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Development of a Risk Assessment Procedure for Industrial Products using Probabilities of Accidents and Injuries

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Abstract

This study develops a risk assessment procedure for industrial products using probabilities based on a causal network that reflects the causal relationship between product defects, accidents and injuries that affects risk, and also presents cases where this procedure is applied. Product risk assessment refers to the assessment based on indices that represent the safety of a product. It assesses the degree of hazard of the product to the human body or property and the likelihood of accidents occurring during the usage of the product. For risk assessment, product factors, accidents and injuries are used to design the causal network structure, and the probabilities of each hierarchies and conditional probabilities are calculated.

Keywords*: Causal Relationship, Product Defect, Accident, Injury, Risk Assessment*

1. Introduction

Recent accidents concerning electric products, manufactured goods and children's products have posed consumer safety. In particular, as the product distribution channels are diversifying, including an increase in direct imports by individuals, illegal or defective products have increased too, bringing about more risk of accidents. As such, the importance of product safety management has been growing.

Product safety management refers to all activities aimed at protecting consumers from the hazards posed by product incidents occurring during the production, import and distribution of manufactured goods including electronic goods. It includes various activities such as the production and import of safe products, assessment of product safety, safety certification and verification based on safety assessments and recall of defective products through market surveillance.

In general, product risk is determined by the likely accidents during product usage and the degree of hazard posed by such accidents (European Commission[4]). Product accidents occur based on probabilities caused by product defects or accident-influencing factors. Once an accident occurs, it can cause injury to the body and damages to property. Given this, there is a causal relation between the accident-influencing factors and accidents, as well as between accidents and injuries. To assess product risk, such a causal relation needs to be reflected onto the assessment.

This study determines probabilities for a product risk assessment model using such causal relation and applies it to a case. In particular, the study presents an assessment method based on a causalnetwork probabilistic model that shows causal relation. The study uses product accident-related information to structure networks with product defect factors and determine product risk based on conditional probability and the severity of injuries.

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2. Background

At present various product risk assessment methods are being used for product safety management. EU uses RAPEX to announce weekly investigation data on products including those with severe risk in each country. Applicable products are manufactured products excluding food and drug items and medical devices. The system is used to limit the sale and usage of products that pose severe risk to the health and safety of consumers. EU also has an RAG (Risk Assessment Guideline) (European Commission[4],Product Safety Enforcement Forum of Europe[12]).

Japan assess risk using the R-Map method. The R-Map method determines the risk by using a rich data base on accident cases, calculating the severity of the hazard and its frequency, and inputting them in a matrix (Ministry of Economy[10]).

Australia and New Zealand apply the Risk Engine method for assessing risk of electric and electronic goods (Morfee[11]). This method is a quantitative system based on the market factors that affect the product's characteristic and observation of rules.

ASEAN (Association of Southeast Asian Nations) legislated RAG in 2011 through the JSC EEE (Joint Sectoral Committee on Electrical and Electronic Equipment)[6]. This is based on the AHEEERR (ASEAN Harmonized Electrical and Electronic Equipment Regulatory Regime) legislated in 2005 and consists of a fitness assessment system and risk level determination process for electric and electronic products.

To verify the product risk management status in each country, Liu *et al.*[8] reviewed the risk assessment methods of EU, Japan and China, and mentioned issues in the Chinese system. Embarek and Hadjadj[3] mentions the difficulty in selecting a risk management method appropriate for a given environment and detailed methods to develop and select the optimal methodology for a given situation.

As a study on the process of risk analysis and assessment, Duijne*et al.*[2] presented a repetitive process of identification, estimation, evaluation and reduction, and described the items that need particular note in each step, along with prerequisites for the evaluation. Meanwhile Burns[1] reviewed the design methods, standards and rules applicable to safety management and presented a guideline for general product safety. In doing so, he presented injuries based on usage frequency, risk level, technical level of the user and user environment, as well as causes of damage, rules for safe design, recognition of risk and principles for control and methods for reducing risk. Moreover,Main[9] presented an evaluation process consisting of 7 steps and took several products such as a table saw as examples. Zhou *et al.*[14] presented a method based on BP neural network to assess fire risk of transmission line and explored the applicability and accuracy of the method by a transmission line in Shanxi province.

