Science-Based Approach for Food Safety Management


Q1: Indonesia has many regulations for food safety. But, the fact is many food producers, mostly small producers, break the law, e.g., use formalin or borax. What will your country do to the producers?

A: So, this is the real situation in Japan. Yes, indeed, small manufacturers need to register to open their business. However, introduction to HACCP is still difficult to some industries in Japan. Therefore, we need to introduce risk-based criteria and have to balance the risk assessment.

IMPLEMENTATION OF FOOD SAFETY MANAGEMENT AT INDUSTRY LEVEL IN DEVELOPING COUNTRIES: IS GMP/HACCP CONFUSING?

Ratih Dewanti-Hariyadi

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ABSTRACT

Food safety management system built on a sound GMP/GHP and HACCP has been introduced and its implementation has shown to improve food quality and safety. The system is readily adopted by large industries; however, small enterprises have many difficulties in implementing food safety management.

In developing countries, in which most of the food industries are of small scale, implementation of food safety management system is still lacking. Several reasons underlying such problems were lack of infrastructures such as water, cold chain, etc., and human resources. Other factors that may have interfered the implementation of GMP and especially HACCP is lack of understanding of the HACCP philosophy. In non-English-speaking countries, language can be a barrier for understanding the HACCP principles. Additional constraints such as behavior or perception may also hamper the implementation of HACCP.

This paper will discuss several problems in implementing GMP/HACCP in developing country and issues regarding misconceptions and confusions that may occur during implementation of GMP and HACCP principles. Several case studies pertaining the implementation of GMP/HACCP in Indonesia will also be presented.

INTRODUCTION

Food safety has become important issues for both international trade and domestic market worldwide. A food safety management system built on a sound GMP/GHP and HACCP has been introduced and its implementation has shown to improve food quality and safety. However, the system is adopted mainly by large
industries, while small enterprises have many difficulties in implementing food safety management.

In developing countries, most of the food industries are of small scale which are using simple technology with inadequate knowledge in food safety. In Indonesia, for example, out of the 6 million units of food industry, most of them are of micro scale with less than IDR 200,000,000 assets and employs 1-4 people or small scale (IDR 200,000,000 - IDR 1,000,000,000 with 5-19 employees) (National Statistics Bureau).

GMP AND HACCP

Good Manufacturing Practices (GMP) is the foundation of food processing operation to achieve consistent quality and safety. GMP provides basic requirement that should be fulfilled to assure good practices pertaining the workers, the facility and environment, the equipment and process control. CMP is generic in nature, although it can be used to built a more customized guidance. It imposed preventive measures and its compliance can be observed visually. Documented implementation of GMP is generally manifested in the form of SSOP. In some country, CMP is mandatory.

HACCP is a preventive approach to minimize hazard in a food production. The system was built on a sound GMP as a prerequisite. HACCP is manifested in a document called a HACCP Plan. HACCP plan was developed based on the seven principles, namely hazard analysis, determination of critical control point, critical limit, monitoring procedure, corrective action, verification procedure and documentation (Mortimer and Wallace, 2001)

IMPLEMENTATION OF FSM IN DEVELOPING COUNTRIES

Implementation of HACCP has been reported to improve assurance in food safety. However reports from many developing countries suggested that implementation is generally not smooth. Several issues concerning the implementation of GMP HACCP itself has been reported elsewhere and here are some of the issues

Table 1. Number of industry in Indonesia*

<table>
<thead>
<tr>
<th>Industry size</th>
<th>No. employee</th>
<th>Assets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large</td>
<td>&gt;100</td>
<td>&gt; Rp. 5,000,000</td>
</tr>
<tr>
<td>Medium</td>
<td>20-99</td>
<td>Rp. 1,000,000,000 - 5,000,000,000</td>
</tr>
<tr>
<td>Small</td>
<td>5-19</td>
<td>Rp. 200,000,000</td>
</tr>
<tr>
<td>Micro</td>
<td>1-4</td>
<td>&lt; Rp. 200,000,000</td>
</tr>
</tbody>
</table>

*National Statistics Bureau, Republic of Indonesia

Infrastructures

Infrastructures in developing countries are com for the limitation of GMP applications in food industry, water or clean water for food handling, processing, sanitizing is not always available. Criteria of clean water for example, may not be sufficient for food processing. Usually built their own water treatment unit, but still no potable water. In some cases, quantity of water is also in addition to the quality issues, especially in the case of raw materials. In this case, cleaning activity can become a source of contamination.

