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An Assessment of the Regulatory Powers of the National Agency for Food and Drugs Administration Council in the Protection of Consumers of its Regulated Products in Nigeria

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I. INTRODUCTION

a) *The National Agency for Food and Drug Administration Control Act*¹

This is the enabling law for the regulation of the manufacture and sales of food and drugs in the country. The importance of food and drugs to a man and animal is obvious. Access to good quality food and drug is the basis of human survival. Accordingly, it is the duty of a responsible government that its citizenry get quality food and drugs.

Government's response to these challenges was the establishment of the Department of food and drugs as an arm of the Federal Ministry of Health. However, the enormity of the challenges faced by this ministry was not met and there was the desire for a more pragmatic solution to this problem. A learned author subsumes the problems faced by the then Department of Food and Drugs to include the following;

- a) Slow mobilization of ideas, men and materials for productive work.
- b) Inadequate resource acquisition and management.

- c) Slow disciplinary and poor reward system and management
- d) Poor funding of activities necessary for effective design and management.²

It is against the background of the perceived failure of the law as it stood then that necessitated the need for the enactment of the National Agency for Food and Drug Administration and Control Act. The fundamental objectives behind the Act is well articulated in its long title which provides that the Act is 'to establish the National Agency for Food and Drug Administration and Control with the functions among others to regulate and control the importation exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled waters and chemicals.'³

b) *Historical Antecedents to the Establishment of the Agency*

The Agency is now the sole body regulating and controlling the manufacture, importation, exportation, advertisement, distribution, sale and use of drugs, cosmetics, medical services, chemicals and locally produced water. It remains a parastatal under the supervision of the Federal Ministry of Health and came into force on the 1st of January 1994.

The Agency was established in response to the resolution of the World Health Assembly declaration of 1988 which laid down the blue print for combating the menace of fake drugs and products in the market place. The Agency replaced the hitherto body known as the Directorate of Food and Drug Administration and Control which was then a department under the Federal Ministry of Health. This Department had its shortcomings traceable to the limited scope of its

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¹ Cap N1, Laws of the Federation of Nigeria, 2004

² See Muhammad TaofikLadan. "The Limits of Legal and Enforcement/Regulatory Frameworks in Consumer Protection Against Counterfeit and Pirated Products; The Nigerian Experience" Being a paper Presented at The Global Conference on Counterfeit and Pirated Products; 3rd-6th February 2008, Dubai, U.A.E ; Page 32

³ The National Agency for Food and Drugs Administration Control shall hereinafter be referred to as the 'Agency'

⁴ For additional information visit www.nigeriafirst.org accessed on 30/08/2011

enabling law as well the lack of independence in the discharge of their functions.⁵

It was in response to these problems that the Agency was established pursuant to the enabling law in 1994. It was in 1992 that the maiden governing Council of the Agency was inaugurated with the then Ambassador Tanimu Salauwa as the chairman and Professor G. E. Osuide as the pioneer Director-General. At its inception, the Agency was charged with the responsibility of changing the bad image of the country in the international world as the leading base for fake and adulterated drugs and food products. To this end, the Agency was divided into six directorates to wit. Registration and Regulatory affairs, Inspectorate, Laboratory Services, Narcotics, Planning Research and Statistics, Finance and Administration. It was through the co-ordination and Complimentary efforts of these inspectorates that the Agency proceeded to reverse the trend of food and drug Administration in the country.

However, in 2001 there was a change at the helmsman ship of the Agency with the appointment of Professor Dora Akinyuli as the Director-General. In an attempt to reinvigorate and re-focus the Agency, additional inspectorates were created; these include the Registration and Regulatory Affairs, Laboratory Services, Narcotics and Controlled Substance, Planning Research and Statistics, Administration and Finance, Ports Inspection, Establishment and Enforcement. These new inspectorates expanded the frontiers of the scope of the Agency and made the implementation of its set objectives less strenuous.⁶

In addition to these new inspectorates, additional inspectorate offices were established in all the thirty-six states of the Federation. Three special inspectorate offices, six zonal offices and three narcotics offices were introduced. These structural changes and the expansion of the powers of the Agency set the basis for its improved services in last ten years.⁷

c) *Statutory Functions of the Agency*

The Agency at its inception was trusted with enormous responsibilities aimed at ensuring the safety of the consumer with respect to his consumption of food, drugs and related products. Specifically by the tenor of this Act, the Agency is entrusted with the following functions:

1. To regulate and control the importation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water and chemicals.
2. Conduct appropriate tests and ensure compliance with standard specifications designated and

approved by the council for the effective control of the quality of food, drugs, cosmetics, medical devices, bottled water and chemicals as their raw materials as well as their production process in factories and other establishments.

