

Supplementary information for trial operation permits with automated vehicles

Guidance for TSFS 2021:4

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Explanations of terms and abbreviations

Automated vehicles: vehicles that have an automated driving system that can independently control and drive the vehicle during all or part of the journey.

Trial operation: activities that include driving automated vehicles on the road to test and evaluate automatic functions that are not part of a type approval, an individual approval or a registration inspection according to the Swedish Vehicle Act (2002:574).

FAT: Factory assessment test. Inspection of systems on site at the applicant.

SAT: Site assessment test. Examination of the vehicle while driving the intended route of the trial operation.

1 Purpose

The purpose of this document is to supplement the Swedish Transport Agency's regulations and general advice on permission to conduct trials with automated vehicles (TSFS 2021:4) with more concrete information and recommendations regarding what an application should contain, as well as describe the application process and certain principles that apply to the trials. Moreover, the purpose is to simplify the application process for the applicant and to give a better understanding of what requirements the Swedish Transport Agency sets for granting a permit for trial operations with automated vehicles.

2 Scope

This supplementary information refers to the application for permission for trial operation with automated vehicles. It is the regulation (2017:309) on trial operation with automated vehicles that enables the driving of automated vehicles in traffic as part of trial operation in Sweden. The regulation states that questions about permits are examined by the Swedish Transport Agency and that the Swedish Transport Agency may issue additional regulations, which we have done through TSFS 2021:4. These regulations describe, among other things, requirements for

- what an application at least shall contain,
- control of the trial operation,
- communication/reporting to the authority and
- evaluation of the trial operation.

The trial regulation applies to trial operations on road. Trials intended to take place off-road are therefore not covered by the regulation. The same applies to trials that are intended to take place exclusively within fenced railway or industrial areas or within fenced racetracks or other similar fenced areas. However, it is important to make sure that the area can be defined as a fenced area in the legal sense. This is a matter for the law enforcement authorities to decide.

3 Target group

This supplementary information is addressed to the actors who intend to apply for a permit for trial operation with automated vehicles (hereinafter referred to only as "trial operation").

4 The permit process

The Swedish Transport Agency has established a process for applying for a permit for the trial operation. The purpose of this process is to ensure equal treatment between applicants and to give the applicant a better understanding and an overview of the stages that are included in the process of obtaining a permit. The processing time for an application is described in chapter 8.3.

The overall process for obtaining permission is as follows:

1. Letter of interest

The applicant begins by submitting a letter of interest. The form for this can be found on our website [1]. The information filled in by the applicant must be concise but give an overall picture of how the trial operation is to be carried out. This is so that the Swedish Transport Agency can classify the case and prepare for the first meeting.

2. Start-up meeting

When the Swedish Transport Agency receives a letter of interest, a case number is added to the case and one of our case managers books a start-up meeting with the applicant. This meeting is free of charge. The meeting normally takes place on site at the Swedish Transport Agency's office in Borlänge or digitally/video meeting. During the meeting, the applicant will have the opportunity to present the plan for the trial operation and the Swedish Transport Agency will provide information about the application process, safety requirements, etc. There will also be an opportunity to ask questions.

3. Application

When the applicant has produced the requested documentation, the application is sent to the Swedish Transport Agency. This is done by completing the application form available on our website together with the relevant attachments. The application should preferably be sent via e-mail to vag@transportstyrelsen.se with the case number on the subject line.

4. The application is being processed

When we have received the application, we will process it by reviewing the enclosed documents. If necessary, we will ask for additional information and have further meetings with the applicant.

It is when we start processing the application that that we start charging a fee for our processing. You will find more about costs under chapter 8.3.

5. **Factory assessment test (FAT)**

The Swedish Transport Agency prefers to have all information regarding the application sent to us, but sometimes on-site demonstrations may be necessary, so-called Factory Assessment Test (FAT). This may, for example, involve inspection or measurement of vehicles or driver environments. If this step is relevant, we inform the applicant about this and how a FAT is carried out.

