

TOWARDS THE HARMONIZATION OF SAFETY ASSESSMENT METHODS OF AUTOMATED DRIVING

SAKURA – SIP-adus - HEADSTART

Introduction

Mission and objectives

This white paper aims to summarise and harmonize the activities performed in the context of automated driving safety assessment methods through different initiatives that are currently led by the Japanese government and European Commission research programs.

The white paper objectives are to:

- 1) Compile and present the different initiatives for which each region is working on the topic and show under which general R&D programs they are operating
- 2) Identify which topics and, or challenges related to safety assessment have been the object of research by each of the referenced initiatives to assess the areas where they are making specific progress.
- 3) Harmonize, whenever possible, the results achieved so far, and identify potential activities for further harmonization that could be encouraged and fostered within the regions and or in future R&D initiatives.

Reasoning behind the white paper

Automated driving safety assessment methods are a complex, multi-faceted challenge that involves a number of concurrent areas of research and technical expertise. Notably, they also rely on several technologies with different levels of maturity. In the case of these safety assessment methods being associated with a safety assurance framework, additional factors need to be considered, e.g., regulatory needs.

Consequently, direct comparisons between diverging approaches are difficult to assess, and potential harmonization efforts need to be carefully identified and agreed on.

Within this paper, an initial approach on how to identify the most promising topics for harmonization has been agreed upon between the participants to trigger further actions. This approach will be achieved through a systematic procedure that enables each project to be independently addressed. The scope of this white paper has been limited to a reduced number of relevant projects, but the systematic approach applied could be extended to incorporate other international activities.

This paper also fosters the cooperation at the international level between Japan and Europe of these different initiatives and supports dissemination and communication of (joint) activities.

Japanese strategic programs on automated driving safety methodologies

SAKURA

The SAKURA project (Safety Assurance KUDos for Reliable Autonomous vehicles) is one of the coordinated initiatives funded by the Ministry of Economy, Trade and Industry (METI) of Japan, under the strategies defined by the Committee on Business Discussions on Autonomous Driving Technologies. This committee was established in February 2015 and oversees All-Japan initiatives by industry, academia, and government sectors, including a Roadmap for Deployment of Autonomous Driving Services, demonstration tests, and efforts for harmonization areas.

The first phase of the SAKURA project occurred from mid-2018 until the end of March 2021, whereas the second phase commenced in April 2021. The contents included in this paper relate to the results of the first phase of the SAKURA project. The second phase of the SAKURA project will take into consideration the outcomes and results from this paper.

SIP- adus

The Cross-ministerial Strategic Innovation Promotion Program (SIP) strives to promote research and development seamlessly from the basic research stage to social implementation with industry, academia, and government cooperation. SIP's Automated Driving for Universal Services (SIP-adus) has been progressing research & development activities aiming to solve issues of concern in today's society, including reducing traffic accidents, alleviating traffic congestion, and securing a means of transportation for people with limited mobility, such as the elderly living in remote regions, among other issues.

The 2nd Phase (FY2018 to FY2022) of SIP-adus is composed of 4 pillars; technology development, public acceptance, international cooperation, and field operational tests. Virtual validation platform for ADS (Automated Driving Systems) safety assurance is one of the focus themes in the technology development pillar.

Horizon 2020 program with regards to HAD

Horizon 2020 is the largest EU research and innovation program ever conducted by the European Commission. Horizon 2020 is meant to achieve smart, sustainable, and inclusive economic growth. Automated driving was included as one of the key research topics in the program with special focus on the improvement of its technology readiness, speeding up its deployment, and its associated societal benefits.

The HEADSTART (Harmonised European Solutions for Testing Automated Road Transport) project was granted in the topic ART-01-2018: Testing, validation and certification procedures for highly automated driving functions under various traffic scenarios based on pilot test data. The project started in January 2019 and is concluded in December 2021.

State-of-the-art of safety assessment methods for automated driving

Safety assessment methods: needs

Technological innovations in road mobility systems for persons and goods follow each other in rapid succession. Fast advances are made in digitalization, which further connects vehicles and infrastructure and increases possibilities for cooperative mobility solutions. Simultaneously, great efforts are

placed to further increase the automation of vehicles, especially for people movers such as shuttles, busses, and passenger cars. The goal is to provide more comfort to drivers and passengers, increase the efficiency of the mobility system while decreasing the role of the human as the driver, and reduce the largest source of traffic error in current vehicles.

