### 発表資料

## グローバル市場における製品コンプライアンスリスク・マネジメント

## 池田 順一

2018 年 7 月 1 日に当学会の大会において会員の池田順一様が研究発表された、北米 CPSC や OECD など先進各国で進められている製品リコールの強化は従来から比べると事業者にとって厳しいものになってきているという内容でした。またこれはわが国の製品安全政策にも、今後大きな影響を与えることになってくることも予想されるところでしょう。

そこで、この研究発表につきまして池田順一様と編集委員会のご了解を得て、当日のパワーポイントを ここに掲載することとしました。





## 製品リコールリスクの位置付け

Nagashima Ohno & Tsunematsu

## 製品リコールリスクの位置付け

スナップショット:世界の 2017 年上位ビジネスリスク



このリスクマップは、選択した国におけるトップ企業リスクを示す。前年比で国の関心が高くなっているリスクも示している。 出典: Allianz Global Corporate & Specialty

「アリアンツリスクパロメーター 2017年の上位ビジネスリスク」3頁



## コンプライアンスリスクの顕在化 ~ 法執行の強化・厳罰化

Nagashima Ohno & Tsunematsu

## 法執行の強化・厳罰化

### 2016年6月米国CPSC

当局に対する通知義務の違反を理由とする 民事罰金\$4.5 millionの支払等



Recalled Mr. Coffee single cup

Release Details

WASHINGTON, D.C. - The U.S. Corsumer Product Safety Commession (CPSC) amounced today that Sunbeam Products, a d/b/a Jarden Consumer Solutions, of Boocs Ratton, Fla., has agreed to pay a \$4.5 million child persally.

The penalty settles charges that the firm knowingly failed to report to CPSC immediately, as required by federal law, that its I Coffee Single Oup Brewing System BVMC-KG1 series coffeemakers were defective and posed an unreasonable risk of serior death to consumers.

Between 2011 and 2012, the company neceived numerous complaints, including at least 32 reports of burn injuries, from the coffeemakers' brewing chamber opening and spraying hot water and coffee grounds toward consumers during normal use. company failed to report this issue to CRSC immediately, as required.

In addition to paying a \$4.5 million civil penalty, Sunbeam Products, Inc. dibia Jerden Consumer Solutions, has agreed to co with and maintain a compliance program that is designed to ensure compliance with the Consumer Product Safety Act (CPS firm has also agreed to comply and maintain a system of internal controls and procedures.

The firm recalled \$50,000 of the single-cup brewers in August 2012. The coffeensives were sold at mass merchandises nat including Bed, Bath & Beyond, Brandsmart, JC Perney, Kmart, Low's, Target and Walmart and online at www.mrcoffee.com September 2010 through August 2012 for between \$60 and \$80.

The firm does not admit to CPSC staff's charges.

The penalty agreement has been provisionally accepted by the Commission by a 3 to 2 vote.

#### UNITED STATES OF AMERICA CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of:

| Sunbeam Products, Inc. d/b/a Jarden | Consumer Solutions | |

CPSC Docket No.: 16-C0004

#### SETTLEMENT AGREEMENT

In accordance with the Consumer Product Safety Act, 15 U.S.C., §§ 2051 2089 ("CPSA") and 16 C.F.R. § 1118.20, Sunbeam Products, Inc. d/b/a Jarden Consumer
Solutions ("the Firm"), and the United States Consumer Product Safety Commission
("Commission"), through its staff, bereby enter into this Settlement Agreement
("Agreement"). The Agreement, and the incorporated attached Order, resolve staff's
charges set forth below.

#### THE PARTIES

- The Commission is an independent federal regulatory agency, established
  pursuant to, and responsible for the enforcement of, the CPSA, 15 U.S.C. §§ 2051 2089,
  By executing the Agreement, staff is acting on behalf of the Commission, pursuant to 16
  C.F.R. § 1118-20(b). The Commission issues the Order under the provisions of the
  CPSA.
- Sunbeam Products, Inc. d'b'a Jarden Consumer Solutions is a Delaware corporation with its principal corporate offices in Boca Raton, FL.

