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Microbial Modeling for Food Safety: What are Some of the Potential Liability Issues?

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SUMMARY

Since the early 1990s, microbial modeling has become an increasingly important part of commercial food preparation and manufacturing. Using mathematical techniques and carefully designed experiments, one can make models to predict microbial growth, survival, or death and use those predictions to formulate and process foods efficiently and with minimal food safety risk. Today, many models exist in both public and private domains. However, they may not be used to their fullest potential for various reasons. One suggested reason is uncertainty over potential liability associated with their use if adverse consequences were to occur. A panel of five individuals representing academic, industry, regulatory, and law professions discussed various perspectives on this topic including risk management, the interplay between challenge studies and microbial models, and liability. The common theme was the critical importance of designing and using models responsibly. This careful use includes being explicit about and documenting assumptions, validating models for accuracy in relevant conditions, and documenting decisions based on model outputs. Decisions should be reviewed against the question "would 12 jurors think that this is a reasonable decision?" If the answer is "no," then it is time to reconsider the decision.

OVERVIEW

While preparing for a symposium on the commercial uses of microbial modeling presented at the 2022 International Association for Food Protection (IAFP) Annual Meeting *(8)*, several corporate quality assurance leaders were asked "What hinders the usage of microbial modeling in industry?" One vice president of quality in a major food company commented that the "liability of model use has not been tested." The implied question was "What is the liability if one uses a microbial model that is incorrect and results in illnesses?" How might this affect the modeler, the company, or any others involved? Consequently, we proposed a roundtable discussion at the 2023 IAFP Annual Meeting *(9)*. The panel consisted of five individuals from academia, industry, and the regulatory community. The discussion is summarized below, listing the main themes among the panelists and based on questions from the audience. This summary was prepared by some of the us who were participants in the panel (D.W.S., S.S., and M.E.) and were the panel organizers and conveners (J.D.L. and D.L.S.).

Food safety professionals have important responsibilities to protect consumers by producing food that is safe to consume. These professionals face exposure to liability and risk every day regarding the decisions they make. One of the options they can consider to support their decision-making process is the use of predictive microbiological models. The roundtable discussion gave insights into how to use some of the tools available to ensure manufacture of a safer product and, by extension, the protection of a company's brand.

The following main topics were discussed:

1. The difference between risk assessment and risk management;
2. The use of modeling to perform microbiological risk assessment, including model credibility, the interplay of challenge studies and appropriate models, models as screening tools, and the acceptable level of risk; and
3. The concept of liability, with a definition, interpretation in the context of food safety and the use of models, and the impact of uncertainty in model results on liability.

1. RISK ASSESSMENT AND RISK MANAGEMENT

Risk refers to the probability of an adverse effect occurring due to the consumption of a food commodity by a specific population. The Codex Alimentarius Commission *(4)* has defined the three main components of risk analysis.

1. Risk assessment is a scientifically based process including (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

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2. Risk management consists of weighing policy alternatives in consultation with all interested parties, considering risk assessment outcomes and other factors relevant for the health protection of consumers for the promotion of fair-trade practices, and if needed selecting appropriate prevention and control options. It is very important that the risk assessment and risk management roles remain distinct.
3. Risk communication is the interactive exchange of information and opinions within the risk analysis process among various stakeholders, including risk assessors, risk managers, consumers, industry representatives, the academic community, and other interested parties. It includes the explanation of risk assessment findings and the basis of risk management decisions.

Risk assessment is done to provide risk managers with a description of the known health risks, but it remains the risk manager's responsibility to make decisions based on the risk assessment outcomes and other criteria such as nutrition, food security, social and cultural aspects, technical feasibility, cost-benefit analysis, and environmental and economic aspects *(6)*.

To make informed decisions, risk managers need a sound understanding of the scientific approaches and assumptions used by risk assessors. Risk managers are responsible for the liability arising from those decisions. Risk management operates at the level of countries, where food safety agencies are in charge of risk assessment and competent authorities are in charge of the risk management, and at the level of companies.

One easily made error is the assumption that a risk that has not been reported in the past need not be considered and that preventive actions are unnecessary. Just because it "never happened before" does not mean that it will never occur in the future.