3. Undertake appropriate investigations into the production premises and raw materials for food, drugs, cosmetics, medical device, bottled water and chemicals and establish relevant quality assurances systems including certificates of the production sites and of the regulated products.
4. Undertake inspection of imported foods, drugs, cosmetics, medical devices, bottled water and chemicals and establish relevant quality assurance systems including certification of the production sites and of the regulated products.
5. Compile standard specifications and guidelines for the production, importation, exportation, sale and distribution of food, drug, cosmetics, and medical devices.⁸

In order to empower the Agency to carry out these enormous functions creditably, there is established for the Agency Supervisory Council. This Council is entrusted with the responsibility of formulating policies geared towards the implementation of the functions of the Agency as highlighted above. The Council is equally mandated to advise the Federal government on issues pertaining to the formulation of National policies on the control, quality, and classification of food, drugs, cosmetics, medical devices, bottled water and chemicals. The Council is the governing body of the Agency and it is therefore charged with the responsibility for the recruitment, remuneration, training and discipline of staff of the Agency.⁹

With respect to the organizational structure of the Agency, it is headed by a Director-General who is appointed by the president. Such a person is expected to have a good knowledge of pharmacy, food and drugs.¹⁰

There are additional provisions dealing with the removal and discipline of staff of the Agency and the funding of the Agency.¹¹ With respect to the finances of the Agency, elaborate provisions have been made to ensure that the Agency is adequately funded and that it has some measure of financial autonomy. Interestingly, their internally generated incomes are exempted from tax and are construed as deductible expenses. This palpably to ensure that the Agency is not handicapped

⁵ See further www.nigeriafirst.org accessed on 30/08/2011

⁶ www.nigeriafirst.org ibid

⁷ As shall be seen shortly, the Agency has been in the fore front of the prevention of fake, adulterated, fake and sub-standard food and drug products in the country.

⁸ See Section 5(a)-(t) of the Act which was reproduced herein for emphasis.

⁹ See Sections 6(a)-(j) and 7 of the Act

¹⁰ See Sections 8 and 9 of the Act

¹¹ See Sections 11 and 12 of the Act

by paucity of funds in the discharge of the enormous duties placed on it.¹²

In an attempt to delineate the scope of the regulatory powers of the Agency, the Act defines the specific products within the jurisdiction of the Agency. Accordingly, the Act defines "drug" to include 'any substance of vegetable, animal or mineral origin or any preparation or mixture thereof manufactured, sold or advertised for use in (i) the diagnosis, treatment, mitigation or prevention of any disorder, abnormal physical state or the symptom thereof, in man or animal (ii) restoring, correcting or modifying organic functions in man or in animal (iii) disinfection or the control of vermin or pests or (iv) contraception'.¹³

On the other hand, "medical device" is defined as any instrument, apparatus or contrivance (including components, parts and accessories thereof) manufactured, sold or advertised for internal or external use in the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof in man or in animal.¹⁴

The Act equally avoided a possible problem that would be associated with the definition and scope of these words by giving a broad definition of the term 'Regulated Products' to mean food, drugs, cosmetics, medical devices, detergents, bottled water and chemicals.¹⁵

It would appear therefore, that the expanded scope of the products to be regulated by the Agency has often being the source of conflict between it and sister Agencies.

It must be noted that the regulatory powers of the Agency are not entirely encapsulated by the Act; so much has been left for Subsidiary Legislations in the form of Regulations.¹⁶ Accordingly, the Council is empowered to make Regulations for prescribing the methodologies for private sector payments into the funds of the Agency, to prescribe the fees to be paid for services rendered by the Agency and generally for the purposes of carrying out or giving effect to the provisions of this Act.

d) *Specific Powers of the Agency*

As highlighted earlier the powers of the Agency are subsumed in the plethora of subsidiary legislation which addresses specific aspects of its functions. However, Section 24 of the Act subsumes the powers of

its implementation of these functions by providing inter alia

Section 24;