As can be seen, preceding studies related to the product risk management has been conducted mainly at a level that provides guidelines.

3. Determination of Probabilities

Let the random variable that represents the product defect factor be F_i and set F_i as the factors presented in the safety standards. Product defect factors are selected by referencing the product's hazard factors, requirements in the safety criteria and details from the product accident investigation. Product hazard factor is already defined as a product characteristics factor(European Commission[4]).

Now $P(F_i)$ represents the probability of factor i not meeting safety standards. $P(F_i)$is the upper most probability of the network concluded from the data of product safety investigation. If there is insufficient data from safety investigations, they can be estimated from the quality warranty documents of the company where actual accidents are reported.

LetNbe the accumulated number of products in operation for that model, and that $N(F_i)$ represent the number of cases where factor i falls short of safety standards. Then $P(F_i) = N(F_i)/N$ can be used to calculate the product defect probability. However, as in the case with new models, if there are insufficient accident data, product defect probability should be estimated based on the scenarios concluded from product risk analysis.

Usage environment factors refer to those affect the occurrence of accidents in association with the environment and the user, usage time and usage place were considered in this study, and the coefficient for each factor was estimated.

The user coefficient is calculated by adding the mediating coefficient for each user to the weighted average of usage by each user type. The mediating coefficient is set as follows by referencing the Korea Agency for Technology and Standards[7]. The usage time coefficient is the ratio of actual usage time to possible usage time and the actual usage time can be acquired through statistics or surveys. For items where the usage place may vary, just as with the user, the usage place coefficient is calculated.

Now, let$A_j$be the random variable of accident j, $j = 1, \ldots, J$ occurring. Andlet $P(A_j|F_i)$ be the probability of accident j occurring under condition factor i, then the conditional probability $P(A_j|F_i)$represents the probability of accident j occurring due to product defect factor i. $P(A_j|F_i)$can be concluded from accident history data. If there is insufficient accident history data, then a subjective estimation must be made by an expert.

When an evaluator is subjectively estimating, the value of product defect factors affecting accidents must be set from very low(1) to very high(5) for input. The input value should be added depending on whether there is a product defect factor for each accident type, the weight for usage environment factor U is multiplied to calculate the Factor Accident Index (FAI).

$P(A_j|F_i)$is calculated as the probability of an accident occurring under FAI andin this paper it is estimated by applying an exponential function. An exponential function is generally used to the probability density function of accident occurrence and can be expressed as in formula (1).

$$f(x) = \begin{cases} \lambda e^{-\lambda x}, & x \geq 0 \\ 0, & x < 0 \end{cases}$$

$$F(x) = \int_0^x \lambda e^{-\lambda x}\, dx = 1 - e^{-\lambda x} \quad (1)$$

Through existing case analyses, for a minimum FAI an accident occurrence probability of approximately 20% is assumed. For maximum FAI, a probability of about 70% to set the mediating variable in f(x) as λ=0.05. Therefore, the conditional probability $P(A_j|F_i)$ is calculated as in formula (2), using the accumulated exponential distribution function corresponding to the FAI for each condition. For reference, when λ=0.05 changes in the accident occurrence probability and accumulated exponential distribution in accordance with changes in FAI are shown in Figure 1.

$$P(A_j|F_i) = F(FAI) \quad (2)$$

x	f(x)	F(x)
0	0.05000	0.00000
1	0.04756	0.04877
2	0.04524	0.09516
3	0.04304	0.13929
4	0.04094	0.18127
5	0.03894	0.22120
…	…	…
20	0.01839	0.63212

