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Performance Audit: Protecting Consumers through the Market Surveillance Directorate's Monitoring Role

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Performance Audit

Protecting Consumers through the Market Surveillance Directorate's Monitoring Role

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List of Abbreviations

ARPA	Agriculture and Rural Payments Agency
CE	European Conformity
CIMS	Continuous Improvement in Market Surveillance
EC	European Commission
EC DoC	EC Declaration of Conformity
EEA	European Economic Area
EFSA	European Food Safety Authority
EU	European Union
EUCP	EU-coordinated Control Programme
GPSD	General Product Safety Directive
LN	Legal Notice
MCCAA	Malta Competition and Consumer Affairs Authority
MRL	Maximum Residue Level
MS	Member State
MSD	Market Surveillance Directorate
MoU	Memorandum of Understanding
NAO	National Audit Office
NAP	National Action Plan for Sustainable Use of Pesticides for Malta's 2013 – 2018
NCP	National Control Programme
PAN	Pesticide Action Network
PPP	Plant Protection Products
PROSAFE	Product Safety Forum of Europe
RAPEX	Rapid alert system for dangerous non-food products
SUPD	Sustainable Use of Pesticides Directive
TARIC	Integrated Tariff of the European Communities
TRD	Technical Regulations Division
USA	United States of America
WSC	Water Services Corporation

Glossary

- **CE marking** means a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing.

- **Childcare articles** shall mean any product intended to facilitate sleep, relaxation, hygiene and the feeding of children or sucking on the part of children, as noted in Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals. Such products include cots, baby prams, high chairs, gates and feeding bottles, as well as children's clothing for the purpose of this Report.

- **Children's Products** comprise toys, other childcare articles such as prams, dummies and gates, as well as children's clothing.

- **EC Declaration of Conformity (DoC)** is a declaration drawn up by the manufacturer or his/her authorised representative to certify and assume responsibility for the compliance of products with essential requirements, which in the case of toys were established through the Directive 2009/48/EC on the Safety of Toys, as well as the relevant harmonised quality and safety standards.

- **Distributor** means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a Children's Product available on the market, including retailers.

- **Economic operators** include manufacturers, importers, distributors and the former's representatives established within the Community.

- **Harmonised standard** means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC on the basis of a request made by the Commission in accordance with Article 6 of that Directive.

- **Importer** means any natural or legal person established within the Community who places a Children's Product from a third country on the Community market.

- **Manufacturer** means any natural or legal person who manufactures or has designed and manufactured a Children's Product, and markets that item under his name or trademark.

- **Manufacturer's representative** is any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks.

- **Market Surveillance** means the activities carried out and measures taken by public authorities to ensure that toys comply with the applicable requirements set out in Community harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection.

- **Maximum Residue Level (MRL)** is the upper legal level of a concentration for a pesticide residue in or on food or feed set in accordance with Regulation (EC) No. 396/2005, based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers. Exceeding the Maximum Residue Levels does not necessarily imply a risk to health. However, it usually indicates that a pesticide has been incorrectly used. Food products that have residues exceeding MRL cannot be placed on the market.

- **Pesticides** or **Plant Protection Products (PPPs)**, that shall be used interchangeably for the purpose of this Report, are active substances and preparations containing one or more active substances, in the form in which they are supplied to the user, intended to protect plants or plant products against all harmful organisms or prevent the action of such organisms; influence the life processes of plants, other than as a nutrient; preserve plant products, in so far as such substances or products are not subject to special provisions on preservatives; destroy undesired plants; or destroy parts of plants, check or prevent undesired growth of plants.

- **Recall** means any measure aimed at achieving the return of a product that has already been made available to the end user.

- **Toys** are defined as products designed or intended, whether or not exclusively, for use in play by children under 14 years of age, as noted in Directive 2009/48/EC on the Safety of Toys.

- **Withdrawal** means any measure aimed at preventing a product in the supply chain from being made available on the market.

Executive Summary

Introduction

1. This performance audit primarily intended to determine the extent to which the Market Surveillance Directorate (MSD) within the Malta Competition and Consumer Affairs Authority (MCCAA) is appropriately safeguarding consumers' interests through adequate monitoring. This audit was mainly concerned with MSD initiatives undertaken between 2014 and 2016.

2. MSD's market surveillance extends to cover a spectrum of products with the aim of ascertaining that goods placed on the market comply with safety standards and other regulatory requirements. These include Children's Products, pesticides, machinery, medical devices and construction products. This review evaluated MSD's operations through two case studies, namely Children's Products and pesticides. This type of analysis is critical in view that substandard products within these specific product categories may have an impact on the well-being of the entire population, including vulnerable groups such as children. Towards this end, this audit sought to evaluate the extent to which:

    a. market surveillance and other initiatives were appropriately identifying and addressing the risks posed by specific products or product categories;

    b. MSD was appropriately coordinating its efforts with international stakeholders as well as local ones including the general public;

    c. the Directorate was taking timely, preventive and corrective actions in cases of infringement; and

    d. organisational and administrative structures in place were conducive for MSD to carry out its mandate appropriately.

Ensuring Safety of Children's Products

3. This performance audit considered Children's Products to relate to toys and childcare articles, including clothing. MSD's monitoring role is critical to ensure that only safe Children's Products are placed on the market. Border Control by the Customs Department also constitutes an important element to ascertain that imported goods comply with the legislative framework as well as the respective safety standards.

4. However, some non-conforming products, a high proportion of which would have been manufactured in non-EU countries, bypass border controls. In this regard, the Customs

Department and MSD, on behalf of MCCAA, signed a Memorandum of Understanding (MoU) in 2014 to enhance their cooperation. Nonetheless, both Entities are still in the process of reintroducing joint inspections, streamlining communication channels between them to facilitate information exchange, and to iron out difficulties concerning the demarcation of each other's remit.

5. The following issues imply that MSD's surveillance scope of Children's Products is not appropriately broad to cover the wide range of products placed on the market:

a. The Directorate's overall monitoring of products at retail outlets marginally declined over the period 2015 and 2016. This situation materialised despite the Directorate's allocation of a relatively high priority to this specific product category by the increase of visits in retail outlets.

b. Consumers and economic operators' awareness of the Rapid alert system for dangerous non-food products (RAPEX) is low. Nonetheless, MSD does not have a comprehensive system in place to disseminate more broadly information about these European Commission notices on product non-conformity through Press Releases or other notification systems.

c. MSD's approach to risk assessment is mostly limited to surveillance related to joint actions with other EU Member States. However, the products covered by MSD through joint actions constitute only a minor proportion of products that the Directorate is mandated to surveil. MSD contends that the Directorate did not have the required technical information, such as hazards posed by specific products as well as the probability of occurrence, to adopt a more comprehensive risk based approach. Thus, officers' experience and subjectivity constitute the main decision-making input towards MSD's product surveillance programme.

d. The Directorate does not allocate risk weightings as part of its risk assessment. MSD's predominant focus on surveilling branded products implies that the Directorate is not extending its inspections to other retail outlets such as market stalls, teleshopping and individuals selling online, unless complaints are received from consumers.

e. MSD's surveillance of toys mainly centres on verifying the European Conformity (CE) marking and other labelling requirements, to the detriment of other critical product safety documentation, such as the EC Declaration of Conformity. MSD officials review such documentation if they are not satisfied with the regularity features of labelling requirements such as the CE marking. This situation prevails even though several sources including the European Commission note that as a rule, the CE marking is not a comprehensive guarantee of safety for consumers.

f. MSD's mandate does not enable it to impose administrative fines and the Directorate is obliged to initiate legal proceedings in cases of irregularities. In the case of Children's

Products, there were no court cases between 2014 and 2016, even though the Directorate encountered two cases of repeated non-compliance.

g. The Directorate does not have the necessary equipment to carry out basic safety checks on Children's Products. MSD testing currently extends to very basic checks on Children's Products, such as testing for small detachable parts.

h. The Directorate does not verify whether products it deemed as non-compliant were actually withdrawn from the market. To this end, the Directorate is highly dependent on the economic operators' feedback and cooperation.

i. Although MSD organises awareness campaigns and training opportunities for economic operators, participation by the latter is very limited.

Ascertaining the Safety of Agricultural Produce

6. In view of the health risks posed by the irregular use of pesticides, MCCAA and MSD are both mandated with key regulatory roles. MCCAA is the lead Authority designated to ascertain the implementation of measures outlined in the 'National Action Plan for Sustainable Use of Pesticides for Malta's 2013–2018' (NAP). The NAP seeks to minimise the human and environmental impacts resulting from the excessive use of pesticides. However, the Pesticide Action Network (PAN) Europe criticised the majority of EU Member States, including Malta, on the premise that respective national plans lack overall objectives, quantitative targets and clear timetables for pesticide use reduction.

7. Recent reports show that in instances, Maximum Residue Levels (MRLs) in agricultural produce exceeded tolerance limits. The issues listed hereunder have, to varying degrees, contributed to this situation:

a. Since the adoption of the NAP in 2013, MCCAA mostly implemented measures related to training as well as information and awareness. On the other hand, NAP measures related to pesticide application and monitoring remain mostly in progress.

b. The NAP entrusts MCCAA with the responsibility of implementing measures therein through collaboration with other National Entities. To date such collaboration included the signing of two MoUs between MCCAA and the Agriculture and Rural Payment Agency (ARPA) as well as the Water Services Corporation (WSC). Initiatives in conjunction with the former agreement extended to information exchange between the entities regarding enforcement action taken by ARPA with respect to farmers benefitting from EU funding. The second agreement is still awaiting the accreditation of WSC testing facilities with respect to pesticides.

c. MSD does not utilise comprehensive risk assessments to target Plant Protection Products (PPP) and MRL inspections as it does not consider a number of the influential

risk variables or allocates respective weightings. With respect to the latter, the risk assessment techniques in place predominantly focus on the European Food Safety Authority (EFSA) related MRL obligations, which were fulfilled and marginally surpassed.

d. The Directorate experiences a number of limitations in the execution of the national inspection programme. These mainly relate to the absence of accredited laboratories in Malta as well as the administrative capacity and budgetary issues within the MCCAA.

e. National coverage concerning the retailing of PPPs is undertaken separately by MSD and ARPA, where the latter's work focuses on registered farmers who benefit from EU funds. Moreover, as less than 50 per cent of farmers benefit from such funds, the number of inspections undertaken by MSD suggests national coverage of PPP enforcement is somewhat limited.

f. MSD's inspections concerning MRLs on agricultural produce placed on the market focused on the Pitkali and Farmer's markets as well as imported goods. Through these inspections, MSD' testing coverage did not extend to around half of the 30 items of agricultural produce considered by the National Statistics Office as being amongst the most consumed products locally.

g. Many products fail to comply with regulations relating to product traceability in terms of country of origin, class, variety or commercial type. Matters within the local context become aggravated due to the common practice of products being sold directly by farmers to consumers. Furthermore, there is no mechanism in place at the Pitkali Market to guarantee the traceability of produce passing through this market. The severance of product traceability poses both legal and operational concerns for MSD.

h. During 2016, MSD received the test results from the foreign contracted laboratory, on average, 40 days following submission. On the basis of this lead-time, consumption of the tested produce would have continued to the possible detriment of consumers' health.

i. The foregoing presents a complex situation for MSD. Prohibiting the sale of produce while testing is ongoing increases storage costs and is financially detrimental to economic operators. The status-quo, on the other hand, results in consumers being possibly placed at risk through the availability on the market of potentially unsafe products.

j. The absence of effective coordination between National Entities prohibits the withdrawal of non-compliant produce at source, that is, at farmers' holdings prior to being placed on the market. These circumstances mainly arise due to some ambiguity in the interpretation of National Entities' jurisdiction. This situation is rendered more serious as MSD's approach is mainly intended to deter future irregular use of pesticides by farmers, rather than to cater for prevailing irregularities.

k. MSD, although legally responsible, does not compile and maintain evidence to determine whether economic operators removed non-compliant products from the market. To this end, follow-up action extended only to notifying the Pitkali and Farmers' markets as well as importers.

l. During the three-year period reviewed, MSD did not carry out subsequent inspections targeting economic operators whose produce had failed previous MRL tests. This state of affairs is further evidenced since none of the economic operators who had legal action instituted against them was targeted with a second inspection. Such circumstances mainly materialised due to logistical reasons, as MSD would not be privy to information as to when the economic operator will be placing produce on the market.

m. MSD initiated Court proceedings against 15 economic operators on the basis of MRL inspections at the Pitkali and Farmers' markets. The Courts, however, dismissed all but one of these cases. The Directorate is in the process of initiating legal proceedings related to the 22 irregularities noted during 2015 and 2016.

