Major Milestones Achieved — MPTP Enters Next Phase

October 6, 2015
DuPont Presenters

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Medical Packaging Fellow

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Global Technical Director

Karen Polkinghorne
Packaging Engineer and MDM Specialist

Margaret (Meg) Pyers
Global Marketing Director
Topics of Today’s Discussion

- Guidance from U.S. FDA and Health Canada
- Tips for Submissions to Notified Bodies
- MPTP Interim Test Results after 7- and 10-Year Accelerated Aging
- Commercialization Plan
- We’re Still Here to Help
Thank You

Today would not have been possible without the collaboration and support of those listed here plus more than 55 MDMs.
Participating Regulatory Organizations

- U.S. FDA Center for Devices and Radiological Health (CDRH)
- Health Canada
- BSI Assurance UK Ltd
- LNE/G-MED
- SGS United Kingdom Limited
- TÜV Rheinland LGA Products GmbH
- TÜV SÜD Product Service GmbH
- China Food and Drug Administration (CFDA)-Jinan Quality Supervision and Inspection Center for Medical Devices
- Japan Ministry of Health, Labor and Welfare (MHLW)
U.S. FDA CDRH Affirms Functional Equivalence

To: Dr. Michael H. Scholla

From: DuPont Protection Technologies

c/o Michael H. Scholla, Ph.D.
Global Director, Regulatory and Standards
Chestnut Run Plaza 735/4250-1
974 Centre Road
Wilmington, DE 19805

Dear Dr. Scholla,

FDA has reviewed amendments 1-4 to the Device Master File (MAF) 1920, received from June 2 to August 10, 2015. You have performed testing as outlined in the “Protocol for Transition of the Medical Device Industry to Tyvek® Manufactured Using an Upgraded Spinning Process” provided August 15, 2012 and demonstrated that the new (Transition) Tyvek® product is functionally equivalent to existing (Legacy) Tyvek® products. Tyvek® is used to fabricate sterile barrier systems for an array of medical devices. The Transition Tyvek® is available in both coated (1073B) and uncoated (1059B) styles.

On the basis of the data you submitted, including testing of the functional performance of Tyvek® during medical device sterilization and maintenance of package integrity over time, FDA has determined that the performance of the new Tyvek material is functionally equivalent to the existing Tyvek material. Therefore, it is not necessary, absent a specific request or notice from FDA or a risk analysis finding to the contrary, for medical device manufacturers to submit a new 510(k) or PMA supplement for a change solely in packaging from the Legacy Tyvek® to the Transition Tyvek® manufactured using an upgraded spinning process.

When DuPont communicates this material equivalence determination to medical device manufacturers, please convey the following information about the documentation of their implementation of the new Transition Tyvek® material, including both coated and uncoated Tyvek® styles 1073B and 1059B, in accordance with FDA’s device Quality System regulation (21 CFR part 820):

- Conduct a Risk Analysis to determine if a premarket submission is needed due to a change in risks (e.g., for IVDs – change in performance, cut-offs).
- Implement their change control procedures in accordance with the Quality System regulation, including, but not limited to, evaluation of the impact of this change on packaging and sterilization (if indicated) processes.
- Document activities associated with this change in accordance with the Quality System regulation, including but not limited to, updating the Device Master Record and the rationale for acceptance of Transition Tyvek®.

Sincerely,

Jeffrey Shuren, M.D., J.D.
Director
Center for Device and Radiological Health, FDA

www.fda.gov  www.areyouready.tyvek.com
On the basis of the data you submitted, including testing of the functional performance of Tyvek® during medical device sterilization and maintenance of package integrity over time, FDA has determined that the performance of the new Tyvek material is functionally equivalent to the existing Tyvek material. Therefore, it is not necessary, absent a specific request or notice from FDA or a risk analysis finding to the contrary, for medical device manufacturers to submit a new 510(k) or PMA supplement for a change solely in packaging from the Legacy Tyvek® to the Transition Tyvek® manufactured using an upgraded spinning process.
U.S. FDA Letter — Bullet Points

- Conduct a Risk Analysis to determine if a premarket submission is needed due to a change in risks (e.g., for IVDs – change in performance, cut-offs).
- Implement their change control procedures in accordance with the Quality System regulation, including, but not limited to, evaluation of the impact of this change on packaging and sterilization (if indicated) processes.
- Document activities associated with this change in accordance with the Quality System regulation, including but not limited to, updating the Device Master Record and the rationale for acceptance of Transition Tyvek®.
What Is Legacy Tyvek®?

Now that we have received U.S. FDA affirmation of Functional Equivalence and are beginning commercialization, the term “Current Tyvek®” is no longer relevant.

