Ministry of Education and Science of Ukraine

ODESSA NATIONAL ACADEMY OF FOOD TECHNOLOGIES

International Competition of
Student Scientific Works

BLACK SEA SCIENCE 2020

PROCEEDINGS

ODESSA, ONAFT 2020

Ministry of Education and Science of Ukraine

Odessa National Academy of Food Technologies

International Competition of Student Scientific Works

BLACK SEA SCIENCE 2020

Proceedings

Odessa, ONAFT 2020

UDC 001.8(063)

Black Sea Science 2020: Proceedings of the International Competition of Student Scientific Works / Odessa National Academy of Food Technologies; B. Yegorov, M. Mardar (editors-in-chief.) [*et al.*]. – Odessa: ONAFT, 2020. – 621 p.

Proceedings of International Competition of Student Scientific Works «Black Sea Science 2020» contain the works of winners of the competition.

The author of the work is responsible for the accuracy of the information.

Organizing committee:

Prof. Bogdan Iegorov, D.Sc., Rector of Odessa National Academy of Food Technologies, Head of the Committee

Prof. Maryna Mardar, D.Sc., Vice-Rector for Scientific and Pedagogical Work and International Relations of Odessa National Academy of Food Technologies, Deputy Head of the Committee

Prof. Stefan Dragoev, D.Sc., Vice-Rector for Scientific Work and Business Partnerships of University of Food Technologies (Bulgaria)

Prof. Baurzhan Nurakhmetov, D.Sc., First Vice-Rector of Almaty Technological University (Kazakhstan)

Prof. Mircea Bernic, Dr. habil., Vice-Rector for Scientific Work of Technical University of Moldova (Moldova)

Prof. Jacek Wrobel, Dr. habil., Rector of West Pomeranian University of Technology (Poland)

Prof. Michael Zinigrad, D.Sc., Rector of Ariel University (Israel)

Dr. Mei Lehe, Ph.D., Vice-President of Ningbo Institute of Technology, Zhejiang University (China)

Prof. Plamen Kangalov, Ph.D., Vice-Rector for Academic Affairs of "Angel Kanchev" University of Ruse (Bulgaria)

Dr. Alexander Sychev, Ph.D., Assoc. Professor of Sukhoi State Technical University of Gomel (Belarus)

Dr. Hanna Lilishentseva, Ph.D., Assoc. Professor, Head of the Department of Merchandise of Foodstuff of Belarus State Economic University (Belarus)

Prof. Heinz Leuenberger, Ph.D., Professor of the Institute of Ecopreneurship of University of Applied Sciences and Arts (Switzerland)

Prof. Edward Pospiech, Dr. habil., Professor of the Institute of Meat Technology of Poznan University of Life Sciences (Poland)

Prof. Lali Elanidze, Ph.D., Professor of the Faculty of Agrarian Sciences of Iakob Gogebashvili Telavi State University (Georgia)

Dr. V. Kozhevnikova, Ph.D., Senior Lecturer of the Department of Hotel and Catering Business of Odessa National Academy of Food Technologies, Secretary of the Committee

5. ECOLOGY AND ENVIRONMENTAL PROTECTION

ANALYSIS OF PHARMACEUTICAL WASTE MANAGEMENT METHODS BASED ON THE EXAMPLE OF THE QUALITY CONTROL DEPARTMENT OF A PHARMACEUTICAL COMPANY

Author: Nosachenko Mykola
Supervisor: Tetyana Zborovskaya
National University of Pharmacy (Ukraine)

Abstract*. The methods of waste management in the pharmaceutical company. Shown classification of waste generated as a result of the quality control department, in their type, a way of recycling and registration. Established line of action designed for waste management enterprises investigated, legislation of Ukraine. The process of waste management in the pharmaceutical company PDCA cycle occurs. Statistical data obtained from the relevant documentation allow us to investigate, analyze and, if necessary, to make corrective actions in the process of waste management.*

Keywords*: ecology, environment, pharmaceutical company, waste management, waste water, plastics, chemicals.*

I. Introduction.

Pharmaceutical products are one of the most in demand on the market of Ukraine. By T. Shabelnik indicates: "that the average Ukrainian spend 10% of their income on medical products (drugs)" [2]. But it is important to note the government's activities in the area of drugs in Ukraine. For example, using the special program "Available drugs" drugs increased turnover because people could get drugs of certain groups for free.

