

Modified QFD Approach for Context Analysis and Risk Management According to ISO Standards

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Abstract

In recent years, the concept of risk has widened to many areas of business management. Substantially born in the economic-financial and industrial safety sectors, today, risk management covers entire business and organization management fields. Lastly, in the latest edition of ISO 9001 (2015), the concept of enterprise risk has been introduced as a tool for the design and development of a management system.

This paper aims to provide a first structured approach to implementing a proper risk analysis and risk management process in accordance with the requirements of ISO standards. The method, based on the Quality Function Deployment (QFD) technique, considers the following steps: (i) an analysis of the external and internal context in which the organization operates, (ii) the collection and analysis of data related to the needs of the stakeholders, (iii) the definition of risk factors and strategic opportunities and (iv) the linkage of these with the processes of the enterprise management system and (v) to define actions for treatment of risks and opportunities to improve the performances. The original operational tool proposed can allow organizations to respond effectively to the requirements of recent international standards concerning management systems and enable the company to define, address and manage strategic risks and opportunities in a structured and systematic process. Within the article, a case study described the methodology.

Keywords: Risk Management, Context Analysis, ISO standards, Quality Function Deployment

1. Introduction

More than 1.3 Million organizations in 170 countries have adopted the ISO 9001 quality management system standard. The last version, ISO 9001:2015, is a step towards Total Quality Management (TQM) and reflects the changes of an increasingly complex, demanding and dynamic environment, while assuring that organizations can provide conformity products and services that satisfy their customers (Fonseca, 2015).

Furthermore ISO 9001 improves worker safety, through the identification and elimination of potentially hazardous practices, development of a formal corrective action process and institutionalization of routine audits and management reviews (Levine & Toffel, 2010).

The updated standard promises to further streamline tasks and information flows as well as better align quality management with overall business management. But to have certification, whose deadline is provided for September 2018, organizations must face stringent requirements, including establish quality objectives, integrate those objectives into business processes, and promote the use of risk-based thinking, not to mention understand the standard, consider a new and improved approach and start the transition process (Javanainen, 2017).

The revision of ISO 9001:2015 presents a strong innovation potential not so much on the specific requirements, but on the formulation and conceptual reference model. Compared to the version of 2008 it was necessary to introduce new concepts in the standard to adapt it at new

needs of companies and environment that is constantly changing to make it always update, efficient and effective.

The revision processes that have been included concern Risk Based thinking, Interested Parties, Change Control, Strategic Direction, Knowledge Management and Leadership (Fonseca, 2015).

Risk-based thinking considers both the current situation and the possibilities of change. *“Analysis of the situation shows opportunities for improvement: a subway leading directly under the road, pedestrian traffic light or diverting the road so that the area has no traffic”* (ISO, 2016).

In this situation, with these difficulties and differences, companies have mistrust and anxiety problems: the international Quality Management System (QMS) standard ISO 9001:2008 has been in use for many years and more than one million certified organizations that comply with it are understandably wary of the change to ISO 9001:2015 (Aston, 2015).

The question is: is there a way, a method to efficiently face the transition to the new standard? But above all, is there a method that allows a correct risk management at strategic level as suggested by the standard?

The literature to date does not provide a suitable technique that is able to represent a systematic and logical approach to help the companies and there is not yet a clear methodology supporting the integration and application of the norm and new concepts. The following proposed method tries exactly to solve this problem. In addition, the proposed methodology, supported by the new concepts of the standard, tries to answer to problems or prejudices that companies still have on ISO 9001. For example, formalization, high costs, small business doubts, too many generalities. The idea is to give a simple, easy to understand and immediate tool.

This methodology is structured in such a way that it can be adapted to the needs and sector of the field of application. Another goal is providing as output to the organizations a clear indication of which are the critical macro-processes, and which are those to pay more attention in terms of risks and opportunities.

