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Risk Occurrence Assessment of the Background Conformity Conditions of Inspection and Quarantine Based on FMEA

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Abstract

In order to promote the scientific and normalized work of the inspection and quarantine, limited inspection and quarantine resources have to be used for efficient management of limitless inspection and quarantine objects, which requires the screening of the background conformity conditions of inspection and quarantine. Failure Modes and Effects Analysis (FMEA) is a methodology for potential reliability analysis and safety assessment, and has been widely applied to the protection system of accident prevention. It is of great significance to use FMEA to assess risk in the field of inspection and quarantine. This paper provides an approach for risk occurrence assessment according to actual needs of inspection and quarantine work, based on risk elements analysis in inspection and quarantine work.

Keywords: FMEA, Inspection and quarantine, Conformity conditions, Risk occurrence

Recent years, China's ranking of foreign trade volume in the world is rising steadily. From 2003 to 2006, China enjoyed an annual foreign trade growth of 29.8%, with export growing at 31.3%, and import 28%. In 2002, the foreign trade volume reached 620.8 billion USD. And in 2004, the volume exceeded 1 trillion USD. In 2006, the volume amounted to 1.7604 trillion USD, which increased by 2.8 times than 2002. Its ranking in the world lifted from No.5 to No.3 in 2004, and it keeps the third ranking since then. China's foreign trade proportion of the world's total volume of foreign trade has increased from 4.7% in 2002 to 7.2% in 2006. Thus China has become a true big trading nation.

The fast growth of China's foreign trade leads to the rapid growth in entry-exit inspection and quarantine demand. In order to promote the scientific and normalized work of the inspection and quarantine, to use limited inspection and quarantine resources for efficient management of limitless inspection and quarantine objects, and to ensure the safe operating of China's economy, risk analysis and screening of the background conformity conditions of inspection and quarantine are required. This paper is a part of the National Key Technology R&D Program "Research on Entry-Exit Inspection and Quarantine Security Early-Warning and Guidance System", mainly focuses on risk occurrence assessment.

1. Conformity Conditions of Inspection and Quarantine

Based on the principle that only the entry-exit objects in conformity with given conditions after inspection and quarantine can be released, the conformity inspection is the basic feature of entry-exit inspection and quarantine, and its corresponding given conformity conditions, inspection methods, and conformity estimation are all the essential elements in the practice of inspection and quarantine, especially the given conformity conditions (including background conformity conditions and objective conformity conditions used to conduct the inspection activities), which has a direct effect upon the conformity inspection.

The conformity conditions of entry-exit inspection and quarantine refer to all the background conformity conditions that the entry-exit objects shall be conformed to and all the objective conformity conditions set by the inspection and quarantine authorities in entry-exit commodity inspection. The conformity conditions cover catalog of compulsory inspection commodity, catalog of forbidden entry-exit objects, entry-exit permit, safety and sanitation conformity indicator, etc., they are all the necessary elements in the administration of inspection and quarantine work. The missing and ambiguity of the conformity conditions will cause the arbitrariness, unconformity in the inspection and quarantine administration; make trade transparence and predictability become worse; result in higher risk in inspection administration and trade; and even arouse suspicion of inspection and quarantine system.

Because of the position of the conformity conditions as the most important foundation in the conformity inspection activities, all the large trading countries attach great importance to construction of the conformity condition system of entry-exit inspection and quarantine. The conformity conditions of entry-exit inspection and quarantine are characterized by great amount of information, wide range of subjects, complex elements, quick updating. And according to principle of transparency of WTO, all the parties involved in entry-exit inspection and quarantine shall have the right to be informed, so as to improve the conformity and normalization in entry-exit inspection and quarantine work. Therefore, only the establishment of conformity condition database of entry-exit inspection and quarantine, screening the objective conformity through model, and providing entry-exit inspection and quarantine administration with legal, real-time, conformable, normative and latest information of objective conformity conditions can ensure the regular administration of entry-exit inspection and quarantine. At present, Australia, Canada, New Zealand and some other countries have established conformity condition database of entry-exit inspection and quarantine with a complete structure. However because of the confidentiality of the information, the structure contents are not know by the outside world.

China has been strengthening the construction of the entry and exit inspection and quarantine conformity conditions, has established the catalog of compulsory inspection commodity, and the catalog of entry restriction on hazardous substances and organisms, enacted foreign technical trading measures and national compulsory standards, which laid a good foundation for the construction of the conformity conditions. However, when compared to large scale entry and exit logistics of more than 1 trillion USD, more than 0.2 billion persons and 60 million vehicles, the present construction development of entry-exit inspection and quarantine conformity conditions is still very backward. The situation of missing, ambiguity, decentralization, confusion, and difficulty in information output are quite common, and the state-level database system of conformity conditions that the entry-exit inspection and quarantine is not formed yet. All the above factors cause the unconformity of the inspection and quarantine practices in different check points, and sometimes the authorities have to conduct inspection and quarantine work according to the given conformity conditions by traders, which may increase the risk of administrative responsibility, weaken the inspection and quarantine administrative enforcement, even make the inspection and quarantine enforcement face potential legal problems.