1. "An officer of the Agency may in the course of his duty, at any reasonable time and upon the presentation of his certificate of designation if so required,
 - a) Enter(if need be by force) any premises in which he reasonably believes any article to which this Act or Regulation apply is manufactured, prepared, preserved, packaged, stored or sold
 - b) Examine any article in the premises which appears to him to be an article which this Act or the regulations apply or anything in the premises which he reasonably believes is used or is capable of being used for the manufacture, preparation, preservation, packaging, storage or sale of any such article
 - c) Take a sample or specimen of any article to which this Act or the regulation apply or which this Act or the regulations apply or which he has power to examine under paragraph(b) of this sub-section
 - d) Open and examine, while on the premises, any container or package which he reasonably believes may contain anything to which this Act or regulations apply or which may help in his investigation
 - e) Examine any book, document or other record found on the premises which he reasonably believes may contain any information relevant to the enforcement of this Act or the regulations and make copies thereof or extract there from and
 - f) Seize and detain for such time as may be necessary for the purpose of this Act any article by means of or in relation to which he reasonably believes any provision of this Act or regulations has been contravened".¹⁷

In order to streamline the powers of the Agency with regards to its powers to regulate the articles or products; Section 24(5) of the Act gives an expanded definition of 'article' to include the following;

- a) "Any food, drug, cosmetics, medical devices, bottled water or chemical
- b) Anything used for the manufacture, preparation, preservation, packaging or storage of any food, drug cosmetics, medical device bottled water or chemical and
- c) Any labeling or advertising material relating to or for use in connection with any food, drug, cosmetics,

¹² See Sections 13-20 of the Act .Additional powers is conferred on the Agency to borrow money and /or accept gifts from individuals or institutions provided the acceptance of such gifts would not compromise it in the discharge of its functions; See Sections 23-24 of the Act.

¹³ See Section 31 which is the interpretation section of the Act.

¹⁴ *ibid*

¹⁵ There is an increasing overlap between NAFDAC, Standard Organization of Nigeria and the Consumer Protection Council in the discharge of their respective duties.

¹⁶ See Section 30 of the Act

¹⁷ See Section 24(2)-(4) of the Act , specifically Sub-Section 3 which makes additional provisions with regards to the powers of the Agency to seize any offending product and subject same to laboratory analysis before returning same to the owner if it is discovered that the article or product conform with the requirements of the Act and the enabling regulations.

medical device, bottled water or chemicals but does not include live animals.”

Having laid down the powers of the Agency and the procedure for exercising same, the Act further made elaborate provisions for the punishment for offences committed by any individual or body corporate. There are litanies of punishment ranging from fines, imprisonment and/or destruction of the offending product or article.¹⁸ There are equally elaborate provisions on the Courts with requisite jurisdiction for the enforcement of the provisions of the Act, the powers of the officers of the Agency as well as the trial and conviction of offenders.¹⁹

e) *Contextualizing the Focus of the Agency*

With the wide range of powers given to the Agency as well as its enormous functions it becomes necessary to attempt a delimitation of the specific focus of the Agency in order to appreciate its efforts at discharging its responsibility. The need for delimitation is also necessary in view of the expanded mandate of the Agency which has often brought it in conflict with similar Agencies.

It must be asserted that by a community reading of all the sub-sections of Section 5 of the Act as highlighted earlier, it is not in doubt that the Agency is expected to focus on the regulation of Food, Drugs and water. Accordingly, all references to Medical devices, Chemicals and Cosmetics should be construed in the context of Drugs.²⁰ This argument brings to for the relevance of the Food and Drugs Act in determining the Scope of powers of the Agency. To the extent that the Agency is expected to administer the provisions of this Act supports the view that it should concentrate on Food and Drugs principally. As observed by a notable commentator, the only addition to the Powers of the Agency in the context of the *NAFDAC* Act is the inclusion of the regulation of water.²¹ It is the authors contention that to the extent that the *NAFDAC* Act does not create specific offences relating to Food and Drugs apart from

the general provision of Section 24 therein, it means that the specific offences created by the Food and Drugs Act should be a benchmark for delimiting the scope of powers of the Agency.²²

The impression created from the scenario is that the Agency is purely regulatory and supervisory and not really an enforcement Agency. A learned author summarizes the scope of the Agency's regulatory powers in the following terms;

The complaint of *NAFDAC* is fluid and one wonders whether consumers should be faulted in the manner *NAFDAC* has made out. To Okwuraiwe, 'it is important to state that *NAFDAC*'s mandate incorporates measures that protect consumer's health in particular and public health in general. But *NAFDAC*'s is not empowered to pursue measures, legal or otherwise to obtain redress for the consumer whenever he is dissatisfied or injured by the use of regulated product.²³ Having underscored the relationship between the *NAFDAC* Act and the Food and Drugs Act, it is necessary to expatiate on the nature and scope of offences created under the Food and Drugs Act, in order to fully appreciate the how the Agency has fashioned its regulatory and supervisory powers in the prevention of these offences and/or prevention of same.²⁴

