Guidance for safety certification and supervision

Enforcement Management Model



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1. Introduction

Under the arrangements in the Railway Safety Directive 2016/798 a Single Safety Certificate may be issued by a National Safety Authority or by the European Railway Agency (The Agency). Safety Authorisations are issued by an NSA. The checking of Single Safety Certificates or Safety Authorisations during their lifespan once they have been granted by the Agency or the NSA, is always carried out by an NSA during its Supervision of the organisation. It follows therefore that if non-compliances are found it is the NSAs who need to take appropriate action using their regulatory powers to address the matter in the first instance. Clearly, too if the attempts of the NSA to rectify the situation are not successful either the NSA or the Agency in consultation with the NSA has the option to revoke or restrict the Single Safety Certificate of the organisation, or in the case of Safety Authorisations the NSA may restrict or revoke it.

Within the Member States of the European Union there are different approaches to the regulatory oversight of railways. Some national authorities charged with the oversight of railways, have limited powers to enforce safe railway operation, whilst in other states the National Safety Authority (NSA) has direct power to intervene. As national legal powers are limited under national law some Member States use provisions within European legislation such as those within Directive (EU) 2016/798 and Directive (EU) 2016/797.

Currently, there is no guidance on the circumstances in which an NSA might use these powers except what is written in Directive (EU) 2016/798. In Article 17(5), it is stated that if an NSA finds that a holder of a single safety certificate no longer satisfies the conditions for certification, it shall either decide to revoke or restrict the single safety certificate itself or, where the European Union Agency for Railways (also named hereafter 'the Agency') issued it, ask the Agency to do so. In either case reasons must be given for the decision. The provision which allows an NSA to revoke or restrict a single safety certificate following evidence gained during supervision could be used to force change.

In addition to the above, there are differences between Member States as to who is responsible for prosecutions of organisations for safety violations and under what circumstances such actions are taken. In some Member States, state prosecuting authorities investigate large incidents rather than the NSA. In some Member States, it is possible to prosecute organisations for breaches of law relating to the safe operation of railways even if there has not been a serious accident. In other Member States, such prosecutions only take place where serious accidents have occurred. These differences in approach between different Member States create challenges to the EU regulatory framework for railways and for NSAs implementing EU law. Finally, in some Member States, the national law on railway safety also covers safety at work issues. In the majority of Member States such matters are dealt with by a different authority to the NSA, operating under a different legal regime. There might also be enforcement issues where there is cross-border traffic as the NSA within each Member State operates under a different legal framework with different powers to intervene to enforce safety improvements.

The supervision principles if applied correctly should mean that NSAs carry out their supervision, including their enforcement activities, in a consistent and fair manner. The Agency believes that it could assist NSAs to have guidance which takes these principles further so there is a basis for a consistent approach to the question of enforcement in Member States.

1.1. Purpose of the guide

This guidance document provides NSAs with a simple Enforcement Management Model (EMM) which will assist them in making judgements on enforcement following an organisations failure to comply with both national and EU law. The model aims through a simple matrix, to categorise the level of failure to control a risk gap observed during supervision.

It addresses the relationship between national enforcement powers and those within Directive (EU) 2016/798 concerning single safety certificates with the aim of helping ensure that there is a level playing field for addressing non-conformities and breaches of law for applicants for safety certificates and for those subject to supervision by NSAs across the European Union.

The EMM is a tool that can be used by NSAs to help provide consistency in the enforcement of laws that permit the issue of penalties or notices to improve some aspect of an organisations' risk control arrangements. The aim of the tool is to provide for the NSAs a means of complying with Article 7(1) of the CSM on Supervision. This requires NSAs to have decision making criteria on how identified non-compliances are dealt with. Recitals (5) (6), (7) and (8) of Commission Delegated Regulation (EU) 2018/761 *[CSM on supervision]* also make it clear that NSAs should carry out their supervision activities aiming to improve mutual trust in their approaches to decision making be proportionate in their actions, and should target their actions at the areas of greatest risk and be accountable for the decisions they make. Again the Enforcement Model provides a means of achieving this.

1.2. Who is this guide for?

The present document is addressed to:

- The NSAs when assessing railway undertakings' and infrastructure managers' SMS during their supervision;
- The railway undertakings and infrastructure managers as a guide to what could follow if they do not meet legal standards.

