DUPONT™ TYVEK® MEDICAL PACKAGING TRANSITION PROJECT (MPTP) FREQUENTLY ASKED QUESTIONS—JUNE 2015

TABLE OF CONTENTS

For more information, including links to data and documents, visit our website at **www.Transition.Tyvek.com**

DUPONT™ TYVEK® MPTP FREQUENTLY ASKED QUESTIONS

JUNE 2015

COMMERCIALIZATION

1. What can MDMs do now to prepare for full commercialization of Transition Protocol material?

If you have not already done so, you should complete your internal change control and risk assessments, as well as any additional testing, as soon as possible and discuss plans with your SPM(s) immediately. For Class III devices sold in Europe, you should have your significant change notification paperwork complete and ready to send to the relevant Notified Body, following the timing guidelines below:

- If the relevant Notified Body is one of the five that have issued guidance letters for European compliance (BSI Assurance UK, Ltd., LNE/G-MED, SGS United Kingdom Limited, TÜV Rheinland LGA Products GmbH and TÜV SÜD Product Service GmbH), you can send your significant change notification immediately after DuPont issues a letter to the industry confirming submission of all cell reports and Regulatory Summary Reports to the U.S. FDA, Health Canada and these five Notified Bodies in July 2015. You do not need to wait until the 1-Year Real-time Industry Summary Report is posted on our website in August 2015 because you can reference the Regulatory Summary Reports in your submission. You should coordinate this approach with your Notified Body.
- For all other Notified Bodies, you should be in discussion with them now.

2. What do I need to do from a regulatory standpoint if my device falls outside the Transition Protocol?

If your device is outside the scope of study performed in the U.S. FDA Transition Protocol (for example, you are using a completely different sterilization modality, such as chlorine dioxide), you will probably need to file amendments with the U.S. FDA, Health Canada and the relevant Notified Body.

3. What if my company is not ready to accept Transition Protocol material interchangeably with Current Tyvek® after DuPont begins supplying the Tyvek® Transition material?

After receipt of the U.S. FDA letter affirming Functional Equivalence (expected September 2015), the Transition Protocol material will become interchangeable with Current Tyvek®. If your company has any concerns on readiness, you should talk to your SPM as soon as possible about your concerns, as well as about the possibility of a customized plan.

4. Will DuPont have inventory of the Transition Protocol material already made before U.S. FDA affirmation of Functional Equivalence?

We continue to manufacture Transition Protocol material to support demand for controlled sales product and build inventory. Upon affirmation of Functional Equivalence from the U.S. FDA (expected September 2015), we will begin confirming new orders from either Current or Transition Protocol material existing inventories, and produce to order as needed.

5. What about orders in place prior to U.S. FDA affirmation of Functional Equivalence, will those be filled with Current Tyvek® or Transition Protocol material?

Unless specifically for controlled sales of Transition Protocol material, orders in place prior to U.S. FDA affirmation of Functional Equivalence will be fulfilled with Current Tyvek®. Only NEW orders received by DuPont after U.S. FDA affirmation may be fulfilled with Current Tyvek® or Transition material, depending on inventory.

DUPONT™ TYVEK® MPTP FREQUENTLY ASKED QUESTIONS

JUNE 2015

6. When can MDMs expect to receive the Transition Protocol material in their facility?

It will depend on your SPM and their supply plans and inventory levels. Please ask your SPM for the best estimates.

7. Why should I consider interchangeability of Current Tyvek® and Transition Protocol material in my risk assessment?

After receiving U.S. FDA affirmation of Functional Equivalence, DuPont will be supplying materials from both the current and newer technology lines during a transition period as we ramp up production on the newer technology lines and phase down the production of Tyvek® 1073B and Tyvek® 1059B on the current lines. Interchangeability between Current Tyvek® and Transition Protocol material eliminates the need to segregate inventories of Transition Protocol material and Current Tyvek® throughout the value chain, enabling flexibility in converting and end-user processes. It also allows all parties in the supply chain to deplete current inventories, which reduces waste.