Another problem in infrastructure is the lack of means of transportation and or establishment. This resulted in the abuse of illegal chemicals such as form preservatives, for example the case with wet noodle
industries, while small enterprises have many difficulties in implementing food safety management.

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Industry size

Most of food industries in developing countries are of small scale that they may not meet the GMP standards. In Indonesia food industry accounts for 40% of the total industry, and it follows the general pattern of all industry (Table 1). Some of these industries arisen from household activities done at home without strict task of the workers, location is mixed with household activities, may be pets etc. When this is combined with lack of infrastructures then the problems are more. The problem would increase when the food produced is of high risk food.

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<thead>
<tr>
<th>Industry size</th>
<th>No. employee</th>
<th>Assets</th>
<th>Total number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large</td>
<td>&gt;100</td>
<td>&gt;Rp 5,000,000</td>
<td>10,913</td>
</tr>
<tr>
<td>Medium</td>
<td>20-99</td>
<td>Rp 1,000,000,000</td>
<td>70,225</td>
</tr>
<tr>
<td>Small</td>
<td>5-19</td>
<td>Rp 200,000,000</td>
<td>640,000</td>
</tr>
<tr>
<td>Micro</td>
<td>1-4</td>
<td>&lt;Rp 200,000,000</td>
<td>16,300,000</td>
</tr>
</tbody>
</table>

*National Statistics Bureau, Indonesia

Infrastructures

Infrastructures in developing countries are common reasons for the limitation of GMP application in food industry. Potable water or clean water for food handling, processing, cleaning and sanitizing is not always available. Criteria of clean water in Indonesia, for example, may not be sufficient for food processing. Hg industries usually built their own water treatment unit, but smaller industry and food service establishment usually do not have easy access to potable water. In some cases, quantity of water is also a problem in addition to the quality issues, especially in the case of street foods. In this case, cleaning activity can become a source of contamination.

Another problem in infrastructure is the lack of cold chain as means of transportation and or establishment. This condition has resulted in the abuse of illegal chemicals such as formalin used as preservatives, for example the case with wet noodle and fish in...
Indonesia which was reported a couple of years ago. Based on our study (Dept of Food Science and Technology, 2005), the abuse rooted from a combination of poor sanitation, GMP implementation and lack of cold chain. Poor hygiene and sanitation program for the workers, equipments, facilities and lack of cold chain has resulted in products with high load of TPC and thus shorter shelf life. Lack of cold storage magnified the problems of spoilage bacterial and mold growth thus prompted some irresponsible producer to use formalin to lengthen the noodle shelf life. It was also unfortunate that the major responses for this problem was to look for "preservatives" with similar killing properties as formalin, instead of enforcing and facilitating GMP. Our study showed that implementation of GMP significantly and consistently reduce the initial microbial counts of wet noodle (Table 2).

With many SMEs, building GMP, providing potable water, cold chain or establishment may require government intervention. In Indonesia, this can not be addressed by institutions mentioned in Food Safety Management regulation (PP 28/2004) but also other institutions such as Ministry of, while enhancing the roles of those already mentioned in the PP such as local district government in providing premises that comply with CMP.

Table 2. Initial load of microorganisms in wet-noodle

<table>
<thead>
<tr>
<th>Wet-noodle type</th>
<th>Total Plate Count (Log cfu/g) at producer's level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Small industry (no. of industry)</td>
</tr>
<tr>
<td>Raw</td>
<td>3.65 - 5.95 (n=8)</td>
</tr>
<tr>
<td>Cooked</td>
<td>1 - 7.2 (n=5)</td>
</tr>
</tbody>
</table>

*FST, 2005; ND= not done

Language

In non-English speaking countries, language can be a barrier for understanding FSM, especially HACCP principles (Merican, 2007; Suwanrangsi, 2000). While CMP components are easier to understand, HACCP introduced several terms not commonly used in local language, and sometimes no equal translation is available. In Thailand, term like "emerging pathogens" is not Indonesia, hazard is translated into "bohaya", "k "cemaran" which sometimes cause confusion and lead to interpretation. It is a challenge already to comprehend all of the HACCP terms and then it become even more they are translated into the local language.