1.3. Scope

An EMM such as this:

- Can provide a framework for those carrying out supervision to assist them in making consistent enforcement decisions;
- Helps NSAs to monitor the fairness and consistency of the enforcement decisions made by those carrying out supervision;
- Can assist in dealing with more complex cases;
- Can demonstrate that the NSA is conducting itself in a manner which is targeted, fair, transparent and proportionate, if the EMM model that the NSA is using is made publically available.

This document does not cover enforcement by regulatory authorities other than the NSA.

1.4. Guidance structure

This document is part of the Agency compendium of guidance supporting the railway undertakings, infrastructure managers, national safety authorities and the Agency, in fulfilling their roles and undertaking their tasks in accordance with Directive (EU) 2016/798.





NSAs should cooperate with other regulatory agencies in the fulfilment of their functions as provided for in EU and national law. More on when to cooperate with other agencies can be found in the *Supervision guide*.

It is important to note that the model should be used by people competent in supervision (see also *Agency guide on competence management framework*) and is an aid to and not a substitute for professional judgement.

2. The Enforcement Management Model

2.1 Limitations

Assessing risk and compliance with national laws varies from the very straightforward to the very complex. In making an assessment and in checking legal compliance it is not always the case that non-compliances can be clearly defined. Moreover it is often the case that several deficiencies of varying seriousness are found during supervision. Whether a law has in fact been broken which organisations or individuals should be held accountable and how to remedy any breach or breaches of the law are often difficult questions to answer.

The EMM is an aid to judgments being made by people in the NSAs who should be competent in its use. Furthermore, it is not a model that will deal with all the possible subtleties that can confront someone carrying out a supervision activity and give 'the right answer' automatically. This is because supervision itself requires the person carrying it out to make judgements about risk. In particular people will need to judge the size of the 'risk gap', as defined in the model, and this is crucial to this model's use. The model should therefore be used as an aid to the decision making powers of those carrying out supervision and not be seen as a constraint upon them. Those who use this framework should be properly trained in its use and how to make judgements about relative risk and to think critically in checking legal compliance against the actual situation.

This model can exist within the context of differing legal frameworks within different Member States. Attention should however be given by each NSA to ensuring that the use of this model is consistent with their existing national regulatory framework. The flowchart at Annex 1 shows the point at which the model is used and how it feeds decisions on prosecution or restriction or revocation of a single safety certificate or safety authorisation.

Within this model there is an extra step concerning the question of whether a single safety certificate should be revoked or restricted.

2.2 Enforcement priorities

NSAs carry out supervision to check that an organisation fulfils and continues to fulfil the conditions under which it was granted a single safety certificate. In practice this means that in awarding a single safety certificate a conclusion has been reached by the assessing authority that the organisation has provided enough information to demonstrate that they have or will have a functioning safety management system (SMS) which meets the evidential requirements of the common safety methods on conformity assessment.

Single safety certificates or safety authorisations last for a period not exceeding 5 years and during their lifetime they are subject to supervision by an NSA which is making sure that the arrangements of the SMS set out in the original application are being maintained in practice during the life of the certificate.

If the NSA discovers that there are non-compliances they will have to consider how to address these. One method for NSAs to assess the SMS in any particular case is to use a management

capability or maturity model which offers a method for assessing the maturity of an organisation's SMS (see also Agency guide on management maturity model).

In addition within each Member State's NSA, there should be a supervision strategy and supervision plans. These documents are required under the common safety method on supervision. The supervision strategy focuses on the key priorities for the NSA in supervising promoting and encouraging railway safety. Each NSA should therefore have a clear idea of where the significant risks in the railway system are and of the management capability of the railway companies which will be derived from the supervision activity, and should be targeting its resources accordingly. Although the NSA may investigate or take action in any area within its remit it should, through its supervision strategy and plan(s), have a clear focus on where to act. It is therefore to be expected that those conducting supervision will target certain areas and that the EMM approach would support decision making on what action to take where breaches of law appear to exist. Finally, the NSAs strategy and plan(s) should take account of the work of other regulatory bodies or enforcement agencies such as the police for example on the environment or workforce safety as appropriate.