This methodology wants to allow the definitive overcoming of the idea of considering the adaptation to the standard relating to the quality only as a prescriptive duty and as a mean to obtain ISO certification. Overall it is regarded as a standard aimed at large companies (Pearson, 2015) but it must be a self-assessment tool for small and big organizations in order to be familiar with the internal dynamics and be proactive in relation to risks and opportunities that affect all their processes.

The method is divided and structured to facilitate the application of the rule, reducing documentation, implementation time, implementation costs and resource of the companies. The application of the method is shown in the case study.

2. Proposed Methodology

This section proposes a methodology that is based on the QFD- Quality Function Deployment technique (Pulmann, 2002); it is a tool, used in design and development process of a new product or service, that relates the needs of customers with the technical characteristics of the product. The chosen instrument is the QFD (Quality Function Deployment) because, besides being an absolute novelty, has a structured form. Indeed, its main tool, House Of Quality, is suitable for the elements contained in sections 6.1, 4.1 and 4.2 which should be compared, placed in relation and integrated with each other.

Indeed, it is possible to modulate the architecture and the composition of the various rooms both in the first part of the methodology and in the second one. In this way we get the main output of the elaborate: the business macro-processes predisposed to the occurrence of risks and opportunities.

This section includes 4 subsections: while the first one discusses just differences between traditional QFD and new methodology, the second one illustrates the flow charts of the methodology, the third one discusses the first part of methodology and the last one discusses the second part of methodology.

2.1. Differences Between Traditional QFD and New Methodology

QFD is based on a tool called HOQ-House of Quality, which it is composed of six rooms as show in figure1. The new methodology uses the structure, the principles and the basic idea of QFD, but it changes the rooms, the activities contained in each room and sometimes eliminates some rooms too. The methodology is divided into two fundamental parts: the output of the first part represents the input of the second one.

The first part uses the procedures and the graph of the HOQ tool. The structure of the new method is almost equal to the traditional one, but room 4 is not present, the one concerning benchmarking, and the other rooms are modified in form and content. Room 3 remains the same; it uses the same scores for the evaluation even if the comparison is now between the relevant stakeholders and the requirements of the relevant stakeholders (related to the relevant contextual factors) despite the traditional QFD comparison between the client's needs and characteristics of the product (rooms 1 and 2). The name of the first part of the methodology is "HOQ 1". Also, the second part of the method uses HOQ technique but in a less formal and more personal way. In particular, there is not a correlation matrix between any element (like room 5 or roof of the traditional QFD) and the evaluation scales used in the interrelationship matrix are completely different from the standard ones. Furthermore, in room 6 are given indications of which actions should be taken to deal with risks and opportunities previously identified in other rooms. The name of the second part of the methodology is "HOQ 2".