6. **Temporary permit and decision on exemption from vehicle requirements**

When the Swedish Transport Agency has reviewed the application and considers that the applicant has been able to prove through the submitted material that the trial operation can be conducted in a safe and non-disturbing manner, we issue two decisions. One decision on exemptions from regulations on requirements for vehicles and one decision on temporary permission to conduct trials. This enables the applicant to be able to prepare the operations on the intended route/area prior to the final on-site inspection. This could, for example, involve route scanning with the vehicle, adjustments to the vehicle's automated functions, etc. The temporary permit usually has a validity period of around two weeks.

7. **Site assessment test (SAT)**

Before the Swedish Transport Agency issues a permit, we inspect the vehicle in traffic at the relevant location for the trial operation. This is done through a so-called Site Assessment Test (SAT). During the SAT, we check that the vehicle meets the applicable traffic rules and that the operation does not cause any significant disturbance or inconvenience to the surroundings and that the applicant carries out the test in accordance with what is described in the application. In case of any observations or remarks, additional SATs may need to be carried out after the applicant has corrected the observations. A planning meeting between the applicant and the Swedish Transport Agency is held a few weeks before the SAT.

8. **Permit for trial operation**

When the SAT has been completed with satisfactory results, the Swedish Transport Agency, usually within two weeks, issues a permit for trial operations with automated vehicles. This permit contains a number of conditions that the applicant must comply with. These conditions may vary and depend on the design and content of the trial operation. Permits are always time-limited.

9. Trial operations are ongoing

While the trial operation is ongoing, any accidents must be immediately reported to the Swedish Transport Agency.

For trial operations that continue for a longer period of time, the applicant must annually evaluate how the trial is progressing. An evaluation must also be done at the end of the trial. More information about reporting and evaluation can be found in chapter 8.4.

See Figure 1 for a flowchart of the application process.

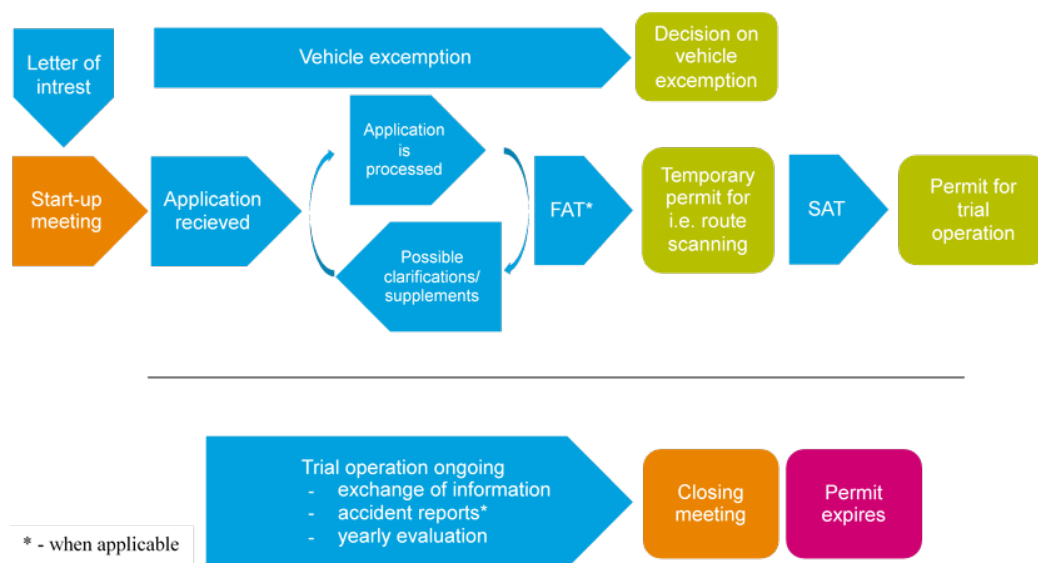


Figure 1. Schematic description of the permit process.