Legacy Tyvek® is the new term for Tyvek® produced on the older manufacturing lines.

DuPont will use the terms Legacy Tyvek® and Transition Tyvek® on product literature, reports and other documents going forward.

Tyvek® Style Names 1073B and 1059B remain unchanged!
Regulatory Update — Health Canada

“Health Canada Requirements for Manufacturers Relating to Manufacturing Change to Tyvek® 1073B and 1059B” was broadcast e-mail by Health Canada on May 7, 2014 and posted at www.areyouready.tyvek.com

Individualized letters were sent by Health Canada on September 30, 2015 to the regulatory contacts for all current Class III and IV Medical Device Licence Holders describing the Action Required.

- Two forms are provided. Both must be completed and signed by a senior official of the device manufacturer and returned by December 31, 2015.
  - September 30, 2015 Licence Notification
    - Specific to each medical device manufacturer listing every Licence Number for that manufacturer. There are two options for completing this form (next slide).
  - Attestation page
    - Attestations from all current Class III and IV Medical Device Licence Holders, regardless of whether or not Tyvek is present in the product. The responsibility for signing the attestation will be that of the medical device licence holders (manufacturers).
**OPTION 1**
☐ None of the medical devices described in the “September 30, 2015 Licence Notification” use Tyvek materials / Aucun des instruments médicaux décrits dans l'Avis de licence du 30 septembre 2015 n'utilise le matériel d'emballage Tyvek

**OPTION 2)**
** Select one response for each licence listed. / Veuillez choisir une réponse pour chaque licence inscrite sur la liste.**
** Do not select multiple responses per licence. / Ne pas choisir des réponses multiples pour une licence.**

Manufacturer’s Name / Nom du fabricant : XXXXXX, Inc.

Manufacturer’s Company ID / Identité de l'entreprise du fabricant : #######

<table>
<thead>
<tr>
<th>Licence # / No de licence</th>
<th>Licence Name / Nom sur la licence</th>
<th>Response RE: Tyvek / Réponse concernant Tyvek</th>
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<tbody>
<tr>
<td>1234</td>
<td>Licence ABC</td>
<td>NT</td>
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<tr>
<td>5432</td>
<td>Licence DEF</td>
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## Health Canada — Attestation Codes (slide 1 of 2)

<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
</tr>
</thead>
</table>
| NT   | • No Tyvek is used in any devices under this licence; or  
• Transition Tyvek will not be used for these devices (e.g. the devices on this licence do use Tyvek, but the licence is being cancelled by the manufacturer and therefore we will not switch to Transition Tyvek) |
| TOK  | • The Transition Tyvek package configuration, sterilization method, and labelled shelf life are fully covered (clearly applicable and representative) by DuPont’s testing; or  
• The Transition Tyvek packaging configuration, sterilization method, and labelled shelf life are **NOT** fully covered by DuPont’s testing; however the manufacturer’s assessment of the licensed packaging configuration, sterilization method, and labelled shelf life are functionally equivalent to one of the packaging configurations, sterilization methods and labelled shelf lives tested by DuPont and will not compromise the packaging’s performance.  

*If the sterilization modality used is Ethylene Oxide (EtO), acceptable EtO residuals will be confirmed by the device manufacturer in accordance with Health Canada’s Guidance Document – Recognition and Use of Standards under the Medical Devices Regulations, in advance of selling devices with Transition Tyvek.  
Given these circumstances and the 2014 Notice, a medical device licence amendment application will not be submitted. Documentation of the above will be included in the manufacturer’s quality management system.*
### Health Canada — Attestation Codes (slide 2 of 2)

<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>AP</td>
<td>The Tyvek package configuration and sterilization method is <strong>NOT</strong> covered by DuPont’s testing and there is a reasonable expectation that differences may negatively impact the device sterility over the stated shelf-life. <em>A medical device licence amendment application will be submitted pursuant to section 34 of the Medical Devices Regulations.</em></td>
</tr>
<tr>
<td>TBD</td>
<td>The implications of the Transition Tyvek on these devices have not yet been determined. <em>Analysis will be conducted and a second attestation and a 2016 Licence Notification will be submitted before December 31, 2016.</em></td>
</tr>
</tbody>
</table>
Attestations Page (slide 1 of 2)

OPTION 1)

☐ None of the medical devices described in the attached “September 30, 2015 Licence Notification” use Tyvek materials / Aucun des instruments médicaux décrits dans l'Avis de licence du 30 septembre 2015 ci-joint n'utilise le matériel d'emballage Tyvek.

