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General Interest

Risk Assessment or Assessment of Risk? Developing an Evidence-Based Approach for Primary Producers of Leafy Vegetables To Assess and Manage Microbial Risks

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ABSTRACT

Over the last 10 years, some high-profile foodborne illness outbreaks have been linked to the consumption of leafy greens. Growers are required to complete microbiological risk assessments (RAs) for the production of leafy crops supplied either to retail or for further processing. These RAs are based primarily on qualitative judgements of hazard and risks at various stages in the production process but lack many of the steps defined for quantitative microbiological RAs by the Codex Alimentarius Commission. This article is based on the discussions of an industry expert group and proposes a grower RA approach based on a structured qualitative assessment, which requires all decisions to be based on evidence and a framework for describing the decision process that can be challenged and defended within the supply chain. In addition, this article highlights the need for evidence to be more easily available and accessible to primary producers and identifies the need to develop hygiene criteria to aid validation of proposed interventions.

Key words: Food safety; Leafy vegetables; Qualitative risk assessment; Quantitative risk assessment

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Consumption of fresh fruits and vegetables is associated with a healthy diet because these foods are important sources of vitamins, minerals, and biochemical cofactors. In recent years, some high-profile foodborne illness outbreaks (FIOs) have been traced back to fresh produce *(10)*. These FIOs can be large, with fresh produce accounting for 10% of FIOs in the European Union from 2007 to 2011, 26% of individual illness cases, 35% of hospitalizations, and 46% of deaths *(10)*. The challenge for ensuring safe produce is greatest for those crops that are eaten uncooked, such as leafy salad vegetables. Even low levels of pathogens on these products could result in a considerable disease burden. Verhoeff-Bakkenes et al. *(38)* estimated that the exposure to *Campylobacter* through vegetables and fruit in The Netherlands was 0.0048 CFU/day (approximately 1.7 CFU per person per year), but this level of exposure could still result in about 30,000 illness cases per million people. In minimally processed produce (e.g., fresh cut) such as chopped lettuce, it is difficult to achieve a significant reduction in microbial load through produce washing *(37)*. An estimated 0.5- to 2-log reduction in naturally present microflora is the best that can be expected from most produce washing systems *(2, 29)*, and even in such systems planktonic contaminants in the wash water may cross-contaminate other clean produce entering the system. The best approach is to ensure that introduction of microbial contamination during primary production is minimized or eliminated; produce washing or disinfection should not be relied on as the main hazard control measure *(14)*.

The starting point for managing the risk of microbiological hazards in fresh produce is an understanding that complete elimination of microbial hazards from field produce is impossible because these products are grown in a field environment *(6)*. Consequently, production standards have been developed that follow the principles of hazard analysis and critical control point (HACCP) systems and apply a systems-based approach to managing food safety *(14, 19)*. Growers are required by many customers to adhere to a quality assurance scheme (QAS), either an industry-wide QAS such as GlobalG.A.P. *(15)* or a customer-specific QAS such as McDonald's good agricultural practices (GAP) guidelines *(22)*. A key aspect of these QASs is the requirement for growers to undertake risk assessments (RAs) throughout the crop production cycle, i.e., field history, water sources, animal manures, and worker hygiene. These assessments are then used to define preventive actions to reduce the risk of biological contamination of the crop and can be independently audited *(27)*. However, the term "risk assessment" can lead to confusion because it is applied

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to both a scientific process consisting of formal components and quantification of levels of risk as outlined by the Codex Alimentarius Commission (CAC) *(4)* and a more general, qualitative approach based more on expert opinion and experience as required by GAP, e.g., GlobalG.A.P. *(15)*.

An expert group was convened in 2014 to discuss the application of microbial RAs in primary production (i.e., by growers) of fresh produce that is usually eaten raw, with particular emphasis on leafy greens entering both the retail and processing supply chains. This article was written based on these group discussions and is intended for those working within the food production chain, including regulatory agencies, and for academics who work in the area of microbiological risk management for primary crop production. The article includes a brief discussion of the contrast between the steps involved in RA as defined by the CAC and those steps commonly involved in RA as understood by primary producers in compliance with QASs. Three scenario examples are given to outline the steps needed to complete a grower RA (GRA) of microbiological hazards, justified with evidence, that can be used for fresh produce that is usually eaten raw.