5 What an application should at least include

In TSFS 2021:4, it is stated what an application must comprise in order for the Swedish Transport Agency to be able to process and assess whether permission should be granted. We have also produced a form which is available on our website [1]. In the form, the applicant must fill in their contact details and refer to appendices for information on the other subject areas.

1. Information about the applicant

Contact details for the applicant, including the names of the persons responsible for the trial operation as well as their address and personal identity number or organisation registration number, as well as the

signature of the legally responsible person, usually the managing director. This is filled in on the application form.

2. **Management and responsibility**

A description of how the trial operation will be managed and how responsibilities will be distributed within the trial, as well as how you ensure that those who participate in the trial operation have the appropriate skills for the task.

Describe how you handle and manage documents that are important to the business and how they are communicated within the organization, as well as how you ensure that accidents, incidents and other deviations are investigated and that preventive measures are taken.

Examples of questions to be answered:

- Is there a specific driver education?
- Are there incident/accident procedures in the trial operation, and how is it followed up?
- Is there a deviation management procedure for the trial operation, and how is it followed up?
- When and how is the Swedish Transport Agency informed regarding, for example, accidents or changes affecting the permit?
- Is the trial operation insured?
- Is there a clear and communicated distribution of responsibilities for the trial operation?
- Are there risks in the risk management plan that are managed via one or more organizational routines?

3. **The purpose of the trial**

An overall description of the purpose and goals of the trial.

4. **Automated functions**

A description of the automated systems and functions to be tested and evaluated in the trial. This includes both a description of the technical system and the system's functionality and limitations. For the driving tasks that is not fulfilled by the automated system, the applicant must show how the trial operation still comply with the applicable traffic rules while driving.

We have produced the supporting document *Compliance with the traffic regulation* which the applicant can use to describe how the automated system complies with current traffic regulations. The document is available on our website [1]. Principles surrounding the functionality of the automated system are also described in chapter 7.2.

5. **Implementation of the trial operation**

A description of how the trial will be conducted and evaluated.

6. **Geographical area**

A description of the geographical area and on which streets or roads the trial is to be conducted, as well as the names of all of specific road owners. If the trial is conducted on public roads, the start and end points of the route must be clearly specified with, for example, a crossing road. Maps can be used to describe and clarify the route.

Read more about the road owner and its opinion under chapter 8.1.

7. **Risk management**

A risk assessment that shows that the risks of the trial are managed to an acceptable level and that the trial does not involve any significant disturbance or inconvenience to the surroundings.

Risk assessment is part of the safety case that must be included in the application. The risk assessment must consist of a system and trial definition as well as a risk analysis. See more about safety case and risk assessment under chapter 6.

8. **Ownership of the vehicle**

Information on the owners of the vehicles included in the trial must be provided.

9. **Technical description of the vehicle**

When trials are carried out with vehicles that have been modified in one way or another to be able to be driven automatically, a decision on exemption from the vehicle regulation is required. The vehicle also needs to be registered in the Road Traffic Register to be allowed to be driven on public road. In order for us to be able to issue such a decision, we need to receive a technical description of the vehicle as well as a certificate of compliance. Read more about technical requirements for the vehicle in chapter 7.

10. **Exemption from requirements for vehicles**

Need for exemption according to chapter 8 section 18 of the Vehicle

Ordinance (2009:211). Read more about exemptions from requirements for vehicles in chapter 7 and on our website [2].

11. Other information

Other information of importance for the permit processing.

6 Safety evidence and risk assessment

This chapter aims to assist the applicant in specifying a framework for the safety demonstration and risk assessment for the trial operation. The documents and analyses described below can be seen as a minimum level of safety evidence.

Methods and risk acceptance criteria are up to the applicant to choose based on the scope and complexity of the trial operation. The trial ordinance states that permission may only be granted if the applicant shows that traffic safety can be ensured during the trial operation. This means that the trial operation needs to maintain a level of safety equal to the current level, i.e. "at least as safe as today" on the intended route/area.

