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Product safety and conformity in the automotive supply chain in the case of Product nonconformities

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Preface

Increasing globalization is accompanied by both new business opportunities and risks. The opening up of new markets offers the opportunity of gaining new customers. However, organizations therefore do not just have to deal with the new customers, but also with their cultures and the country-specific laws and requirements that apply for products. Furthermore, the sensitivity and connectedness of product users and authorities as well as the public discussions concerning the topic of product safety and conformity have increased significantly.

In this context, the question arises as to which organizational structures and processes must be established in an organization and how it should react if a product is classified as potentially non-conform or as potentially safety-critical due to nonconformities in one or multiple countries.

The answer to this question is subject to a certain level of complexity that results from, among other things, the number of parties involved (authorities, product users, OEM, suppliers) and their various requirements.

The goal is to define a possible organizational structure and establish processes to allow a coordinated approach for identifying relevant product nonconformities with respect to this. In this context, it may be useful to individually define a collaboration model with the parties involved in advance, so that each individual party can meet their own obligations.

The present VDA volume sets out recommendations for action. Terms and approaches are explained using examples.

The purpose of this practical paper with its examples is to further strengthen the collaboration between the automotive manufacturers and their suppliers in the field of quality.

Contents

Introduction

Each organization is obliged to ensure the safety and conformity (valid laws and regulations) of the goods it produces. Product safety means that products must not endanger people's health and safety. This applies to both the intended use and foreseeable misuse of the products. Conformity means that the products comply with the legal requirements in the relevant sales region.
The question of when a product is safe and conform is not uniformly defined in the various legal systems in the different sales regions. Never the less almost all legal systems agree on one thing – only safe and conform products may be introduced to market. Product conformity means conformity of product features or product functions with a specification. If unsafe products are on the market, the manufacturer is obliged to do everything possible to protect the product user. Alongside the fundamental interest of every organization to protect the product users and third parties, quick and effective handling of product nonconformities also serve the further interests of the organization. A safe and conform product safeguards its good reputation and thus its economic interests.

In order to meet the country-specific obligations, it is essential that product nonconformities that have been identified are processed internally, quickly and effectively, and a decision concerning further action is made with all parties involved in the process.

Each organization should take suitable measures to monitor the product in the market. However, it is not the object of this VDA volume to set up an organizational structure suitable for this purpose. Instead, this must be ensured on an individual organization basis (taking into consideration size, product, customer and market peculiarities etc.).

The purpose of the present VDA volume is not to outline the individual obligations for all parties involved within the supply chain or provide them in the various country-specific legal systems. The publication is rather intended to give recommendations to all parties involved in the product manufacturing process concerning collaboration in the event that a product nonconformity is identified regarding product safety or conformity. Product nonconformity is understood to be non-conformity with the agreed upon characteristics or functions of a product. Furthermore, this VDA volume also gives

recommendations concerning swift internal processing and evaluation of the circumstances. In doing so, the objective is to allow a timely and appropriate decision about measures, where necessary.

A prerequisite for an effective approach is that the organization involved is engaged preventively with the individual requirements in its organization and establishes an organizational structure along with processes for monitoring, identifying, and processing product nonconformities. Only by doing so is it possible to reliably identify product nonconformities and process them without delay.

A possible organizational structure, from the identification of a product nonconformity to the decision concerning the appropriate reaction (which may range from a recall of the affected vehicles to determining that no action is necessary), is shown and explained below using practical examples.

The example process sequence in the automotive supply chain presented in the following section should be used for guidance.

Moreover, all parties involved may (depending on the individual legal systems) have further obligations (e.g. to report to authorities) after the decisions have been made.

Each individual organization must determine individually whether, and to what extent, they are subject to such obligations. For example, this can take place in coordination with the local authorities. The individual obligations are expressly not the object of this VDA volume.

Irrespective of this, each manufacturer has the option of protecting itself from the effects of possible product nonconformities with further measures (e.g. with insurance). Obligations to provide information may result from this type of contractual relationship, and they are also not the object of this yellow print.

The following explanations may be relevant for each of the parties involved in the supply chain (from the smallest organizations to large corporations), whereby the required scope and implementation has to be individually customized on a case-by-case basis. The present VDA volume therefore makes no pretense of being complete.