2.3 Risk gap analysis

During supervision activities, NSAs should collect information about hazards the associated risks and the adequacy of control measures. This is used to make an initial assessment of the actual risk compared with the level of risk accepted by legislation, standards or guidance (benchmark risk). The difference between this benchmark and where the organisation is in practice is the '**risk gap**'.

Depending on the difference between the reality and the expected position, the relative size of this gap can be rated as follows:

- 'Extreme' means there is a significant lack of compliance with the requirements of EU and/ or national legislation. For example, the complete absence of safety controls may lead directly to a dangerous event i.e. the risk gap is large. This in turn implies that the SMS has failed to put in place arrangements to control risks on several levels or it has not considered them at all in the risk assessment process.
- 'Substantial' means that there is a significant lack of compliance with the requirements of EU and/or national legislation for example, a consistent or deliberate failure to maintain authorised interoperable infrastructure in compliance with agreed TSIs, perhaps for economic gain. This might also affect the performance of either the rolling stock or infrastructure and impact on other railway undertakings. The risk gap is not as large as in the extreme case but is still significant. This could also imply that the SMS has not sufficiently considered the potential failure in the risk assessment process.
- 'Moderate' means that there is variation in the SMS which is inadequate but these failures are not significant in the context of risk control and are unlikely to have adverse safety effects. For example, there may be components used which whilst working adequately do not comply with the interoperability or accessibility rules. No competitive advantage is sought and the discrepancy has arisen from inadequate controls. The risk gap is relatively small and the implications are not large enough to cause serious concern. Where national law allows it some sanctions may be available to the NSA to require corrective action.

'Marginal' means the variation in the safety management system is minor and can be easily corrected. Problems of compliance with national and European law are not significant. The risk gap is not significant and what issues there are can be easily rectified.

The risk gap can be used in two ways:

- Firstly, to decide on what is the appropriate course of action the NSA should take to ensure that the organisation is brought into compliance with the law; and
- Secondly to determine whether any enforcement action permitted by the laws of the Member State, such as prosecution or notices, should be taken.

Where there are multiple 'risk gaps' in a particular area these should be considered separately. There are then two possible approaches:

- The risk gaps can be dealt with individually, targeting particular action at each risk gap if the national law gives the NSA sufficient power to do this. For example, it would be possible to issue a letter for a moderate risk gap requiring remedial action or requesting the organisation to produce an action plan to resolve the issue, at the same time, if there is also an extreme risk gap in the same area, more punitive enforcement action such as an enforcement notice or prosecution could be considered;
- The 'risk gaps' are collected in a particular area and then looked at as a whole targeting action at the highest level one finds. This approach also implies that an action plan is created to address the remaining lower level deficiencies. For example, if there are 5 'risk gaps' and three of these are moderate, one substantial and one extreme, then the action for the extreme risk gap should be followed, but a time bound action plan to address all other identified deficiencies should be agreed with the organisation involved. If there are several gaps in risk at the substantial or moderate level it may be appropriate to elevate the risk gap to the level above to reflect the combined overall risk and again create an action plan to address the lower level matters. However, care will need to be taken that if this is done it is carried out in a proportionate and transparent way, rather than in an arbitrary manner.

In determining the actual risk those carrying out supervision should base their judgement on information about hazards and control measures informed by their competence, training, experience, guidance and other relevant sources of information. It is the potential for harm which informs the decision not what (if anything) has actually happened.

To determine the risk and therefore the risk gap (i.e. the difference between the actual risk and the benchmark risk) from a supervision perspective, the simplest approach is to use three risk elements to make a judgement about the risk. The three elements are consequence, likelihood and extent.

- Consequence is the nature of the harm that could reasonably be expected to occur;
- Likelihood is the probability of the event happening where this means the event which may lead to injury, not the activity itself;
- Extent means the number of people likely to be affected or the amount of damage caused.

When carrying out supervision it should be recognised that some control measures may be put in place to: mitigate the consequence or the extent of an event; address the likelihood of an event happening or address all three. The difference between the sum of the conclusions of the judgements about the three elements in reality and the benchmark position (i.e. the position an organisation should be in if it applied all the control measures set out in legislation, standards and guidance), forms the risk gap. This means that NSAs carrying out supervision should have a clear idea of the standard that should be expected to be in place and are able to compare this with the reality to establish the risk gap.