S. Kulytskyi in his work "The pharmaceutical industry and pharmaceutical market in Ukraine: Status and Problems of Development" reports that the: "results of 2018 the volume of sales made in Ukraine of basic pharmaceutical products and pharmaceutical preparations by about 6% higher than the figure in 2013 (in comparable prices) and reached UAH 34.2 billion" [3].

This substantiates the joint influence of socio-cultural and demographic factors which include: alcohol, not active healthy lifestyle, improper use of drugs, , migration of diseases from abroad. resistance.

In this regard, to ensure that the basic function of drugs – to improve human health pharmaceutical companies are increasing their capacity. However, the increasing amount of waste pharmaceuticals that affect the environment.

II. Analytical review of the literature

Nowadays, manufacturers of medicinal products governed by the rules and principles set out in the guidelines of good manufacturing practices. This instruction is used to build a pharmaceutical quality system and proper organization of production of finished drugs and active ingredients; for the design, construction, reconstruction and technical re-equipment of enterprises producing finished products and active ingredients, which usually improves the quality of products produced. But, unfortunately, the principles and rules laid down in the GMP, do not apply to issues of environmental security [4].

According to the book by A.M. Kasimov, V.T. Semenova, N.G. Shcherban, V.V.

Myasoedov "Modern problems and solutions in the system of hazardous waste management": "it is impossible to make production waste-free". The accumulation of some types of waste can worsen the environmental situation, which is the pattern we can see today. Therefore, reducing their impact is a priority for pharmaceutical companies [1]. Performing this task will increase not only the level of social security, but also the degree of consumer confidence in the manufacturer.

The main document on which all participants pay attention production companies, including pharmaceutical, in the field of environmental safety is ISO 14001, the essence of which is that it contains the requirements for environmental management. Doing it organization can increase their efficiency and increase loyalty to their environmental stakeholders.

For example one of the requirements of this standard are: "the organization should evaluate those activities associated with its identified significant environmental aspects and ensure that these activities are conducted in a manner that allows you to control or reduce the associated adverse effects to meet the requirements of its environmental policy and achieve their goals and objectives. This should include all activities, including support and maintenance". [5]

The aim of the competition is:

– research aimed at determining the environmental safety of the pharmaceutical company an example of quality control.

– Analysis of waste disposal methods that can be used in work of department quality control of medicines.

III. The object, subject and research methods.

Object research – the process of disposal of waste generated as a result of laboratory quality control of medicines in the pharmaceutical company.

Subject research – pharmaceutical waste disposal methods on the example of the quality control department.

Methods research. In the course of analysis used causation to identify potential waste by building causal chain to determine the possible consequences and methods of their utilization.

IV. The results

Any analysis process begins with the definition of relevant terms. So relying on legislative acts of Ukraine:

"Waste– is any substances, materials and objects resulting from human activity and can't be used in place further education or identification and must be taken or destroyed". [6]

The process of waste management is their detection, identification, collection in special containers depending on their type (preventing mixing of different types of waste) registration.

The road of utilization is determined according to internal documents, internal instructions Company obtained a passport and map register waste.

Step identify waste includes not only identifying them at work, but predicting their formation using documented information, such as chemicals used in chemical laboratories.

At the stage of identification can be concluded that overall waste produced in the

laboratory as a result of analytical work can be divided into the following main categories: chemical nature, domestic nature, biological nature and packaging materials, which in turn are divided into different types, presented in Figure 1.

Waste generated as a result of the laboratory shall be:

1. Collection.
2. Placing in designated areas.
3. Recoded.
4. Timely removal.
5. Transfer on destruction.

Therefore, the most important step is the correct identification of waste, because it affects the correct action in management.

Correct waste identification requires to collect waste and placed according to their types.

The first step in identifying waste in the company is to establish classes of danger to the environment. The requirement to establish classes of waste hazard to the environment and human health legislated the Law of Ukraine "About Waste".