Whole head lettuce is a field grown crop that can be eaten raw and has been associated with FIOs in various countries *(10)*. Lettuces are often grown from transplanted young plants (although some crops may be raised from seed), and the time from transplanting to maturity is 6 to 8 weeks *(32)*. The high water content needed for mature lettuce heads (~95%) means that crops are commonly irrigated. Lettuce is harvested by hand by cutting with a knife, and heads are either collected in field crates for packing in a packinghouse or processing at a factory or are packed in retail packaging in the field with mobile packing rigs *(24)*. Lettuce is eaten raw or may be minimally processed as a sliced or shredded product for sale as a ready-to-eat ingredient.

During a field growing season, any foodborne pathogens present will encounter variable environmental conditions such as UV radiation *(18)*, humidity *(8)*, and temperature *(14, 16)* that affect their persistence, particularly on leaf and soil surfaces. Quantitative microbial RAs have been developed to study the prevalence of *Escherichia coli* O157:H7 *(23)*, *Salmonella (23, 30)*, and *Listeria monocytogenes (7)* in leafy greens. These approaches provide information that can help policymakers and researchers develop better food safety management systems for crop production. However, quantitative microbial RAs are very difficult to develop at the primary producer level because the necessary data are not available because of limited testing abilities and the low prevalence of foodborne pathogens in the production environment *(3, 23)*. Thus, qualitative RAs are utilized at the primary production level.

RA OR ASSESSMENT OF RISK FOR PRIMARY PRODUCERS

A number of RAs are required by QASs and GAP to be completed by growers covering contamination hazards, including those relating to microbial food safety as part of a risk management process. However, the structure of RAs in QASs differs from that defined by the CAC as "a scientifically based process consisting of four steps: hazard identification, hazard characterization, exposure assessment and risk characterization" *(4)*. For example, GlobalG.A.P. Annex AF1 *(15)* defines the five steps for RAs as: (i) identify the hazards, (ii) decide who or what might be harmed and how, (iii) evaluate the risks and decide on precautions, (iv) record the work plan and findings and implement them, and (v) review the assessment and update if necessary. This approach is widely followed by QASs. However, this structure does not satisfy the CAC definition of an RA *(4)*. Hazard identification (ID) is undertaken at a superficial level, where relative hazards are not considered between different species, e.g., verotoxigenic *E. coli* versus *Salmonella (15)*. Exposure assessment considers the consumer exposure to microbial hazards in a very limited way; in essence the growers address this question: is it probable or possible that any microbial contamination on the product could lead to illness in a consumer? Because hazards have not been identified at a species level and subsequent domestic processing steps may not be known, growers cannot estimate the level or likelihood of the occurrence of microbial hazards in the produce at the time of consumption. Generally speaking, neither hazard characterization nor risk characterization are conducted at the grower level but rather are addressed by food safety enforcement agencies (i.e., governmental agencies) *(12)* and developed by academics and researchers.

Clearly, the process followed by growers does not entail a "true" RA as defined by the CAC, and the term "risk assessment" may not well suited to the assessment of risk that growers are completing. However, this term is used widely throughout fresh produce risk management programs, including industry-led QAS initiatives *(15)* and commercial Codes of Practice *(22)*. As a consequence, we have attempted to construct an assessment of risk that moves toward complying with the concepts of an RA as defined by the CAC, calling this a GRA.

GRA tools are available to growers to help with exposure assessment estimations, e.g., as a decision tree *(15)*, a spreadsheet-based likelihood times severity score *(34)*, or a Web-based accumulated score *(31)*. These tools can be used to allocate an absolute value to a qualitative relative factor. Although widely utilized by growers, these approaches rely on a third party to prescribe risk, leading to an inability to adapt an GRA to a specific local crop or local environmental conditions. The GRAs developed are routinely audited by third parties to ensure compliance with the requirements of many QASs and ideally justify the allocation of risk levels.