Therefore, the scientific and normalized work of the inspection and quarantine will be improved and the efficiency of Customs inspection and quarantine will be promoted by carrying out the research on the intelligence system of entry-exit conformity conditions conformed to the situations in China, using FMEA based on the information integration system of background conformity conditions, screening the objective conformity conditions out of background conformity conditions, and establishing the unified intelligence navigation system of the conformity inspection within the whole inspection and quarantine system.

2. Analysis of the risk factor of background conformity condition of inspection and quarantine.

There is no strict and uniform definition of risk, but all the risks contain the following two characteristics.

(1) Uncertainty——Risks may occur or may not. In other words, there is no risk occurs 100%.

(2) Loss——If the risk becomes a reality, the vicious consequence and loss will happen.

The risk management master, Robert Charette (1989), thinks that we have to define a scene for each potential loss, which describes the cause or trigger factors of the risk. He described the three-elements-group for the definition of risk: which scene will cause a loss (S_i), the possibility of this loss (L_i), the influence of this loss (X_i), as follow:

$$\text{Risk}=\left\{\left(S_i, L_i, X_i\right) \mid i=1\text{L}\ \ n\right\}$$

The cause or trigger factors of the risk which described in the scene S is called the *risk factor*. S_i can be expressed as the function of a series of risk factors (as *rf*) and time (as *t*), as follow:

$$S_i = \{(rf_{i1}, rf_{i2,\mathrm{L}}\ rf_{in}, t) \mid i = 1\mathrm{L}\ \ n\}$$

During inspection and quarantine, the risks mainly focus on the loss probability, the severity of the loss and its consequences. Rules on the Risk Analysis Management of Entry Animals and Animal Products which issued by AQSIQ in December 2002 made follow definition for the *risk*: Risk is the entry possibility of animal diseases, parasitic disease pathogens and toxic and harmful substances which enter the frontier with the imported animals, animal products and animal genetic material, animal-derived feed material and biological products and animal pathological material, and the harm toward the ecological environment, including agriculture, husbandry, fishery and the health of human.

Generally considered, the risk factor of background conformity condition of inspection and quarantine is the qualitative statements which cause the increase of the frequency of inspection and quarantine loss or loss degrees of factors to happen. The analysis of the risk factor of background conformity condition of inspection and quarantine is the classification work according to the risk factors which may cause risks to the research of inspection and quarantine targets. In the research of the risk of background conformity condition of inspection and quarantine, the analysis and classification of the risk factors is very important. For the specific targets of inspection and quarantine, there are many risk factors, which lead to the risks and losses of inspection and quarantine targets together. Only after have a clear analysis about the risk factors of inspection and quarantine, we can aim to the screening of background conformity condition of the inspection and quarantine targets.

In this research, the basic idea of the analysis of the risk factor of background conformity condition is analyzed according to the process which may cause the increase of the frequency or loss of inspection and quarantine.

Tier one, classifying the major categories of products. Classifying all inspection and quarantine goods into eight major categories according to the characteristics of products.

(1) packages; (2) animals (animals and animal products); (3) plant (plants and plant products); (4) food, cosmetics and raw materials; (5) light products; (6) mineral products, chemical products, metals and metal products; (7) mechanical and electrical products; (8) special items

Tier two, collecting the corresponding public risk factor according to different product categories. For example, the public risk factor of plants (plants and plant products) mainly refers to quality, toxic substances, harmful organisms, diseases, transgenic, etc.

Tier three, doing further analysis to the public risk factors mentioned above so that we can collect the quantifiable and operational indicators. Take harmful organisms as an example, in accordance with the rules and history records, the analysis way as following table (table 1).

