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Predictive microbiology models and operational readiness

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Abstract

A diverse field of predictive microbiology models has emerged in the past 30 years and has advanced our understanding of microbial behavior in foods. As most of published models have for objective to provide operationally relevant information to decision makers, predictive microbiology models have now found their place within both the academic, and the food industrial communities.

Given the importance of these models to food safety, the decision makers are in need of evidence-based advices in order to assess confidence in the predictions provided by models they use. The objectives of this work were (i) to review current approaches in predictive microbiology used to build, verify and validate models, and (ii) to propose a categorization scheme that would tend to define a model's viability for use in an operational setting.

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Keywords: technological readiness level ; verification; validation; best practices

1. Introduction

Predictive microbiology, the quantitative microbial ecology of foods, has made a lot of progress thanks to the interdisciplinary research efforts of both food microbiologists and scientists involved in the mathematical modeling. It has now found its place in the academic communities and tends to be more and more used by food industrial.

Predictive microbiology models are diverse and help to answer a lot of questions asked by food industry and risk assessors: “what is the growth potential during cooling?”, “what is the efficacy of my pasteurization process?”, “what is the dose to which consumers are exposed at the end of shelf-life?” *etc.*

As stated by Zwietering & den Betsen[1]: “*predictive models are never perfect, due to intrinsic inaccuracies, extrapolations, and unexpected biological behavior*”. Yet, whatever the scope, it is important to know the reliability

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of predictions or recommendations derived from these models. The model developers need to have an estimate of the reliability of the models to measure quality, determine the interest, draw biological conclusions or need for improvement and thus guide their work. More importantly, model users need to know the accuracy and reliability of models to consider this information in the decision making. In order to extend the use of predictive microbiology models in the industry, an effort has to be made on these latter points. Moreover to help users, a categorization scheme that defines a model's viability for use in an operational setting is needed.

2. Current practices

2.1. Data used for model building

For the construction (and validation) of secondary models for growth or inactivation, more and more studies are based on data extracted from existing literature data. The modeling of data from different studies raises particular difficulties. Datasets should not be selected just because they yield favorable results for the model. Similarly, one should not exclude a dataset just because it yields “bad” results. It is thus necessary to define the criteria for inclusion of data. Quality of kinetic (number of points of the kinetics, minimal difference between the inoculated level and maximum level) can be part of the potential inclusion criteria[2]. These criteria are not systematically reported in existing literature. Fig. 1 illustrates some inclusion/exclusion criteria.

Criteria	Condition for exclusion
Difference between minimal and maximal levels	N_{max}-N_{min} $\leq 1.5\ log_{10}$
Difference between initial and final levels	N(final)-N(0) $\leq 1\ log_{10}$
Number of points in the kinetic	$n \leq 4$

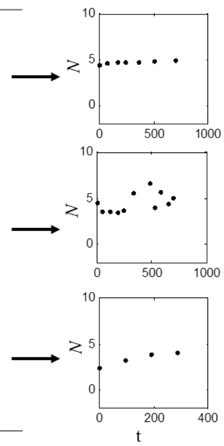

Fig. 1. Three criteria with their conditions for data quality checks and illustration with a dataset.

2.2. Verification

Verification of PM models is less documented than validation. The most often reported verification technique in PM consists in plotting observed data against predicted data (the observed data being part of the model's training data).

Within the modeling and simulation community, verification of a model consists in confirming it accurately represents the developer's conceptual description and specifications. Many software engineering technology applied for software verification are applicable to simulation model verification. During verification, the model is tested to find and fix errors in its implementation. Example of techniques to verify a model include the following: having the model reviewed by an external expert, examining the model output for reasonableness under a variety of settings of the input parameters, maintaining complete documentation of the code; verifying separate parts of a model one by one; programming, sections of the model independently by two programmers; performing trace analysis (in which each event are tracked); checking compatibility of the software.

There are verification and validation standards, including some that are specifically focused on modeling and simulation[3]. These standards could help to better define verification of PM models, especially tertiary models.

2.3. Validation

Validation of predictive microbiology models is well developed. Several indices have been proposed to quantify potential biais and accuracy[4]. During validation, data not used for model building should be used. These data may come from the literature. Dynamic conditions (temperature, pH, etc.) are often used to validate a model obtained in static conditions. Validation is also the place to check the range of application (food types) of the model.

