SAMPLING COLUMN

Representative sampling and society

Claudia Paoletti[a] and Kim H. Esbensen[b]
[a]Deputy Head GMO Unit, European Food Safety Authority—EFSA, Via Carlo Magno 1A, 43100 Parma, Italy. E-mail: claudia.paoletti@efsa.europa.eu
[b]KHE Consulting (http://www.kheconsult.com) and Guest Professor (Denmark, Norway, Puerto Rico)

The last sampling columns have focused on the advantages the Theory of Sampling (TOS) can bring to companies, producers and manufacturers significantly reducing costs due to inferior sampling, and maximising efficiency and logistics. Here instead we take a look at sampling from the point of view of buyers, consumers and from a broader societal perspective, exploring the economic benefits and other advantages (e.g. transparency) that can be obtained through proper sampling. We address the point of view of the ultimate users and beneficiaries of TOS, on the market place or elsewhere. We are going to explore the other side of the coin, the one linked to the ethical and moral obligations that pertain to decision-makers of responsible public and governmental bodies, which indeed should apply equally also to producers and manufacturing companies.

Sampling: from the point of view of buyers, consumers, citizens

Let us start by thinking of the role of sampling from the point of view of consumers dealing with market products which are essential in terms of both *security* and *safety*, primary examples would be food, agricultural commodities, beverages, drugs and other medicinal products, air, soil and water quality. Here inferior sampling may not only threaten economic optimisation in the narrow production and commercial sense, but also result in a potentially negative impact on public health, for example. Quantitative and analytical data are used daily all over the world to take important decisions which ultimately affect every single citizen; and single citizens have no other choice than to *trust* that such decisions are made on the best available basis and knowledge. The question is how, and on what basis, are decisions made regarding product and commodity safety or environmental thresholds regarding maximally allowed pollution levels? Upon reflection, there are very many such decisions that are dependent upon proper sampling… usually hidden far away in early stages of causal pathways, e.g. "from-field-to-table".

The problem is linked to the concept of "best available knowledge" for which a universal definition cannot be identified, even though it is often used to claim/guarantee quality in the interest of consumers, stakeholders and, ultimately, society at large.

However, often what is "best available" is just not good enough.

During the last fifteen years we have provided documented evidence of sampling situations where "the best available" was, and sometimes still is, insufficient. A few examples can be found in References 1–4, where the critical issue of proper sampling for GMO detection and quantification was treated in a series of papers in *Trends in Analytical Chemistry*.[2–4] In the food and feed realm, a major achievement was the 2015 special issue section of *Journal of AOAC International*: "Representative Sampling for Food and Feed Materials" presenting a compact handbook for this important societal sector,[5] complete with many consumer, user and societal viewpoints. There has also been a consistent critique of existing "sampling" sections and paragraphs in current ISO standards. Indeed, this topic remains highly critical: *much* of what is presented in international standards does not meet what is required to guide towards, far less guarantee, "representative sampling". The very wide spectrum of recommendations offered ranges from acceptable (not often) to "home-grown statistics" (quite often), which, although maybe correct w.r.t. the statistical formulations, do not apply to the harsh reality of heterogeneity.[4,5]

Despite such first forays, representative sampling is not yet recognised as one of the key tools needed to ensure that the quantitative analytical data used to take subject-matter decisions are truly the "best available". As responsible scientists, we must be realistic and accept that, on the present basis, claims identifying the Theory of Sampling (TOS) as the *only* frame for correct sampling may not always be understood; there is much more work to be done before significant impacts on the general population will be achieved. A newly released report dealing with a topic that runs parallel to the present (indeed it overlaps significantly: proper sampling is a critical prerequisite to circular economy)[6] shows this compellingly. Another, "Barriers to the circular economy: evidence from the European Union" by Kircherr *et al.*[7] reveals the complexity and immensity of this kind of awareness and educational endeavours.

Sampling champions feel a moral obligation to find innovative ways and means to incorporate representative sampling as a key criterion for any quality statement, ensuring a step-forward in

the correct application of scientific knowledge to practice.

So, two basic questions arise:

1) **Who** should decide when "the best available" is indeed the best?
2) **How** can we convince stakeholders and citizens that correct sampling is a necessary pre-requisite, among others, to ensure security and safety of the relevant products and services essential for society?

