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August 6, 2018

**VIA ELECTRONIC SUBMISSION**

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

**Re: Docket No. FDA-2012-N-0961 (83 Fed. Reg. 26,477, June 7, 2018) Agency Information Collection Activities; Proposed Collection; Comment Request; Environmental Impact Considerations**

Altria Client Services ("ALCS"), on behalf of Philip Morris USA Inc. ("PM USA"), John Middleton Company ("JMC"), Sherman Group Holdings LLC and its subsidiaries ("Nat Sherman"), U.S. Smokeless Tobacco Company LLC ("USSTC") and Nu Mark LLC ("Nu Mark"),[1] submits these comments to the U.S. Food and Drug Administration ("FDA" or the "Agency") in response to the above captioned Agency Information Collection Activities; Proposed Collection; Comment Request; Environmental Impact Considerations ("PRA Notice").[2]

The National Environmental Policy Act[3] ("NEPA") requires the preparation of an environmental impact statement ("EIS") for every major Federal action that will significantly affect the quality of the human environment.[4] For other actions, such as premarket tobacco product applications,

[1] PM USA, JMC, Nat Sherman, USSTC and Nu Mark are wholly-owned subsidiaries of Altria Group, Inc. ("Altria"). PM USA manufactures cigarettes, JMC manufactures cigars and pipe tobacco and Nat Sherman manufactures cigarettes, cigars and pipe tobacco. USSTC manufactures smokeless tobacco products and oral tobacco-derived nicotine products and Nu Mark manufactures e-vapor products. ALCS provides certain services, including regulatory affairs, to the Altria family of companies. "We" and "our" are used throughout to refer to PM USA, JMC, Nat Sherman, USSTC and Nu Mark.
[2] 83 Fed. Reg. 26,477 (Jun. 7, 2018).
[3] 42 U.S.C. §§ 4321 *et. seq.*
[4] *Id.* at § 4332.

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applicants must submit to the Agency a claim for a Categorical Exclusion ("CE") or an Environmental Assessment ("EA").

In 2014, FDA opened a docket soliciting public comment proposing revisions of its "NEPA implementing regulations to provide CEs for certain actions related to substantial equivalence (SE) reports, SE exemption requests, and tobacco product applications."[5] We submitted comments in which we suggested that FDA should categorically exclude all classes of SE review.[6]

In 2015, the Agency amended 21 C.F.R. Part 25 to categorically exclude marketing orders associated with Substantial Equivalence ("SE") Reports for provisional tobacco products ("Provisional SE Reports").[7,8] For Nonprovisional SE Reports[9] and SE Exemption Requests,[10] however, tobacco product manufacturers would still be required to submit EAs to FDA as part of their premarket applications.

We continue to agree with FDA that marketing orders for Provisional SE Reports will not significantly affect the quality of the human environment individually or cumulatively. We also continue to believe that the same rationale supports FDA categorically excluding other actions related to SE Reports – namely, marketing orders for Nonprovisional SE Reports and SE Exemption Requests.

Our comments are organized as follows:

1. FDA Should Categorically Exclude all Categories of SE Applications from the EA Requirement;

2. FDA has Gained Sufficient Experience with Nonprovisional SE Reports to Categorically Exclude all Categories of SE Applications; and

3. Categorically Excluding all Categories of SE Applications Would Reduce Regulatory Burdens and Promote Efficiency for the Agency and Regulated Industry.

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[5] 79 Fed. Reg. 3,742 (Jan. 23, 2014).
[6] *See* attached ALCS comments to FDA-2013-N-1282 National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions. Filed Apr. 8, 2014. *Available at* https://www.regulations.gov/document?D=FDA-2013-N-1282-0005.
[7] 80 Fed. Reg. 57,531 (Sept. 24, 2015).
[8] Provisional Products are those first introduced to the market between February 15, 2007 and March 22, 2011, and for which an SE report was submitted to FDA by March 22, 2011. A Provisional SE Report is the marketing application submitted by a tobacco product manufacturer to FDA's Center for Tobacco Products ("CTP") under Section 910(a)(2)(B) of the Family Smoking Prevention and Tobacco Control Act (the "Act" or "TCA").
[9] Nonprovisional Products are those that were not commercially marketed before March 22, 2011. These products must receive a marketing order from FDA before they may enter the market. A Nonprovisional SE Report is the marketing application submitted to FDA's CTP under Section 910(a)(2)(A) of the TCA.
[10] An SE Exemption Request is the marketing application submitted under Section 905(j)(3) of the TCA for minor modifications to products that can be sold under the TCA, and for which a full SE report is unnecessary to ensure that marketing the product with the minor modification is appropriate for protection of the public health.

