



PERMANENT MISSION OF THE REPUBLIC OF KOREA
GENEVA

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The Permanent Mission of the Republic of Korea to the United Nations Office and other International Organizations in Geneva presents its compliments to the Secretariat of the Office of the United Nations High Commissioner for Human Rights (OHCHR) and has the honor to refer to the latter's letter: AL KOR 1/2016 dated 12 February 2016 regarding the joint communication sent by the Chairperson of the Working Group on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, the Special Rapporteur on the Implications for Human Rights of the Environmentally Sound Management and Disposal of Hazardous Substances and Wastes, and the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health. The Permanent Mission has further the honor to submit attached herewith the responses of the Republic of Korea to the aforementioned joint communication.

The Permanent Mission of the Republic of Korea to the United Nations Office and other International Organizations in Geneva avails itself of this opportunity to renew to the Secretariat of the Office of the United Nations High Commissioner for Human Rights the assurances of its highest consideration.

Enclosure: As stated

20 April 2016

Office of the United Nations High Commissioner for Human Rights
Palais des Nations
CH-1211 Geneva 10, Switzerland



**Response of the Republic of Korea to the Joint Communication
from the Chairperson of the Working Group on the issue of human rights
and transnational corporations and other business enterprises; the Special
Rapporteur on the implications for human rights of the environmentally
sound management and disposal of hazardous substances and wastes; and
the Special Rapporteur on the right of everyone to the enjoyment of the
highest attainable standard of physical and mental health**

【Questions and Answers】

I. Please provide, in detail, additional information and any comment you may have on the above-mentioned allegations.

1. The Government of the Republic of Korea (hereinafter referred to as “the Government”) would like to refer to the concerns about the adequateness of the remedy. Acknowledging that the victims of humidifier sterilizers may face financial difficulties if their litigations against the relevant companies are protracted, the Government has covered medical expenses for the victims, with a plan to claim indemnity from responsible companies later. The Government considers the support to be helpful for the victims as it covers expenses for physical health treatment from the onset of health impacts as well as costs for related mental health treatment.
2. Having expressed deep regrets over the damages caused by humidifier sterilizers at their early stage, the Government has carried out studies to identify the cause of the damages, along with providing the above-mentioned support. Additional measures, such as an official apology and compensation from the Government, may be taken depending on the outcome of the ongoing litigation filed by the victims against the Government.
3. With regard to legal or expert assistance, the basic stance of the Government is to take necessary measures to support the victims in their lawsuits against relevant companies, despite the fact that the Government is also a defendant of the litigation filed by the victims. Legal representatives of the victims have utilized in lawsuits the findings of the epidemiological studies and animal tests conducted by the Government to identify the cause of the damages. In addition, the Government has made efforts to help establish the causal relationship between the exposure to humidifier sterilizers and the damages to the victims by providing relevant materials requested by the court. Further information on the Government’s legal aid is given in the answer to question V.
4. Information on the Government’s measures to prevent recurrence of similar incidents is given in the answer to question VII.

II. Please explain why the cases began to surface in 2011, despite the product being on the market for many years, and whether any changes were made to the formulation of the humidifier sterilizer since their introduction to the market until 2011.

5. During the epidemiological studies conducted by the Government, doctors stated that they had seen several patients with similar symptoms before April 2011. However, it seems that the issue was not raised at the time because it was difficult to pinpoint the cause of the symptoms.
6. The details on the formulation of humidifier sterilizers are not accessible as companies regard them as confidential business information. Major substances of humidifier sterilizers, such as PHMG and PGH, were initially reported for their usage as sterilizer for carpets (e.g. PHMG in December 1996) and for textile products, rubber products, and food packaging materials (e.g. PGH in February 2003). Hazard examination was carried out for the reported usage, pursuant to the *Toxic Chemicals Control Act*. However, the substances were later used as components of humidifier sterilizers without additional examination to verify the safety of the changes in route of human exposure.

III. Please provide information on measures taken by the Government to identify victims of the humidifier sterilizers, including measures taken by the Government to identify victims beyond subjects of the three investigations carried out by the Government. Please also provide information on the rationale of the classification of subjects of the investigation and how the classification is appropriate to provide adequate remedy to all alleged victims.