8. How can manufacturers use Current Tyvek® and Transition Protocol material interchangeably following U.S. FDA affirmation of Functional Equivalence?

Interchangeability allows the MDM to use either Current Tyvek® or Transition Protocol material for devices already on the market, provided that:

- The MDM has considered this in their change control, risk management and regulatory submission processes.
- The specifications for the device package do not restrict the use of Current Tyvek® or Transition Protocol material.
- There were no changes to the packaging or sterilization process conditions.
- Any required regulatory submissions for the transition are structured and approved to allow both products to be used (if applicable).

9. Will customers know if material supplied after U.S. FDA approval is Current or Transition Protocol material?

After receipt of the U.S. FDA letter affirming Functional Equivalence, which is expected in September 2015, the Transition Protocol material will become interchangeable with Current Tyvek®. Initially, we will fill orders using Current Tyvek® and Transition Protocol material to allow for an orderly changeover.

10. Will customers receive styles from both the current and new lines during the transition?

Yes. The style names (i.e., 1073B and 1059B) will not change.

11. How do I ensure that I can use both Current Tyvek® and Transition Protocol material for my new devices?

To ensure that you can accept Current Tyvek® and Transition Protocol material for new devices, we recommend that you perform qualification testing utilizing Current Tyvek® and accept Functional Equivalence of the Transition Protocol material once affirmed by regulatory bodies. You may also choose to run parallel testing of Transition Protocol material to build your internal data set to augment MPTP results.

DUPONT™ TYVEK® MPTP FREQUENTLY ASKED QUESTIONS

JUNE 2015

12. What type of information is being provided in the Industry Summary Reports?

The Industry Summary Reports will contain study background and data summaries. Each of the metrics, including: seal strength, microbial barrier and package integrity will be broken down by seven categories to facilitate individual risk analysis where applicable. These seven categories are:

- Coated 1073B Pouches/Bags
- Coated 1073B Form-Fill-Seal
- Coated 1073B Lids/Rigid Trays
- Uncoated 1073B Pouches/Bags
- Coated 1059B Form-Fill-Seal
- Uncoated 1059B Pouches/Bags
- Uncoated 1059B Form-Fill-Seal

13. When will MPTP test results be publicly available?

We will be updating the MPTP Package Test Results Selector Tool and posting Industry Summary Reports on our website as follows:

- Pre- and post-sterilization (t=0) – Oct 2014
- Accelerated aging (1 year) – Feb 2015
- Accelerated aging (3 years) – June 2015
- Accelerated aging (5 years) – July 2015
- Real-time aging (1 year)–Aug 2015
- Accelerated aging (7 and 10 years)* – 2016
- Real-time aging (3 years) – 2017
- Real-time aging (5 years) – 2019
- Real-time aging (10 years)* – 2024

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

In addition, we will continue to post extensive Transition Protocol material data on our website as it becomes available.

14. Is commercial launch only contingent on U.S. FDA approval or other regulatory bodies also?

It is still our intent to begin transitioning to the newer manufacturing lines upon receipt of the letter from the U.S. FDA affirming Functional Equivalence, which is expected in September 2015.

15. Is the Transition Protocol material the same as what will be sold commercially?

Yes. Transition Protocol material used to create the packages for testing, sold for controlled sales and sold commercially after we receive affirmation from the regulatory bodies we have engaged, will all be made under the same manufacturing conditions.

16. When can we place a last order for Current Tyvek®?

MDMs should work with their SPM suppliers to coordinate demand and availability of Current Tyvek®. DuPont has been working with SPMs on plans and options to support these needs. Please communicate your transition schedule, supply needs and provide forecast information to your SPM immediately if you have not already done so.

17. What will be done if results don't demonstrate Functional Equivalence?

Any package anomalies will be investigated for root-cause and the results of these investigations will be documented and reviewed with the U.S. FDA. Results to date indicate that the Transition Protocol materials are Functionally Equivalent to Current Tyvek®.