Automation solutions become progressively complex, and driving functions become increasingly integrated. Current systems that enter the passenger car domain market can completely take over the control of the vehicle from the human driver for portions of the trips. A new UN-ECE regulation that manages ALKS (advanced lane-keeping system) under conditions allows drivers to take their hands off the steering wheel and their eyes off the road during such driving phases. These systems may significantly impact road safety, as they pose major challenges for both the machine and human driver. In this case, the machine becomes responsible for driving without the possibility of an emergency fall-back, the human driver, regardless of possible unexpected critical situations. Conversely, the human driver must always be aware of the mode of the vehicle, entrust all of the driving responsibilities to the system, and risk over-trusting it. Besides driving skills, a human driver might also need additional training to operate these vehicles. At this time, this is neither part of driver training nor driver license evaluation. Such limitations are not only present for the operation of vehicles with higher levels of automation (SAE J3016, L3, and L4) but already for vehicles with current state-of-the-art L1 and L2 ADAS functions.

Vehicle authorities are asked to allow such vehicles onto the public road. However, an appropriate system for the type approval of such innovative vehicles is not yet in place. Road authorities express a clear need of establishing a framework for the type of approval and safety assessment in place that is:

- Capable of dealing with these great challenges and fast developments in technology, not only now but also in the future. Developments in digitalization (including V2X communication and positioning) and Artificial Intelligence should be considered. Also, the increasing vulnerability of systems for cyber-attacks needs to be incorporated.
- Feasible in the required testing effort. Systems need to be tested against all possible scenarios that the vehicle can be confronted with during its lifetime. An increasing role for virtual testing is foreseen.
- In line with European regulations (UN-ECE) and international standards such as ISO and SAE, this requires a link to such standards and the need to influence these standards to stay in line with national and international policies and regulations.
- Capable of changing roles with the human driver, who is inattentive, operates and drives the vehicle. The frequent back and forth transfers of control from the human driver to the vehicle, especially in unplannable transfers due to unexpected situations or events on the road, must be considered in the safety assessment.
- Fair, explainable, and understandable. Though vehicle systems are complex and the assessment procedure might be complicated, the assessment results should be unambiguous, easily understood by experts in the field, and explainable to politicians and the general public. An important metric in such a framework is the residual safety risk when a vehicle is allowed

onto the road. The concept of risk is widely understood, and basing the safety assessment on that concept helps to come to a fair and acceptable assessment process.

Consumer organizations such as Euro NCAP express a similar need to increase safety, reduce traffic fatalities and serious injuries drastically, and inform consumers on the potential safety benefit that newly developed ADAS and AD functions can offer.

SAKURA, SIP-adus, and HEADSTART projects aim to realize a scenario-based safety assurance approach that meets the identified needs, based on an assessment of safety risk by combining the results of different test results methods. For example, virtual testing (model in the loop), hardware-in-the-loop testing (HiL), testing on proving grounds, and field operational tests. To define relevant¹ and realistic test cases (independent of the testing method), one or more scenario databases that are complete², need to be available. The scenario database should provide a view on currently possible scenarios (and their variations, also depending on region, traffic rules, and driving culture). It should provide a view of how scenarios evolve with the changes in the mobility system. Scenarios should cover nominal everyday driving and more rare and extreme cases such as edge and corner cases. The scenario-based approach needs to be contextualized within comprehensive safety strategies, and other complementary aspects of safety shall be addressed, including functional safety (e.g., ISO 26262), the safety of the intended functionality (e.g., ISO 21448), or cybersecurity (e.g., ISO 21434).

Assessing the safety performance of a vehicle requires putting the vehicle through a predefined scheme of tests and audits, having a clear view of when the results are satisfactory. Both metrics and references (acceptable limits for the resulting value of the metric) are being developed:

- The remaining safety risk provides a widely accepted metric for safety. The UN-ECE regulation for ALKS, released in 2020, indicates that Connected ADS should be free of ***reasonably foreseeable and preventable safety risks***. What is reasonably foreseeable can be based on scenario database statistics.
- How to determine preventable safety risks requires further assessment of the residual safety risk. As a reference for safety, the concept of a well-trained, attentive and fit human driver is taken.