A. Identification of Victims

7. The Government has completed two investigations on 530 applicants by April 2016, and is currently investigating 752 additional applications submitted by December 2015. The third investigation is scheduled to be completed by 2018. For reference, the Government does not limit the subjects of investigations. Any individual suspected of suffering from exposure to humidifier sterilizers can apply for the investigations.
8. The Government has conducted a campaign through newspapers, broadcasts, and local governments to encourage those suspected of suffering from exposure to humidifier sterilizers to apply for the investigations. The Government has also promoted the investigations at academic conferences in the related fields such as pulmonology so that doctors can advise patients with suspected symptoms to apply for the investigations.
9. In addition to the three investigations based on applications, the Government operated a nationwide real-time monitoring system in 2012, which aims to detect new cases of severe lung disease of unknown cases. The government also restricted the launch, sales, and use of humidifier sterilizers

10. Furthermore, the Government established an Environmental Health Center at the Asan Medical Center in May 2015. The center has been carrying out studies on health impacts of humidifier sterilizers other than lung disease. If meaningful findings are presented through the studies, the Government may set up new criteria for identifying additional victims and provide them with support. From 2016, the Government will also conduct studies on health impacts of humidifier sterilizers on fetuses and on the connection between exposure to humidifier sterilizers and gene expression in lungs.

B. Classification of Victims and Provision of Remedy

11. The Government organized the Committee on Lung Injury Investigation consisting mainly of doctors who had diagnosed and treated the patients and experts who had participated in related studies such as the epidemiological studies. Taking causal relationship in the fields of exposure, histopathology, radiology, and clinical pathology into consideration, the Committee developed categories to assess damages from humidifier sterilizers.
12. The categories and their definitions are given below.

【Categories to assess damage】

Category	Definition
Definite	<ul style="list-style-type: none"> • Exposure to humidifier sterilizers has been identified. • Development and progression of lung disease accompanied by lobular fibrosis can be partly identified at a certain point through histopathological examination, radiological examination, or clinical findings. • There is no other specific cause that can explain the entire progression of the disease. It is almost certain that the disease developed around terminal bronchioles due to humidifier sterilizers.
Probable	<ul style="list-style-type: none"> • Exposure to humidifier sterilizers has been identified. • Development and progression of lung disease accompanied by lobular fibrosis can be partly identified at a certain point through histopathological examination, radiological examination, or clinical findings. • There may be other specific cause that can explain the entire progression of the disease. However, it is more likely that the disease developed around terminal bronchioles due to humidifier sterilizers.
Possible	<ul style="list-style-type: none"> • Exposure to humidifier sterilizers has been identified. • Development and progression of lung disease accompanied by lobular fibrosis can be partly suspected at a certain point

	<p>through histopathological examination, radiological examination, or clinical findings. The impact of humidifier sterilizers cannot be completely excluded.</p> <ul style="list-style-type: none"> • However, as the entire progression of the disease is not consistent with the development and progression of lung disease accompanied by lobular fibrosis, there is a low possibility that the disease could develop around terminal bronchioles due to humidifier sterilizers, taking other causes into account.
Unlikely	<ul style="list-style-type: none"> • Exposure to humidifier sterilizers has been identified. • Development and progression of lung disease accompanied by lobular fibrosis cannot be identified at a certain point through histopathological examination, radiological examination, or clinical findings. • As the entire progression of the disease is not consistent with the development and progression of lung disease accompanied by lobular fibrosis, there is almost no possibility that the disease could develop around terminal bronchioles due to humidifier sterilizers.

13. The committee on Lung Injury assessed damages of each applicant by: sending investigators to applicants' homes and carrying out environmental investigations; conducting health examinations, such as computed tomography scans, at the National Medical Center; and collecting medical records which had been kept during diagnosis and treatment of the applicants.

14. Based on legal and expert consultation on factors including possibility of claiming indemnity from responsible companies, the Government has covered medical and funeral expenses for the victims classified into the "definite" and "probable" categories. In addition, individuals classified into the "definite", "probable", and "possible" categories are currently under Government health monitoring.

IV. Please provide, in detail, information on additional measures being taken by the Government to provide necessary access to medical services to its potential victims in order to address the health impacts resulting from the sterilizer products that may surface in the future.

15. The Environmental Health Center established by the Government in May 2015 has been monitoring impacts on lungs and other organs as well as mental health of the victims. When adverse impacts are found, the center provides treatment as well as advice on an appropriate treatment.

V. Please provide information on any legal assistance and aid that the Government has provided to the identified victims and the alleged victims vis-à-vis current legal proceedings and future legal proceedings in the Republic of Korea and abroad.