DUPONT™ TYVEK® MPTP FREQUENTLY ASKED QUESTIONS

JUNE 2015

18. What is the purpose of controlled sales?

The purpose of controlled sales is to make Transition Protocol material available in advance of full commercialization to allow MDMs to conduct their internal risk assessments, including validating material for new or existing device packaging and/or conducting additional testing. It is **not** intended for packaging of existing commercial devices until applicable regulations in the country of sale are met.

19. How do I get controlled sales material ?

Controlled sales of Transition Protocol material to our direct customers (SPMs) began in July 2013. You should contact your SPMs to purchase controlled sales material.

20. Can I specify that I want specific line/polymer combinations when ordering controlled sales material?

Because ALL line/polymer combinations represent the specification and miscellaneous properties published for Transition Protocol material, DuPont will fill orders from ALL line/polymer combinations randomly.

21. When will DuPont shut down the older manufacturing lines?

We will begin transitioning to our newer lines upon receipt of the U.S. FDA letter affirming Functional Equivalence. We encourage you to complete your change control, risk assessments and necessary paperwork and be ready for the transition following U.S. FDA affirmation of Functional Equivalence (expected September 2015).

22. How will DuPont communicate test results for specific material combinations?

We will communicate results in various ways including posting documents to our website, global webinars and the MPTP Package Test Results Selector Tool. With this Tool, you will be able to track specific material combination results; however, based on the complexity of the data, test method variations and confidentiality requirements, specific package material results will be combined into broader result categories.

23. Will there be a cost difference between the Current and the Transition Protocol material?

Pricing for all products will continue to be reviewed on an ongoing basis and adjusted based on a number of factors, including market dynamics, investment and cost to serve, among others.

24. Who can I talk to if I have more questions?

We have DuPont experts available in all regions to answer your questions. You can find contact information on our website.

25. How can I stay up to date with this ongoing process?

There are multiple ways for you to stay informed. You can visit our website; attend our global webcasts (or view them on-demand for up to a year); participate in one of our face-to-face seminars; or request an individual meeting with a member of our global team.

We encourage you to sign up to receive notifications when new information is posted. Signing up is easy; simply click on “Contact Us” in the upper right corner on our home page and complete the form.

REGULATORY

26. What role does the U.S. FDA play in the transition?

We engaged the Center for Devices and Radiological Health (CDRH) at the U.S. FDA to help mitigate regulatory requalification. CDRH provided input to the Transition Protocol design. Over the course of the protocol implementation, CDRH will review extensive data analysis by DuPont of independent third-party generated data to show that Tyvek® produced as a result of the transition does not represent a significant change in functional performance compared to Current Tyvek®. If CDRH agrees with DuPont's analysis and conclusions, then it would issue guidance indicating that MDMs would not routinely be required to file amended 510(k)s or PMAs for existing devices because the transition represents a merge, or lot, change.

27. What guidance have you received from regulatory authorities outside the United States?

Europe

In Europe, five Notified Bodies: BSI Assurance UK Ltd, LNE/G-MED, SGS United Kingdom Limited, TÜV Rheinland LGA Products GmbH and TÜV SÜD Product Service GmbH issued guidance letters for European compliance. These five Notified Bodies received a copy of the U.S. FDA Transition Protocol Amendments and no issues have been reported.

In addition, AMTAC Certification Services Ltd and Intertek SEMKO AB, DQS Medizinprodukte GmbH and NSAI Inc. have issued position statements.

For implementing the change, it is expected that manufacturers will have to review the change in Tyvek® and have documented records of their change review, including: review of risks, rationale for accepting the protocol conclusions for their application and/or identification of further testing required in accordance with their specific change assessment process, risk management process and sterilization standards. Published data from the Transition Protocol can be used in the MDM risk assessments. These records will need to be included in the respective medical device design files.

For Class Is, IIa and IIb devices: It is also expected that the Legal Manufacturers who hold CE Certification for Class Is, IIa and IIb will assess DuPont information within their specific change control process in accordance with sterilization standards and implement the change through their Quality System, which will be reviewed at the next scheduled Notified Body Audit.

