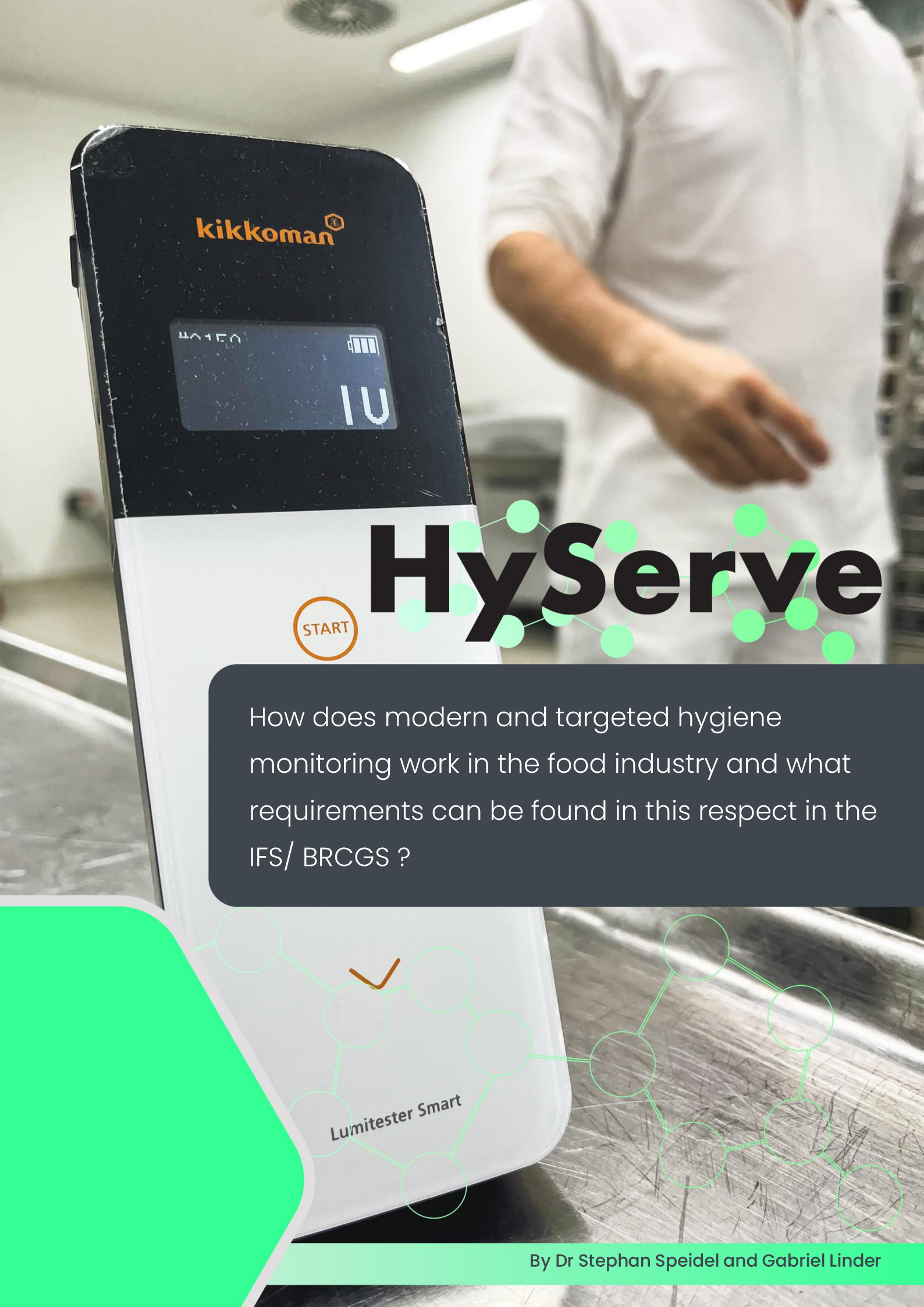

HyServe

How does modern and targeted hygiene monitoring work in the food industry and what requirements can be found in this respect in the IFS/ BRCGS ?