Microbiological risk assessment (MRA) is an evolving science, and guidance documents are available on how to perform such an assessment *(7)*. The four components of an MRA are:

i. hazard identification to identifying the hazard(s) of concern from the consumption of a specific food;
ii. exposure assessment, which is a qualitative or quantitative evaluation of the likely intake of a microbial hazard via the consumption of the studied food;
iii. hazard characterization, including the dose-response relationship; and
iv. risk characterization, which is the integration of the three previous steps to estimate the likelihood and severity of the adverse effects that could occur in a given (sub)population from the consumption of a contaminated food commodity.

Risk assessments can be quantitative, semiquantitative, or qualitative. When possible, the means by which variability and uncertainty are being considered should be included and documented. The risk assessment should be adequate to answer the risk management question, considering data quality and availability, the degree of consensus and/or scientific knowledge related to the topic, and the available resources. A good risk assessment will also identify any data gaps that if filled could improve the accuracy of future evaluations *(2)*.

2. USE OF MODELING TO PERFORM RISK ASSESSMENT

Modeling is a recognized methodology to perform microbiological food safety assessments. The Codex Alimentarius Commission *(3)* has proposed five main approaches to validate control measures to ensure food safety: (i) reference to scientific or technical literature, (ii) use of challenge tests studies, (iii) monitoring data during operating conditions, (iv) mathematical modeling, and (v) surveys. These approaches may be used individually or in combination *(3)*.

2.1. Models as screening tools

Models can be used to screen formulations for new products before spending the resources to make them. One speaker recalled an experience when they were asked to evaluate 40 new products that included a new natural preservative intended to control *Clostridium botulinum*. The model indicated that 40 to 50% of the products would fail. However, subsequent challenge studies revealed that most of the products did not support *C. botulinum* toxin production, probably because of inhibitors present in the food but not considered as model factors. This scenario reveals the need for a thorough understanding of the model, what factors it includes, and how it relates to the formulations in question when used as a screening tool.

2.2. Choosing the best model

Predictive microbiological models can help to quantify a potential risk that was not observed before, and when data are scarce such a model can also include additional information acquired through expert elicitation methods. The primary consideration concerning the model is that it be accurate within the relevant range of conditions. This accuracy should be demonstrated by validation against independent data not used in building the model. This approach is analogous to validations required to show that a given process is sufficient to reduce the potential hazard. Although the U.S. Food and Drug Administration does not require the use of microbial modeling to determine the risk profile of any given process, any models used should always be validated.

Choosing the "best" models to use is part of the risk assessment exercise, and it is typically left to the risk assessor to substantiate the most appropriate model choice. Regulatory authorities in Europe and the United States allow for the use of predictive microbiological models but do not

prescribe which ones to use or how to use them. Properly trained risk assessors can use an applicable existing model or develop a new model if necessary.

Traditional risk managers may be unfamiliar with predictive modeling and its output, especially when results are presented considering variability and uncertainty. Risk assessors would usually bring different scenarios so the risk managers can make an informed decision. Even when risk assessment and risk management are kept separate, in practice the risk assessors may need to spend time refining the risk managers' questions and educating the managers as to their role in the process, what models can and cannot do, and the strengths and weaknesses of any given model.

2.3. Interplay of challenge studies and appropriate models and tools

Models can always be used to inform challenge studies and vice versa. When a model is used instead of a challenge study, one needs to be sure the model is valid for the conditions in which it is being used. The U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) determined years ago that the growth of *Clostridium perfringens* should be restricted to <1-log increase during cooling. The FSIS inclusion of ComBase Perfringens Predictor *(5)* and other modeling tools in their guidance for assessing cooling deviations has been extremely valuable to the industry because it simplified the path to handling *C. perfringens* in cooling deviation situations.

Predictive microbiological tools also can be used for other applications, including safe-by-design formulations, shelf-life prediction, and determination of cooking instructions. These tools make the models accessible to the broader microbiology community, who might not otherwise have the required coding and statistical skills.

2.4. Model users

Experts who understand the math and statistics behind modeling should be consulted. The expert should be able to add context to the estimates and explain the true risks. Regulatory agencies will often have questions around the robustness of a model and its degree of validation. Regulatory agencies may also want to know how closely the model applies to the product and situation in question.