For Class III devices: For Legal Manufacturers who hold CE Certification for Class III devices, it is expected that the impact of the change will be assessed, as well as the applicability of DuPont's information on the product, rationale for accepting the protocol conclusions for their application and/or identification of further testing required. This information should be submitted to the relevant Notified Body under a significant change notification. (Refer to FAQ #1 on page 2 for timing guidelines.) It is expected that the Notified Bodies will give consideration to the work carried out by DuPont in relation to the general aspects of the material equivalence when reviewing the significant change notification.

(continued on page 7)

(continued from page 6)

Japan

In Japan, a three-party meeting was held on September 25, 2013, with the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceutical and Medical Device Agency (PMDA); the Association of Registered Certification Bodies (ARCB) under PAL; and the Japan Federation of Medical Device Association (JFMDA). Specification and miscellaneous properties of Transition Protocol materials were reviewed during the meeting. The recommendation from the three-party committee for Class II, III and IV medical devices is that MDMs should review their entries of record and assess if any information needs to be updated. If updates are required, MDMs simply need to submit a minor change notification (Keibi Henkou Todoke). This notification will **not** be audited or investigated by regulatory bodies; it is simply a report only. An example of the Japanese registration form of packaging material part, with English translation, is available on our website. The official Japanese guidance (Yakushokuki) describes the process of reporting partial changes made to medical devices under a minor change notification.

China

In China, we are working with the China Food and Drug Administration (CFDA) Jinan Quality Supervision and Inspection Center for Medical Devices. CFDA-Jinan performed material property testing on current product as part one of a two-part study. In part two, they repeated the testing using Transition Protocol materials and control materials. Testing included: basis weight; Mullen burst; delamination; hydrostatic head; Gurley Hill porosity; microbial barrier; and tensile strength. Criteria were previously established for determining Functional Equivalence of specification and miscellaneous properties. A final report with results of Functional Equivalence was issued by CFDA-Jinan in December 2013. The report states: "For the DuPont™ Tyvek® products manufactured with DuPont's latest flash spinning technology and current manufactured DuPont™ Tyvek® products, all the testing results meet the criteria of functional equivalence and non-inferiority under the DuPont Validation Protocol." An English translation of the report was issued by CFDA-Jinan in March 2014; a summary is posted on our website.

Canada

Health Canada's current guidance on significant changes applicable to Class III and IV devices is that packaging changes require a formal license amendment or a Health Canada review in a previous medical device license application. With regards to the Tyvek® change, Health Canada issued a guidance notice, which is posted on our website. In summary, Health Canada will:

- Review DuPont test results submitted to a pilot Device Master File;
- Utilize a unique, modified and simplified notification process solely for the DuPont™ Tyvek® Medical Packaging Transition Project (MPTP);
- Provide further specific Tyvek® change notification communication

The guidance further specifies that the packaging risk management processes also apply to Class II devices, but there is no notification required.

For more information

For additional information or to schedule a meeting with a DuPont representative, contact us through "Meet with DuPont Team Members" at www.Transition.Tyvek.com.

JUNE 2015

28. Have you taken into account the regulatory requirements of other countries such as Australia, Brazil and Korea?

We are working with authorities where the majority of medical devices are sold. The regulatory authorities we've engaged to date govern countries that account for greater than 90 percent of global single-use medical device sales.

If MDMs sell devices in a country other than those referenced here, they should contact their regulatory resources for that country to get change management guidance.

29. Guidance letters from Notified Bodies posted on the DuPont website indicate that a Change Notification must be submitted for Class III devices. How can we handle the time it takes to receive a response?

First, you should have already begun discussions with your SPM and Notified Body for planning and preparation with the information already available to you. This allows the Notified Body to properly plan resources and processes during this peak time. To minimize response time from the Notified Body, you may want to file your submission immediately following confirmation of DuPont submission to the Notified Bodies, and reference the DuPont report in your submission. If you prefer to wait for the 1-Year Real-Time Aging Industry Summary Report before submission, then you need to forecast your continued needs for current product with your SPMs so they can develop a plan on how best to meet your needs.