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- 1 CPSCとは
- 米国消費者製品安全委員会(The U.S. Consumer Product Safety Commission)。米国消費者製品安全法(Consumer Product Safety Act ("CPSA")・連邦法)に基づき1972年に設立された独立の規制機関( independent regulatory agency)
- 2008年に制定されたConsumer Product Safety Improvement Act (CPSIA)
   により予算、権限等拡大。
- 2 関連する法令
- CPSCは、CPSAのほか、連邦有害性物質法(Federal Hazardous Substances Act)、可燃性布地法(Flammable Fabrics Act)などの法執行を行う。
- 対象製品は消費者製品 (Consumer Product)であり、食品、薬品、化粧品、 医療機器、自動車、たばこ等についてはCPSCは管轄を有さない。

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## 法執行の強化・厳罰化

3 CPSCに対する通知義務

## Consumer Product Safety Act Sec 15(b) SEC. 15. [15 U.S.C. § 2064]. SUBSTANTIAL PRODUCT HAZARDS

- **(b)** Every <u>manufacturer</u> of a <u>consumer product</u>, (中略) ,distributed in commerce, and every distributor and retailer of such product, who obtains information which reasonably supports the conclusion that such product—
- (1) fails to comply with an applicable consumer product safety rule or with a voluntary consumer product safety standard upon which the Commission has relied under section 9 [15 U.S.C. § 2058];
- (2) fails to comply with any other rule, regulation, standard, or ban under this Act or any other Act enforced by the Commission;
- (3) contains a defect which could create a <u>substantial product hazard</u> described in subsection (a)(2); or
- (4) creates an unreasonable risk of serious injury or death,

shall <u>immediately inform</u> the Commission of such failure to comply, of such defect, or of such risk, <u>unless</u> such manufacturer, distributor, or retailer has actual knowledge that the Commission has been adequately informed of such defect, failure to comply, or such risk. (略)

- 4 CPSCに対する通知義務 違反の効果
- (1)民事罰 (Civil Penalties)

## Consumer Product Safety Act SEC. 20. [15 U.S.C. § 2069].

(a) (1) Any person who <u>knowingly</u> violates **section 19** [15 U.S.C. § 2068] of this Act shall be subject to a <u>civil penalty</u> not to exceed \$100,000, for each such violation. Subject to paragraph (2), a violation of <u>section 19(a)</u> (1), (2), (4), (5), (6), (7), (8), (9), (10), or (11) [15 U.S.C. § 2068(a)(1) – (11)] shall constitute a separate offense with respect to each consumer product involved, except that the maximum civil penalty <u>shall not exceed</u> \$15,000,000 for any related series of violations. A violation of section 19(a)(3) shall constitute a separate violation with respect to each failure or refusal to allow or perform an act required thereby; and, if such violation is a continuing one, each day of such violations shall constitute a separate offense, except that the maximum civil penalty shall not exceed \$15,000,000 for any related series of violations.

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SEC. 19. [15 U.S.C. § 2068]
(a) It shall be unlawful for any person to—
(1) – (3) 省略
(4) fail to furnish information required by section 15(b) [15 U.S.C. § 2064(b)];
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### 法執行の強化・厳罰化

- 4 CPSCに対する通知義務 違反の効果
- (2)刑事罰 (Criminal Penalties)

## Consumer Product Safety Act SEC. 21. [15 U.S.C. § 2070].

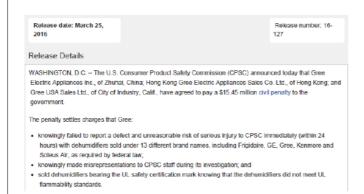
- (a) Violation of section 19 of this Act is punishable by—
  - (1) imprisonment for <u>not more than 5 years</u> for a knowing and willful violation of that section;
  - (2) a fine determined under section 3571 of title 18, United States Code, or
  - (3) both.