## I. FDA Should Categorically Exclude all Categories of SE Applications from the EA Requirement

Beyond categorically excluding Agency actions related to Provisional SE Reports, FDA should provide CEs for FDA actions on: (1) Nonprovisional SE Reports under Section 910(a)(2)(A) of the TCA; and (2) SE Exemption Requests under Section 905(j)(3) of the TCA.

A Federal agency can categorically exclude certain types of actions that they determine, based on "sufficient experience,"[11] do not significantly affect the quality of the human environment either individually or cumulatively. Because actions qualifying for a CE should not meet the "significance" threshold triggering NEPA review, those actions generally do not need an EA or an EIS under the statute.[12]

Federal courts often address the propriety of categorically excluding agency actions from NEPA's EIS requirement in terms of those actions' effects on the status quo. Courts have explained that where an agency action would not change the status quo, an EIS is not necessary.[13] FDA's rational in the preamble to the final rule[14] categorically excluding Provisional SE Reports reflects the rationale of those courts. "FDA expects that any new tobacco product that receives marketing authorization through any of the available premarket pathways will have less – or no more – environmental impact than do tobacco products currently on the market."[15] Courts and FDA's own analysis, therefore, recognize that CEs are appropriate in situations where the Agency's actions do not result in a change to the status quo.[16]

FDA's assessment of reasonably foreseeable environmental effects associated with manufacturing and use of products covered by the CE for Provisional SE Reports applies equally to Agency actions on Nonprovisional SE Reports and SE Exemption Requests. For reasonably foreseeable impacts associated with product manufacturing, FDA considered the 2011 Toxics Release Inventory National Analysis and concluded that "the amount of waste released, recycled, and treated due to the manufacture of ***all tobacco products*** on the market is a fraction of the total toxic waste released from and managed in industrial facilities in the United States."[17] For possible impacts from product use, the Agency considered tobacco product consumption rates, secondhand smoke from cigarettes and environmental impacts resulting from the use of smokeless tobacco products and concluded "that ***any new tobacco products*** that receive

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[11] 80 Fed. Reg. at 57,534.
[12] 40 C.F.R. § 1508.4.
[13] *See, e.g., San Louis & Delta Mendota Water Authority v. Jewell*, 2014 U.S. App. LEXIS 4781, 173-74 (9th Cir., March 13, 2014); *Upper Snake River Chapter of Trout Unlimited v. Hodel*, 921 F.2d 232, 235 (9th Cir. 1990); *Pacific Coast Fed'n of Fishermen's Ass'ns v. DOI*, 2014 U.S. Dist. LEXIS 015072, 79-80 (E.D. Cal., Feb. 6, 2014) ("an action that does not change the status quo cannot cause any change in the environment and therefore cannot cause effects that require [NEPA] analysis").
[14] 80 Fed. Reg. at 57,533.
[15] *Id.*
[16] *See Sierra Club v. Hassell*, 636 F.2d 1095, 1099 (5th Cir. 1981); *see also Nat Res. Def. Council v. Vaughn*, 566 F. Supp. 1472, 1475-1476 (D.D.C. 1983).
[17] 79 Fed. Reg. at 3,744 (emphasis added).

marketing authorization through the ***available pathways*** … would have less or no more environmental impact than that of tobacco products currently on the market."[18]

Because FDA's analysis of reasonably foreseeable impacts from product manufacturing and use accounted for the entire tobacco product market as well as any new tobacco products entering the market following FDA actions on Nonprovisional SE Reports and SE Exemption Requests, that analysis should apply to those FDA actions the same as it does to actions on Provisional SE Reports.

Other aspects of the rationale underlying the CE for Provisional SE Reports also support CEs for Nonprovisional SE Reports and SE Exemption Request because FDA's actions on Nonprovisional SE Reports and SE Exemption Requests are virtually identical to its actions on Provisional SE Reports. Nonprovisional SE Reports differ from Provisional SE Reports in that Nonprovisional SE Reports concern products not currently on the market. For several reasons, however, that difference should not cause the Agency's actions on Nonprovisional SE Reports to significantly affect the quality of the human environment.

First, when FDA makes an SE determination for a nonprovisional cigarette, that determination is unlikely to result in a larger overall tobacco product market. As with provisional SE products, the only reasonably foreseeable effect of FDA finding a nonprovisional product substantially equivalent would be a potential change in the market share held by the manufacturer, but otherwise would not change the status quo. FDA's actions on Nonprovisional SE Reports, therefore, should not result in significant impacts on the quality of the human environment, either individually or cumulatively.

