

The potential for the use of near infrared analysis of food materials in the regulatory context of the European Union

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Introduction

Membership of the European Union (EU) implies agreement to enact and enforce nationally, community-wide laws or directives. In 1985, however, the Commission for the European Communities (CEC), the EU “Civil Service”, published a communication on the completion of the internal market. It was apparent from this document that the previous policy, which attempted to “harmonise” standards across Europe, was not to be continued across every aspect of community life. The areas, however, of public health, consumer and environmental protection and fairness in community transactions would still be subject to the harmonisation process.

In the context of food, to which all the above areas apply, EC regulations embody the following issues:

- (i) composition.
- (ii) origin denomination.
- (iii) species origin.
- (iv) adulteration.
- (v) condition.
- (vi) quality.
- (vii) toxicity.
- (viii) safety issues.
- (ix) environmental issues.

Reliable, validated, rapid, economic analytical methods are required to enforce these elements of EC Directives which become enacted in national laws. How can near infrared (NIR) analytical techniques become validated official methods? It is essential to understand the mechanism by which a method might gain official recognition, and in the EU the international structure for establishing standards and specifications for a food product and associated tests is illustrated in Figure 1.

The two main European organisations through which one may progress an NIR analytical method towards official recognition are CEN (Comité Européen de Normalisation) and SMT (The Standards, Measurement and Testing programme). Within SMT, funding is available for EU member countries to submit projects to enable measuring techniques to be developed into protocols suitable for consideration by CEN or ISO (International Standards Organisation).

OFFICIAL ORGANISATIONS

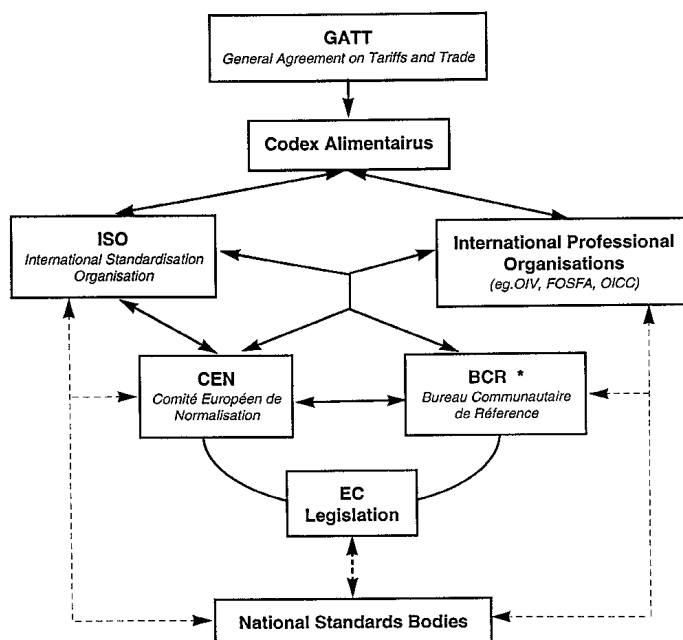


Figure 1. Official organisations for establishing standards and specifications for a food product. Note BCR is now called Standards Measurement and Testing (SMT).

A further mechanism which can help to establish the infrastructure of a concerted European approach to the science and the exchange of information which can facilitate the establishment of new techniques is that of the EU R&D framework. An example of this was the EC FLAIR/QUEST (Food Linked Agro-Industrial Research/Quality Established by Spectroscopic Techniques) project launched in 1990. The project brought together 38 scientists from 17 European or “associated countries” and included scientists from Scandinavia, Romania, Bulgaria and the Czech Republic, as well as those from the present EU.

Workshops or action groups worked closely over a period of four years, applying themselves to providing EU-wide useful information and data within a set of closely defined objectives. The final delivery from this activity was a set of ten action group guideline documents and accounts of plenary meetings which brought the action groups together under a wider banner.