Tradition

In some instance, implementation of GMP as tradition that has been part of the life style. This is when hazard does not cause immediate effect or long products have been known for a long time. Examples include; use of horaxine certain traditional chips (gen Java or red illegal colorant such as Rhodamin B in certain chips from West Sumatera (kerupuk merah) are good this case. People are unwilling to give up the en because they are used to consuming the products a hazard are not apparent. For this problem, a continu program with good social approach is required.

Behavior/Attitude

Food safety management system based on GMP design to prevent hazard to become a risk to the society. Actions are prevention in nature and this could be high cost activity for certain industry, because of "the things for not happening". Examples include putting of light bulb, use of non food grade materials in container/cover that is not thought to be in contact materials. To change this behavior, continuous education is given. In Indonesia for example, we could use to the in of helmet use for motor vehicle and or seat belt as refer

Financial Cost

In many cases, the burden of the GMP implementation in SMEs is the cost. Major financial cost in GMP for implementation or the prerequisite progra. A study showed the average cost of GMP/HACCPimpl (14 companies in Turkey) is shown in Table 3.
Science-Based Approach for Food Safety Management

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<tr>
<th>Wet-noodle Type</th>
<th>Total Plate Count [Log CFU/g] at producer's level</th>
<th>Laboratory</th>
<th>Small industry applying GMP (no of industry)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw</td>
<td>3.65 - 5.95 (n=8)</td>
<td>1.6</td>
<td>3.68 (n=2)</td>
</tr>
<tr>
<td>Cooked</td>
<td>1.72 (n=5)</td>
<td>1.0</td>
<td>ND</td>
</tr>
</tbody>
</table>

*DFST, 2005; NB= not done

Language

In non-English speaking countries, language can be a barrier for understanding FSM, especially HACCP principles (Merican, 2007; Suwanrangs, 2000) While CMP components are easier to understand, HACCP introduced several terms not commonly used in local language, and sometimes no equal translation is available. In Thailand, term like "emerging pathogens" is not recognized. In Indonesia, hazard is translated into "bahaya", "kontaminan" or "cemaran" which sometimes cause confusion and led to different interpretation. It is a challenge already to comprehend and absorb all of the HACC terms and then it became even more difficult when they are translated into the local language.

Tradition

In some instance, implementation of GMP is hampered by tradition that has been part of the lifestyle. This is especially true when hazard does not cause immediate effect or long term and when products have been known for a long time. Examples from Indonesia include: use of borax in certain traditional chips (gendar) in Central Java or red illegal colorant such as Rhodamin B in certain traditional chips from West Sumatera (kerupuk merah) are good examples for this case. People are unwilling to give up the consumption just because they are used to consuming the products and the health hazard are not apparent. For this problem, a continuous education program with good social approach is required.

Behavior/Attitude

Food safety management system based on GMP and HACC is design to prevent hazard to become a risk to the society. Most of the actions are prevention in nature and this could be perceived as a high cost activity for certain industry, because of "the possibility of things for not happening". Examples include putting on cover for the light bulb, use of non food grade materials for secondary container/cover that is not thought to be in contact with food materials. To change this behavior, continuous education has to be given. In Indonesia for example, we could use to the implementation of helmet use for motor vehicle and or seat belt as references.