By Dr Stephan Speidel and Gabriel Linder

In summary:
Nowadays, food producers face the challenge of ensuring the basic supply of the population with safe, high-quality food at affordable prices.
The rising costs of energy, raw materials, as well as external and internal laboratory analytics, especially of microbiological environmental monitoring which, depending on the process and product risk, must be carried out very carefully - are now pushing companies to the breaking point. Therefore, it is not uncommon for management to ask those responsible for QM and QA to identify potential savings in analysis costs without jeopardising food safety or quality and, thus, the company's image.

In addition, conventional microbiological methods have the major disadvantage that results are only available after cultivation and counting - which takes a minimum of 24-48 hours, depending on the type of germ. By taking samples using microbiological cultivation methods, the hygiene status after cleaning and disinfection can only be verified afterwards and thus much too late. It is therefore not at all possible to take immediate corrective measures.

If samples are taken using conventional microbiological cultivation methods, the hygiene status after cleaning and disinfection can only be verified afterwards and thus much too late. It is therefore not at all possible to take immediate corrective measures. This is why even the most common GFSI product safety standards such as the BRCGS Global Standard Food Safety as well as the IFS Food refer to the use of rapid tests in order to enable immediate monitoring of the effectiveness of cleaning and disinfection.
Cost-effective, but above all reliable rapid test technologies for checking the hygiene status within seconds are therefore increasingly in demand in the food sector.

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IFS Food and BRCGS Food Safety requirements for the verification of cleaning and disinfection measures

In IFS Food 7, Chapter 4.10. Cleaning and Disinfection in Requirement 4.10.5 states in this respect:

"The effectiveness of the cleaning and disinfection measures is checked in light of the risk assessment. The verification is based on a defined, appropriate sampling scheme.
This includes:
- visual check,
- rapid tests,
- analytical test methods. Corrective measures derived from these are documented."

Very similar, but somewhat more detailed, the BRCGS Food Safety describes in the fundamental criterion 4.11 Operational Management and Hygiene:

"For areas in contact with food and processing for processing equipment, it is necessary to specify limit values for acceptable and unacceptable cleaning performance. These limit values are based on the potential hazards that are relevant to the product or the processing area (e. g. Microbiological contamination or contamination with allergens or foreign bodies or product-to-product contamination). Therefore, acceptable cleaning standards can be defined as applicable by visual appearance, ATP bioluminescence technology, microbiological tests, allergen tests, or chemical tests."

Although the use of rapid tests is often methodically very simple, some tests could not establish themselves in the past. This is mainly due to the fact that there are a number of things to consider depending on the measuring principle. And the interpretation of the determined values also requires experience.
The present White Paper is intended to support businesses in the use of AXP - in other words, rapid test methods based on ATP, ADP, and AMP (hereinafter called A3 technologies for short).
It should be noted, however, that the recommended limits and applications are specifically tailored to the A3 technology and therefore cannot be adopted for the usual ATP rapid tests.

The bioluminescence method for detecting organic or microbiological contamination

Using the bioluminescence method, organic contamination and microbiological impurities can be detected within seconds. The degree of the contamination correlates with the ATP-dependent intensity of the generated light signal, so that conclusions can be drawn about the hygiene status of the examined area. The light signal is stronger the more ATP or the more degradation products of ATP, namely ADP and AMP, are present. The Lumitester Smart shows this on the display using the RLU value. RLU stands for Relative Light Unit.

Although the bioluminescence procedure is non-specific and the RLU value determined cannot distinguish between somatic ATP, i.e. organic food residues, and microbial ATP, i.e. microorganisms present, the informative value of the new A3 technology is nonetheless remarkable. The potential applications of LuciPac A3 swabs are diverse and the added value for the food industry is evident.