Japan strategic automated driving safety assurance activities

Figure 1 provides a schematic of the major AD safety assurance strategic activities in Japan in context with the ADS safety development process. These activities jointly target the development of a scalable virtual platform to support safety planning, design, and evaluation of the ADS.

SAKURA develops the scenario-based safety assurance methodologies and a scenario database linked to the SIP-adus DIVP virtual environment. After the release of the product, several other activities include field operation tests that collect sensor data to feedback complex scenarios back into the database.

¹ Test cases need to be generated that sufficiently cover the operational envelope of the system-under-assessment, also known as the Operational Design Domain according to SAE J3016.

² The completeness metric indicates how well the scenarios collected in the database cover the true scenario space in the real-world.

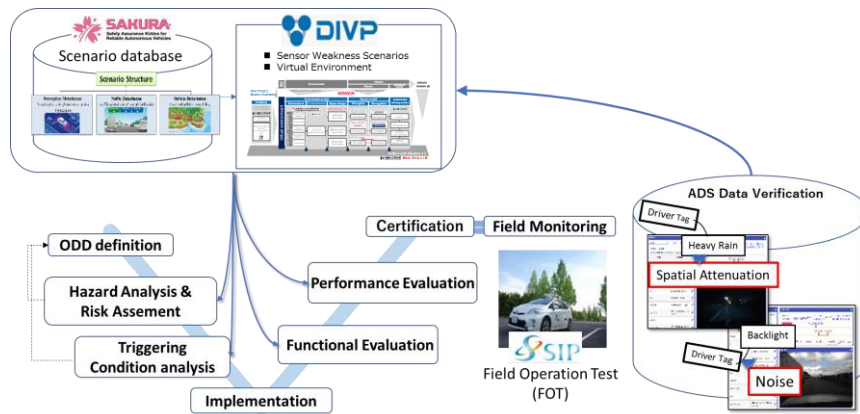


Figure 1. Japan AD safety evaluation process showing the relationship between SAKURA and SIP-adus activities

Japanese projects and initiatives

The first stage of the SAKURA project is to harmonize data acquisition, develop research methodologies, and coordinate standardization activities through joint efforts by the vehicle industry and traffic safety research institutions in Japan and abroad. Within this stage, the scope was limited to level 3 and higher systems and with a predominant focus on limited-access highways. The SAKURA safety assurance methodologies largely rely on a scenario-based approach, with an emphasis on a Physics Principles Approach and a focus on developing a complete scenario generation process and tools, including a scenario database. A brief introduction of the Physics principles approach is provided below, followed by a definition of the scenario generation process that was used to guide the SAKURA activities.

SAKURA Physics Principles Approach

In real traffic, it is commonly considered that the number of possible safety-relevant disturbance factors that an AD system may confront is infinite. To facilitate the maneuver of a large number of variables and capacitate the scenario testing of these through the adoption of a scenario-based safety evaluation approach. Conversely, there are limitations in the physics principles to how an AD can safely respond to these scenarios due to the number of possible safety-relevant scenarios that an ADS may encounter in real-traffic situations. Presently, the ADS coordinates the decomposition of the dynamic driving task (DDT) to perception, judgment, and control subtasks, which are associated with one or several specific physics principles. Henceforth, the holistic coverage of all foreseeable safety-relevant fundamental causes for a provided DDT is possible through the decomposition and logical structuration of the disturbance factors and relevant scenarios concerning the physics of the ADS (see figure 2).

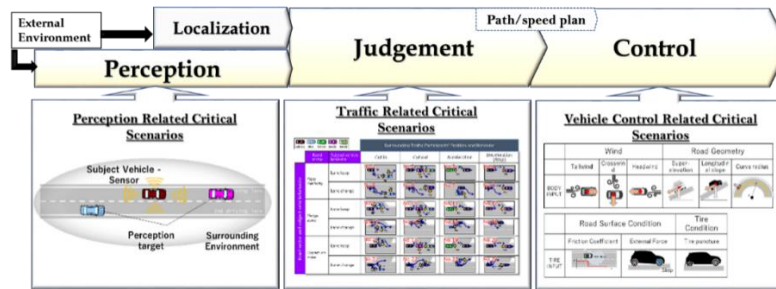


Figure 2. SAKURA project physics principles approach

SAKURA Scenario generation and safety evaluation process

Figure 3 presents the SAKURA project scenario generation and safety evaluation process created based on the adaptation of the adopted definitions for function, logical, and concrete scenarios developed initially by the German PEGASUS project.