Financial Cost

In many cases, the burden of the GMP and HACC implementation in SMEs is the cost. Major financial cost actually lies in GMP for implementation or the prerequisite program for HACC. A study showed the average cost of GMP/HACC implementation of 14 companies in Turkey is shown in Table 3.
GMP and HACCP goes hand in hand as a way to assure food safety. Implementation of HACCP requires GMP to be in place thus CMP is considered as the prerequisite for HACCP implementation. Often people are so fascinated by the HACCP principles that they do not take care of the more basic need, i.e., GMP. Implementation of HACCP principles with low compliance of GMP will create many problems. When infrastructure related to GMP implementation is lacking, it is best to first assure that the requirement is met. Step by step improvement must be planned by industries and in some instances, government through their regulations to assure improvement of food safety. The food-star program launched by the National Agency for Drug and Food Control (NAFDC) in Indonesia is a good approach that needs to be strengthened. However, advancing facilities and basic also needs help from other regulations/policy such as those regulating small industry (local/discret institution), bank credit, etc.

It is also important to understand that GMP and HACCP should be made into "self" food safety objective, thus all efforts are made to produce a good quality and safe products, not just because of international trade pressure. This is a phenomenon that is suggested by Franco (2009) that in developing countries there is a tendency of having double standards in which exported foods are produced with a good food safety management while foods for domestic market has not received the same enforcement. In Indonesia and many countries in SEA, risk assessment studies have been carried out with seafoods since this food category is the most exported foods.

When food industry is implementing HACCP and is a HACCP plan, it is always important to evaluate implementation and verify whether the implementation in an acceptable level of conditions. Routine evaluation, for example, is one of a good example. GMP requirement. Because of the lack of understanding, first are drives to establish a specific GMP manuals by same. While they may be useful, GMP needs not to be different. It is too much resources is spent on making the GP derivative.

On the contrary, HACCP is product specific, even at a specific industry or line process specific. A generic HACCP plan is made, however, in reality, this plan will not fit all sizes and is not always possible to have the same control measure. HACCP plan when the source of raw materials is total even though all of the production steps are the same. All plan of the same products with similar quality criteria produced in an industry could be different because of the technology applied on the processing of the products.

Presence of different standard SQF 200, ISO 22000, sometimes also confused people. This is especially true for the different terms used. ISO 22000:2005 for example, the terms operational prerequisite program in addition to HACCP and a distinction between corrective action. Fast development of food safety management has also introduced new metrics such as food safety objective, performance objectives (PO), performance criteria (PC) supposed to be built on GMP/HACCP and not to replace it.

Because of the above reasons, HACCP implementation is constrained too. Establishing a HACCP plan in food industry has been a challenge. Often call for consultant inputs because of the resources and confidence. Several regulations exist. Principles, especially principles 1-3, are illustrated below.

**CONFUSIONS COMMONLY ENCOUNTERED REGARDING GMP/HACCP**

Table 3. Average cost of GMP/HACCP implementation of 14 food industry in Turkey*

<table>
<thead>
<tr>
<th>No</th>
<th>Cost</th>
<th>€</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Building, ground and planning of the surrounding</td>
<td>12,178</td>
<td>42.17</td>
</tr>
<tr>
<td>2</td>
<td>Hygiene and sanitation</td>
<td>5,162</td>
<td>17.88</td>
</tr>
<tr>
<td>3</td>
<td>Insect control</td>
<td>3,400</td>
<td>11.78</td>
</tr>
<tr>
<td>4</td>
<td>Personal training</td>
<td>2,057</td>
<td>7.13</td>
</tr>
<tr>
<td>5</td>
<td>Calibration, maintenance and repairing</td>
<td>6,076</td>
<td>21.28</td>
</tr>
</tbody>
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*Media et al., 2005
Science-Based Approach for Food Safety Management

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<td>5</td>
<td>Calibration, maintenance and repairing</td>
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*Mutlu et al., 2005

Confusions Commonly Encountered Regarding GMP/HACCP

GMP and HACCP goes hand in hand as a way to assure food safety. Implementation of HACCP requires GMP to be in place thus GMP is considered as the prerequisite for HACCP implementation. Often people are so fascinated by the HACCP principles that they do not take care of the more basic need, i.e. GMP. Implementation of HACCP principles with low compliance of GMP will create many problems. When infrastructure related to GMP implementation is lacking, it is best to first assure that the requirement is met. Step by step improvement must be planned by industries and in some instances government through their regulations to assure improvement of food safety. The food-star program launched by the National Agency for Drug and Food Control (NAFDC) in Indonesia is a good approach that needs to be strengthened. However, advancing facilities and basic also needs help from other regulations/policy such as those regulating small industry (local/district institution), bank credit, etc.