30. You said that MDMs should not make submissions to the U.S. FDA prior to DuPont's submission unless they have generated their own data. Are all MDMs making submissions to the U.S. FDA?

No. DuPont designed the Transition Protocol Project to help mitigate regulatory requirements for the industry. MDMs that choose to follow the guidelines for interchangeability will not need to make submissions to the U.S. FDA. These MDMs should not put a letter in their file **prior to DuPont's submission and receipt of the letter affirming Functional Equivalence** unless the MDM has generated their own data.

31. Does DuPont have a Drug and/or a Device Master File for Tyvek®, and will these files be updated or replaced after the transition?

DuPont has a Drug Master File and a Device Master File for Tyvek®. We will update both of these files, not open new ones. More information regarding the Transition Protocol material will be contained in the Device Master File than the Drug Master File because the U.S. FDA Transition Protocol is with CDRH.

If you seek permission to reference the DuPont™ Tyvek® Device Master File at the U.S. FDA or at Health Canada, or the DuPont™ Tyvek® Drug Master File at the U.S. FDA, go to the Tyvek® for Medical & Pharmaceutical Packaging Reference Library on our website, select the "Request Permission" button and complete the form. Our business team will review the information you provide and may request additional information before making a decision.

JUNE 2015

32. What information will be included in your submission to the U.S. FDA?

Independent third-party data will be submitted and includes: visual inspection; package integrity; seal strength; and microbial barrier after the following conditions: pre-sterilization, post-sterilization, 1-, 3- and 5-year accelerated aging and 1-year real-time aging.

33. Has the U.S. FDA provided something in writing indicating MDMs will not need to submit 510(k) amendments? If so, how can we get a copy for our files?

We engaged the Center for Devices and Radiological Health (CDRH) at the U.S. FDA to help mitigate regulatory requalification. CDRH provided input to the Transition Protocol design. Over the course of the protocol implementation, CDRH will review extensive data analysis by DuPont of independent third-party generated data to show that Tyvek® produced as a result of the transition does not represent a significant change in functional performance compared to Current Tyvek®. If CDRH agrees with DuPont's analysis and conclusions, then it would issue guidance indicating that MDMs would not routinely be required to file amended 510(k)s or PMAs for existing devices because the transition represents a merge, or lot, change. A copy of the letter from the U.S. FDA indicating their intent is currently posted on our website. A copy of the subsequent letter from the U.S. FDA affirming Functional Equivalence will be posted on our website when it is received.

34. Can you provide more information on how the Functional Equivalence limits were set?

Functional Equivalence limits are set by industry experts. There are two areas where we have set limits: for the China Food and Drug Administration (CFDA) Jinan Quality Supervision and Inspection Center for Medical Devices sheet property study and for the U.S. FDA Protocol. In the CFDA-Jinan sheet property study, we primarily based our Functional Equivalence limits on our specifications and typical ranges for our nominal properties. The specifications and the range of nominal values represent the range of functionally equivalent product that is sold into the marketplace today.

For the sealing study, we focused our efforts on what practical difference would create a noticeable change in the opening of a package in the operating room. We also considered the ranges of reasonable seal strengths from externally manufactured packages that were tested in our laboratory during the development phase of this project. If MDMs or SPMs provided a minimum specification, that was also considered in setting the Functional Equivalence limits. It is important to remember that while we must meet the Functional Equivalence criteria, packages made with Transition Protocol material must meet or exceed Current Tyvek® performance with respect to meeting the minimum seal strength requirement.

35. Did the U.S. FDA actually recommend DuPont use the Functional Equivalence approach?

Yes. We submitted and discussed a few approaches but use of Functional Equivalence was recommended by the U.S. FDA for this project.

