GENETIC MATERIAL ON MARKET – A NEW CHALLENGING FIELD FOR RFID

Alexandre Cotting [1], Prof. Yann Bocchi [1], Grégory Mermoud [2] & Dr Vincent Pellissier [3]
[1] Haute Ecole Valaisanne (HEVs)
[2] Ecole Polytechnique Fédérale de Lausanne (EPFL), School of Computer and Communication Sciences
[3] Ecole Polytechnique Fédérale de Lausanne (EPFL), College of Management of Technology

Abstract: The rapid growth in the development of Life Technologies is currently asking for the emergence of first business models involving genetic material, as for example, people's DNA. Then, new questions arise. Problems are appearing as well in terms of ethics as at the supply chain management level. To answer those questions the society is improving legislation. It's in that context of constant evolution that enterprises have to conceive logistical solutions answering diverse and sometimes contradictory imperatives; economic viability, traceability, quality, data safety or yet the respect of privacy.

This document presents, based on a case study of an enterprise active in the confection of personalized products made from its customers DNA, the technological strategies set up to assess those different aspects. The choice of the RFID technology has allowed building an information management infrastructure adapted to the context. That technological choice presents, in terms of tracking security, an elegant alternative to warrant the quality level required by the product. This case study allows putting in perspective the importance of the simultaneous process of the logical and physical flows, and the interdependence between those flows.

Finally, a few general learning could be get and used for business models of the same domain. In particular, the setting of the required security level will decide for the choice of the design of the logistic chain elements.

Keywords: Traceability, security, modelling methodology, good practices for genetic market.

1 Introduction

The coming to maturity of biotechnologies made it possible to see these last years the first commercial applications. Indeed, the domain clearly passed from the phase of research in that of the development. This life industrialization consequently will leave the laboratories to meet the market. This inescapable established fact tends to accelerate and the near future will see an acceleration of the rising innovations to arrive on the market, in a traditional way compared to the cycle of maturation of the products of innovation, schematized on figure 1.

This report is accompanied by new considerations, depending on this particular field. In particular, the consecutive ethical aspects with an intervention on living parts and the potential attacks to the privacy represent a major stake of the domain.

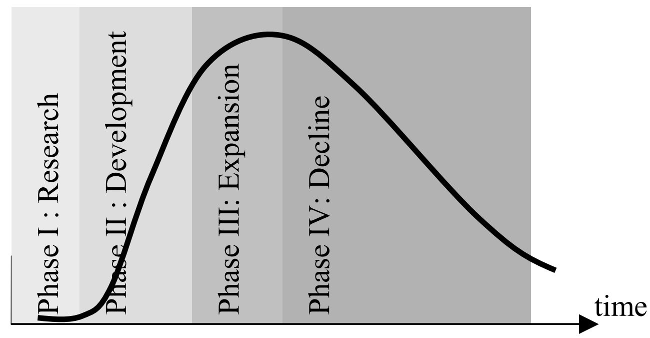


Figure 1. Phases of the maturation cycle of an innovation product

This article briefly presents the stakes of the legal framework fixing to ensure as well as possible the development of such an industry while guaranteeing the ethical and human principles. In the second time, a case study sharing in a summarized way the components of supply chains for a cosmetic product based on the customers DNA is presented. The various elements of the logistic chain and the advantages of the recourse to RFID technology are also shown in that case study. The RFID Technology opens interesting prospects to accompany the logistician in the design of the logistic chain and the management of physical and logical flows, related to the field implying genetic material.

2 Which juridical frame in the Swiss context?

The Swiss legislative corpus fixes the framework in which the industrialists evolve, and its adequacy with the technological reality of the projections must absolutely be guaranteed. In Switzerland, the Cantons fix various constraints related to the specific domain. For example, the specific aspects to the analysis laboratories or the laboratories of environmental protection remain reserved for the federal legislation, in particular, the law on data protection (LPD, 1992) and the future law on the genetic engineering (LGG, 2003), like their respective ordinances of application. The legal arsenal is to our knowledge sufficient (Udry, 2005) to be able to consider an industrialization within the framework wanted by the legislator.

It is significant to raise that as soon as a product is marketed in several countries, it must respect the whole of the laws and regulations in force in the country. One will see in the example presented further in this article the impacts on the design of the supply chain of the product.

3 Case Study

3.1 Studied problems

The case study presented here relates to the marketing of innovating cosmetic products, named ChronosomeTM. These products are tailored for each customer starting from a DNA sample taken in the mouth of the people using a sterile swab.