It is also important to understand that GMP and HACCP should be made into "self-food safety objective", thus all efforts are made to produce a good quality and safe products, not just because of international trade pressure. This is a phenomenon that is suggested by Franco (2009) that in developing countries there is a tendency of having double standards in which exported foods are produced with a good food safety management while foods for domestic market have not received the same enforcement. In Indonesia and many countries in SEA, risk assessment studies have been made mainly with seafoods since this food category is the most commonly exported foods.

When food industry is implementing HACCP and is establishing a HACCP plan, it is always important to evaluate their GMP implementation and verify whether the implementation has resulted in an acceptable level of conditions. Routine environmental evaluation, for example, is one of a good example. GMP is a generic requirement. Because of the lack of understanding, frequently there are drives to establish a specific GMP manuals by government. While they may be useful, GMP needs not to be differentiated such that too much resources is spent on making the GP derivatives.

On the contrary, HACCP is product specific, even sometimes it is location or line process specific. A generic HACCP plan may be made; however in reality, this plan will not fit all sizes and types. It is not always possible to have the same control measures and thus HACCP plan when the source of raw materials is totally different even though all of the production steps are the same. Also, a HACCP plan of the same products with similar quality criteria that were produced in an industry could be different because of the difference in the technology applied on the processing of the product.

Presence of different standard SQF 200, ISO 22000:2005 sometimes also confused people. This is especially true because of the different terms used. ISO 22000:2005 for example, introduced the terms operational prerequisite program in addition to prerequisite program and a distinction between corrective actions and correction. Fast development of food safety management worldwide has also introduced new metrics such as food safety objectives (FSO), performance objectives (PO), performance criteria (PC) etc that are supposedly built on GMP/HACCP and not to replace it.

Because of the above reasons, HACCP implementation have some constraints too. Establishing a HACCP plan in food industries has been a challenge, often call for consultant inputs because of lack in resources and or confidence. Several questions regarding HACCP principles, especially principle 1-3, are illustrated below.
Principle 1: Hazard analysis

Conducting hazard analysis has to consider all hazards possibly present or entering the processing steps. Therefore it is important that no ingredient or no steps are are missing in the flow diagram. When assessing hazard it is very important to have the scientific data regarding presence of a certain pathogen in a certain food and whether an outbreak of the pathogen as a results on consuming the food has occurred. A lot of time it is good to know the source of the hazard, since it will dictates the control measures that may be used to overcome the problem. The first HACCP principle is a very simple risk assessment in which the team assess what kind of risk is still acceptable. When deciding severity of illness, objective then what considered low. Small, medium or high frequency should be translated into what is acceptable for the company in terms of having a low quality or possibility of releasing a defective or hazardous products.

Principle 2: Determination of CCP

Determining the CCP can be done using the decision tree, however it does not always the case. In a more simple processing steps, a CCP can be determined with common senses. Sometimes there is assumption that the number of CCP has to be a certain number, thus the HACCP team keep trying to look for the certain number of CCPs eventough it is not appropriate.

Principle 3

Critical limit of a CCP should be established based on scientific data obtained from reference or other guidelines (for example guidelines for commercial sterilization). However, CL determination in an industry should always be based on the materials, processing steps, environment and GMP that is implemented in the industry. Critical limits based on other company or importing country company is therefore not appropriate. In the new food safety metrics, CL can be derived from performance criterion (PC) needed to achieve certain POs and thus FSOS. When this done, it only contribute to a safe product but also reduction of cost due to the food.

ILLUSTRATION OF FSM IMPLEMENTATION IN INDONESIA

The first case study was the development of a Nata for an instant drink in a food industry. The product is not through grinding of sugars, flavor and coloring. With sugar and high sugar content, it is concluded that there was a biological and chemical hazard. However, intensive has been concluded as the source of physical hazard thus a metal detector. At the time that the assessment was made the metal detector request is still pending at the top level. The study suggested that top management had to vision and understanding when implementing a GMP/HACCP plan.

