SAMPLING COLUMN

Framing the Theory of Sampling in risk assessment: a compelling 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, application fields where good sampling practices are a source of economic gain—and bad sampling performance results in significant but unnecessary loss of money, such as the mining/minerals/metals industrial sectors—explicate the role of sampling more than others. In stark contrast to other fields (the realm of food and feed safety assessment is a prime example), sampling is largely perceived as an economic burden and a technical necessity to be fulfilled because of regulatory demands, rather than a vehicle with which to ensure reliable evidence to support management and regulatory decisions. Risk assessment and sampling are both probabilistic disciplines, the first devoted to estimate and minimise economic, safety and other risks, the latter devoted to estimate and mitigate sampling risks (the effects of sampling errors). Here we offer an exposé showing that the Theory of Sampling is an essential discipline and practical tool needed to ensure the best possible estimation of risks in support of both narrow economic objectives (industry, technology, trade, commerce), as well as broader safety decision-making and risk management environmental and biological sciences, and society at large. This contribution offers a novel perspective arguing for proper sampling, one where the economic argument ("what's in it for me") for proper sampling is demonstrated in practically all contexts, hereby complementing the compelling 25-author "Economic Arguments for Representative Sampling".[1]

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 characterisation and exposure assessment are critical pre-requisites for taking informed decisions regarding public, animal and environmental health. 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. 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.

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A confluence of frustration

Over the course of the last 20 years, working alone and together, exploring the application of the

TOS to very different disciplines and application fields, M3 vs F2, the present authors often felt challenged by meeting two fundamentally contrasting attitudes towards the TOS: **why sampling?** and **who/what benefits from proper sampling?**

In this period, we addressed, analysed and discussed on multiple occasions the likely causes for the divergent attitudes towards the TOS,[1–5] and arrived at the understanding that different *a priori* motivating factors driving the modes of application of the TOS and practical sampling are the root cause for this. We here choose 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, the TOS is here rightly perceived as the main underlying agent *safeguarding business endeavours*.[1] 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 the 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.

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 education, 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.

An emerging synoptic TOS framework

The plethora 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 as well as a trend towards more reflected TOS references in ISO standards a.o. Notably, the technical application of the 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 eight types of sampling error effects, to deliver a defensible representative analytical aliquot to the laboratory. 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*.

In the TOS realm, mitigation (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 range from large to almost non-existing, only using composite sampling. The key principle is clear: all sampling procedures must be representative of

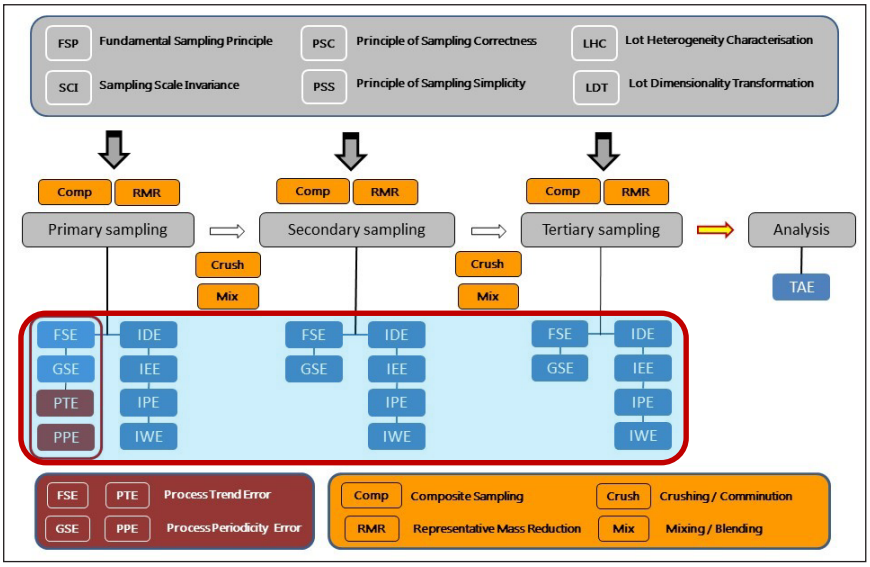

Figure 1. Theory of Sampling (TOS), synoptic overview. Practical sampling is governed by six Governing Principles (GP) [top grey panel], using four Sampling Unit Operations (SUO) [bottom yellow panel] in an informed effort to reduce unwanted sampling error effects, IDE, IEE, IPE, IWE, GSE, FSE … [blue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

the original sampling target, the lot. 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.