A. Legal Assistance

16. According to the *Legal Aid Act*, the Korea Legal Aid Corporation provides legal assistance, such as a legal representation in a lawsuit, for citizens and foreign residents, whose average monthly income is below 125% of standard median income.

17. Personal information such as case number, name, and date of birth is required to ascertain whether a certain individual received the legal assistance. Due to the regulations on the protection of personal information, the Government is not in a position to confirm whether the victims of the humidifier sterilizers received legal assistance.

B. Identification of the Cause of Damage

18. Information on the utilization of epidemiological studies and animal tests carried out by the Government in lawsuits to identify the cause of the damages is given in the answer to question I.

VI. Please provide information on the process of the first two criminal charges, including the reasons for the suspension of proceedings and the detailed outcome. Please also provide information on the most recent criminal charges filed and the response by the Government.

19. In 2012, a provisional stay of prosecution had been implemented to await the result of government investigation conducted by the Committee on Lung Injury Investigation on whether there exists a causal relationship between the exposure to humidifier sterilizers and the damages to the victims, which is a crucial issue of the accusation.

20. After the result of the investigation was published in March 2014, the accusation filed by the victims of humidifier sterilizers in 2012 was reopened. The accusation in 2014 has been consolidated with the accusations filed in 2012 and in 2015 and is currently under investigation by an ad-hoc investigation team established by the Seoul Central District Prosecutors' Office. The Government cannot provide further details about the ongoing investigation as it may undermine a fair and prompt investigation, but the Government gives assurances that the cases will be thoroughly investigated according to the law and relevant principles.

21. The Government seeks understanding of the special procedures on the fact that it is not in the position to provide further details about the ongoing investigation as it may

undermine a fair and prompt investigation. The Government gives assurances that the cases will be thoroughly investigated according to the law and relevant principles.

VII. Please provide information on measures taken by the Government to prevent human rights violations from the exposure to hazardous substances.

A. Please provide information on the Government's assessment of recent legislative and administrative and other appropriate measures taken in response to the humidifier sterilizer case including whether such measures are sufficient to prevent similar incidents or other incidents involving hazardous substances and health impacts suffered by individuals.

22. The *Act on Registration, Evaluation, etc. of Chemical Substances* (hereinafter referred to as "AREC") was enacted in May 2013 and enforced in January 2015, with a view to protecting public health and the environment from risks of unknown chemical substances.

23. The key element of AREC is to ensure that the Government evaluates hazards and risks of chemical substances before their distribution on the market and takes preventive measures for safety management of chemical substances with potential risks. In particular, each usage of the chemical substances shall be registered and reviewed, thereby allowing the Government to restrict or prohibit any usage which is deemed likely to pose risks. In addition, changes in the usage of chemical substances shall be reported and registered.

24. AREC is a regulatory system to assess risks to public health and the environment to an extent beyond the *Significant New Use Rule* (SNUR) of the United States. It is expected to prevent recurrence of similar incidents by preventing human exposure to hazardous chemical substances.

- SNUR: Limitations or conditions are placed on usage of chemical substances with potential risks. If the substances are intended to be used in violation of such limitations or conditions, one should notify it to the United States Environmental Protection Agency (EPA), which may approve or turn down the use.

B. Please explain what systems the Government has now in place to provide early warnings of adverse health impacts that may be due to hazardous substances in consumer products.

25. AREC also strictly manages the safety of chemical products.

26. First, AREC introduces the declaration system for hazardous chemical substances contained in products, in line with the registration system for chemical substances.

- Given that most chemical substances reach the general public as components of

chemical products, the declaration system aims to understand potential risks of chemical products before their distribution in the market and utilize the relevant information for safety management.