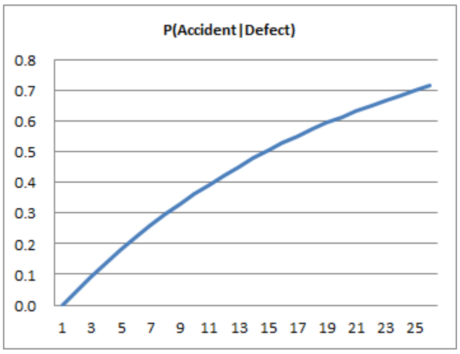

Figure 1. Changes in the Accident Occurrence Probability and Accumulated Exponential Distribution in Accordance with FAI Values

The probability of an accident caused by product defect factors is calculated as follows. The occurrence probability of accidents $A_j,\ j = 1,\ldots,J$ can be calculated as in formula (3).

$$P(A_j) = \sum_{(i\in I)} \sum_{(F_i = T,F)} P(A_j, F_1, \ldots, F_I), j = 1, \ldots, J$$

$$= \sum_{(i\in I)} \sum_{(F_i = T,F)} P(A_j | F_1, \ldots, F_I)\, P(F_1, \ldots, F_I), j = 1, \ldots, J \quad (3)$$

The injury composes the nodes from injuries caused by accidents. Let I_k, $k = 1,\ldots,K$ be the random variable of injury degree k occurring and $P(I_k|A_j)$ be the occurrence probability of injury k occurring under condition j to calculate the injury probability caused by an accident. $P(I_k|A_j)$uses the value calculated from accident-related data. If there is no accident history data, an expert's subjective estimation is used as in the accident hierarchy. That is, the value for the injury effect scale which is the degree of accidents affecting the occurrence of an injury, is input from very low (1) to very high (5). The input value becomes the injury occurrence likelihood score. Using this score, the Accident Injury Index (AII) is calculated. AII is a concept that corresponds the score of the likelihood of an injury occurring to the injury occurrence probability. It is presumed to correspond linearly to the score for the likelihood of injury occurrence. It is set to have very low to be 0.1, medium to be 0.5, and very high to be 0.9. Next, for each injury, the AII value is used to calculate conditional probability for accident occurrence $P(I_k|A_j)$.

Now, let's assume the AII of accident $A_j$causing injury $I_k$be $A_{kj},\ j = 1,\ldots,J,\ k = 1,\ldots,K$. then the conditional probability of injury occurring I_k against total accidents, which is $P(I_k|A)$ can be calculated as in formula (4).

$$P(I_k|A) = \sum_{j\in \mathrm{True}} P(I_k|A_j), \forall k = 1, \ldots, K$$

$$= \sum_{j\in \mathrm{True}} P(I_k|A_j) \sum_{p=1}^{j-1} AI_{(j-p)k} + \sum_{p=1}^{j-2} \sum_{q=1}^{j-p-1} AI_{(j-p)}\, AI_{(j-q)} - \prod_{r=1}^{j-1} AI_{(j-r)})\, AI_{jk}, \forall k \;= 1, \quad (4)$$

example, the conditional probability of accident A_1, A_2, A_3causing injury $I_k$which is conditional probability$P(I_k|A)$is as seen in formula (5). That is, using each occurrence of accident as an independent axis, corresponding AII values to the probability of injury occurrence are made so that their sum becomes 1 within the entire space.

$$P(I_k|A)_{j\in\{1,2,3\}} = \sum_{j=1}^{3} P(I_k|A)$$

$$= AI_{1k}+(1-AI_{1k})AI_{2k} + (1-AI_{1k}-(1-AI_{1k})\,AI_{2k})\,AI_{3k}$$

$$= AI_{1k} + (1-AI_{1k})AI_{2k} + (1-AI_{1k}-AI_{2k}+AI_{1k}AI_{2k})\,AI_{3k} \quad (5)$$

Then the probability for injuryI_k, $k = 1,\dots,K$in the injury hierarchy which is $P(I_k)$ can be calculated as in formula (6).

$$P(I_k) = \sum_{(j\in J)}\sum_{(A_j=T,F)} P(A_1,\dots,A_J),\ k = 1,\dots,K$$

$$= \sum_{(j\in J)}\sum_{(A_j=T,F)} P(I_k|A_1,\dots,A_J)\,P(A_1,\dots,A_J), k = 1,\dots,K \quad (6)$$