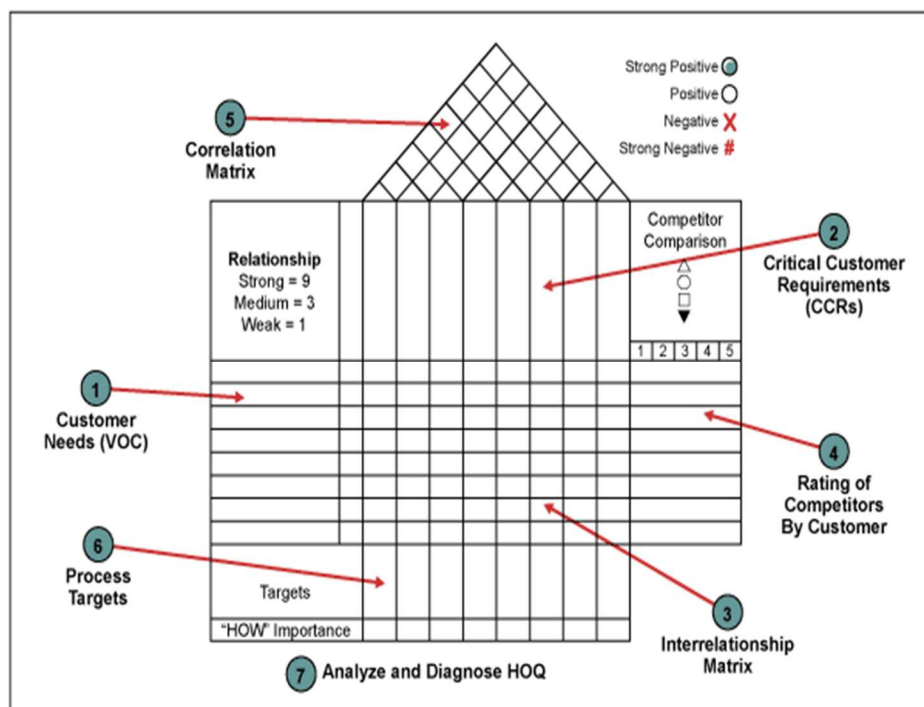


Figure 1. HOQ - House of Quality

It is important to remember that the method is designed for a standard company, so that each company can adapt the method to its specific needs and can complete the rooms with its specific key activities.

2.2. HOQ 1 – The first part of methodology

The HOQ 1 is performed by using the procedure that is discussed in detail in the following.

First, analysis of the context, the company must understand which are the factors of the external environment and which are the factors of the internal environment. The two analyses can be done through a decomposition of each environment into three basic components:

- Physical component
- Social component
- Economic component

It is possible to decompose into a lower level the three components finding the factors that characterize the internal context and external context of the organization.

The physical component can be decomposed into aspects related to natural environment and aspects related to artificial environment.

The social component can be decomposed into ethical, cultural, security and protection aspects, aspects of public interest and public administration and demographic factors.

The economic component can be divided into competition, profitability, performance and organizational efficiency, efficient management of the supply network, partnerships, strategies and market variables, economic and financial management.

This breakdown is generic, it can be reduced or increased according to the context of the organization. Every company must consider its aspects and make a specific decomposition of them.

In addition to that, to determine the factors that characterize the internal environment a PEST analysis is made, while to determine the ones of the external environment a brainstorming and an analysis of the audit report are made.

Through this analysis the company finds the relevant factors that will be related to the stakeholder needs found through the stakeholder's analysis (described below) in order to determine the requirement of interested parties/relevant stakeholders (room 2).

In the stakeholder's analysis, the organizations must identify the relevant stakeholders and their needs that can affect the Quality Management System.

Every company has its interested parties but the standards ISO 9001:2015 and ISO 9002:2015-guideline for the application of the ISO 9001:2015 provide a list of stakeholders from which choose. That list includes the following points: customers, related organizations, end users, owners and shareholders, employees, suppliers, financial institutions, legislative authorities, partner, collective/community, competitors, non-profit organizations, professional associations.

Through brainstorming a team of the company carries out a screening of the list of stakeholders to identify which ones influence the conformity of products/services and the customers satisfaction. The stakeholders identified by the team are the relevant stakeholders and they represent the contents of room 1 of HOQ 1.

The identification of room 2 starts with the determination of relevant stakeholder needs.

The company can identify the needs of its stakeholders through two ways: the team can identify itself with the interested parties or it can engage stakeholders in the process through interviews and brainstorming performed together.

Not all identified needs will be considered important, some of them will be redundant and unnecessary for the purpose. The project team will carry out a screening in order to identify only those requirements concerning relevant factors identified in the analysis of the context.

The output of this screening will be a limited number of requirements related to the relevant factors, which will be contained in room 2 of HOQ 1.

So, room 2 of HOQ 1 is stakeholder's requirements concerning relevant factors.

In Relationship Matrix (room 3) the project team judges which relevant stakeholders influence which stakeholder's requirements and how much.

To these relationships is given a score of 1, 3 or 5 based on how much the two elements are influenced, where 1 is the weaker relationship, 5 is the strongest and 3 is a medium relationship. A score equal to 0 corresponds to relationship absence between the two elements, and an empty cell is left in the Relationship Matrix.

