

ENHANCING THE MONITORING SYSTEM OF SFDA IN SAUDI MARKETS

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ABSTRACT

In the present market, most of the public and private sector entities are using various mobile applications for communication with their customers. Whether it is a notification, information or an alert, the means of communication using mobile applications made life easy so as to reduce the relevant risks. Recently the health related issues due to imported food in Saudi Arabia (SA) raised many concerns to consider serious reforms. The Saudi Food and Drugs Authority (SFDA) is responsible to control, examine and save the citizens of SA from any kind of serious health related issues or deaths. The present research aims to facilitate a runtime monitoring system to check the quality of food imported from various countries and to assure the safety of citizens. This runtime monitoring system is based on the proposed integration model of SFDA policy to attain both safety and quality property with respect to manageability property. Such practice will surely help the consumers, suppliers and authorities to ensure a quality health of citizens in SA. Above and all the SFDA policy during runtime can control the flow of imported food supplies, validate the food products and can establish a fair communication between consumers and suppliers.

KEYWORDS

Runtime Monitoring, Saudi Markets, Food and Drugs, Communication, Integration, Policy

1. INTRODUCTION

Food and Drug Authorities (FDA) around the world are in demand to improve the public policies to protect society, economy, quality of life, and to ensure a safer place to live from the evolving risks. In the recent times many cases have been identified across the world with food related illness, adulteration, low quality drugs and food frauds. These authorities around the world are helping to reform the industries, laws, and regulations to enhance the performance of monitoring authorities. Due to adverse geographical and climatic nature, Saudi Arabia imports many food and drug products from different countries across the world [1]. Various reforms are being incorporated by SFDA, a central authority established in 2004 [2], to ensure a quality food and drug policy is established throughout the nation for the safety of its citizens. This authority will take care of various legislative roles with respect to food and drugs in kingdom.

1.1 Background

The urgency to upgrade the Food and Drug authorities were at peak after a report identifying 264 food poisoning cases at different households and commercial sources in 2010. One death and 1647 people were ill due to commercial sources and a total 62 per cent raise was recorded in the

same year [1]. In the year 2011, the reported outbreaks were 255 leading to an illness of 2066 people. The increasing trend of people falling ill due to food and drugs was seriously considered by Prof. Bawazir, Vice President for Drug Affairs in a Global Healthcare Conference held at Seoul [2]. The importance of protecting the public of SA demands the SFDA to follow stringent rules and regulations in the food and drug sectors. Importing quality products, safety, efficacy and accessibility of human and veterinary drugs needs an efficient and consistent method of monitoring and controlling system. Most of the drugs are imported in SA are from Europe (70%), USA (13.1%), Middle East and North Africa (12.3%) and others (4.6%) [2], whereas the overall contribution by local markets range from 17 to 20 %. In such scenarios large share of imported drug products, the role of SFDA will be more complicated to monitor and control the drug suppliers.

1.2 Motivation

This research helps to provide an integrated monitoring system for the customers to identify quality food and drug products. The outcomes of this research not only help the customers but also help the super markets to be cautious from wrong doing and to maintain a fair relation with customers while performing rules and regulations fairly. This research also creates a platform for the SFDA to establish a centralised communication centre by which each department will be interconnected and hence the fair business practice is possible at each level.

This project will help the entire kingdom and its people towards keeping up a fair and healthy environment in the society. Above and all this practice will give an environment for the people to know the original products (food and drugs) before they're trapped by any kind of health related issues. The ultimate motive of this research is to improve the effectiveness and efficiency of SFDA in terms of providing quality food and drug supply to the citizens of KSA.

1.3 Related Work

A lot of the research is being conducted to integrate the food and drug safety management services around the worldwide countries. So many factors impacting the food safety in UK was critically assessed and analysed by Mensah and Julien in [3]. The food safety management showed a great result as most of the food manufacturing enterprises implemented the techniques by which they could deal with associated risks with respect to food safety. However, most of the regulations are reported be biased for the benefit of customers by imposing an extra burden on the stakeholders, otherwise could have been avoided. Based on the evolution, the governance of food safety is being reviewed in Britain for last two decades to assure safety in global market.