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SEC. 19. [15 U.S.C. § 2068]
```

- (a) It shall be unlawful for any person to—
  - (1) (3) 省略
  - (4) fail to furnish information required by section 15(b) [15 U.S.C. § 2064(b)];

### 2016年3月米国CPSC

## 当局に対する通知義務の違反等を理由とする 民事罰金\$15.45 millionの支払



#### UNITED STATES OF AMERICA CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of:

GREE ELECTRIC APPLIANCES, INC.,
OF ZHUHAL HONG KONG GREE
ELECTRIC APPLIANCES SALES CO.,
LTD., AND GREE USA SALES, LTD.

CPSC Docket No.: 16-C0002

#### SETTLEMENT AGREEMENT

1. In accordance with the Consumer Product Safety Act, 15 U.S.C. §§ 2051–2089 ("CPSA") and 16 C.F.R. § 1118.20, Gree Electric Appliances, Inc., of Zhuhai, Hong Kong Gree Electric Appliances Safes S. Lul., and Gree USA Safes, Lul. (collectively "Gree"), and the United States Consumer Product Safety Commission ("Commission"), through its staff, hereby enter into this Settlement Agreement ("Agreematt"). The Agreement, and the incorporated attached Order, resolve staff's charges that Core is subject to civil penalties in this matter, under section 20 of the CPSA, 15 U.S.C. § 2009, as set forth below.

#### THE PARTIES

- The Commission is an independent federal regulatory agency, established
  pursuant to, and responsible for the enforcement of, the CPSA, 15 U.S.C. §§ 2051–2089. By
  executing the Agreement, staff is acting on behalf of the Commission, pursuant to 16 C.F.R.
  § 1118.20(b). The Commission issues the Order under the provisions of the CPSA.
- Groe Electric Appliances, Inc., of Zhuhai, is incorporated in Chira, and its principal place of business is in China. Hong Kong Gree Electric Appliances Sales Co., Ltd., is incorporated in Hong Kong, and its principal place of business is in Hong Kong. Gree USA

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## 法執行の強化・厳罰化

### 2017年6月米国CPSC

## 当局に対する通知義務の違反等を理由とする 民事罰金\$5.2 millionの支払



#### UNITED STATES OF AMERICA CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of:

KAWASAKI HEAVY INDUSTRIES,
LTD.;

KAWASAKI MOTORS CORP., U.S.A.;

and

KAWASAKI MOTORS

KAWASAKI MOTORS

MANUFACTURING CORP., U.S.A.

CPSC Docket No.:

#### SETTLEMENT AGREEMENT

1. In accordance with the Constitute Product Statery Act, 15 U.S.C. § 2007–2009

(CPSA") and 16 C.F.R. § 1118.20, Krwasski Henvy Industries, Ltd., Krwasski Motors Corp.,

U.S.A., and Krwasski Motors Manufacturing Corp., U.S.A. (collectively), "Krwasski"), and the

United States Constitute Product Safety Commission ("Commission"), through its staff, hereby

enter into this Settlement Agreement ("Agreement"). The Agreement and the incorporated

attached Order resolve staff's charges set forth below.

#### THE PARTIES

- The Commission is an independent federal regulatory agency, established purvaunt to, and responsible for, the enforcement of the CPSA, 15 U.S.C. §§ 2051–2089. By executing the Agreement, staff is acting on behalf of the Commission, pursuant to 16 C.F.R. § 1118.20(b). The Commission issues this Order under the provisions of the CPSA.
- Kawasaki Heavy Industries, Ltd. ("KHI") is a corporation, organized and existing under the laws of Japan, with its principal place of business in Japan.

## 2018年4月米国CPSC

## 当局に対する通知義務の違反を理由とする 民事罰金\$27.25 millionの支払



UNITED STATES OF AMERICA ONSUMER PRODUCT SAFETY COMMISSION

In the Matter of:
POLARIS INDUSTRIES INC.

CPSC Docket No.: 18-C0001

#### SETTLEMENT AGREEMENT

 In accordance with the Consumer Product Safety Act, 15 U.S.C. §§ 2051–2089 ("CPSA") and 16 C.F.R. § 1118.20, Polaris Industries inc. ("Polaris"), and the United States Consumer Product Safety Commission ("Commission"), through its staff, hereby enter into this Settlement Agreement ("Agreement"). The Agreement and the incorporated attached Order resolve staff's charges set forth below.