I, as a senior official of manufacturer’s name, hereby attest that none of the medical devices described in the attached September 30, 2015 Licence Notification use Tyvek materials; or Transition Tyvek will not be used for these devices. / À titre de cadre supérieur de nom du fabricant, je, soussigné(e), confirme qu'aucun des instruments médicaux décrits dans l'Avis de licence du 30 septembre 2015 n'utilise le matériel d'emballage Tyvek ou n'utilisera la transition de l'emballage médical Tyvek pour ces instruments.

Name

Signature

Title

Date
Attestations Page (slide 2 of 2)

OPTION 2)

☐ As indicated in the attached “September 30, 2015 Licence Notification” table, there are licences that will use Transition Tyvek / Tel qu'il est indiqué dans le tableau de l'Avis de licence du 30 septembre 2015, certaines licences touchent des instruments qui utiliseront la transition de l'emballage médical Tyvek.

I, as a senior official of manufacturer’s name, hereby attest that I have direct knowledge of the change in Tyvek packaging materials supplied by DuPont and declare that the information presented in the attached “September 30, 2015 Licence Notification” table is true and complete and that device records for each device have been appropriately revised to document the specific considerations in arriving at these responses.

Where the TBD code has been entered, I hereby attest that I will provide a further 2016 Licence Notification and another signed attestation letter by December 31, 2016 once an analysis has been completed.

Name

Signature

Title

Date
Health Canada Acknowledgement

Health Canada will send an acknowledgement e-mail to the regulatory contact once the attestation and licence listing have been validated for completeness and added to the manufacturer’s file.

If an error is made in completing the table (i.e. multiple responses have been indicated for a given licence, or no response has been provided for a given licence), the package will be returned to the regulatory contact with an indication of where the error was made. A revised licence listing and attestation will be requested within 15 days.

After Health Canada acknowledges the submission of the Attestation and the September 30, 2015 Licence Notification, depending on the device manufacturer’s responses in the attestation and the 2015 licence notification, the next step in the process for the device manufacturer will be one of the following:
Health Canada Next Steps after Acknowledgement

No further action, either because

- The medical device does not use Tyvek; or
- Transition Tyvek will not be used for these devices; or
- The Tyvek configuration, sterilization method, and labelled shelf life are fully covered (clearly applicable and representative) by DuPont's testing. *These assessments will be documented in the device manufacturer’s quality management system.*; or
- A Senior Official of the manufacturer attests that the device manufacturer has assessed its own packaging configuration, sterilization methods, and labelled shelf life of the Tyvek packaging as functionally equivalent to a configuration included in the DuPont testing such that the packaging's performance will not be compromised. These assessments will be documented in the device manufacturer’s quality management system; or

A medical device licence amendment application will be submitted to Health Canada; or

Further analysis will be undertaken in the coming year and a more fulsome response made to Health Canada before December 31, 2016.
Health Canada Summary

Class III and IV Licence holders have/will receive an individualized communication from Health Canada
  • If your regulatory contact hasn’t received their package, contact Health Canada

The two forms in this communication must be completed and returned by December 31, 2015

The assessments must be documented in the device manufacturer’s quality management system

Depending upon the responses in the returned form, additional actions may be necessary

For the TOK response:
  • If EtO is the sterilization modality, acceptable EtO residual levels must be confirmed prior to sale of product using Transition Tyvek®
Review of Executive Summary with U.S. FDA, Health Canada and 5 Notified Bodies

- Met with each organization over a 3-week period to specifically address the 6 occurrences of non-equivalence or non-inferiority in greater detail than described in the Executive Summary Report*

- All were satisfied with our analysis and explanations

- Meetings with the Notified Bodies clearly indicated similarities and differences between them

- Many of the differences between Notified Bodies are due to requirements of their respective Competent Authority

*Refer to Industry Executive Summary Report published in August (pg. 13-14) available at www.areyouready.tyvek.com
Tips for Submissions to Notified Bodies

- Have very specific discussions with your Notified Body regarding referencing reports or a requirement to include DuPont reports
  - Be mindful of confidentiality of Cell and Participant Reports

- Notified Bodies’ major concern was submissions by MDMs that simply cited DuPont reports without any analysis on how this applies to the specific device(s)
  - Make your analysis meaningful

- Several Notified Bodies have made guidance available to their customers; read their guidance to meet requirements for successful submission

- Be aware that Notified Bodies may be asking for specific information to allow them to document the audit process

- Realize that requirements vary by Notified Body
Regulatory Update — Japan

September 25, 2013 Guidance was to file a Minor Change Notification Form (Keibi Henkou Todeke); however, laws have changed