Overall Conclusions

8. The two case studies, focusing on diverse product categories – namely Children's Products and pesticides, provided a detailed insight into the workings of MSD. This Directorate is responsible for protecting consumers by primarily ensuring the safety of products placed on the market. This audit showed that Malta, where applicable, is fulfilling and marginally surpassing its EU related obligations with respect to the monitoring of products placed on the market. MSD, rightly so, is actively involved in European product safety forums. This facilitated the execution of MSD's regulatory functions while minimising the burden of costs through co-financing arrangements.

9. However, this performance audit noted that the opportunity exists to further strengthen this regulatory function. To this end, the case studies elicited similar conclusions, though in some cases, product specific circumstances prevailed.

10. The Directorate's market surveillance initiatives do not fully address the risks posed by specific products or product categories. The absence of formal and structured risk analysis restricts broad inspection targeting at retail outlets selling Children's Products, whilst MSD's inspection targeting for pesticide residue levels on agricultural produce is effectively limited to traceable products and those retailed through the Pitkali and Farmers' markets. Market surveillance effectiveness is, to varying degrees, also influenced by long lead-times in conducting tests as well as the limited follow-up action. The foregoing does not guarantee that substandard products are withdrawn or withheld from retail.

11. The situation discussed in the preceding paragraph results through two main factors. Firstly, the public information mechanisms at MSD's disposal are not fully synchronised

to ascertain that consumers are informed about non-conforming products at the earliest opportunity. Secondly, an enforcement gap exists due to the need for more effective coordination between National Entities to ascertain a broader coverage of the supply chain as well as reach a wider spectrum of producers. Despite the signing of three MoUs with other stakeholders, cooperation has still not reached the expected levels. To this end, the recently introduced policy, 'Improving Business Inspections', recognises these issues and aims to encourage more effective communication channels between National Entities, while minimising the burdens of compliance costs to economic operators.

12. MSD contends that the level of resources at its disposal as well as operational, procedural and management information weaknesses are limiting factors to a broader approach to product safety. This performance audit detected other limiting factors influencing MSD's work. To this end, online shopping and imports that may bypass product safety-related border controls severed product traceability. Moreover, the absence of locally available testing laboratories influence the regulatory function intended to ascertain consumer protection from substandard products available on the market.

Recommendations

13. In view of the findings and conclusions emanating from this performance audit, the National Audit Office (NAO) is proposing a number of recommendations. These proposals take into consideration the conclusions elicited from both case studies including product specific concerns. The recommendations listed hereunder are broadly categorised in terms of the strategic and operational levels.

Recommendations aimed at the Strategic Level:

a. National Entities are encouraged to enhance coordination amongst each other. This will strengthen the regulatory function related to product safety by ensuring timely enforcement action and adequate coverage within the supply chain as well as the wide spectrum of economic operators. Improved cooperation between National Entities will also contribute towards optimising the use of specialised resources available at the different Institutions.

b. MSD through MCCAA together with the respective Signatories of MoUs, namely ARPA, the Customs Department and WSC, are to focus their collective efforts to enhance cooperation. Such cooperation will contribute towards addressing outstanding issues within MoUs, namely those relating to communication, clarification of stakeholders' remits and respective obligations.

c. National Entities involved in the monitoring of products for consumers' safety, are to take on board at the earliest opportunity the principles and mechanisms outlined in the recently published policy 'Improving Business Inspections'. Regulators are to

increasingly embark on risk-based joint inspections, which will minimise compliance costs for economic operators while ensuring fair competition and consumer's safety.

d. Cooperation and coordination between Governmental Entities namely MCCAA, ARPA, Ministry for Health and the Customs Department is to extend to the compilation and maintenance of product-safety and injury related data. Efforts in this respect will enable the more expedient extraction of critical information required for policy and operational decision-making. Within this context, National Entities are to establish respective needs and determine the mechanisms for more effective sharing of information.

e. Consideration is to be given to further strengthen provisions within the NAP. This can be attained through the establishment of more measurable objectives and targets, including detailed Key Performance Indicators. The strengthening of the NAP contributes towards further ensuring that the desired outputs and outcomes in relation to product safety and consumer's protection are attained as planned.

f. MCCAA is to sustain efforts with respect to the implementation of integrated pest management. It is imperative that these initiatives are supported through the appropriate level of resources to ensure the expedient adoption of these sustainable concepts.

Recommendations aimed at the Operational Level:

g. MSD is encouraged to adopt a more risk-based approach in the selection of the economic operator, the product category as well as the specific product to be monitored to ensure that unsafe goods are withdrawn to ascertain timely consumer's protection. Criteria such as the country of origin eliciting most product recalls, economic operator's history of non-compliance and common non-compliant product features are to be allocated their due weighting for inspections targeting purposes. This will ensure a more efficient allocation of the Directorate's limited resources.

h. MSD is to consider the setting up of an online platform, supported by a comprehensive database management system, primarily intended to facilitate the sharing of product safety-related information with other stakeholders, including Governmental Entities, economic operators and consumers. Various access levels may enable such an online information-sharing system to cater for cooperation with local stakeholders as well as raising public awareness particularly with respect to product safety alerts. Such an information-sharing platform will also minimise duplication of work and enables timelier consumer protection interventions.

i. MSD is to follow up RAPEX notifications as well as its own direction issued to economic operators with respect to product recalls and withdrawals from the market. This will ascertain that, as far as possible, the risk of non-conforming products available for retail is minimised.

j. MSD is to consider redesigning inspection forms to provide more effective guidance to officials carrying out inspections related to Children's Products. Inspection forms are to be more comprehensive and list the relevant harmonised standards.

k. MSD is to consider linking training with licensing-related obligations, as is the case for PPPs. Whilst acknowledging the Directorate's efforts to organise training in relation to the safety of Children's Products, economic operators' participation is still very low.

l. MSD is to ensure that the lead-time between the collection of agricultural produce for MRL testing to the receipt of results from the accredited Laboratory is minimised. The more expedient availability of test results would facilitate timelier and more effective action by the Competent Entities.

m. The Directorate is to consider increasing MRL exceedance testing, to include a broader range of agricultural produce than that indicated at a European level. This will ensure that such testing more readily reflects local consumption patterns and ascertains a higher degree of statistical representativeness.

n. MSD is to seek alternatives to current practices whereby MSD officials personally deliver samples of agricultural produce for MRL testing. The Directorate is encouraged to carry out a thorough evaluation of the options available in terms of sample preservation, legal implications and cost-effectiveness.

Chapter 1

Terms of Reference

1.1. Market surveillance aims to ascertain products' safety and fair competition

1.1.1. Substandard products increase the risk of injury to consumers. Such products are usually cheaper than fully tested and certified items, resulting in distorted market competition.[1] Thus, the primary objective of market surveillance is to ensure the free circulation of safe and otherwise compliant products on the market, with the minimum regulatory burden on economic operators. Through actions such as product withdrawals, recalls and the application of sanctions to stop the circulation of non-compliant products and/or bring them into compliance, market surveillance aims to ensure that non-food products do not endanger consumers.[2] Nonetheless, the Market Surveillance Directorate (MSD) monitoring also extends to agriculture produce to ascertain that approved pesticides are used within the permitted Maximum Residue Levels (MRLs).

1.1.2. The legislative framework, comprising of a significant number of EU Directives, Regulations and harmonised standards, as well as the national legal framework, highlight the range of responsibilities assigned to the various economic operators involved in the supply chain, to ascertain that only compliant products are placed on the market. To this end, varying responsibilities are attributable to the manufacturer, the importer, the distributor and the former's representative/s, as applicable.

1.1.3. Market surveillance is therefore crucial for the smooth functioning of the EU's Single Market as it does not only endeavour to protect consumers against unsafe products, but it also aims to safeguard other public interests such as the environment, security and fairness in trade.[3] Consequently, action taken by the Authorities responsible for market surveillance should be accountable, targeted, proportionate, consistent and transparent.[4] On the other hand, consumers' responsibility when purchasing products should include the reading of safety instructions and other basic labelling checks such as, where applicable, validating the European Conformity (CE) marking and other warnings.[5]

[1] OECD, (2007). The Economic Impact of Counterfeiting and Piracy, page 6.

[2] European Commission, Market Surveillance of Products. [online] Available at: http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance_en [Accessed May 2017].

[3] Ibid.

[4] Department for Business Innovation and Skills, (2011). The General National Market Surveillance Programme for the UK December 2012-2013, page 2.

[5] CE marking applies for 20 product categories including low-voltage electrical equipment, construction products, lifts, machinery, medical devices and toys.

1.1.4. Against this backdrop, the National Audit Office (NAO) conducted the performance audit: '*Protecting Consumers through MSD's Monitoring Role*'. The primary aim of this audit was to determine the extent to which the MSD within the Malta Competition and Consumer Affairs Authority (MCCAA), the regulator entrusted to ensure product safety for consumer protection, is effectively and efficiently carrying out market surveillance.

1.1.5. MSD's market surveillance extends to cover a spectrum of products with the aim of ascertaining that goods placed on the market comply with safety standards and other regulatory requirements. These include Children's Products, pesticides, machinery, medical devices and construction products. To this end, MSD's surveillance encompasses the enforcement of a very broad legislative framework.

1.1.6. This audit focused specifically on market surveillance initiatives related to Children's Products – including toys, childcare articles and children's clothing as well as pesticides. The two case studies were selected on the basis of the high risks associated with such products, and the safety-related issues that may impact vulnerable user groups and society in general.

1.2. On an international level, to varying degrees, there are safety concerns relating to Children's Products

1.2.1. The European Child Safety Alliance acknowledged Malta's efforts to strengthen its legal and policy framework with respect to Children's Products. Malta's positive stance is reflected in the change from a fair performance in 2009 to a good performance in 2012. This assessment, however, does not extend to an evaluation of the effective implementation or otherwise of such policy actions.[6]

1.2.2. Children's Products, that is, toys and other childcare articles namely products intended to facilitate sleep, relaxation, hygiene and the feeding of children such as cots, baby prams, changing tables, high chairs and clothes, are expected to comply with high safety standards as they are meant to be used by a very vulnerable user group. Figure 1 refers.

[6] European Child Safety Alliance, (2012). Child safety report card 2012 – How safety conscious are European countries towards children, page 55.

Figure 1: Children's Products

Toys

Childcare Articles

1.2.3. EU statistics, however, highlight that childcare articles remain in the top 10 list of items leading to child injuries. Infant or child products account to two per cent of product related non-fatal home and leisure injuries.[7] Childcare articles fall under the General Product Safety Directive (GPSD) 2001/95/EC, whilst the safety of toys is specifically addressed through EU Directive 2009/48/EC. Official statistics show that registered toy imports amounted to over €13 million in 2015.[8]

1.2.4. The issues listed hereunder raise a number of concerns about substandard products, which despite the regulatory regime in place, may still end up being utilised by this vulnerable group of consumers. The following refers:

a. The rapid alert system for dangerous non-food products (RAPEX), which notifies Member States of dangerous products being retailed within the EU market, features on a weekly basis, a number of product recall alerts, including Children's Products. During 2014 to 2016, there were 5,990 total RAPEX notifications out of which 2,684 related to Children's Products. MSD raised 13 of these notifications.[9] This number of notifications for this specific product category is considered at par with the majority of other RAPEX members.

b. However, the proportion of Children's Product alerts (2,684) out of the total number of RAPEX notifications (5,990) amounts to a 45 per cent notification rate. This rate is over double than that registered by MSD. This proportion among RAPEX Member States ranged from zero to 85 per cent.

[7] European Association for Injury Prevention and Safety Promotion (EuroSafe), 2013. Injuries in the European Union Summary of Injury Statistics for the years 2008-2010; pages 13 and 21.