3.2 Design of the Supply Chain

We describe hereafter the supply chain specific to the product. Description is separated in two aspects; physical flows and logical flows. The approach adopted to work the supply chain was based on a systemic reflection. Thus, the elements of the chain were identified according to the following traditional typology:

- Actors of the process (customers, retailers, manufacturer 1 (biotechnology laboratory working on the genetic material), manufacturer 2 (conditioning factory of the final cosmetic product)).
- Flows (physical and logical).
- Stakeholder (legal, juridical and financial context).
- Vectors of support (swabs sterile and Eppendorfs), of transport (box of transport of the swab and transport of the creams) and of storage (Eppendorfs storage box).
- Transported and stored Material (DNA and conditioned creams).
- Documentation of accompaniment (not treated in this article).

This systemic approach made it possible to model the reality in a simplified way and to dimension, a priori, the components of the supply chain. The following paragraphs briefly present the various processes generated by the model.

3.3 Contextual legal impacts on the supply chain design

The juridical legal aspects have impacts on many points of the supply chain. In particular, the following reflections were led, certain requiring still a validation from the federal officer for data protection, and thus still likely to be modified:

- Establishment of the laboratory working with the DNA on the Swiss territory.
- Implementation of a procedure differentiated and adapted to each country for taking a sample of the DNA. Indeed, this one requires the assent in many countries and the guarantee of this assent must be proven by the signature of a document by the customer.
- The problems presented by the storage for conservation of the data bank of the customers DNA for a later use required security means on the quality and the storage mode (i.e. redundancy of the systems guaranteeing an adequate temperature, mode of access management, ISO certification).
- The management of the logical data confidentiality required a basic architecture centralized for the whole of the retailers, on a single server, redundant and highly protected.

3.4 Physical flows

This paragraph describes the processes and operations implying the generation of physical flows in the logistic chain. These processes are represented schematically on figure 2. The operations are represented by rectangular blocks and flows by directed arrows (direction origin - destination).

1. Operation of taking a sample of DNA on the customer; this operation is carried out by a trained retailer.

→ The genetic material is repatriated in Switzerland.

2. In a laboratory which carries out the biotechnological stages necessary to work on the DNA of the person, a personalized buffer solution, containing the active ingredients, is carried out. This buffer solution is placed in a series of Eppendorfs.

→ The Eppendorfs are transmitted to the conditioning factory.

3. In this factory, conditioning is then carried out by a series of methods for leading to the cosmetic product. Each Eppendorf allows the making of a cosmetic product.
4. The surplus buffer solutions of the customers are preserved for later uses.

→ The cream is then conveyed at the retailer.

