

Food Chemical Unit,
Bureau of Hygiene
Ministry of Health
14 June 2000

A joined divisional meeting of the Food Toxicity Investigation Division and Utensil, Container, Packaging Division, both of Food Hygiene Investigation Department was held on 14 June 2000. The results of the discussion are as described below.

Based on the results of discussion held at the divisional meeting, as described in Attachment 1, all the Hygiene Divisional (or Bureau) Heads of Prefecture, City, and Special Administrative Area are hereby informed by the Head of Food Chemical dated today, to give directive to the industries concerned to avoid the use of vinyl (PVC) gloves that contain the di-(2-ethyl hexyl) phthalate (DEHP) plasticiser for handling food, as an emergency measure. In addition, the associations of the industries concerned had also been informed as indicated in Attachment 2.

Note:

I. Evaluation at the joined meeting of Food Toxicity Division and Utensil, Container, Packaging Division, Food Hygiene Investigation Department

1 Summary of Health Scientific Research, 1999.

- (1) DEHP in foods of commercial lunch box detected per serving: 322µg/g ~ 4,306µg/g (average 1,768µg/g)
- (2) DEHP in foods of set meal detected per serving: 6.9 µg/g ~ 177.1µg/g. (average 40.0µg/g)
- (3) DEHP in foods of one-day-meal supplied in hospital: 27µg/g ~ 2,549µg/g (average 519µg/g)

2 A sampling on foods during the preparation of commercial lunch box was carried out in Jan 2000 and results of analysis are as follows:

- (1) The DEHP in foods packed in lunched box using vinyl gloves was found to increase drastically when compared with that of the foods before packing.

Example: Immediately after preparation → Before packing → After packing
DEHP level: Not detected → 166ng/g → 8,900ng/g

- (2) In factory where vinyl gloves were not used and other utensil was used to pack the foods into lunch box, low level of DEHP was detected.

Example Potato salad: 303ng/g

- (3) Model experiment where foods were allowed to be in contact with vinyl gloves

In a model experiment, the migration of DEHP from vinyl gloves to foods was confirmed. Therefore a big portion of the DEHP detected in the foods of commercial lunch box was recognised to be originated from the vinyl gloves.

(4) Other types of phthalate ester

Since other types of phthalate ester orally taken are relatively low in concentration, it is not necessary to take any specific measure at the moment.

3 DEHP Tolerable Daily Intake (TDI)

40~ 140µg/kg/day (e.g., body weight of 50kg → 2,000 ~ 7,000µg/day)

II Future Measures

(1) As an emergency measure, instruct the industries concerned to avoid the use of vinyl gloves that contain DEHP in handling foods.

(2) In near future, the Department of Food Hygiene Investigation will review the amendment of the specifications of the relevant standards.

Contact: Food Chemical Unit, Daily Hygiene Bureau, Ministry of Health

Head of Unit: Y. Uchida

Officer-in-charge: T. Ikeda (2483)

Y. Inoue (2488)

Tel: 03-3503-1711

03-3595-2341 (Direct line at night)

=====

(Attachment 1)

Eika No 31
14 June, 2000

To: All Heads of Hygiene Division (Bureau) of
Prefecture,
Governmental City,
Special Administrative Area

From: Head,
Food Chemical Unit
Daily Hygiene Bureau
Ministry of Health

The Use of Vinyl Gloves in Handling of Foods

According to the scientific research of the Ministry of Health and others, foods in the commercial lunch box were found to contain di-(2-ethyl hexyl) phthalate (hereafter "DEHP). The presence of this substance in the foods was confirmed to be due to the migration of the substance from the vinyl gloves (hereafter "PVC gloves").