The three disturbance categories mentioned above described a systematic approach that defines all safety-relevant elements of a scenario and their combinations which represent the structure of functional scenario development.

In order to define logical scenarios, the assignment of parameter ranges in the functional scenarios is made. It is preferable to define these ranges by enabling a data-driven approach to extract and process vehicle trajectories from traffic monitoring data systematically. Nevertheless, the traffic data will not contain enough critical situations and crashes to address statistically significant results in most scenarios. Thus, the SAKURA project has developed complementary methodologies, such as the generation of synthetic scenarios with safety-critical conditions obtained by the extrapolation of collected data [Nakamura et al. 2021].

Lastly, the definition of concrete scenarios is obtained by using the logical scenario parameter search engine to select concrete values from the parameter distribution. Application of other methodologies may be applied for this purpose, notwithstanding that the SAKURA project has investigated and developed several of them [Akagi et al. 2019, Thal et al. 2020, Stepien et al. 2021]. After the definition of concrete scenarios, it becomes necessary to discriminate between safety criteria that are considered safe and unsafe conditions. Corresponding authorities shall define the safety criteria.

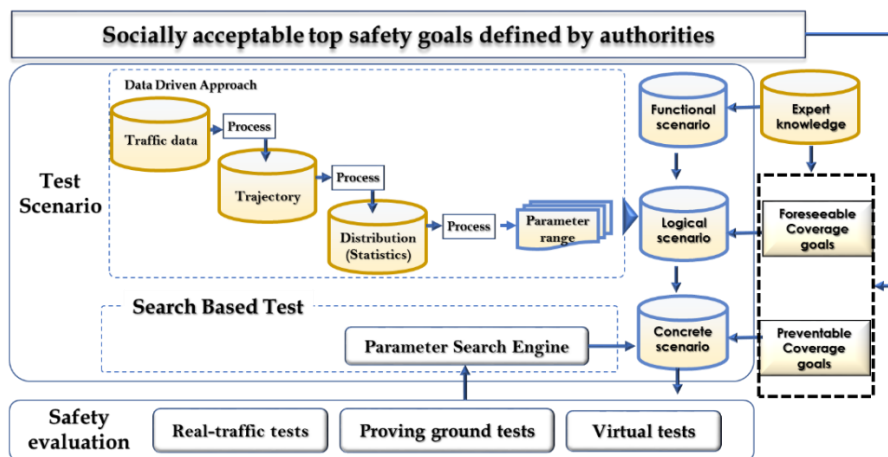


Figure 3. SAKURA project scenario generation and safety evaluation process

Table 1: Activities within the SAKURA and SIP-adus projects related to safety validation of HAD

Japanese activities			
Activities		Within the project	Sakura & SIP-adus
Topic (Focus points)	Subtopics	Yes/no/partially	Free text
Considered target end users	Technology developers (e.g. OEM, TIERx, etc.)	Yes	JAMA technical and strategic leadership. See [JAMA AD safety evaluation framework]
	Consumer testing	Yes	Incorporation of Euro NCAP car-to-pedestrian protocols, including perception simulation [ref DIVP]
	Technical support to roadworthiness efforts	Yes	Human driver modelling proposals for possible use as driver performance reference models.
Types of vehicles	Passenger vehicles	Yes	JAMA technical and strategic leadership [JAMA AD safety evaluation framework]
	Trucks and commercial vehicles	No	
	Urban vehicles (robotaxi) / shuttles	No	Not in the first phase of SAKURA. Currently undertaking in the second phase
ODDs and intended areas	Urban areas	No	Not in the first phase of SAKURA. Currently undertaking in the second phase
	Highways	Yes	
	Closed areas	No	
Test methods	Simulation	Yes	Covered by both SAKURA and SIP-adus DIVP activities
	Xil	Partially	
	Proving ground	Yes	
	Open road	No	
Scenario based safety validation	(Optimal) Scenario allocation (according to test methods)	Yes	
	Scenario workflow and test case definition	Yes	See [ISO/DIS 34502:2021]
	Derive scenarios from data (databases)	Yes	See [Akagi et al. 2019] [Stepien et al. 2021]
	Assignment of tests to test platforms	Partially	See [ISO/DIS 34502:2021]
	Test evaluation	Yes	See [ISO/DIS 34502:2021]
	Traffic disturbance	Yes	See [ISO/DIS 34502:2021 Annex B]
	Safety assurance	No	The project has focused in the development of a harmonised validation methodology [ISO/DIS 34502:2021] and models for competent and careful human driver.