What is the advantage of A3 technology over conventional ATP tests?

Pure ATP tests provide only limited meaningful results. This is because all organic contaminants and bacteria always contain all molecules ATP, ADP, and AMP in varying ratios.

In addition, the relatively unstable ATP is degraded by many processes such as heat, acids, alkalis, enzymes, or bacteria to the more stable ADP and AMP.
The Lumitester Smart with the LuciPac A3 swabs, produced by the Japanese company Kikkoman Biochemifa, is a luminometer that detects all phosphorated adenosine variants.

Unlike in pure ATP degradation tests, not only ATP but also its stable degradation products ADP and AMP are detected. For this reason, this state-of-the-art detection method is also called A3 technology. As a result, the Lumitester Smart provides more accurate, sensitive, and reliable results than traditional ATP test devices.

Figure 1: Comparison of the detection of RLU levels in meat (raw minced beef, raw sausage, and turkey) with A3 technology and conventional ATP test devices (Kikkoman Biochemifa Company 2022).

The Lumitester Smart with the LuciPac A3 swabs therefore brings food processing companies the certainty that contamination and residues are reliably detected.

All organic impurities on surfaces or in liquids are detected with high sensitivity. These can be both food residues and microbiological contamination (HyServe GmbH & Co. KG 2022). Residues of allergenic foods are also detected precisely (Saito et al. 2020).

The principle of the A3 technology detection is shown in Figure 2. ATP is quantified via the luminescence reaction using firefly luciferase. The AMP that has already been created is recycled into ATP by the pyruvate orthophosphate dikinase (PPDK) reaction so that the cycle can start again. The conversion of ADP takes place by means of pyruvate kinase (PK) into ATP and is transferred to the recycling process. The amount of luminescence is proportional to the amounts of ATP, ADP, and AMP present.
The more intense the light reaction, the more organic impurities there are in the sample.
(Bakke 2022; HyServe GmbH & Co.KG 2022)

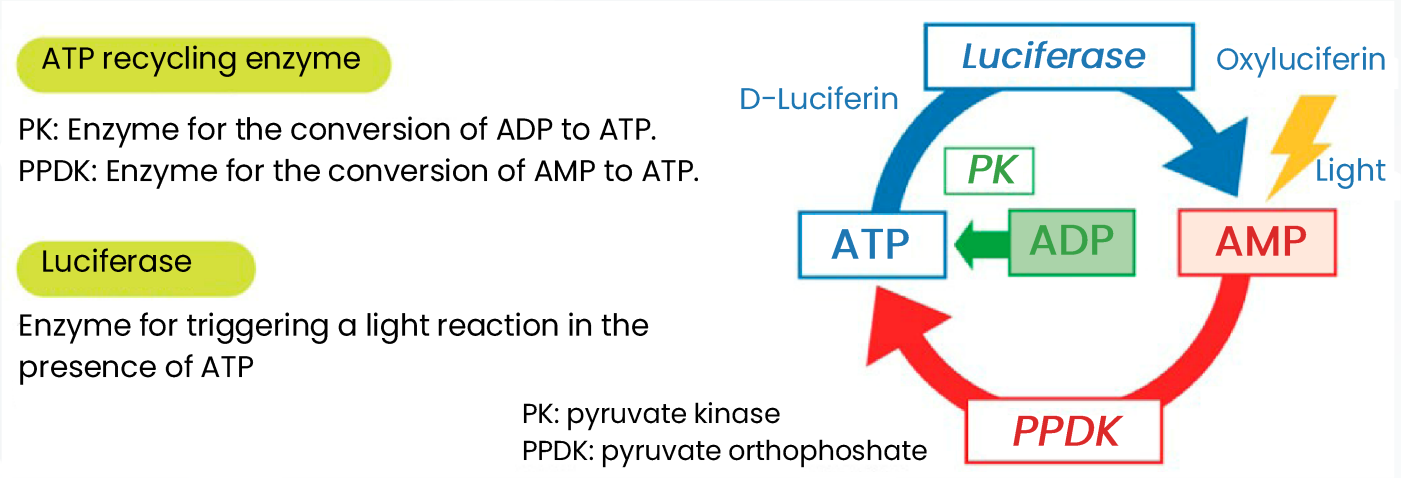

Figure 2: Principle of the luminescence method using the Bakke enzyme cycle (Bakke 2022)