Table 1. Analysis of the risk factor of harmful organisms

<table>
<tr><td rowspan="11">Harmful organisms</td><td rowspan="9">Have colonization capacity</td><td rowspan="4">History testing data</td><td rowspan="3">Frequency</td><td colspan="3">High</td></tr>
<tr><td colspan="3">medium</td></tr>
<tr><td colspan="3">Low</td></tr>
<tr><td colspan="4">no</td></tr>
<tr><td rowspan="7">The severity level of the limitation index</td><td rowspan="7">Final use, Type of trade, Trade country, Etc.</td><td rowspan="4">Technical standards</td><td>International standards</td></tr>
<tr><td>National standards</td></tr>
<tr><td>Industry standards</td></tr>
<tr><td>Enterprise Standards</td></tr>
<tr><td rowspan="2">Regulations</td><td>Yes</td></tr>
<tr><td>no</td></tr>
<tr><td colspan="5">Have no colonization capacity</td></tr>
</table>

Table 1 analysis the factor according to the colonization capacity of the harmful organisms. If it has the colonization capacity of the harmful organisms, we make further analysis according to history testing data and extent of the limited

indicators. The history testing data is the quantitative result which mainly based on the history situation of inspection and quarantine. The severity level of the limitation index is based on the final usage, trading modes and the requirements of the trading countries to lookup the corresponding technical standards and regulative standards, and offer the catalyzing elements of risk in inspection and quarantine

3. The analysis of assessment cases of the risk occurrence of background conformity condition of inspection and quarantine based on FMEA.

Take soybeans which belong to the major categories of plants and plant products as an example, overall inspection and quarantine situation of soybeans in Jiangsu province in recent years as follow in table

Table 2. The General Situation of the Problems arisen in the Inspection and Quarantine

	Total import amount (batches)	Problem batches in inspection (batches)	Rating (%)	Total import amount (10thousand tons)	Problem amount in inspection (10 thousand tons)	Rating (%)
2003	133	13	9.77%	500.20	65.53	13.12%
2004	129	17	13.18%	495.69	75.96	15.32%
2005	177	42	24%	630.57	145.82	24.71%
2006	208	40	19.2%	669.35	134.2	20.1%

The inspection and quarantine situation of import soybeans are as follow:

(1) the quality and food sanitation inspection of import soybeans

a. Quality inspection

Table 3. Inspection results of imported soybeans (2004~2006)

	Item	Unqualified			Percent of unqualified	
		Lots	Weight(T)	Value(USD)	Lots(%)	Weight (%)
2004	Oil content	1	35,800	13million	0.78%	0.72%
	Content of impurity	2	82,400	28million	1.55%	1.66%
	Bulk density	7	323,000	99million	5.43%	6.52%
	Percent of damaged kernel& heat-damaged kernel	5	263,000	78million	3.88%	5.31%
	Content of protein	6	278,500	94million	4.65%	5.62%
2005	Item	Unqualified			Percent of unqualified	
		Lots	Weight(T)	Value(USD)	Lots(%)	Weight (%)
	Oil content	2	57,300	17million	1.1%	0.91%

	Content of impurity	4	164,900	46million	2%	2.62%
	Bulk density	11	413,000	117million	6.2%	6.55%
	Percent of damaged kernel& heat-damaged kernel	21	629,200	179million	11.9%	10%
	Content of protein	6	311,300	91million	4%	4.94%
2006	Item	Unqualified			Percent of unqualified	
		Lots	Weight(T)	Value(USD)	Lots(%)	Weight (%)
	Oil content	1	48,600	12.69million		0.7%
	Content of impurity	17	1,590,300	17.081million		23.8%
	Bulk density	2	73,500	20.22million		1.1%
	Percent of damaged kernel& heat-damaged kernel	22	654,700	186.96milliom		9.8%
	Content of protein	2	60,200	16.59million		0.9%

The testing items all contain different level of percent of defective. Compared with in 2004, in the year of 2005, the unqualified items still remain in the items “oil content ”, “content of impurity”, “bulk density”, “percent of damaged kernel” and “percent of heat-damaged kernel”. Among these, the inconformity between the percent of damaged kernel with percent of heat-damaged kernel and the requirement of the contract increases more than before. This inconformity rate is 5% higher that in 2004. In 2006, the percent of pass of “oil content”, “content of protein”, and the “bulk density” is more higher than that of 2005 and the percent of defective is respectively 0.7%, 0.9% and 1.1%; the “percent of damaged kernel” and the “percent of heat-damaged kernel” is comparatively decreased but still remain at 9.8%; the disqualification of the “content of impurity” is the most severely, and the percent of defective increases from 2.6% of 2005 to 23.8%, 8 times than the number before.

b. Testing of toxic and dangerous substance

From 2003 to 2006, the items listed on the contract include phosphide, prussiate, arsenic, Hg, chrome, malathion, sumithion, aflatoxin (regular lab testing item on soybean) were tested. The result showed that the contents of all the items meet the health requirement of imported food. No toxic and harmful substance was found in the soybean.

c. Testing of weight

In the year of 2004, it was found that the imported soybean was in short of 21 lots with 7046.35 tons totally in Jiangsu port. And the year of 2005 witnessed the shortage of 51 lots with 15425.242 tons. Comparatively, the situation of 2005 is worse than in 2004, because the shortage of lots and weight increased 143% and 119% respectively. And in 2006, 59 lots of soybeans with 16421 tons of soybeans had been found lost.

d. Testing of GMO

From August of 2004, our bureau started to conduct the test for GMO. After the cargos were discharged, the samples should be sent to Jiangsu Food Testing Center by the port to do conformity test. The results of the tests during 2004 to 2006 were all in conformity with the declaration.