Data collection and DB implementation	Data gathering methods	Yes	Data collection with instrumented vehicles and fixed cameras. See [Nakamura et al. 2021]
	Scenario extraction	Yes	See [Thal et el. 2020]
	Parameter space definition	Yes	See [Nakamura et al. 2021]
	Used standards (e.g. OpenScenario)	Yes	Used to link SAKURA scenario database to SIP-adus DIVP platform
	Ontologies	Yes	ISO/DIS 34502:2021 Annex B to D
Supporting/enabling technologies	Communications	No	
	Positioning in the context of CAV	No	
	Cybersecurity	No	Cover in other SIP-adus activities outside Safety Assurance
Standardisation efforts	ISO Scenario-based safety evaluation	Yes	ISO/DIS 34502:2021 development lead
	ASAM and others	Partially	

EU Activities – HEADSTART project

The HEADSTART project consists of 17 partners and aims to define testing and validation procedures of Connected and Automated Driving functions, including key technologies such as communications, cyber-security, and positioning. Tests are considered for different testing approaches, from virtual simulations, Hardware-in-the-Loop, and proving ground testing to field-testing in the real-world, to validate safety and security performance according to the key users’ needs.

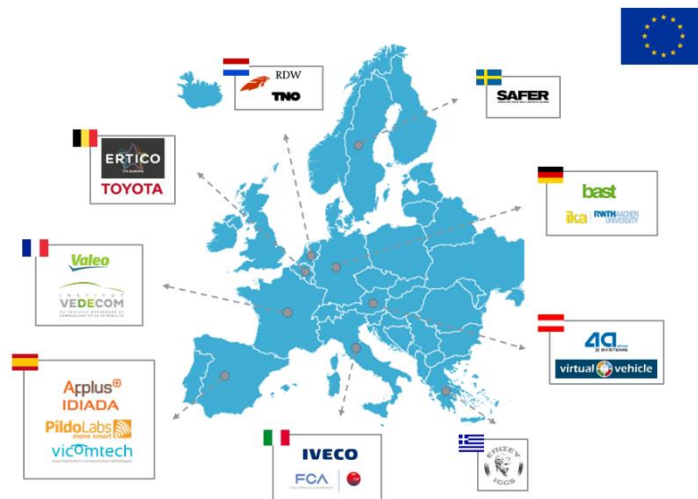


Figure 4. The HEADSTART consortium

The HEADSTART project brings consortium partners together with other European and national stakeholders in (connected) automated driving to cluster the most relevant existing initiatives, develop methodologies, procedures, tools, and support a harmonized European solution for testing and validation of automated road vehicles. Within the lifetime of the project, relevant stakeholders can

join the experts' network to configure together the methodologies used and promote the adoption of project results.

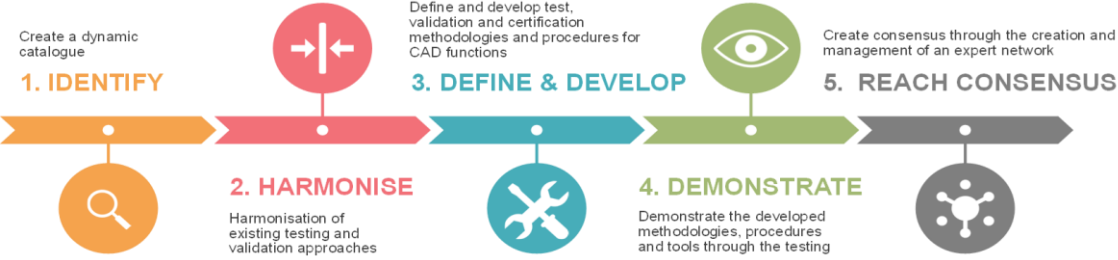


Figure 5. The HEADSTART objectives

Figure 6 shows a scheme of the developed HEADSTART methodology. Scenarios are identified, characterized, and stored in a scenario database based on a collection of real-world data (recorded by vehicles in traffic, from drones, or roadside sensors), enriched with data from accidentology and results from simulator studies. A scenario describes possible situations on the road, including a description of the environment and the weather and lighting conditions. The scenarios in the database can be further enriched by injecting scenarios that experts provide.