5. The retailer gives in fine the cream to the customer.
   The whole of these stages is schematized on figure 2 below.

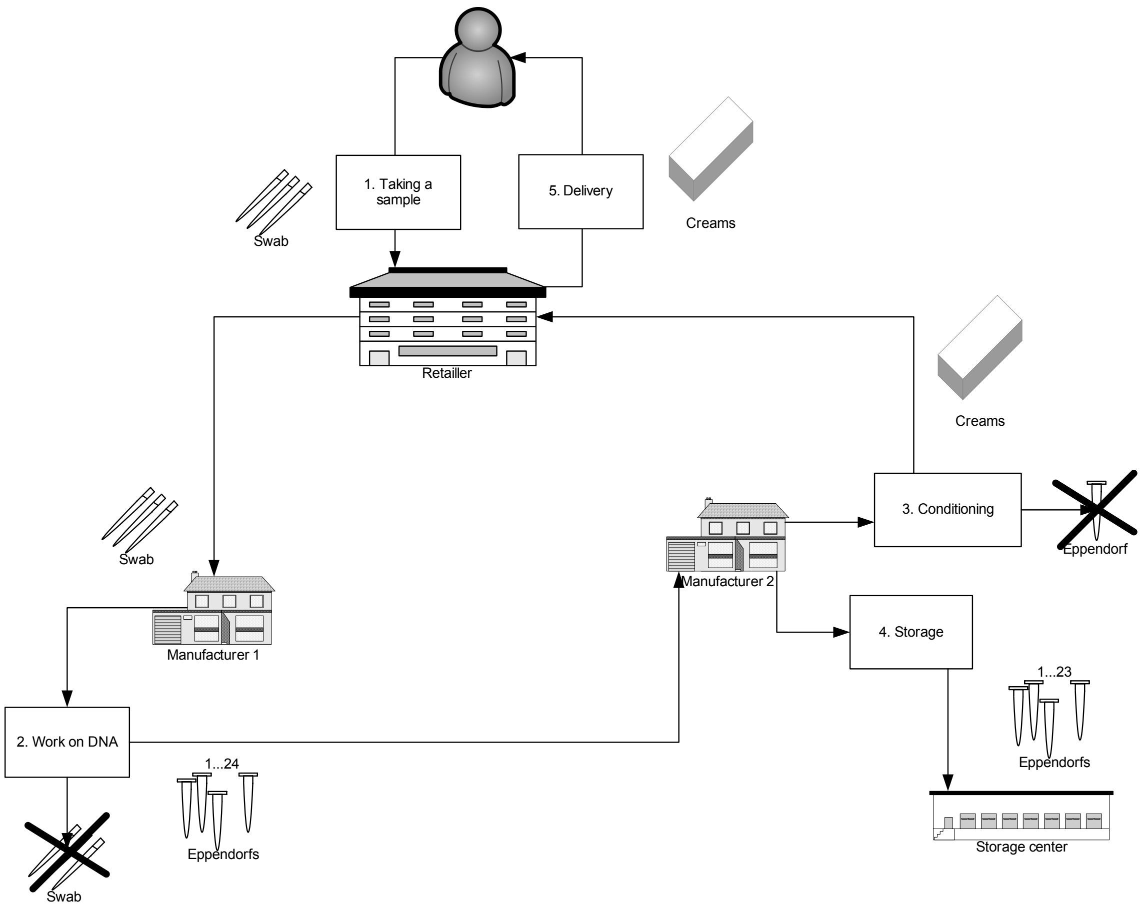


Figure 2. Schematization of physical flows

3.5 Logical flows

We present in this article the data-processing flows implied in the processes in simple modes, without to linger on the degraded modes (order modification on behalf of the customer, production chain breakage...). The various elements accompanying the organisational aspects related to the systems of quality control and safety also leave the framework approached in this article. It is obvious that those had to be solved within the framework of the practical installation.

Consequently, so as to ensure the traceability of the various objects appearing in the system, an IS (Information system) was set up, (cf Figure 3), making it possible to manage flows of information coming from the RFID readers, installed by the actors implied in the processes. At the time of the operations described previously and schematized on figure 2, these speakers will mark by the means of a reading of RFID tags contained in each box, the course of the aforesaid boxes containing the genetic material. This marking makes it possible to follow at any moment the state of each process, to make sure that the box of creams received by the customer corresponds to the preceding element of the logistic chain, i.e. the box of Eppendorfs, with the swab corresponding to the sample of DNA of the person. This management also makes it possible to ensure orders and stages historic, as well as an inventory control of buffer solutions available for each customer.

Various logical flows are here briefly reviewed and schematized on figure 3 as well as the processes related to the elements of RFID marking.

1. After taking a DNA sample on the person, the retailer introduces the box of swabs identifier in IS. The identifier is related to the order, this one being related to a customer identifier and the retailer.
2. Manufacturer 1 binds the swabs box received with the produced Eppendorfs box. The state of the corresponding order is updated.