The summary of the findings on the migration of DEHP from PVC gloves to the foods in lunch box (results from scientific research of Ministry of Health and others) and the summary of evaluation on safety data of DEHP are given in Appendix 1 and Appendix 2, respectively. Due to the seriousness of the problem, a joined meeting of Food Toxicity Division and Utensil, Container, Packaging Division, both of Food Hygiene Investigation Department was held. The conclusion of the meeting was that as an emergency measure, the use of PVC gloves containing DEHP plasticiser for handling foods should be avoided.

Therefore, please instruct the industries concerned, within your jurisdiction, to avoid the use of PVC gloves for handling foods.

Please also take note that other related associations have been informed of the emergency measures, as shown in Appendix 3.

(Appendix 1)

1. Summary of Health Scientific Research, 1999.

- (4) DEHP in foods of commercial lunch box detected per serving: 322 $\mu\text{g/g}$ ~ 4,306 $\mu\text{g/g}$ (average 1,768 $\mu\text{g/g}$)
- (5) DEHP in foods of set meal detected per serving: 6.9 $\mu\text{g/g}$ ~ 177.1 $\mu\text{g/g}$. (average 40.0 $\mu\text{g/g}$)
- (6) DEHP in foods of one-day-meal supplied in hospital: 27 $\mu\text{g/g}$ ~ 2,549 $\mu\text{g/g}$ (average 519 $\mu\text{g/g}$)

2. Summary of Foods and Others Testing and Inspection Grant Research Report, 1999

(1) A sampling on foods during the preparation of commercial lunch box foods was carried out in Jan 2000 and results of analysis are as follows:

- (1) The DEHP in foods packed in commercial lunch box using vinyl gloves was found to increase drastically when compared with that of the foods before packing.
 - (2) In factory where vinyl gloves were not used and other utensil was used to pack the foods into lunch box, low level of DEHP was detected.
 - (3) For highly processed foods that were sent to lunch box food factory, the DEHP content was found to be in the order of 10^3 even though they were uncooked foods,
- (2) Model experiment where foods were allowed to be in contact with vinyl gloves
In a model experiment, the migration of DEHP from vinyl gloves to foods was confirmed. The concentration of DEHP migrated was found to increase when alcohol was used for disinfections. It is recognized that the use of PVC gloves caused a sharp increase in the DEHP level in foods.
- (3) Other types of phthalate ester
Since other types of phthalate ester orally taken are relatively low in concentration, it is not necessary to take any specific measure at the moment.

(Appendix 2)

Safety Aspect of DEHP (Summary)

(Different types of effects of toxicity)

In evaluating the safety of DEHP, there is a problem of variation in the effects of toxicity when different types of animals were tested. When tested on rodents, both liver and testis were found to be affected by DEHP. However, in the case of primates, such as monkey, the effects were not observed.

(Effects on liver)

The effects of DEHP on the liver of rodents were investigated. In the case of mice and mouse, liver tumor was found when they were fed with DEHP for 2 years.

A recent review by experts from IARC (International Association of Research on Cancer) revealed that:

- (1) DEHP was found to promote the growth of peroxisome and caused liver tumor.
- (2) In the cancer research of mouse and rat, an increase in peroxisome and liver cell growth was observed.
- (3) When cultivated human liver cells and liver of primates were exposed to DEHP, the growth in peroxisome was not found.

Based on these observations, the cancer-causing effects of DEHP was re-classified from Group 2B (may be carcinogenic to human) to Group 3 (can not be classified as carcinogenic to human).

(Toxicity to testis and reproductive system)

Many research works on the toxicity effects of DEHP on the testis and reproductive system of rat and mouse had been carried out. However, only a few reports indicated the well-defined non-toxic level (NOAEL) of DEHP. In a study on the toxicity to the reproduction (such as fatality and deformed embryo) of mouse, Lamb et al (1987) reported the NOAEL level as 14mg/kg/day.

Poon et al (1997) reported that when a low level of DEHP was fed to rat and the effects of testis disease studied, the NOEAL level was 3.7mg/kg/day.