Another example of study was conducted in a company. Nata de coco is a popular dessert in Asia consisting of cubes of nata in light syrup. Nata itself is product, i.e. bacterial cellulose produced by Acetobacter. The general flow diagram of the nata de coco processing is Figure 1. During the HACCP plan development, it is co vegetative microbial pathogens are not the main concern of the heat treatment received. Problems that arise to physical contaminants from equipment, environment, workers. Implementation of a HACCP plan has address and evaluation of the implementation between Sept until June 2005 suggested a reduction of rejected product to 5.32%, which could be translated into USD 43,000 (data in conjunction with EC-ASEAN Economic Cooperation).

The third case study compared food safety applied in two different frozen shrimp company. The conducted independently for a different objective at different industries that processed frozen shrimp for export. Both have implemented CMP and due to the regulation in Indonesia also implemented HACCP plan. Company A received Nata from traders while company B received raw materials.
Science-Based Approach for Food Safety Management

Principle 1: Hazard Analysis

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Determining the CCP can be done using the decision tree, however it does not always the case. In a more simple processing steps, a CCP can be determined with common senses. Sometimes there is assumption that the number of CCP has to be a certain number, thus the HACCP team keep trying to look for the certain number of CCPs even though it is not appropriate.

Principle 3

Critical limit of a CCP should be established based on scientific data obtained from reference or other guidelines (for example guidelines for commercial sterilization). However, CL determination in an industry should always be based on the materials, processing steps, environment and GMP that is implemented in the industry. Critical limits based on other company or importing country company is therefore not appropriate. In the new food safety metrics, CL can be derived from performance criterion (PC) needed to achieve certain POs and thus FSOS. When this is done, a CL does not only contribute to a safe product but also reduction of certain illness due to the food.

ILLUSTRATION OF FSM IMPLEMENTATION IN INDONESIA

The first case study was the development of a HACCP plan for an instant drink in a food industry. The product is manufactured through grinding of sugars, flavor and coloring. With such a low raw and high sugar content, it is concluded that there was no significant biological and chemical hazard. However, intensive grinding has been concluded as the source of physical hazard thus an installation of metal detector. At the time that the assessment was conducted, the metal detector request is still pending at the top management level. The study suggested that top management had to have similar vision and understanding when implementing a GMP/HACCP.

Another example of study was conducted in a nata de coco company. Nata de coco is a popular dessert in Asian countries consisting of cubes of nata in light syrup. Nata itself is a fermented product, i.e., bacterial cellulose produced by Acetobacter xylinum. The general flow diagram of the nata de coco processing is shown in Figure 1. During the HACCP plan development, it is concluded that vegetative microbial pathogens are not the main concerns because of the heat treatment received. Problems that arises was mainly due to physical contaminants from equipment, environment and workers. Implementation of a HACCP plan has addressed the issues and evaluation of the implementation between September 2004 until June 2005 suggested a reduction of rejected product from 14.43 to 5.32%, which could be translated into USD 43,000 (unpublished data in conjunction with EC-Asean Economic Cooperation, 2005).

The third case study compared food safety management applied in two different frozen shrimp company. The study was conducted independently for a different objective at different time, but it is a good lesson learned. Company A and B both are large industries that processed frozen shrimp for export. Both companies have implemented GMP and due to the regulation in Indonesia, have also implemented HACCP plan. Company A received raw material from traders while company B received raw materials from farmer

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supervised by the company. In fact, the company owned 3500 ponds located in the vicinity of the processing plant. A small study carried out in company A showed that Salmonella was frequently found in raw materials entering the plant. The study also showed that chlorination of product and GMP compliance only resulted in small reduction of Salmonella finding (Dewanti et al., 2005). Meanwhile, company B could eliminate chlorine use and still obtained a lower Salmonella frequency in the product. Export data of the two companies showed high disparity in terms of their export performance: company A has 20 rejection while company B got only 1 rejection between November 2004-April 2005 (www.oasis.org)

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