Experts responsible for safety of thermal processing operations are often called process authorities. A process authority is defined in the United States as "someone with expert knowledge," but there is no legally required test or certification needed to prove this expert knowledge. Although courses designed to teach the skills needed by a process authority are available, no formal examinations are required. Process authorities and modelers require distinct skill sets, although some individuals possess both.

The question about whether to use individuals within a company who have expertise in modeling or to use a food safety modeling consultant in crisis situations can be difficult to answer for several reasons. Large multinational companies may have all the expertise they need in-house; thus, hiring a consultant may not bring added credibility. When the model used to solve the problem in question has been available for a long time and has been shown repeatedly to be reliable, then expert credibility may be less important. When the model and its application are relatively new or have been generated in response to a specific problem, a third-party expert may be beneficial.

3. LIABILITY

3.1. Definition and types of liability

Liability is defined as being obligated to account pursuant to the law or to be called upon to answer for. Food safety risks usually have low-probability but severe consequences, leading to potentially significant customer or consumer damages and resulting liability. For example, the risk linked to the consumption of a food may be quite low when preventive controls are in place, but if an adverse event were to occur (such as a large-scale foodborne illness outbreak), any resulting liability or costs may be large.

Three general types of liabilities have been described.

1. Regulatory liability. This type of liability can be triggered when the production, holding, distribution, and sale of a food is subject to specific regulations but the relevant rules are violated. When this occurs, the company (or companies) involved can face regulatory enforcement actions from the agency ranging from adverse observations and warnings from the regulators to more significant actions, including but not limited to threats by the government to withdraw or suspend regulatory registrations and licenses.
2. Civil liability. This type of liability is usually triggered as a result of injury following the consumption of a contaminated or defective food product. Civil liability usually takes the form of threatened or actual civil lawsuits against the company responsible for producing the offending food, with the injured consumer seeking to recover their personal injury damages. Civil liability can also take the form of food companies bringing civil commercial claims against each other. For example, a food company manufacturing a finished product that includes a contaminated ingredient obtained from a supplier may elect, following a recall caused by the offending ingredient, to bring a claim against the supplier seeking to recover any losses suffered as a result of the recall.
3. Criminal liability. This type of liability exposure can be triggered when the company producing an offending product that injures consumers (or that could injure consumers) knew before shipment of a condition that could lead to the product being defective. If the company were aware of the condition and able to

prevent the condition that could lead to the defect but failed to do so, criminal charges could be brought against the company.

Any of these liabilities can be triggered by relatively small food safety risks. One can imagine a company risk manager weighing various risks against the costs of managing events that are very rare but would have severe public health consequences. Microbial modeling can remove some of the subjectiveness from risk assessments and provide, in many cases, a more objective and scientifically based decision.

The panelists and the authors suggested that when food companies are considering the use of predictive microbiological models, they consider engaging with inspection authorities for their perspective on the development and implementation of such models. This consultation might be done to achieve consensus (or at least no objection) on the model and provide an opportunity for the transparent airing of any potential concerns or possible areas of improvement. Companies can use such opportunities to explain the model, the rationale behind its use, and how any model outputs would be used and interpreted.

The application of models to specific situations may reveal risks that were not previously considered or known. In this regard, modeling can help structure risk assessments to ensure that all relevant factors are considered. For example, if the model were to indicate that wide changes in pH could influence the safety of the process, then pH should be monitored and controlled.

Although product pathogen testing is useful for monitoring the overall performance of a quality management system, testing can provide a false sense of control. The lack of detected pathogens in a sample does not guarantee that these pathogens are not present somewhere in the product lot. Hence, processors should apply proactive approaches to ensure food safety and quality based upon hazard analysis critical control point (HACCP) principles.

3.2. Modeling and liability

Various lenses can be used when considering the uses of microbial models: the scientific lens, personal experiences, how one was trained, one's education, and the culture of the organization. We also have the lens of litigation if something were to go wrong in the way the model was developed and/or used. If the model were not adequate or failed or if consumers were to become ill, litigation would likely follow. Lawsuits would result in discovery and potential trials. Plaintiff lawyers would demand production of internal text messages, emails, and documents. Plaintiffs would also retain experts who would attempt to criticize and tear apart the model that was created. These experts would likely point out what should have been considered and what other variables should have been used. These examples emphasize the point that we should work to ensure that everything we do to prevent a significant issue from occurring is as perfect as we can make it. Thus, if we are going to use models, we must plan to use them correctly, just like we would with a validation study.