The examples given are examples, it is the responsibility of the applicant to identify the constituent parts of the various deliveries based on the project needs.

6.1 Basic documentation and analyses

Safety plan

Description of the safety work, roles, responsibilities and methodology used to demonstrate that the trial operation can be conducted safely.

System and trial definition

Description of the technical system, its essential functions and interfaces to adjacent systems, both internal and external. The system definition must also describe the intended operating conditions for the trial (for example, maintenance and environment) as well as limitations with the technical system.

The description of the technical system must be sufficient to be able to identify the risks with the system. It must be clearly stated which parts the automated functions consist of and the degree of maturity for each part.

Risk analysis

The applicant must show that they have identified and categorized the risks that the trial operation may entail through risk analysis of the system

described in the system and trial definition. Risks at interfaces with neighbouring systems must also be analysed. As a minimum, the following should be included in the risk analysis:

- Description of hazard
- Initial probability (the different levels of probability must be clearly defined and weighted against the trial operation)
- Initial consequence (the different levels of consequence must be clearly defined and weighted against the trial operation)
- Initial risk classification (based on acceptance criteria/risk matrix)
- Mitigation with reference to action taken
- Final probability
- Final consequence
- Final risk classification

The participants of the risk analysis and their competence must be specified.

Identification of risks is an ongoing process. The risks identified during the project, for example during risk analyses, can be collected in a hazard log.

6.2 Fulfilment of requirements

The risks identified by the applicant must be reduced to an acceptable safety level. The acceptance criteria for a sufficient safety level must be specified by the applicant. The Swedish Transport Agency wants to see evidence that the risk-reducing measures have been implemented.

For example, if the applicant reduces a risk with

- a technical solution: we will need to see the technical documentation as well as verification and validation of the technical solution,
- the routine: we will have to see it,
- the driver: we will need to see relevant parts of the driver training as well as specified requirements for the driver (regarding system - driver interaction, read more in chapter 7.2.4.

6.3 Independent assessment

If the applicant relies on technical systems to ensure traffic safety, depending on the system's complexity, it may be difficult for the Swedish Transport Agency to assess the system's safety. Therefore, the Swedish

Transport Agency has decided on the following general advice regarding independent assessment:

The Swedish Transport Agency's regulations and general advice on permission to conduct trials with automated vehicles (TSFS 2021:4) §4.

If the application includes trials where technical systems are used to a large extent to ensure traffic safety, the risk assessment should be supplemented with a statement about the trial from someone who is organizationally independent and has expertise in complex and automated systems. It should be stated whether the person who issued the statement considers that the system can ensure traffic safety.

This enables the applicant to hire an independent assessor themselves. The purpose of the independent assessor is to review the risk assessment and the evidence of risk management linked to the technical systems included in the safety work (other parts of the application are not to be reviewed by the independent assessor but by the Swedish Transport Agency). It includes assessment of the implementation of the safety plan as well as assessment of the safety plan including method and its suitability to be used for this system/technology in order to achieve a trial that can be carried out without affecting traffic safety.

This must be summarized in a report. This report should include at least:

- **Description of the assessed system**
A description that explains the system's function, intended use, interface, limitations and any conditions for using the system.
- **Description of assessment method**
A description that explains how the assessment has been carried out, and what the basis for the assessments that have been conducted are.
- **References**
The report must contain an account of which documents or other sources that form the basis of the assessment and how these have been reviewed. This may also include applied standards or other external requirements documents.
- **Results**
The result of the assessment must be stated and any deviations or observations shall be accounted for.
- **Conclusion with statement**
A summary of the work carried out as well as a final statement from the independent assessor on whether the system can ensure traffic safety. It must be clearly stated in the conclusion if there are any limitations or conditions for the system.

For the credibility of the assessment, it is important that the person performing the assessment is organizationally independent in relation to the current project and that the assessor has sufficient knowledge of the technology and the process of how these safety-critical systems are developed. If applicants hire an independent assessor, we want to see documents that show that he/she has sufficient competence.