One of these groups led by Roberto Giangiacomo from ISLC in Lodi, Italy, addressed the subject of “Spectroscopic techniques applied to EC Regulations relating to food” (STER).¹

This document addresses the application of several types of spectroscopy, including NIR, to EU legislation and lays out a systematic approach to enabling NIR methods (and other spectroscopic techniques) to become officially recognised.

Stepwise approach to official recognition of an NIR method within the context of the EU

Research the legislative and scientific background

You need to know what the official specifications are for the food material and the component or components for which you wish to propose a method. CODEX ALIMENTARIUS, relevant EU legislation, current published methods are example sources of information.

Comparing your proposed method with the current method, does your new method offer advantages?

- Is the new method reproducible?
- Is it more rapid?
- Is it more economical?
- Is the technique more environmentally friendly than the old one?
- Is the new method easier to use?

Identify the national and the EU official organisations with whom you need to work

It will be essential to convince the relevant official organisations of the efficacy of your technique.

Carry out work to demonstrate your method is valid

A number of approaches could be used at this stage, for example, publication of method development in appropriate scientific journals prior to preparing a protocol. Within the EU context, a successful proposal to the SMT programme which includes a properly designed laboratory intercomparison will probably provide the firmest footing. The author, and two of his European colleagues who were members of QUEST, are currently using this mechanism in the hope of gaining funding for a proposal to establish a recognised NIR instrument standardisation using aspects of cereal quality as the exemplars.

Develop the protocol

The proposed instrument standardisation project noted above is unlikely to be able to reach the stage of a full protocol ready for submission to the appropriate organisations and the draft protocol, which is expected to be produced, will require further development. It is possible that SMT funding may assist this stage.

Submission of the protocol

It is perhaps true that this stage should be decided upon prior to protocol development, since the organisation(s) you choose to submit to may require different approaches. Within the EU context CEN is likely to be most appropriate. It is possible, however, as demonstrated by the adoption of the SNIF-NMR (Site-Specific Nuclear Fractionation, Nuclear Magnetic Resonance) technique for the detection and quantification of sugar addition to wine, to have a technique accepted by the relevant official body which can recommend it to be included as an official method in EU Directives. In this case the OIV (Office International du Vin et de la Vigne) adopted the technique and it became enshrined in EC Directive No. 2676/90.

You may consider, however, that you wish your method to be recognised in a wider international context, in which case submission to ISO, AOAC or other relevant worldwide recognised bodies would be appropriate. The longer route via a national or EU official body followed by

submission to ISO etc. may be a more effective way of gaining full official international recognition for the method.

It is not suggested that the stages set out above are comprehensive for successful official recognition of an NIR method but consideration of, at least, these steps should optimise the chances of success.

Why seek official recognition for NIR methods?

As practising scientists we would perhaps be loathe to engage with the bureaucracy of obtaining official recognition for our methods. This is perhaps especially so for a spectroscopic technique like NIR which, to date, is only recognised as an official method in two cases (wheat, flour, protein and hardness). Indeed for NIR, NMR and UV/visible (as a colour test for wine) spectroscopies were only found by the QUEST/STER team to be recognised in six cases within the European context. A further consideration is that almost all officially accepted food component analytical techniques are wet chemistry based and spectroscopically based techniques therefore are not very familiar to those who are assessing them. Neither are they familiar to legislators who may wish to include them in EC Directives.

This background would appear to be piling obstacle upon obstacle but at the same time it can be perceived as offering a host of golden opportunities. The QUEST/STER group identified sixty-four food component analysis, currently carried out non-spectroscopically, which would be possible to develop into NIR, FT-IR, Raman or NMR techniques. This survey only covered eight food product groups, so the potential for introducing NIR official methods is enormous.

Conclusion

NIR, along with other spectroscopies, offers many advantages over traditional proximate chemistry analyses, but it will require determination, persuasion and diplomacy to overturn the balance of officially recognised methods in favour of NIR or other spectroscopic methods.

Reference

1. R. Giangiacomo and C.N.G. Scotter, *Spectroscopic Techniques Applied to EC Regulations Relating to Food* (STER). A FLAIR/QUEST Action Group guideline document, (1994).