1 Product safety system

For manufacturers in the supply chain (from software suppliers, service suppliers, and parts suppliers up to overall vehicle manufacturers) different obligations and tasks arise. This is the case when product nonconformities with regard to product safety or conformity could be present in products that have already been supplied.

If a manufacturer or a distributing organization becomes aware of product nonconformities, it must determine the circumstances, carry out a risk analysis, and make a decision about necessary measures. In order to determine the circumstances, it is generally necessary for the vehicle manufacturer and supplier to collaborate closely. This likewise applies to the overall supply chain.

It must be ensured within the organization that internal and external information is collected, processed, and evaluated.

The aim is that relevant circumstances are quickly, efficiently, and comprehensively processed and a decision is taken. This can be achieved by establishing an appropriate structure within the organization and by defining relevant processes.

A possible structure and the associated processes are described in the following section and illustrated by means of examples. Whether and to what extent the individual manufacturer should adopt this type of structure is dependent on the organizational structure and size, and therefore has to be individually considered and adapted.

1.1 Structure of an organization for product safety and conformity

Product monitoring and the obligations derived from it are a fundamental and legally-prescribed requirement of product manufacturers and distributing organizations.

In order that swift and precise action can be taken in the case of relevant product nonconformities, it is necessary that the responsibilities and approach are clearly structured within an organization.

Internationally operating organizations are faced with additional challenges due to the diversity and complexity of various legal systems. The structure of product monitoring within the individual organization may differ significantly depending on the requirements in different countries. It is essential that the people that deal with nonconformities from product safety and conformity for each of the relevant markets are specified in advance and qualified accordingly.

As a part of these activities, not only does the individual organization deal with the topic, but instead cooperates with other organizations involved in the relevant value-added chain. Skills, obligations, and responsibilities must be clearly defined and known to all parties involved in advance.

Responsibility for product safety and conformity fundamentally lies with the top management, but can be delegated depending on the organization size and structure in the course of assigning decision making.

The examples shown in the following section are intended to illustrate how it could possibly be implemented in the organization.

1.2 Implementation of a recall management system in the organization

If the safety or conformity of a product is not ensured, suitable measures must be taken. For example, this can include an obligation to report to authorities, a product warning, reworking, or a recall of the product. The aim is to protect the product user or third parties against possible harm caused by the product or its usage, or to ensure conformity with legal requirements.

For larger organizations, it is currently advisable to set up an internal recall management system. External suppliers can generally also assume subtasks, e.g. legal advice, field data analysis, sorting activities, reworking, modifications, etc.

1.3 The flow of information within the supply chain

It is in the interests of the manufacturer to implement a product safety system, in order to exclusively have safe and legally-conform products in the field. A product safety system is a structure within the organization with clearly specified processes, tasks, and skills for ensuring product safety and conformity. This approach does not only relate to the organization itself, but also to the interfaces to the process partners in the supply chain.

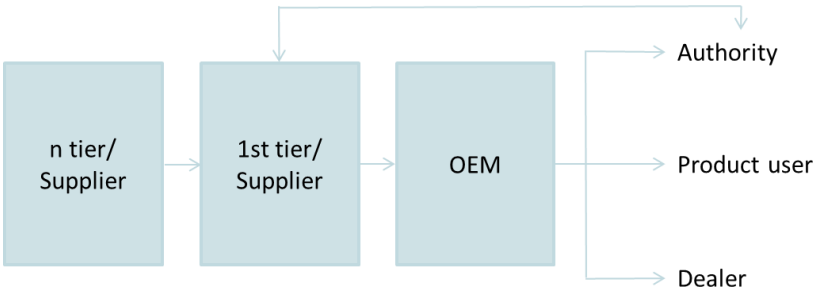

Figure 1: Reporting processes

If possible nonconformities relevant for safety or conformity are identified in the course of product monitoring, this information must be promptly passed

on to the affected interface partners in the supply chain for further risk analysis. In the event of a nonconformity that has to be reported, it is generally advisable for the OEM to submit the report to the authorities and, if necessary, to the product users or dealers. The reason for this is that the consequence of possible nonconformities on a component can only be evaluated in the overall vehicle system. However, if the supplier has its own reporting obligations, it must, if necessary, also individually report to the authorities. This should take place with the involvement of the OEMs affected. Moreover, suppliers with direct customer contact (e.g. via direct marketing in the spare parts market) can switch to the “OEM role”.

