Is The Time Coming for Plant-Made Vaccines?

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Vaccines have significantly improved human health since their introduction in the last century. They are the most potential weapons to fight the majority of infectious diseases, which are responsible of more than 45% of the total deaths in developing countries [1]. Traditional vaccines are made of a live attenuated or killed pathogen, and either injected or given orally. There are other two categories of vaccines, subunit vaccines and nucleic acid vaccines, being the choice of producing one of them related to factors such as pathogenesis, immunobiology, and epidemiology of the disease [2].

The considerable extension in time of the vaccine production process, its high cost, the stringent conservation conditions required, the need to provide immunization to a high world population with marked differences in packaging, storage, and delivery capacities, and the emerging and re-emerging outbreaks needing a fast response from the pharmaceutical industry have triggered the search for new production platforms of immunogens [3]. As a result, there are numerous reports on the use of yeasts, insect cells, plant cell cultures and transgenic plants for producing recombinant vaccine subunits not only directed to human health but also towards the development of veterinary vaccines [4].

In comparison with the traditional production platforms (microorganisms, animal cell cultures), the plant platform has several characteristic features that had made it a complementary and attractive alternative. Plants could perform post-translational protein modifications and folding typical of eukaryotes with a few differences in glycosylation respect to the animal cell, proteins are not accumulated in inclusion bodies as in bacteria and they do not present biosecurity concerns such as the occurrence of human or animal pathogens, prions, oncogenes or toxins. These advantages have a great influence in the total cost and simplicity of the productive process. As a drawback, there are regulatory concerns regarding GMOs producing biopharmaceuticals that have to be taken into account which are variable according to the legislation of each country. On the other hand, when the plant platform is in a confined placement (e.g.: in vitro cultures) the management of the process in controlled conditions (temperature, humidity, photoperiod, sterility) allows the immunogen production in good manufacturing practices and good laboratory practices are a requirement of the pharmaceutical industry. As a consequence, the process would take place in secure facilities operated by trained personnel. Since 1989, when for the first time it was proposed the use of plants for producing edible vaccines [5], a huge amount of reports has been the proof-of-concept of the platform [6,7]. Those successful expression systems included stable transgenic or transplastomic plants, in vitro plant cell cultures, and also the transient expression of the recombinant protein of interest. Some of the efficient models expressed recombinant immunogens against pneumonia and bubonic plague [8], human respiratory syncytial virus [9], non-Hodgkin lymphoma [10], human papillomavirus [11], enteroviruses [12], anthrax [13,14], malaria [15], dengue [16], hepatitis B [17] among others. As for veterinary vaccines, there are promising reports about vaccines against Newcastle disease [18], Bovine diarrhoea viral disease [19], foot and mouth disease [20], and Bovine herpes virus [21].

Nevertheless, when comparing yields of all the available production platforms, plants do not attain yet the high production levels of microorganisms or animal cell cultures [22]. That inconvenience seems partly solved when the expression of the recombinant protein is transiently achieved. On the other hand, plants yield a high amount of available productive biomass hence diminishing the total cost of the productive process. Thus, a considerable effort is being conducted in order to optimize the productivity of the processes in development.

In 2006, the US Department of Agriculture for Veterinary Biologics approved the first vaccine produced in plant cells to protect chickens from the Newcastle Disease Virus (NDV). However, a lot of work has still to be done concerning to dosage, best delivery method and type of immune response elicited for each plant-vaccine system before a plant-made vaccine could be in the market for human use.

The recent news about the FDA approval of the drug Eleyso® (taliglucerase alfa) is a consequence of development and acceptance of biopharming research which was carried out for more than 20 years. The drug is produced in carrot cells and is used for Enzyme Replacement Therapy (ERT) in patients with Type 1 Gaucher disease.

With many plant-made proteins in the pipeline, and a huge amount of work in the labs, it is expected that in the coming years more recombinant proteins produced in a plant platform will be in the market, and among them, vaccines.

References

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Received: October 01, 2012 Accepted: October 04, 2012 Published: October 08, 2012

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