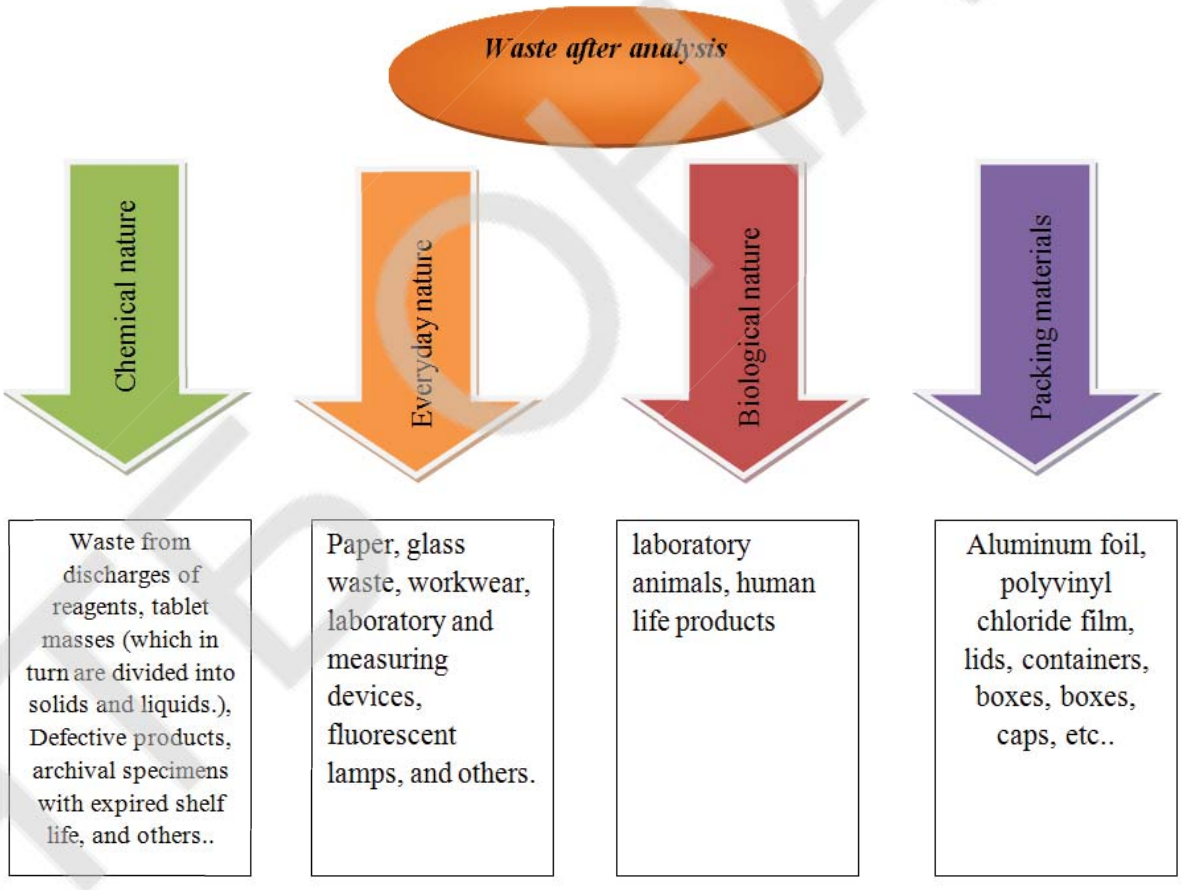

Fig. 1. Types of waste produced in the laboratory activities.

Under the criteria to hazardous waste hazard class are four classes of danger for the environment:

- extremely dangerous (1)
- high-risk (2)
- moderately hazardous (3)
- low-hazard (4).

Waste hazard class set depending on the degree of harmful effects on the environment by direct or indirect impact of hazardous waste on it.

The problem of plastic waste is a big problem, not only pharmaceutical companies, but also the whole country. Plastic, thanks to its pluses (ease, efficiency, satisfaction of consumer properties, less energy-intensive production, so for manufacturing the first plastic bottle costs of energy in the manufacture of up to 21% than for the manufacture of glass) [7] were quick substitute different materials used in human life. However, the rapid growth in popularity of plastic led not only to environmental pollution, due to its improper disposal, but also to a shortage of raw materials from which it is produced, what make it more expensive. Therefore, waste polymers are raw materials and energy resources. [7].

By the plastic used for the work of enterprise include: tape, lids, containers, bottles, caps, trays, buckets, bottles of drinking water, the film t / a.

Using in its work products from polymeric raw materials, the pharmaceutical company selected for analysis cooperates with special organizations on recycling of plastic waste.