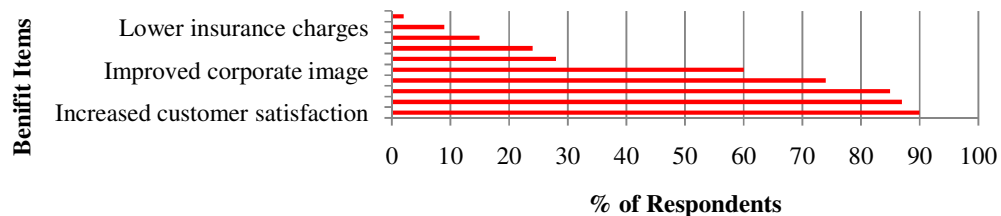


Figure 1. Benefits expressed in UK due to FSMS

Globally the food safety control includes performance based approach and integrated process based approach. The performance based approach includes end-product testing, inspection and sample testing at regular intervals. However, in integrated process based approach, it includes accreditations, third party assessments and regular audits [3]. Above two approaches establishes a stringent food safety process to deal with risks involved in food supplies so as to meet the regulations established by worldwide organizations. Such stringent rules are helping the UK food authorities to meet up with various proliferation standards, such as British Retail Consortium's global Food safety standard (BRC), International Food Standards (IFS), Dutch Hazard Analysis and Critical Control Point (HACCP), Safe Quality Food (SQF) 2000 and ISO 22000:2005 [3]. Most of the food manufactures ($\approx 97.5\%$) are following the food safety management system (FSMS) as per the survey conducted by Mensah and Julien and the benefits acquired by manufacturers are as shown in Figure 1. Though serious challenges were identified by most of the food manufacturers are due to lack of technical knowledge, skills, awareness, inappropriate infrastructure, employee resistance and high cost of implementation.

Similar assessment of food control system was conducted by Alomirah et al. in [4] in Kuwait to study the imported foods and control systems. A serious unsustainable scenario has been reported after testing the legal frameworks, structure of administration, enforcement activities and provisions of training and education. Only 5% of the imported consignments are examined by the food inspectors and increasing population and demands of the people in Kuwait created an excess work load of food inspectors. The Kuwait government is moving towards a risk-based system [4] of inspecting the food items instead of random end-product inspection to assure a quality food supply in the nation.

Al-Kandari and Jukes [5] conducted an analysis of food control system in Arab countries found the interest shown by all countries to give an attempt for improved food control systems. Gulf Cooperation Council (GCC) is trying to increase the harmony [5] among these countries as they have individual approaches for food control management. The council is trying to establish a standard practice by all these nations for food control in the region.

Recently, HACCP system [6] was seriously considered by the government of United Arab Emirates (UAE) as a food control tool. This tool is aimed to identify the strengths and weaknesses in food industry along with the opportunities and threats which government may need to deal with. In UAE, high levels of food imports are highlighted to be facing serious difficulties in terms of quality of food and their sustainability in the markets. Introduction of HACCP in UAE proves to be an effective tool to overcome the difficulties, setbacks and deficiencies in the food industry. Such initiation by GCC helped to avoid overlapping and conflicts of various responsibilities in the region. However, in KSA, SFDA proved to be a major establishment for food control system but it could not solve all the issues and considered to be a time consuming process to implement all the laid down policies and procedures by the regulatory authorities [6, 7].

Centralization of food control activities and restructuring different established controlling institutions [7] were considered by Saudi government to get them under one strong roof, i.e. SFDA. Various studies are being conducted by government agencies to streamline and reform the activities due to increase in deaths as a result of food related issues and problems. As a part of GCC initiation to implement HACCP system as a mandatory tool, the SFDA needs to overcome the challenge of educating and training the people involved in food industry for an effective food safety system. Due to involvement of foreign workers in the food industry the challenges to maintain this system smoothly face the language barriers also. A serious assessment is being

carried out in the country to meet the international standards and challenges due to changing environmental conditions and market trends. SFDA implemented an approach to be adopted is generally termed as “oversee and verify” for maintaining the quality of food products [7].

2. EXISTING STRUCTURE OF SFDA SYSTEM

In the present SFDA policy they have a track and trace system with benefits of preventing the sale of counterfeit drugs, smuggled drugs, illegal sales, barcode scams and to support ration used of medicines. The tracking and tracing system adopted by SFDA is considering supply chain management concepts [2] as shown in figure 2.