Section 1 of the Food and Drugs Act creates the offences of the sale, manufacturing, importation as well as the storage of food, drugs, cosmetics and related devices that contain poisonous substances or that are harmful to consumers, that is unfit for human consumption, that is filthy, disgusting, rotten or diseased, that is adulterated, that is sold under insanitary conditions.²⁵

It is within the context of the definition of these specific powers that the regulatory powers of the Agency under reference can be appreciated. For example what amounts to poisonous food? This is definitely a question bothering on scientific analysis and proof. Whilst a legal definition of poison and poisonous food or substances can be attempted, it is however the duty of *NAFDAC* to use its regulations to set the standards for what amounts to poisons or poisonous

¹⁸ See Section 25 (1) –(4) of the Act which encapsulates these penalties, of note is Sub-section 1 thereof which makes it an offence for any person to obstruct any officer of the Agency in the performance of his duties under section 24 of the Act. The penalty for this offence upon conviction is N5,000 or imprisonment to a term of 2 years or both. The appropriateness of this sanction amongst others would be examined shortly.

¹⁹ See Section 25(5) which confers exclusive jurisdiction in the matters aforesaid on the Federal High Court. Furthermore, Section 25A –26 make elaborate provisions on the procedure for the commencement and sustenance of legal proceedings in relation to matters connected with the Act. As would be seen shortly, problems of technicalities and procedural bottlenecks may slow down the pace of the activities of the Agency.

²⁰ The definition given to the term 'Regulated Products' under the Act supports this view. In addition the *ejusdem generis* rule of construction would permit of such interpretation.

²¹ See Felicia Monye "Legal Restrictions on the Manufacture, Sale and Advertisement of Drugs in Nigeria" *Modern Practice Journal of Finance and Investment Law*; 2 no.4(1998):152-164 at page 160

²² See Sections 1-3, 5-6, 11-12 of the Act which makes elaborate provisions for specific offences under the Act. Section 17 thereof provides for specific penalties for contravention of these provisions.

²³ See Kanyip 'Consumer Protection Law' 310. The learned author was relying on the views of P.EOkwuraiwe, an Assistant Director, Regulatory/ Consumer Affairs of *NAFDAC*, in his paper 'Regulatory Role of Government Agencies in Consumer Protection-*NAFDAC* perspective ' Presented at a Nigerian Institute for Advanced Legal Studies Roundtable on Consumer Protection Laws in Nigeria held in Lagos in December 3rd 1996.

²⁴ It must be noted that the usual vices fought consistently by *NAFDAC*, for example counterfeiting of drugs and food products, Adulteration of Food and drugs, Sale of expired food and Drugs amongst others can be subsumed in these offences under the Food and Drugs Act.

²⁵ See Section 1(1)-(5) of the Food and Drugs Act

food or substances. It is equally the responsibility of NAFDAC through their various laboratories to carry out investigative analysis in determining when a food or drug contains poison or poisonous substance. As a starting point the Black Law's Dictionary defines poison as a 'substance having inherent deleterious property which renders it when taken into the system capable of destroying life. A substance which on been applied to the human body internally or externally is capable of destroying the vital functions of the human body.'²⁶

Accordingly, it is in the context of the aforesaid, that NAFDAC Regulations prohibit the use of excessive additives, colourings and preservatives in food and drugs substances. It is therefore arguable that excessive additives or colourings in food and drugs could be construed as poisons or poisonous substances.²⁷

In the same vein there are legal issues pertaining to the definition of food 'unfit for human consumption'. It could be assumed that any food that contains poisonous or noxious substances would be unfit for human consumption. In the same vein, any food containing deleterious or strange substances whether poisonous or not would naturally be unfit for human consumption. It does appear that food or drink items containing such items as decaying tooth, bark of trees, decomposing snail amongst others are unfit for human consumption.²⁸

In the context of the regulatory efforts of the Agency, it would appear that it would be rarely be able to pre-empt or intercept such food or drink substances containing such deleterious or strange substances unless it (Agency) goes beyond its inspection of the manufacturing and packaging processes of these food and drinks. The Agency would have to be more proactive in its monitoring of the distribution process to pre-empt the incidences of such complaint of food or drinks containing such strange substances. The problem may be more overwhelming when it is one off incidence as in one bottle in twelve crates of soft drinks containing the offensive substance.