DEVELOPING AN EVIDENCE-BASED GRA FOR PRIMARY PRODUCERS

We propose that a GRA should use locally relevant evidence to allocate risk and justify decisions made throughout the process; evidence should be drawn from "scientific literature, from databases such as those in the food industry, government agencies, and relevant international organizations and through solicitation of opinions of experts" *(5)*. Peer-reviewed scientific reports can provide clear evidence to support specific interventions and are

TABLE 1. *Potential vectors and microbiological risk factors at different stages (10) in primary production of a leafy crop such as lettuce, with indication of whether the risk factor is actively introduced by the grower (managed) or occurs without the active introduction (unmanaged)*[a]

Vector	Risk factor	Growing[b]	Harvest[c]	Primary processing[d]	Storage and transport[e]
Water	Irrigation	M			
	Cooling systems			M	M
	Wash water			M	
	Flooding	UM			
Soil	Manure-based soil amendments	M			
Livestock	Farmed livestock in rotation	M			M
	Incursion by farmed livestock	UM			
	Wildlife, pests	UM			M
Surfaces	Workers	M	M	M	M
	Equipment		M	M	M

[a] M, managed risk factor; UM, unmanaged risk factor.
[b] Cultivar selection, site selection, planting, irrigation, application of fertilizers, pest and weed management, canopy manipulation, and crop rotation.
[c] Hand and mechanical harvesting.
[d] Field sanitation, field trimming, field coring, field packing, removing field heat, and field containers.
[e] Transport to the packinghouse and cooling.

becoming increasingly available through open-access publishing agreements. However, these reports are not always best suited to use by risk managers in small to medium grower businesses where a tertiary level of microbiology training may be needed to utilize the information. Evidence may be summarized in information available to support QASs (e.g., GlobalG.A.P. *(15),* McDonald's GAP *(22),* and the Red Tractor fresh produce scheme *(31)*) or government bodies responsible for food safety (e.g., the U.K. Food Standards Agency and the European Food Safety Authority [EFSA]). Manufacturers or suppliers of equipment may provide evidence on effectiveness of processes such as water treatment. Growers are more often utilizing microbial testing to monitor process controls, and an *E. coli*–based hygiene criterion for leafy greens at preharvest, harvest, or postharvest at the farm has been recommended by the EFSA *(11)* as being useful at the primary production stage. Growers could use historic site-specific microbiological sampling data to provide evidence of intervention effectiveness. The validity of evidence, both the source and application, may be open to challenge, and food safety agencies such as the EFSA and the U.S. Food and Drug Administration and the journal *Quality Assurance and Safety of Crops and Foods* play and important role in clearly identifying and summarizing acceptable evidence to support decisions about interventions in GRAs.

The proposed GRA consists of the following four components:

1. *Hazard ID*. Microbial organisms that could lead to an FIO from identified product types are identified from information sources.
2. *Initial exposure assessment*. How likely is it that any microbial contamination occurring during crop production would be at a level on the product that could cause illness in the consumer at the time of consumption?
3. *Intervention assessment*. How likely is it that an individual intervention during crop production will reduce the level of microbial contamination of the product?
4. *Exposure assessment following intervention*. How likely is it that any microbial contamination occurring during crop production would be at a level on the product that could cause illness in the consumer at the time of consumption, following single or multiple mitigation steps or hurdles?

Hazard ID. The process of hazard ID in an industry context is familiar to many as the first part of any HACCP system *(28)*. A review of risks posed by food of nonanimal origin revealed that the main hazards to consider in leafy salads are *Salmonella* and norovirus *(10)*. Uyttendaele et al. *(36)* identified *E. coli* O157, *Salmonella,* norovirus, and *Cyclospora cayetanensis* as the main causes FIOs associated with leafy salad. In these cases, the most probable route of contamination (i.e., risk factor) of the produce was through direct or indirect fecal contamination from infected livestock or workers. Not all microbial hazards in fresh produce are linked to fecal contamination, but unless other evidence is available, from a primary production perspective microbial pathogens from feces are a generic hazard with no discrimination between microbial species unless an emphasis on a particular species is required. Thus, the GRA would list "generic fecal hazard" at the hazard ID stage.

Irrigation water, harvesting conditions, sanitation practices, worker hygiene, and storage conditions are all identified as factors that influence the risk of fecal contamination of crops and need particular consideration *(11, 14)*. Useful information includes the individual stages of production and the means by which fecal contamination can occur. An example for lettuce is presented in Table 1 using the stages of production suggested by the EFSA *(10)*. The GRA can then follow a systematic and transparent approach for each step of the process using suitable relevant evidence.

TABLE 2. *Probability descriptors for likelihood that microbiological contamination can occur at levels associated with human illness*[a]

Probability category	Interpretation
Negligible	So rare that it does not merit consideration
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

[a] Categories were agreed on by the U.K. Advisory Committee on the Microbiological Safety of Food in their meeting on 29 May 2012 as appropriate for classifying risk levels in their risk assessments for the U.K. Food Standards Agency. Categories were derived from EFSA *(9)* and modified from World Organization for Animal Health *(40)* descriptors.