But before passing the waste received their need to find, identify and collect. According to the requirements of enterprise waste plastic collected in a separate container that prevents their connection with other types of waste.

Choosing such a plastic waste management policy, the company investigates not only does not harm the environment (because it does not use the method of waste disposal with PET methods of disposal in the ground, burning), but on the contrary promotes the processing of plastic waste into polymeric raw materials, providing not only environmental safety, but also making it economical for businesses that use polymeric raw materials to create polyethylene items, as this is not only more cost effective but with recycling creating a large number of useful products for the national economy [7].

Table 1 shows the different types of waste generated during the quality control department and transferred to a specialized company for destruction and disposal.

Table 1.

Types of waste delivered to specialized organizations

Types of waste	Operations
Fluorescent lamps and waste containing rut (mercury thermometer)	Transferred to specialized organizations for recycling
Packing materials (aluminum foil fused PVC)	
Plastic packaging materials (film, lids, containers, bottles, caps, trays, buckets, bottles of drinking water, the film t / a).	
Paper for recycling paper and cardboard (waste paper and cardboard printed products made of twisted hoforokartonu and others.)	
Tools and instruments for general-mechanical nature, thermomechanical physico-chemical, biological (worked office, laboratory and measuring equipment, alcohol thermometers)	
Protective clothing (gloves)	
Waste utilities incl garbage from bins (rubbish from territories household waste polyethylene)	

Not all waste produced during laboratory quality of medicines are subject to disposal outside organizations.

This type of waste include waste chemical type, semi drugs domestic production (archival samples with expired) to be destroyed at the institution.

The life cycle of chemicals in a laboratory begins with the delivery necessary materials from supplier firms. The substances are used in the synthesis or analysis. In a work process can formed contaminated raw materials, products, contaminated solvents and reagents should be collect or recycle if their selection for reuse impossible. Unlike industrial wastes, chemical wastes in the laboratory are usually formed in small quantities and are very complex mixtures. Laboratory waste that are in different locations can differ in composition, acceptable way, need to know the types of experiments and used materials. But some types of hazardous waste produced in laboratories, can not be spread in their original form, they must first be prove to the required condition. Using the appropriate processes, the waste can be subjected to detoxification in place of their education. The advantage of detoxification is to reduce the probability of impact on untrained staff who can deal with these wastes and accidents that reduce the risk of environmental pollution.

Depending on the physical state of chemical waste used different methods of disposal. The method for encapsulation of solid waste, and a method for breeding liquid. The method of breeding is to create a solution of 1: 200, and the drain of the solution concentration in the pipeline.

It is important to understand that after this procedure the life cycle of chemicals does not stop as they enter the waste water.

Wastewater are any liquid that is poured into the sink. Ideally, they contain only water. But in practice they usually are aqueous solutions previously neutralized to a pH of 6 to 9, and do not contain heavy metals

The problem of waste water treatment in Ukraine remains today. The most influential reasons for this are:

1. Very limited funding construction of new treatment plants and to maintain the technical level of existing facilities sanitation.
2. Motivated by rising prices on energy reduce energy consumption for wastewater treatment.
3. High (compared with those of developed countries) labor to operate the facilities for wastewater treatment.
4. The lag in dewatering and disposal of sewage sludge [8].

In the process of recycling waste water must comply with concentration limits adopted for domestic wastewater. Can merge only those substances relating to dangerous substances. Substances which merge into the sewer must be environmentally friendly and does not create technological barriers when operating water purification stations. [9].

Wastewater under Ukrainian law shall:

1. Contain flammable gaseous impurities and dissolved substances that can form explosive mixtures.
2. Contain substances that are able to block up the pipes, wells, lattice or deposited on their surfaces (litter, soil, abrasive powders and other coarse suspension, gypsum, lime, sand, metal and plastic shavings, fats, resins, oil, brewer's grain, bread yeast etc).

3. Contain only inorganic substances or substances that are not amenable to biological degradation.

4. Contain substances that are not set maximum permissible concentration (MPC) for water reservoirs or toxic substances that prevent the biological wastewater treatment, as well as substances for which no definition developed analytical methods of control.

5. Contain dangerous bacterial, viral, toxic and radioactive pollution.

6. Have a temperature above 40 ° C.

7. Mother pH below 6.5 or above 9.0, [9].

Based on the requirements of environmental legislation with established periodicity is controlled as waste water, emissions control, research soil. Quality control of wastewater that enter the city sewer carried out according to schedule, developed annually, according to the rules of admission wastewater into the sewer network. To control the quality of wastewater analyzes the content of these elements:

– chlorides;
– phosphates;
– iron;
– sulfates;
– zinc.