Addressing both questions

1) Normally consumers decide quality, but this rule is difficult to apply when the quality under discussion is not the one of the final product(s), but rather of the *process* used to manufacture process or deliver products (or services). Suddenly quality becomes *invisible* for the consumer. This is why *individual citizens* can only trust that market decisions taken for essential products are made on the best available knowledge and must be happy (if not happy… at least willing) to pay taxes so that public control systems have sufficient resources to protect them! This admittedly oversimplified scenario is meant to illustrate the ethical responsibility that regulatory science bears towards society, a complex responsibility. But when one accepts this logic, we can easily answer the first question, **who** should decide when "the best available" is indeed the best? Only those having sufficient competence and knowledge of the process leading to a product can decide if "the best available" information is sufficient. If we project these considerations to sampling, it becomes clear that the quality of the sampling used in the decision-making regarding products essential for society cannot be assessed by the individual final costumer. Assessment of sampling quality relies on the professional integrity, expertise and objectivity of those controlling the production process. This completely changes the frame within which sampling problems are addressed and resolved, making it incomparable to that faced by TOS consultants working in the commercial realms, where the quality of their work is assessed directly by their clients. The part of the TOS community interested in engaging in sampling of societally essential products must be fully aware of these additional difficulties and responsibilities, which can frustrate (hopefully only temporarily) even the most motivated and determined sampling expert.

"Where it all begins." The dominating errors behind the final analytical uncertainty are always largest at the primary sampling step. Here soy beans are off-loaded from a cargo ship's holds. It is decidedly not a trivial issue how to sample this type of lot in a documented representative fashion—professional TOS competence is needed.

2) However, even if society in its role as final consumer of essential goods cannot monitor the quality of processes, it should be educated and aware (enough) to fully appreciate the practical relevance and implications that representative sampling has, even if oftentimes invisible to its final consumers. Here is a fact simple enough to be intuitively understandable **by all**: if sampling is not representative it is futile, indeed useless, to analyse the ensuing "samples", because it has no meaning to produce such analytical results without a clear provenance; the sampling + analytical uncertainty becomes totally unknown. This issue has been well illustrated in previous columns and has been explained many times in various fora. So much so that gradually various international normative documents now do mention that "good sampling *should be* representative". True, this is a much milder and timid version of "non-representative sampling is useless", but whether we like it or not, this is currently the only reward the sampling community has received for some 15–20 years of hard work. Now is the time to explore new strategies to speed up progress and ensure that representative sampling becomes a central element in the list of the essential quality criteria. But exactly **how to do so** requires careful thinking, because it will unavoidably entail identification and correction of deficiencies in current practices, which of course is never popular. Examples of the first steps in this direction could be References 8 and 9, against which there is non-trivial resistance. These issues were plentifully illustrated in the recent Sampling Column: "Sampling—*Pro et Contra*".[10]

The way forward: some proposals

First, we should better *substantiate* the claim that TOS is the **only** sampling frame universally applicable to any type of material and heterogeneity. We should demonstrate, with empirical evidence that this is in fact the case.

The KeLDA project[2–4] did so ten years ago, but no other examples of simi-

SAMPLING COLUMN

lar dimension (outside the mining and minerals processing sectors) have been produced ever since. No misunderstanding regarding the mining sector: from here comes the evergreen "How much TOS saves you in monetary terms" publication paper *par excellence* by Carrasco, Carrasco and Jada: "The economic impact of correct sampling and analysis practices in the copper mining industry",[11] which was summarised in the previous column.[12]

The sampling community has provided seminal books and many excellent scientific papers explaining with various degrees of complexity and comprehensibility the mathematics upon which TOS is rooted, and where TOS is currently technically progressing. The series of Proceedings, from eight consecutive World Conferences on Sampling and Blending, in which applications to a much broader societal field are presented, especially in the later three editions constitutes further progress in such direction.