JUNE 2015

TECHNICAL

36. Will Tyvek® that is manufactured using the latest flash-spinning technology perform the same as Current Tyvek®?

Package results to date continue to indicate Functional Equivalence. See the MPTP Package Test Results Selector Tool and Industry Summary Reports on our website. There is also extensive Transition Protocol material data posted on our website.

37. Will there be any differences in the polymer used?

All polymers will continue to be virgin high-density polyethylene (HDPE). The HDPE being used was selected for specific attributes required to produce functionally equivalent Tyvek® styles.

38. How do you prevent cross contamination on the Tyvek® lines?

We have quality assurance measures and standard operating procedures in place to manage style and polymer transitions and prevent cross contamination.

39. The conditions for testing the effects of steam sterilization were listed as 127°C for 30 minutes. What could the effects be on the Transition Protocol material if the exposure time is longer?

We are testing longer exposure times through Phantom Protocol cell testing. See the MPTP Cell Descriptor Selector Tool on our website for details.

40. Will you perform longer-term aging studies as part of the Transition Protocol, for example 10-year aging studies?

In the Phantom Protocol we will be generating 7- and 10-year accelerated aging data and 3-, 5-, and 10-year real-time aging data for a limited number of cells containing devices that currently have these extended expiry dates. In addition to these longer-term aging studies on packages, we will be generating 1-, 3-, 5-, 7- and 10-year accelerated **and** real-time aging data on Transition Protocol material.

41. What about Pharmacopeia and Food Contact Regulations?

While not an official part of the Transition Protocol, Tyvek® 1073B and Tyvek® 1059B produced on the newer assets will be Pharmacopeia and Food Contact compliant by meeting extractable testing and compositional requirements, as are the current commercial offerings. Test data required to meet these regulatory requirements will be generated as part of Biocompatibility, Food Contact and Pharmacopeia Testing. Results can be found on our website.

42. What was the rationale behind choosing the accelerated aging conditions (i.e., 50°C ±4°C, and relative humidity of 23 ±7%)?

Accelerated aging conditions were nominally 50°C and 23% relative humidity; aging times were calculated based on an ambient temperature of 25°C, which is the nominal temperature for real-time aging. We chose 50°C for accelerated aging after surveying the industry and finding this to be the least common denominator used today.

DUPONT™ TYVEK® MPTP FREQUENTLY ASKED QUESTIONS

JUNE 2015

43. Why is dye penetration testing (ASTM F1929) being done, but no bubble leak testing (ASTM F2096)?

Dye penetration assesses the quality and integrity of the sealing interface between the (coated) Tyvek® and the film/tray. Bubble leak testing not only assesses this interface, but the adequacy of the package design and other materials of construction as well. The Transition Protocol is concerned with the seal integrity and not the package adequacy.

Bubble leak testing would require significantly more test method validation due to the wide range of coatings and packaging configurations being considered (e.g., a 1" x 4" pouch vs. 8" x 75" pouch). Additionally, ASTM precision and bias statements indicate ASTM F1929 provides higher confidence levels.

44. Are all line/polymer combinations represented by the specification and miscellaneous properties published for Transition Protocol material?

Yes, all line/polymer combinations are represented.

45. We approve our validations to 3X EO cycles. Is it possible to perform 3X EO sterilization cycles on the Transition Protocol material?

There are several examples of package configurations being tested in the MPTP that are sterilized by 3X ethylene oxide (EO) cycles. You can conduct a search for these examples using the MPTP Cell Descriptor Selector Tool found on our website.

46. Do you have any test results for the mechanical strength of Transition Protocol material vs. Current material?

We have posted a wealth of physical and mechanical property data for Transition Protocol material on our website. In addition, we have posted a data sheet showing a side-by-side comparison of the specification and miscellaneous properties of Current Tyvek® vs. Transition Protocol material.

47. What type of printing processes were tested on Transition Protocol material?

Two printing technologies commonly used in the medical packaging industry—flexography and thermal transfer—have been assessed. Results of the printing trials are posted on our website. It is also important to note that SPMs and MDMs participating in the MPTP have successfully printed Transition Protocol material using existing printing equipment and process conditions with no issues observed or reported.

