were not identified as being cause for concern as long as no cross-contamination occurs throughout the rearing and food production process (FSA 2020, EFSA 2015).

Toxic chemicals may accumulate in edible insects from the substrate they feed on or by direct contact with contaminants during rearing. These chemicals can also form through the processing of the insects after harvesting, although there is a significant knowledge gap in the literature concerning this topic.

Evidence from EFSA and FSA's risk profiles showed that heavy metals (particularly cadmium and arsenic) are very likely to accumulate in edible insects when fed contaminated substrates. The accumulation potential is also species dependent. The bioaccumulation of mycotoxins and pesticides is possible, but the scientific evidence is contradictory, showing the existence of a knowledge gap.

## 5. Hazard characterisation

#### 5.1 Food uses of edible insects in the UK

There is a general lack of data and information on the edible insect market in the UK. In 2018, the UK represented about 8% of the EU's edible insect and insect protein market and had an estimated market revenue of £3.34 million per year in 2021 prices (Research and Markets 2018). In 2020, the International Platform of Insects for Food and Feed (IPIFF) forecast that UK edible insect firms would produce around 40 tonnes of product in 2021 (IPIFF, 2020).

The Woven Network, a platform that includes over 25 edible insects' companies operating in the UK, presented to the FSA Board a list of 36 products currently sold in the UK. These are whole or

powdered dried insects, sold on their own or forming part of protein bars, pasta, cookies and food for sporting people. The two main edible insect species described in the document were A. domesticus and *T. molitor. Alphitobius diaperinus* was the basis of 3 out of 36 products described (Woven Network 2021).

#### 5.2 Prevalence of insect protein allergy

Historically there have been reports of allergic reactions to the consumption of insects and the cross-reactivity between mealworm and crustaceans has been repeatedly confirmed. However, the exact mechanism and potential for both cross-reactivity and de novo sensitisation to insect proteins is still an area with a lot of unknowns (EFSA, 2015).

There is very strong evidence of the high risk of patients allergic to shellfish experiencing crossreactivity with edible insects. Shellfish (crustaceans and molluscs) are part of the 14 named allergens that require precautionary labelling in the UK, but the exact prevalence of shellfish allergy in the UK is difficult to determine and varies depending on the sector of the population studied. Several systematic reviews have estimated prevalence values for shellfish at the European and Global scale. The estimated prevalence for shellfish allergy in Europe was 1.3% for self-reported based studies and 0.1% in food- challenge based studies (Nwaru et al., 2014). At the global level, shellfish allergy reported prevalence varied from 0% to 10.3%, where food challenges showed prevalence between 0% and 0.9% (Moonesinghe et al., 2016).

Cross reactivity between shellfish (crustaceans and molluscs) and mites, and edible insects has been extensively reported in the literature (FSA 2020, EFSA 2015, EFSA NDA Panel 2021a,b,c,d). This phenomenon is expected to be occur similarly in the UK population.

De-novo sensitisation to any protein source is a possibility, and edible insect protein is no different in this regard. Several examples of de-novo sensitisation have been reported in the literature of allergenic responses to edible insects, either through long-term occupational exposure (Broekman et al., 2017), inhalation (de Gier et al., 2018) or first-time ingestion (Gautreau et al., 2017). It is expected that more knowledge of de-novo sensitisation potential will be acquired as new cases appear after the introduction of insects in the diet of UK consumers (Barre et al., 2019).

#### 5.3 Severity of insect protein allergy

The data in the literature on symptoms caused by edible insect protein allergy is very limited. Symptoms reported included general urticaria, oral allergy, flushed and dry skin, and increased heart rate. We are not aware of reports of severe illness associated with edible insects in the UK.

An FSA-funded NHS data project examined data relating to hospital admissions for anaphylaxis and deaths in the UK during a 20-year period from 1998-2018. In total, 152 deaths were identified where the fatal event was probably caused by food induced anaphylaxis; out of these, 7% (11 adults) and 6% (9 children) corresponded to the category 'fish and crustaceans'. There were no reports of hospital admissions or anaphylaxis due to edible insects' consumption reported in the paper although we cannot account for the 'other' (9%/14 adults and 5%/8 children) or 'unknown' (26%/40 adults and 29%/44 children) food categories (Baseggio Conrado et al., 2020).