Once the Matrix is completed, the project team sums the scores of each requirement to evaluate which one is the more relevant for the company. Those with the highest scores will form room 4, that contains the requirements to investigate further.

The requirements of the stakeholders can have a positive or a negative effect one to each other: the improvement of one requirement that lead to an improvement of another one correspond to a positive correlation between the two requirements, despite an improvement of one requirement that lead to a deterioration of another one correspond to a negative correlation between the two.

When the improvement of one requirement does not lead to any change of another one, these two requirements are not correlated between each other.

All the requirements of room 2 are analysed in order to find the correlations between each other, creating a roof over room 2 where each requirement is correlated with the others with a "+" sign in case of positive correlation, a "-" sign in case of negative correlation and an empty cell is left in case of no correlation. This room is the Correlation Matrix and represent room 5 of the HOQ 1.

The last step is to sum the correlation, positive or negative without counting the sign, for each requirement.

The requirements with a number of correlation even or higher of the number of correlation of the requirements to investigate further of room 4 are selected to populate room 6 with the ones of room 4.

This final screening of requirements (room 6) point out which are the requirements most important to identify the possible risks and opportunities, giving the input for the second part of methodology: HOQ 2.

2.3. HOQ 2 – The second part of methodology

The HOQ 2 is performed by using the procedure that is discussed in detail in the following.

The first step is to investigate further the highlighted requirements through the identification of the risks for each of them. The project team must analyse only the risks that affect the achievement of the objectives of the quality management system and avoid those that have no impact on the management system. Such analysis is done with brainstorming technique: the results of this activity are “check list analysis”, a simple list of the risks, or “what if analysis” in which the process is divided into sub-processes and the team wonders what might happen to each sub-process in case of failure.

For each requirement are thus identified risks and opportunities, which will be contained in room 2 of HOQ 2. Through to the definition of macro-processes step, the project team finds the macro-processes present within the company that have impact on the management system, and that will be related to the risks and opportunities in room 3. The company, represented by the project team, can choose the macro-processes that are considered most interesting and relevant for the discussion and especially for the proper application to quality management system.

The identified macro-processes are contained in room 1.

Up to now the risk analysis was carried out with FMEA, FTA or other method, but in “the new methodology” is made with the relationship matrix. This is the real innovative step of this study.

In Relationship Matrix (room 3) the project team judges which risk/opportunity influence which macro-process and how much. To these relationships is given a score of 1, 2 or 3 based on how much the two elements are influenced, where -1 is the weaker risk, -2 is a medium risk and -3 is the highest, +1 is the weaker opportunity, +2 is a medium opportunity and +3 is the highest. A score equal to 0 corresponds to relationship absence between the two elements, and an empty cell is left in the Relationship Matrix.

Once the Matrix is completed, in the score analysis and ranking step, the project team sums the scores of each macro-process (each row) and each risk/opportunity (each column) to evaluate which ones are the most relevant for the company.

The first sum is related to each macro-process and if the result is a number less than zero means that the process is more subject to risks, if it is a number greater than zero, the process is more subject to opportunities, while if it is equal to zero risks and opportunities are balanced. Those with the highest scores will form room 4 that contains the total impact of risks/opportunities on macro-processes. The score in absolute terms indicates what macro-process provides the greatest opportunities or the greatest risks. Through the ranking the macro-processes are put in order of importance regarding to the risks and opportunities.

Analysis of each risk/opportunity (room 5) contains the total amount of each risk, helping the project team to understand which are the risks and opportunities that really matter to decide which are the actions to deal with them. Sometimes happens that an event considered as a risk at first can be pointed out as an opportunity to work out for the company, like the ISO 9001:2015 underlines.