Not all scenarios are applicable or relevant for the different types of automated vehicles, having different functionalities and operational design domains. A method has been developed to select scenarios and generate test cases based on a description of the driving functions and the operational design domain. Based on functionalities related to the Key Enabling Technologies (KET) in HEADSTART (communication, positioning, and cyber security), additional attributes are added to the description of the test cases for appropriate testing of the impact of the KET on the functionality and consequently on safety.

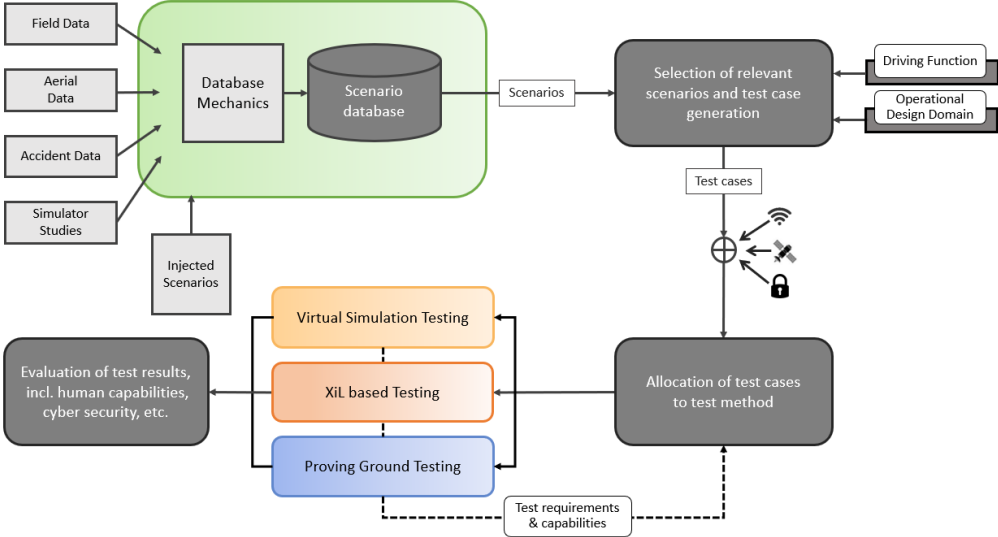


Figure 6. HEADSTART methodology and process for the generation of test cases and the allocation of test cases to test methods for safety assessment of connected cooperative AD systems

In HEADSTART, procedures have been developed to allocate test cases to the available test methods: virtual simulation testing, XIL based testing, and Proving Ground testing. A feedback loop has been organized in which the allocation of test cases is based on the capabilities of the test methods in relation to the test requirements. The overall safety assessment subsequently evaluates the test results from the different test methods, see [De Gelder et al. 2022].

Table 2: Activities within the HEADSTART project related to safety validation of HAD

HEADSTART project			
Activities		Within the project	Description
Topic (Focus points)	Subtopics	Yes/no/partially	Free text
Considered target end users	Technology developers (e.g., OEM, TIER x, etc.)	Yes	Involvement of industry within the project and integration of their validation needs within the methodology.
	Consumer testing	Yes	Inform Euro NCAP on developments and how the methodology can be extended for consumer testing purposes.
	Authorities / certification bodies	Yes	Demonstration of the developed methodology on few use cases taking into account new regulations (R.157)
Types of vehicles	Passenger vehicles	Yes (Highway pilot and traffic jam chauffeur)	Different platforms and AD functions used as target of the project activities
	Trucks and commercial vehicles	Yes (truck platooning)	Limited to V2V communication in platooning use case [see Op den Camp et al. 2021]
	Urban vehicles (robotaxi) / shuttles	No	
ODDs and intended areas	Urban areas	Partially	Methodology takes into account urban areas. Low speed scenarios are included in the demonstrators.
	Highways	Partially	Main area within the project
	Closed areas	Partially	Methodology takes into account closed areas
Test methods	Simulation	Yes	Included in the project demonstrators
	Xil	Yes	
	Proving ground	Yes	
	Open road	Partially	Associated to R.157 and national license exemption (Spain)
Scenario based safety validation	Scenario selection and test case generation	Yes	The HEADSTART methodology considers the selection of scenarios for the different use cases based on the specified ODD and functionality.
	Scenario workflow and test case definition	Yes	Extensions to scenario and test case definitions have been made to serve specific requirements resulting from the KETs. Expert injection is also considered.
	Scenario collection from road driving data (databases)	No	The project acts as user of existing Scenario Databases.
	Assignment of tests to test platforms	Yes	Basic procedures developed within the project.

