WHAT IS A REFERENCE CULTURE?

Most reference cultures are organisms that originated in nature (not genetically modified or artificially selected) that have had particular aspects (growth characteristics, biochemical behaviour and/or genome) characterized. They may have been cited in literature and referred to in standard test methods as being a strain that typifies the characteristics of a particular genus and species of microorganism.

A reference culture may also be something that is different. For example, an atypical example of an organism could be part of a collection of cultures.

It is a culture that is referred to as a standard / baseline in testing and research laboratories.

This document refers to cultures that are commonly used as control strains in testing facilities and that have not been genetically modified.

WHAT IS THE SOURCE OF REFERENCE CULTURES?

Reference Cultures originated in nature and were deposited into culture collection(s) by people who wanted to have them preserved, either for their own later use or for other people's use. They may also have been purchased by the curators of the collection from other collections.

WHY DO REFERENCE CULTURES EXIST?

The original purpose of a culture collection was to share microbes amongst those who wished to study them or test them. They are also used to compare other cultures obtained by scientists in the course of their work.

Such purposes were for the greater good of the world's population. Originally, reference collections existed for reasons other than commercial gain. Although many collections now exist for commercial gain, the majority of collections serve the greater good of the community.

WHAT HAS A CULTURE COLLECTION PROVIDER DONE TO THESE CULTURES?

The provider has preserved microorganisms for storage in their collections. The provider may have performed identification tests and checks to ensure that each batch prepared has retained the characteristics as at the time when they were originally deposited. This could be termed value adding.

The level and type of value adding may be different for different collections.

Those culture collection providers that are accredited as reference material producers and provide certificates endorsed by their accreditation body have a duty to ensure the history and traceability of the culture is sure, that the batch of culture supplied is clearly identified and that the relevant checks have been conducted regarding homogeneity, purity and suitability according to claims made about the product.

The reference culture provider ensures that when the culture is obtained by the next user, they will receive:

- Mandatory information relating to the culture
- An organism that:
    - matches the advertised characteristics
    - is viable
    - is useful
    - is fit for the intended use

Note: the providers of reference cultures have not created the culture. The culture itself is not their invention, nor is it a product of their "imagination". Therefore, any claims of intellectual property for the actual culture are not applicable. The culture came from nature.

WHAT DOES THE CUSTOMER GET WHEN THEY PURCHASE A REFERENCE CULTURE?

They do not purchase intellectual property but rather, the value that was added by the reference material provider: viz;

- preparation
- preservation
- identification or verification
- chain of traceability
- checks of viability and purity, etc.

Basically all that is required for convenience in order that the user can focus on their daily testing and research work.

WHAT DOES IFM GIVE THEIR CUSTOMERS WHEN THEY PROVIDE CULTURES?

- Independent verifications of organism identity,
- Assurance of viability and purity,
- Unbroken chain of traceability to IFM's source,
- History once received at IFM and
- Where relevant, the levels of quantification.

WHAT DOES IFM REQUIRE OF ITS CUSTOMERS AFTER THEY PURCHASE AN IFM CULTURE?

Users of IFM's cultures are requested to adhere to this policy:

- IFM requires that our customers understand that the culture, once opened and grown by the purchaser is no longer IFMnnnn.
- Customers must incorporate the culture into their own laboratory collection and give the culture a unique identification.
- The records of opening and passaging must be kept, including traceability and provenance. This is to ensure the unbroken chain of comparisons back to the source as required by ISO/IEC 17025:2005 clause 5.6.2.1
- Purchasers of IFM cultures are free to pass these cultures to others. Please take note of ISO/IEC 17025:2005 requirements below.
- They are also free to sell such cultures for monetary gain. However, if the culture is no longer in its original packaging from IFM, the identification of the culture must NOT be IFMnnnn. The identification must be the unique ID given to the culture in the customer's laboratory and a statement of traceability to IFMnnnn.

> The reason for this is that once a culture leaves IFM's laboratory and is opened, IFM no longer has any control over the handling or treatment of the culture. IFM also no longer has control over possible contamination and viability issues. These issues become the responsibility of the person now holding the culture.

The creation of the cultures in the useable format may include intellectual property. However, once the material has been re-cultured by the recipient laboratory, the only part remaining of the product is the item originally coming from nature. Therefore, the extent of the intellectual property is limited to the process that resulted in the purchasable format of the culture.

For this reason, IFM agrees with the on-selling of cultures or free distribution of cultures amongst peers and colleagues. For this reason also, IFM disagrees with the concept of cultures having trade marks or being subject to royalty payments. IFM's only stipulation is that once opened and cultured, and no longer in IFM's original format, the culture cannot retain an IFM designation, but rather be "traceable to" the original IFM designation.

WHAT DOES ISO/IEC 17025 REQUIRE OF REFERENCE CULTURES?

The wording in 17025 requires that certain aspects of measurement are adhered to and suppliers of references must be deemed to be *competent* and have complied with all the requirements of 17025 (which refer to ISO G34.) This is more difficult to establish unless the supplying organization is in itself accredited. Most accreditation bodies require that reference materials used by accredited laboratories arise from an accredited source.