The correlation matrix (room 6): all the risks and opportunities of room 2 are analysed in order to find the correlations between each other, creating a roof over room 2 where every risk or opportunity is correlated with the others with a “+” sign in case of positive correlation, a “-” sign in case of negative correlation and an empty cell is left in case of no correlation.

In room 7, total amount of risks and opportunities, the correlations are summed, positive or negative without counting the sign, for each risk and opportunity. The scores found in this step will give a further indication of which are the most important risks and opportunities that the company have to take actions about, as already pointed out in room 5.

In the eighth and last room, definition of actions for treatment of risks and opportunities, the project team identifies possible actions to undertake for the treatment of the risks and the opportunities highlighted in rooms 5 and 7; this represents the last step to complete the risk management process.

The following figure shows the total procedure previously described for the HOQ 1 and HOQ 2.

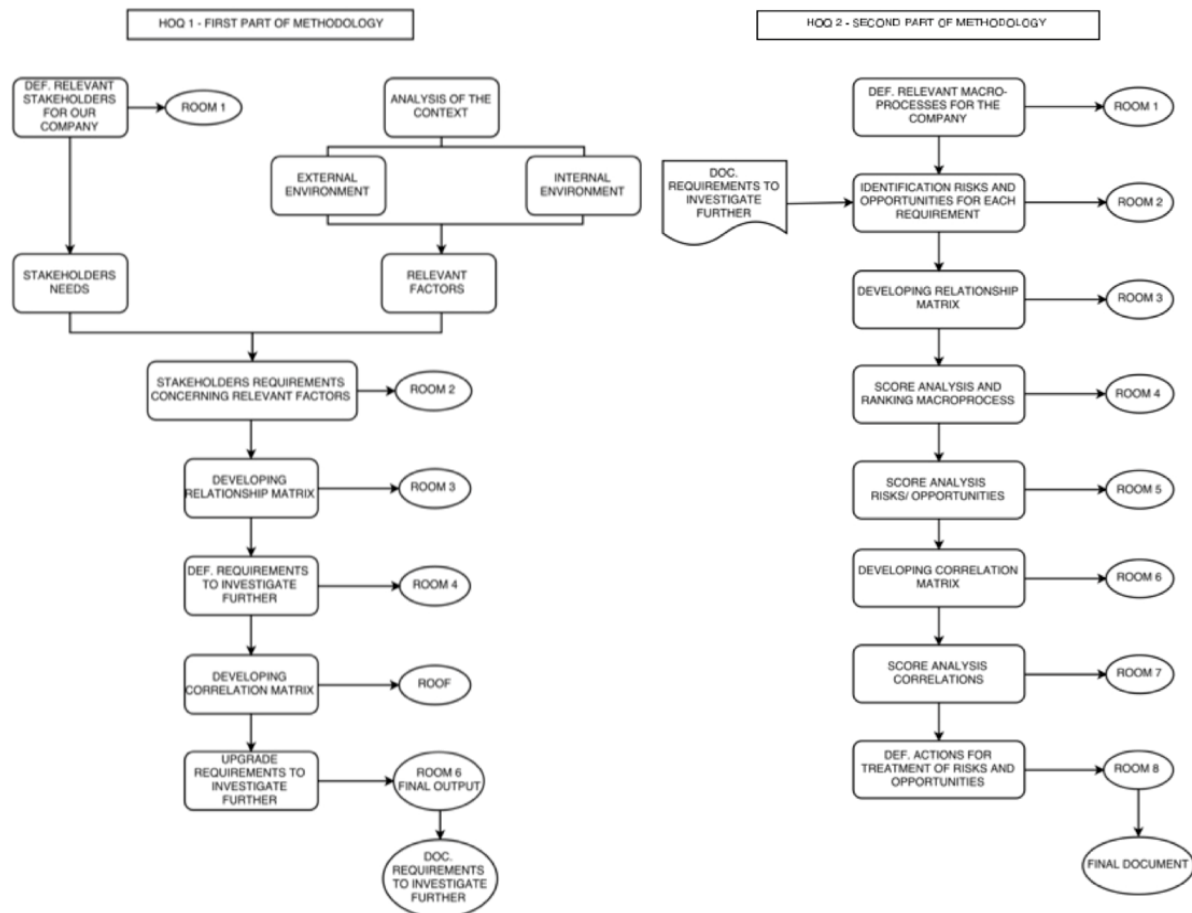


Figure 2. HOQ procedure

3. Case-Study

The proposed methodology has been applied to the case study of a winery. The choice was made for the large presence of such companies on the territory and the greater chance of obtaining information. The case-study, which will be presented and discussed in this paper, aims to show how this methodology works in practice. Then all main findings and results will be analysed.

3.1. HOQ 1

The first step is to identify the relevant factors for a wine company; through the analysis of physical, social and economic components, turned out to be important:

- Supply chain management, an economic component related to the external environment
- Artificial environment, a physical component related to the external environment

- Security and protection aspect, a social component related to internal context
- Market strategies and variables, an economic component related to the external environment

The second step is to identify the relevant stakeholders that can affect the Quality Management System of a winemaking company. Through a screening of the list provided by the ISO 9001 standard, stakeholders who have an impact on this type of processes have been identified. After a careful analysis results, the relevant stakeholders are: customers, owners, employees, suppliers, legislative authorities, partner, collective/community, competitors and end users. These relevant factors will be contained in room 1.

At this point, through the identification of the team with the stakeholders, their needs are identified. Only the necessary needs for the purpose, therefore those related to the relevant factors, will be considered. This stakeholder's requirements will be contained in room 2.