	Test evaluation	Yes	Theoretical approach described. Data driven approach in process.
	Traffic disturbance	Partially	Considered at scenario level.
	Safety assurance	No	The project has focused in the development of a harmonised safety validation methodology and not in the definition of thresholds and references
Data collection and DB implementation	Data gathering methods	No	Data is only gathered in the use case demonstrators for AD function assessment.
	Scenario extraction	Partially (methodology wise, yes)	Only as users of Scenario DBs. However, it is described and integrated in the developed methodology.
	Parameter space definition	Yes	Appropriate ranges for test parameters have been identified from the scenario databases.
	Used standards (e.g. OpenScenario)	Yes	Open scenario proposal to include communications and positioning technologies
	Ontologies	No	Only to access scenario DBs
Supporting /enabling technologies	Communications	Yes	Test parameters identified and aligned with current OpenScenario standard. V2V in truck platooning considered as use case.
	Positioning in the context of CAV	Yes	Test parameters identified and aligned with current OpenScenario standard. Included in some of the use cases and linked projects.
	Cybersecurity	Partially	Additional blocks and procedure branches included in the methodology to integrate cybersecurity.
Standardisation efforts	ISO Scenario-based safety evaluation	Yes	Mainly on scenario ontology
	ASAM and others	Yes	Addenda and recommendations on OpenScenario for KETs.

Summary of common topics

Table 3. Mapping of EU/Japan activities on safety validation with topic overview

Mapping			
Activities		HEADSTART	SAKURA and SIP-adus
Topic (Focus points)	Subtopics		
Considered target end users	Technology developers (e.g., OEM, TIERx, etc.)	Yes	Yes
	Consumer organisations (e.g., Euro NCAP)	Yes	Yes
	Authorities / certification bodies	Yes	Yes
Types of vehicles	Passenger vehicles	Yes	Yes
	Trucks and commercial vehicles	Yes	No
	Urban vehicles (robotaxi) / shuttles	No	No
ODDs and intended areas	Urban areas	Partially	No
	Highways	Partially	Yes
	Closed areas	Partially	No
Test methods	Simulation	Yes	Yes
	XiL	Yes	Partially
	Proving ground	Yes	Yes
	Open road	Partially	No
Scenario based safety validation	Scenario selection and test case generation	Yes	Yes
	Scenario workflow and test case definition	Yes	Yes
	Scenario database from road driving data	No	Yes
	Assignment of tests to test platforms	Yes	Partially
	Test evaluation	Yes	Yes
	Traffic disturbance	Partially	Yes
Data collection and database implementation	Safety Assurance	No	Partially
	Data gathering methods	No	Yes
	Scenario extraction	Partially	Yes
	Parameter space definition	Yes	Yes
	Used standards (e.g. OpenScenario)	Yes	Yes
Supporting/enabling technologies	Ontologies	No	Yes
	Communications	Yes	No
	Positioning in the context of CAV	Yes	No
Standardisation efforts	Cybersecurity	Partially	No
	ISO/TC22/SC33/WG9 Scenario-based safety evaluation	Yes	Yes
Colour coding legend:	ASAM and others	Yes	Partially
	In focus with the project and its partners		
	No implication with the project, but covered by (some of) the project partners		
	Partially covered by the project		
	Not in focus with the project		

Main commonalities between the projects

The SAKURA, SIP-adus, and HEADSTART projects from Japan and the EU show the following commonalities:

- Same targeted end users and a predominant focus on passenger vehicle developers, consumer organizations and authorities/certification bodies.
- Similar scenario-based safety approaches from data collection and database development to test case generation and test evaluation.
- Alignment on the need for simulation and proving ground testing methods.
- Involvement in international standardization efforts, including ISO and ASAM.