The synoptic framework representation of the TOS in Figure 1 has only very recently allowed the sampling community to recognise that proper handling, i.e. management of the gamut of sampling errors is in fact a critical risk management operation,[6] to be explicated below.

Risk, risk assessment, risk management

The apparently very diverse drivers for applied TOS in the exemplar M3 vs F2 sectors indicated above, 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 the TOS' basic systemic elements of Governing Principles (GP), Sampling Unit Operations (SUO) and Sampling Error Management rules (SEM), see Figure 1 and basic TOS references as found in References 1 and 5.

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

Risk assessment has been defined in many different contexts see, e.g., a Google search.

Positioning the TOS as a risk management task provides a broader perspective, both at the theoretical as well as the practical level, illustrating the far-reaching responsibility vested in the TOS community. This awareness began with the recent publication "Economic arguments for representative sampling", which addresses how to engage better with management, offering more than 25 different points of view.[1] This collective publication expresses well the *status quo* for the International Pierre Gy Sampling Association (IPGSA) and identifies areas where the sampling community needs to expand its activities to promulgate the 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.

Fundamental risk definitions

Risk: probability that something unknown and/or unwanted happens.
Risk Assessment: the process to identify risks, so they can be minimised, often in order to maximise a critical goal, e.g., economic gains (business scope), consumers protection (societal scope) or quality control (technical quality control/quality assurance/quality management scope).
Risk Management: the process of monitoring and managing risks, optimising success by minimising identified risks as much as possible. Risk management capitalises on data as a reliable asset, for which reason all data must be representative.

Fundamental risk definitions applied to the TOS

TOS Risk: probability of unwanted, unmitigated sampling errors (SE)—both incorrect (ISE) and correct (CSE) sampling errors—resulting in uncontrolled, inflated sampling variability. This is a scenario damaging to every stakeholder.
TOS Risk Assessment: the process to identify 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 the TOS literature for technical details.
TOS Risk Management: the process of monitoring and managing sampling error effects, specifically through complete elimination of ISE and the concomitant reduction of CSE, thereby, a.o., eliminating the fatal sampling bias, while complying with the Fundamental Sampling Principle (FSP) at all scales.

Discussion

The goal of 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 not to take them.

The sampling community should expand its horizon and offer its expertise to all sectors in society where the 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 the business community and 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.

But "*consumption*" shall be seen here in a context much broader than just human and animal consumption of food and feed, indeed 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 that do not rely on sampling-before-analysis considerations along the information flow involved, even if well hidden from immediate reflection. Explicating the risk management scope of what makes sampling representative allows a fresh and powerful look at some of current hindrances for a more successful drive to *go beyond* the TOS' traditional borders. Framed in this perspective, the TOS becomes an essential practical tool needed to ensure the best possible estimation of risks to inform decision making across societal sectors at large, including biological sciences, agro-business, technology, industry, trade, commerce, environment.

Conclusion

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 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 animal health protection, however, other factors such as economic costs, cost/benefits, technical feasibility and risk perceptions are also considered appropriate. Nonetheless, the TOS is indispensable under either scenario—or beyond.

It is hoped that the risk assessment scope will allow the sampling 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 beyond the mere "technicalities" of the TOS.

Disclaimer

Claudia Paoletti is employed by the European Food Safety Authority (EFSA). The positions and opinions presented in this article are those of the authors alone and do not necessarily represent the views or scientific works of EFSA. Kim H. Esbensen is an independent researcher and consultant, having left behind a three-decade university and government employee career in 2015.

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