#### THE PARTIES

- The Commission is an independent federal regulatory agency, established pursuant to, and responsible for the enforcement of, the CPSA, 15 U.S.C. §§ 2051–2089. By executing the Agreement, staff is acting on behalf of the Commission, pursuant to 16 C.F.R. § 1118.20(b). The Commission issues the Order under the provisions of the CPSA.
- Polaris is a corporation, organized and existing under the laws of the state of Minnesota, with its principal place of business in Medina, Minnesota.

#### STAFF CHARGES

 Between February 2012 and April 2016, Polaris manufactured or imported, distributed and offered for sale in the United States approximately 133,000 Model Year 2013-2016 RZR 900 and Model Year 2014-2016 RZR 1000 recreational off-road vehicles ("RZRs").

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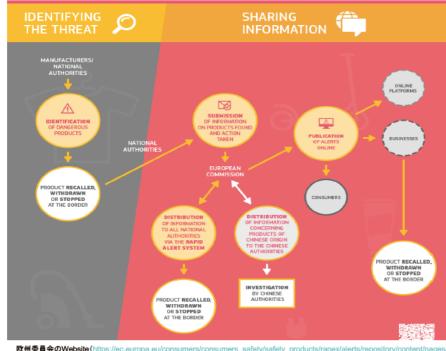
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## 当局による市場監視の強化

## 当局による市場監視の強化

Rapid Alert System for non-food, dangerous products (RAPEX)



- EU加盟国(28か国)、 アイスランド、ノル ウェー及びリヒテン シュタイン
- 中国製の製品につい ては、中国の当局とも 情報を共有(RAPEX-CHINA)

欧州委員会のWebsite (https://ec.europa.eu/consumers/

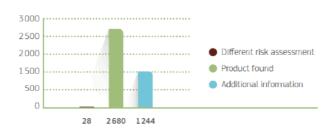
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## 当局による市場監視の強化

Rapid Alert System for non-food, dangerous products (RAPEX)

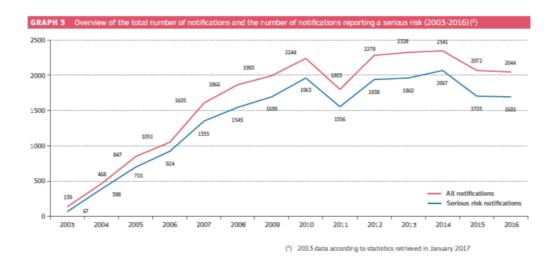
RAPEXによる通知をした参加国と、Follow-upをした参加国の対応に違いがある場合

TYPE of follow up



2017 result of the EU Rapid Alert System for dangerous non-food products

## 当局による市場監視の強化



Rapid Alert System for dangerous products 2016 Annual Reportより引用

2003年RAPEX開始以来、参加国当局による危険を伴う製品についての通報件数が増大し、近年は年に2000件程度の通報件数で安定

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## 当局による市場監視の強化



2017 results of the EU Rapid Alert System for dangerous non-food products より引用

玩具、自動車、衣類、電子製品・機器、子供用品は、他の製品に 比べ、とりわけ当局が安全性について関心を寄せている。



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## 各国当局間の協力

## International cooperation



A global market place requires a **global approach to the enforcement of product safety rules**. Growing international trade means that the same products are traded on markets across the world. Closer cooperation between global regulators in the area of consumer product safety is necessary to address the challenges posed by increasingly complex supply chains and higher volumes of trade.

European Commission has developed close cooperation with international partners to:

- exchange information on emerging risks and unsafe products;
- · coordinate standardisation efforts;
- ensure that manufacturers worldwide are aware of the applicable safety requirements and comply with them.

欧州委員会のHPより

### 【EUと米国】

- ・EU/米国間でガイドラインを締結
- ・EUと米国の市場において販売されている製品が同じであることから、製品安全に関する情報交換、とりわけ危険な製品についての緊密な情報交換を実施。



GUIDELINES FOR INFORMATION EXCHANGE AND ON ADMINISTRATIVE COOPERATION

BETWEEN

THE U.S. CONSUMER PRODUCT SAFETY COMMISSION

AND

THE DIRECTORATE-GENERAL HEALTH AND CONSUMER PROTECTION OF THE EUROPEAN COMMISSION

The U.S. Consumer Product Safety Commission (CPSC) and the Directorate-General Health and Consumer Protection of the European Commission (Directorate-General) share the common goal of improving information exchange between them.

The CPSC is an independent federal regulatory agency formed to protect the public against unreasonable risks of injuries and deaths associated with consumer products. It is charged with implementation of the U.S. Consumer Product Safely Act (CPSA), the U.S. Federal Hazardous Substances Act (FHSA), the U.S. Fiammable Fabrics Act (FFA), the U.S. Polson Prevention Packaging Act (PPPA) and the U.S. Refingerator Safety Act (RSA).