It can be asserted therefore that once the Agency certifies the production process of the food and drinks, and certifies the raw material content of samples of the food or drink, it would rarely be expected to examine every bottle, carton or crate of the food or drink to determine the incidence of the presence of these offensive substances. Accordingly, the civil rights of the

consumer as premised in the law of Torts and Contract would appear to be preferable in the circumstances. Criminal prosecution would be at the discretion of the Attorney-General if a prima facie case of violation of the provisions of the Food and Drugs Act is made out.²⁹

In any case, it has been held in some English cases that the presence of deleterious substances in food and drinks is not ipso facto evidence that the food or drink is unfit for human consumption

In *J. Miller Ltd v. Battersa Borough Council*,³⁰ a chocolate bun containing a piece of metal was not necessarily unfit for human consumption. Accordingly, the court reached a verdict of not guilty in favour of the Appellant who had been charged under Section 9 of the Food and Drugs Act of U.K 1938.³¹ Similarly, in *Turner & sons Ltdv. Owen*,³² the English Court of Appeal held that a loaf of bread containing a string was not unfit for consumption, since it was established that the said string got there by accident.³³

Incidentally, there is no recorded Nigerian case of prosecution of a manufacturer or retailer for selling any food or drink containing deleterious substances, most cases relating thereto had been resolved by civil litigation.³⁴

With respect to the sale of food or drink containing filthy, disgusting or rotten substances, it is submitted that the same principles applicable to the sale of food or drinks containing deleterious substances should be applied.³⁵

With respect to the sale of food or drink products in a filthy or insanitary condition, this would fall squarely within the jurisdiction of the Agency. It is expected that in the exercise of its investigative powers it would liaise with the Health departments of the various local Governments to inspect factories, eateries, markets, Abattoir and other places where food and drinks are processed or manufactured to ensure that they are produced in safe and sanitary conditions.

The most fundamental of the provisions dealing with specific offences under the Food and Drugs Act is that dealing with the sale of adulterated products.³⁶ No doubt, the centre focus of the activities of the Agency is the prevention of the adulteration and counterfeiting of food and drugs. The Agency's frontal attack in this regard could only be fully appreciated in the context of the nature and scope of adulterated products as

²⁶ See the Black Laws Dictionary 9th edition, 2004,

²⁷ See Sections 1 -2 of the Non-Nutritive Sweeteners in Drug Products (Prohibition) Regulations of 1999 as amended in 2005.

²⁸ See the cases of *Osemobor v Niger Biscuits Co Ltd & Anor*(1973) N.C.L.R 382,*Soremi v Nigerian Bottling Co Ltd* (1977) 12 CC.HCJ 2735, *Okwejinor v Nigerian Bottling Co Ltd* (2008) 5 N.W.L.R.(PT 1079) 172 amongst others discussed in Chapter two of this thesis. Admittedly, the defendants could have been culpable under the Food and Drugs Act, if the necessary mental elements of the offence were established in a criminal prosecution.

²⁹ See Section 25(1) (a) of The Act

³⁰ (1956) 1 Q.B 43

³¹ This is a similar provision to section 1 (b) of the Food and Drugs Act under reference.

³² (1956) 1 Q.B 48

³³ See also *Lindley v George.W.,Hornes Ltd* (1950)1All. ER 234

³⁴ See the views of Okaraiwe, supra footnote 33

³⁵ The Agency in 2009 sealed up the premises of some major eateries in Lagos on the grounds of the insanitary conditions they operated in the preparation of their food and confectionaries.

³⁶ See Section 1 (2) of the Act

provided under the Food and Drugs Act. Accordingly, the Black Law's Dictionary defines "adulteration" as "To debase or to make impure by adding a foreign or inferior substance" the Dictionary further defines an "adulterator" as "A corrupter, forger, a counterfeiter" the Dictionary equally defines "adulterated drug" as a 'drug that does not have strength, quality or purity represented or expected'.³⁷ Similarly, the Encyclopaedia Britannica defines 'Adulteration' as the act of debasing a commercial commodity with the object of imitating or counterfeiting a pure or genuine commodity or substituting an inferior article for a superior one in order to gain an illegitimate profit,³⁸

It is implicit from this definition that the concept of adulteration is limited to the deliberate mixing of food or drugs with an inferior substance. The necessary men read of the offence would invariably include knowledge and deliberate act on the part of the person mixing the food or drink. The elements of recklessness and negligence are equally inclusive in determining the guilty mind of the accused person. It does appear that negligence in the act of mixing the food or drink would not ground culpability as these definitions suggests that the culprit would be acting with sole aim of presenting the adulterated product as genuine and thereby reaping undeserved profit thereby.