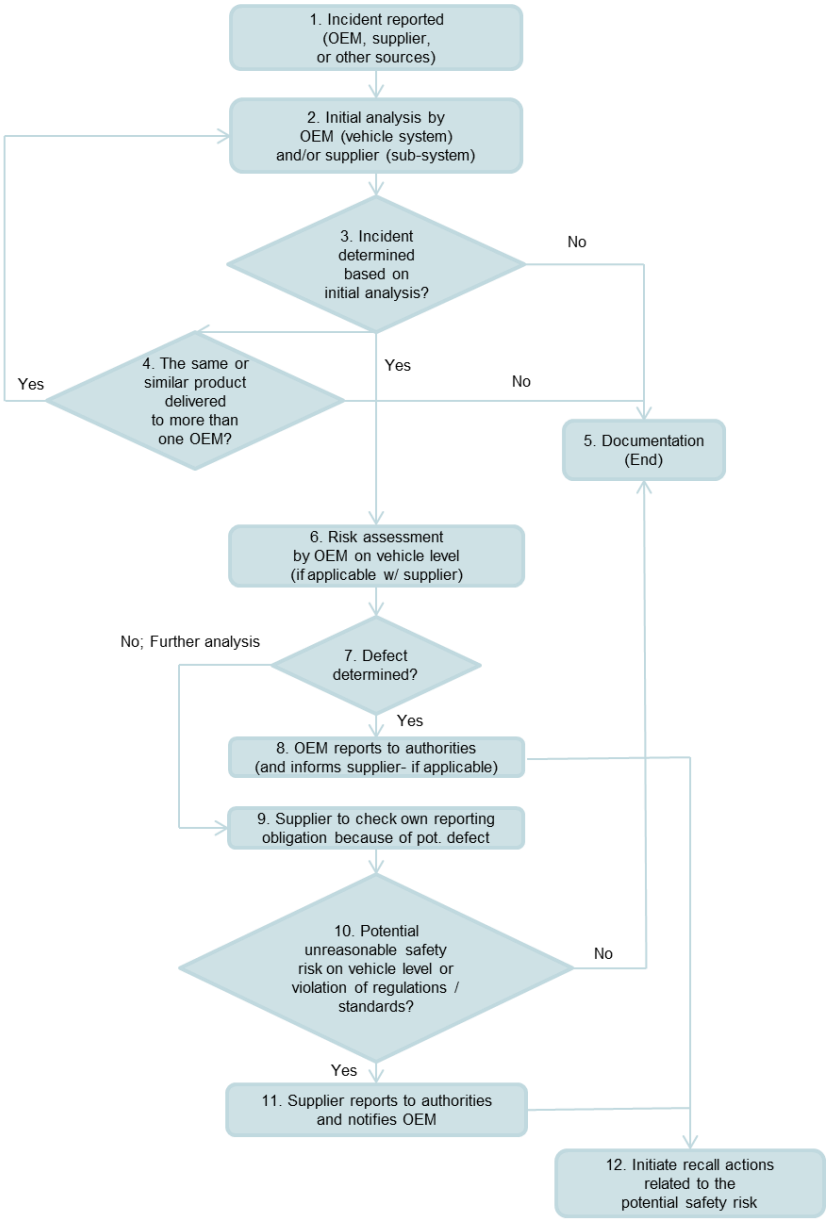

Figure 2: Example reporting process from the German-Chinese product safety working group as part of the collaboration of BMWi and AQSIQ from 2017.

Step	Authority	OEM	Supplier	Remark
1		R	R	Possible incidents maybe triggered by following issues: abnormalities occurred or detected in the process of testing or validation, analysis of field claims, during the production or information from authorities or social media
2		R / S	R / S	The initial analysis can be performed on two different levels: -on the overall vehicle level by the OEM -on the sub-system level by the OEM or the supplier
3		R / S	R / S	The incident is to be verified after the initial analysis.
4		I	R	If the supplier delivers same or comparable product to more than one OEMs, the initial analysis is to be applied for each of the other OEMs. According to the related system impact of this incident on the whole vehicle level, the analysis result might be different.
5		R	S	All relevant information will be documented and the process will be closed.
6		R	S	OEM performs risk assessment for the verified incident. The assessment is performed on overall vehicle level. The supplier provides support on sub-system-level if requested.
7		R	S	Based on the result of the risk assessment to determine whether there are non-conformities with state standards or industrial standards regarding protection of personal or property safety or any other unreasonable risks to personal or property safety.
8		R	(I)	If a potential risk cannot be excluded, the OEM shall report to the authorities within 5 working days. If applicable, the supplier is to be informed by OEM as well.
9			R	If the joint risk assessment performed by OEM and supplier does not lead to a report to the authorities through OEM, the supplier has to check his own reporting responsibility.
10			R	The supplier shall further evaluate whether the incident related to his product could lead to nonconformities with state standards or industrial standards regarding protection of personal or property safety or any other unreasonable risks to personal or property safety in the vehicles in China market use this product.
11	I	I	R	According to the provisions in article 13 of AQSIQ Order No. 176 regarding the notification obligation of supplier (auto product part manufacturers), in case the circumstance described in step 10 is determined, the supplier shall provide the related information to the authorities and notify the OEM.
12	R	R	S	According to the procedure defined by the authorities, actions related to a recall would be initiated.