4. Product Risk

Based on the probability and severity of injuries that may occur during the usage of a product, the product's risk is determined. Assume that due to accident A_j, injury I_k occurred. And assume the severity of injury $I_k$is $S(I_k)$. Then in the PI (Probability and Impact) matrix in Figure 2, the risk corresponding to$P(I_k)$and$S(I_k)$ which isR_{jk}, $j = 1,\dots,J$, $k = 1,\dots,K$ can be calculated.

The severity of injury is categorized into five grades of none, negligible, marginal, serious and fatal. All types of injuries such as contusions, lacerations, fractures, suffocation and many others that affect the human body are all included in the term injury.To determine the severity of injury, this study uses the AIS (Abbreviated Injury Scale) as presented by the IISC (International Injury Scaling Committee) (International Injury Scaling Committee[5]).

PI Matrix references EU RAPEX's RAG to categorize risk based on the injury probability and injury severity for a given product (European Commission[4]). Risk is categorized into four types of A(Acceptable), L(Low), M(Medium) and S(Serious). For example, if the probability of an injury occurring is >0.00001 and the severity of injury is medium, then risk becomes A.

8	>0.5	A	M	S	S	S
7	>0.1	A	L	S	S	S
6	>0.01	A	L	S	S	S
5	>0.001	A	A	M	S	S
4	>0.0001	A	A	L	M	S
3	>0.00001	A	A	A	L	M
2	>0.000001	A	A	A	A	L
1	<0.000001	A	A	A	A	A
Injury probability		none	negligible	marginal	serious	Fatal
	Injury severity	0	Ⅰ	Ⅱ	Ⅲ	Ⅳ

Figure 2. Probability Impact Matrix for Risk Assessment

Final product risk is determined as the maximum risk that appears on the PI matrix based on injury probability and injury severity (Formula (7)). If there are multiple injuries for product categories, the injury risk with the largest value is determined as the final risk.

$$\text{Risk} = \text{Max}_{j=1,\dots,J}\text{Max}_{k=1,\dots,K}(R_{jk}) \quad (7)$$

The above is summarized and based on the summary, a risk evaluation procedure is presented.

Risk Assessment Procedure:

Step 1: Product's safety investigation data, accident history data and safety standards are reviewed to determine the network structure. That is, the product defect factors, accident occurrence type and injury occurrence type are determined.

Step 2: Defect occurrence probability by product defect factor $P(F)$ is estimated. If there is safety investigation data, it is concluded from the data, but if not, an expert's subjective opinion is used for estimation. In such a case, the usage environment factor coefficient is also estimated.

Step 3: From the accident history data, the conditional probability between factor accidents $P(A|F)$ is determined. If there is insufficient accident history data, the following is done.

3.1 The accident impact scale value for each product defect factor is input to calculate the FAI.

3.2 Using the accumulated exponential distribution function corresponding to FAI, $P(A|F)$ is determined.

Step 4: the combined probability of accident occurrence and product defect $P(A, F)$ is calculated, then the probability of accident occurrence $P(A)$ is concluded.

Step 5: The conditional probability in accordance with accident occurrence $P(I|A)$ is determined from the accident history data. If there is insufficient data, the following is done.

5.1 After inputting injury impact scale value for each accident, AII is calculated.

5.2 Using the AII value, the conditional probability in accordance with the accident occurrence $P(I|A)$ is determined.

Step 6: After calculating the combined probability for injury occurrence and accident occurrence $P(I, A)$, the probability for injury occurrence $P(I)$ is concluded.

Step 7: AIS scores for each injury type are input to calculate ISS scores and determine the severity of injury.

Step 8: Using the combination of injury probability and severity of injury and referencing the PI matrix, final risk is determined.