In the work of the enterprises of pharmaceutical and chemical orientation emissions into the atmosphere are also formed: sulfur compounds, oxides of nitrogen, ammonia and carbon monoxide - in the use of sulfuric and nitric acids, chlorine and hydrochloric acid - in the use of chlorine compounds.

Control of emissions of air pollutants emissions makes, outside-organizations o that have a license for this activity. Using guidance on methods for determining pollutants in the air determine the content of the following elements: ammonia, hydrogen sulfide, phenol dioxide and nitrogen oxide, mercury, cyclohexane, formaldehyde, chlorine, carbon monoxide.

Sampling was performed by aspiration certain amount of air via the absorbing device filled with a liquid or solid sorbent material to absorb or through aerosol filter that retains part contained in the air. The study admixture is concentrated in a small volume of sorbent or filter. Type absorbing device or filter is determined depending on the substance to be tested.

In addition to safe waste activities in the laboratory can be formed dangerous, which include: inorganic acids, mixtures of acids, alkali, alkaline compounds, solvents and waste containing silver and caustic substances.

These substances prohibited disposed through the collection of household waste or sewage. Types of waste that include dangerous should be collected separately and transmit licensed companies that recycle hazardous waste. Manufacturer of waste should also be able to provide data on the type of hazardous waste. Each type of waste meet certain thresholds set for the departure of the components and their properties.

Since the legislation Ukraine does not fully regulate the sphere of hazardous waste, the most viable option would be to avoid the formation of such waste on the start.

To this end, it is important to try to reduce or completely eliminate the use of substances whose disposal costly, or replace them suitable analogues that can be disposed of at a lower price and more acceptable environmental manner.

For example, in the target company in the quality control department abandoned the use of chromium compounds, because it has carcinogenic properties. Therefore laundering persistent contaminants encouraged to use other means (alcoholic solution of alkali).

Hazardous waste is collected in special containers separately from other waste and sent to a place of storage of hazardous waste containers that store hazardous waste must be signed and marked.

The world is spreading practice of returning excess amounts of chemicals and solvents manufacturer. For example, a company Merck offers a service called Retrologistics®. The type and condition chemicals supplied and the number documented. After analysis and quality control of these substances are used in the production and synthesis. If re-use is not possible, these chemicals are disposed of according to regulations.

Any management is impossible without the use of statistics generated in the control process of waste management, as the company recorded every type of care in designated magazines, illustrated in Table 2.

Information on emissions control, wastewater quality, recycling and transfer to third parties, documented in the relevant documentation, allows for an annual waste generation and disposal limit, which can in turn be directly investigated and adjusted. This is how the PDCA cycle is performed in the waste control and management process.

Analyzing the activity of the studied company in waste management, we can conclude that the waste management in company is accordance with the requirements of the regulations presented in the legislation of Ukraine.

As noted above, the process of waste minimization is constantly updated and must meet modern requirements and trends. Especially now, when Ukraine became a step closer to European integration, is important not only quality products, but also protect the environment.

Among the theoretical constructs designed to address environmental and economic issues and at the same time acceptable to the scientific substantiation of activities related to waste management should be highlighted: the concept of technological determinism; the concept of "zero waste"; concept of assimilative capacity of the environment; concept of externalities. Each of these concepts can serve as a theoretical arguments of certain items of environmental waste management program. The problem is that the development of such programs usually involved officials of relevant government authorities, primarily using their practical experience, logic administrative actions and legislative rules that may come into conflict with each other and proposed the scientific community conceptual views. It is therefore important to develop an algorithm using scientific provisions allowing justify the measures planned environmental programs [10].

Table 2.