R – Responsible, S – Support, I – Information

Table 1: Explanation of the example reporting process in Figure 2.

This reporting process can also be transferred to the n-tier in a similar form. It correspondingly reports to its respective higher-level suppliers at all times.

The figures and approaches described in this chapter relate to the status at the date of publication of this volume. The manufacturer must always independently keep themselves informed of the current country-specific reporting obligations and times.

2 Organizational structure

2.1 Organization guideline

It is advisable that the top management defines clear responsibilities in terms of a consistent quality management system. What form this takes is particularly dependent on the size and organizational structure of the relevant organization.

It can be useful, particularly in large organizations, to implement an organization guideline concerning the topic of product safety and conformity which employees can access (for example, via an internal platform). Furthermore, it must be ensured that at least the employees involved are sensitized to the contents of the organization guidelines at regular intervals.

The organization guidelines concerning product safety and conformity should define both the process and the responsibilities, as well as roles, including the supervisory duty of the management when delegating responsibilities within the process and supply chain.

2.2 Regulation of responsibility

The top management is responsible for product safety and conformity. Tasks from the product safety process can be delegated. In the event of transfer of responsibility, it is necessary to establish defined decision-makers or a decision-making committee. This committee or the decision-makers should generally evaluate potential nonconformities concerning product safety and conformity and, if necessary, specify measures. All process participants must have sufficient skills and opportunities for action for their tasks, in order that coordinated, focused, and responsible processing is possible. If the organizational structure or topic complexity requires it, a multi-level committee organization for fact clarification, decision preparation, decision making, and, if necessary, decision confirmation by organization management may be advisable.

This decision-making process must be clearly described in terms of responsibilities within the organization and, if necessary, the internal and external supply chain. Internal suppliers must be dealt with in line with the relationship with external suppliers. This also includes documentation and communication.

In practice, it has been shown to be advisable, if possible, to staff a decision-making committee as follows.

- Quality
- Product development and release
- Product safety
- Production
- Sales, Aftersales
- Legal

If further departments are required to make a decision, experts can also temporarily be consulted.

2.3 Communication and documentation

If a potential nonconformity that is relevant to product safety and conformity has been identified by a party involved within the supply chain, the relevant parties involved, both external and internal, must be informed about it. To this end, a previously defined, consistent reporting process should be referred to in order to ensure that the necessary reports are made consistently.

If possible, the interfaces in the supply chain should be defined in advance and the responsible contact persons in the organization should be announced, in order to ensure smooth communication. Each report should be neutral, purely fact-based, i.e. without subjective evaluation of the effects. Relevant documentation is part of the reporting process between the affected organizations.

If possible, it should include the following content:

- Date the nonconformity was identified
- Affected product
- Type of nonconformities

- Who reported the nonconformity
- Number of parts identified with the product nonconformity
- Containment of the production volume potentially affected

The report must be made immediately when the product nonconformity is identified, following the process defined in the organization. If necessary, open issues must be submitted or updated in a timely manner.

Relevant information must always be available for referral during each process step. Structured, consistent, and appropriate documentation of the processes is necessary for this purpose. Furthermore, all information relevant for the decision should be documented in a comparable manner. In doing so, it must be ensured that objective traceability of the process is ensured.

Evidence of the entire product safety process, from identification of a product nonconformity (this may affect both the availability and the security against manipulation of vehicle software or hardware) up to resolution of the product discrepancy, must be documented. The documentation retention requirements are described in the VDA volume “Documentation and Archiving”.