[8] The TARIC product classification system adopted by the Customs Department does not permit the quantification of imports with respect to childcare articles.

[9] Additionally, MSD contends that the Directorate recalled another eight products. However, due to the lack of product traceability details as required by RAPEX, consumers were not informed of the withdrawal of these products.

c. Around three quarters of the 2,684 RAPEX alerts issued between 2014 to 2016 relating to Children's Products originated from outside the EU, mainly China. It is clear that the high level of imports of Chinese products to the EU is a contributing factor for the high presence in RAPEX statistics. Nevertheless, the European Commission contends that Chinese products, and in particular toys, remain overrepresented in RAPEX statistics. As a result, the Commission is working in partnership with the Chinese authorities to improve the safety of Chinese products.

d. Between 2014 and 2016, MSD detected 38 products without CE marking. This marking is required for many products and shows that goods meet EU safety, health and environmental requirements. Both the Customs Department and MSD contend that in instances, substandard products also infiltrate the local market through imports from Sicily. Generally, such products originate from outside the EU, as Maltese importers seek more advantageous wholesale prices by dealing with larger traders in other EU Member States. The freedom of movement of goods between EU Member States permits that border inspections are undertaken only when there is reasonable suspicion of irregularities.

e. During 2015, Mater Dei Hospital's Injury Database noted that 24 children of up to 12 years of age were injured while using Children's Products. However, many injuries remain either unreported or are classified erroneously within this Hospital's database.

f. The Online Customs Tariff Database, the Intergrated Tariff of the European Communities (TARIC) product classification system in use by the Customs Department across the European Union, including Malta, poses some limitations in establishing the total imports of Children's Products. This situation arises since this classification system does not always sub-categorise products. Furthermore, importers may erroneously misclassify products on import documentation. Consequently, it may be problematic for National Entities to quantify the total imports for specific categories of products. This state of affairs hinders a more comprehensive coverage of enforcement action by MSD.

1.3. Pesticide residues above stipulated levels in agricultural produce constitute major health and environmental concerns

1.3.1. Pesticides residue in fruit, vegetables and cereals ranks as the top health related concern among EU citizens.[10] The concern over the use of pesticides revolves around their impact on human health and their long-term effect. The World Health Organisation estimates that, worldwide, pesticides poison at least three million people each year, which in cases prove fatal.[11]

[10] EFSA, (2011). Pesticide residues in food – Monitoring programs in Europe.

[11] World Health Organisation, The Impacts of Pesticides and Health. [online] Available at: http://www.who.int/mental_health/prevention/suicide/en/PesticidesHealth2.pdf [Accessed May 2017].

1.3.2. Pesticides or Plant Protection Products (PPPs) are widely used within the agricultural industry. However, their use involves a level of risk, because most have inherent properties that can endanger health and the environment if not used properly.[12] Each pesticide comes with a specific set of environmental concerns. Such undesirable effects have led many pesticides to be banned, while regulations have limited and/or reduced the use of others. Within this context, it is estimated that over 98 per cent of sprayed insecticides and 95 per cent of herbicides reach a destination other than their target species, because they are sprayed or spread across entire agricultural fields.[13]

1.3.3. Similar to the case of Children's Products, specific EU legislation controls the use of pesticides, namely Regulation (EC) No. 1107/2009 concerning the placing of PPPs on the market and Regulation (EC) No. 396/2005 on MRLs of pesticides in or on food and feed of plant or animal origin. Due to the health hazard associated with pesticides, in terms of the latter Directive, every three years the EU issues a coordinated multiannual control programme. This program identifies the produce that needs to be tested.

1.3.4. MCCAA is the competent authority responsible for endorsing imports and regulating the use of pesticides in Malta. This Authority performs these functions through its Technical Regulations Division (TRD) and MSD. The functions of the latter Directorate are intended to ascertain that pesticides being retailed in Malta comply with regulations. Within this context, the role of the MSD is rendered critical since the issues depicted below imply that, to varying degrees, concerns exist over the use of pesticides within the local market. The following refers:

a. MSD's inspections between 2014 and 2016 revealed that 33 out of 451 samples tested exceeded the legally set MRL on agricultural produce placed on the market.

b. During the period 2014, 2015 and 2016, MSD carried out four, zero and four PPP inspections respectively. MSD records show that in 2014, MSD instructed two retailers to dispose of two products from their outlets since these did not conform to legal specifications. Similarly, during 2016, MSD instructed three out of the four retail outlets inspected to dispose of ten products.

c. During the period under review, MSD tested 451 samples, 94 per cent of which were required by the European Food Safety Authority (EFSA). While satisfying EU obligation, the MRL testing undertaken does not fully reflect the local produce.

d. The Customs Department and MSD contend that undeclared pesticides infiltrate the local market through imports from Sicily. These Authorities contend that such a situation materialised despite the legal obligation to declare all pesticide imports – regardless

[12] European Commission, Agriculture and Pesticides. [online] Available at: http://ec.europa.eu/agriculture/envir/pesticides/index_en.htm [Accessed May 2017].

[13] Miller, G. T., (2004): Sustaining the Earth, 6th edition. Thompson learning, Inc. Pacific Grove, California. 9, pages 211-216.

of origin. However, detection through border control becomes more complex since the freedom of movement of goods between EU Member States permits that border inspections are undertaken only when there is reasonable suspicion of irregularities.

1.4. Audit Focus and Methodology

1.4.1. This performance audit sought to determine the extent to which MCCAA, through MSD, undertakes market surveillance to ascertain that substandard goods are withdrawn from the local market. Towards this end, this audit evaluated the extent to which:

a. market surveillance and other initiatives were appropriately identifying and addressing the risks posed by specific products or product categories;

b. MSD was appropriately coordinating its efforts with international stakeholders as well as local ones including the general public;

c. the Directorate was taking timely, preventive and corrective actions in cases of infringement; and

d. organisational and administrative structures in place were conducive for MSD to carry out its mandate appropriately.

1.4.2. Unless otherwise indicated, this audit discusses findings and conclusions based on data pertaining to the period 2014 to 2016. This Report has considered data made available to the NAO as at end of April 2017. This audit was, to varying degrees, influenced by a number of limitations relating to the quality and timeliness of data.

1.4.3. This audit aimed to determine the degree to which the MSD is intervening effectively in the areas of Children's Products and pesticides. This type of analysis is critical in view that the whole population, including vulnerable groups, depends on such products.

1.4.4. The realisation of this performance audit's objectives entailed the conduct of structured and semi-structured interviews with key personnel at MSD, as well as with other key stakeholders such as the Customs Department. Various exercises, based on the analysis of the Directorate's data, sought to analyse MSD operations against compliance and effectiveness criteria outlined within the legal and regulatory framework governing the safety of Children's Products as well as agricultural produce.

1.5. Report Structure

1.5.1. Following this introductory Chapter, the Report proceeds to discuss the following:

- Chapter 2 discusses MSD's initiatives to ascertain that Children's Products placed on the market comply with safety standards. The discussion mainly focuses on the inspections carried out by the MSD as well as the relative testing procedures and follow-up measures. The Chapter also evaluates MSD's level of coordination with other entities and stakeholders.
- Chapter 3 discusses MSD's operations relating to the use of pesticides on fruit and vegetables consumed in the local market. As in the case of the previous Chapter, the discussion revolves around the Department's inspections as well as the testing procedures and follow-up measures adopted. This Chapter assesses MSD's coordination with other entities and stakeholders. The discussion therein also focuses on value for money aspects relating to the laboratory testing of agricultural produce.

1.5.2. The overall conclusions and recommendations emanating from this audit are included in this Report's Executive Summary on pages 8 to 15.

Chapter 2

Ensuring Safety of Children's Products

2.1. Introduction

2.1.1. Ascertaining the safety of products used by children is of utmost importance due to the vulnerability associated with this age group. Children's Products, that is, toys and childcare articles including clothing, are an innovative goods group in constant development. Manufacturers, importers and distributors are obliged to be aware of the hazards their products might pose, offer safe products and provide consumers with information that allows them to evaluate and prevent injuries.

2.1.2. This performance audit revealed that the Market Surveillance Directorate (MSD) within the Malta Competition and Consumer Affairs Authority (MCCAA) is not comprehensively addressing the risks posed by specific products or product categories used by children. MSD does not draw up and document formal and exhaustive risk assessments. Within this context, the Directorate's inspections are, generally, carried out on the basis of individual officer's experience or by following-up product safety-related complaints.

2.1.3. Against this backdrop, this Chapter discusses the following issues:

a. Border Control of imports by the Customs Department;
b. MSD's surveillance coverage of Children's Products;
c. MSD's participation in the Product Safety Forum of Europe (PROSAFE) Joint Actions;
d. Action on the Rapid alert system for dangerous non-food products (RAPEX) notifications;
e. Retail outlets monitored by MSD;
f. Follow-up inspections;
g. Testing of Children's Products; and
h. Training of economic operators in relation to safety regulations and standards.

2.2. Some non-conforming products bypass border controls

2.2.1. Border Control by the Customs Department constitutes an important element to ascertain that imported goods comply to the legislative framework and the respective safety standards. To this end, the Customs Department is empowered to affect Border Control checks when there is reasonable doubt of product compliance. The Customs Department's role to ascertain that imported goods comply with the regulatory framework entails liaison with the MSD.

2.2.2. In this respect, MSD receive queries from the Customs Department, which the former follows up as required. In 2014, both parties signed a Memorandum of Understanding (MoU), with the aim of strengthening cooperation amongst each other, as well as to facilitate information exchange and communication. Representatives from both entities also attend joint meetings, seminars abroad as well as training sessions.

Coordination between the Customs Department and MSD is not yet at the level envisaged by the MoU

2.2.3. The previous paragraph portrayed the presence of a number of elements aimed at strengthening the collaboration between the Customs Department and MSD. The former is responsible for ensuring product compliance at border control while MSD's remit relates to compliance of products placed on the market. Within this context, the MoU between the two entities, signed in June 2014, outlines that the two entities recognise the importance of close cooperation and coordination with each other. Nevertheless, this performance audit revealed that the following factors remained outstanding:

a. This Office is not aware of any joint initiatives during the period under review. However, the Customs Department contended that there are plans for joint inspections to be reintroduced.

b. As at the time of drafting this Report, discussions between the Customs Department and MSD with respect to the demarcation of each other's remit and jurisdiction were still ongoing. Consequently, such a critical element pertaining to the remit and coordination between these two departments remain outstanding. In such circumstances, the risk increases that substandard product become available on the market.

Online shopping poses higher risks related to the importation of substandard Children's Products

2.2.4. The Custom's remit and jurisdiction implies a very broad role to prevent illegal activities, such as preventing the infiltration of illicit substances and intercepting illegal trade, including through online shopping. Over 65 per cent of Europeans buy products online and the number of online shoppers has grown by 27 per cent between 2006 and 2015. A new challenge is now to address the online channel, which also brings products from outside the EU through mail into consumers' households that may not have been subjected to safety verification.[14] Similarly, 47 per cent of Maltese nationals have resorted to e-commerce during 2016.[15]

[14] European Commission Press Release, *Protecting European consumers: toys and clothing top the list of dangerous products detected in 2015*. [online] Available at: http://europa.eu/rapid/press-release_IP-16-1507_en.htm. [Accessed May 2017].

[15] Eurostat, *E-Commerce statistics for individuals*. [online] Available at: http://ec.europa.eu/eurostat/statistics-explained/index.php Ecommerce_statistics_for_individuals [Accessed May 2017].

2.2.5. Control mechanisms relating to internet shopping become more complex since shipments, which are not intercepted through Border Control, may eventually end up on the market. At this stage, the responsibility for enforcement shifts from the Customs Department to MSD. However, unless alerted by the former, MSD does not have any importation information through primary sources relating to online shopping to enable it to target its inspections accordingly.

The Customs Department encounters major difficulties to implement more effective border control with respect to direct individual importation from Sicily

2.2.6. The Customs Department undertakes more stringent physical checks and documentary controls on imported goods from outside the EU. Consequently, the Department does not physically check products imported from EU countries unless there is reasonable suspicion about their conformity. Due to the free movement of goods, anyone can import products from other EU countries.