In general terms, a higher level of enforcement should be expected where the status of the benchmark, legislation, standard or guidance is well known and established and the organisation is operating well below it.

Some legal requirements are largely administrative in nature and do not directly impact on risk. For these types of issues, where the Member States' legal arrangements allow this, it is not usually appropriate to prosecute the offending organisation or pass a file to a prosecuting authority although other sanctions may be imposed. The sanctions available before considering prosecution will vary from Member State to Member State but could include for example a formal notice requiring rectification of the deficiency in a specified timeframe or some restriction of the operators activities. For cases where prosecution is appropriate and this is allowed by the Member States' legal system there will usually be a combination of high risk and extreme failure to meet an explicit or clearly defined standard which is well known and obvious.

Where the incident giving rise to the possible enforcement involves a personal failure to follow an administrative rule or procedure created under EU law but there are also wider organisational failures. It should be unusual that enforcement takes place against that individual alone, unless there is evidence that the individual deliberately and knowingly did not follow the appropriate procedure. NSAs who have the power to prosecute individuals should be aware that prosecuting a person and not looking at the whole situation in regards to the organisation means that higher level safety management systems failings can be missed. There is then a risk that the incident is repeated by another individual in the future.

When considering possible action the NSA should take into account a number of factors. These can include factors that reduce the likelihood of action by the NSA or might reduce the action taken. Alternatively, these factors could include matters which act to increase the severity of NSA action or its type. Factors which might act to mitigate or increase the action to be considered in relation to the organisation subject to enforcement and that may therefore affect the action to be taken by the NSA include but are not limited to:

- The relevant incident history;
- Previous relevant enforcement including by other regulatory bodies e.g. the national police;
- Previous warnings and notices", also when it concerns multiple minor non-compliances (administrative);
- Whether any economic advantage was deliberately sought in not applying safety laws or requirements;
- The level of actual harm;
- Previous inspection history; and
- The overall standard of compliance within the organisation.

Other strategic issues which the NSA might also take into account in deciding on possible enforcement action include whether the action:

- Is in the public interest,
- Is necessary to protect vulnerable groups (e.g. children or the elderly);
- Results in sustained compliance;
- Has an effect on other organisations within or outside the railway sector; and
- Will result in the risk gap being closed and the benchmark being achieved.

Note: nothing in the preceding paragraphs limits the NSAs ability to take enforcement action within its legal powers and responsibilities. The factors above are matters which an NSA may take into account if the legal system within the Member State allows this.

Following this assessment, the NSA should address the following principles when coming to a conclusion on enforcement:

- Does the proposed enforcement action deal with the risks in order of priority with the most serious risks dealt with first?
- Has the cause of the risk been addressed by the enforcement action proposed?
- Have the immediate failures to control the risk or comply with the law been dealt with by the enforcement action proposed?
- Are the underlying problems addressed by the enforcement action proposed?
- Have the issues been sufficiently considered at organisational rather than a personal level?

The table below is a guide to decision making. It is not an absolute arbiter of the correct action to take in any given situation, NSA's also need to consider how any action taken may be implemented within the context of the legal system in operation in that Member State.

| Deviation | Initial Risk Gap | Initial enforcement expectation | | |
|--|---------------------|--|--|---|
| from legal requirements included in the SMS | | Action to mitigate risk If yes drop down to resultant Risk Gap | National law applied to address safety risk | Possible action on single safety certificate/ safety authorisation |
| | | No | Yes | Revocation (Refer to ERA with reasons if Certification carried out by ERA as SCB) |
| | Extreme | Yes | Yes | No Action on Safety Certificate (ERA Notified of any action taken by NSA with the organisation concerned if ERA the SCB) |
| | | No | Yes | Restriction (Refer to ERA with reasons if Certification carried out by ERA) |
| Contravention | Substantial | Yes | No | No Action on Safety Certificate (ERA Notified of any action taken by NSA with the organisation concerned if ERA the SCB) |
| | Moderate | No | Yes | No Action on Safety Certificate (ERA Notified of any action taken by NSA with the organisation concerned if ERA the SCB with reasons) |
| | | Yes | No | No Action on Safety Certificate |
| | Marginal | No | If necessary | No Action on Safety Certificate |
| | marginai | Yes | No action | No Action on Safety Certificate |
| None | None | No | No | No Action |

Where:

In the **first column**, contravention means a breach in law. So the starting point is that there has been a breach of the law (either national, EU or both).