2.4 Sensitization of the organization to product safety and conformity

The overarching organization goal must be to ensure product safety and conformity for all sales markets. In doing so, it is necessary to regularly check that the established organization guideline is up-to-date and, if necessary, to modify it. At least the employees involved must be made aware of the correct handling of topics potentially relevant to product safety and conformity at regular intervals, and the possible consequences of improper handling.

3 Product safety process

The product safety process is, among other things, closely related to the regular failure elimination process, which is described in IATF 16949.

The product safety process differs from the regular failure elimination process in its consequences by the nature of the impact on product safety or nonconformities. These nonconformities result in a differing process.

Figure 3: Process chart

3.1 Product monitoring and complaint reporting

Based on the regular failure elimination process, organizations should install and maintain a system for product monitoring in the field.

The product monitoring system can fundamentally be divided into a reactive and preventive section. Reactive product monitoring can be understood as being informed of complaints about the product in the field, e.g. customer complaints, warranty claims or inquiries from authorities. Preventive product monitoring can be understood as, for example, targeted analysis of possible nonconformities in the manufacturing or validation process, demand for spare parts, or media research of comparable products.

A possible product nonconformity may be found during product monitoring. Assessment of the nonconformities must take place in the course of the failure elimination process. If a possible safety issue or nonconformity is present, this topic must be transferred into the product safety process. Otherwise, the regular failure elimination process applies.

The scope of the obligations for product monitoring may differ for the parties involved in the supply chain. In particular, the production monitoring obligation for the OEM relates to the overall vehicle; for suppliers it generally only refers to the supplied product.

3.2 Analysis of the facts

After information concerning a product nonconformity have been reported by a structure within the organization or by third parties, they must be analyzed, prepared, and documented for the subsequent steps in the process sequence. The resulting statement of facts forms the basis for the subsequent evaluation of the situation, for deriving alternative actions and the resulting decision made by the decision-makers or in the decision-making committee.

The statement of facts includes all the findings from the analysis process carried out by the parties involved. The contents of the statement of facts should follow a defined standard in order to ensure that all relevant information is reported as completely as possible. With this in mind, documentation should also be in a standard format.

The following contents provide a guideline as to what should be covered in the statement of facts.

- Reported nonconformity or complaint
  - ➔ What nonconformities/complaint has been identified?
- Cause
  - ➔ What is the root cause of the nonconformity/complaint?
  - ➔ What results are there with regard to analyses (component, system, system environment)?
- Effect
  - ➔ What effect does the complaint/nonconformity have during product use?
  - ➔ Likelihood of occurrence and risk assessment
- Containment
  - ➔ Narrowing down of the affected components or vehicles (production batch, production periods, etc.)?
- Amount affected
  - ➔ How many components or vehicles are affected?
- Country distribution
  - ➔ To which countries were the affected components or vehicles supplied?
- Measures
  - ➔ Which measures have been taken (immediate measures) or will be taken (long-term solutions) in order that current series production can be carried out without product nonconformities?
    What options are there for correcting the components or vehicles that have been manufactured and/or delivered?
  - ➔ Is part correction in the supply chain (e.g. spare parts in the aftermarket, parts in the plants) necessary?

The process cycle should take place in a period of time and to a level of detail that is appropriate for the circumstances.

3.3 Risk assessment

Risk assessment is a fundamental component of the product safety process.

3.3.1 Special characteristics

The technical product or process characteristics that are helpful for the risk assessment are obtainable or can be identified with little effort. To that end, these characteristics should be clear and internally regulated by the people affected.

Established special characteristics are described in detail in the VDA volume “Special characteristics”.

3.3.2 Risk assessment in the supply chain

A risk assessment must be carried out by the parties involved in the supply chain with regard to their products. The vehicle manufacturer carries out the final inspection of the overall vehicle system. Each of the parties involved in the supply chain must individually determine which criteria should be used for the risk assessment. The particularities of the different countries should be considered when doing so.

3.3.3 Methodological example in the course of RAPEX

The guidelines for management of the community system for rapid information exchange “Rapid Exchange of Information System” (RAPEX) were defined in the European Commission’s resolution of 16/12/2009 (reference number K (2009) 9843). The description of a guideline for the risk assessment of consumer products is an integral component of the resolution. This guideline also applies to risk assessment of circumstances in the automotive industry and is summarized in the following section.