2.2.7. The Customs Department contends that it encounters major difficulties to ascertain that imports transported directly from Sicily through individuals' own transportation arrangements conform to regulations and standards. The Department noted that it is fully aware of the potential risks, nevertheless, regulations pertaining to the freedom of movement of goods together with limited information on individual importers preclude stronger and more focused action in this regard.

2.3. Children's Products surveillance by MSD does not fully cover the range of economic operators and products

2.3.1. MSD's market surveillance extends to cover a spectrum of products with the aim of ascertaining that goods placed on the market comply with safety standards and other regulatory requirements. In this regard, the Directorate's remit extends to more than 100 pieces of legislation that entail very wide and varying requirements.

2.3.2. This Report has already alluded to the critical importance of ascertaining the safety of Children's Products placed on the market. It was in this spirit that the National Audit Office (NAO) selected this category of products as one of the case studies to evaluate the effectiveness of MSD's initiatives in this respect.

2.3.3. Table 1 contextualises MSD's product surveillance initiatives over a three-year period, up to December 2016. This Table presents the total visits made by MSD in retail outlets and the respective products reviewed, relating to PROSAFE joint actions (Section 2.4 refers) and the Directorate's own surveillance initiative.

Table 1: MSD's product surveillance initiatives (2014 – 2016)

Product Category	2014		2015		2016	
	Total visits	Total products sampled	Total visits	Total products sampled	Total visits	Total products sampled
Child Care Articles	24	4	53	12	38	32
Children Clothing		1		26		5
Toys		210		231		227
Pesticides	4	39	-	-	4	43
Pesticide Residue Monitoring[16]	31	175	16	124	18	152
Chemicals	29	274	23	299	26	213
Construction Products	-	-	1	7	-	-
Electrical	24	169	21	145	13	71
Food Labelling	1	4	1	8	2	3
Gas	11	29	4	13	3	14
General Products Safety	12	29	5	8	15	62
Lifts	15	15	13	21	45	45
Machinery	6	29	6	23	13	51
Medical Device	1	1	-	-	3	19
Motor Vehicles	1	1	-	-	-	-
Personal Protective Equipment	25	145	7	42	8	53
Pyrotechnic Articles	-	-	-	-	-	-
Recreational Craft	-	-	-	-	-	-
Total	**184**	**1,125**	**150**	**959**	**188**	**990**

2.3.4. The overall product surveillance by the MSD is on a declining trend, as shown in Table 1. While the number of visits generally remained at the same level during the three-year period under review, the number of products inspected declined by 12 per cent from 2014 to 2016. MSD contends that this circumstance materialised since the Directorate has experienced considerable increases in the number of enquiries from economic operators and consumers. On the one hand, dealing directly with economic operators and consumers restricted the allocation of more time for product surveillance and subsequent testing. Nonetheless, the Directorate sustains that it benefited through such enquiries as it was able to direct its resources in areas of concern.

2.3.5. Table 1 also portrays that the MSD is allocating a relatively higher priority to the surveillance of toys. Regardless of such a priority, the number of outlets retailing Children's Products, which were inspected, does not reflect the local market. This assertion is made on the

[16] Data provided regarding the number of visits performed to collect MRL testing relates to the number of times MSD officials carried out fieldwork rather than the number of visits at different suppliers. This limitation emerges, as the required information is not readily available.

basis of comparing the number of economic operators visited with those listed in a local business directory, which lists at least 150 establishments authorised and registered to sell such goods. It is to be noted that the number of such retail outlets is, in practice, much higher as these products are also sold by general stores, including supermarkets, stationers, market stalls and bazaars. MSD contends that by carrying out inspections at distributors, the Directorate is indirectly broadening its coverage of retail outlets.

2.4. MSD seeks to exploit the advantages emanating through PROSAFE Joint Actions with other EU Member States

2.4.1. MSD plays an active role in Joint Actions organised by the Product Safety Forum of Europe (PROSAFE). This is a non-profit professional organisation for market surveillance authorities representing various countries from the European Economic Area (EEA). Its primary objective is to improve the safety of users of products and services in Europe.

2.4.2. PROSAFE has also coordinated various specific market surveillance activities dealing with Children's Product safety within the EEA. The European Union co-funds these initiatives. To this effect, during the period 2014 to 2016, PROSAFE reimbursed MSD with €43,965 for travelling-related expenditure. PROSAFE also reimburses MSD for 55 man-days for each joint action and subsequent testing. The benefits arising from participation in PROSAFE are two-pronged. Firstly, MSD acquires and shares knowledge regarding product safety and surveillance with its European counterparts. Secondly, MSD has the opportunity to boost its surveillance coverage at a significantly lower cost. The Directorate acknowledges the benefits arising from participation and ensuing testing programmes. In this regard, MSD contends that it is on the forefront when compared to other EU countries in terms of the number of joint actions that it has participated in.

2.4.3. Despite the potential benefits of participating in PROSAFE, MSD forfeited the opportunity to participate in all joint action initiatives. Firstly, as MSD deemed that not all joint actions were relevant for Malta. Secondly, administrative capacity constraints prohibit MSD from broadening its participation. Consequently, the Department took part in 31 out of the 42 joint actions that were active during the years under review. Table 2 refers.

Table 2: MSD's participation in Joint Actions (2014, 2015 and 2016)

	Active Joint Actions	Joint Actions MSD was involved in	Joint Actions in which MSD was not involved
Childrens' Products	12	10	2
Other	30	21	9
Total	**42**	**31**	**11**

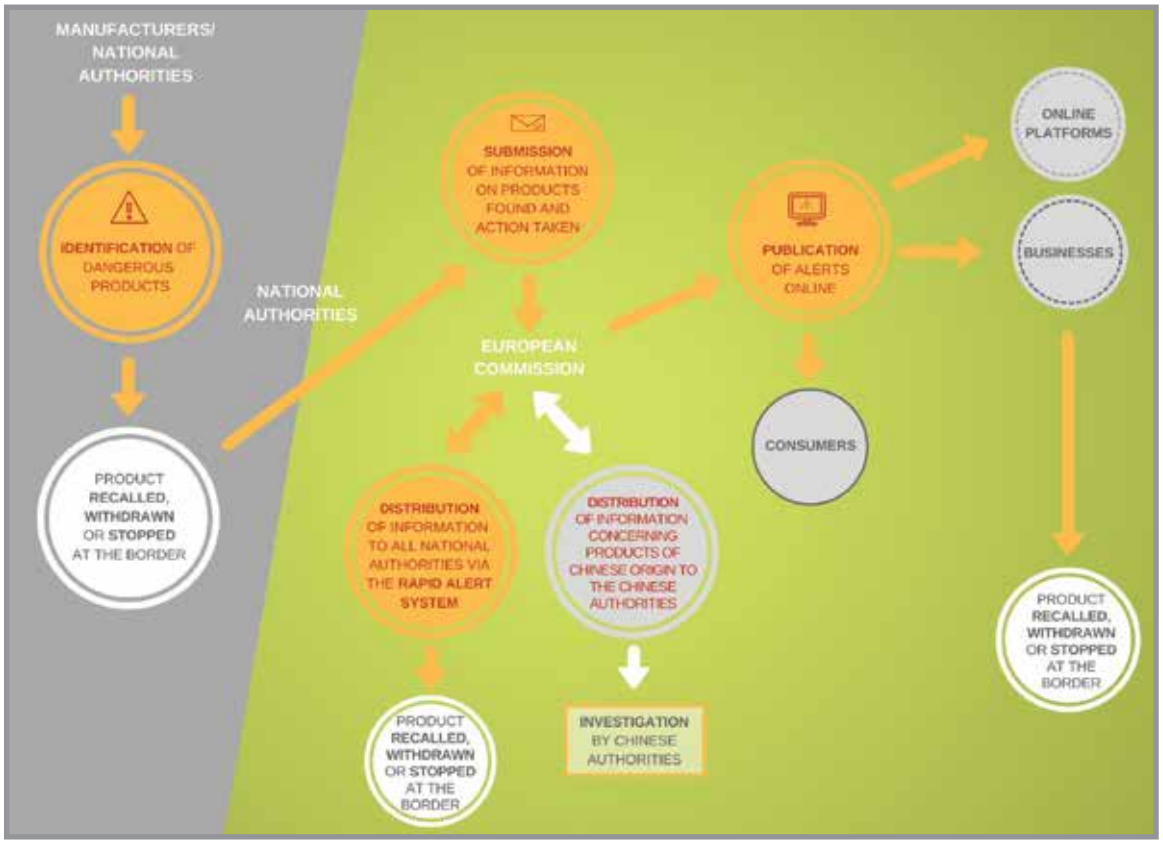
2.4.4. Table 2 also shows that during the years under review, MSD surveillance of Children's Products constituted around 30 per cent of the active joint action participation. The foregoing implies that MSD did not participate in two of the 12 Children's Products joint initiatives. These related to, amongst others, chords and drawstrings in children's clothing, which may pose significant safety risks to children.

2.5. MSD did not follow-up RAPEX notifications with subsequent public notices

2.5.1. RAPEX enables quick exchange of information between 31 European countries and the European Commission about dangerous non-food products posing a risk to the health and safety of consumers. Between 2014 and 2016, there were a total of 2,684 RAPEX notifications related to Children's Products. Out of these notifications, less than one per cent[17] was initiated by Malta. Figure 2 depicts the processes involved with respect to RAPEX notifications.

2.5.2. Figure 2 shows that businesses and consumers are to be informed about substandard products. In this regard, the EU Commission issues weekly RAPEX notifications, which are forwarded to MSD as the National Competent Authority. These notifications are publicly available on the RAPEX portal and can also be accessed directly through the MCCAA's website.

Figure 2: RAPEX Notification Process



[17] 0.5 per cent of notifications related to Children's Products were initiated by Malta (13 notifications).

2.5.3. MSD acknowledges that consumers' knowledge and awareness of RAPEX is low. MSD informs economic operators of a RAPEX alert through an email notification. In 2013, the PROSAFE Continuous Improvement in Market Surveillance (CIMS) reviewing team regarded this approach as a best practice that other Member States should follow.

2.5.4. Nonetheless, between 2014 and 2016, only 47 businesses were informed of the 2,684 RAPEX notifications. The situation materialises since current practices relating to RAPEX notifications entail that MSD only informs businesses listed on its records following previous surveillance initiatives. This approach, however, implies that many businesses do not receive MSD's notices of RAPEX alerts since they do not feature on the Directorate's records. To partially mitigate this situation, MSD forwards RAPEX alerts to two main industry organisations to enable the dissemination of such communications to their respective members. However, economic operators that are not affiliated with these organisations remain unaware of RAPEX notifications. Additionally, consumers may not be aware of the alert system available on the RAPEX portal and also available through MCCAA's website.

2.6. Formal Risk Assessment techniques do not feature prominently in MSD's choice of economic operators and products inspected

2.6.1. MSD's limited resources and the broad spectrum of products it has to surveil make it imperative that its surveillance programme is based on risk analysis. This ensures that the MSD is in a better position to target the riskiest products on the market.

2.6.2. To date, however, MSD's approach to risk assessment has been limited to surveillance related to PROSAFE Joint Actions. To this end, participating authorities of joint actions discuss and determine a coordinated approach on risk assessment. The risk assessment is based on available test results as well as other technical and scientific knowledge. Furthermore, the PROSAFE E-learning tool on risk assessment is available to all participating authorities. This tool also facilitates a coordinated and synergised approach to risk assessment by Member States participating in joint actions.

2.6.3. The products covered by MSD through PROSAFE Joint Actions constitute only a minor proportion of products that the Directorate surveils. MSD acknowledges the absence of formal risk assessments related to product surveillance targeting. To this effect, the Directorate established a number of variables in relation to a priority setting exercise for product targeting purposes. However, this exercise did not consider all the elements required for a more comprehensive risk-based approach as indicated in 2.6.6. Furthermore, MSD is hindered to undertake a formal risk assessment process due to the lack of technical information such as the severity of the hazards posed by the products, availability of an injury database as well as the probability of injury occurrence. MSD contends that this state of affairs is replicated in many other EU Member States where the main cause of these circumstances relates to costs.