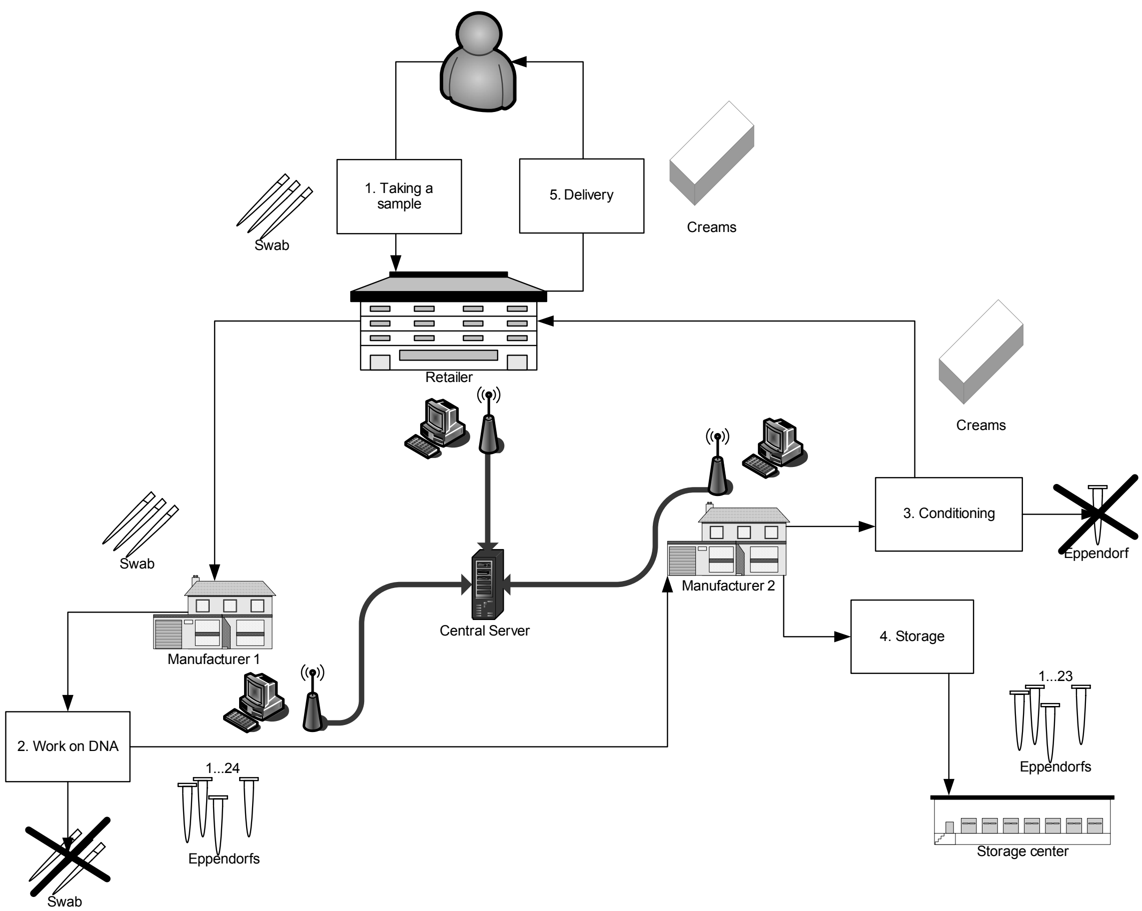


Figure 3. Schematization of logical flows

3. Manufacturer 2 indicates to IS the place of storage of the Eppendorfs box which it has received. The produced pots of cream are related to the Eppendorfs box. The state of the order still evolves.
4. Manufacturer 2 questions the system in order to obtain the co-ordinates of the retailer corresponding to the pots of cream which it has received. He transmits the box and the state of the order is updated.
5. The retailer finds the identifier of the customer corresponding to the received pots of cream. He can then establish the link with his own system and contact the customer.

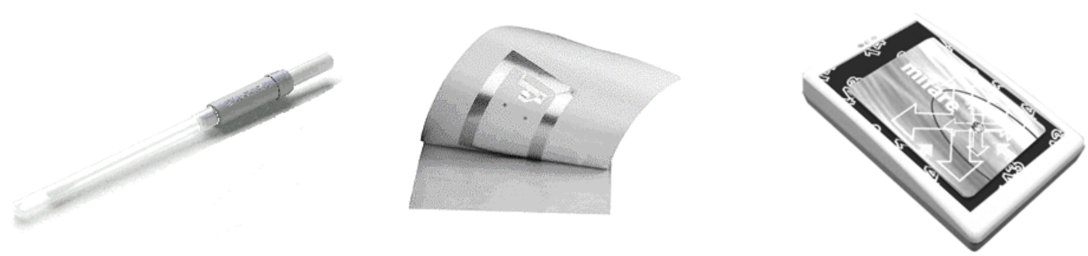
Note that with each stage, a checking is made as for the correlation of IS information and reality, in order to detect a possible handling error of the various elements and to correct it (i.e. at the time of the reception of one box of swabs at manufacturing 1, the system checks that the object presented is well identified as box of swabs). The setup by double control makes it possible to improve the reliability of the total system without weighing down too much the human interventions on the chain logistics.

The complete traceability is consequently ensured thanks to the identification of all speakers at each stage, but also by the time-stamping of each handling.

3.6 The usage of RFID technology

Several technological possibilities were evaluated within the framework of this project, including the code bars and the RFID. The final choice was made on RFID technology for reasons of high-tech image of the company, to allow a simultaneous reading of several tags and also to ensure a longer lifespan the identification of products, some elements of the chain having to be stored during several years under particular climatic conditions.

The following phase of the analysis of the needs showed that a reading distance of ten centimetres was enough. Consequently the choice of RFID technology was made on tags and readers functioning at a frequency of 13.56 MHz, in conformity with the standard ISO 14443 A.



a) *b)* *c)*

Figure 4. RFID Elements a) sterile Swab, b) incorporated RFID Tag, c) Mifare reader

It was then decided that the tags would be placed on the vectors of transport only and not on each element of the contents of the boxes. The boxes being closed, out of the context of the retailers and manufacturing and, the internal processes of work of each one of them having shown their reliability as for the traceability of the objects, it appeared disproportionate consequently to affix a tag on each element. The images of figure 4 befure show some elements of the system set up.