A seldom discussed issue is what to do when experimenters or modelers make mistakes. Sometimes these mistakes are the result of wrong assumptions. Sometimes implicit assumptions are made by the modeler or the model user. For example, when using ComBase to predict the growth of *Salmonella*, one must recognize that the model has a lower temperature limit of 7°C for growth and does not permit predictions below 7°C. However, S*almonella* may still grow very slowly below that temperature. The modeler may assume that the model is good enough if it delivers an answer above 7°C, but is this assumption correct? Even if the modeler were to add disclaimers about the temperature limit, the restrictions put in place by ComBase provide a high probability that a nonexpert user could misinterpret the results as showing that *Salmonella* does not grow below 7°C.

In all cases, the modelers should document all assumptions being made when doing the calculations because the modelers may be bringing in assumptions based on data availability or quality or others factors they are not even aware of. Some of these assumptions may have very minor consequences, but others may be profound. To ensure the appropriate application of the model, one must identify and critically evaluate the impact of those assumptions. Transparency is required to make sure modeling hypotheses are clearly understood by the users, who require a minimum level of training and critical thinking to make valid predictions.

Some say that modeling is an art. Because variability and uncertainty exist in the world, the way we integrate such variability and uncertainty in our given situation should always aim to be as accurate as possible so we can adequately support and defend our choices. No science is perfect, modeling or otherwise, and when new information, data, and facts are brought to our attention, it is our responsibility to appropriately consider them.

If we consistently adopt this approach, then we will be in the best position to defend our actions if called upon in the context of that proverbial "bad day." From a regulatory standpoint, we will have the appropriate support for each of our decisions (even if, despite best efforts, they were to prove erroneous) so we can defend the basis of these decisions. From a litigation standpoint, when our models are appropriately considered and applied we will have a story to tell the jury about a company that cares deeply about doing the right thing for the right reasons. People can make mistakes, and models are human creations that can be used to make predictions that turn out to be wrong, so the key will be to establish that the right things were considered, the right decisions (or what appeared at the time to be the right decisions) were made. If a failure were to occur, it would be merely an unforeseen circumstance outside of the company's control. In most instances, both regulators and jurors will likely view the company and its actions favorably.