To facilitate an efficient permit process, it may be appropriate to have a dialogue with the Swedish Transport Agency if you intend to use an independent assessor. This is primarily to ensure the requirements for the assessor's competence and the plan for his/her work before the assessor begins its assignment.

7 Vehicle requirements

7.1 Vehicle approval

In order for a motorized vehicle to be used in traffic, it must be registered in the Road Traffic Register, have valid traffic insurance and be reliable from a safety point of view and otherwise suitable for traffic. The latter can be shown by the vehicle having a:

- type approval¹,
- individual approval,
- approved registration inspection.

More information on approval of vehicles can be found in the vehicle regulation (2009:211) and on the Swedish Transport Agency's website.

As trials are often carried out with vehicles that have been modified in one way or another to be able to be driven automatically or are unique prototype vehicles, a decision on exemption from the vehicle regulation is required. The vehicle exemption process can be divided into the following points:

1. Verification of origin
2. Classification of vehicles
3. Fulfilment of vehicle requirements
4. Assessment of exemptions

¹ Implementing Regulation (EU) 2022/1426 [5] applies to type approval of automatic driving systems in fully automated vehicles.

5. Decision and registration

In order for us to be able to carry out the points mentioned above, we need to receive a technical description of the vehicle as well as a certificate of compliance.

The Swedish Transport Agency has produced a support document in Excel format where the applicant can fill in what requirements the vehicle has as well as registration information for the vehicle. The supporting document is available on our website [1] (Swedish only).

More information about exemptions from prescribed technical requirements for a vehicle can be found on our website [2].

More information about individual approval can be found on our website [3] and in the Swedish Transport Agency's regulations and general advice on individual approval (TSFS 2010:4).

7.2 Principles of the automated vehicle

Some principles (approaches) that emerged through previous case and practice are described below. Applicants must take these into account when planning their trial operations.

7.2.1 Safety-critical technical systems

In cases where the applicant relies on safety-critical technical systems (hereinafter referred to as "systems"), these systems will need to have been verified and validated with regard to function and reliability and reviewed by an independent assessor (see chapter 6.3 for more information).

If the applicant uses systems that are already certified, safety certificates or similar must be attached. The applicant must also demonstrate that the application of the system falls within the intended area of use.

If the applicant relies on novel systems or systems with a different application area, the independent assessor must assess whether the development and construction of the system follows guidelines or applicable standards and best practices. This could be, for example, international regulations, standards for the approval of automated vehicles or similar functions that can already be type-approved today.

7.2.2 Driver outside the vehicle

The trial ordinance normally requires that there be a driver located inside or outside of the vehicle. According to the trial ordinance, permission can be granted for trial operations for vehicles that have an automated driving system that can independently control and drive the vehicle during all or

part of the journey. Therefor exclusively remote driving does not fall under the regulation.

(1) Applicable regulations for remote control

Remote control is limited by UN regulation no. 79 (R79) regardless of whether it is performed as part of trial operation or not [4], but the possibility of vehicle exemptions exists. From R79 it is stated that:

1. The speed must not exceed 10 km/h (+2).
2. Fault diagnosis must be available.
3. If there is an obstacle (in the vehicle's direction of travel), the vehicle must always stop in front of it (it must not be possible to deactivate this functionality remotely when the vehicle is remotely operated).
4. If an interruption in the communication link occurs, the vehicle must stop unconditionally and immediately.
5. The distance must not exceed 6 meters in a remote connection.

Based on the above-mentioned requirements in R79, trial operations with drivers outside the vehicle can be carried out. Note, however, that remote control is only an emergency control option and not a primary control for propulsion. Therefore, the restrictions above are considered appropriate. Exceptions from R79 are only allowed for:

- Speed, must be limited and suitable for the vehicle and its manoeuvrability.
- Distance 6 meters. In the case of exemptions from 6 meters, we must ensure that the driver has the opportunity to observe/manage the traffic situation as if the driver were in the vehicle and its regular driver's seat (if any).

