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MiCoFCI study - Strategy and Recommendations for microbiological cleanliness of future cargo integration

D2

ABSTRACT

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The aim of the project “Strategy and Recommendations for microbiological cleanliness of future cargo integration” was to review current measures implemented to ensure the microbiological cleanliness of cargos and recommendations how to enhance the microbiological cleanliness. The lessons learned from the ATV campaigns and the current cargo processes were summarized based on interviews with representatives of all the steps of the cargo process. Further information was collected from Expert workshop where all the stakeholders expressed and shared current gaps, constraints and possible improvements. All information was synthesized into recommendations.

Microbial contamination is both a potential risk on-board for the crew and for the equipment. Specific measures to limit potential microbial contamination are thus essential, especially in view of future exploration missions. Apart from the specific measures on the crew, the most efficient pre-flight prevention is to ensure that none of the cargo item, as well as cargo transfer bag (CTB) will be a source of microbial contamination. Ensuring the microbiological cleanliness of cargos is thus essential.

“State-of-the art of ATV cargo experience and international cargos process” - concluded that there are currently no specific microbiological cleanliness requirements on the cargos, except the requirement for items to be visibly clean. Except for very specific payloads involving potentially biohazardous materials, there is thus no specific measure to ensure the microbial cleanliness of the item in the whole upstream process from manufacturing up to its packing into CTB. Despite no specific microbial requirements, it has been agreed at international level to implement disinfection measures prior to launch on the exterior surfaces of the CTBs. However these measures do not at all guarantee that the items inside the bags are “microbially cleaned”. In addition, a lack of harmonization of the disinfection, sampling and analysis methods at international level prevents any efficient and fair analysis and interpretation of the results. Regarding the cargo vehicle itself, microbial cleanliness requirements (ISS MORD) are also not necessarily applicable under the industrial contracts. There are thus no specific microbial cleanliness measures in the upstream process up to the steps just prior to launch. Cleaning and disinfection is however performed prior to launch.

The results of a series of interviews of stakeholders provides first insights on current gaps and possible areas for improvements. The lack of requirements for cargoes is highlighted, but also the lack of harmonization and overall incoherence in the way microbial cleaning measures are managed in the whole process. Additional gaps are highlighted regarding the current limitations of the current disinfection means, sampling and analysis methods. Preliminary suggestions for improvement include the need to provide evidences to demonstrate that microbial cleanliness of cargoes is essential, the review of the whole cargo process to identify how to optimise an adequate microbial cleanliness level from the design phase up to the loading, a review of the requirements and of the related responsibilities. Alternative disinfection and sampling methods should also be proposed and the disinfection and analysis methods should be harmonized at international level. In parallel specific measures should be implemented regarding operators including possibly a certifying training. Finally packing items should be analysed to identify possible improvement for further efficiency and compatibility with possible disinfection methods.

The experts’ points of views about current measures implemented to ensure the microbiological cleanliness of cargos, gaps and critical points in cargo integration chain were collected during Expert workshop and reported in TN2 “Outputs of technical meeting with experts”. The objective of the

MiCoFCI Expert workshop was to review the limitations of the current procedures and to assess the potential areas for improvement with external experts representing both the space specific context but also taking advantage of expertise of international experts in other similar ground specific contexts. The main critical points raised by experts include in particular the lack of harmonization in cleaning, disinfection and detection procedures, the lack of coherence in the whole process since the main measures are only applied on CTBs just before integration in the vehicle and the need to refine the requirements and responsibilities throughout the process.

Main critical points and gaps identified and possible improvements at cargo integration process are summarised in following table.