3.7 Technology advantages and disadvantages

We review in the table below the principal advantages and disadvantages of the recourse to RFID technology instead of a traditional technology by code bars.

	Advantages	Disadvantages
RFID	• No need for direct line of sight • More resistant support in time • Possibility of refining the traceability on the item level (unique identification) • Aspect "New Tech" • Possibility of reading several tags simultaneously • High data storage capacity (up to 4 KB)	• Currently relatively expensive to produce
Code bars	• Economic to produce • Tested technology • Easy to use	• Fragile, easily damageable • Direct line of sight necessary • Usable with small volumes of data only • No possibility of simultaneous reading

Table 1. Advantages – Disadvantages

4 Software architecture

The reading of the identifiers of each box being defined, it was then necessary to develop the Information System making it possible to manage these data. The sales goal of the creams, strongly international, pushed the software choice towards a solution containing a central server, installed in Switzerland, and collecting in a SQL database the information sent by applications installed in the various actors.

The whole system is designed so that its use remains as simple as possible for the retailer and its customer. To achieve this goal, we sticked to three principles:

1. Order and deliver processes should involve a minimal number of actions: RFID plays a key role in reducing the complexity of the retailer tasks (no data entry e.g.).
2. The interface has to be highly straightforward in order to reduce the learning curve: it displays all the steps that the retailers would have to follow, as the number of objects to be identified and a progress bar indicating the time left for RFID scanning.
3. Both the installation and the update of the software must be simple, or even transparent to the retailer.

For all these reasons, we chose Java as primary programming language because it enables us to be computer platform independent and hence facilitates integration on the retailers data-processing platform. We also included an automated update system. An alternative would be to use Java Web Start which allows launching any Java application directly from the web.

An important contribution of our work is the development of a Java package that is intented to provide a framework for handling many types of RFID readers. We have fully implemented and tested our architecture with two types of readers. One is accessed through a TCP/IP connection while the other requires a local connection through the serial port. Our architecture is flexible enough to allow implementation of systems using both types of readers.

The software architecture is highly modular in order to support efficient extension in team work. Thus, we provide a handy platform for semester or diploma projects in the context of HEVs while bringing in value added to the original system.

5 Conclusion

On the basis of the lessons drawn from the case study presented in this article, two interesting conclusions emerge for the logistician confronted with the industrial field concerned with the genetic material. The first is of contextual nature. Indeed, the Swiss legislative corpus makes it possible to plan apprehending this type of problems within a sufficient framework and presenting the guarantees necessary in terms of data protection and privacy protection. The second is of technological nature. The recourse to a RFID technology made it possible to set up a logistic chain where the aspects of safety of the customer, privacy and data protection can be elegantly regulated. Although requiring an adaptation of the components of the supply chain, therefore implying an investment in resources (economic, human and of knowledge), this technology provides an interesting response to the problems raised by the arrival on the market of genetic material.

6 References

Delessert F. (2005), Avis de droit, not publicated, property of Eatech SA, Sion, Switzerland, 2005.

Loi fédérale sur la protection des données (LPD) du 19 juin 1992 (1992), Recueil systématique Suisse, *RS23.1*, Bern, Switzerland.

Loi fédérale du 21 mars 2003 sur l'application du génie génétique au domaine non humain (Loi sur le génie génétique, LGG) du 21 mars 2003 (2003), *RS 814.91*, Bern, Switzerland.

Perret F.-L., Jaffeux C., ed. (2002),The Essentials of Logistic and Management, *EPFL Press*, Lausanne, Switzerland.

Udry D. (2005), Avis de droit, not publicated property of Cellap SA®, Geneva, Switzerland.

7 Biography

FIRST AUTHOR is research assistant at ICARE Institut since 2005. He studied electrical engineering, followed by a post grade in Management of Technology (MoT) at EPFL. He is in charge of building a RFID network for the Haute Ecole Valaisanne (HEVs) with both academics and industries, as well as a competency centre around Automatic Identification.

SECOND AUTHOR is Professor at the Haute Ecole Valaisanne (HEVs), since 2002. His research field is mainly about Information Systems engineering, databases modelling and management, and objects programming. His work aims providing middleware development competencies to RFID projects.

THIRD AUTHOR is master student at the School of Computer and Information Sciences in the Ecole Polytechnique Fédérale de Lausanne (EPFL). His research field is about complex and collective systems, self-organization and multi-agents information systems.

FOURTH AUTHOR is research assistant of the College of Management of Technology in the Ecole Polytechnique Fédérale de Lausanne (EPFL). His research interests aim to better understand impacts of technology on supply chain design and management. His PhD thesis treated with risk management.