Actions performed by the waste generated in the department of quality control

Type of waste	Operations	Supporting documents
Rubbish bins of (municipal solid waste)	To collect solid waste in labeled containers with a plastic bag tucked in the space, weigh. Remove waste in solid waste containers, which are located on the premises	Journal of waste.
Waste paper and cardboard paper	Pick, crushed, transmit specialized enterprise	Journal of waste, waste deed to the warehouse
Waste chemical reagents, solvents showers	Daily collected in labeled glass container, weighed, placed in a specially designated place for recycling rent	Journal of waste, the act of transferring the warehouse
Archived samples from bypassing the shelf life and storage	Collected and placed in the space	The act of cancellation, the act of transferring waste to the warehouse
battle of glass	Battle of glass: -empty ampoules after analysis, collect, and place a special place in the presence of Commission crushed, crushed ampoule collected in a plastic bag, weigh, label, later the same battle transferred to the glass composition. -on excluding ampoules, collect, weigh, label, transfer enterprise specialized	The act of destruction logbook waste, waste deed to the warehouse
Plastics	Packing materials, plastics spoiled or contaminated waste is collected in containers marked separately (depending on the type of plastic), transmit specialized enterprise	Journal of waste, waste deed to the warehouse
The bodies of laboratory animals	Pick a special place, of the destruction carried out under the contract	The act of euthanasia
Aluminum foil	Pick aluminum foil containers labeled in a plastic bag tucked in the space, weigh label, transfer enterprise specialized	Journal of waste, waste deed to the warehouse
Protective clothing spoiled	Pick a plastic bag, weigh, label transfer to the container for solid waste	Journal of waste

In addition to ensuring that waste is reduced at the legislative level, it is also important to make changes at the level of the pharmaceutical enterprise itself. These may include more frequent filter replacement and inspection, moving from more dangerous solvents to safer ones that may not be used for analysis alone.

V. Conclusions

1. According to different authors demand for pharmaceutical products in Ukraine is high. In this regard, to ensure range of drugs pharmaceutical companies are increasing their capacity, leading to increased pollution.

2. Since GMP principles do not apply to the issue of environmental safety, the main document that recommends methods of environmental activities in environmental security companies are ISO 14001 and legislative acts of Ukraine in the field of

environmental protection.

3. The pharmaceutical company quality control department is used as an example for research.

4. The work analyzes the main stages of waste management produced during pharmaceutical organization. These include: detection, identification, collection, filling in the necessary documentation, further recycling, disposal or transfer to specialized enterprises.

5. It is established that the actions performed in the management of waste in the target company complies with legislation of Ukraine, which are used in environmental protection and waste management recommendations presented in ISO 14001.

VI. References

1. Shabelnik T. (2013). The current camp of the pharmaceutical market of Ukraine. *Economist*, 6, 40-42 [in Ukrainian].

2. Kulitsky S. (2019). Pharmaceutical industry and pharmaceutical market in Ukraine: STI problems and development. *Informational-analytical magazin "Ukraine: informations, facts, comments"*, 6, 41-53 [in Ukrainian].

3. *Medicinal products "Good Manufacturing Practice"* (2016). ST-N MOZU 42-4.0: 2016 Kyiv: The publication is official , 1-334. [in Ukrainian].

4. Kasimov A.M., Semenov V.T., & Shcherban N.G., Myasoedov V.V. (2008). *Modern problems and solutions in the hazardous waste management system.* KHARKIV: KNUME [in Russian].

5. *Systems environmental management. Requirements and Application Guide*. (2015) DSTU ISO 14001: 2015. Kyiv: Derzhstandart Ukraine [in Ukrainian].

6. Law of Ukraine about wastes № 187/98. (2020, February, 13). *Vidomosti Verkhovnoyi Rady Ukrayiny* [in Ukrainian].

7. Suprun L.V., Romanenko S.V.,& Tsygankova T.S. (2012). Analysis and solution of the problem of utilization and recycling of polyethylene terephthalate (PET) waste in the city of Tomsk. *Bulletin of Siberian Science*, 4, 107-112 [in Russian].

8. Voloshin M.D., Shcherbak A.L.,& Chernenko Y.M., Kornienko I.M. (2009). *Improvement of biological sewage treatment technology.* DNEPRZERZHINSK: [in Ukrainian].

9. Order of Ukraine on approval of the Rules for acceptance of sewage to the systems of centralized drainage and the Procedure for determining the amount of payment for excessive regulatory discharges of wastewater to the systems of centralized drainage № 56/31508 .(2018, January, 15). *Vidomosti Verkhovnoyi Rady Ukrayiny* [in Ukrainian].

10. Zynovchuk N.V. (Ed). (2013). *Waste – secondary resources: management, economics and organization.* (Vol.1). Sumy: SUMDU [in Russian].