If for “simple model” in PM, validation is not a challenge, it becomes for complex for exposure assessment model. A model of the exposure assessment is a combination of "simple" models that have been independently validated. Yet, the validation of exposure assessment models is an elusive goal and is costly and time-consuming.

3. Operational readiness

Given the importance of PM models to food industry (HACCP, shelf-life determination, product formulation) and to risk assessor, it would be important to dispose a categorization scheme that would define a model's viability for use in an operational setting. It seems that none exists for PM, but recently one was proposed for epidemiological models[5]. Their scheme was based upon the “technology readiness level” (TRL) originally defined by NASA, in order to assess the technology readiness of space development programs.

"Operational readiness" is a concept that may be seen as intended use dependent. A model that one user may consider ready may not suffice for readiness with another user. For example, in the case of growth prediction of a pathogen for shelf-life establishment, some will need to take into account variability for assessing the probability of exceeding a limit, while other users may just need a deterministic output to check is the limit is met or not. The operational readiness level rating of any given model should not depend upon the complexity of the modelling approach.

Several criteria can help to define the readiness level. Three of them (at least) are essential whatever the level: (i) modelling assumptions and the range of application of the model should be defined, (ii) equations and parameters should be transparent and explicitly reported, and (iii) data used for model building and validation should be given for traceability and reproducibility. Good examples can be found in current models and tools for these three criteria see respectively[6,7,8]. Two other criteria help to define the readiness level, validation and verification. High confidence on these two aspects permits to increase the level on the scale. Finally, the capacity of the model to be used by food industry and the recognition of the results by food control authority (or third-party food safety auditors), permit to reach the highest levels (including accreditation, i.e. the official certification that a model or simulation is acceptable for use for a specific purpose).

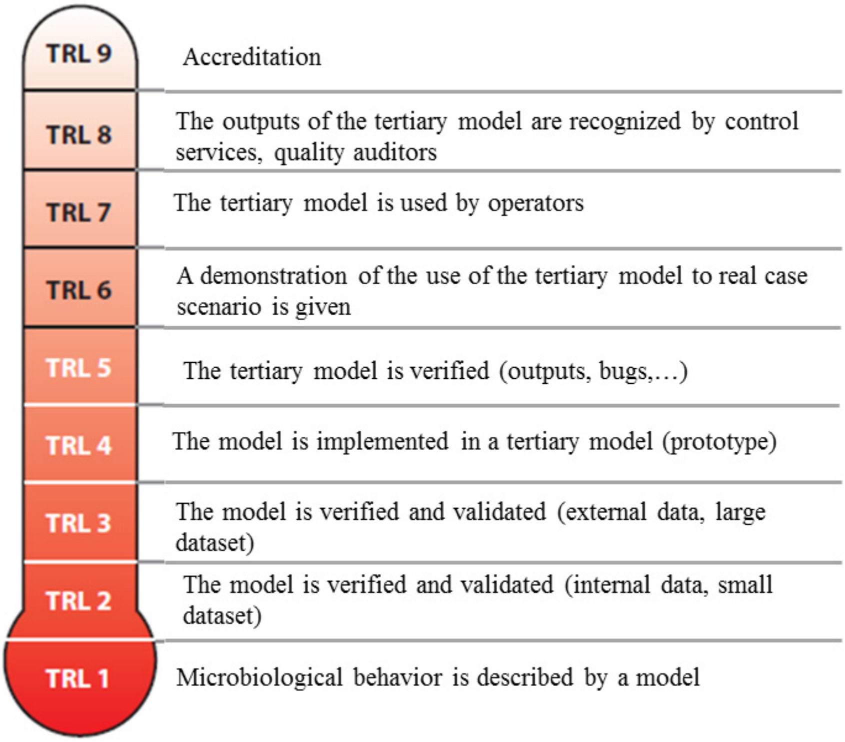

Fig. 2. Initial definitions of operational readiness levels for predictive microbiology models.

4. Conclusion

Transferring in large scale, the knowledge of predictive microbiology models for real world food industry applications is a major challenge. The proposal of a categorization scheme of models is an initiative that may help to choose the right model and give confidence in their use. In order to test the proposed operational readiness levels, we suggest further development of the criteria and application of the levels to existing models to evaluate their usefulness.

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