Framing TOS in risk assessment: an outreach perspective for the future

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Sampling is necessary every time inferences are to be made to take informed, optimal decisions in science, technology, industry, trade and commerce. For reasons extensively addressed over the last two decades, some fields, normally those where good sampling practices are a source of economic gain such as the mining/minerals/metals industrial sectors, explicate the role of sampling more than others. However, this is not the case within the realm of food and feed safety assessment, for example, where sampling continues - still today - to be perceived more as an economic burden and a technical necessity to be fulfilled because of regulatory demands, rather than a need to ensure reliable evidence to support management and regulatory decisions. This is true today and will become even more central in the future when society must address the challenges posed by the accelerating climate crisis, resources depletion and increasing food demand. Risk assessment and sampling are both probabilistic disciplines, the first devoted to estimate and minimise safety risks, the latter devoted to estimate and mitigate sampling risks (the effects of sampling errors). Here we offer an exposé with the aim of positioning TOS as an essential discipline and practical tool needed to ensure the best possible estimation of risks in support of safety decision-making and risk management in biological sciences, technology, industry, trade, commerce, and society at large. We demonstrate that sampling plays an integral, but an often much overlooked role in all these fields.

Sampling: a border-crossing discipline

Sampling is a border-crossing discipline relevant every time inferences are to be made for taking informed, optimal decisions in science, technology, industry, trade and commerce. Scientific experiments and technical endeavours are very often dependent upon correct sampling at certain fundamental stages. Trade and international agreements recommend duplication (or even triplication) of primary samples to allow buyers and sellers performing analyses to compare results for contractual compliance purposes. Market and commercial agreements also rely on sampling for monitoring of quality.

Sampling plays a self-evident role in food and feed (F2) safety assessment as representativity of test materials for hazard identification, hazard characterization and exposure assessment are critical pre-requisites for taking informed decisions regarding public, animals, and environmental health[1]. Indeed, potential health risks for humans and animals can only be estimated accurately when exposure scenarios to a given food or feed are realistic, i.e. based on reliable sampling of food consumption habits. Furthermore, from an analytical perspective, the vast variety of food and feed matrices and commodities, raw or (semi-) processed, pose challenges to develop *appropriate* sampling strategies that best facilitate correct analytical methods[1,2]. Similar issues exist in other sectors of society, e.g., in pharmaceutical manufacturing.

Nonetheless, despite abundant evidence documenting the pervasive relevance of sampling, the Theory of Sampling (TOS) is not (yet) universally accepted.

Over the course of twenty years, working alone and together, exploring the application of TOS to very different disciplines, we felt challenged by two fundamentally contrasting attitudes towards TOS: **why sampling?** and **what benefits from proper sampling?** In this period, we have addressed, analysed and discussed on multiple occasions the likely causes for the divergent attitudes[1,3], and have recently arrived at the understanding that at the root lies different *a priori* motivating factors driving the modes of application of TOS and practical sampling.

We here chose to focus on the mining/minerals/metals (M3) and food and feed (F2) sectors as lighthouse examples to *illustrate* this contrasting mindset. In the M3 sector, incorrect sampling unavoidably translates into hidden or clearly predictable economic losses. Consequently, TOS is here rightly perceived as the main underlying agent safeguarding business endeavours[4].

In the equally broad global F2 sector however, sampling is seen as a tool to verify the accuracy of claims and/or the quality of products, forcing TOS more to be the operative agent with which to search for possible problems or to verify their absence, providing results in a statistical context offering merely degrees of confidence to inform the decision-making process. This is clearly a very different driver for invoking correct TOS when compared to safeguarding information factors for hardcore business interests.

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An emerging synoptic TOS framework

The contra-positioning of the underlying drivers for sampling is a key point dividing the views of samplers, process engineers, managers, regulators: even if from a technical and practical point of view exploration for, and processing of metalliferous resources is not so different from sampling for, say, aflatoxins in a 60,000-ton shipment of grain kernels — the motivations for investing intellect, time and money in correct, representative sampling are fundamentally different. In the M3 sector, the better the sampling the better for business, whereas in the F2 sector the better the sampling, the higher the risk of lot rejection or similar, which always carries a heavy negative economic and/or reputational penalty. The gamut of TOS applications in the last 20 years documents this dichotomy, witnessed by the comprehensive historical record of the Proceedings from ten World Conferences on Sampling and Blending (WCSB) in the period 2003-2022.