#### 5.4 Methods to control exposure: allergen

The methods to control exposure listed here are assumed to be in place, in line with labelling and food hygiene regulations, when characterising the risk in section 7 of this risk assessment. Understanding the conditions of the feed with which insects are reared is necessary, to avoid cross-contamination of known allergens present in the insect feed that may remain in the final

edible insect product.

- in order to limit exposure to allergens that may induce cross-reactivity with shellfish and mites' allergens, appropriate labelling of the food is necessary.
- in order to limit exposure to known allergens that may be present in the food as a consequence of the allergen being present in the feed of the insects, labelling describing it may contain traces of said known allergens is necessary.

#### 5.5 Presence of insect microbial and heavy metal contamination

There is no data on the microbial contamination of edible insects' products available in the UK market, due to the limited amount of time that these have been on the shelves. Through evaluation of RASFF data, no incidents related to microbial contamination of edible insects have been reported in the UK to our knowledge.

There are still numerous knowledge gaps regarding the precise identification of the microbial profile of edible insects. The FSA risk profile identified several studies reporting levels of different bacteria, yeasts and moulds, showing a significant reduction in microbial levels when the insects were boiled, blanched, dried at high temperatures for several minutes or freeze-dried. Several studies in the literature evaluated the presence of highly pathogenic microorganisms such as Salmonella, Listeria monocytogenes and Escherichia coli in edible insects, but no positive results were reported (FSA 2020). It was also reported that spores and spore-forming bacteria may be capable of surviving certain processing methods, and that specific heat treatments are required to reduce the concentration of spores (Grabowski et al. 2016). According to a systematic review by Garofalo et al. (2019), no outbreaks have been described in the literature due to any highly pathogenic bacteria.

In the four EFSA opinions on Acheta domesticus, Tenebrio molitor and Locusta migratoria, levels of aerobic colony counts, Enterobacteriaceae, E. coli, L monocytogenes, Salmonella, B. cereus, Staphylococcus, yeasts and moulds reported through batch testing of the products were low enough to not raise safety concerns (EFSA NDA Panel 2021a,b,c,d).

There is no data on the heavy metal contamination of edible insects' products available in the UK market, due to the limited amount of time that these have been on the shelves. Through evaluation of RASFF data, no incidents related to heavy metal contamination of edible insects have been reported in the UK to our knowledge.

The reviewed data on the capacity of edible insects to bioaccumulate toxic compounds varies between species, chemicals and stages of development. Evidence suggests that insects have a higher tendency to accumulate heavy metals, particularly cadmium and arsenic than any other type of toxic compound. The literature reports a low capacity of larvae of edible insects to accumulate mycotoxins (FSA 2020).

In the four EFSA opinions on Acheta domesticus, Tenebrio molitor and Locusta migratoria, levels of lead and cadmium reported through batch testing of the products were low enough to not raise safety concerns (EFSA NDA Panel 2021a,b,c,d).

#### 5.6 Severity of insect microbial and heavy metal contamination

Consumption of food contaminated with highly pathogenic microorganisms can produce illness in humans, with varied symptoms that range from very mild to severe (general discomfort, abdominal pain, vomiting, diarrhoea, high fever) and generally present themselves acutely a few hours or days after consumption of the food (HPA 2009). High levels of aerobic counts, lactic acid bacteria, yeasts and moulds are generally associated with food spoilage and unfit for

consumption. The severity of impact of disease depends on the pathogen, dose and hostdependent factors (HPA 2009).

Data from the literature and from four EFSA opinions on edible insect products did not reveal a concerning concentration of highly pathogenic microorganisms. There have been no reports of hospital admissions or outbreaks caused by contamination of edible insects' products with pathogenic microorganisms (EFSA NDA Panel 2021a,b,c,d).

Absorption of ingested lead may constitute a serious risk to public health. Chronic effects of lead poisoning include colic, constipation and anaemia, increased blood pressure and cardiovascular disease. Neuro-developmental effects and reduced learning capacity are among the most serious effects in children (Wani 2015).

Cadmium accumulates primarily in the kidneys and may induce kidney dysfunction, skeletal changes and reproductive deficiencies. In 1993 International Agency for Research on Cancer (IARC) classified cadmium and cadmium compounds in Group I - Human Carcinogens (IARC 2022).