Challenges in the practice of food producers

It is not uncommon for cleaning and disinfection processes in the food industry to be carried out by external service providers. However, the control of efficient cleaning and disinfection and ultimately the responsibility for it remain with the food producer.

This monitoring is done visually and through contact tests such as dip slides and swab smears. By the time the results of the analysed dip slides/swab samples are available, several productions have usually already taken place, which means that complaints to the external cleaning service provider can only be made retrospectively and will only lead to a sustainable improvement to a limited extent. The formulation of the complaint after the analysis of the conventional microbiology requires time, and the response of the responsible person on the part of the service provider is often a long time coming.

If cleaners do not clean/disinfect systems or surfaces adequately, these issues should be addressed immediately so that corrective measures can be taken immediately if required. If the Company has specified pass/fail limits for rapid test analysis for the individual sampling points, then the consequences, i.e. release for production or renewed cleaning and disinfection, are predefined and can also be clearly implemented. What would be the benefit if, in future, mistakes made in the course of cleaning and disinfection could be rectified directly and without bureaucracy by means of predefined, corrective measures?

On the one hand, direct communication is always more effective than e-mail communication after a few days.
Furthermore, the fault can be rectified immediately, as the external service provider/cleaning contractor is still on-site.

If the cleaning is carried out by internal staff, the ability to intervene immediately is also a considerable advantage. The following describes the various application options in which the A3 technology has already proven its worth.

Various application areas of the A3 technology in practice

The Lumitester Smart can be used with two different A3 types of swabs:

1. with the Lucipac A3 Surface Swab to test surfaces and
2. for water-based analyses such as rinse water analyses, the Lucipac A3 Water Swab is used.

The description of the Lumitester Smart and the measurement per se are described in the manual.

This White Paper discusses the various application options, the interpretation of the results, and the RLU pass/fail limits in more detail.

In principle, A3 technology can be used to evaluate the following use cases:

1. Determination of the hygiene status of cleaned surfaces
2. Testing of hygienically impeccable surface condition of reusable packaging units in the catering/commercial kitchen sector
3. Detection of allergenic food residues after cleaning
4. Assessment of the hygiene status of rinse water samples
5. Control of the degree of contamination of circulation water/process water

1. Determination of the hygiene status of cleaned surfaces

To check the hygiene status of surfaces, the surface to be tested must be cleaned and disinfected in accordance with a defined procedure. The effort a company has to put into cleaning and disinfection is strongly process- and product-oriented.

For comparable results during monitoring, it should be ensured that a defined length/area is scraped/swabbed depending on the surface/installation. It is not essential to use, for instance, sample grids, as it is quite sufficient to run a sampling specimen such as a curved 8 several times or, in the case of pipe/plug-in connections, to sample the thread diameter on the inside. Every business should decide on an easily practicable swab procedure and define the process.

The swabs are designed so that they can be easily inserted even in places that are difficult to access for dip slides.

The RLU limits to be determined are also set based on the risk.

For egg, meat, fish, delicatessen and beverage producers, manufacturers of ready-to-eat products as well as dairy products, the following RLU limit values of plant components/equipment have proven to be effective.

RLU limit values for stainless steel surfaces in contact with the product:

After the cleaning and disinfection of stainless steel surfaces that come into contact with products in the case of hygienically highly sensitive products, such as in the area of filling of already heated products, packaging area of ready-to-eat or already heated products, it is recommended that the following RLU limits be observed.