Still the sampling community must continue to make extra efforts to put itself on the side of society, where intimidating mathematical formulae are respected, but only occasionally understood and where practical/direct examples are seen as the primary evidence that allows seeing the light in what is perceived as an intricate forest of technical and scientific complexity. History teaches that significant, mass-scale changes in attitude towards scientific innovation have only taken place when triggering explanations were simple, clear and self-evident. The TOS community has not yet found a fully comprehensive, winning formula to achieve this. But two previous columns made serious attempts.[10,12] What a challenge—one cannot wait to contribute! Below follows a few views on what *can* perhaps be done to trigger increased societal attention to sampling.

Beyond traditional application fields

The use of fortified foods, food supplements and "functional foods" is on the rise. This may result in a higher intake of nutrient substances, which *could* turn into a concern if intake levels become sufficiently high to induce adverse effects. Nutrients, in contrast to contaminants, are essential for human/animal health and have their positive nutritional effects within specific concentration ranges, governed by homeostatic mechanisms in the human/animal body. Adverse health effects may occur due to over-consumption or may lead to deficiency symptoms in case of under-consumption. Therefore, upper intake levels (ULs) of nutrients from food sources by humans/animals not inducing adverse health effects and minimal required intake levels should be identified in order to avoid such effects. Obviously proper sampling methods to be applied in various stages of production and processing of these foods are needed in order to be able to correctly determine actual intake levels of nutrients by humans and compare these with the established upper safety limits and minimal required intake levels.

Another well-known fact is the increased spread of *pathogens* in the food production chain, presumably due to globalisation of trade and to the migration of people.[13] New pathogenic micro-organisms have been detected and characterised, as well as an increase in antibiotic-resistant bacteria, presumably due to massive (over-) use of antibiotics for human therapy. Ingestion of pathogens or their toxins may induce a variety of diseases in humans/animals, ranging from acute illness like diarrhoea to many chronic diseases and death. Specific guidance for risk assessment of microbial food and feed contamination has been developed[14] and the importance of the dynamics of microbiological growth, survival and the (rapid) transfer of micro-organisms throughout the food production chain in many types of foods, raw or processed, and further spread in the environment has been underlined. Exposure assessment is of critical importance for risk assessment and consequently also for definition of suitable sampling plans, that take into account the specific distributional characteristics of microbial populations and of their spreading dynamics. These issues are of the utmost importance to allow an effective safety evaluation of food and feed commodities.

Consumption and request for *niche and brand* products, e.g. mono-cultural products, extra-virgin olive oil, mozzarella cheese, designed to capture the interest of an elite portion of consumers, is also increasing, at least in wealthy countries. In such cases, proper sampling may raise interest in **both** producers and society. For producers, correct sampling may facilitate the conquest of a portion of the market at the global level, ensuring/proving specific quality standards of unique products. Indeed, producers are aggregating into consortia with the objective of facilitating their business. For society the same holds true: representative sampling becomes a tool to ensure that the final niche-product on the market, possibly at a higher price to cover the specific production costs, indeed has the

Pathogens (or toxins), irregularly distributed in the lot (material).

For niche and/or brand product proper sampling actually benefits both sides of the traditional producer–consumer issue equally.

compositional, organoleptic and nutritional properties it should have. Here proper sampling benefits both sides of the traditional producer–consumer issue equally.

The TOS community needs to accept that sampling is up against a series of inherent difficulties linked to the nature of products in a wide societal sense, in particular beyond TOS' traditional target fields of mining, minerals processing and cement. The great diversity in food and feed sources and commodities and the different kinds and degrees of food/water contaminations are just a few examples, focussed on the difficulty for society to directly verify the quality of the production processes involved.

Here is a problem that only a few want to entertain today: the sampling frameworks currently used for quality assessments too often rely on *specific* statistical distributional assumptions (i.e. "homogeneous distributions" of compounds/test materials, "assumed" normal distributions), but which are very nearly *never* **verified** in practice, as current protocols do not even stipulate characterisation of inherent heterogeneity patterns stemming from the specific properties of the targeted materials. Moreover, current quality assessment protocols do not provide estimates of the risk associated with the sampling surveys *themselves*, nor do they address the uncertainties associated with spatially irregular distributions (material distributional heterogeneity).