The next phase is to fill the relationship matrix (room 3) to show how each stakeholder influences each requirement. After giving a score to each relationship, a summation is made for each requirement; For each relevant factor, the requirement with the highest score is chosen; to these requirements is assigned the red colour. To make the analysis more complete, requirements with score equal or higher than the worst "red requirement" are also taken. These requirements, identified by the light blue colour, have such a high score that would be ridiculous not to consider them. Moreover, this would lead to an inadequate and potentially incorrect analysis. Both these groups of requirements will be contained in room 4 and they are the attributes that the company must investigate further.

The latest requirements to be analysed are identified through the correlation matrix, the room 5 or ROOF. The roof contains the effects that each requirement has on the other. If the effect is positive there is a + (positive correlation), if it is negative there is a – (negative correlation), an empty box otherwise (no correlation).

After giving a score to each correlation, for each requirement is made a summation of all positive and negative correlations; the requirements with a number of correlation equal or higher of the number of correlations of the requirements to investigate further contained in room 4 are chosen. To these requirements is assigned the green colour. Red, light blue and green requirements are the most important to identify the possible risks and opportunities for a winery and are contained in room 6.

So, this final screening leads to choose 7 requirements on 25 that represent the output of the first part of the methodology and the input for the second.

The first part of methodology is complete and all six rooms of HOQ 1 are reported in full, with its legend, in Figure 3.



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3.2. HOQ 2

Starting by the 7 requirements identified in HOQ 1, the first step is to analyse, for each of these, risks and opportunities. Through this analysis, 21 risks and opportunities have been determined that may be of interest and improved by a company that produces wine. Jointly the macro-processes presented within the organization are defined; they will go to compose the room 1 of HOQ 2. The macro-processes are: production, purchases, sales, logistics, marketing and planning & development. The 21 risks and opportunities, initially analysed, will be contained in room 2.

The next step is to fill the relationship matrix (room 3) to show how risks/opportunities and macro-processes are influenced by each other. After giving a score to each relationship, a summation is made for each row, so for each macro-process; in this way it is possible to identify the total impact of risks/opportunities on macro-processes and to make a ranking to understand which macro-process mainly needs to be monitored and analysed by the company. The result is the following and composes room 4 of HOQ 2.