Second, for cigarettes and smokeless tobacco products, our EAs have shown no anticipated environmental effects or impacts as a result of the manufacture, use, disposal, energy consumption or release of the products into the environment. The amount of waste generated by a new tobacco product would be a miniscule fraction of the total waste disposed of annually in the United States. Finding[s] of No Significant Impact ("FONSI") by FDA are warranted. As such, no additional environmental protection measures or alternative actions are necessary to address changes in environmental impact between our new and predicate products. Our analyses support FDA's conclusion that "any new tobacco product that receives marketing authorization through any of the available premarket pathways will have less – or no more – environmental impact than do tobacco products currently on the market."[19]

Third, FDA's SE determination for Nonprovisional SE Reports is based on the same standard as its determinations for Provisional SE products. That standard, set forth in the TCA's definition of SE, will help ensure that agency actions on Nonprovisional SE Reports will not exceed NEPA's significance threshold.[20] The SE standard limits FDA's SE determinations to only those products that: (a) have the same characteristics as a predicate product *(i.e.,* materials, ingredients, design, composition, heating source or other features); or (b) have different characteristics, but

[18] *Id.* at 3,745 (emphasis added).
[19] 80 Fed. Reg. at 57,533.
[20] TCA §§ 910(a)(3)(A)-(B).

do not raise different questions of public health.[21] As a result, the SE standard itself will help prevent FDA's actions on Nonprovisional SE Reports from significantly affecting the quality of the human environment. FDA's extraordinary circumstances review, requiring NEPA review in the rare case where the Agency's action on a "substantially equivalent" product may have significant environmental impacts, will further ensure protection of the quality of the human environment.

Fourth, for SE Exemption Requests, the reasonably foreseeable environmental effects would be even less significant. As with FDA's actions on Provisional and Nonprovisional SE Reports, the environmental effects of the Agency's actions associated with SE Exemption Requests would be limited by decreasing cigarette sale volumes, the operation of FDA's extraordinary circumstances review and the circumstances appropriate for granting SE Exemption Requests. For example, FDA may only exempt a proposed tobacco product from the substantial equivalence requirements of Section 910(a)(3) of the TCA if it represents a "minor modification" of a tobacco additive in a tobacco product that can be sold under the TCA, and an SE Report "is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health."[22] Because SE exemptions are appropriate only in limited circumstances, FDA's actions granting SE exemptions do not alter the status quo and cannot significantly affect the quality of the human environment for purposes of NEPA.

Finally, categorically excluding Agency actions associated with Nonprovisional SE Reports and SE Exemption Requests would be consistent with FDA's regulatory approach to premarket clearances and approvals for other product categories regulated by the Agency. Nearly every other category of FDA-regulated products benefits from CEs that cover all classes of similar agency actions as long as each similar class of actions independently meets the criteria for a CE. For each of those categories of products, FDA has taken the reasonable position that NEPA analysis is not necessary if the Agency actions for a product type are not expected to increase overall use of the product.[23]

Limiting CEs to only some FDA SE actions is not necessary given that none of FDA's three possible affirmative SE actions is expected to significantly affect the quality of the human environment individually or cumulatively. Accordingly, the three FDA SE actions all should receive the same treatment that FDA accords similar actions for products in other industries with coverage under a CE.

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[21] *Id.*

[22] TCA § 905(j)(3).

[23] *See, e.g.,* 21 C.F.R. §§ 25.15(c) (Agency actions that "do not significantly affect the quality of the human Environment" are ordinarily excluded), 25.30(k) (labeling changes that do not affect levels of use are categorically excluded); 25.31(a) (new drug approval applications that will not "increase the use of the active moiety" are categorically excluded), 25.31(g) (bioequivalence determinations for human drugs and comparability determinations for biologics are categorically excluded), 25.32(f) (determinations that food is GRAS are categorically excluded if it is already marketed for the proposed use), 25.33(a) (new animal drug approval applications that will not increase use are categorically excluded), 25.34(b) (device classification determinations that will not increase or expand the use of the device are categorically excluded), 25.34(d) (class III medical device approvals are categorically excluded if the device is of the same type and use of a previously approved device), 25.34(f) (restricted device regulations that will not expand or increase the use of the product are categorically excluded).

By amending 21 C.F.R. Part 25 to categorically exclude all SE actions,[24] FDA would reduce paperwork and delay, and benefit the public interest by eliminating unnecessary NEPA analyses, thereby allowing the Agency to focus its resources on actions that are expected to significantly affect the quality of the human environment.[25] Finally, as a safeguard, FDA would retain the authority to require NEPA analysis based on extraordinary circumstances for all actions that are subject to a CE.