We want to remind you to always print on the smooth side and seal to the rough side of Tyvek®, as recommended in the *DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging.*

48. Is there a table that you can provide which lists and compares all the parameters between current and Transition Protocol material?

Specification properties and miscellaneous properties of Current Tyvek® and Transition Protocol material are shown side-by-side on data sheets that are available on our website.

JUNE 2015

49. Can you explain why the published data formats will be good enough to create a rationale for risk assessment and why raw data is not needed in the majority of cases?

To protect both DuPont and participating MDM proprietary information, we cannot publish raw data. Per the approved protocol, data will be shared with the U.S. FDA for their analysis to confirm Functional Equivalence. If you need more specific results than those we are able to publish, please contact your DuPont Medical Packaging representative with a specific request and justification therefore.

50. On a project of this size and magnitude, wouldn't you expect a range of results, including some non-functional equivalence?

First, it might be good to remember that DuPont commercially produces Tyvek® 2FS™ on the newer assets. In addition, several other Tyvek® styles are manufactured on the newer assets. Lastly, we have worked closely with SPMs and MDMs during the Development Phases of the project so we have a very good understanding of how the Transition Protocol material should perform. Per the defined U.S. FDA Protocol, we have established Functional Equivalence criteria for all the testing we are doing. Statistically speaking, when testing more than 100,000 packages, there may be some anomalies. Each anomaly will be thoroughly investigated to determine root cause and what impact, if any, it may have on Functional Equivalence. All of this will be shared with the U.S. FDA as part of our study.

51. Do MDMs need to do their own testing for configurations not covered in the Transition Protocol or the Phantom Protocol?

The intent of the MPTP is not to capture every possible material combination and sterilization method, but rather to show a broad cross-section of materials and sterilization methods used in the industry and prove the material produced using the latest flash-spinning technology is functionally equivalent to the current product. It's not practical to test every possible combination and sterilization method, which is why DuPont is using the principle of Functional Equivalence as the basis for this project.

52. Will I know what package configurations and constructions are being tested for each Transition Protocol Test Matrix cell and any cells in the Phantom Protocol?

We have created the MPTP Cell Descriptor Selector Tool (available on our website) to provide MDMs with an easy way to view details about each cell, including package configurations and constructions, as well as sterilization information. Individual MDMs for each cell are not identified to protect proprietary and confidential information. Refer to the Testing Summary on our website.

JUNE 2015

BACKGROUND

53. What is the DuPont Medical Packaging Transition Project (MPTP)?

This project is a plan to transition Tyvek® 1073B and Tyvek® 1059B to the latest flash-spinning technology and equipment. The project includes a systematic method for generating data to prove that the Tyvek® produced on the new lines is functionally equivalent in performance to the Tyvek® you purchase today, in an effort to help mitigate requalification.

There are three study components:

1. U.S. FDA Transition Protocol ("Transition Protocol")–a study plan involving production and testing of sterilized medical device packages that has been reviewed and accepted by the Center for Devices and Radiological Health (CDRH) at the U.S. FDA. Their letter of acceptance and the study plan are available on our website.

2. Phantom Protocol–additional testing of applications and technologies that are outside the scope of the Transition Protocol but have been requested by the industry to support risk assessments.

3. Biocompatibility, Food Contact and Pharmacopeia Testing–every DuPont product that is commercialized requires testing to assess product risk and fitness for use.

54. What is included in the Phantom Protocol?

The Phantom Protocol includes things such as additional sterilization methods (steam, low-temperature oxidation and dry heat); package testing beyond 5-year aging; and studies of the effect of sterilization and aging on mechanical and microbial barrier properties. We are also conducting additional testing requested by the industry, including particle generation, printability and dimensional stability, to name a few. For a complete listing, visit our website.