Notably, the practical application of TOS is virtually identical in all applied fields, including F2 and M3. When sampling heterogeneous materials of any nature, the task for practical sampling is to counteract the effects of the same sampling errors (SE), making use of the same Sampling Unit Operations (SUO) following the same Governing Principles (GP). The purpose of sampling is to conduct the optimal elimination and/or reduction of all nine recognised types of sampling error effects, to deliver a defensible representative analytical aliquot to the laboratory (horizontal yellow arrow in Figure 1 below). To be able to do this, all pre-analysis sampling operations must be representative, no exception allowed. In the schematic TOS framework developed by one of the present authors over the past 20 years[5], the critical task of eliminating and reducing sampling error effects can also be seen as appropriate sampling error management.

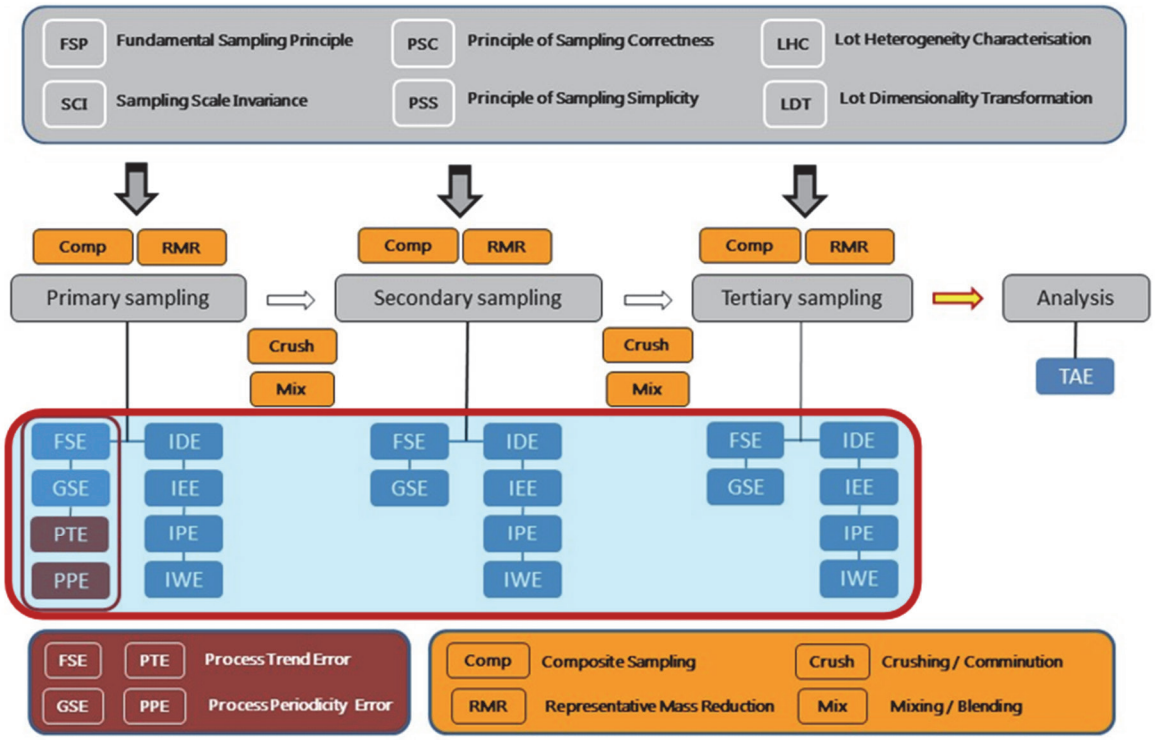

Figure 1. Theory of Sampling (TOS), synoptic overview. Practical sampling is governed by six Governing Principles (GP) [top grey panel], using four Sampling Unit Operation (SUO) [bottom yellow panel] in an informed effort to reduce unwanted sampling error effects, IDE, IEE, IPE, IWE, GSE, FSE … [blue rectangle]. This constitutes the realm of risk management in TOS: Correct, complete elimination of ISE and reduction of CSE sampling errors (incl. those occurring in the analytical laboratory).