Based upon new laws, **NO ACTION IS REQUIRED**; translation of new June 1, 2015 Guidance available on our website in the regulatory section

If you file a Minor Change Notification Form (Keibi Henkou Todeke) for another reason, delete the references to sterile packaging material

Available at: [www.areyouready.tyvek.com](http://www.areyouready.tyvek.com)
## Regulatory Report Submission Status

<table>
<thead>
<tr>
<th>INDIVIDUAL CELL REPORTS</th>
<th>U.S. FDA</th>
<th>Health Canada</th>
<th>BSI Assurance UK Ltd</th>
<th>LNE/G-MED</th>
<th>SGS UK Ltd</th>
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*Eleven cells designated for extended accelerated aging (7 and 10 year) and real-time aging (10 years).
Publication of MPTP *Industry Summary Reports*

Pre-sterilization and Post-sterilization
Accelerated Aging (1 Year)
Accelerated Aging (3 Years)
Accelerated Aging (5 Years)
Real-Time Aging (1 Year)
Executive Summary
Accelerated Aging (7 Years)*
Accelerated Aging (10 Years)*
Real-Time Aging (3 Years)
Real-Time Aging (5 Years)
Real-Time Aging (10 Years)*

Timing
October 2014 ✓
February 2015 ✓
June 2015 ✓
July 2015 ✓
August 2015 ✓
August 2015 ✓
March 2016
September 2016

2017
2019
2024

*Eleven cells designated for extended accelerated aging (7 and 10 years) and real-time aging (10 years).
MPTP Testing Update

Data to-date represents:
more than 50,000 seal strength tests and 2,500+ microbial barrier tests

In summary, the data indicates:
• 796 out of 798 instances of seal strength Functional Equivalence
• 468 out of 468 instances of microbial barrier Non-Inferiority
• 14,039 out of 14,040 instances of No Dye Penetration
• 114,726 out of 114,729 instances of No Material Defects

Page 11 of the Industry Executive Summary Report published in August contains the Functional Equivalence assessment of Package Integrity

Bottom Line: Testing results indicate Functional Equivalence
Industry Summary: MPTP Interim Test Results (7/11 Cells) after *7-Year Accelerated Aging*, Pass/Fail Summary for Seal Strength — ASTM F88

<table>
<thead>
<tr>
<th>Tyvek® Style</th>
<th>Coating Type</th>
<th>Sterilization Type</th>
<th>Pouches and Bags</th>
<th>Form-Fill-Seal</th>
<th>Rigid Trays</th>
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<tbody>
<tr>
<td></td>
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<td></td>
<td>Number of Cells</td>
<td>Pass</td>
<td>Fail</td>
</tr>
<tr>
<td>1073B</td>
<td>Coated</td>
<td>EO</td>
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<tr>
<td></td>
<td></td>
<td>Gamma</td>
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<td>2</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Low Temp. H₂O₂</td>
<td>1</td>
<td></td>
<td></td>
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<tr>
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<td>Uncoated</td>
<td>EO</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

**Legend**

- **AWAITING ANALYSIS**
- **THERE ARE NO CELLS IN THIS CATEGORY BEING TESTED AFTER 7-YEAR ACCELERATED AGING**
- **THERE ARE NO CELLS IN THE MPTP FOR THIS CATEGORY**
## Industry Summary: MPTP Interim Test Results
(3/11 Cells) after **10-Year Accelerated Aging**, Pass/Fail Summary for Seal Strength — ASTM F88

<table>
<thead>
<tr>
<th>Tyvek® Style</th>
<th>Coating Type</th>
<th>Sterilization Type</th>
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<td>Uncoated</td>
<td>EO</td>
<td>1</td>
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</tr>
</tbody>
</table>

**Note:**
- **Awaiting Analysis**
- **There are no cells in this category being tested after 10-Year Accelerated Aging**
- **There are no cells in the MPTP for this category**
NEW Transition Protocol Material Data on Our Website

- Effects of sterilization and *7-year accelerated aging* on:
  - material puncture strength
  - material tensile strength
  - material elongation
  - material microbial barrier (ASTM F2638)

- Effects of sterilization and *10-year accelerated aging* on:
  - cytotoxicity

- Japan Food Sanitation Law

- Transition Tyvek® Specification Properties – No Changes
All of this and more can be found on our website at:
www.areyouready.tyvek.com

Documents on this website will be available through 5-Year Real-Time Aging (2019)
Are You Ready Website – Regulatory Section

Regulatory Guidance

In addition to Tyvek® transition project data, guidance obtained from regulatory authorities around the world is posted to help medical device manufacturers stay informed. For more information on regulatory letters, testing certificates, as well as Device Master Files, please visit our Medical Packaging Reference Library.