Initial exposure assessment. An initial exposure assessment requires a qualitative estimation of the likelihood that a microbial hazard or hazards would be at a level on the crop that could subsequently cause illness in the consumer. At this stage the GRA needs to consider the routes of contamination that could lead to a potentially significant level of contamination and hence a significant level of risk to the consumer. Table 1 summarizes multiple risk factors, i.e., routes of potential contamination, at different times during the production of a lettuce crop. A separate initial exposure assessment should be developed for each of these risk factors, defining the qualitative probability of contamination. The relative value ascribed should be justified with evidence based on quantitative data, such as regular environmental monitoring. To ensure consistency between multiple assessments, a proposed table of descriptors for the likelihood of contamination is presented in Table 2.

Intervention assessment. The assessment of intervention effectiveness can be quantitative if there are appropriate data, e.g., a water filter with validation data from the manufacturer that the filter will consistently remove 4 log units of a bacterial hazard from a water source when data are sufficient to suggest a maximum contamination of 2 log units. However, in most hazard–stage of crop production–intervention scenarios, data will not be specific enough or sufficient to make quantitative conclusions. The data may instead come from such sources as expert opinions (e.g., the Food and Agriculture Organization of the United Nations *(13)*), QASs (e.g., Annex FV1 and GlobalG.A.P. *(15)*), or published studies *(14)* in which qualitative descriptions of effectiveness may be used.

We propose the use of the following two categories of effectiveness: effective or partially effective. "Effective" is interpreted as a validated reduction intervention to produce a consistently negligible exposure risk. "Partially effective" is interpreted as a nonvalidated reduction intervention that may not consistently reduce the exposure risk to negligible levels. Validation of a process can be defined as "the action of proving and documenting that any process, procedure or method actually and consistently leads to the expected results" *(39)*.

We limited the descriptors to two because in many cases clear differentiation among more categories would be difficult. Both categories must be further defined for any given RA to allow a consistent evaluation of independent interventions. When several interventions are targeted at one risk factor, an assessment of the additive effectiveness of all the interventions is needed. In many cases, this assessment will be subjective; however, the evidence for each intervention must be documented, and the rationale for the overall effectiveness must be captured. Table 3 summarizes possible interventions and their effectiveness for the hazards identified in Table 1. No uniquely effective or singular control point for microbial hazards in field grown leafy vegetables such as lettuce is available *(14),* and harvested leafy greens are not subjected to physical interventions that completely eliminate microbial contamination *(11)*. This situation highlights the challenge of minimizing risk to a consumer and the particular challenge in developing robust GRAs for crop production.

Exposure assessment following interventions. Single or multiple preventive and/or interventive actions may be utilized in a leafy crop production system, and hazards may be introduced at different stages of production *(11)*. Thus, the combined risk reduction at the end of primary production must be summarized. Assessing the exposure following one or more interventions can be facilitated by a simple qualitative matrix that combines the inputs of exposure probability (before intervention) and the effectiveness of interventions as described above. Such an approach could be used to consistently and transparently document the likelihood of postintervention exposure to significant levels of microorganisms associated with human illness. Exposure assessment after intervention is used as a proxy for risk because the actual risk to consumers is not readily calculable. An example matrix with outputs in terms of acceptability of residual risk after intervention is given in Table 4. This assessment would be completed for each potential route of microbial contamination (see Table 1). The outputs of "acceptable" or "review" (where the decision to accept the intervention must be justified) would be determined by the individual business. A series of partial steps may also act as hurdles, where each intervention leads to an assumed reduction of risk leading to an acceptable output.

SCENARIOS

We have proposed a structured RA that requires the user to justify actions and decisions at each step by drawing on a range of evidence from quantitative to best practice recommendations. The approach is illustrated in the three following scenarios.