The wording of Section 1 of the Act under reference imports a strict liability standard as it proceeds with the phrase "No Person shall sell import, manufacture or store any article of food....". This epitomizes the desire of the state to use the instrument of criminal Legislation to punish such unwholesome conduct without reference to the guilty mind of the perpetrator.

f) *The Agency's Powers of Inspection and Investigation*

The Agency's power of registration and certification of the regulated products is the starting point for assessing its efficiency in the discharge of its enormous statutory mandate. However it is clear that its power of investigation and inspection is the most potent in its drive to prevent the incidences of the fake, adulterated and/or sub-standard products.³⁹

It is expected that through its investigative and inspectorate units the Agency can detect the incidence of fake and sub-standard regulated products and prevent their consumption and use by the consumers. In this way the Agency would be adopting the 'Compliance Strategy' as a tool for regulation as against the usual

penal or sanctioning strategy, which is more often an exercise in post-mortem.⁴⁰

It is equally arguable that the failure of the Agency to fully exercise its powers of investigation and inspection could be the basis for imposing some form of liability of the Agency to the public. This would sound more plausible in view of the controversy surrounding the culpability of the Agency or similar regulatory Agencies for affixing a mark or insignia of quality and certification on the regulated products.⁴¹

How well has the Agency used its investigative and inspection powers since its establishment? Whilst an empirical analysis of its performance is not the focus of this thesis it suffices to state that documented records of the Agency's efforts in this regard are abound. This is more particularly so in the tempestuous five years of the Agency's former Director- General, Professor Dora Akinyuli (of blessed memory).

Accordingly, in the five years of her stewardship there were documented records of inspection of factory and manufacturing sites. The invasion of markets and retail outfits to confiscate and destroy these offending products. This was in the aftermath of the debilitating effects of fake and substandard drugs in the country.

In 2002, three patients reacted adversely to infusions manufactured by a Nigeria firm. The Agency reacted swiftly and stopped the administration of the infusion. Subsequently, the Agency collected the samples of the infusion and its investigation revealed that the muscle relaxant used in the infusion was sub-standard. Similarly, in 2004, three Nigerian hospitals recorded cases of adverse reactions from the use of contaminated infusion manufactured by four Nigerian firms. The results of tests conducted on samples of the infusion showed that some of the samples were seriously contaminated with micro-organisms. The investigation also revealed that almost 147 of the 149 brands of water for the in injections screened were contaminated and not sterilized.⁴²

However, the most bizarre of cases of Drug related deaths in Nigeria is the horrible death of about 34 children in the country as a result of their consumption of a teething analgesic christened "My *Pikin*". The incidents which were recorded within one week in November, 2008 involved children within the ages of 3-4 months to 3years. The outbreak was adjudged to be caused by the presence of a solvent,

⁴⁰ See footnotes 4-7 of this chapter, where these various methods of regulation and their utilitarian values were discussed.

⁴¹ See footnote 68 where the contending views of Inegbedion and Kanyip with respect to the liability of S.O.N with respect to its N.I.S certification marks on goods was discussed.

⁴² See Victor Ochiggi "Curbing the menace of Fake Drug, Counterfeiting in Nigeria" Published in the Newspaper, National Vision Newspapers Online Edition; www.nationalvisiononline.com accessed on 05/09/2011.

³⁷ See Black Law's Dictionary 9th Edition 2009, West Gade Publishing Co. New York.

³⁸ See Encyclopaedia Britannica (London, Encyclopedia Britannica Ltd, 2009): 188.

³⁹ See Section 5 (c) and (d) of The Act

Diethylene Glycol, a solvent for the manufacture of *paracetamol*.