5. Application Case

This chapter shows an example of the procedure applied to an inline roller skate product that had already seen an actual accident occur. It is assumed that there is no distribution information or accident history data. The accident involves a boy (age 6) having the buckle coming loose two times during 10 minutes of riding inline skates within the apartment complex. There was no injury, but such accidents pose the concern of contusion and concussion.

Step 1: Determination of network structure (defect factors, accidents, and injuries)

By referencing the safety requirements of the product, the appearances, structure and function of the product are selected. (F1: appearances, F2: structure, F3: function)

Select fall which was the actual case of accident, as well as sliding and crashing as potential accidents. (A1: fall, A2: sliding, A3: crashing)

Although there were no actual injuries in the case, contusion, concussion and fracture were selected as potentially possible injuries. (I1: contusion, I2: concussion, I3: fracture)

Step 2: Calculation of product defect probabilities and usage environment factor coefficients

For product defect probabilities,let's assume that a review of the distribution information and data related to quality assurance led to a set of simplified data.

N: Total number of units in circulation (accumulated number of units) = 80,000

E: Accumulated number of cases for after-sales services or accidents = 1,300

$N(F_1)$:Number of cases that did not meet safety standards related to F1(appearances) = 800 cases

$N(F_2)$:Number of cases that did not meet safety standards related to F2(structure) = 80 cases

$N(F_3)$:Number of cases that did not meet safety standards related to F3(function) = 800 cases

Then the probability for product defect factors can be calculated as follows.

$P(F_1) = N(F_1)/N = 800/80{,}000 = 0.01$

$P(F_2) = N(F_2)/N = 80/80{,}000 = 0.001$

$P(F_3) = N(F_3)/N = 800/80{,}000 = 0.01$

For Usage environment factor coefficients:

- User: Boy (age 6) -> User coefficient = 0.84
- Possible usage time = 8 hours, Actual usage time = 2 hours -> Usage time coefficient = 0.25
- Usage place: Normal usage place -> Usage place coefficient = 1.0
- Weight for usage environment factor: w = User coefficient * Usage time coefficient * Usage place coefficient = 0.84 * 0.25 * 1.0 = 0.21

Step 3: Determination of conditional probability $P(A|F)$

Input accident impact scale: Input the degree to which F1, F2 and F3 impacts A1, A2 and A3.

Accident impact scale (1-5) by product defect factor

	A1	A2	A3
F1	3	2	3
F2	3	5	4
F3	4	3	2

Calculation of factor accident index: Depending on whether there is a product defect factor for each accident, the accident impact scale value is summed up and multiplied with the weight for usage environment factor w.

FAI(Factor Accident Index)

F1	F2	F3	A1	A2	A3
T	T	T	2.10	2.10	1.89
T	T	F	1.26	1.47	1.47
T	F	T	1.47	1.05	1.05
...	...	...	...	...	...
F	F	F	0.00	0.00	0.00

Using the accumulated exponential distribution function that corresponds to the FAI, the conditional probability $P(A|F)$ is determined.

P(A|F)

F1	F2	F3	P(A1|F)	P(A2|F)	P(A3|F)
T	T	T	0.09968	0.09968	0.09017
T	T	F	0.06106	0.07086	0.07086
T	F	T	0.07086	0.05115	0.05115
...	...	...	...	...	...
F	F	F	0.00010	0.00010	0.00010

Step 4: Determination of accident occurrence probability $P(A)$

The combined probability for accident occurrence and product defect $P(A, F)$ is calculated.

P(A, F)

F1	F2	F3	P(A1,F)	P(A2,F)	P(A3,F)
T	T	T	0.00000	0.00000	0.00000
T	T	F	0.00000	0.00000	0.00000
T	F	T	0.00001	0.00001	0.00001
...	...	...	...	...	...
F	F	F	0.00010	0.00010	0.00010

From the combined probability $P(A, F)$, the accident occurrence probability $P(A)$ is concluded.

P(A)

A1	A2	A3
0.00086	0.00067	0.00066

Step 5: Determination of conditional probability $P(I|A)$

The likelihood scores for occurrence of I1, I2, I3 in accordance with A1, A2, A3 are input.