2) Inspection of imported soybeans

Table 4. Data of epidemic organisms captured in imported soybeans

2004 ~ 2006

Year	Type Ⅰ Ⅱ Ⅲ harmful organisms		General harmful organisms		In total	
	Sorts	Lots	Sorts	Lots	Sorts	Lots
2004	12	312	144	1248	156	1560
2005	12	510	204	3654	217	4162
Compare with last year	0	63%	42%	293%	39%	167%
2006	16	582	281	5538	297	6120
Compare with last year	23%	14%	52%	72%	37%	47%

From the form 4 it can be recognized that there was a great increase, in not only the types, but also in the lots, of the harmful organisms captured on the ports. The types and lots increases 39% and 167% respectively. Among these, the numbers of type Ⅰ,Ⅱ,Ⅲ were almost the same in 2004 and 2005 while the lots increased 63% in 2005. For the general harmful organisms, the types and lots increased 42% and 293% respectively in 2005. This number increased continuously in 2006.

Failure Modes and Effects Analysis (FMEA) is a risk assessment technique for systematically identifying potential failures in a system or a process. It is widely used in the manufacturing industries in various phases of the product life cycle. In the process of an FMEA, analysts compile lists of component failure modes and try to infer the effects of those failure modes on the system. FMEA is used during the design stage, identify the weak points and key items in the system with an aim to avoid future failures so that to formulate improving measurements. As the mode is preventative rather than a correction way afterwards, it is very suitable for the screening of the background conformity condition of the inspection and quarantine. It can improve the reliability and safety of inspection and quarantine. According to the theory of FEMA, the form below is about the occurrence levels of conformity condition:

Table 5. Occurrence levels of conformity condition

Possibility of Occurrence	Occurrence rate	Levels
Very high: Almost inevitable	>=1/2	10
	1/3	9
High: Always happens	1/8	8
	1/20	7
Medium: Happens now and then	1/80	6
	1/400	5
	1/2000	4
Low: Seldom happens	1/15000	3
	1/150000	2
Very low: Almost no possibility	<=1/1500000	1

According to the analysis to the risk assessment of the background conformity condition of inspection and quarantine and historic records, we listed the form 6 as below which manifests the risk occurrence levels of imported soybeans background conformity condition. The data listed in the form is only a part of the whole, as the data is not enough. With

the establishment of the database, the basic data could be developed so that the occurrence assessment in the form will be more exact.

Table 6. Risk occurrence of the inspection and quarantine background conformity condition of imported soybeans

Background conformity condition		Imported country				Rate of the unqualified in 2005	Occurrence level	Standard
		USA (77 lots)	Brazil (64lots)	Argentina (35lots)	Paraguay (1 lot)			
Quality inspection	Percent of heat-damaged kernel	17	4	0	0	11.90%	8	Regulations and contracts of Dep.
	Content of protein	3	3	1	0	4%	7	Regulations and contracts of Dep.
	……							
Test of toxic and harmful substance	Hg	0	0	0	0	0	3	GB 2763-2005
	……							
GMO	35 promoters	0	0	0	0	0	3	"Inspection and quarantine management for entry-exit GMO products"
	……							
Inspection of weeds	Johnsongrass	74	56	34	1	165/177	10	National Quality Control Action [2004]No.332
	……							
Inspection of insects	Almond moth	0	0	1	0	1/177	6	National Quality Control Action [2004]332
	……							
Inspection of epidemic illness	Phytopht-hora sojae	11	1	2	0	14/177	8	National Quality Control Action [2004]332
	……							

In the risk occurrence levels listed as above, we always choose the highest level for sure, i. e. we follow the strict principle of doing random test.

4. Conclusion

The rapid development of foreign trade has brought more requirements to the Chinese entry-exit inspection and quarantine. To make the inspection and quarantine more scientific and more regular, the management to the boundless objects should be realized by limited inspection and quarantine resources. Inspection and quarantine, in a sense, is to control the risk in the course of inspection and quarantine which depends on the analysis of the related risks. For some special inspection and quarantine objects, there always exist many reasons of risks, and they decide the risk and lose of the object together. As an important method of reliability analysis and risk control, FMEA can be used to deal with the risk control and analysis of the background conformity of the inspection and quarantine. The essay is written on the basis of clear analysis on the risk reasons of inspection and quarantine, and designs the assessment method of the risk occurrence according to the practical needs. The imported soybean case analysis indicates that this method is feasible.

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