RLU target area for stainless steel surfaces that come into contact with products in HIGH RISK (hygienically sensitive) area: max. 200 RLU

If 200 RLU are exceeded, cleaning and disinfection should be repeated.

However, it must be added that the RLU values, depending on the age and condition of the stainless steel surfaces in the case of damage such as surface scratches, can be as high **as up to 400 RLU**, assuming professional cleaning and disinfection.

With the RLU values are higher than 200 RLU, the company may also decide to rework the surface finish. Depending on the product category/durability to be achieved/required hygiene level, the company should decide which pass/fail limits to set

When selecting sampling points, it is advisable to always take into account cleaning points that are difficult to access, i.e. worst case points, - such as grids, sieves, internal threads, installation openings for measuring equipment, etc.

Since the Lumitester, as already mentioned, detects non-specific microbial impurities, the A3 technology cannot replace specific risk-based pathogen monitoring, such as listeria monitoring in meat and dairy product plants, but it can certainly serve as a valuable and helpful enhancement to be able to react immediately to a deterioration of the measured RLU values in the high-risk hygiene area.

Especially Listeria spp. colonies are also often detected when a certain accompanying flora is present, or a biofilm has already formed. Obviously, in such highly sensitive risk areas, the RLU limits are set as low as possible.

Even if significantly higher RLU limits can be accepted in low-risk areas, it should not go unmentioned that scratched surfaces and the associated higher RLU values also foster microbiological contamination.

RLU target area for stainless steel surfaces that come into contact with products in LOW RISK area: 300-1000 RLU

RLU limit values for plastic surfaces in contact with the product:

For cutting boards made of plastic, conveyor belts, plastic containers, boxes that are used in contact with the product, the following RLU limit values have proven effective after cleaning and disinfection:

RLU target area for plastic surfaces that come into contact with products in HIGH RISK area: 200 RLU

The RLU values of conveyor belts are often slightly higher due to their design.

The RLU value of RLU 500 should not be exceeded under any circumstances, even in the case of conveyor belts - provided they are used in hygienically sensitive areas.

RLU target area for plastic surfaces that come into contact with products in LOW RISK area: 250-1500 RLU

If the limit values of the RLU target range are not complied with, then the equipment is not to be authorised for further use. Instead, it must be cleaned and disinfected again (C&D).

If the RLU values for the plastic surfaces remain high after repeated C&D, this is most likely due to the rough/scratched nature of the plastic surface. Badly scratched surfaces allow microorganisms to multiply and do not comply with GMP requirements.

In practice, it should then be decided, depending on the process and product risk, whether to replace the plastic parts or - where technically possible - to order them to be reworked. However, RLU limits higher than the upper target range (i.e. > 1500 RLU) should no longer be accepted even for hygienically less sensitive areas for cleaned and disinfected plastic surfaces in contact with the product.

2. Testing of the hygienically perfect surface condition of reusable packaging units in the catering/commercial kitchen sector

Many catering companies have decided to offer their products in reusable single-serving units due to the sustainability demanded by consumers. Due to the transport conditions, the more manageable plastic containers are nevertheless better suited than heavy, fragile glass containers.

Customers use the plastic portion packs to reheat some of the food, and it is not uncommon for the food to be consumed directly from these plastic containers. This means that partially scratched containers are also returned and thus put back into circulation after cleaning. The same principle also applies to larger reusable plastic containers, from which the individual portions of food are then removed for the guest by the canteen kitchen staff using cooking utensils. This also causes the surface to be scratched to some extent.

Even if the catering business/commercial kitchen cleans the containers according to a standardised process, excessively scratched surfaces can lead to hygienic requirements no longer being met. With the A3 technology, these businesses now have a quick and objective assessment option when evaluating their reusable containers.

The link between sustainability, which is now demanded by all sides, and food safety, which is taken for granted, can thus be established, and customers can be assured of safety at all levels.