Injury impact scale byaccident(1~5)

	I1	I2	I3
A1	5	2	4
A2	4	2	3
A3	5	2	3

AII (Accident Injury Index) is calculated.

AII(Accident Injury Index)

	I1	I2	I3
A1	0.9	0.3	0.7
A2	0.7	0.3	0.9
A3	0.9	0.3	0.9

Using the AII value, the conditional probability in accordance with the occurrence of accidents $P(I|A)$ is determined.

$P(I|A)$

A1	A2	A3	P(I1|A)	P(I2|A)	P(I3|A)
T	T	T	0.99700	0.65700	0.99700
T	T	F	0.97000	0.51000	0.97000
T	F	T	0.99000	0.51000	0.97000
...	...	...	...	...	...
F	F	F	0.00000	0.00000	0.00000

Step 6: Determination of injury occurrence probability $P(I)$

The combined probability of injury occurrence and accident occurrence $P(I, A)$ is calculated.

$P(I, A)$

A1	A2	A3	P(I1,A)	P(I2,A)	P(I3,A)
T	T	T	0.00000	0.00000	0.00000
T	T	F	0.00002	0.00001	0.00002
T	F	T	0.00002	0.00001	0.00002
...	...	...	...	...	...
F	F	F	0.00000	0.00000	0.00000

From the combined probability $P(I, A)$, the probability of injury occurrence $P(I)$ is concluded.

$P(I)$

P(I1)	P(I2)	P(I3)
0.00180	0.00065	0.00176

Step 7: AIS is input to determine the ISS and the severity of the injury.

For I1, I2, I3, AIS scores are given.

	Injury	AIS score
I1	Contusion	3
I2	Concussio n	5
I3	Fracture	4

Using the AIS score, ISS(Injury Severity Score) is calculated and the severity of injury is determined.

	AIS	ISS	Severity
I1	3	9	Minor
I2	5	25	Serious
I3	4	16	Medium

Step 8: Final risk is determined

Using the combination of probability for injury and the severity of injury, the product's final risk is determined.

	P(I)	Severity	Risk
I1	0.00180	Minor	A
I2	0.00065	Serious	M
I3	0.00176	Medium	M

Final risk = M (Medium)

To compare the procedure as suggested in this study against other methods, RAG of EU RAPEX and the R-Map method of Japan were used. First, EU RAPEX RAG was used to evaluate the risk for the above inline roller skate. To that end, two scenarios were composed as follows.

Scenario 1: A child has suffered bruises from collapsed inline roller skate due to structural defect of it.

Scenario 2: A child has suffered laceration from collapsed inline roller skate due to performance defect of it.

The process of evaluating risk for the above two scenarios for EU RAPEX RAG are shown in Figure 3, Figure 4, and Figure 5.