Presently, the Company that manufactured the said teething syrup are facing criminal prosecution for sundry offences under Food and Drugs Act and the Penal Code before High Court in Kano state.⁴³ from these incidents relating to drugs, there have been isolated incidents relating to food and water contamination and counterfeiting in the country and injury and death resulting there from. Sometime in March 2004, there was the incidence of the death of some persons including children as a result of the consumption of a popular brand of noodle product in the country. The explanation proffered by the Company involved was the alleged fakery and adulteration of its products; they denied that the offending products were produced by it. However the Agency's investigation revealed that about three batches of the *indomie* product had been contaminated with *carbofurana* chemical used a pesticide for Agricultural purposes. Accordingly within March 30th –April 4th 2004, about 21,025 cartons of the product was recalled from the distribution network and destroyed by the Agency. While the process of recall and destruction of the contaminated product was going on, the Agency sealed up the company's factory at Ota.⁴⁴

These incidences are only but a few of the problems that innocent and gullible Nigerians have faced in the hands of unscrupulous businessmen. It is humbly submitted that they reflect the imperfection in the Agency's inspectorate Division and its failure to leave up to the expectations of the citizenry. It is our view that these incidences highlighted above and many more were avoidable if the Agency's inspectorate unit was more proactive and looked beyond the factories and other places for the manufacture of these regulated products. They ought to go beyond these frontiers and monitor the distribution network of these regulated products. The searchlight beamed on the retailers ought not to be limited to known markets but through the use of covert investigative skills to pre-empt the introduction of these alleged fake and counterfeit products in the market place. Incidentally, the Agency is empowered to set up special task forces both at the federal and state levels for this purpose. The Agency is empowered to pay unscheduled visits to the border posts and all other entry points of the offending products. It is empowered

to seize and destroy the offending products. However, this taskforce has not been as functional in its investigative and inspectorate functions as expected.⁴⁵ It is submitted that until the Agency is able to up its ante in the elimination of these offending products, it would still be unwittingly blamed for any injury or death resulting from the consumption of these offending products by the ultimate consumer.⁴⁶

The guidelines and procedure for the exercise of the Agency's powers of inspection and investigation are well documented and if followed to the letter, the incidences highlighted above would be grossly limited. The Agency is expected to closely monitor the importation channels for most of the regulated products. This is because it is now generally acclaimed that most of the substandard regulated products especially drugs are imported from the Asian countries.⁴⁷

Furthermore, the Agency is expected to liaise with the Customs and Excise, the National Agency for Drug Law Enforcement Agency, and other Agencies to monitor the sea ports, the wharfs and other entry points to prevent the infiltration of these offending products into the market place. However, conflicts of interest and power tussle between these Agencies led to the withdrawal of *NAFDAC* from the Airports in 1994 it was during the civil rule of Chief Obasanjo in 2000 that the Agency was empowered to go back to the Airports and Wharfs.⁴⁸

This was after some spirited efforts by the then Director-General of the Agency to ensure that the Agency takes it proper position in the implementation of the Pre-Shipment Inspection of Imports Act.⁴⁹ This lull and void in the Agency's role in the enforcement of its mandate through the complimentary legislation-The Pre-Shipment Inspection Act led to the high level of infiltration of the offending products into the country within this period. Additionally, in a survey conducted by an NGO '*Globalization and Health*' in 2009 on the activities of *NAFDAC*, most of the respondents scored

⁴³ See JamesAkpan "The Calamity of my Pikin" accessed on www.leadershipnigeria.com/news on 22/01/2009. See also; Ogundipe .S. "Experts allege Epidemic of Acute Renal Failure" accessed on www.vanguardngr.com/content/view on 22/01/2009, MuarizioBonati "Once Again, Children are the main victims of Fake Drugs" published in the Journal of Pharmacy and Pharmacology, accessed on line in www.medicinewebofscience.com on 22/01/2009

⁴⁴ For further details ,see www.newsbiafranigeriaworld.com/archive/2004/jun/18/017.html,accessedon 06/09/2011; See also; www.allafrica.com/stories/200405130578.html. accessed on 06/09/2011

⁴⁵ See Sections 6-9 of the Counterfeit and Fake Drugs Unwholesome processed Foods (Miscellaneous Provisions) Act ,1999

⁴⁶ See Inegbedion supra footnote 68

⁴⁷ Available data shows that most of the sub-standard products especially, drugs are imported from China, India, Indonesia and some parts of Eastern Europe .See Ladan ,supra footnote

⁴⁸ Sadly, in 2012, the Minister of Finance ordered the withdrawal of *NAFDAC* and similar Agencies from the sea ports and Airports. Most Commentators view this as a big blow to the efforts of the Agency at combating the influx of fake and sub-standard drugs into the country.

⁴⁹ By Sections 1-7 of the Pre-Shipment Inspection of Imports Act Cap LFN 2004, makes it offence for any person to knowingly import goods into the country not subject to pre-shipment inspection and without a clean report of finding. Whilst, the Agency has over the years liaised with other agencies like Customs, NDLEA,SON amongst others in implementing this Act, cases of conflict had slowed down the Agency' efforts in this regard. The Agency's ban from the airport was as a result of such conflicts.

the Agency low in its inspectorate function.⁵⁰ One of the reasons hazarded by most of the respondents was the perceived corruption and compromise of officials of the Agency in the inspectorate division.