The "Marketing" macro-process, that has obtained the highest score and way far than zero, provides the greatest opportunities; the company has to pay attention and study action plans to get the most benefits from marketing operations. The macro-process that the company has to keep under control is the "Production", which has obtained the lowest overall score, followed by "Logistics" and "Planning & Development"; these are the most critical processes that contain the greatest number of risks. Considering "Purchases" and "Sales", which amounted respectively to -1 and 0, the company may pay little attention because they don't seem to have much influence on the quality management system. At this point the same summation is made for each column, so for each risk and opportunity individuated before.

These scores, forming room 5 of HOQ 2, can be of help to the organization to understand which are risks and opportunities for the company system (through a comprehensive analysis of all the macro-processes considered) and which ones the company should consider making decisions about the treatment actions to be performed. And right here is where the new concept of ISO 9001: 2015 becomes effective, that is to consider a risk (and also its effect) a possible opportunity to be captured and developed for the company and vice-versa.

The effects that each risk or opportunity has on the other are contained in the correlation matrix, room 6 or roof. If the effect is positive there is a + (positive correlation), if the effect is negative there is a - (negative correlation), an empty box otherwise (no correlation). After giving a score to each correlation, for each risk/opportunity is made a summation of all positive and negative correlations; the total correlation score provides only an indication of what benefits may lead the risk or opportunity management. In fact, acting on a risk can bring benefit to another risk and another opportunity. The company can decide which risk has to be treated also according to the correlations. The total correlations are contained in room 7.

The eighth and last room contains some examples of highlighted risks and opportunities treatment, and is the last step to take to complete the risk management process. These examples are merely indications, as mentioned above, regarding a wine company. Depending on their own needs, other types of companies can detect completely different actions or behavioural patterns. However, it is evident that the model is applicable to any sector and organization.

The figure 4 shows HOQ 2, the complete second part of the methodology, including all the rooms described in detail. It gives a clear indication of the path made.