In the **second column**, the initial risk gap means the difference between the level of risk accepted by legislation, standards or guidance, (where these are used as the basis for legal compliance) for the activity being looked at and the actual risk position in practice, **before** any action is taken to mitigate the risk. The relative size of this gap is rated 'Extreme', 'Substantial', 'Moderate' or 'Marginal' depending on the difference between the reality and the expected position.

In the **third column**, the NSA attempts to address the risk gap identified. The NSA will attempt to get the organisation involved to resolve the problem. Either the organisation will do something to resolve or mitigate the immediate risk in which case the answer is 'yes' or they will not, in which case the answer is 'no'. It should be noted that it is for the NSA to be saitisfied that the action proposed by the organisation is sufficient or not. If they are not they may further use the model to escalate the possible enforcement measures.

In the **fourth column**, the NSA applies national law applied to address safety risk means that the NSA applies the powers that it has to address deficiencies in national legal provisions for safety. This also means that the NSA is addressing deficiencies in compliance with European provisions where these have been translated into national law. Where the National Law allows it this will also mean the NSA carrying out or initiating prosecution or referring the matter to state prosecutors where appropriate. So here the answer is again a 'yes' or 'no'.

The **fifth column** addresses the question of what to do with the safety certificate of the applicant. So in general terms if the applicant is uncooperative and the NSA has had to apply national law to address an extreme risk gap, it is appropriate to consider the revocation or restriction of the single safety certificate or safety authorisation.

The revocation of a single safety certificate or safety authorisation is the appropriate response where an organisation is not managing risks at all well and is putting the travelling public or others at serious risk of harm. This would represent an extreme risk gap. Revocation of a certificate also creates problems since it means that the train service will stop. It is considered therefore that revocation is something that should only take place where all other solutions or enforcement options have failed or there is an expectation that these solutions will not lead to the desired result.

In the case of the restriction of a single safety certificate or safety authorisation it will be necessary to be very clear about the scope of the restriction and any conditions which have to be met for it to be lifted. For example it might be appropriate to restrict a freight company from the transport of dangerous goods (TDG) if it could not demonstrate that it was in full compliance with EU law on TDG transport. This would therefore mean that once the organisation can demonstrate compliance they can apply for an updated certificate to remove the restriction.

In any practical case, such as in the examples given in Annex 2, the NSA will have to take into account a number of other mitigating or aggravating factors in making its decision as to action. These factors include but are not limited to:

- The previous safety history of the organisation;
- Whether others outside the control of the railway organisation were more responsible than the organisation itself for the event, e.g. in cases such as incursions onto the railway;
- Whether the organisation has ever received advice from or had action taken against it by the NSA in the past in areas related to that in which the event occurred;
- Whether the organisation has sought economic advantage by neglecting safety requirements and its management responsibilities under the SMS;
- What the actual harm is or potentially could have been;
- The attitude of the organisation, i.e. they are pro-active in seeking to redress the situation or conversely, it is clear that safety issues are not of great importance to them.

The NSA may consider a number of strategic factors in deciding what enforcement action if any to take balancing these against the powers that it has to take action and its legal responsibilities. These include but are not limited to:

- Societal and political concerns,
- The safety culture in the organisation and the speed with which it can correct the defect/ non-conformity,
- The public interest,
- The impact of the proposed course of action on the company and society as a whole, in terms of the example it sends as well as the affect it will have on the organisations ability to continue to operate.

The NSA may take the output from the table as a guide for the enforcement expectation and may then apply the factors above to assist its judgements in any individual case on what action to take.

As any decision taken by the NSA needs to be justified and communicated to the organisation (principle of transparency), it is strongly advised that the reasons for the change in approach are recorded within the report into the situation which led to the suggestion that legal action or prosecution should take place or not.

ANNEX 1 Flowchart



ANNEX 2 Examples

Example 1: Contravention – Risk gap 'extreme'

A railway undertaking states that in its SMS that it has a comprehensive driver training and management programme involving the use of simulators, proactive use of train data recorders and driver manager oversight of driver activities.