The Directorable-General is the Directorate within the European Commission responsible for monitoring the application of the General Product Safety Directive (GPSD), which regulates in a horizontal manner the safety of non-food consumer products placed on the European Union (EU) market, for operating the Rapid Exchange of Information System (RAPEX) established by the GPSD, initiating standardization and recognizing standards, taking rapid measures if necessary in case of serious risks and initiating regulatory action in other cases. The Directorate-General is also responsible for promoting and organizing administrative cooperation between the enforcement authorities of the EU Member States with a view to accomplishing the objectives of the GPSD.

It is noted that the EU responsibility for some of the information sought to be exchanged under these Guidelines belongs to the EU Member States or is shared between the EU Member States and the European Commission and that the EU registation applicable to some of the products of concern under these Guidelines is under the responsibility of other Directorate-Generals of the European Commission.

Nothing in these Guidelines calls on providing assistance or information if such is prohibited by their respective laws and regulations, enforcement policies or other essential interests.

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## 各国当局間の協力

## 【EUと中国】

- ・EU/中国間でMOUを締結
- ・EUのRAPEXにおける中国製品情報を中国当局に開示(RAPEX-CHINA)。これにより、中国当局(AQSIQ)が欧州委員会より受領した通知について調査を行い、必要に応じて、更なる中国からEUへの当該製品の輸出を制限。







JOINT STATEMENT ON THE EXTENSION OF THE MEMORANDUM OF UNDERSTANDING
ON ADMINISTRATIVE CO-OPERATION ARRANGEMENTS BETWEEN DG SANCO AND
AOSIO

The political commitment to good and fruitful ecooperation in the areas of consumer product safety, and food safety and sanitary and phytosanitary (SPS) issues finds one of its most prominent expressions in the Memorandum of Understanding on Administrative co-operation arrangements between the European Commission's Detectorate General for Health and Consumer Protection (GG ANVCO) and the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AGSIO), which was first signed on 16 January 2006.

Over the past three years, this Memorandum of Understanding has proven to be an excellent basis for administrative cooperation between DG SANCO and AQSIQ, and both sides wish to continue and further strengthen this cooperation.

Therefore, the two sides have decided to renew their political commitment, extend the Memorandum of Understanding and upgrade its Annexes as attached, reflecting the achievements over the past three years and strengthening the framework for further administrative ecoeperation.

The Joint Statement is signed in Brussels on 17 November 2008 in the English and Chinese languages.

For the Directorate General Health and Consumers of the European Commission For the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China

Meglena Kuneva
EU Commissioner for
Consumers
Health

Wei Chuanzhong Vice Minister of AQSIQ for

Wang Yong Minister of AQSIQ

## 【EUと日本】

・近時の非食品に係る大きなリコールその他の市場措置に係る情報を交換

"Summit leaders share the same challenges and determination to ensure a high level of consumer safety and protection and public health. They will aim to strengthen their cooperation at international and bilateral levels on safety of food and other products, security of the supply chain and the food chain, the security of networks and ICT usages."

[17th Japan-EU Summit Tokyo, 23 April 2008 Joint Press Statement]