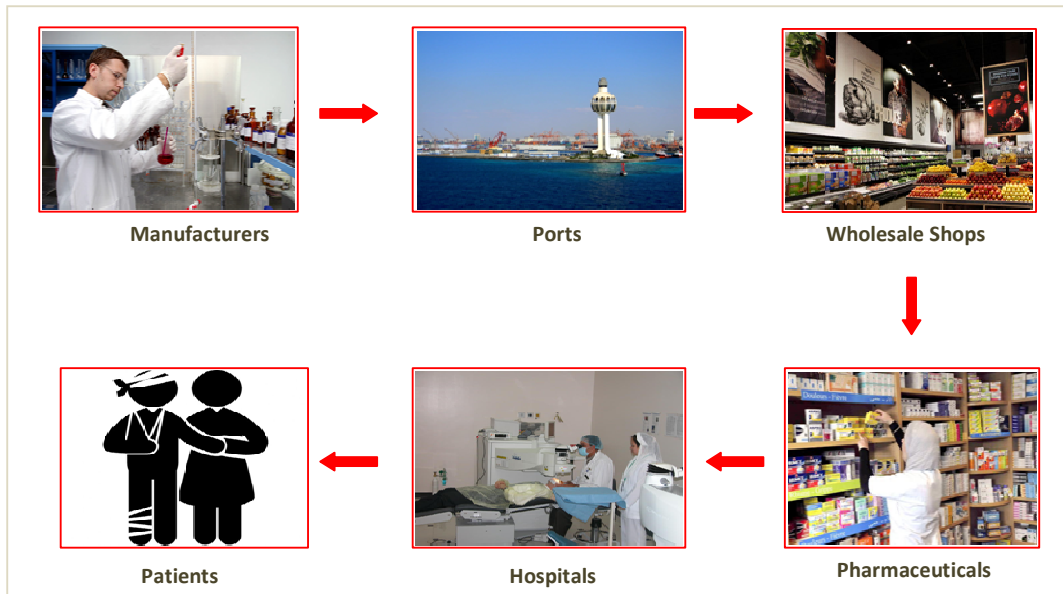


Figure 2. SFDA Tracking System and Flow Diagram

- In the first supply chain SFDA considering the following parameters for manufactures: GMP, batch number, expiration date, bar code, Tamper proof and serialization for drug products. Based on these parameters a detailed list of products by individual manufacturer will be classified and supplied.
- In the second supply chain SFDA considering ports based on priority release, inspection, temperature logger reading, product inspection, shipment recording in IPRICS. For all the imported drug products *import and batch release clearance system* (IBRCS) will produce the clearance in SA by using a GTIN. A communication will be established between IBRCS and SFDA for a fair and smooth process of tracking system.
- In the third supply chain SFDA consider the wholesalers based on storage and distribution practices, tracking and tracing history, license and permits, effectiveness in recalling the products, quarantine and the process of destruction for expired products. The wholesalers’ needs to maintain a fair account of above mentioned aspects to sustain in the market.
- Finally in the fourth supply chain SFDA consider pharmacies at the root level where the customers are involved directly or by means of hospitals or healthcare centres.

Pharmacies are tested based on storage and inventory control of drugs, bar coding, tracking and tracing aspects, product authenticity and finally the management of expired products.

Ministry of Commerce and Industry is responsible for testing and assessing the food products imported by means of air, land and sea transportations. This ministry contains ten food control and analysis laboratories along with eleven branches at different ports across the kingdom [7]. The complete process involved in the above mentioned process deals with various databases at food control and analysis laboratories. Such distribution of databases is shown in figure 3 represents various authorizing units and agencies.



Figure 3. Distribution of data bases food control and analysis laboratories

Some of the departments of food control and analysis laboratories are listed below include various activities and processes [7]:

1. Sample Receiving Department: Need to consider the rules and regulations while receiving the Samples of Food and Drug products.
2. Chemical Analysis Department: Analyses the chemical contamination levels and accuracy of food and drug products.

3. Microbiological Department: Analyze the meat, poultry and baby food products.
4. Food Irradiation Testing Department: they will check the background of the food supplied or imported from different destinations.
5. Standardization and Meteorology Department: It checks for international standards and the local policies with respect to safety and usage.
6. Quality Assurance Department: This department will ensure whether the product is genuine to reach the customer or not.
7. Research Department: Keeps on investigating the advantages and disadvantages of the products imported and sold to the public.