Implicit in this report is the additional acknowledgement of the problem of adequate personnel in the Agency especially in the inspectorate unit to man the multifarious entry points for these offending products, the manufacturing sites and ware houses as well as the distribution network in the country. This is indeed an area where the Agency is in need of some measure of improvement.

However, it must be conceded that the Agency has recorded some huge successes over the years. It has been able to use of its inspectorate and investigative division to prevent the flooding of the market place with these offending products. These successes are legion and are well documented. For example, the Agency has over the years mounted vigorous campaign against the use of excessive salt and the absence of iodine in most food products across the country. Through its inspectorate units it has been able to intercept at the ports, the entry importation of such food products that failed to meet this standard. It has equally been able to seal manufacturing premises as well as seized and destroyed such sub-standard food products.⁵¹

Additionally, sometime in 1995 the Agency had to ban the use of a popular seasoning agent *Ajinomoto* which was adjudged to be injurious to the health of consumers. In the same vein, the Agency has through its inspectorate unit fought a relentless war against the use of Saccharine as sweetening agent in food and drink products. Saccharine is adjudged as a cheap sweetener that is injurious to the liver and is known to cause cancer of the colon. As at 1995, a World Health Organization survey assessed the consumption of saccharine worldwide to be in the neighborhood of 1000 million pounds.⁵² It has equally been discovered that a particular seasoning product *Vedan* containing monosodium glutamate which is manufactured in Taiwan and is duly registered by *NAFDAC*, is equally dangerous to health. It was adjudged to contain a bleaching agent as well as containing high sugar content. Happily, *NAFDAC* has banned the use of this

seasoning agent and has in the last ten years mounted vigorous efforts at mopping it from the market.⁵³

One other, area where the Agency has maintained a frontal attack on the incidence of unregulated food through its inspectorate unit, is with regards to the use of *Bromate Potassium* in the production of bread. The health implications of the use of *bromate* in bread are well documented. Bromate potassium is known to also cause cancer when consumed in excess.⁵⁴

With respect to bottled and table water, the Agency has been proactive in preventing the flooding of the market with questionable bottled water products. It has acted within the precincts of its powers under the Bottled Water Regulations to ensure that only tested and certified bottled water products are sold to the public.⁵⁵

II. CONCLUSION

No doubt, the scope of the Powers and functions of the Agency is enormous and challenging, whilst the foregoing analysis shows the avalanche of substantive and subsidiary legislation that have defined the scope of these powers and duties, it has been discovered that the Agency has worked assiduously in the last two decades of its existence to fulfill its statutory role in the regulation and control of the regulated products under its enabling law'

As shown, in the course of this analysis there are quite a handful of areas deserving of improvement, especially in the area of preventive measures to ensure that minimal volume or quantum of the offending products get to the market place and ultimately to the innocent consumer. The issue of adequate funding of the Agency, the strengthening of its inspectorate and investigative departments are amongst other issues that can be improved upon by the regulatory agency.

⁵⁰ See Ahmed Garuba et al" Transparency in Nigeria's Public Pharmaceutical Sector; Perception from Policy makers" A Research conducted on behalf of Globalization and Health, Page 1-13 published on 29th October 2009 accessed on www.globalizationandhealth.com/content/30/08/2011

⁵¹ In May 2008, a 20ft container containing counterfeit pharmaceutical products was intercepted by the Agency at the Apapa Wharf. See www.in-pharmatechnologist.com/processing-qc/Nigeriancounterfeit-drug.html accessed 07/09/2011

⁵² See www.nafdac.gov.com accessed on 07/09/2011

⁵³ See World Health Bulletin, Volume 84, February, 2006 accessed on www.who.int/bulletin/volumes/84_02/06-020906/en/ accessed on 07/09/2011, where the efforts of the Agency in the fight against counterfeit drugs and food products was well documented.

⁵⁴ See I. Kurokwa "Potassium Bromate in Bread; What are the implications?" (1982) Medical Nigeria. www.medicalnigeria.net/bromate_in_bread.htm accessed on 09/09/2011

⁵⁵ See Sections 1-6 of the Bottled Water Registration Regulations of 1996, See also Sections 1-9 of the Bottled Water (Labeling) Regulations of 1996.