Study by Arcadi et al (1998) on the effects of DEHP on rat revealed that when a low level was used, toxicity to testis was observed. However, the amount of DEHP used was not clear and the actual toxicity was not mentioned in the report.

(Disruption to hormone)

Although there are possible effects of phthalate esters on hormone and the subsequent harm to the human body, when the esters were introduced to the human breast cancer cells (MCF-7), they did not promote the growth of the cells. In addition, when tested on yeast system, the activity was not observed. However, in other report where the growth

of MCF-7 was observed, the rate of growth was also found to increase with the increasing amounts of DEHP used. The minimum concentration was found to be 10 μ M (=3.9mg/kg).

Based on these and other reported in vitro experiments, further research to clarify the effects of DEHP on the disruption of hormone is desirable. When compare to the NOEAL value from the study of toxicity DEHP to testis, the minimum effective concentration of 10 μ M obtained from the in vitro experiment can not be concluded to be significantly low.

(Tolerable Daily Intake (TDI))

As a result of the above review, the NOAEL values can be used to derive the TDI of DEHP. Based on the NOAEL values of 3.7mg/kg/day and 14mg/kg/day, obtained from the experiment on the toxicity of NEHP to testis and reproduction system, using 100 as an arbitrary index, at the moment, it is appropriate to set the TDI of DEHP as 40 ~ 140 μ g/kg/day.

(Reference) Safety Evaluation of DEHP in Foreign Countries

(Evaluation in EU)

TDI: 37 μ g/kg/day ('98) (NOAEL 3.7mg/kg/day, toxicity to testis: Poon et al, 1997, SF=100)

(Evaluation in UK)

TDI: 50 μ g/kg/day ('96) (NOAEL 5mg/kg/day, toxicity to liver: RIVM, 1992, SF=100)

(Evaluation in Denmark)

TDI: 5 μ g/kg/day ('96) (NOAEL 5mg/kg/day, toxicity to liver: RIVM, 1992, SF=1,000)

(Evaluation in USA)

NOAEL: about 10mg/kg/day ('99)

(Toxicity to testis: Poon et al, 1997, toxicity to reproduction system: Lamb et al 1987)

NOAEL: 4mg/kg/day, NOAEL 14mg/kg/day

(Appendix 3 Omitted)

(Attachment 2)

Eika No 32
14 June 2000

To:
President, Japan Food Hygiene Association
President, Japan Vegetable Association
President, Japan Cooked Rice Association
President, Japan Lunch Box Food Service Association
President, Japan Lunch Box Association
President, Japan Catering Service Association
President, Japan Chain-Store Association
President, Japan Supermarket Association
President, Japan Frozen Food Association
President, Japan Co-operative Union Association
President, Japan Self-service Association
President, Japan Retailer Association

From: Head,
Food Chemical Unit
Daily Hygiene Bureau
Ministry of Health

Concerning the Use of Vinyl Gloves in handling Foods

I hope everybody is doing well.

I wish to thank you for your co-operation and understanding in the administrative matters of the Food Chemical Unit in the past.

According to the scientific research of the Ministry of Health and others, foods in the commercial lunch box were found to contain di-(2-ethyl hexyl) phthalate (hereafter "DEHP). The presence of this substance in the foods was confirmed to be due to the migration of the substance from the vinyl gloves (hereafter "PVC gloves"). The summary of the findings on the migration of DEHP from PVC gloves to the foods in lunch box (results from scientific research of Ministry of Health and others) and the summary of evaluation on safety data of DEHP are given in Appendix 1 and Appendix 2, respectively. Due to the seriousness of the problem, a joined meeting of Food Toxicity Division and Utensil, Container, Packaging Division, both of Food Hygiene Investigation Department was held. The conclusion of the meeting was that as an emergency measure, the use of PVC gloves containing DEHP plasticiser for handling foods should be avoided.

With these findings, I hope that based on this notice, your association could instruct the members to avoid the use of PVC glove that contain DEHP plasticiser for handling foods.

Thank you.