The RAPEX risk assessment is structured relatively simply (see Figure 4). First of all, a product’s consumer group is defined and a risk group is derived from this. A potential injury scenario is now created using the consumer and risk groups defined. Both the injury’s possible level of severity and its likelihood of occurrence is then identified from this. The groups are

defined using RAPEX help tables. A RAPEX table also shows the resulting risk. The help tables can be found on the German Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin) (baua) site.

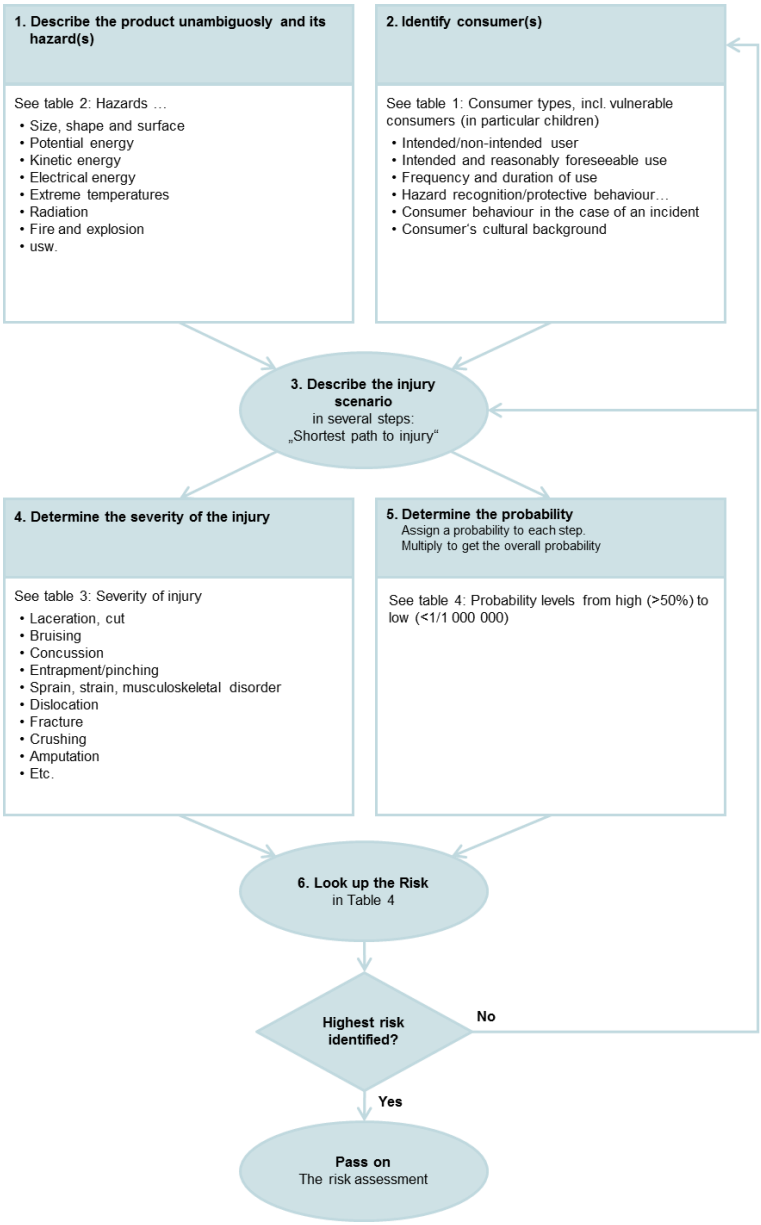

Figure 4: Schematic flow of the RAPEX risk assessment

3.4 Resolutions concerning further action

Decisions are made in the decision-making committee based on the analysis of the facts. The range of options for decisions conforms to the role that the relevant organization takes in the course of its business activities. Examples of this are: Supplier for an OEM, supplier with direct business (aftermarket sales), OEM, vehicle conversion or modification. The legal obligations of the relevant organization must be considered here.

Possible common scopes of measures are described in the following section for the roles OEM and supplier, depending on the above-mentioned risk assessment. The list includes but is not limited to:

Supplier for an OEM:

- No measures required
- Introduction of an appropriate internal corrective action
- Reporting of the circumstances to the affected OEMs in order to agree the further approach
- Report to the authorities

OEM:

- No measures required
- Introduction of an appropriate internal corrective action
- Quality improvement measure (customer service campaign without customer notification, during next repair shop/ garage/dealer visit)
- Quality improvement measure (customer service campaign with customer notification)
- Recall with customer notification and information sent to the relevant authority
- Report to the authorities

A supplier with direct business takes over the role of an OEM in its obligations for the direct business.