In the TOS realm, mitigation - i.e., management - of SE is a compound operation driven by the necessary sampling competency, which can range from adequate to non-existing, fighting material heterogeneity, which can also range from large to almost non-existing. The chief principle is clear: all sampling procedures must be representative. Therefore, the starting point is always the Lot Heterogeneity Characterisation (LHC) which allows the design, implementation and performance of optimal representative sampling with respect to the specific heterogeneity profile of a lot of interest. This framework representation has only very recently allowed the sampling community to recognise that proper handling of the gamut of sampling errors is in fact a critical risk management operation[5], to be further elucidated below.

Pushing the envelope for applied TOS

During their 20-year journey, the authors gradually grasped the dichotomous background attitudes explained above, but also experienced a certain level of frustration. Amidst tremendous success for the International Pierre Gy Sampling Association (IPGSA) concerning theoretical deepening, organisational development and TOS application in many traditional fields, we never felt quite satisfied with the degree to which our community has increased the diversity of application's fields beyond M3 for example in the medical arena. In the F2 sector significant progress has been made as today the concept of 'representativeness' is discussed, understood and incorporated in several of the key international standards governing the food and feed arena. This signifies an important step forward, triggered by exhaustive efforts in promulgating proper sampling in the F2 world. In this respect the challenging journey of broadening TOS's scope beyond the boundaries of the original realm of geological resources and raw materials has fared well, such that today, for example, also the pharmaceutical world considers TOS a valuable tool. Other progresses have been made recently in process industry at large, as witnessed by many contributions to WCSB10 as well as by DS3077 (2013)[6]. However, documenting representativeness with data-based evidence is not yet mandatory and often not even considered as a fundamental requirement for good decision making-process in many of the applied fields where sampling *de facto* takes place.

Here we wish to continue promoting the expansion of TOS beyond the boundaries of M3, where things started and remained confined for long, by elaborating on the probabilistic nature that sampling and risk assessment have in common: proper sampling estimates and minimises the effects of unmitigated sampling errors, risk assessment estimates and minimises the risk associated to a given hazard in each activity or undertaking.

From M3 to F2 – and beyond

The market we live in was for a long time steadily increasing in its global dimension and interconnectedness, and until recently most models indicated that this trend would continue. It is yet to early to assess the magnitude of the effects on the global marketplace by the war in Ukraine, but severe global disruptive impacts are certain.

Despite the universally recognised right of any citizen to be guaranteed the same level of protection, as of today risk assessment (RA) approaches in food and feed safety are not harmonised, creating trade problems and inequality in safety protection around the world. The future will demand even stronger efforts towards RA harmonization by exploring innovative approaches to resolve the problems that prevent this aspiration today. The development of large databases to share information is strongly needed; the revision RA methodologies to address new food products continuously emerging and imposing new interdisciplinary approaches, is also necessary. To effectively tackle F2 safety problems, we must develop new approaches capable of considering the multiple interactions that the complexity of innovative food producing systems will require in the future. But most importantly, our generation has the responsibility of ensuring the sustainability of food/feed industry, a big challenge that governmental organizations are trying hard to resolve.

In this setting, correct sampling is and will continue to play an important role in ensuring that all the relevant information necessary to take the best possible decisions is collected appropriately. Sampling is about being accountable for the trust that society puts into governmental and inter-governmental regulatory and control systems for the safety of food and feed products of today and of the future. Society has no other choice: we all eat food that we buy at supermarkets, trusting it is safe, trusting that the control system works to protect us, the consumers, the citizens.

This logic can to a large degree be transferred to many other fields of TOS application like pharmaceutical industry, chemical industry, medical sector, packaging industry just to name a few. The technical discipline TOS serves a societal role of the greatest importance, in effect putting a substantial ethical responsibility on these communities, albeit this role is almost totally unseen and unrecognised by the world's populations at large.

Going beyond the *status quo*

For the past 20 years the authors have documented how sampling enters full force in food and feed safety assessment, even though most times this means raising costs rather than resulting in economic gain. This opened our eyes towards the hidden common aspects between the somewhat crass utilitarian business role of TOS in the M3 sectors and its role in the service of public and animal health.

But these apparently diverse roles for applied TOS can also be seen from a common viewpoint, with a much broader impact, introducing the unifying concepts of risk, risk assessment and risk management in the sampling arena. In the following it is assumed that the reader is familiar with TOS' basic systemic elements of Governing Principles (GP), Sampling Unit Operations (SUO) and Sampling Error Managements rules (SEM).