55. What is included in Biocompatibility, Food Contact and Pharmacopeia Testing?

Every DuPont product that is commercialized requires testing to assess product risk and fitness for use. For the MPTP, the study will include tests that are important to the medical device industry, including: cytotoxicity; bioburden; endotoxins; skin irritation and sensitization; U.S. and European Pharmacopeia/Food Contact; and extractables and leachables. Results will be published on our website. Refer to the Testing Summary on our website.

56. Why is DuPont making this transition?

The transition of Tyvek® 1073B and Tyvek® 1059B to manufacturing lines using our latest flash-spinning technology will help ensure the continuity and flexibility of future supply.

57. Are Tyvek® Asuron™ and Tyvek® 2FS™ part of this transition?

No. Tyvek® Asuron™ and Tyvek® 2FS™ were commercialized on manufacturing lines that already use our latest flash-spinning technology, and, therefore, will not be part of the transition.

58. Are the MDMs who are participating in the MPTP representative of the entire spectrum of companies—from large to small and from all regions of the world?

The MDMs participating in the MPTP are from various regions around the world. Their packages represent a variety of different materials and configurations, collectively reflecting how Tyvek® is used in the industry.

DUPONT™ TYVEK® MPTP FREQUENTLY ASKED QUESTIONS

JUNE 2015

59. Why are MDMs not identified on the list of companies participating in the MPTP?

To protect confidential information, we will not be publishing the list of MDMs participating in the MPTP.

60. Can I see an actual copy of the Transition Protocol submitted to the U.S. FDA?

Since the document contains DuPont proprietary information, we cannot make it publicly available. Under confidentiality agreements, we will make details of the Transition Protocol available to companies participating in the MPTP.

61. Why are fewer packages made with Tyvek® 1059B included in the Transition Protocol?

Tyvek® 1073B is used in more applications globally and enables more complete matrix testing than Tyvek® 1059B. However, several of the more demanding applications for Tyvek® 1059B were added to demonstrate Functional Equivalence for this style. Any effects of radiation sterilization on Tyvek® 1059B will be identified through the data generated using Tyvek® 1073B, as the polymers used are identical.

62. How can the Transition Protocol be reflective of all the different packages that are possible?

When you look at all the types of packages that exist, they fall into three basic categories: 1) pouches & bags; 2) form-fill-seal applications; and 3) rigid trays & lids. Because every Transition Protocol package fits into one of these three categories, we are testing a representative cross-section of materials, package designs and manufacturers. It would be unrealistic and cost prohibitive to test every bottom web and/or coating combination in the industry.

63. When did DuPont issue a formal change notification for the Transition?

In 1Q 2014 we issued a formal Change Notification letter for DuPont™ Tyvek® 1073B and Tyvek® 1059B to all customers who have a Change Notification Agreement in place with DuPont.

64. Is distribution testing included in the Transition Protocol?

No. The Transition Protocol focuses on the sterile barrier performance of Tyvek® whereas transportation testing also tests the package design, pack-out configuration and protective packaging.

65. Why are steam, dry heat and/or low-temperature oxidative sterilization not included in the Transition Protocol?

The Transition Protocol is focused on the most commonly used sterilization methods, which include: ethylene oxide (EO), gamma irradiation and electron-beam. Steam, low-temperature oxidative and dry heat sterilization will be included in the Phantom Protocol.

66. Has DuPont performed any test that covers dry heat sterilization?

Dry heat sterilization is one of the sterilization methods included in the Phantom Protocol. The package configuration being tested is rigid trays with a lid of coated style 1073B.

JUNE 2015

67. What about drug and other medicine or vaccine producers; are they covered in the Transition Protocol?

No. The Transition Protocol only includes medical devices regulated by the Center for Devices and Radiological Health (CDRH). Products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologic Evaluation and Research (CBER) are not included in the Transition Protocol. However, the Phantom Protocol includes combination products and pharmaceutical packaging applications.

Through the Phantom Protocol and Biocompatibility, Food Contact and Pharmacopeia Testing, we are generating data that drug companies typically reference on our current products.

Producers who market their products under pharmaceutical regulations should begin their change management process, including risk assessments, to prepare for full commercial launch.