(2) Compliance with regulations in the traffic ordinance (1998:1276) when the driver is not in the vehicle

According to the trial regulation, it is the person who activates the automated driving that is to be considered the driver until the automated driving is deactivated. This means that if automated driving is activated by a driver in a place other than in the vehicle (remotely), then it is this person who must fulfil the driver's responsibility according to the traffic regulation. Examples of this responsibility are being helpful in the event of accidents and placing warning triangles. The applicant must show in the application how the driver's responsibility can be fulfilled when the driver is at a distance from the vehicle.

A remote driver also needs to have the correct driver's license for the vehicle in accordance with the Driving License Act.

We have produced the supporting document *Compliance with the traffic regulation* which the applicant can use to fill in how the automated system complies with current traffic regulations. The document is available on our website [1].

(3) Vision requirements for drivers outside the vehicle

As the driver-outside-the-vehicle, the driver needs to meet the requirements of the traffic ordinance, where the driver needs to have a good view of the surrounding traffic environment. This places demands on the design of the driver's environment and its technical system linked to, among other things, video resolution, viewing angles and frequency. As there are no set requirements regarding this, we recommend the applicant to consider the vision requirements that apply to drivers and put these in relation to the technical system. Regulation on vision requirements, among other things, can be found in the Swedish Transport Agency's regulations and general advice (TSFS 2010:125) on medical requirements for holding a driving licence, etc.

7.2.3 The technical limitations of the automated system

The automated system must not be able to act outside its technical limitations without the explicit consent of the driver. In the absence of consent, the vehicle must be placed in a safe state. Continued travel can/may take place after confirmation from the driver.

7.2.4 System – driver interaction

For automated systems that are not proven safe, drivers can be used to reduce risks associated with the automated system. An important part of the safety case is then the interaction between the automated system and the driver. If the driver is used to reduce an identified risk, we want to see evidence or arguments that the driver can act as such a barrier. This means that control strategies and the driver's reaction time must be considered so that, in the event of a deviation, the driver can take control of the vehicle (for example by pressing an emergency stop button).

For this proof or argument, it may be appropriate to start from the existing regulation on automatic lane keeping systems, UN regulation no. 157 (R157) [6].

8 Other information

8.1 Other stakeholders

In the trial ordinance, it is stated that the Swedish Transport Agency shall take the road owners opinion into consideration. This means that before a decision on permission is made, we contact the road owner to check how the road owner sees trials taking place on its road. Any conditions from the road owner to accept the trial operation can be included in the Swedish Transport Agency's decision.

We recommend that the applicant engage in dialogue with the road owner about the planned route or geographical area for the trial operation at an early stage.

Other stakeholders that the Swedish Transport Agency recommends the applicant to contact are the local police and emergency services. Since trials usually take place with prototype vehicles and electrified vehicles, for example, emergency services need information about how the vehicle's high voltage system or automated functions can be disabled.

8.2 The implications of the permit

The permit enables traffic on the road for trial operation with automated vehicles. The permit may include conditions that must be followed.

Those who have been granted permission by the Swedish Transport Agency will not be exempt from requirements found in other laws or regulations to which the trial operation may be subject.

For example, a trial operation with automated buses for passenger traffic also needs an authorization to pursue the occupation of road transport operator in order to be able to transport passengers. Requirements regarding, for example, data protection, work environment, electrical safety, research ethics and safety protection need to be agreed with the respective authority concerned. The requirements for driving license in the Driving License Act apply to the person who is the driver, even when the vehicle is driven automatically.

8.3 Fees and processing time

The Swedish Transport Agency charges a fee for case processing. It is when the application is received that we start charging for our processing. This means that the start-up meeting is free of charge.

Fees are charged according to time consumption and are charged through an ongoing hourly rate that is paid for each 30-minute period started. Invoicing

takes place monthly. The fee is charged in accordance with the Swedish Transport Agency's regulations on fees (TSFS 2016:105) where the current hourly rate is stated.