There are few non-governmental organizations involved in testing and assessing the food and drugs in Saudi Arabia includes [8]:

- Saudi Society of Food and Nutrition
- Consumer Protection Association
- The National Standing Advisory Committee on Food Irradiation

These organizations are providing cooperation and assurance of safety and quality for the food and drug supply from local and imported products.

3. PROPOSED ARCHITECTURE

The proposed method to enhance the performance of SFDA involves four important areas as shown in figure 4:

1. Shopping environment
2. Runtime Monitoring Environment
3. Action Component and
4. Food and Drug authority

3.1. Shopping Environment

This environment includes the super markets and the customers along with their interaction for purchasing the food and drugs. In this environment a customer with his requirements will enter the list of products (viz., item number, bar code number, manufacturing code, etc) to be purchased using the proposed application. This application needs to verify and update the customer about the status of a particular product by creating an alert on the given mobile number. If the product is safe to purchase the listed item will be marked as original and allowed to purchase and otherwise it is marked to be rejected and action component will alert the FDA with a feedback. This feedback will be considered and re-verified with FDA so as to send a caution notices to the super market owner.

Here in this research the proposed method not only alerts the customer but also ensures that super market owner is aware of the issues with particular product. Such practices will help the government to avoid negligence aspects due to outdated food and drug products, low quality supply, etc.

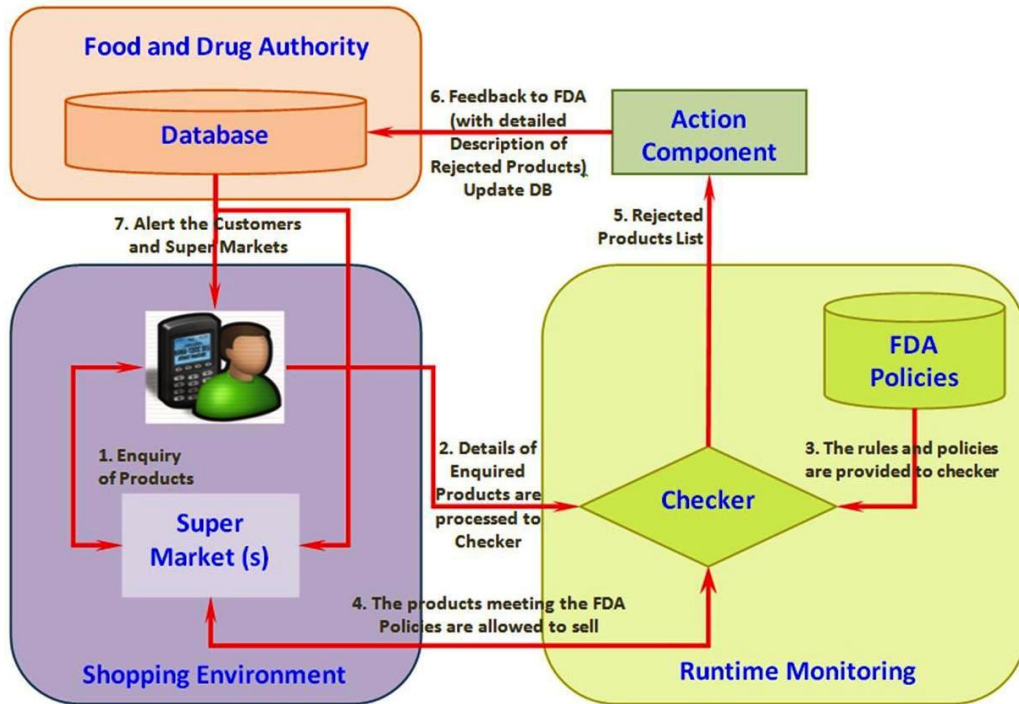


Figure 4. Proposed Monitoring System to Enhance SFDA Performance

3.2. Runtime Monitoring Environment

This environment always checks the queries from customers by comparing the listed products with government rules and FDA policies. The checker will be working as a communication tool between customers, super markets, and FDA authorities.