The Lumitester Smart clearly shows that scratched, damaged surfaces have a significantly elevated RLU value after cleaning. New containers, on the other hand, achieve those low RLU values that also meet GMP requirements. Commercial kitchens and catering companies can thus embrace sustainability with reusable systems while at the same time respecting food safety and hygiene requirements.

Using A3 technology, reusable plastic containers can be objectively assessed for hygiene and integrity and removed if a defined RLU limit is exceeded.

If reusable plastic containers in the catering sector that are cleaned in the dishwasher exceed an RLU value of 2000 RLU, they should be replaced.

3. Detection of allergenic food residues after cleaning

Depending on whether allergenic residues are supposed to be detected in the rinse water or on cleaned surfaces, the Lucipac A3 Water or Lucipac A3 Surface Swab is used for this purpose.

Ultimately, an allergen (except sulphur dioxide) is a protein-containing component of a foodstuff, which should no longer be detectable on the equipment even after it has been thoroughly cleaned. Since all allergenic foods except for sulphur dioxide also produce ATP, Lumitester Smart can also detect non-specifically whether the allergenic product's residues are still present.

Of course, if there are several allergens on the surface or in the final rinse water, it is not possible to distinguish which allergen is still on the surface or in the rinse water.

Assuming that the allergen milk is everywhere and always present but that the allergen walnut, for example, is only used occasionally in special recipes, then it is, of course, not possible to differentiate using A3 technology which allergen (milk or walnut) has contributed to the ATP increase and thus to the determined RLU value. If one wants to exclude a specific allergen, an allergy test must be carried out.

In addition, it should be mentioned that the detection of allergenic residues can only be meaningfully achieved if the processed food (the recipe components) contains a large proportion of allergens (e.g. the allergen cow's milk in dairy production or the allergen fish in fish processing). It is also to be assumed that the allergen is homogeneously distributed in the recipe.

A chutney producer who also uses sesame in the recipe in minute quantities cannot reliably test for the absence of sesame after cleaning using A3 technology, since sesame is not homogeneously distributed, for one thing, and sesame only contributes a tiny proportion to the ATP load. Most of the ATP here would come from the other remaining ingredients.

Furthermore, it must be determined in advance which RLU limit can be accepted as a limit value - i.e. at which RLU values the specific allergen test also reacts - e.g. in the case of milk production, the RLU value to be accepted would be below that at which the detection limit of the highly sensitive allergen test also begins and would indicate a qualitative detection of the allergen milk.

An advantage of the A3 technology for detecting allergenic residues is that no high-dose hook effect (false negative result due to too high allergen concentration) can occur. The high-dose hook effect occurs, for example, in laterflow rapid allergen tests and leads the user to believe that no allergen is present.

This is due to a too-high concentration of protein to be detected (i.e. allergen = antigen) so that the complex formation in the allergy test is too low because there are not sufficient antibodies in the allergen test strip, which generally lead to the formation of an antigen-antibody complex.

RLU limit values for residues of food containing allergens are to be determined individually and validated for suitability using specific allergen testing.

It is important to note, however, that the RLU acceptance values for allergen control will be significantly lower than the tolerances in, for instance, low-risk areas would allow from a microbiological point of view.

4. Assessment of the hygiene status of rinse water samples

Another area of application of the A3 technology is the testing of rinse water samples. When pipes and tanks are flushed using CIP technology, the cleaning success can be detected using Lumitester Smart. If there are still food residues in the pipe system and therefore in the rinse water, the Lumitester Smart detects this.

However, detergent residues do not produce ATP and therefore A3 technology is not suitable for detecting detergent residues.
The rinse times in the course of the CIP programme must be validated anyway to prevent contamination of the subsequent product with residual cleaning agents. If this can be ruled out on the basis of a reliable cleaning process, no inhibiting effect of cleaning agents or disinfectants is to be expected during the RLU assessment.