Regarding processing time, it is difficult to give an approximate picture as the scope and complexity of the trial operation can vary greatly between trials. From initial contact to permission being obtained, the processing time can be estimated at between three to six months, but it is not unusual for processing times of over a year. A more detailed schedule can be provided during the start-up meeting. A basic prerequisite for effective case handling is that the application is thoroughly processed and as complete as possible when it is sent to us.

8.4 Reporting and evaluation during the trial

The permit holder must continuously report accidents and incidents to the Swedish Transport Agency. This also applies to other deviations that can affect traffic safety. For the definition of accident and incident, definitions under Annex III Part 5 of 2022/1426 [5] can be used where "Accident" is equated with "Critical Occurrence" and "Incident" with "Non-critical Occurrence".

An evaluation of the trial must be sent to the Swedish Transport Agency annually and at the end of the trial. This is done through a written report that is submitted with the case number. The content of this evaluation must be linked to the purpose and goals of the trial and must also contain the following information:

- Distance driven
- Number of runs
- Number of passengers (if applicable)
- Accidents
- Incidents

As the evaluation are of public interest, it should be written so that it can be released publicly.

8.5 Public access and confidentiality

The right for individuals to access public documents and information from such documents is an important part of the principle of openness, which in turn is an important part of our democratic state. Through this opportunity for transparency in the activities of an authority, legal certainty and also

efficiency in administration increases. However, there is information that cannot be disclosed as it would damage the applicant's business.

When requesting the disclosure of information from public documents, the Swedish Transport Agency makes an assessment of what can and cannot be disclosed due to confidentiality rules. To facilitate this assessment, the applicant can mark the attachments in the application where the applicant considers that confidentiality applies. However, it is important to know that the Swedish Transport Agency is the one who decides whether confidentiality applies or not. The Swedish Transport Agency's decision not to disclose information upon request can be appealed to the Court of Appeal.

Confidentiality applies to permit and audit activities at the Swedish Transport Agency for information on, among other things, an individual's business or operating conditions if it can be assumed that the individual will suffer damage if the information is disclosed. This according to chapter 30 § 23 Public Access to Information and Secrecy Act (2009:400), in conjunction with § 9 of the Public Access to Information and Secrecy Ordinance (2009:641) and point 17 of the appendix to the ordinance.

9 Administration

If you have questions or comments about this document, you can contact us via our function mailbox:

automatedvehicles@transportstyrelsen.se

10 References

- [1] The Swedish Transport Agency's website for the trial operation with automated vehicles
<https://www.transportstyrelsen.se/en/road/Vehicles/self-driving-vehicles/> (website in English)
<https://www.transportstyrelsen.se/sv/vagtrafik/Fordon/forsoksverksamhet/sjalvkorande-fordon/> (website in Swedish)
- [2] The Swedish Transport Agency's website for exemptions from prescribed technical requirements for vehicles (only Swedish)
<https://www.transportstyrelsen.se/sv/vagtrafik/Fordon/dispens-fran-foreskrivna-tekniska-krav/>

- [3] The Swedish Transport Agency's website for individual approval (only Swedish)
<https://www.transportstyrelsen.se/sv/vagtrafik/Fordon/Enskilt-godkannande/>
- [4] Regulation No 79 of the Economic Commission for Europe of the United Nations (UN/ECE) — Uniform provisions concerning the approval of vehicles with regard to steering equipment [2018/1947]
- [5] Commission Implementing Regulation (EU) 2022/1426 of 5 August 2022 laying down rules for the application of Regulation (EU) 2019/2144 of the European Parliament and of the Council as regards uniform procedures and technical specifications for the type-approval of the automated driving system (ADS) of fully automated vehicles
- [6] UN Regulation No 157 – Uniform provisions concerning the approval of vehicles with regards to Automated Lane Keeping Systems [2021/389]