Scenario 1—open water source with no water treatment. In this scenario (Table 5), a leafy vegetable producer has a winter storage irrigation reservoir or lagoon. The hazard ID is listed as generic fecal hazard because the microbial risk is not specified. Because the lagoon provides irrigation water, the stage of production where the risk is

TABLE 3. *Table of interventions for potential microbiological hazards during the primary production of a leafy vegetable crop*

Vector	Risk factor	Interventions[a]: Growing[b]	Harvest[c]	Primary processing[d]	Storage and transport[e]
Water	Irrigation	**Clean water source, water treatment,** *timing before harvest, avoid leaf contact*			
	Wash water			**Clean water source**, **water treatment**	
	Cooling systems			**Clean water source, water treatment**	**Clean water source, water treatment**
	Flooding	*Site selection*			
Soil	Manure-based soil amendments	**Composting, heat treatment,** *timing before planting*			
Livestock	Farmed livestock in rotation	*Timing before planting*			
	Incursion by farmed livestock	**Fencing, site location**			
	Wildlife, pests	*Pest control, fencing*			**Pest-proof structures**, *pest control*
Surfaces	Workers	*Training, adequate facilities*	*Training, adequate facilities*	*Training, adequate facilities*	*Training, adequate facilities*
	Equipment		*Cleaning, disinfection*	**Cleaning, *disinfection***	**Cleaning, *disinfection***

[a] Interventions in this table are drawn from previous detailed reviews *(11, 13, 14)*. Text in bold indicates effective elimination of hazard; text in italics indicates partial reduction of hazard.
[b] Cultivar selection, site selection, planting, irrigation, application of fertilizers, pest and weed management, canopy manipulation, and crop rotation.
[c] Hand and mechanical harvesting.
[d] Field sanitation, field trimming, field coring, field packing, removing field heat, and field containers.
[e] Transport to the packinghouse and cooling.

being considered is the growing stage, and this is a managed risk factor (as defined in Table 1) because the grower will actively control the act of irrigating the crop. The potential exposure assessment is the first step that requires evidence. In this scenario, historical water testing for *E. coli* is available to the producer, and the range is 10 to 850 CFU/100 ml over the last 5 years. This value complies with current guidance in GlobalG.A.P. *(15)* of <1,000 CFU/100 ml, allowing use of this irrigation water on crops that will be eaten uncooked, but this value is at the upper end of indicator levels and shows that the fecal contamination of the water occurs regularly and thus is assigned the potential exposure assessment value of medium (see Table 2). The producer could propose to undertake no intervention, but the

TABLE 4. *Matrix of initial exposure assessment (from Table 2) by effectiveness of intervention (from Table 3)*

Initial exposure assessment	Effectiveness of intervention: Effective	Partial	No intervention
Negligible	Acceptable	Acceptable	Acceptable
Very low	Acceptable	Acceptable	Action required
Low	Acceptable	Acceptable	Action required
Medium	Acceptable	Action required	Action required
High	Acceptable	Action required	Action required
Very high	Acceptable	Action required	Action required

exposure assessment following intervention would be medium × no intervention = action required. The producer would need to propose one or more interventions and provide associated evidence to allow this water to be used to irrigate the leafy crop.

In scenario 1, the grower proposes two interventions: (i) avoiding leaf contact by using drip tape to apply the irrigation and (ii) stopping irrigation 7 days before harvest. These now need to be identified as either effective or partial, and the assessment must be justified. Both interventions would be classed as partial. Avoiding contact with the leaf is a suggested intervention from an industry source of information *(15)*, but soil splash can occur *(25)* so contamination is still possible. Allowing a period of time between the last irrigation step and harvest could also reduce the risk of harvesting a contaminated crop because bacteria rapidly decline on the leaves of lettuce under warm, dry conditions *(16)* but bacteria can persist under cooler conditions *(17)*. Hence, neither intervention can be viewed as effective, and are both classified as partial, leading to a postintervention exposure assessment of action required for both interventions. In this scenario, the grower has no other higher quality water sources to consider. However, because both interventions are applied to the irrigation water, combined exposure following intervention needs to be considered. This decision is difficult with very little information available to base it on. A combination or

TABLE 5. *Summary of decision points and evidence for undertaking evidence-based grower risk assessment; scenario 1: assessing an open irrigation water source with no water treatment*