- **FDA Policies Database:** The rules and regulations laid down by different departments will be available in the database in the runtime environment with all updates and recent amendments by the government. The information available in this database will be checked continuously with the queried products by the customers.
- **Checker:** This component is the heart of runtime monitoring system and also for the entire research. This checker component will be checking for the requests by the customers, super market owners and also communicates with the FDA for latest updates to ensure that the customer is provided with correct information with less effort as shown in figure 5. Any delay between communicating components of checker might lead to a serious scenario as listed below:
 - A customer may purchase a wrong product
 - Customers may find themselves into serious health problems due to bad food or drugs.
 - Possibility of supermarket owners get into risk by selling the blacklisted food and drug items due to changing rules and regulations with fluctuating market trends and

research outcomes. Few products are declared unsafe by authorities after sometime and such information may / may not be with the supermarkets.

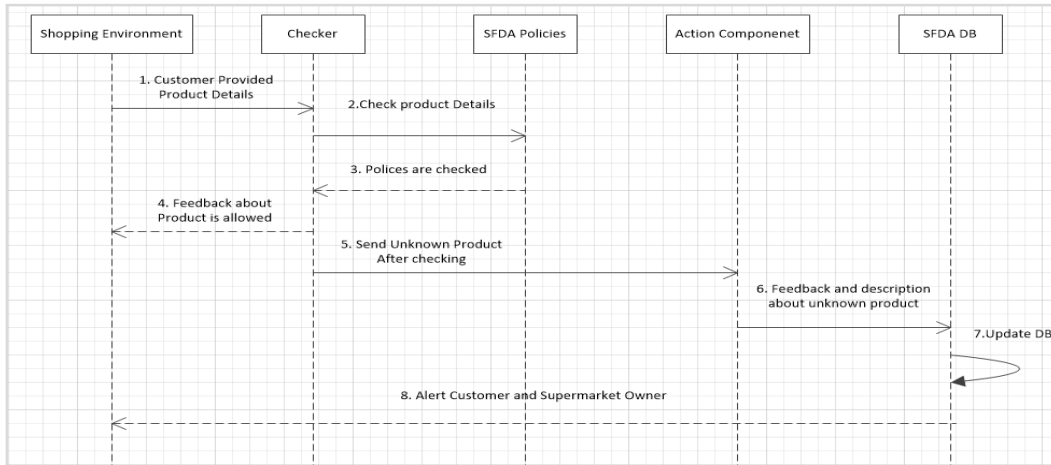


Figure 5. Product Tracking Process

- **Alerts:** The alerts are generated by the Checker component on the identification of unknown products or queries made by customers are communicated with action component.

3.3. Action Component

This component will receive the alerts from the runtime monitoring environment and communicates detailed process of issues taken place between customers, super markets and checker component. It will communicate the FDA authorities so as to establish a further action on the wrong events.

SQL Trigger technique is used to in this action component to alert the customers and FDA authorities when an unknown product or invalid product is identified and will be declared as a rejected product. In the proposed approach, the trigger is used to for rejected products and to provide a communication to customer and FDA authorities to take necessary actions.

Generally the SQL trigger syntax contain three parts: desired conditions, rules to be satisfied and actions to be performed. Figure 6 shows the SQL trigger structure for the proposed architecture. Various reasons to use this trigger component are listed below for the proposed architecture:

- Complete information about the UNLISTED or REJECTED products will be stored into the database of FDA when the trigger is generated.
- It is easy and efficient way of collecting latest information about unknown products from various super markets, manufacturing units and imported products.
- Previous information or source code stored in the overall architecture will not be affected as a trigger will activate and communicate with database only.


```
1 CREATE [or REPLACE ]
2 TRIGGER trigger - name
3 LISTED [ or UNLISTED ]
4 APROVE [ or REJECT ]
5 ON table - name
6 FOR EACH PRODUCT
7 BEGIN
8 IF condition 1 THEN
9 ACTION 1
10 IF condition 2 THEN
11 ACTION 2
12 .
13 .
14 .
15 IF condition n THEN
16 ACTION n
17 END ;
```

Figure 6. Structure of SQL Trigger

3.4. Food and Drug Authority

The FDA is responsible for making the rules and regulations from the starting point to ending point of the whole process, i.e. from importing the goods to test and analyse the supplied products so as to allow them to be sold in the super markets. Out of various departments in this process, the action component needs to be identified and establish appropriate communication upon an alert of rejected product and corresponding department need to conclude the issue and place the order for an immediate action.

The action taken by the corresponding department will contain the instructions to the super market owner with respect to the rejected product either to destroy or replace with suitable steps to be followed. This information can be considered or treated as a notice to the super markets to avoid the mistake of selling the unauthorized products and if they do so they are entitled to go through legal action or punishments as per the law.

