Guidelines for validation of qualitative real-time PCR methods

Abstract:
As for many areas of molecular testing, detection of Genetically Modified Organisms (GMO) relies on the real-time Polymerase Chain Reaction (qPCR) technology. Due to the increasing number of GMO, a screening approach using qualitative screening methods has become an integrated part of GMO detection. However, specific guidelines for the validation of these methods are lacking. Here, a pragmatic approach to conduct in-house and inter-laboratory validation studies for GMO screening methods, is proposed. Such guidelines could be adapted to other areas where qualitative qPCR methods are used for molecular testing allowing to implement easily a more reliable screening phase where necessary.

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