- Guidance from U.S. FDA
  - March 1, 2011
  - October 18, 2012
  - Letter Affirming Functional Equivalence

- Regulatory Guidance from Japan
  - September 19, 2012
  - September 25, 2013
  - June 1, 2015

- Summary of Guidance from China, CFDA/Inman

- Guidance from Health Canada
  - May 7, 2014
  - September 30, 2015

European Notified Bodies

- Position Statements with Protocol Review
  - BSI Assurance UK Ltd
  - LNE/G-MED
  - SGS United Kingdom Limited
  - TÜV Rheinland LGA Products GmbH
  - TÜV SÜD Product Service GmbH

- Position Statements
  - DQS MedizInprodukte GmbH
  - NSAI Inc.
  - AMTAC Certification Services Ltd and Intertek SEMKO AB

Resources

- MPTP Industry Collaborators
- DuPont MPTP Experts
- Industry Organizations
- Return back to MPTP Home Page

U.S. FDA Letter Affirming Functional Equivalence

Japan Guidance, June 2015

Health Canada Guidance, September 2015
Helpful Hints for MDMs

- **U.S. FDA**
  - Make sure you meet the 3 bullet points outlined in the U.S. FDA letter
  - Class II and III devices, place letter(s) in each applicable device record **before** beginning to use Transition Tyvek®

- **European Notified Bodies**
  - Complete risk assessments and notifications per guidance from your Notified Body
  - Class III devices sold in Europe – Continue to submit to your Notified Bodies

- **Health Canada**
  - Class III and IV devices sold in Canada – Packages from Health Canada were e-mailed to your authorized regulatory contact on September 30, 2015. Responsibility for signing and submitting the attestation will be that of the medical device licence holders (manufacturers).
  - Refer to Health Canada Guidance for required submission dates
Updated DuPont Commercialization Plan

- Both Legacy and Transition Tyvek® are now available from DuPont to SPMs.
- We recognize the real-world dynamics of our customers’ needs, regulatory submissions and short-term supply constraints.
- DuPont is extending the availability of Legacy Tyvek® through June 2016 in response to customer requests.
- Each SPM has their own inventory management systems. Please contact your direct Tyvek® supplier for any questions related to the supply of Legacy Tyvek®.
2015 Will Be a Record Production Year for Tyvek®
Sold into Medical and Pharmaceutical Packaging

While we expect to ship more medical packaging product this year than any other year in recent history, the demand for these products is more than 40% higher than the same time last year.

As a result, we are experiencing some supply limitations, which we expect will improve by mid-2016.

To better support the industry, we have decided to extend the availability of Legacy Tyvek® through June 2016.

Although we have not announced a specific date for the full discontinuation of DuPont production of Legacy Tyvek®, sufficient notice will be given, allowing MDMs to plan accordingly with minimal disruption to their business.
Upcoming Events and Other Ways to Stay Informed

- Attend a DuPont Seminar near you:
  - Dallas, TX – October 20
  - East Lansing, MI – November 10

- Visit us at Medica/Compamed 2015 in Düsseldorf, Germany – November 16-19

- Global webcasts – available on-demand for up to a year at www.medicalpackagingcommunity.com

- Tyvek® Rx eNewsletter – next issue coming in November
  - www.transition.tyvek.com
  - www.areyouready.tyvek.com
The Bottom Line

U.S. FDA Affirmed Functional Equivalence
Health Canada Issued Guidance
Notified Bodies Are Approving Submissions

Transition Tyvek® is now interchangeable with Legacy Tyvek®

Use of Transition Tyvek® should be documented in each applicable device record

We have extended the availability of Legacy Tyvek® to support your needs
Thank you to the hundreds of DuPont employees around the world from R&D, technical, manufacturing, QA, regulatory, sales and marketing who have dedicated their time and talent to help ensure the success of MPTP.
In Closing, Why Tyvek®?

For more than 40 years, you have relied on DuPont products, technical expertise and global response capabilities

We’re committed to the medical and pharmaceutical industries and the protection of people and critical processes around the world
  • Continuing to invest in our manufacturing operations and reliability

We look forward to continuing to work with you to better meet your current and future needs as we explore new ways to help address the ever-growing global challenge of infection control

Thank You
Questions?

Tyvek.

www.transition.tyvek.com
www.areyouready.tyvek.com
Thank you!

Today’s webcast will be archived for one year for on-demand viewing within this environment

For any additional questions, please contact us:

Daphne Allen, Editor, Pharmaceutical & Medical Packaging News at daphne.allen@ubm.com

Or a member of the DuPont team at www.transition.tyvek.com