Conclusions

Above, it is underlined that representative sampling is **key** in order to reduce the possibilities of either misestimating actual exposure levels for humans and animals or, worse, underestimating the risks for consumers to exceed tolerable intake levels. We need to prove this correct framework understanding with real data.

When you go to a wine cellar or wine store, you taste (***sample***) the wine before buying it: you do not ask the seller **if** the wine is good. The TOS community cannot expect to be listened to if they cannot also document our claims with **facts**, compelling visual, graphic and quantitative facts. This calls for superior examples and resources to support well-thought out research and demonstration projects with the same purpose. Examples from these frontlines will be presented in sequel columns.

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.

References

1. K.H. Esbensen, F. Pitard and C. Paoletti, "Sampling errors undermine valid genetically modified organism (GMO) analysis", *TOS forum* **1,** 25–26 (2013). doi: https://doi.org/10.1255/tosf.9
2. K.H. Esbensen, C. Paoletti and P. Minkkinen, "Representative sampling of large kernel lots – I. Theory of Sampling and variographic analysis", *Trends Anal. Chem.* **32,** 154–165 (2012). doi: https://doi.org/10.1016/j.trac.2011.09.008
3. P. Minkkinen, K.H. Esbensen and C. Paoletti, "Representative sampling of large kernel lots – II. Application to soybean sampling for GMO control", *Trends Anal. Chem.* **32,** 166–178 (2012). doi: https://doi.org/10.1016/j.trac.2011.12.001
4. K.H. Esbensen, C. Paoletti and P. Minkkinen, "Representative sampling of large kernel lots – III. General Considerations on sampling heterogeneous foods", *Trends Anal. Chem.* **32,** 179–184 (2012). doi: https://doi.org/10.1016/j.trac.2011.12.002
5. K.H. Esbensen, C. Paoletti and N. Theix (Eds), "Special Guest Editor Section (SGE): Sampling for Food and Feed Materials", *J. AOAC Int.* 249–320 (2015). http://ingentaconnect.com/content/aoac/jaoac/2015/00000098/00000002
6. K.H. Esbensen and C. Velis, "Editorial: Transition to circular economy requires reliable statistical quantification and control of uncertainty and variability in waste", *Waste Manage. Res.* (Dec. 2016).
7. J. Kirchherr, L. Piscicelli, R. Bour, E. Kostense-Smit, J. Muller, A. Huibrechtse-Truijens and M. Hekkert, "Barriers to the circular economy: evidence from the European Union (EU)", *Ecol. Econ.* **150,** 264–272 (2018). doi: https://doi.org/10.1016/j.ecolecon.2018.04.028
8. H.A. Kuiper and C. Paoletti, "Food and feed safety assessment: the importance of proper sampling", *J. AOAC Int.* **98,** 252–258 (2015). doi: https://doi.org/10.5740/jaoacint.15-007
9. C. Paoletti and K.H. Esbensen, "Distributional assumptions in food and feed commodities – development of fit-for-purpose sampling protocols", *J. AOAC. Int*. **98,** 295–300 (2015). doi: https://doi.org/10.5740/jaoacint.14-250
10. K.H. Esbensen and C. Paoletti, "Theory of Sampling (TOS): *pro et contra*", *Spectrosc. Europe* **30(1),** 23–26 (2018). http://bit.ly/2jWjnKH
11. P. Carasco, P. Carasco and E. Jara, "The economic impact of correct sampling and analysis practices in the copper mining industry", in Special Issue: 50 years of Pierre Gy's Theory of Sampling. Proceedings: First World Conference on Sampling and Blending (WCSB1), Ed by K.H. Esbensen and P. Minkkinen, *Chemometr. Intel. Lab. Syst*. **74(1),** 209–213 (2004).
12. P. Minkkinen and K.H. Esbensen, "Following TOS will save you a lot of money (pun intended)", *Spectrosc. Europe* **30(2),** 16–20 (2018). http://bit.ly/2IkwfJi
13. L. Saker, L. Kelly, B., Cannito, A., Gilmore and D.H. Campbell-Lendrum, *Globalization and Infectious Diseases: A Review of the Linkages*. World Health Organization, Geneva (2000).
14. Report of a Joint FAO/WHO Consultation entitled *Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards, Guidelines and Related Texts*. FAO and WHO (2002).