If a measure is defined resulting from the decision-making process, it must be implemented in the affected markets in a period of time appropriate for the circumstances. However, business activity does not stop when the measures are implemented. Product monitoring must continue to be carried out in the field in line with the regular failure elimination process, in order to assure that the success of the measure implemented is monitored.

4 Examples

4.1 Example presentation of an organizational process in a medium-sized organization

In the following section, a product safety system is presented as a whole using the example of a medium-sized organization.

- The top management has decided to delegate the decision-making process to a committee with regard to potential product nonconformities.
- The delegation has been defined and established in an organization guideline.
- The decision-making committee is comprised of the following employees:
    - Quality manager (skills: quality and product safety)
    - Development manager (skills: product development and release)
    - Sales manager (skills: sales, aftersales, market know-how)
    - Organization lawyer or external lawyer (skills: law)
- The quality manager is chair.
- Absence management guidelines are defined for all participants.

- To this end, the job description for the employees affected has been updated accordingly. The employees are provided with resources and capacities to fulfill their function.

- In the organization guideline it is specified that the decisions in the committee must be unanimous. If an agreement is not reached, the decision is escalated to the top management.

- The committee can only make decision if all skills are represented. This is determined by the chair at the beginning of each meeting.

- The decision-making committee meets as required.

- All documents required for this process are defined as standardized forms and are stored centrally.

- Storage of data, with regard to protection against tampering and access rights, is managed internally.

- The agenda topics are discussed and decided by means of a presentation that presents the circumstances in full.

- Each meeting must be recorded. The minutes are filed centrally by the chair of the committee.

- The internal reporting process is defined and known to the relevant employees and is part of the quality management system.

- The external reporting process is defined for the supply chain and communication is standardized.

- The employees are continuously made aware of the issue of product safety and conformity in the course of annual training.

4.2 Example case

The risk evaluation process and the reporting path is presented as a whole with an example case.

- In the course of its business activities, a supplier supplies the same liquid container to two different OEMs, hereafter called OEM A and OEM B.

- OEM A receives leaky liquid containers in the course of its regular field monitoring and passes them to the suppliers for detailed analysis.

- The supplier identifies in the course of its analysis that a different raw material (granulate) has been used to manufacture the component.

- The supplier verifies the results of its detailed analysis with its sub-suppliers.

- The supplier compiles the following information in agreement with the sub-suppliers:

    - Which incorrect raw material was used?

    - Why was it used (cause)?

    - Which production period is affected?

    - Has the failure already been corrected?

    - If yes, using which measure? If no, which measure will correct the failure and when will it be implemented?

    - Who in the supply chain is still affected?

    - If yes, how does the correction take place and whose responsibility is it? If no, when was the first OK delivery and how will the correction be carried out?

- The supplier evaluates the effect of the incorrect raw material being used on the component. This shows that the temperature resistance of the defective components is only given to a lower value. This has an ef-

fect on the strength of the component during vehicle operation. These components thereby do not correspond to the originally defined specification. A potential safety issue cannot be ruled out in the case of a premature failure.

- The supplier informs both OEMs about the circumstances for evaluating the component nonconformities in the relevant vehicle system environment.

- OEM A determines in the course of its failure consequence analysis that potential danger could result from operation of the vehicle. OEM B comes to the conclusion in the course of its analysis that no safety hazard could occur. Its component is in a different, non-critical installation situation in comparison with OEM A.

- OEM B transfers the circumstances into its regular failure elimination process.

- In the case of OEM A, the circumstance process is presented to the decision-making committee with all available information. The decision-making committee decides further action. In the example case, OEM A prepares the steps for a safety recall and the information to the relevant authorities.

- The whole supply chain is informed about the respective circumstances and the associated result.

- The whole process is communicated, documented, and archived in accordance with the internal organization guidelines.

- Both OEM A and OEM B continue their field observation as part of the regular failure elimination process. In doing so, OEM A also includes the effectiveness check of the measure implemented (safety recall).

Quality management in the automotive industry

The current version of published VDA volumes regarding quality management in the automotive industry (QAI) can be found at http://www.vda-qmc.de.

You can also place orders directly on this homepage.

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