Decision point	Description
Risk assessment	Irrigation water source (lagoon 1)
Hazard ID	Generic fecal hazard
Stage of production	Growing
Managed or unmanaged	Managed
Potential exposure	Medium
Evidence	Monthly water tests for *E. coli* reveal 10–850 CFU/100 ml over last 5 yr
Intervention 1	Avoid leaf contact by using drip tape
Effectiveness	Partial
Evidence	Annex FV1 GlobalG.A.P. guidelines 5.1.1, water at preharvest *(15)*; water or soil can be splashed onto the leaf *(25)*
Intervention 2	Stop irrigation 7 days before harvest
Effectiveness	Partial
Evidence	Rapid decline of indicators, i.e., 3–5-log reduction on lettuce leaves in 1 wk when conditions are warm and dry *(16),* but indicators can persist when cool and wet *(17)*
Exposure assessment following intervention	
Intervention 1	Medium × partial = requires action
Intervention 2	Medium × partial = requires action
Combined exposure assessment	Acceptable
Evidence	Multiple partial interventions
Monitoring action	Monitor water quality over the growing season

bundling of strategies can be viewed as following the principle of the hurdle effect or hurdle technology *(20)* more commonly applied in food preservation. A combination or bundling of strategies can be viewed as following the principle of the hurdle effect or hurdle technology *(20),* more commonly applied in food preservation, where an assumed synergy, or even a multiplicative interaction, between combinations of partial treatments with different modes of action, leads to increased efficacy. The authors are unaware of scientific studies on or evidence for the effect of a hurdle approach in leafy crop production, yet the grouping of multiple partial interventions is a common recommendation to growers (e.g., GlobalG.A.P. *(15)* and Red Tractor Assurance *(31)*) because there are few stages where an intervention can be classed as effective. Consequently, growers would need to establish their own evidence base for the effectiveness of the combination of these two interventions to justify the postintervention exposure assessment of acceptable. One approach would be to implement a sampling strategy where levels of *E. coli* would be routinely monitored in the irrigation water at point of abstraction and on harvested heads using *E. coli* as a hygiene criterion, as suggested by EFSA *(11)*. The frequency of the tests would also need to be decided based on best practice recommendations. Although most standards suggest tests should be done more frequently for water sources deemed to be higher risk, there is little actual indication of the numbers of tests required. The McDonald's Corporation *(22)* standard derived from the Food Safety Modernization Act in the United States *(35)* recommends that five samples be taken during the growth of a lettuce crop or over a period of 30 days, whichever is shorter. This approach is thus listed in the monitoring actions for this scenario.

Alternatively, the grower could monitor irrigated soil for indicator species, investigate use of a relatively safer water source, avoid the use of uncontrolled surface water, or treat the water *(1, 36)*. This last option is presented in scenario 2.

Scenario 2—open water source and UV-C treatment. In this scenario (Table 6), the same water source is available to the grower, and the same stages would be completed as described for scenario 1, i.e., generic fecal hazard at the growing stage with a managed risk factor. In scenario 2, the intervention proposed would be an in-line UV-C treatment system *(1)*. This technology has a reported microbial reduction range of 0.5 to 5.0 log CFU/ml *(1)*. For this intervention to be assessed as effective, the reduction in bacteria through the process would need to be validated, i.e., evidence would be needed to demonstrate that the equipment "actually and consistently leads to the expected results" *(39)*. This evidence could be gathered through regular monitoring of water before and after treatment at a frequency suggested by the manufacturer or customer QAS. For example, the Marks and Spencer guidelines *(21)* require a 3-log reduction of a range of indicator species as validation for irrigation water treatment. This result would allow the postintervention assessment of medium × effective = acceptable, with the monitoring requirements listed in the monitoring action.

Scenario 3—worker hygiene on a lettuce harvesting rig. In this scenario (Table 7), the hazard ID is again generic fecal hazard because the microbial risk is not specified. The stage of production is harvest, and this is a managed risk factor. The potential exposure assessment is medium because the worst-case scenario is assumed, where hands are regularly contaminated following the use of a field toilet before any interventions are implemented. In scenario 3, the grower proposes three interventions: (i) training for all field workers, (ii) provision of adequate toilet and hand washing

TABLE 6. *Summary of decision points and evidence for undertaking evidence-based grower risk assessment; scenario 2: open irrigation water source with UV treatment unit*

