

From: [REDACTED] <[REDACTED]@inexto.com>
Sent: jeudi 15 décembre 2016 17:46
To: SANTE TT SW
Cc: [REDACTED]; [REDACTED]
Subject: Additional comments from Inexto

Categories: Blue Category

Dear Madam, Dear Sir,

Thank you for the offer to submit this feedback in an email and as supplement to the earlier discussions that took place this past December 12th.

As we have continued to observe allegations against on our company, its employees, and its track & trace technology, we feel it necessary to reiterate points raised by the Chairman of Impala SAS, our parent company, in a previous letter to you from October 26th. In addition, we wish to clarify some additional points where we feel that innuendo, conjecture and/or misrepresentation by third parties of Inexto's technology may have been used at the expense of verifiable facts and therefore to our company's disadvantage... and provide some additional feedback on EU commission.

Firstly, we wish to highlight that Inexto SA is beginning to implement, with success, its track & trace technology across a variety of industries and views its independence vis a vis any particular industry as a strategic imperative. Our parent formed Inexto, along with its intellectual properties and core team of technologists & software developers, based on an exhaustive search for the most performant authentication, identification, serialization and track & trace technologies in the marketplace. It is in Impala's interest, and therefore a key objective of Inexto, to ensure its assets in the field of authentication/track & trace can most effectively compete in this emergent sector and meet the needs of demanding regulations and customers across a variety of industries. Independence is a key element toward fulfilling this objective.

In furtherance of Inexto's objective to serve a broad spectrum of industries, to include Pharma, Food & Beverage, Spirits, Automotive, Luxury, Electronics, and Tobacco, we are committed to the concept of interoperability. Given that supply chain networks can differ from market to market and that legitimate actors can also vary over time, supply chain tracking remains a critical element within a comprehensive track and trace system. Inexto's solutions are based on globally recognized Open Standards (e.g.: GS1, EPCIS, GTIN/SGTIN, GLN), thereby supporting interoperability within and between networks of economic operators. Inexto believes Open Standards are key to enhancing competition and thereby driving innovation, improving performance, and lowering costs. As a leader in this emerging sector, we welcome this challenge.

A key element to cost effective and efficient implementation of Open Standards will also be the introduction of high speed data carriers for sectors with higher manufacturing speeds. To date, the only proven data carrier able to support these higher speed manufacturing environments is the DOTCODE.

To prepare our company for the demands of an increasingly diverse customer base, Inexto has invested in its software portfolio to ensure its solutions meet regulatory requirements and customer specifications across a variety of sectors, markets and regulatory regimes. Our newly developed software portfolio has been designed for maximum supply chain visibility, transparency and trust. Inexto's secure serialization technology, INEXTOR[®], is not a "black box". In fact, INEXTOR was redeveloped, based on the Codentify patents, to ensure the controlling authority's total control and full visibility at the machine level. Inexto welcomes the opportunity to demonstrate the transparency of its solutions through an assessment by neutral/qualified experts and is prepared to meet regulatory regimes that leverage unannounced audits.

With regards to INEXTOR, our secure serialization software, we would like to clarify a few of the key capabilities of this innovative solution. First, it is impossible to generate the unique code twice under our patented method and robust algorithm. Second, each unique code is part of a unique track & trace event, as the securely serialized item is further aggregated and moved through the supply chain. Third, we are able to record these track & trace events in near real time.

Inexto is not alone in leveraging the benefits of encrypted mass serialization. We invite you to review an article by Ranga Iyer, former Managing Director of Wyeth Limited, in Pharma Pro & Pack, Volume 1, Issue 4 from Oct-Dec 2011. In the article, he emphasizes the benefits of encrypted mass serialization with respect to ensuring uniqueness of each code, "immunity from hacking and/or corruption by ensuring code invisibility until its printed on a product", and offering the "best

security through maintaining the data in an encrypted form at the code level, entirely bypassing the need for database [code] storage”.

With respect to governance, Inexto is neutral concerning the presented models A3 or A1 (with appropriate government controls). Given the EU TPD regulation requiring descriptors, such as machine ID, date, time, etc., to be incorporated within the Unique ID, it is necessary that the Unique ID be serialized on the machine. However, the model must ensure that the government authority retain control of the generation of codes and complete visibility of the serialization process and that the system remain secure and unobtrusive to the manufacturing process. Fundamentally, both models, A3 or A1 (with appropriate government controls), can meet these objectives and Inexto’s solution will accommodate either approach. In addition, both models would also support digital tax stamps and production volume control, capabilities for which our technology can deliver. We invite you to review our Public Consultation input for more detail on Inexto’s views in this regard.

As well, supply chain visibility remains a key requirement and it must provide a high degree of transparency and trust when observing the movement of goods. Therefore, we stress that GS1’s recommendation for event tracking, known as the EPCIS model, be adopted. As distributors covering multiple sectors already leverage the interoperability provided by EPCIS, we see the adoption of this Open Standard as critical to a cost effective and efficient implementation strategy.

Finally, we would like to reiterate our open invitation for the Commission and Everis to meet with us and we remain at your disposal to meet with Commission Representatives and to provide any additional information you may require.

Most Respectfully Yours,