However, the customer will be having straightforward information, i.e. whether to purchase the product or not. Customer safety and quality food supply is the ultimate goal of this architecture will help the government to reduce the number of suffering people due to food contamination and bad products.

To establish such a smooth process in timely manner coordination between various departments of SFDA, healthcare systems, policy makers and a consolidated database must be established. This is possible by integrating various departments SFDA at the earliest.

4. CASE STUDY: INTEGRATED SFDA STRUCTURE

The complete Ministry of Commerce and Industry along with other relevant ministries which are involved in food and drug activities must be carefully integrated to establish a smooth process. In this section, two scenarios are discussed to understand the importance of integration and its applications to establish an effective SFDA functional structure to solve most of the food and

drug related problems. The major area of focus in these scenarios tries to draw the attention on important issues which are going to be solved by the proposed method. The issues involved in present scenario includes delayed communication, lengthy processing steps to deal with issues, multiple locations of data storage, improper training, awareness of various facilities, language issues due to involvement of foreign workforce, etc.

4.1. Scenario 1: Existing SFDA Structure

In the existing SFDA structure most of the interactions and communications are taking place independently so that it comes out to be a time consuming process. The customers need to wait for a long time to know whether a product is genuine or not as shown in figure 7. Sometimes the queries submitted to SFDA by the customers will not get immediate response due to which some of the wrong products are being sold to customers leading to serious problem. Even the super markets are also in a blindfold situation where the updated information, rules and regulations are delivered after a lengthy process of different department’s approval.

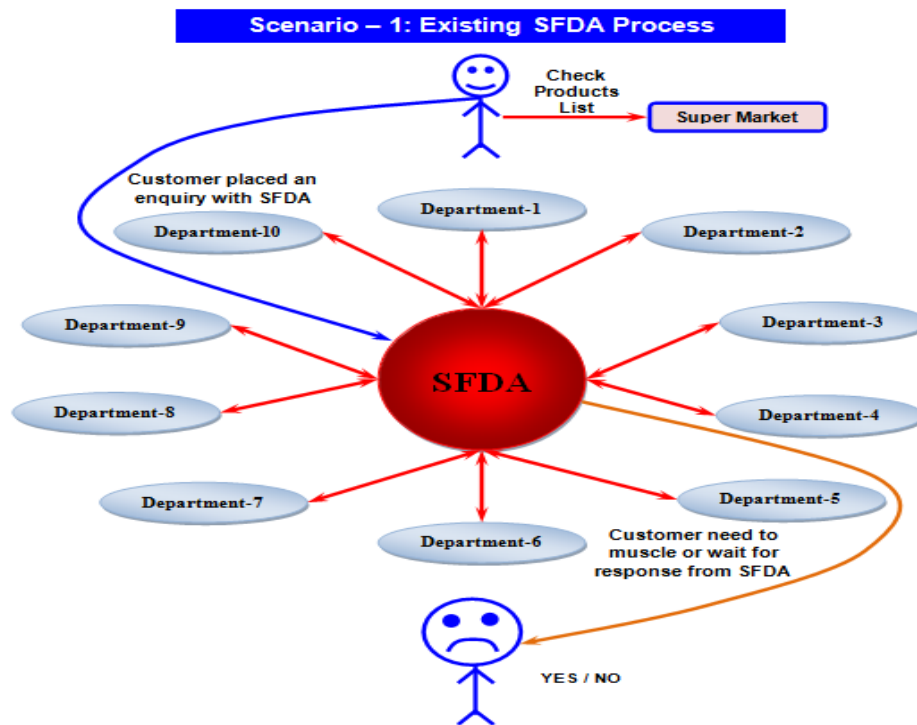


Figure 7. Existing SFDA Process

4.2. Scenario 1: Proposed SFDA Structure

Integration of various departments will help to establish an easy communication between each department and entity as shown in figure 8. This integration process will help to increase the number of viewers and parallel data interpretations and analysis is possible. However, based on the restrictions or approvals the data will be managed by concerned departments and authorities. Only authorized persons in SFDA will be allowed to have full authentication powers to

administrate to the role of each entity and define the rules for various sub elements in the total process.