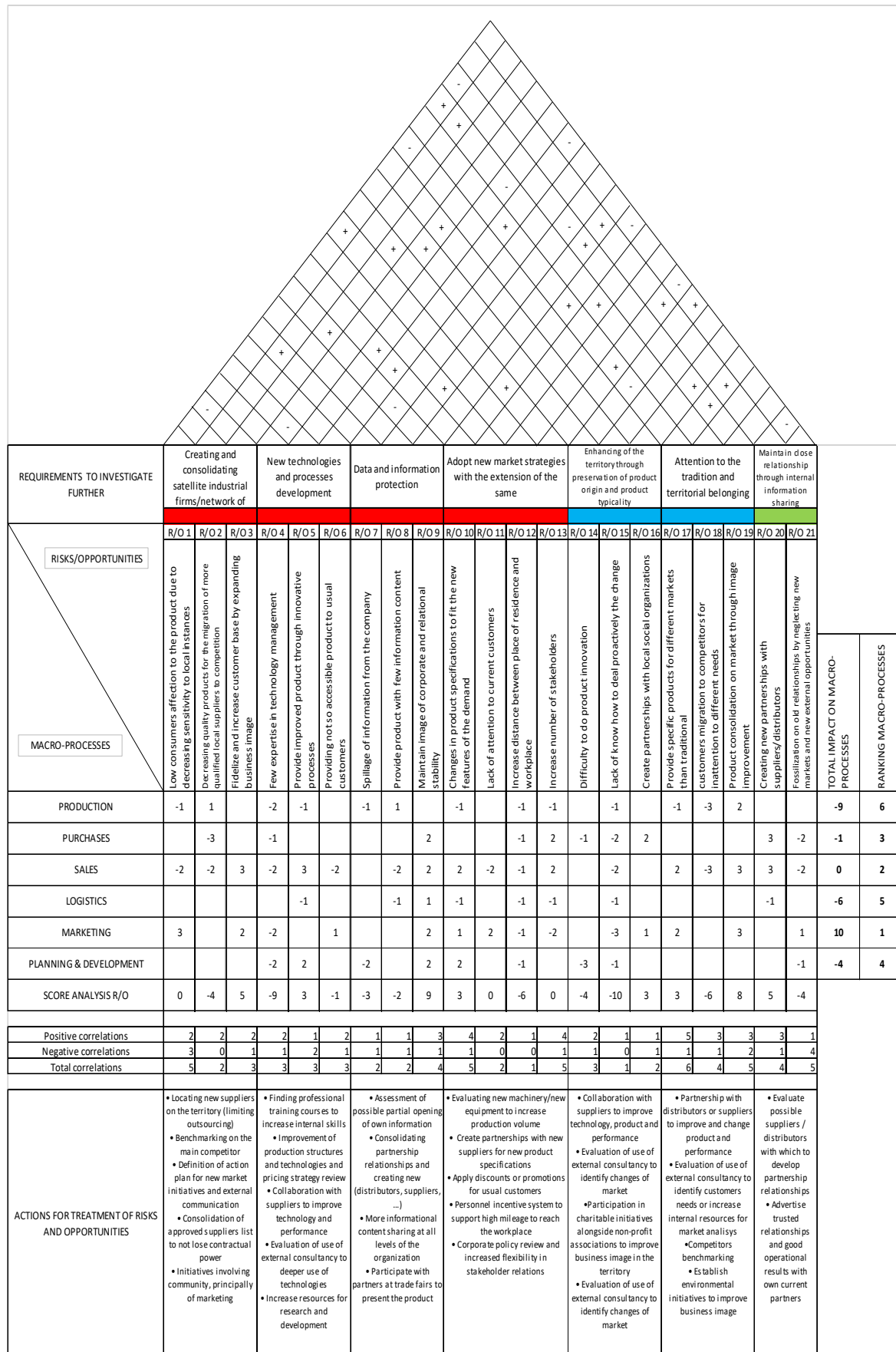


Figure 4. HOQ 2

4. Conclusion

The creation of a tool for accurate, clear and fast identification of possible risks and opportunities related to any company has been presented in this paper. Through its implementation the companies have at their disposal a structured and systematic methodology that represents a general application of the major innovations emerging from ISO 9001:2015 standard compared to the previous edition. The main purpose of the methodology is to provide as output the critical macro-processes that require most care in terms of risks and opportunities. So, its application permits to (i) highlight potential positive and negative criticalities, related to requirements, that can occur in the macro-processes analysed and (ii) define the improvement actions that must be implemented to complete the analysis and improve the customer satisfaction and the organization as a whole. It allows the company to plan and control proposed actions in terms of responsibility, cost, time and results. This thesis is demonstrated through the case-study. The results, related to a wine company, show that the most critical process, containing the greatest number of risks, is Production. As far as opportunities the company must pay attention to Marketing for obtaining the most benefits. The analysis of each risk / opportunity results that (i) the risks with a lower score are "Low expertise in technology management" and "Lack in knowing how to deal with the change proactively" and (ii) the opportunities with the best scores are "Maintain an image of corporate and relational stability" and "Product consolidation on market through image improvement". Furthermore, this study tries to make the application of the tool as the basis for obtaining the mental approach contained in Risk Based Thinking concept that is to consider the company like a human being and not as a mechanism. The described methodology does not want to be an exhaustive and comprehensive treatise of all the themes of the standard. It only provides an application for the companies in order to better deal with the transition to the new edition. An example is the summation of correlations, in HOQ 2, that is not considered like a quantitative and restrictive indication, but only provides a weak signal on the benefits that the treatment of a risk or opportunity has on others. Therefore, it is considered in choosing the risks to be addressed, but there is no numerical evidence of this. It would be interesting to improve it again. Future ideas can be: in HOQ 1, assign weights to relevant factors and stakeholders to obtain total weighted scores, making the analysis more accurate; in HOQ 2, give numerical relevance to correlations for choosing the risks or opportunities to be treated.

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