2.6.4. These circumstances, coupled with MSD's administrative capacity issues, limits the Directorate from extending risk assessment approaches to all product surveillance initiatives. Consequently, despite its importance to risk assessment, officers' experience and subjectivity constitutes the main decision-making input towards MSD's product surveillance programme.

2.6.5. The situation portrayed in the preceding paragraph implies that there is no formal profiling of products, which would help MSD's inspectors to comprehensively plan which products are to be targeted when inspecting shops. Furthermore, the officers' daily workload, such as complaints and queries from the general public and other Government Departments, constitute the major criteria with respect to the frequency and quantity of product surveillance visits. In this regard, the PROSAFE CIMS report outlines that the Directorate may find it useful to try to include more details why it has chosen to focus on certain product sectors.

2.6.6. In the absence of a formal risk assessment, MSD is forfeiting the opportunity to profile products on the basis of various risk-based elements. These include the country of origin eliciting most product recalls, common non-compliant product features, past manufacturer and retail outlet history of non-compliance.

2.6.7. By way of example, the NAO analysed RAPEX notifications in the case of Children's Products, and it was noticed that out of a total of 2,684 notifications issued between 2014 and 2016, 1,943 products were Chinese imports, making up a vast majority of 72 per cent. However, even when taking into account joint action initiatives, during 2015 and 2016, the Directorate's targeting of imports from China totalled less than half of the products surveilled. All things being equal, this implies that MSD's focus on such products is less then it would have been if product surveillance was based on formal risk assessment techniques.

2.7. Risk analysis shortcomings are reflected in targeting weaknesses of non-joint action initiatives

2.7.1. MSD is focusing its inspections in areas where there is a higher tendency of economic operators selling Children's Products. Nonetheless, the lacunae relating to formal risk analysis discussed in the preceding Section resulted in the following issues:

a. Over 66 per cent of the Children's Products surveillance visits carried out by MSD between 2014 and 2016 focused on established outlets or franchise shops rather than other retail outlets such as markets and hawkers. MSD contends that such a situation materialises as these retail outlets, in cases, are also key importers and distributors. In these circumstances, the Directorate sustains that it is indirectly extending the surveillance of products distributed to other retail outlets.

b. The predominant focus on surveilling branded products implies that MSD is not extending its inspections to other retail outlets such as market stalls, teleshopping, jumble sales and individuals selling online such as through websites and social media[18], unless any complaints are received from consumers. During the period 2014 to 2016, MSD's surveillance visits at outlets such as bazaars and market stalls amounted to 15 out of the 115 product surveillance visits.

c. Similarly, notwithstanding the aforementioned risks associated with social media retailing, during the past three years, through a joint action initiative, MSD allocated only five man-hours for an online review of products being retailed through such channels. MSD noted that its resource and infrastructure limitations prohibit the Directorate from extending its product surveillance to such initiatives.

d. MSD's planning of its product surveillance visits does not consider all economic operators selling Children's Products across Malta and Gozo. Such a circumstance materialises since MSD does not have comprehensive information pertaining to all economic operators in this line of business. This situation resulted as information on this matter is not exchanged with the concerned entities.

e. MSD does not consider economic operators' history of non-compliance prior to inspections. Out of the 37 retail outlets in which the Directorate identified non-compliance, MSD only carried out a subsequent inspection in six cases. The Directorate contends that it aims to target a broader spectrum of economic operators rather than focusing on the economic operator's history of compliance. Furthermore, the Directorate always assumes that operators are working in bona fide, unless there is reasonable doubt on specific products.

2.8. Non-joint action toys surveillance visits predominantly focus on CE marking to the detriment of other critical product safety documentation

2.8.1. As a case study, during October 2016, NAO officials accompanied MSD inspectors on two on-site inspections, where the inspection included 14 toys. In addition, the NAO supplemented this exercise by an analysis of 653[19] inspections undertaken during the period under review. MSD inspectors document product surveillance visits in retail outlets on Departmental inspection forms. Table 3 presents the issues elicited during the NAO's on-site visit as well as the review of MSD's inspection documentation.

[18] This excludes second hand goods sold through social media.

[19] This number excludes 46 joint action inspections relating to toys.

Table 3: Product surveillance observations

Product compliance features as per Safety of Toys Directive	Observations elicited on-site	Observations through MSD's inspection sheets
CE marking must be visible on the product.	MSD inspectors consistently verified this feature.	MSD inspectors consistently verified this feature.
A Declaration of Conformity must be available for each product.	This document was only requested in case of any other non compliance issues where further action by MSD was required.	MSD records do not indicate whether this document was requested or otherwise.
Retailer is obliged to have access to a technical file.[20]	This documentation was only reviewed in case of any other non-compliance issues where further action by MSD was required.	MSD records do not indicate whether this documentation was requested or otherwise.
Toys should bear a type, batch, serial or model number.[21]	MSD inspectors did not review this feature.	The lack of photographic evidence to support all inspections undertaken by MSD hindered the NAO from verifying the batch, serial or model number.
Toys should indicate manufacturer name, registered trade name or registered trademark and the address at which they can be contacted.[22]	MSD inspectors only reviewed manufacturer details.	MSD inspectors consistently verified this feature.
Instructions and safety information should be supplied in an appropriate language (English or Maltese).	MSD inspectors consistently verified this feature.	MSD inspectors consistently verified this feature.
Warnings must be marked in a visible, easily legible and understandable and accurate manner on the toy, label or packaging. Warnings shall be preceded by the words "Warning" or "Warnings".	MSD inspectors consistently verified this feature.	MSD inspectors consistently verified this feature.

[20] The technical file should contain information about the toys and kept for a period of 10 years after the toy has been placed on the market.
[21] If this is not possible, then the information should be included on the packaging or an accompanying document.
[22] Ibid.

2.8.2. Inspection data maintained by MSD revealed that the predominant focus of on-site product surveillance related to the verification of the European Conformity (CE) marking and other labelling features. These aspects of product safety are of critical importance and constitute a legal requirement as per Directive 2009/48/EC. Figure 3 refers.

2.8.3. The Safety of Toys Directive states that toys bearing the CE mark comply with the requirements of this legal framework. Nonetheless, this Directive also requires that product compliance is to be complemented by an EC Declaration of Conformity (DOC) and respective technical documentation.

2.8.4. The comprehensive requirements of the Directive materialises as several sources highlight that as a rule, the CE marking is not a general safety label or a comprehensive guarantee of safety for consumers[23] or implies product superiority. The European Commission outlines that the CE marking is a minimum requirement and National Authorities are free to adopt additional controls to ensure that products carrying the CE label do truly conform to its requirements. Nonetheless, as shown in Table 3, MSD places a high reliance on such marking given that the main focus of the Directorate's inspections relate to the presence of the CE mark on products. Despite the limitations associated with inspections being predominately based on CE marking verifications, MSD practices do not entail that on-site visits are routinely followed-up by requests for product documentation, namely the Declaration of Conformity and technical file. This product documentation lends itself to the identification of non-conforming products due to the information presented therein, namely in conjunction with the harmonised testing standards and the respective notified bodies.

2.8.5. Despite the economic operators' legal obligations associated with the drawing up and/or presentation of the DoC for inspection by the responsible market surveillance Authority, as shown in Appendix I, such documentation may not be available on-site particularly in the case of distributors who would not have imported directly the product on sale. MSD sustains that the Directorate requests this document when it has reasonable doubt that there are irregularities associated with CE marking.

[23] Finnish Safety and Chemical Agency, *CE Marking*. [online] Available at: http://www.tukes.fi/en/Branches/consumer-safety/Consumer-goods/CE-marking/ [Accessed April 2017]; Toys Advice UK, Toy Safety Standards in the UK. [online] Available at: http://www.toysadvice.co.uk/toy-safety-standards-uk.html [Accessed April 2017]; European Commission, Enterprise & Industry online magazine, *A mark Europeans can trust*. [online] Available at: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=4112 [Accessed May 2017].

Figure 3: CE marking, traceability and specific warnings

MSD's inspection template does not appropriately guide the Directorate's officials to carry more comprehensive product surveillance

2.8.6. MSD documentation in use during surveillance work does not serve as an appropriate check-list as it does not capture all information related to the product under surveillance. The following refers:

a. Inspection documentation is conducive to an over-reliance on product description and standards quoted on the package of the item being inspected. For instance, when standards are printed on the package, the inspection form checklist is ticked as the item having standards indicated on the packaging. MSD does not carry out additional checks to confirm that the standards listed are correct and relate to the type of product under inspection. Similarly, MSD officials do not verify whether other standards are applicable for the product under surveillance.

b. The General Product Safety Directive (GPSD) legally covers childcare articles, while the Safety of Toys Regulations specifically covers toys. However, the inspection forms used by the MSD do not distinguish between the respective legal requirements.

2.9. MSD's product surveillance procedures do not always ascertain the withdrawal of substandard products from the market

2.9.1. So far, this Report highlighted a number of procedural deficiencies in MSD's product surveillance regime. These procedural shortcomings together with administrative capacity issues and the wide availability of Children's Products classified by RAPEX as 'high risk' influence MSD's ability to ascertain that substandard products are withdrawn from the market in a timely manner.

MSD does not verify that economic operators withdraw substandard products from the market

2.9.2. MSD's surveillance mechanisms are not fully conducive to ascertain that economic operators withdraw non-conforming products from the market. These circumstances arise since MSD does not verify whether such products were actually withdrawn from the market.

2.9.3. The significant number of economic operators, products on the market and the 2,684 RAPEX notifications makes it inevitable that the Directorate becomes highly dependent on the economic operators' feedback and cooperation to withdraw non-conforming products from the market. This situation prevails even though there is limited awareness of this European product safety alert system amongst both economic operators and consumers. Current mechanisms employed by MSD do not fully ascertain that all economic operators and consumers are duly informed of RAPEX notifications. Despite notifying economic operators of non-conforming products, MSD do not always receive feedback about the course of action taken by economic operators. Nonetheless, MSD does not, as a matter of routine, follow-up non-responding economic operators or verify that action was taken with respect to product recalls or withdrawals.

2.9.4. Additionally, MSD supplements RAPEX alerts to withdraw substandard products from the market through its own surveillance initiatives. During the period under review, MSD identified 13 products that were of a substandard nature and required their withdrawal from the market. Similarly, to the case of RAPEX notifications, MSD does not carry out subsequent checks to verify that the economic operator had actually withdrawn the identified substandard products from the market.

Product safety enforcement is hindered as MSD is not mandated to impose administrative penalties and a Tribunal has not yet been set up

2.9.5. At present, MSD is not is a position to directly impose administrative penalties on non-conforming economic operators, which makes it more difficult to withdraw dangerous products from the market. This state of affairs also prohibits the setting up of a tribunal to deal with issues of product non-compliance and economic operators' redress.

2.9.6. In such circumstances, MSD has to refer cases of non-compliance to law courts. In the case of Children's Products, there were no court cases between 2014 and 2016. This situation prevailed even though in two instances of repeated non-compliance, a court referral would have been an appropriate course of action. However, MSD contends that there was not the need to proceed with a court case.

2.10. MSD organises awareness campaigns and training opportunities for economic operators

2.10.1. Awareness raising and education about non-conforming products is an important measure to counteract the purchasing of substandard goods by consumers. For this purpose, MCCAA regularly organises awareness campaigns through various media.

2.10.2. MCCAA officials from the Office for Consumer Affairs and MSD regularly participate in radio and television shows as well as publish newspaper articles. The aim of the information campaign is to make the public more aware about the dangers of non-conforming products

and how to ensure that products bought are safe. Similarly, during 2016, MSD targeted an educational campaign at public officials, economic operators and the general public. This event was organised in collaboration with the Malta-EU Steering & Action Committee. This campaign mainly addressed issues relating to CE marking. However, only six economic operators participated in this event. Such a situation replicates the 2015 circumstances whereby only 14 economic operators attended an information session in relation to RAPEX.

2.11. Conclusions

2.11.1. This Chapter has shown that despite the border controls in place, substandard Children's Products still end up on the market. Such products also tend to bypass border control through online shopping. To this effect, the opportunity exists for the strengthening of coordination between the Customs Department and MSD to the level envisaged by the MoU, which was signed between the two entities in June 2014.