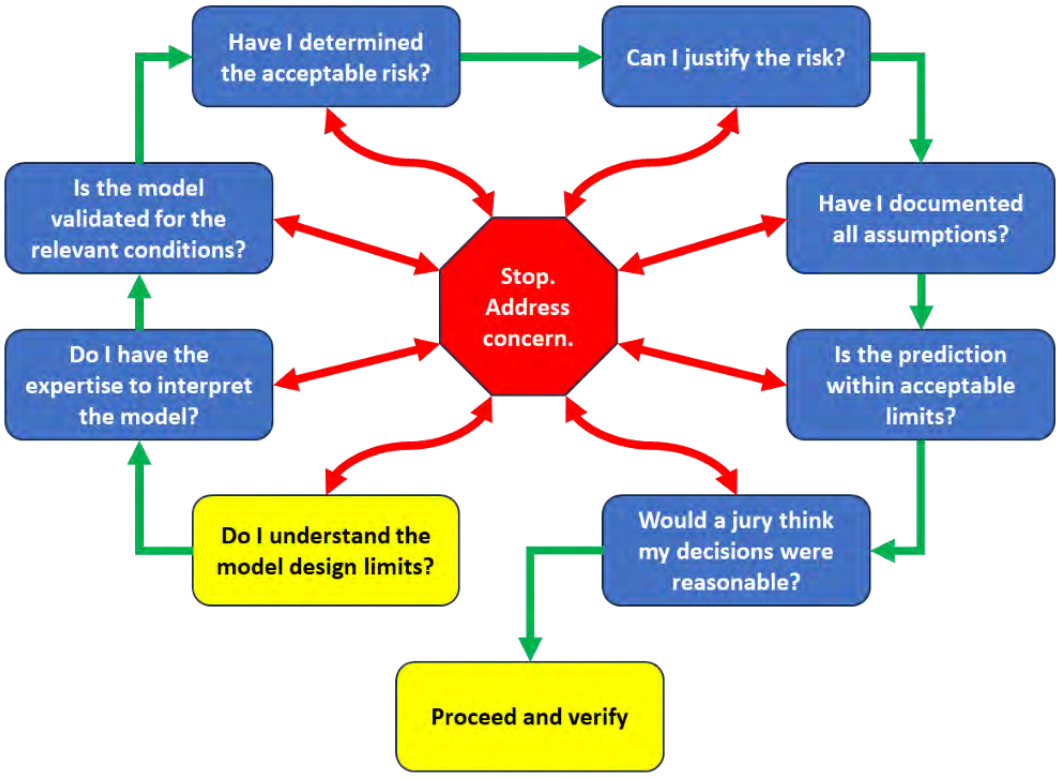

Figure 1. Thought process to evaluate model acceptability. Proceed from question to question as long as the answer is "yes." Each time the answer is "no," stop and address the concern.

3.3. What is the acceptable level of risk?

The potential risks associated with the presence of pathogenic bacteria in foods are being increasingly recognized. The Jack-in-the-Box foodborne illness outbreak in the early 1990s and other large outbreaks have spurred changes in national surveillance, including creation of PulseNet *(10)* and subsequently GenomeTrakr *(11)*, which have significantly improved outbreak detection. In this context, even though the risk foodborne illness may be very small, there could be massive consequences. The meat industry has struggled for years to improve the safety of ground beef after *Escherichia coli* O157:H7 was declared to be an adulterant. Within the industry, managers know that although they could test 99% of the hamburgers they processed and find no detectible *E. coli*, the pathogen might nevertheless be present in the remaining 1%. The single person eating that 1% might end up becoming hospitalized with kidney failure, which could potentially result in lifelong kidney damage or even death.

Ultimately, this scenario could result in a lawsuit costing the company millions of dollars. It also highlights the limitations of finished product testing and emphasizes the needs for proactive modeling approaches based upon risk assessment and the implementation of HACCP principles and preventive controls. Modeling will not always help to reduce risks, but it will help to quantify risks. Risk managers and other stakeholders determine the acceptable level of risk. For example, we all take risks when crossing a busy street, but our internal modeling (based on our personal experiences) helps us to quantify the risk and we decide what level of risk is acceptable when making the decision on the exact moment to cross.

The ultimate success of the use of modeling is not strictly limited to science; legal principles also must be considered. When using modeling to determine the precise level of risk that we have accepted (because there is always some level of risk), we might also consider the legal consequences if our assessment were wrong. From a legal perspective, one question we might ask when assessing the acceptable levels of risk is "What would 12 jurors think?" Presuming there could someday be a potential failure of the model at the risk level we chose, we should always consider what those jurors would think about the application of the model, and what they would think about the final decision regarding the selection and use of the model. A summary of the thought process is shown in *Figure 1*.

If, following this analysis, we were to conclude that a jury of peers would not likely agree with our conclusions, we probably have made the wrong decision. If we ask ourselves that question and we are honest, we will in virtually all cases end up in the right place. It really comes down to being able to say "This is the decision I made. These are all the different reasons that I considered in making that decision, and that

is why we landed where we did." If reasonable people would likely nod their heads and say "that sounds reasonable," then the decision has likely resulted in an appropriate and defensible position.

Because some people believe that no level of risk is "acceptable," the term "tolerable risk" has been proposed. The concept of tolerable risk provides an opportunity to look for analogous situations where something is currently allowed in the regulations. If models can quantify that existing allowance mathematically and then translate it into a different set of circumstances that are mathematically (or risk-level) equivalent, one can make the case that the new situation has a tolerable level of risk. In other words, if the regulations already allow A, and B is analogous to A (as shown by the math), then if we tolerate A we should also be permitted to tolerate B. The detailed assumptions that we make to get from A to B are critical, should be substantiated with science and appropriately documented, and should constitute an argument that 12 jurors would find acceptable.

3.4. Liability and uncertainty in model results

How does one connect the liability issue with the variability and/or uncertainty of the model's outcomes? Various statistical techniques can be used to make this connection, such as a sensitivity analysis that helps define the scope where the model can be used and situations where it cannot be used. Extrapolations of model results outside of the intended scope of use should not be allowed when making decisions.