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Fundamental definitions

- **Risk** = probability that something unknown and/or unwanted happens.
- **Risk assessment** = the process to identify risks, so they can be minimised to maximise a critical subject-matter goal e.g., consumers protection (societal scope), economic gains (business scope), or sampling variability (technical quality control/quality assurance/quality management scope).

- **Risk management** = the process of managing and monitoring risks, optimising success by minimising them as much as possible. Risk management capitalises on data as an asset and data must be relevant and reliable i.e., representative.

Fundamental definitions applied to TOS

- **TOS Risk** = probability of unwanted, unmitigated sampling errors (SE) - both incorrect (ISE) and correct (CSE) sampling errors - resulting in uncontrolled, excessive sampling variability. This is a scenario damaging every stakeholder.
- **TOS Risk Assessment** = the process to estimate the effects of unmitigated sampling errors in terms of ISE + CSE and material heterogeneity - i.e., the total sampling error (TSE) - employing, for example, pairwise sampling, replicated experiments or variographic characterisation, see TOS literature for details.
- **TOS Risk management** = the process to mitigate sampling error effects, preferentially through the complete elimination of ISE and the concomitant reduction of CSE.

Positioning TOS as a risk management endeavour provides a broader perspective, both at the theoretical as well as the practical level, illustrating the far-reaching scope and responsibility vested in the TOS community. This awareness already began with the recent monumental publication "Economic arguments for representative sampling" addressing how to engage better with management, offering more than 25 different point of views[4]. This collective publication expresses well the *status quo* for IPGSA and identifies areas where IPGSA community needs to expand its activities to promulgate TOS as a tool necessary for optimal risk management decisions across many disciplines.

Sampling is about providing reliable data and information necessary to take managerial decisions. In some areas such information is sufficient on its own, in others additional considerations must be taken into account. In the M3 sector, once the effects of unmitigated sampling errors are estimated (TOS risk assessment), the decision is univocal: eliminate ISE and reduce CSE to the minimum possible to maximise business achievement (TOS risk management). The IPGSA community is very familiar with this logic. In other sectors, however, risk assessment outcome is not the only factor considered in the managerial decision-making process. This is the case, for example, for F2 where ethical, political and societal considerations must also be taken into account to reach a compound final decision.

Food for thought

Because of its complexity, risk management is a particularly challenging endeavour. The goal of correct risk management is not elimination of all risks (which would be an impossibility), but rather getting to know which risks are worth taking, which must be minimised, and which ones have enough of an assured negative pay-out to not take them.

The IPGSA community should expand its horizon and offer its expertise to all sectors in society where TOS is a *de facto* essential tool to deliver the appropriate information for critical decision making. Correct sampling is about being accountable for the trust that society puts into decision making systems. Society has no other choice: we all consume what is available on the market trusting its quality and safety, trusting that the control system has worked as intended. "*Consumption*" shall be seen here in a much broader context than just human and animal consumption of food and feed, as the responsible *use* of resources and commodities. Upon reflection, there are virtually no examples of management decision making in the technical and industrial society not based on proper sampling somewhere in the information flow involved, although this may in many cases be a much-overlooked insight.

Explicating the risk management scope of sampling allows a fresh and powerful look at some of the current hindrances revealed for a more successful drive to go beyond traditional borders. Framed in this perspective, TOS becomes an essential practical tool needed to ensure the best possible estimation of risks to inform safety decision-making across societal sectors at large, including biological sciences, agro-business, technology, industry, trade, commerce, environment. Successful risk management considers the full range of risks, examines the relationship among the identified risks and their cascading impact(s). In some areas the number of factors informing management decision is limited, like in the M3 sector where the attention is always tightly focused on mitigation of sampling error effects on the business bottom line. In others, like F2, the primary consideration is always human and animals' health protection, however other factors such as economic costs, benefits, technical feasibility, risk perceptions are also considered appropriate.

Nonetheless, TOS is indispensable under either scenario – and far beyond. It is hoped that the risk assessment scope will allow the IPGSA community an easier, and perhaps more powerful, way to reach out to business, commerce, trade as well as regulating and law-enforcement authorities by starting to speak a more common language.

Disclaimer

Claudia Paoletti is employed by the European Food Safety Authority (EFSA). The positions and opinions presented in this article are those of the author alone and do not necessarily represent the views or scientific works of EFSA.

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