Decision point	Description
Risk assessment	Irrigation water source (lagoon 1)
Hazard ID	Generic fecal hazard
Stage of production	Growing
Managed or unmanaged	Managed
Potential exposure	Medium
Evidence	Monthly water tests for *E. coli* reveal 10–850 CFU/100 ml over last 5 yr
Intervention	Water UV treatment unit
Effectiveness	Effective
Evidence	Validated as producing a consistent 3-log reduction of a range of indicator species following manufacturer's protocol at the start of the irrigation period
Exposure assessment following intervention	Medium × effective = acceptable
Combined exposure assessment	Acceptable
Evidence	Effective water treatment used
Monitoring action	Monitor water quality before and after UV treatment unit weekly

facilities in the field, and (iii) using gloves while handling the crop. All three interventions would be classed as partial based on evidence in the scientific literature and observed in the field. Training improves knowledge of food safety requirements for field workers, but compliance still requires motivation from supervisors *(33)*. Provision of adequate toilet and hand washing facilities will enable correct hygiene procedures to be followed by field workers, but facilities can become dirty through use (as observed in the field in this scenario) and door handles and latches of field toilets also become sources of contamination *(27)*. Use of gloves can also prevent transfer of microorganisms from workers' hands to the lettuce but only if the gloves are put on correctly over clean hands *(26)*, and gloves can split during fieldwork (as observed in the field in this scenario). The three interventions would therefore be assessed as medium × partial = action required. As for scenario 1, a hurdle technology approach *(20)* would be required to assess the

TABLE 7. *Summary of decision points and evidence for undertaking evidence-based grower risk assessment; scenario 3: worker hygiene on a lettuce harvesting rig*

Decision point	Description
Risk assessment	Worker hygiene, lettuce harvesting rig
Hazard ID	Generic fecal hazard
Stage of production	Harvest
Managed or unmanaged	Managed
Potential exposure	Medium
Evidence	Hands not sampled previously, so assuming worst-case scenario where hands are regularly contaminated following use of field toilet
Intervention 1	Training for all field workers
Effectiveness	Partial
Evidence	Training improves knowledge for workers but motivation from supervisors also needed *(33)*
Intervention 2	Provide adequate toilet and hand washing facilities
Effectiveness	Partial
Evidence	Facilities may become dirty over time (observed)
Intervention 3	Use gloves while handling crop
Effectiveness	Partial
Evidence	Gloves can split (observed)
Exposure assessment following intervention	
Intervention 1	Medium × partial = requires action
Intervention 2	Medium × partial = requires action
Intervention 3	Medium × partial = requires action
Combined exposure assessment	Acceptable
Evidence	Multiple hurdles reduce total risk
Monitoring actions	
Intervention 1	Recorded training for each worker
Intervention 2	Daily start-up sheets to record condition of toilets and reemphasize hand hygiene standards
Intervention 3	Hand swabs of sample of field workers monthly through harvest season

exposure assessment following intervention as acceptable. Quantification of the risk of contamination from field workers' hands at harvest is difficult. One approach is to undertake a regime of swabbing sampling workers' hands throughout the season and testing for levels of *E. coli* on the hands of randomly selected workers. Recording training for each worker and checking and recording the condition of field toilets and hand washing facilities at the start of each day would provide evidence that the interventions were being applied *(14, 15)*. These actions would be recorded in the monitoring actions section.

LIMITATIONS

Requiring evidence to justify RAs and the effectiveness of interventions will strengthen decisions made within a GRA. Although evidence is increasingly accessible through open access publishing, academic articles are not always best suited to use by risk managers in small to medium grower businesses, thus limiting the use of relevant data to provide evidence for stages in the RA process.

GAP indicate that multiple interventions may be applied to minimize risks of contamination of the final product; however, no direct scientific studies have been conducted to quantify the effect of the hurdle technology approach in the field. As a consequence, RAs are being built on assumptions rather than evidence. One solution for growers is the implementation of wide-ranging monitoring of microbial indicators. However, no accepted validation or monitoring hygiene criteria currently exist. The EFSA *(11)* has recently proposed using *E. coli* as a hygiene indicator for primary production but has recommended that more data and standardization of sampling procedures are needed before values could be identified. A key challenge to undertaking the GRA approach is the cost of collecting evidence. However, some supply chains are already being modified to increase both environmental and product testing, particularly in the area of water quality monitoring *(22)*. The development of "big data" analysis (i.e., microbiological analysis combined with real-time environmental logging of agricultural processes) may allow large amounts of anonymized data from across the industry to establish evidence for interventions and support best practices in primary production.

CONCLUSIONS

This article outlines an approach based on a structured qualitative GRA that requires all decisions to be based on evidence and a framework for describing the decision process that can be challenged and defended within the produce supply chain. An evidence base needs to be developed that is easily understood by primary producers. QAS managers and food safety agencies should summarize and translate the outputs of academic research in the area of risk management to help primary producers understand the evidence supporting risk management decisions.

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