Identified critical points and gaps	Improvement possibilities and other comments
Manufacturing phase	
Basis for the hygiene of cargo items is created already at the manufacturing stage. Design and material choices do not currently enable efficient disinfection at subsequent phases.	Microbiological cleanliness needs to be considered already at the manufacturing phase for instance by thinking about correct material choices, hygienic design, providing detailed documented instructions for cleaning and disinfection, following good manufacturing practices, defining responsibilities, and creating/improving the tracking system.
Bench review phase	
Knowledge about cargo items, their disinfection and responsibilities needs to be at sufficient level. This is the step in the cargo integration process when microbial contamination of cargo items is reduced to an acceptable level and cargo items are sealed in CTB. This is a critical point for microbiological cleanliness of both cargo items and inner surfaces of CTB's.	Knowledge exchange with the manufacturer needs to be in detailed enough level to allow the optimal disinfection treatments of cargo items. Detection methods for the verification of compliant cleanliness of cargo items are needed as well as threshold limits for microbial contamination.
Final integration phase	
Efficacy of cleaning and disinfection of cargo vehicle and CTB's is important in the final integration phase so that the cleanliness level will be at the predetermined level.	Efficient documented cleaning and disinfection procedures are needed. It is important to avoid cross contamination from personnel, CTB's, cleaning and loading tools.
Generally - all integration phases	
There is a lack of international harmonized quality control system for the whole cargo integration process. Microbiological control has to cover all cargo items, CTBs and vehicle equally since one weak point can cause unwanted contamination making other microbiological control measures pointless.	Systematic identification of critical points in cargo integration process can be performed for instance with the HACCP-system, which includes precise protocols for the documentation of analytical results, methods for the determination of critical control points with threshold limits for microbial contamination, clearly defined unambiguous responsibilities and continuous support for the improvement of the processes.

Further recommendations how to improve the existing gaps in microbiological cleanliness of the whole cargo process were elaborated and reported in details in TN3 “Recommendations and Strategy Elaboration”. The main level recommendations are summarized below.

	Recommendation
R1	To update pre-flight microbiological requirements and to have them applicable
R2	To define reference protocols for cleaning and disinfection and to integrate the requirements for compatibility with the relevant possible disinfection methods in the requirements hardware
R3	To provide reference guidelines, protocols and dedicated certifying training for operators and developers (including training on preventive measures, training for cleaning and disinfection and when required training for microbiological monitoring)
R4	To provide recommendations for the working areas
R5	To define an international standard for microbiological examination of cargo items, packaging items including CTBs and international surfaces of cargo vehicles
R6	To perform an HACCP analysis of the cargo processes taking into account the operational constraints and assessing the potential impacts (costs, time, etc.)
R7	To implement traceability tools and protocols for the microbiological cleanliness measures throughout the process
R8	To promote rational design taking into account possible microbial contamination
R9	To develop supporting tools for rational design in particular based in predictive modelling
R10	To publish training material to support cleaning/disinfection measures limiting possible additional microbial contamination, according to ECSS standards or others
R11	To assess and propose other optimised tools for cleaning
R12	To propose, evaluate and validate various alternative disinfection methods
R13	To provide additional guidelines regarding the operations to be performed in clean rooms
R14	To improve the protecting equipment for the dressing of operators working in clean rooms
R15	To refine and harmonize the sampling plans based on HACCP analysis
R16	To propose standardised optimised tools for surface sampling improving the recovery rate and the relates operational time
R17	To propose standardised reference protocols for sample preparation for culture and for molecular analyses and for sample transportation
R18	To refine and harmonize culture based analysis methods
R19	To propose complementary analysis methods (e.g automated molecular based techniques)
R20	To improve the design of CTBs to limit microbial contamination and to ensure optimised compatibility with disinfection measures
R21	To recommend measures to ensure microbiological cleanliness of foams and plastic foils

There is a clear need for data and evidences demonstrating why microbial cleanliness is important and the potential impact and the related risks related to microbial contamination of the cargoes and cargo vehicles. A detailed HACCP (Hazard Analysis and Critical Control Points) analysis should be realised on the cargo process. Main advantages of HACCP system for cargo integration process are clarity of responsibility issues as well as use of acceptable and synchronized detection methods and documentation, which supports communication.