Potential harmonization items

The next topics have been defined as possible action items for international harmonization, leaving standards out of scope unless new standardization items are identified:

- Coordination on data collection, database development, and data interchangeability
- Harmonization of data collection and data processing accuracy verification
- Harmonization of simulation and proving ground testing methods.

Recommendations and next steps

The following recommendations are made on how to proceed in the future with special relevance to international cooperation:

- Continued dialogue on safety argumentation, including risk acceptance and coverage/completeness. A discussion is required on appropriate metrics to quantify safety and/or risk, separate from the references/thresholds to be set by authorities (what level of safety is required, or what level of risk is acceptable).
- Industrialization of safety assurance tools and methods to become applicable by industrial development processes.
- Incorporation of perception scenarios, including simulation of the required phenomena and standardization of interfaces to allow for both industrial protection and transparent safety assurance.
- Integration of human driver reference / human driver models in the safety assessment methodologies and safety assurance process
- Database interoperability, data interchange, and comparative studies across countries to support the development of the international applicability of the proposed methods.
- Expansion to ODD outside highways includes necessary adaptations of scenario-based methodologies and the development of strategies for urban vehicles (robotaxi) / shuttles.
- Interchange possible future actions concerning Virtual Proving Grounds, Model-Based Design, and Digital Twins. Assessment of impact and potential integration ways to include Artificial Intelligence-driven decision making

VERSION Control

Date	Authors	Comments and improvements
16/06/2021	Álvaro Arrúe	First draft of the content and Table of Content
08/07/2021	Jacobo Antona-Makoshi, Umeda Manabu, Carlos López, Olaf Op den Camp, Sandra Watanabe	Second draft: Update of the ToC. Reorganization of the Japanese projects so they work as one input. Additional input points on the framework programs included. Deadline for SIP-adus workshop included in comments.
25/08/2021	Álvaro Arrúe	Section on H2020 and HEADSTART project filled up. First draft on content for HEADSTART. Reorganization of focus points to be arranged.
09/09/2021	Jacobo Antona-Makoshi, Manabu Umeda, Álvaro Arrúe	First draft of Japanese activities and umbrella framework description. First draft in mission, objectives and reasoning behind the paper
10/07/2021	Olaf Op den Camp	Description of state of the art safety assessment methods
21/10/2021	Jacobo Antona-Makoshi	Complete review and editing. Refinement of Table 1
26/10/2021	Carlos Lopez, Olaf Op den Camp, Nicolas Wagener, Álvaro Arrúe	Update of Table 2 "Activities within the HEADSTART project related to safety validation of HAD" with a simplified scheme of the methodology Update of table "HEADSTART project" in pages 10, 11 and 12. Update of the HEADSTART column in table 2 "Mapping of EU/Japan activities on safety validation with topic overview"
04/11/2021	Jacobo Antona-Makoshi	Minor editing Update of the SAKURA column in table 2 "Mapping of EU/Japan activities on safety validation with topic overview". Added list of items for main commonalities, potential harmonization items. Preliminary ideas for Commonalities, Harmonization and recommendations for next steps.
05/11/2021	Olaf Op den Camp, Álvaro Arrúe	Added Figure 6 caption and description text and refined recommendations
08/11/2021	Sandra Watanabe	Proof read and clean up (accept changes, delete comments, etc.) before circulation for SIP-adus Breakout Workshop purposes.
11/11/2021	Alvaro Arrue, Adrian Zlocki, Olaf Op den Camp, Satoshi Taniguchi, Manabu Umeda, Jacobo Antona-Makoshi	Consolidation of contents at the SIP-adus safety assurance breakout workshop
30/11/2021	Sandra Watanabe	Final proof reading
09/12/2021	Adrian Zlocki, Olaf Op den Camp, Álvaro Arrúe, Satoshi Taniguchi, Manabu Umeda, Sandra Watanabe, Jacobo Antona-Makoshi	Final review

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