Particular attention should be paid to the temperature dependency of the measurement results, which is also described in detail in the manual. When the rinse water samples are very hot or very cold, it is recommended to temper the rinse water to 10-40 °C, i.e. briefly warm the sampling container by hand or allow it to cool down before taking the sample using the Lucipac A3 Water Swab and then measuring it in the Lumitester Smart.

The limit values for rinse water samples are in the range of the RLU value of pure drinking water. Since drinking water can vary in pH range according to the Drinking Water Ordinance, the drinking water blank samples are mainly in the range of 5-15 RLU.

Since the rinse water should not contain any organic residues and should be more or less pure drinking water, the acceptance range of rinse water samples should also be in line with that of drinking water.

For rinse water samples, the recommended limit value is a maximum of 20 RLU

5. Control of the degree of contamination of circulation water/process water

A fifth area of application for the Lumitester Smart is monitoring circulation water or process water.

Measuring the process water in a cooking basin, for example, in which packaged products are (re)heated, can indicate leaking packaging.

It also makes sense to observe the degree of contamination of the pasteurisation water in tunnel or tank pasteurisers, as the RLU values here also allow conclusions to be drawn about existing glass breakage and leakage of the packaging.

Another example would be the monitoring of circulating washing water, which must be replaced on a recurring basis according to the product category and depending on the degree of contamination and the required hygiene level.

Limit value ranges for RLUs of circulation water or process water can and should be determined entirely individually - but above all, product- and risk-based.
For instance, limits of a maximum of 4000 RLU as well as also, for instance, a maximum of 40,000 RLU can be set.

Validation of the A3 method

Depending on the application, the business should demonstrate the suitability of the A3 method and revalidate it periodically or in case of changes. Especially when A3 technology is used to detect allergenic food residues, the correlation between the RLU readings and the classical allergen tests should also be shown, and a corresponding RLU limit value should be established.

In the case of efficacy tests of cleaning and disinfection using A3 technology, it should be proven/validated in advance that no residues of the C&D agents used remain in the rinse water or on surfaces and that there is, therefore, no inhibiting effect in the course of the bioluminescence measurement. Residues of C&D agents would, in any case, also lead to the withdrawal or recall of the product placed on the market and are therefore also not permissible for health and consumer protection reasons.

Conclusion

Rapid tests are therefore listed in the IFS Food and BRCGS Global Standard Food Safety during the cleaning verification because they can significantly contribute to the increase of food safety in companies.

The rapid, corrective intervention in the event of insufficient results and the diverse field of application of the AXP-based rapid tests are convincing in everyday use.

The A3 technology has a comprehensive detection spectrum due to its ability to identify the ATP degradation products AMP and ADP. It promises very accurate information about the actual cleanliness of a surface or the purity of rinse water.

In addition, the A3 technology offers the potential to detect protein defects in the C&D process, where microorganisms are embedded among the organic residues.

If the pre-cleaning of the sampled point is poor, the disinfectant reacts with the protein components of the organic contamination, is consumed in the process, and can no longer penetrate the microorganisms below the denatured protein layer. To prevent protein defects, sufficient cleaning must be carried out before disinfection. Insufficient cleaning, despite appropriate disinfection, poses a significant risk of re-germination. Classical microbiology cannot display the protein defect, and colonies are not found. However, the Lumitester Smart detects even the slightest traces of organic residues despite disinfection and thus provides more safety.

Another key factor is the saving of money and time for the company. The measurement results are available within 10 seconds, and the costs per test are significantly lower than in an external laboratory. With a high volume of tests, the cost savings are substantial. As mentioned, conventional microbiology cannot be dispensed with altogether, but AXP-based rapid tests should be seen as a perfect addition.

Furthermore, it is possible to control the cleaning process directly. In the event of unsatisfactory results, the cleaning process can be repeated immediately, and the fault rectified. This significantly reduces the risk of contamination of the subsequent product and avoids the necessity of destroying entire batches.

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