2.11.2. As evidenced by RAPEX notifications, substandard goods are a common feature of any market. Despite MSD's initiatives and active participation in RAPEX, this Directorate's scope of operation is not broad enough to cover all aspects of this market. The cause leading to such a state of affairs is multifaceted and mainly centres around resource shortages, operational and procedural weaknesses as well as MSD's lack of powers to impose fines for non-compliant cases.

2.11.3. At the outset, this Office acknowledges MSD's administrative capacity limitations. The number of resources deployed at this Directorate restricts MSD from broadening its scope and frequency of product surveillance. Despite its resource limitation, MSD does not fully resort to risk assessment techniques, which will enable it to deploy its resources to review products that constitute heightened risks. Furthermore, MSD's predominant emphasis on CE marking and other labelling obligations during on-site product surveillance visits, in itself, does not guarantee product safety.

2.11.4. Product safety enforcement is, to varying degrees, hindered as MSD is not legally empowered to impose administrative fines and has to refer cases to law courts in cases of non-compliance. The absence of such powers limits the Directorate's enforcement efforts since it cannot deal with substandard products and non-compliant economic operators in a more expedient manner. Furthermore, MSD's inability to impose administrative fines weakens the deterrent effect of this Directorate's enforcement initiatives.

Chapter 3

Ascertaining the Safety of Agricultural Produce

3.1. Introduction

3.1.1. Recent reports issued by the Market Surveillance Directorate (MSD) show that, in instances, the Maximum Residue Level (MRL) in agricultural produce exceeded tolerance limits, where in 2016 such instances trebled over the previous year. Pesticides, which for the purpose of this Report are also referred to as PPPs, are intended to protect plants or plant products against all harmful organisms.

3.1.2. MSD's role in this respect is critical due to the health implications associated with excessive pesticide residues on agriculture produce. Within this context, MSD's role is two pronged. Firstly, MSD carries out inspections in retail outlets for Plant Protection Products (PPPs). The aim of these inspections is to ascertain that PPPs placed on the market are duly registered with the Malta Competition and Consumer Affairs Authority (MCCAA). Such registration implies that these substances comply with EU as well as National regulations and safety standards. Secondly, the thrust of MSD's work relates to testing samples of agricultural produce available on the market to ascertain that the level of pesticides therein is safe, that is, within the established MRLs. This involves that MSD officials deliver personally samples to an accredited laboratory abroad. The Directorate contends that this state of affairs materialises to satisfy legal requirements, which necessitate a full audit trail with respect to sample traceability.

3.1.3. Within this context, this Chapter seeks to determine the extent to which:

a. MCCAA is implementing the requirements of the National Action Plan for the Sustainable Use of Pesticides for Malta 2013 – 2018 (NAP);
b. MSD is adopting risk assessment techniques;
c. MSD is testing sampled agricultural products expediently; and
d. MSD is carrying out follow-up inspections.

3.2. A number of critical measures listed in the NAP remain outstanding

3.2.1. The NAP has been developed to reflect Malta's obligations emanating from Directive 2009/128/EC, which aims to establish a framework for Community action with the primary intention of achieving a more sustainable use of pesticides. The objective of the NAP relates to reducing the risks and impacts of pesticide use on human health and the environment, promoting the use of integrated pest management and of alternative approaches or techniques such as non-chemical alternatives to pesticides.

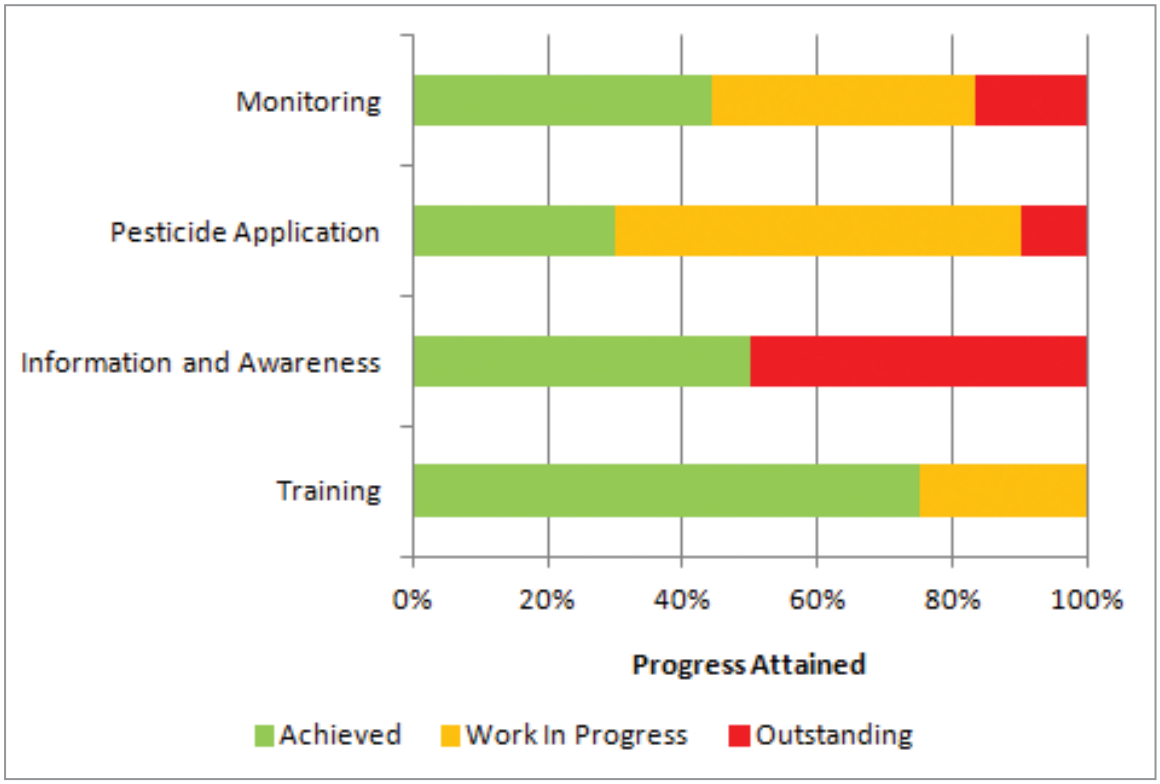
3.2.2. The MCCAA is the lead authority responsible for the implementation of the NAP. However, implementation of the Plan requires collaboration with other entities, including the Agriculture Rural and Payment Agency (ARPA), Local Councils and Mater Dei Hospital.

3.2.3. The Plan lists 34 measures, which can be categorised as follows:

a. training distributors of pesticides;
b. information and awareness raising campaigns targeted at professional users and the public;
c. pesticide application; and
d. monitoring mechanisms to ascertain the sustainable use of these chemicals.

3.2.4. Since the adoption of the Plan in 2013, MCCAA implemented or started to implement a number of measures. Analysing progress in terms of the number of measures implemented has various limitations since such an evaluation excludes consideration of the type of measure, materiality involved, timeframes as well as inherent complexities. To mitigate as far as possible such limitations, the ensuing sections aim to engage in a more in-depth discussion of the NAP's implementation progress. Figure 4 aims to provide a rudimentary overview of the NAP's implementation progress.

Figure 4: The NAP's implementation progress (December 2016)



Training and Awareness Campaigns measures implemented constitute the foundations for further initiatives related to the NAP

3.2.5. Figure 4 shows that MCCAA has commenced the implementation of measures across all of the NAP's categories. At the outset, MCCAA focused its implementation efforts on training and awareness campaigns. These mainly adopted the train the trainer approach in order to increase the outreach of these programmes. To this end, all four measures relating to training have been implemented, whilst one of the two measures relating to awareness campaigns is still in progress. Table 4 outlines MCCAA's initiatives, which have been implemented.

Table 4: Measures implemented pertaining to the training and awareness campaigns categories (December 2016)

Training	Information and Awareness campaigns
The MCCAA offers a number of courses to professional users of PPPs	Liaison with Government Entities such as Local Councils and schools to promote awareness and also participation in fairs, campaigns and media programmes
Offering training to distributors of PPPs by adopting a train the trainer approach	
Distributors of PPPs need to be certified by MCCAA	
List of authorised retailers	

3.2.6. The foregoing implies that MCCAA acknowledges that training as well as information and awareness campaigns constitute the foundations for ensuring that the further implementation of measures lead to the desired outcomes. MCCAA was the sole entity involved in the implementation of these measures.

Around two-thirds of measures related to pesticide application and monitoring must be implemented by 2018

3.2.7. Despite the progress achieved regarding training and awareness campaigns, developments relating to NAP measures on pesticide application and monitoring are ongoing but must be fully implemented by 2018. To date, MCCAA implemented 30 and 44 per cent of the 10 and 18 measures related to pesticide application and monitoring. Furthermore, 60 and 40 per cent of measures are works in progress respectively. The following concerns arise:

a. Delays in implementing these measures are tantamount to potentially increasing the risks of environmental and health hazards. This mainly results since the relative enforcement would not be up to the level envisaged by the NAP.

b. The NAP does not indicate implementation timeframes and consequently it is assumed that these measures are to be implemented by 2018 – the effective period of the Plan. However, this performance audit did not find any evidence that imply that these measures will be in place by this date.

c. Additionally, neither the NAP nor internal MCCAA documentation show that funds have been secured to enable the implementation of these measures. Until such time that budgetary allocations are available, MCCAA is not realistically in a position to plan the implementation schedule of these projects.

d. Since the implementation of measures constitutes an EU obligation under the terms of Directive 2009/128/EC, delays could be subject to penalties and / or infringement procedures outlined therein.

e. The NAP entrusts MCCAA with the responsibility of implementation of this Plan through collaboration with other national entities such as the Ministry for Resources and Rural Affairs[24], Plant Health Directorate and Mater Dei Hospital. To date such collaboration extended to the signing of the Memorandum of Understanding (MoU) between MCCAA and ARPA. Collaboration between these governmental entities with respect to the sustainable use of pesticides extends to ARPA notifying MCCAA regarding inspections undertaken at farmers' holdings benefitting from EU funding.

f. Similarly, MCCAA signed a MoU with the Water Services Corporation in 2016. Clauses therein enable MSD to carry out MRL testing at WSC facilities. However, to date, such a measure remains outstanding since the Water Services Corporation (WSC) is still in the process of obtaining accreditation of its laboratories for such a function.

The NAP does not clearly establish quantifiable goals

3.2.8. The delays in implementing the measures outlined in the NAP, in part, stem from deficiencies within the Plan itself. Generally accepted practices dictate that targets included in the plan should embrace the 'SMART' principle, that is, targets are to be specific, measurable, achievable, reachable and timely. The preceding paragraphs clearly show that the NAP contains a number of gaps, namely relating to quantifying objectives, identifying timeframes, allocating implementation responsibility as well as key performance indicators relating to outcomes. Specific outcome-related gaps within the NAP particularly relate to the rate and level of the use of pesticides.

[24] During 2013, the responsibilities under the remit of the Ministry for Resources and Rural Affairs were transferred to the Ministry for Sustainable Development, Environment and Climate Change.

3.2.9. The Pesticide Action Network (PAN) Europe affirms the situation depicted in the previous paragraph in its report entitled 'Reducing Pesticide Use Across the EU (2013)'. This report outlines that there is a lack of overall objectives in the NAP for pesticides reduction by the majority of Member States, including Malta. Moreover, there is a failure to set quantitative objectives, targets and clear timetables for pesticide-use reductions as foreseen in the Sustainable Use Directive on Pesticides (SUDP).

3.2.10. The PAN report outlines that Member States fail to set a goal for overall pesticide reduction. To this effect, the report notes that Malta's NAP does not set a clear overall quantifiable objective aiming at a percentage reduction of pesticide use over a specified period. Neither does it set a sub-objective of reducing for example MRLs in produce. With respect to implementation progress, the PAN Europe report outlines that the majority of Member States (MS) argue for implementation of the SUDP by stating that they are enforcing other EU laws such as MRLs in food without proposing any new actions.

3.2.11. Thus far, this Chapter discussed the MCCAA's role in implementing the NAP. This Plan mainly focuses on the strategic way forward to reduce and regulate the use of pesticides. The ensuing sections of this Chapter focuses on the operational aspects involved in ascertaining that pesticides placed on the market are appropriately regulated. The primary responsibilities of this function pertain to the MSD within the MCCAA.