Data from the literature and from four EFSA opinions on edible insect products did not reveal a concerning concentration of heavy metals. There have been no reports of hospital admissions or outbreaks caused by contamination of edible insects' products with heavy metals (EFSA NDA Panel 2021a,b,c,d).

#### 5.7 Methods to control exposure: microbial and heavy metal contamination

The methods to control exposure listed here are assumed to be in place, in line with labelling and food hygiene regulations, when characterising the risk in section 7 of this risk assessment. In both cases, understanding the conditions of the feed with which insects are reared is necessary, to avoid cross-contamination of microorganisms and heavy metals present in the insect feed that may remain in the final edible insect product.

- in order to limit exposure to microbial contaminants, rearing the insects under legalcompliant hygiene conditions is required. This includes the presence of HACCP protocols that lower pathogen microbial levels and to avoid cross-contamination
- in order to lower microbial counts, freezing, boiling, blanching, or drying at high temperatures over several minutes has been demonstrated to reduce microbial contamination significantly. Submitting the edible insect product to some form of effective thermal treatment is required if a safe level of microbial counts is to be achieved and will ideally take place during the production process of the food.

For ground insect products, a further cooking step is recommended prior to consumption. HACCP protocol procedures should be in place to ensure no cross-contamination occurs throughout the production and packaging process.

• in order to limit concentration of microorganisms and heavy metals in the final edible insect product, the animals should be reared with non-contaminated feed, which should meet the legal hygiene requirements of food.

## 6. Exposure assessment

There is almost no data available regarding consumption data of edible insects in the UK. The FSA carried out a survey of consumer perceptions of alternative or novel sources of protein in England, Wales and Northern Ireland, between 8th-11th December 2021. Around 50% of respondents considered edible insects to be safe, 26% were willing to try edible insects. 60% of

respondents reported unwillingness to try them as whole insects, whereas 37% were willing to try them as ground food added to other foods.

In third countries, consumption of edible insects has been common practice for generations. Consumption of L. migratoria has been widely reported in Madagascar, Cameroun, Congo, Zimbabwe, Sudan, South Sudan, Papua New Guinea, Thailand, China and Morocco. In the EU, L. migratoria has been in the Swiss market since 2017 and in the Dutch market since 2016, as whole foods or added to other food products (EFSA NDA Panel 2021c). Consumption of T. molitor has been reported in Thailand, China and Mexico, and the food is available in Australia, New Zealand and Switzerland, whole or as part of other food products (EFSA NDA Panel 2021a,d). Acheta domesticus consumption has been documented in Thailand, Lao PDR, Cambodia, Ghana and Mexico. It is also marketed in Australia, New Zealand, Switzerland, Canada and the US, as a whole food or added to other products (EFSA NDA Panel 2021b).

The four EFSA opinions published in 2021 produced an intake estimate of four edible insect products:

Edible insect product	Infants	Young children	Other children	Adolescents	Adults
L. migratoria	0-110	27-524	65-356	22-226	67-197
A. domesticus	4-121	47-416	39-249	21-130	53-124
T. molitor dried	0-77	10-216	1-248	0-104	1-40
T. molitor frozen	9-179	81-651	71-580	41-248	34-359

#### Mean intake (mg/kg bw per day)

For all estimates, the EFSA panel concluded that consumption of the novel foods under the proposed use would not contribute significantly to the exposure to undesirable substances, such as microorganisms and heavy metals (EFSA NDA Panel 2021a,b,c,d).

#### 6.1 Exposure assessment limitations

There is no exposure data of edible insect products from the UK. Estimates produced by EFSA in their opinions can be extrapolated to the UK population with an acceptable degree of confidence, but these only cover three insect species in four different conditions of use.

No exposure assessment data is available for Alphitobius diaperinus larvae, Gryllodes sigillatus, Schistocerca gregaria or Hermetia illucens, although it is expected that similarities will apply between certain species, under the same conditions of use: T. molitor and A. diaperinus; G. sigillatus and A. domesticus; L. migratoria and S. gregaria.

Regulators cannot predict how well people will cook edible insects' products at home. Therefore, treating edible insect products either through freeze-drying or a heat-induced treatment is preferred to be carried out during the production process.

It is impossible to accurately estimate the allergenicity pattern of de-novo sensitisation to edible insects' products in the UK. It is expected to increase with higher levels of exposure, like with any newly introduced proteinaceous food. Reports of new cases will have to be monitored.