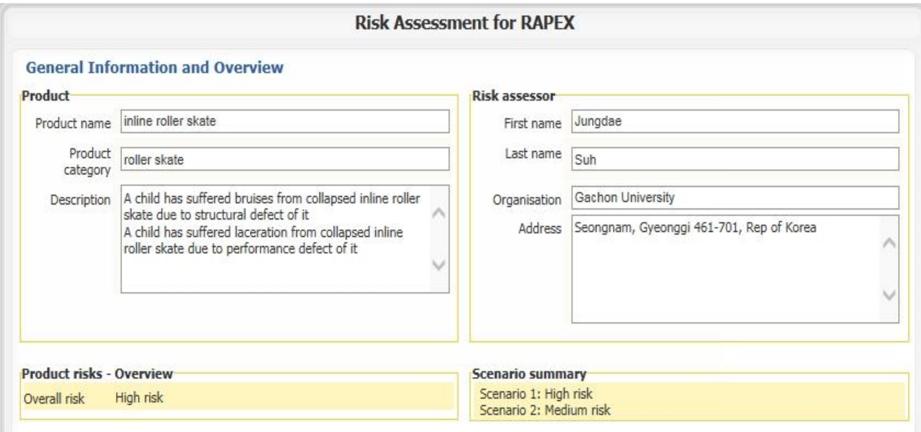

Figure 3. The Results of Risk Assessment for RAPEX RAG

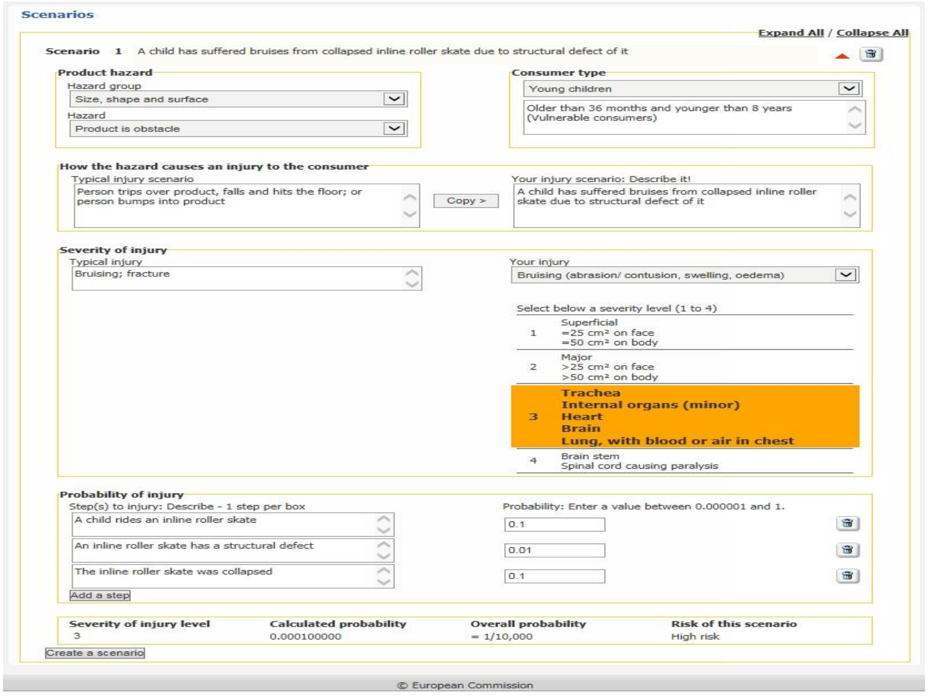

Figure 4. The Results of Risk Assessment for RAPEX RAG – Scenario 1

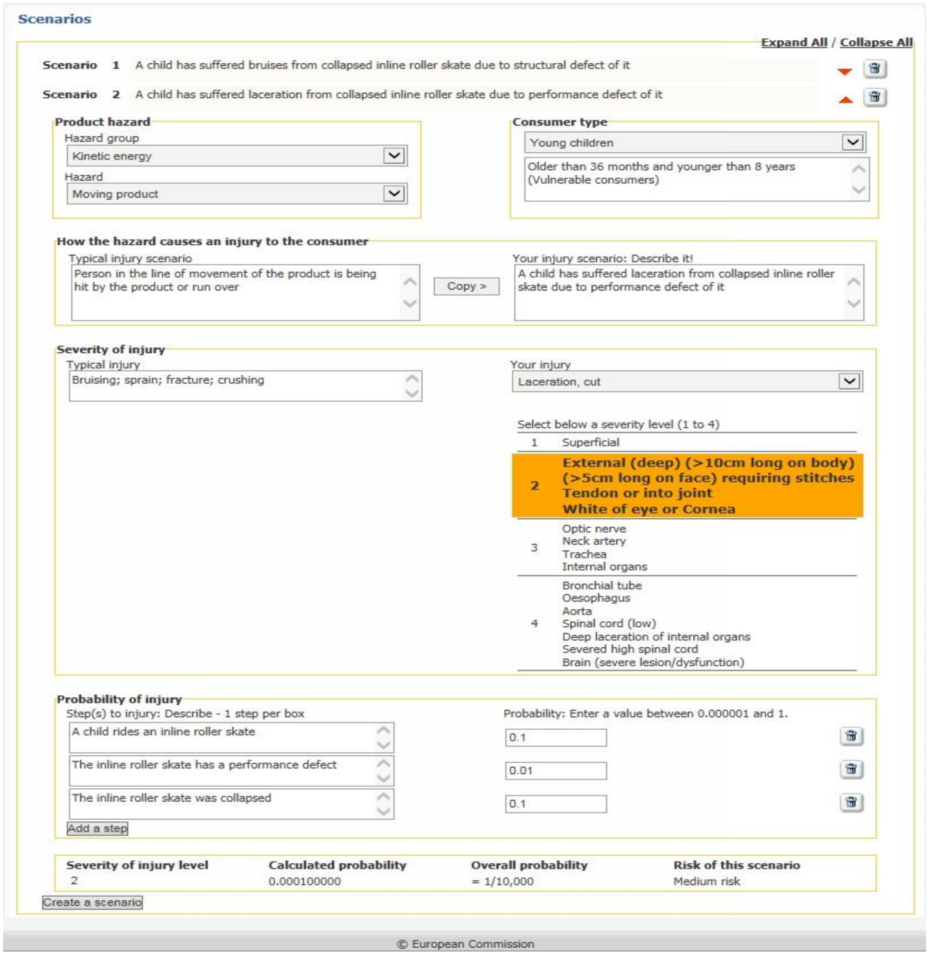

Figure 5. The Results of Risk Assessment for RAPEX RAG – Scenario 2

The evaluation results in Figure 3 show scenario 1 to have 'high risk' and scenario 2 to have 'medium risk', but the final risk is determined as 'high risk'. Since 'high risk' under the EU RAPEX RAG corresponds to 'medium risk' in the procedure in this paper, as for the inline roller skate, the results from the EU RAPEX RAG and from the procedure in this paper are the same.

The R-Map method by Japan's NITE determines risk by taking into account the frequency of the occurrence of a hazard and the degree of hazard. Occurrence frequency is the ratio of number of accidents to the accumulated number of units in operation. The accumulated number of units in operation is shown as the sum of the accumulated number of units in operation during the production period and the accumulated number of units after the end of production. That is, for the above application case, frequency of occurrence = number of accidents/accumulated number of units in operation = 1,300/80,000 = 0.01625 and thus is determined as grade 5 (frequent). The degree of hazard refers to the injury types shown in quality assurance (accident history) records, 1,300 cases in total. Injury type includes minor and medium, but in cases where there are more than one definitions, the strictest definition is adopted under the rules of the R-Map manual, As such, the degree of hazard is determined as grade II which is medium. The occurrence frequency of 5 and the degree of hazard which is II determine the risk on the R-Map to be A1.

R-Map risk A1 corresponds to 'serious risk' in the EU RAPEX RAG and S(Serious) in the procedure in this paper. Therefore, the result of R-Map gives a risk level one grade higher than that of EU RAPEX RAG or the procedure in this paper. Since evaluations are not done for each injury type in the R-Map, the risk tends to increase if there are multiple types of injuries occurring.

6. Conclusion

This study designed a causal network structure and developed a risk assessment procedure using probabilities that reflects causal relation that may affect product risk. Network structure consists of product factors, accidents, and injuries hierarchy. Using quality assurance data and accident history records, the network structure of each hierarchy is designed and the hierarchy probability and conditional probability are concluded. The product factor hierarchy consists of product defect factors and usage environment factors, while product defect factors were set based on safety standards. Usage environment factors consist of user, usage time and usage place. Finally, based on the probability of injury and severity of injury, PI matrix was referenced to determine product risk.

The paper used the example of an inline roller skate to assess final risk. To do this, accident-related documents that detail the product defect factors, accident and injury are required. As a follow-up, it is suggested that the rationale of the process to conclude such probabilities be secured during the subjective estimation process. Moreover, validity of categorization should be reviewed by applying cluster analysis and comparing with the results from using the assessment model as suggested in this study.

Acknowledgments

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