3.3. MSD does not consider all risk variables when conducting its national annual programme of product surveillance

3.3.1. A number of factors, to varying degrees, influence the risks associated with the use of pesticides on agricultural produce. These factors range from the volume of the product placed on the market, the extent to which particular produce is conducive to retain an excessive amount of pesticide and the type of pesticide used with respect to climatic aspects, such as the level of precipitation. Moreover, the compliance history of producers also impinges on the resultant risks.

3.3.2. MSD does not utilise a formal risk assessment approach, that is, the risk variables mentioned in the preceding paragraphs are not allocated respective weightings. Consequently, MSD cannot be in a position to rank products in accordance with their risks and compile their annual national market surveillance programme accordingly.

3.3.3. MSD's approach to determine its surveillance programme is two pronged. Firstly, the Directorate seeks to determine agricultural produce that exceed the MRLs. This includes fulfilling EU Commission and European Food Safety Authority (EFSA) related obligations whereby EU Member States have to analyse pesticides residues on an obligatory sample of agricultural products. MSD marginally supplements this obligatory sample with additional surveillance activity. Secondly, MSD also seeks to identify non-compliant PPPs. The latter surveillance exercise encompasses the verification of safety information made available to

the consumer at the point of sale. This Section proceeds to discuss risk assessment related concerns with respect to these two initiatives.

Risk Assessment techniques concerning MRLs predominantly address EU wide concerns

3.3.4. As outlined in the preceding paragraph, MSD aims to fulfill EFSA-related obligations whereby EU Member States have to analyse pesticide residue on an obligatory sample of agricultural produce placed on the market. To this end, each EU Member State and European Free Trade Association countries participate in two pesticide control programmes, namely an EU-coordinated Control Programme (EUCP) and a National Control Programme (NCP).

3.3.5. The purpose of EUCP is to generate MRL exceedance data for food of plant and animal origin placed on the European common market, and which can be used to estimate the actual long-term consumer exposure of the European population. Discussions between the participating countries take into consideration the prevalent risks within each State. The evaluation of these risks lead to the selection of agricultural produce and respective quantities to be sampled by participating countries. While such a sample considers the various risks within each country, its main intention is the extrapolation of findings on a European level.

3.3.6. EFSA suggests that participating States undertake their respective national control programmes through a risk-based approach. The national control programmes are intended to be complementary to the random, non-targeted controls performed in the context of the EU-coordinated programme.

3.3.7. While acknowledging that MSD exceeds its EFSA obligatory testing, its sampling of local agricultural produce does not fully take into account the risk variables outlined in paragraph 3.3.1. MSD's sampling with respect to the national programme is primarily based on its officials' knowledge and experience. Furthermore, MSD experience a number of limitations to implement the NCP. These mainly relate to the absence of accredited laboratories in Malta as well as the administrative capacity and budgetary issues within the MCCAA.

3.3.8. MSD's sampling with regard to its National Programmes for 2014, 2015 and 2016 did not consider a number of product categories deemed as high risk. This can be seen through an evaluation of three critical risk variables, namely consumption of produce, product history on the basis of previously failed MRL tests as well as product risks as determined by influential agencies.[25] The following refers:

a. Based on the 10 most consumed agricultural products in Malta, during the period 2014 to 2016, MSD did not perform tests on watermelons, sugar melons and vegetable marrows. Furthermore, MSD did not sample any of the 10 most consumed products in consecutive years.

[25] Environment Working Group, USA.

b. Notwithstanding the circumstances of the preceding paragraph, MSD's risk analysis did not appropriately consider products' testing history. MSD's sampling pertaining to the national programme did not include any of the products that failed MRL tests in previous years. Products which failed the MRL tests included oranges, carrots, beans, spinach, cucumber, potatoes, sweet peppers and olive oil.

c. Influential agencies such as the Environment Working Group USA, listed a number of agriculture products that are considered as high risks in terms of pesticide residue. Out of the 12 top ranked products, over the three-year period under review, MSD did not test three of these products, namely celery, cherries and nectarines.

d. MSD's risk analysis is also subject to limitations when evaluating the potential risks posed by individual farmers. Malta's agricultural make-up consists of many farmers working small-sized parcels of land. MSD, however, is not in possession of an updated and comprehensive list of farmers. This state of affairs limits any risk assessment based on farmers and respective holdings.

e. Product traceability-related issues constrain MSD from inspecting produce, which is not labelled. This implies that MSD's coverage of MRL testing excludes a broad range and significant quantities of agriculture produce.

3.3.9. The above concerns, particularly (a) to (c), are based on the total number of products sampled for MRL purposes by MSD. These include 440 products sampled for EFSA purposes and 26 products sampled for the NCP under MSD's own initiative. The foregoing implies that MSD's priority with respect to MRL tests was to fulfill EFSA's obligations.

3.3.10. Despite the standard operating procedures and guidelines available to MSD, these documents only provide broad direction with respect to risk assessment and inspection targeting. Such circumstances reemphasise previous comments in this Report that MSD's officials' experience and subjectivity constitute the predominant basis of the Directorate's risk assessment.

3.4. Gaps exist within the inspection regime of pesticides

3.4.1. MSD's remit regarding pesticides extended to the verification of PPPs placed on the market and the testing of samples for maximum residue levels. During the period 2014 to 2016, MSD carried out eight inspections and reviewed 82 PPPs, however none were carried out during 2015. It is to be noted that ARPA also carried out PPP inspections in conjunction with its remit relating to EU agriculture funding programmes. Nonetheless, despite ARPA's PPP inspections, the absence of MSD enforcement action suggests that more than 50 per cent of registered farmers remain outside the enforcement scope stipulated by the NAP.

3.4.2. MSD contends that such a situation materialised due to a lack of resources. The Directorate also noted that since the 2014 inspections did not reveal any major shortcomings, it was probable that PPPs placed on the local market at the time posed minimal risk.

MSD is predominantly targeting products sold through the Pitkali and Farmers' markets

3.4.3. During the period under review, MSD also carried out 65 visits at the Pitkali and Farmers' markets as well as importers of agricultural produce. On evaluation, it transpires that the MRL inspection regime focuses only on specific market segments and on traceable produce.

3.4.4. The number of MRL inspections increased from 16 to 18 visits between 2015 and 2016. Nevertheless, these remain just over half of the MRL visits carried out by MSD in 2014. During such visits, MSD randomly targeted economic operators mainly through the Pitkali and Farmer's markets. Additionally, the Directorate also targets imported agricultural produce including in supermarkets. MSD records show that around one third of the sampled produce was imported.[26] Figure 5 presents an overview of MSD's initiatives relating to MRL inspections.

3.4.5. During the period under review, MSD tested 16 out of the 30 fruit and vegetables considered by the National Statistics Office among the most consumed products locally. These figures show that MSD managed to test just over half of the most consumed products locally.

MRL inspections focus on agricultural produce where the production source can be validated

3.4.6. Product traceability is a business process that enables trading partners to follow products as they move through the supply chain. Traceability protects consumers through faster and more precise identification of products. This is critical if a non-conforming product is to be withdrawn from the supply chain. MSD encounters considerable traceability related problems, which impinge negatively on its enforcement role.

3.4.7. Proving the source of origin is a complex task since it involves validating information relating to:

a. trading parties that is the suppliers, retailers and any third party carriers;
b. trading locations such as warehouses, packing line and receiving dock;
c. the products the supplier produces; and
d. the distribution logistics, including inbound shipments in cases of imports.

[26] The lack of data with respect to MRL visits and the classification of agriculture produce hindered a more comprehensive analysis in this regard.

Figure 5: MRL regulatory inspections (2014 – 2016)[27]

[27] Detailed MRL information for 2016 was not available at the drafting of this Report.

3.4.8. Despite the provisions stipulated in EC Regulation 1308/2013 and LN 109 of 2015 (Supplies and Services Act) which caters for product traceability in terms of country of origin, class, variety or commercial type, many products within the local market fail to comply. Traceability matters become more complex due to the common practice of products being sold directly by farmers to consumers. Moreover, the small retail outlets, including hawkers, which characterise the local industry, further pose traceability related concerns. The National Agricultural Policy for Malta, which is currently at the public consultation phase, notes that traceability at the production and retailing stage is not always being provided, with the majority of consumers basing their trust on the person, be it the farmer at the market or the street hawker, rather than on the information printed on the label.

3.4.9. Additionally, there is no mechanism in place at the Pitkali to guarantee traceability of produce passing through this market.[28] MSD mitigates such circumstances by inspecting produce just before it enters the Pitkali market.

3.4.10. The foregoing prevails despite that traceability constitutes one of Malta's obligation concerning Marketing Standards as per EC Regulation 1308/2013, which is mandatory for all marketed fresh fruit and vegetables. Legal Notice 109 of 2015 (Supplies and Services Act) was published and is currently in the initial period of its implementation phase by the Directorate of Agriculture who are introducing obligations with producers and processors. These standards oblige producers, processors and retailers to follow established benchmarks on labelling, traceability and food presentation to ensure fair trade across the marketing chain.

3.4.11. Non-traceable products raise legal concerns for MSD. Such issues mainly arise when the Department is compelled to take enforcement action due to MRL-related irregularities. The risk exists that MSD could be held liable if an economic operator proves that the produce ordered to be withdrawn from the market had a different source of origin than that contended by the Directorate.

3.4.12. Product traceability concerns also pose operational complexities for MSD. MSD focuses its MRL inspections at produce where traceability can be validated. This implies that MSD is excluding a significant number of retail outlets, including hawkers from its MRL testing. To varying degrees, MSD is taking this approach since it has no mechanisms or internal policies relating to the course of action to be adopted by the Directorate if it detects MRL-related irregularities on produce of unknown origin. Traceability-related concerns mainly arise through the following:

a. To date, a sustained national enforcement campaign relating to marketing standards, which includes product traceability is yet to be conducted. National Authorities are fully cognisant of this situation, and to this end, the Draft National Agricultural Policy for

[28] Ministry for Sustainable Development, the Environment and Climate Change (2016). *National Agricultural Policy for the Maltese Islands 2016 – 2025*: *Issues Paper*, page 3.

Malta outlines that the Agricultural Directorate was scheduled to start an enforcement campaign in this regard by the second half of 2016. Since this policy is still in draft form, this milestone has already been exceeded.

b. Malta is still in the process of implementing integrated pest management. Consequently, the absence of such management systems further inhibits reliable audit trails associated with traceability. To date, MCCAA published guidelines and delivered courses aimed at professional users of pesticides. However, on a national level, there exists a shortfall of specialised human resources in this field. Moreover, MCCAA is still in the process of securing funds to enable the implementation of pest management in accordance with the provisions of the NAP.

3.5. Testing procedures in place do not ascertain that contaminated agricultural produce is withdrawn from the market prior to consumption

3.5.1. The absence of accredited laboratories in Malta is a critical element influencing MSD's logistical arrangements to test the samples of agricultural produce collected during inspections. Consequently, MSD has contracted laboratories abroad to perform such testing.

3.5.2. The Directorate, during the period under review, on average collected samples of agricultural produce about a month prior to testing. Until such time that MSD officials personally deliver the samples to an accredited laboratory abroad, the Directorate ensures that samples remain preserved through freezing. MSD contends that the Directorate would like to solve as quickly as possible the issues whereby its personnel are acting as couriers for delivery of samples. However, to date the Directorate is contending that hand-to-hand delivery is the only means to ensure both traceability and the qualitative state of the product to primarily satisfy legal requirements.

3.5.3. During 2014, 2015 and 2016 MSD received the laboratory test results on average 29, 21 and 40 days following submission. This implies that by the time MSD is informed whether or not the product complies with stipulated MRLs, consumption of the product would have continued to the possible detriment of consumers' health.

3.5.4. MSD maintained documentation show that as an absolute minimum, the contracted laboratory will only be able to provide test results within three to four days. Such a scenario, however, would only materialise if National Authorities have reasonable doubt that the samples are critically suspect, and that the contracted laboratory has testing slots available. The foregoing suggests that even if this minimum lead-time was secured, consumers would have possibly been at risk since MSD would not have withdrawn the product batch from the market.

