Why harmonized standards are key for market safe, effective and affordable biostimulants

Objectives of Harmonized Standards

The objective of harmonized standards, under the New Legislative Framework, is to promote the free movement of goods in a single market and eliminate barriers to trade.

Implementing harmonized standards is a way to ensure that only safe and compliant products find their way to market, enabling all economic players to benefit from a level playing field.

Providing the right data

Safety and compliance are top priorities for the biostimulants industry. Developing safety criteria for micro-organisms, within this legal framework, will allow manufacturers to provide the **right** data to conformity assessment bodies. This will enable risk to be assessed more accurately and ensure that **defined** criteria have been met.

It is common belief that collecting more information makes us more informed and leads to a better decision making process. However, too much information kills information. Having the right data is what matters!

A dramatic example comes from emergency medicine. Doctors in the USA developed a protocol to standardize the decision making process for the treatment of patients arriving with chest pain. Initially, doctors conducted individual risk assessments based on as much data as they could obtain.

Then a new process was implemented by examining past practices to define exactly what data was required and which key indicators would enable doctors to make extremely accurate decisions. This led to the creation of an algorithm.

Before using the algorithm process, doctors were making the right judgment call 75-89% of the time. The new procedure led to a significant jump in accuracy levels of over 95%, whilst reducing costs. (Learn more here)

Standardized decision making improves outcomes for all stakeholders

Combining evaluation criteria with harmonized standards will help ensure that only safe products are brought to market. It will also be more cost effective for industry and the authorities than the traditional risk assessment approach.

This approach encourages manufacturers to continue to seek out safe and effective micro-organisms as they do not have to reveal their discovery to competitors. At the same time, other manufacturers who discover the same micro-organism may use the same protocol to demonstrate their product is safe.

Read the EBIC position: How can the European Union Encourage Innovation in Microbial Biostimulants?