Another way (in the context of asking "What would 12 jurors think?") is to consider what the proverbial "bad day" might look like if an offending product were to be shipped into commerce. We may have one or two retail customers or consumers who might mishandle a product by not following the instructions, for instance by not cooking it appropriately. If the mishandled product were to produce a cluster of illnesses and show up in GenomeTrakr, the regulatory agencies would get involved.

Such scenarios should be considered upfront by companies by envisioning possible misuse by consumers. For instance, in this scenario any cooking instructions should consider the potential for undercooking and include a margin of safety (i.e., extra cooking time at a temperature higher than scientifically required to ensure safety). Although significant deviations from the instructions may still occur, the probability of harm resulting will likely be significantly reduced. The risk manager should decide on the most appropriate course of action. The risk assessor's job is to evaluate everything about the data, the tested scenarios, and the possible consequences. This process, when done right, will typically ensure that the decision makers are fully informed so they can make the most appropriate decisions.

CLOSING COMMENTS

Don Schaffner

I like to think about using models like using a map. You can use a map to get from Toronto to New Brunswick, NJ, but that map is only an abstraction of reality. If I have a real-time digital map, it might even be able to tell me about traffic delays and give a relatively accurate estimate of when I will arrive. But I do not confuse the map with the reality of driving from here to home. I might decide to fly to my destination, in which case the road map is of little value. If I do drive, the map may be incredibly useful when making the journey, but it is not the journey. It's a representation of the journey that's going to inform my decisions about when to leave and where to stop along the way. I still must make intelligent decisions, but I am going to be informed, and at least I know I am heading in the right direction.

Mariem Ellouze

We should use models as one of the food safety tools that are available to perform MRAs or food safety evaluations. So, it is up to you to look at your toolbox and identify the right tool you need for your specific question. If you do not need a hammer, do not use a hammer. Sometimes, it is simply the application of a safe harbor that helps you decide without investing in additional experiments or justifications. Often, a well-designed challenge study is what you need. Sometimes, you need a first partial assessment, using a model to design your challenge study. If modeling appears to be the best option for answering your question, make sure that you understand what you are doing. Will you use a publicly available model in a user-friendly information technology tool? Do you have enough data and the right skills to develop your own model? Will you validate the model? Will you interact with the authorities to ensure that the use of the model is acceptable to them in your situation?

David Legan

I always keep in mind the words of George Box *(1)*: "all models are wrong, but some are useful." That puts the responsibility onto us to make smart decisions when building and using models. Be explicit about assumptions, then test them. Use sound experimental designs and appropriate statistical analyses, then validate the resulting models against independent data. Don't stray outside the model design range when using models to support decisions. If we do those things, then, to build on Don's analogy, we have created a map. By using that map, we can estimate whether we are traveling safely on level ground or perhaps are close to falling off the edge of a cliff. A single challenge study can never tell us how close we might be to the cliff edge. Therefore, I believe that we can manage risk better with a well-designed model than with a challenge study. Ultimately, we must make the best and most defensible decisions that we can make with the information that we have at hand. If we are not confident

in our decisions, we must find a way to supplement the available information to improve our confidence.

Dennis Seman

First, I want to thank all of the participants in this panel discussion for their concise and thoughtful treatment of the subject. Microbial models are simply tools—sometimes complex tools—that can be used to more effectively and efficiently assist food product developers to create new and better products. But models need to be used in the context of the whole process. Many times, the answers provided by models must be interpreted to correctly apply what they are telling us, which is why having individuals trained in their use is very important.

Shawn Stevens

Managing the health of a food facility is, in many ways, like managing the health of the human body. If there is evidence of disease in a food facility (resident pathogens) or a human body (cancer cells), the disease must be treated. If left unmitigated, the disease will spread and continue to affect its host until the disease is so pervasive that the host eventually perishes. As food safety professionals, we are the physicians, the physician's assistants, and the nurses, depending upon our role within the company. In turn, the advice we give is critically important, and we must impress upon our company leadership to follow our advice. If you aren't into the doctor thing, just be the lawyer and say "What would 12 jurors think?"

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