This integrated data provides an easy understanding of complete framework and dataflow helps the SFDA to take instant decisions based on the priority. The communication established using this method will be more superior as compared to the existing model of SFDA. Each activity from different source systems is fairly viewed and can be understood by the higher authorities of SFDA to avoid complex situations.

Integration of different databases may consider many forms based on the requirement and application to be developed. In the present integration module as shown in figure 5 the three main forms of integration are used, they are: Extract Transform and Load (ETL), Enterprise Application Integration (EAI) and Enterprise Information Integration (EII).

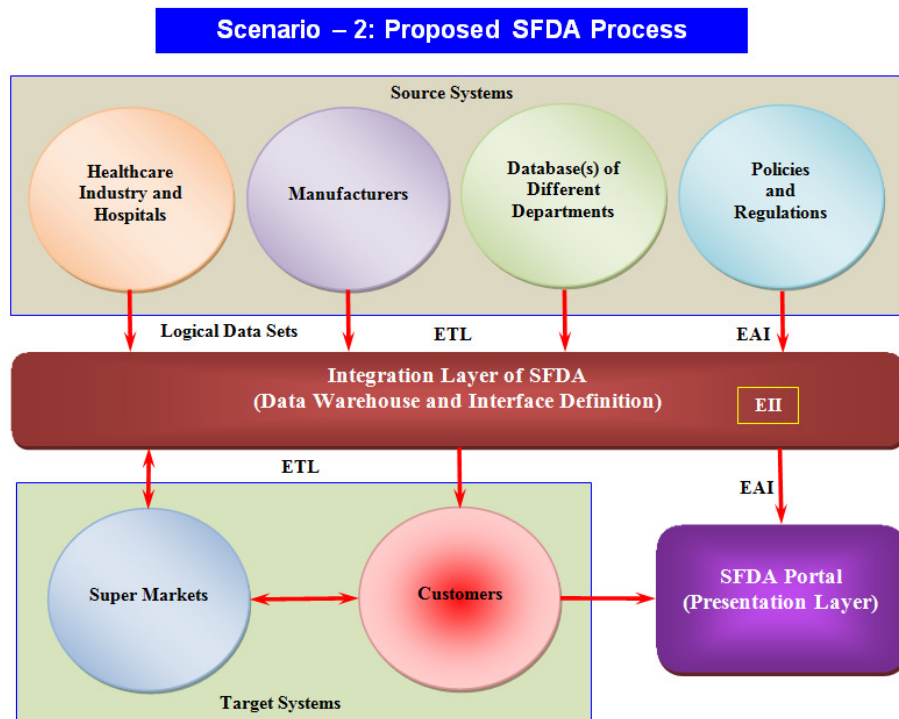


Figure 8. Proposed Integration Module for SFDA

The data from different source systems is extracted by using ETL and transforms the data properly so that integration process will be smooth. This form will simplify the creations, maintenance and expansion of different data warehouses and data sources [9]. EAI helps in combining different applications (such as database and web applications) by placing a semantic layer on top of individual application. EAI is a helpful in planning, applying methods, tools, modernizing, consolidating and also helps to coordinate the complete functionalities of the system. Due to the involvement of semantic layers the data from the established legacy systems and databases also can be extracted or migrated to a modified set of applications. This in turn allows the implementation of new policies and decisions with less effort using the proposed integration process. However, in the present system of SFDA, the information at different departments is stored in different formats and databases with variety of applications. Extracting

information from different systems might create a serious implementation issues at different levels. A middleware is needed to bridge the applications in present system. Here in this integration module the EII will provide real-time access to overall information for the complete integrated data management. These graphical EII data mapping tools are easy to handle and provides a speed integration process. EII also helps in capturing the metadata to drive various data transformations [9].

Now over integration process of SFDA will be interconnected with the checker component in the architecture along with the SFDA portal. This portal is being updated and developed with a customer friendly version of web applications.

The proposed integration module of SFDA includes the following policies:

1. Customers check the list of products from the super markets to verify with SFDA
2. Sends the request for approval from SFDA with product details
3. Runtime checker will compare the databases and information on the integration layer of SFDA
4. If the product details are matching the COMMUNICATION will be established with the customers to buy the product
5. If the product details are not matching or not meeting the regulated norms and rules it will be COMMUNICATED with the customer to stop buying (REJECTED) it and also creates an alert with FDA database to save the issue with complete details.
6. Finally the FDA authorities will assess and the summary of results will be communicated with the super markets to avoid legal problems for selling REJECTED products.