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### 各国当局間の協力

## 【米国、EU及び中国】

- EU-China-US product safety summits
- ・2008年以来、米国、EU及び中国の製品安全当局(CPSC、欧州委員会及びAQSIQ)は、非食品の消費者製品についての製品安全問題を3者間で協議する機会を毎年設けてきた。
- ・情報シェア、規制上の協力等。

Fifth Consumer Product Safety Trilateral Summit

Among

The General Administration of Quality Supervision, Inspection and

Quarantine of the People's Republic of China;

The United States Consumer Product Safety Commission;

The European Commission, Directorate General for Justice and

Consumers

Joint Press Statement

June 22, 2016

Beijing, China

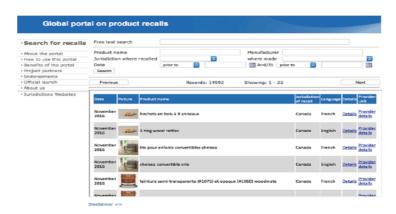
Since 2008, the product safety authorities of China and the United States as well as the European Commission have pursued joint efforts to strengthen non-food consumer product safety and protect the end consumers. The first four Consumer Product Safety Trilateral Summits have promoted information sharing, regulatory cooperation, and coordination among regulators, to further advance consumer product safety.

During this Fifth High-Level Consumer Product Safety Trilateral Summit held today in Beijing, China, Sun Dawei Vice-Minister of China's General

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## (Global Recalls Portal)



- 2012年10月に立ち上げられたWebポータル
- 各国当局から提供された消費者製品の強制・自主的リコール情報をアップデート
- 対象製品は消費者製品。ただし、各国当局の権限により自動車や食品が入る。
- 欧州、米国、カナダ、オーストラリア、日本等の当局が参加。
- 消費者は、このWeb上でリコール情報を検索可能。

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## 法整備

- 製品安全法制の近代化
  - 中東、中国、ベトナム等
- 製品安全法制の改革
  - 欧州、米国、日本、オーストラリア等
- 製品コンプライアンスに影響を与える隣接分野の法令整備
  - 化学物質規制についての法令整備(韓国等)



## リコール実施の複雑化 ~ 事故情報・危険情報に係るReporting

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## リコール実施の複雑化 ~ 事故情報・危険情報に係るReporting

1 タイミング

リコールを実施する対象製品には、何らかの危険を惹起させるリスクが存在することが少なくないが、かかる危険・事故について当局に「いつ」報告をする必要があるか。

- 2 対象製品
  - ・報告の対象となる製品は消費者製品に限るか。
  - 消費者製品でなければReportingはないのか。
- 3 報告対象となる事故情報・危険情報の範囲

国内で起きた事故・危険に限るか。

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## リコール実施の複雑化 ~ 事故情報・危険情報に係るReporting

4 通知を行うべき主体

複数の義務者

5 通知義務とは別のリコール義務

通知義務の懈怠について罰則を設けているのが通常。リコール義務(Voluntary Recall)についてもその懈怠に罰則を設けている場合がある。

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## リコール実施の複雑化 ~ 事故情報・危険情報に係るReporting

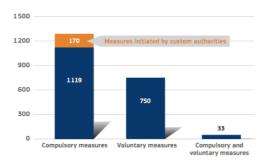
例: 米国と欧州におけるReporting の対比

	米国 (CPSA)	欧州 (GPSD)
報告義務	安全基準等に合致していないこと、重大な製品の危険を生み出す欠陥があること、重大なケガ又は死亡を引き起こす不合理な危険があること	消費者に危険をもたらすこと
報告期限	直ちに (immediately) 報告すべき情報を入手してから24時 間以内	直ちに(immediately) 報告すべき情報を入手してから10日以内 (重大な危険の場合は3日以内)
報告すべき当局	合衆国消費者製品安全委員会 (CPSC) →対応は区々にならず	欧州委員会ではなく、各加盟国の当局 →対応が区々になる可能性
報告すべき事項	製品の詳細、製造者/輸入者の詳細、 欠陥/基準不適合/危険の詳細、すぐに 提供できない情報については提供を予 定する時期	製造者/輸入者の詳細、製品の詳細、危険の詳細、是正措置の詳細、サプライチェーンにある他の会社の詳細
守秘義務への考慮	一定程度の配慮	基本的には公開

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## リコール実施の複雑化

Graph 9 • Number of notifications in 2015 by type of measure (absolute values) including compulsory measures initiated by border authorities



Rapid Alert System for dangerous products • 2015 Resultsより引用

- 強制措置(compulsory measure)は、当局が命じるもの。他方、自主的 措置(voluntary)は企業が自ら開始するもの
- 強制措置が自主的措置を上回っている。
- Worldwideで整合性の取れた市場措置を実施したいのだが...



### 訴訟戦略・競争戦略

■ ディスカバリー制度がない地域におけるPlaintiff barによる刑事手続の利用



■ 競争戦略としての製品安全規制の利用

Nagashima Ohno & Tsunematsu

## 訴訟戦略・競争戦略

- 米国製造物責任訴訟におけるコスト増要因としてのディスカバリー対策
  - ・ MDL (Multidistrict Litigation:広域係属訴訟手続) とは?
    - 米国訴訟のコスト増要因はディスカバリー(document production, deposition, interrogatories)
    - 製造物の瑕疵による損害が全米に及んだ場合、異なる地域に存在する原告が同じ内容の訴えを提起
    - MDLは、複数の地域の連邦地方裁判所に係属した訴えを特定の地区の裁判所に移送し、そこでプレ・トライアル手続を併合
    - 州裁判所に同じ訴えの訴訟が係属した場合は?

# ご静聴有り難うございました。 連絡先

## 池田順一

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