## 7. Risk characterisation

In this risk assessment, we used the qualitative scales for the frequency of occurrence and severity of foodborne risks and level of associated uncertainty that is described in the multidimensional risk assessment framework outlined by the Advisory Committee on the

Microbiological Safety of Food (ACMSF 2020), as described in Annex I.

#### 7.1 Allergenicity

Based on the cross-reactivity between edible insects' protein with shellfish and mites, the exposure assessments of EFSA, and assuming that the correct labelling methods are in place to account for this cross reactivity as well as potential traces of other allergens from insect feed, we estimate:

- the frequency of allergic reactions to edible insects to be very low (very rare but cannot be excluded)
- the severity of illness reported in relation to allergic reactions to edible insects is generally low (mild illness, not usually life-threatening, normally short duration, symptoms are selflimiting). In individuals with strong allergic reactions to shellfish (particularly crustaceans) and mites, the severity of illness has the potential of being high (may cause anaphylactic shock)
- the level of uncertainty for cross-reactivity between insect and shellfish/mite allergens is low (strong evidence is provided in multiple references)
- the level of uncertainty for de-novo sensitisation to edible insect protein is medium (there are some but no complete data available)

Note that the estimates given above would be significantly higher level if the measures to control exposure (labelling) were not in place.

#### 7.2 Microbial and heavy metal contamination

Based on data from the literature and on the exposure assessments made by EFSA, and assuming that the measures for control are in place for the insect feed, rearing, and edible insect product, we estimate that:

- the frequency of exposure to harmful microorganisms or heavy metals to be very low (very rare but cannot be excluded)
- the severity of illness from exposure to edible insects contaminated with harmful microorganisms or heavy metals to be low (mild illness, not usually life-threatening, normally short duration, symptoms are self-limiting). Severity of illness from acute exposure to Salmonella and other highly pathogenic microorganisms can vary from asymptomatic to requiring hospitalisation in severe cases
- the level of uncertainty for exposure to edible insects contaminated with harmful microorganisms or heavy metals to be low (strong evidence is provided in multiple references).

Note that the estimates given above would be significantly higher level if the measures to control exposure (process control) were not in place.

## 8. Key sources of uncertainty

- the knowledge of consumers about the risks of cross-reactivity between edible insects and shellfish, for example, whether consumers with an allergy to shellfish would be aware of the risks of consuming edible insects
- the pattern of de-novo sensitisation that the UK population will develop through exposure to edible insects.
- the ability of the FSA to enforce that all products currently in the market adhere to the exposure control measures listed above.

- the full microbial profile of edible insects.
- the lack of data of continuous exposure to edible insects in the UK population.
- the quantity and quality of consumer education on the risks of consuming edible insects.
- the risks associated with all seven species listed, understanding that some species have been more researched than others, and it is known that there are relevant existing differences in microbial profiles and accumulation potential between species.
- the fact there are no maximum microorganism count levels for different types of insect product specified in legislation
- the knowledge gap regarding bioaccumulation of mycotoxins and pesticides in different edible insects' species

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# Annex I: Interpretation of probability categories used in this risk assessment

(Tables from ACMSF (ACM/1065) adapted from EFSA 2016 modified from OIE 2004).

Frequency category	Interpretation
Negligible	So rare that it does not merit to be considered
Very low	Very rare but cannot be excluded
Low	Rare but does occur
Medium	Occurs regularly
High	Occurs very often
Very high	Events occur almost certainly

Severity category	Interpretation	
Negligible	No effects, or so mild they do not merit to be considered	
Low	Mild illness: not usually life threatening, usually no sequelae, normally of short duration, symptoms are self-limiting (for example, transient diarrhoea)	
Medium	Moderate illness: incapacitating but not usually life threatening, sequelae rare, moderate duration (for example, diarrhoea requiring hospitalisation)	
High	Severe illness: causing life threatening or substantial sequelae or illness of long duration (for example, chronic hepatitis)	

Uncertainty category	Interpretation	
Low	There are solid and complete data available; strong evidence is provided in multiple references; authors report similar conclusions	
Medium	There are some but no complete data available; evidence is provided in small number of references; authors report conclusions that vary from one another	
High	There are scarce or no data; evidence is not provided in references but rather in unpublished reports or based on observations, or personal communication; authors report conclusions that vary considerably between them	