Formalized rules for the proposed SFDA architecture and the policies involved in it are shown below.

The Customers (C) needs to identify the list of products to buy from the super market with their details is formalised as shown below:

$$\begin{array}{l}
 \text{Policy1} \triangleq \\
 \left(\begin{array}{l}
 \text{fin}(\text{enterSupermarket}) \wedge \\
 (\text{Customer}(C, \text{Module}) \wedge \\
 \text{ListofProducts}(P, \text{Module}) \wedge \\
 \bigwedge_{i=0}^{t=\text{total products selected}} \text{done}(C, P, \text{Submit})
 \end{array} \right) \mapsto (\text{Enquiry}^+(C, P, \text{ListReady}))
 \end{array}$$

Now the request for approval from SFDA for the selected products by customers is given below:

$$\text{Policy2} \triangleq$$

$$\left(\begin{array}{l} \text{fin}(\text{SubmitProdcutList: RuntimeChecker}) \wedge \\ \text{CheckList}(L, \text{Module}) \wedge \\ \bigwedge_{i=0}^{i=\text{compete list}} \text{done}(L, \text{Submitted}) \end{array} \right) \mapsto (\text{ListAccepted}^+(L, \text{ListReady}))$$

List of products is sent to SFDA authorities are to be checked for the quality of the product is given below.

Policy3 \triangleq

$$\left(\begin{array}{l} \text{fin}(\text{ListofProducts: Databases}) \wedge \\ \text{ListofMatchingProducts}(M, \text{Module}) \wedge \\ \text{Quality}(Q, \text{Module}) \wedge \\ \bigwedge_{i=0}^{i=\text{Matching}} \text{done}(M, Q, \text{Submit}) \end{array} \right) \mapsto (\text{Authorize}^+(M, Q, \text{AcceptProductList}))$$

Communication with customers for matching products list is given below:

Policy4 \triangleq

$$\left(\begin{array}{l} \text{fin}(\text{ListofProducts: Listed}) \wedge \\ \text{OriginalityCheck}(O, \text{Module}) \wedge \\ \text{EstablishCommunication}(E, \text{Module}) \wedge \\ \bigwedge_{i=0}^{i=\text{Listed}} \text{done}(O, E, \text{Submit}) \end{array} \right) \mapsto (\text{Communicated}^+(O, E, \text{ApproveList}))$$

Communication with customers for unmatched / REJECTED products list is given below:

Policy5 \triangleq

$$\left(\begin{array}{l} \text{fin}(\text{ListofProducts: NotListed}) \wedge \\ \text{RejectedList}(R, \text{Module}) \wedge \\ \text{EstablishCommunication}(E, \text{Module}) \wedge \\ \bigwedge_{i=0}^{i=\text{NonListed}} \text{done}(R, E, \text{Submit}) \end{array} \right) \mapsto (\text{Communicated}^+(R, E, \text{RejectList}))$$

Assessment by FDA for unmatched / REJECTED products list is given below:

Policy6 \triangleq

$$\left(\begin{array}{l} fin(Assessment:FDAauthorities) \wedge \\ DeatiledRejectionInformation(D, Module) \wedge \\ CommunicationSupermarkets(S, Module) \wedge \\ \wedge_{i=0}^{i=Actions} done (D, S, Communicated) \end{array} \right) \mapsto (Communicated^+(D, S, RejectList))$$

The above mentioned policies will help the customers, super markets and SFDA authorities maintain a smooth food and drug controlling process with greater efficiency.

5. CONCLUSIONS

The proposed approach enhances the communication between different departments by minimizing the efforts of various entities involved in SFDA. This model implementation will allow the customers in KSA to identify the different between genuine and bad products when they visit a super market. Decision making will be easier by using this method for both customers and super market owners. The authorities are allowed to establish a direct contact or communications with the super markets after finding the facts from rejects products from proposed runtime monitoring checker. Care has been taken to provide suitable information from the complete application to each entity based on their eligibility and role in the complete process. The entire SFDA process established using this method can be more cost effective and time saving as compared to the present model. The complete model is derived to an easy model after using the proposed integration module and authorities can easily understand the seriousness of each rejected product in very short time and can take immediate action. The policies introduced in this research will help SFDA authorities to carryout smooth operations and communications with customers and these policies also allows immediate action to the real time issues.

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