3.5.5. Another consideration relates to the non-availability of cold storage with the appropriate capacity to store batches while the relative samples are undergoing tests. Nevertheless, the storage of produce while testing is being undertaken raises economic concerns, since such action implies that the produce is not available on the market when it is at its prime condition. Moreover, not all types of agricultural produce lend itself to cold storage. There could also be legal implications since MSD could be held liable if test results reveal that the produce was in conformity with standards and regulations.

3.5.6. The foregoing presents a complex situation for MSD. The Directorate exposes itself to legal action if it is proven that a product was withdrawn from the market unnecessarily. Prohibiting the sale of produce while testing is ongoing increases storage costs and is financially detrimental to economic operators. Nevertheless, MSD contends that the primary aim of such an exercise is to act as a deterrent for economic operators. The status-quo, on the other hand, results in consumers being possibly placed at risk through the availability on the market of untested products.

3.5.7. Such a situation mainly results since non-compliant produce is not being detected and withdrawn whilst still at source, that is, at the farmers' holdings. This Chapter elicited a number of issues concerning MSD's processes relating to excessive MRLs. Nonetheless, the reduction of lead times to a minimum would not ensure the withdrawal from the market of non-compliant products. Such circumstances demonstrate a gap in the enforcement regime as MRL testing is not being undertaken while products are still at the farmers' holdings. To this end, there are no effective mechanisms in place to coordinate National Entities' efforts, namely MSD, Ministry for Health and Department of Agriculture. Consorted efforts in this regard are currently experiencing delineation concerns regarding respective jurisdictions.

Some clauses within the current contract for MRL testing do not appropriately address MSD requirements

3.5.8. During the period under review, MSD incurred an estimated annual cost of €42,534 for MRL-related laboratory tests. The cost of each sample tested ranged from €136.68 to €283.56. These costs are in accordance with the provisions of the contract between a foreign accredited laboratory and MCCAA. The parties belatedly signed this contract in April 2016, which is effective for the period 2015 to 2017. The number of samples to be tested through this contract is equivalent to those required under the Commission Implementing Regulation No. 400/2014.

3.5.9. To varying degrees, MSD interests are not appropriately safeguarded through the following clauses and ensuing implications:

a. The Contract obliges that samples are to be personally delivered by MSD officials. MSD contends that this approach ensures product quality and traceability for testing purposes as well as satisfying legal requirements. This implies additional costs than if

MSD was to engage a courier service. Moreover, the deployment of staff to perform these duties further depletes MSD's resources, which would otherwise be engaged in initiatives related to the Department's core functions.

b. The Contract stipulates that test results must be delivered within 15 days unless otherwise stated. This raises two issues. Firstly, within such a lead-time many products would have been consumed. Secondly, the contract does not cater for urgent requests by MSD and the respective variation in costs.

c. The Agreement does not cater for the eventuality that the contractor is unable to fulfill contractual obligations through either a force majeure or any other cause. To this effect, the contract does not define Parties' responsibilities in such cases.

d. The Contract omits references relating to the availability of Contractor's personnel if required to present evidence during Court proceedings.

e. The contract does not contemplate administrative fines or penalties in cases of contract breaches. In this regard, during 2016, MSD was not in a position to take the necessary action against the contractor even though 81 per cent of the samples' results were delivered after the 15-day timeframe stipulated by the contract.

3.6. Follow-up action of non-compliance is limited

3.6.1. The Pesticides Control Act states that the Director Technical Regulations Division (TRD) within MCCAA is responsible for MSD initiatives, and is obliged to the take actions deemed appropriate should PPPs and MRL samples analysed fail compliance testing. Additionally, this Act stipulates that non-compliant produce must be withheld from consumption or use.

3.6.2. Nonetheless, MSD is not fully adhering to the provisions noted in the preceding paragraph due to the following:

a. In view of the lead-time required for laboratory testing, it is reasonable to assume that most of the produce exceeding MRL levels would have been consumed. Consequently, follow-up action envisaged by MSD would only relate to initiating legal action against the economic operator. This reemphasises the point outlined in paragraph 3.5.7 which highlighted that currently MRL testing by National Entities does not extend to comprehensive cover products available at farmers' holdings. The current lack of coordination between National Entities does not guarantee the non-consumption of contaminated agricultural products.

b. Additionally, MSD did not ensure that products failing MRL testing were actually withdrawn from the market. MSD's follow-up action extended only to notifying the Pitkali and Farmers' markets as well as importers to ascertain that these entities take

the necessary action following notification of non-compliant products. MSD, although legally responsible, does not have any evidence to determine whether or not the economic operator disposed of any non-compliant product.

c. During the three-year period reviewed, MSD did not follow up action through a subsequent inspection targeting economic operators whose produce failed MRL tests. This state of affairs is further evidenced since none of the economic operators who had legal action instituted against them were targeted with subsequent sampling.

d. During 2015 and 2016, MSD did not carry out PPP inspections. Consequently, MSD did not follow-up any of the economic operators who placed substandard products on the market during 2014.

Most of the economic operators arraigned in Court for MRL related cases between 2014 and 2016 were acquitted of charges

3.6.3. MSD's legal mandate outlines that economic operators whose produce failed MRL tests are to be arraigned in court. Nonetheless, MSD records show that the Directorate is still to conclude its legal actions with respect to 22 economic operators whose sampled produce failed MRL tests during 2015 and 2016. At the time, MCCAA was experiencing a high turnover within its legal section.

3.6.4. During the three years under review, on the basis of MRL inspections at the Pitkali and Farmers' markets, MSD initiated Court proceedings against 15 economic operators. The produce involved in these cases included potatoes, peaches and cabbages. Information forwarded to the National Audit Office (NAO) indicated that the Courts dismissed 14 cases on the basis of the following:

a. On eight occasions, the Courts dismissed the case as witnesses summoned to testify on test reports produced by MSD contracted accredited laboratory could not be traced. This situation materialised as the then contracted laboratory had wound up its operations.

b. In one case, the Courts dismissed the case since the MRL test results produced as evidence emanated from a local laboratory, which was not accredited to perform such tests.

c. The Courts dismissed the remaining four cases.

3.7. Conclusions

3.7.1. The unregulated use of pesticides is harmful to human health and the environment. This Chapter focused primarily on MSD's initiative to ascertain that PPPs and agricultural produce placed on the market comply with regulations. Admittedly, this is a narrow scope, which deals with one aspect of a complex topic. Nonetheless, the discussion herein raised a number of concerns, which ultimately can impinge on consumers' health, the environment and stakeholders within the agriculture industry.

3.7.2. MSD's contention that it lacks the adequate administrative capacity to fulfill its remit influenced its logistical and operational approaches. Nonetheless, the Directorate forfeited the opportunity to implement risk analysis approaches more rigorously to enable it to focus on high-risk areas. This performance audit also showed that while inspection targeting address EU requirements, it is not appropriately broad to cover the diverse range of local and imported produce.

3.7.3. Additionally, the Directorate's enforcement processes are not in full synchronisation as the lead-time for laboratory testing and reporting does not permit MSD to withdraw non-compliant products from the market in time to minimise the risk of consumption of such produce. The circumstances noted in this paragraph materialise through a number of technical, legal, administrative and infrastructural factors.

3.7.4. Product traceability does not only pose technical complexities but also raises legal problems. The legal implications of product traceability expose MSD to liability proceedings. In such a situation and the current operational environment, MSD faces a choice. Firstly, the Directorate can focus its enforcement action solely on traceable goods to the detriment of the other produce, which possibly poses a higher risk of contamination. Alternatively, MSD can broaden its inspection base to include all produce but risk the possibility of liability claims. Unfortunately, neither option fully safeguards consumers' interests.

3.7.5. The absence of effective coordination between National Entities is forfeiting the opportunity for inspections to be carried out at farmers' holdings prior to produce being placed on the market. In view of its remit, MSD's current approach is mainly intended to deter future irregular use of pesticides. However, this approach does not fully cater for the timely withdrawal of contaminated goods since currently inspections at farmers' holdings target economic operators who are benefitting from EU funds, which accounts to around half of the farming population. In part, such a situation is currently being addressed through the recently published policy entitled 'Improving Business Inspections'. This policy aims to synergise the efforts of various governmental entities in regulating the use of pesticides and the residual limits on agricultural produce. Moreover, this policy also seeks to limit the cost of compliance of economic operators through the coordinated action of regulatory agencies.

3.7.6. Infrastructural gaps also influence the situation depicted in this Chapter. MSD lacks an adequate IT infrastructure, which integrates all of its data and activities. On the other hand, Government lacks cold storage facilities that can also be available to economic operators. This infrastructural lacuna coupled with Malta's climatic environment is driving producers to preserve their produce with pesticides.

3.7.7. The concerns presented in this Chapter are to varying degrees noted in the Draft Agricultural Policy, which is currently at the public consultation phase. The main conclusion drawn therein is similar to the one elicited through this performance audit, that consumers' and economic operators' interests are not appropriately safeguarded through an integrated approach involving industry stakeholders as well as regulators.

Appendix 1

Summary of economic operators' obligations emanating from the Safety of Toys Directive 2009/48/EC

<table>
<tr><th>MANUFACTURER</th><th>IMPORTER</th><th>DISTRIBUTOR</th><th>REPRESENTATIVE</th></tr>
<tr><td>Design and manufacture in accordance with essential safety requirements</td><td>Only place compliant toys on the market</td><td>Act with due care</td><td rowspan="3">No obligation</td></tr>
<tr><td>Draw up technical documentation</td><td rowspan="2">Ensure the technical documentation has been drawn up and the conformity and safety assessments have been carried out</td><td rowspan="2">No obligation</td></tr>
<tr><td>Assess the conformity of the toy and carry out safety assessment</td></tr>
<tr><td>Keep the technical documentation for ten years after placing on the market</td><td colspan="2">No obligation</td><td>Keep the technical documentation for ten years after placing on the market</td></tr>
<tr><td>Upon reasoned request from an authority, make available the technical documentation to that authority</td><td colspan="3">Upon reasoned request from an authority, ensure the technical documentation can be made available to that authority</td></tr>
<tr><td>Draw up the EC declaration of conformity</td><td colspan="2">No obligation</td><td>Draw up the EC declaration of conformity</td></tr>
<tr><td colspan="2">Keep a declaration of conformity and have it available for the authority for ten years after placing on the market</td><td>Make it available upon reasoned request from an authority</td><td>Keep a declaration of conformity and have it available for the authority for ten years after placing on the market</td></tr>
<tr><td>Affix CE marking and identification: type, batch, serial or model number</td><td>Ensure the CE marking, the type, batch, serial or model number are affixed</td><td>Verify the CE marking, the type, batch, serial or model number are affixed</td><td>Affix CE marking and identification: type, batch, serial or model number</td></tr>
<tr><td>Ensure conformity of series production</td><td colspan="3">No obligation</td></tr>
<tr><td colspan="2">Add name and address</td><td>Verify the name and address is present</td><td>Add name and address only if manufacturer is outside EU</td></tr>
<tr><td colspan="3">Ensure the required documents accompany the toy in the correct languages</td><td rowspan="4">Depends on the written mandate</td></tr>
<tr><td colspan="2">Bring non-conforming toys into compliance. Inform authorities if there is a safety risk. Recall or withdraw. Provide information to the authorities on request</td><td>Ensure non-conforming toys are brought into compliance</td></tr>
<tr><td colspan="2">Sample test marketed toys (taking into account risk)</td><td rowspan="2">No obligation</td></tr>
<tr><td colspan="2">Keep register of complaints, non-conforming toys and recalls. Inform distributors of this monitoring</td></tr>
<tr><td colspan="3">Ensure that conditions of storage and transport do not impact the toy's compliance with the requirements (not an obligation for manufacturers, but they should bear that in mind)</td><td rowspan="2"></td></tr>
<tr><td colspan="3">Identify the other economic operators in each toy's supply chain</td></tr>
</table>

Source: Toy safety in the EU – A practical guide to the legal obligations of Manufacturers, Importers and Distributors, European Commission (EC) and Toy Industries of Europe (TIE).

Appendix 2

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