- If the quantity of a hazardous chemical substance contained in a product is more than 0.1% of the product and its total quantity exceeds one ton per year, a manufacturer or importer of such product is obliged to declare the name, usage, and content of the hazardous chemical substance to the appropriate Regional Environment Office or River Basin Environment Office.
27. Second, in order to ensure the safety of chemical products in the final stage of consumption by the general public, the Government has designated products with potential risks and has developed the safety and labeling standards for such products.
- Products with potential risks fall into two categories: products used by general public mainly as household or office items, such as air fresheners, deodorants, and cleaners; and biocidal products such as disinfectants, repellents, and preservatives. As of now, fifteen types of chemical products are designated as products with potential risks.
28. The safety standards include, among others, designation of hazardous chemical substances that cannot be used for certain types of products and determination of maximum content of hazardous chemical substances permissible in a product. The safety standards were developed based on cumulative results of product risk assessments conducted by the Ministry of Environment, the Ministry of Food and Drug Safety, and the Korean Agency for Technology, as well as relevant regulatory standards of institutions such as EU and WHO.
- In particular, according to safety standards, chemical substances with higher risks, such as PHMG and PGH in humidifier sterilizers and carcinogenic substances, are designated as restricted substances for certain types of products including cleaners, thereby prohibiting the use of such substances in the products.
 - Concerning biocidal products, a list was drawn up for substances which can be used. A substance which is not on the list can be used only after review of the Minister of Environment. This system aims to prevent untested substances from being used in biocidal products.
29. The labeling standards aim to provide clear and accurate safety information to consumers.
- By taking the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) as reference, the Government has enforced labeling of name, content, function, and toxicity of hazardous chemical substances under AREC.

- In particular, when carcinogenic, mutagenic or toxic for reproduction (CMR) substances contained in a product exceeds a permissible level, information on toxicity should be displayed on the product, for example by means of pictogram, regardless of the content of the substances in the product.

Third, the Government has conducted market monitoring and safety investigations regularly with regard to products with potential risks that are available in the market.

- The Government has designated an investigation center for chemical product-related accidents and has organized a market monitoring team in cooperation with consumer organizations so as to monitor compliance with labeling standards. The Government has also conducted intensive supervision on compliance with safety standards by collecting, testing, and analyzing products in the market.
30. Conducting risk evaluations for the products which are currently not designated as products with potential risks in due order, the Government will continue to designate products with potential risks, develop the safety and labeling standards for the newly designated products, and monitor compliance with the standards.

VIII. Please provide information on what steps have been taken to provide effective guidance to the business enterprises concerned on how to respect human rights in their operations.

31. The corporate responsibility to respect human rights is reflected in relevant laws and regulations such as AREC and the *Act on Liability for Environmental Damage and Relief Thereof*, which was enacted in December 2014 and enforced in January 2016, in line with the UN Guiding Principles on Business and Human Rights.

- Article 5(4) of AREC: A business entity that manufactures or imports products shall prevent any damage to public health or property due to hazardous chemical substances contained in products.
- Article 4(3) of the *Act on Liability for Environmental Damage and Relief Thereof*: Business owners shall endeavor to prevent environmental damage arising from the installation and operation of facilities, take measures necessary for mitigating damage if an environmental pollution accident occurs, and cooperate in effectively implementing the policies of the State and local governments.

IX. Please provide information on the Government's plan to ratify the Optional Protocol to the International Covenant on Economic, Social and Cultural Rights.

32. The Government has studied the necessity and the expected effects of ratifying the Optional Protocol to the International Covenant on Economic, Social and Cultural Rights upon its adoption.

33. In 2014, the Government commissioned a study on domestic legal remedies for the rights enumerated in the International Covenant on Economic, Social and Cultural Rights. It has also participated in various discussions on the ratification of Optional Protocol to the International Covenant on Economic, Social and Cultural Rights. It will continue to review the possibility of ratification by delving into the jurisprudence and principles of the Court in cases on the rights stipulated in the International Covenant on Economic, Social and Cultural Rights.

【Additional Comments】

34. The Government would like comment on some of the information mentioned in the joint communication.

- With regards to categories to classify victims, it is preferable to use the term “**definite**” instead of “very likely”, which was used by the Committee on Lung Injury Investigation.
- The subjects of Government monitoring are not individuals classified as the possible and unlikely categories, but individuals classified as the **definite, probable, and possible** categories.
- The number of the deceased and the number of the individuals classified as the “definite” and “probable” categories are given below.

【Applicants investigated from July 2013 to present】

Total	Eligible for Government support			Not Eligible for Government support				
	Subtotal	Definite	Probable	Subtotal	Possible	Unlikely	Unable to Judge	
530	221	157	64	309	61	240	8	
Survivor	387	126	86	40	261	50	205	6
Deceased	143	95	71	24	48	11	35	2

- The juridical basis regulation upon which the Government’s provision of medical and funeral expenses to the victims was based is not Article 12(2), but **Article 13-2** of the *Enforcement Ordinance of the Environmental Health Act*. /End/