Supervision activities reveal that the simulator has not functioned in several months, there has been no use of downloads from data recorders to monitor driver behaviour in the last 6 months. Due to sickness and retirements, driver manager oversight of driver behaviour has either not been taking place or is outside the time limits provided in the relevant organisational standard.

In addition it is noted that there has been an influx of new drivers in the organisation and the number of driver caused incidents, signals passed at danger (SPADs), station over runs and door release incidents has shown a rise in the period leading up to the supervision activity.

From the table the risk gap is 'extreme' as firstly, there is clear evidence of a management failure to deal with driver competence. Secondly, there is a clear and growing link between failure to manage the driver activity and a rise in the number of driver related safety incidents. Legal action should be taken by the NSA to address this with the railway undertaking. Given the seriousness of the increased number of incidents the size of the risk gap is clearly large.

In this case it is probable that an incident involving multiple fatalities is at risk of occurring if the situation is not addressed. The NSA carrying out supervision should be considering enforcement action for the failure to control risk to the organisations staff and passengers and others if the law in the Member State allows this. Enforcement action could comprise the NSA formally requiring in a letter or notice that the deficiencies be remedied according to a time bound action plan. If the deficiencies and resulting risks are severe enough this might also include prosecution or referral to a state prosecutor. If following NSA action to improve the situation there are still significant issues that have not been rectified then the NSA may decide to revoke the organisations single safety certificate or safety authorisation or refer the matter, (with the reasons why such action is necessary) to the Agency where it is the safety certification body. If the railway undertaking acts to correct the deficiencies, the NSA may conclude that a restriction (such as restricting the period of validity) of the single safety certificate is appropriate until it can be satisfied that the organisation can maintain control of the situation as well as/or applying national law as a punitive measure.

Example 2: Contravention – Risk gap 'substantial'

An infrastructure manager states that it has a competence management system in place which addresses competency requirements for its own and contracted staff carrying out work on its behalf. On paper the system looks to be comprehensive. Site visits however, show that there are staff on site sub-contracted by the main contractor who are not covered by the competence management system. Investigation of the use of such sub-contractors reveals they are widely used and many do not in reality have the competences that they are supposed to have. There is evidence of poor quality maintenance activity as a result with work having to be re-done. Some of the activities in question are safety critical. The risk gap here is 'substantial', if the infrastructure manager acts to address the issues either on its own or after being formally advised of the need to by the NSA then national law may be applied as a punitive sanction but it would not be expected that action would be taken on the safety authorisation. If the infrastructure manager does not act as expected to correct the deficiencies national law would be applied and the NSA should consider whether it is appropriate to restrict the safety authorisation.

Example 3: Contravention – Risk gap 'moderate'

A railway undertaking has a risk assessment process which is on paper comprehensive and the staff appear to be involved in and understand it. During the audit/inspection however, it becomes apparent that the risk assessment process is not being applied properly because the control measures identified in the risk assessments have not all been implemented due to weaknesses in the process verification. The consequences of this lack of application is not particularly serious as the risks that have not been mitigated are not the significant ones.

Working through the table it can be seen that there is a contravention and the risk gap here is moderate because although the risk assessment process has not worked correctly the consequences are not serious. In this case then, the decision on what action to take is a marginal one and could depend on the enforcement options available to an NSA. An enforcement letter or notice may be appropriate for some NSAs to rectify the problems with the risk assessment process especially if there is not any historical evidence of similar issues in the same organisation. The problems with the risk assessment process in the organisation may require an amendment to the SMS which might need to be notified to the NSA.

Example 4: None – Risk gap 'none'

A railway undertaking has a process for maintaining its rolling stock. Audit/Inspection reveals that the process is in place and the staff interviewed understand their roles and responsibilities under it. Incident investigation does not reveal any incidents which could be attributed to poor maintenance or a misunderstanding of a maintenance process. Working through the table there is no risk gap and therefore no action is required by the NSA.



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Guidance for Safety certification:

- Application guide for the granting of single safety certificates - A guide for the applicants
- Application guide for the granting of single safety certificates - A guide for the authorities
- Safety management system requirements for safety certification or safety authorisation
- Supervision guide
- Management maturity model
- > Enforcement management model
- Coordination between national safety authorities A common approach to supervision
- Competence management framework for authorities



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