## II. FDA has Gained Sufficient Experience with Nonprovisional SE Reports to Categorically Exclude all Categories of SE Applications

In 2015, in declining to categorically exclude Nonprovisional SE Reports and SE Exemption Requests,[26] FDA explained that it "expects that any new tobacco product that receives marketing authorization through any of the available premarket pathways will have less – or no more – environmental impact than do tobacco products currently on the market. However, ***FDA does not yet have data*** to determine whether these [SE] actions, in the aggregate, will significantly impact the environment."[27] The Agency also noted that "at this time, ***FDA is not yet able to effectively evaluate*** whether these classes of action will lead to a larger overall tobacco product market or expand tobacco product consumption … FDA will continue to monitor submissions and will consider issuing a new proposed rule if the Agency determines that additional tobacco product actions should be categorically excluded."[28]

Since 2015, FDA has received thousands of Nonprovisional SE Reports and issued final actions on nearly 2,000 Nonprovisional SE Reports.[29, 30] The Agency should now have data sufficient to "determine whether these [SE] actions, in the aggregate, will significantly impact the environment."[31] To the best of our knowledge, FDA has never denied a Nonprovisional SE Report or SE Exemption Request on the basis of the product's environmental impact. That fact alone demonstrates that nonprovisional products and those determined to be exempt for the SE requirements do not present any different environmental impacts from provisional products, and thus should be categorically excluded from the EA requirements.

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[24] Correspondingly, the Agency would need to remove the requirement to perform an environmental assessment for SE Exemption Requests in 21 C.F.R. § 1107.1(b)(9).

[25] In its justification of its CE for Provisional SE Reports, FDA states that "this rule would benefit the public health by allowing both FDA and industry to better focus their resources on other matters that could have a direct impact on public health." 79 Fed. Reg. at 3,747.

[26] 80 Fed. Reg. at 57,533.

[27] *Id.* (emphasis added).

[28] *Id.* at 57,534 (emphasis added).

[29] The PRA Notice indicates that "based on actual report data from fiscal year (FY) 2015 to FY 2017, on average FDA estimated it received approximately 260 premarket review of new tobacco PMTAs…3,601 provisional reports intended to demonstrate the substantial equivalence of a new tobacco product (SEs)…2,375 regular SE reports…101 exemption from substantial equivalence requirements applications … and 27 modified risk tobacco product applications..." 83 Fed. Reg. at 26,480.

[30] Total final agency action on nonprovisional SE Reports FY2015 – 516, FY2016 – 612, FY2017 – 717, FY2018 – 152. *Available at* https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&status=public&id=CTP-OS-total-provisional-SE-since-Program-Inception&fy=All https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&status=public&id=CTP-OS-total-regular-SE-since-Program-Inception&fy=2018

[31] 80 Fed. Reg. at 57,533.

In conjunction with our own SE submissions, we have supplied FDA with extensive information and analyses showing that, even under worst case scenarios, no significant environmental impacts are associated with the requested Agency action on our Provisional and Nonprovisional SE Reports.[32] In granting market orders on our Nonprovisional SE Reports, FDA has made FONSIs and has not required preparation of an EIS for any of our applications.

Beyond our SE Reports, FDA has reviewed hundreds of additional EAs[33] since 2015. These reviews support the Agency's prior conclusions "that any new tobacco products that receive marketing authorization through the available pathways … would have less or no more environmental impact than that of tobacco products currently on the market,"[34] and "the amount of waste released, recycled, and treated due to the manufacture of all tobacco products on the market is a fraction of the total toxic waste released from and managed in industrial facilities in the United States."[35] Accordingly, FDA should categorically exclude Nonprovisional SE Reports and SE Exemption Requests.

## III. Categorically Excluding all Categories of SE Applications Would Reduce Regulatory Burdens and Promote Efficiency for the Agency and Regulated Industry

In January 2018, FDA opened a docket entitled "Review of Existing Center for Tobacco Products Regulatory and Information Collection Requirements."[36] This docket reflected the Administration's focus on reducing burdens and increasing efficiency in the regulatory process. We filed comments to that docket in which we argued that categorically excluding all classes of SE applications would make the regulatory process less burdensome and more efficient.[37]

In the PRA Notice, FDA estimated the EA reporting burden for tobacco products to be 80 hours on average per EA, with 5,832 total annual EAs for a cumulative annual burden of 466,560 hours.[38] This estimate, while low, is still a significant burden on FDA and industry that provides no corresponding environmental benefit. The estimated burden on tobacco products is also significantly greater than the burden estimated for any of the other FDA-regulated product categories analyzed in the PRA Notice including; human drugs, medical devices, biological

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[32] Our consultant, ERM, has prepared all of the EAs for our SE Reports that include both Nonprovisional and Provisional SE Reports for both cigarettes and smokeless tobacco products. ERM's April 1, 2014, memorandum, summarizes its approach and conservative assumptions for conducting our EAs. ERM concluded that, even under worst case scenarios, no significant environmental impacts were associated with the requested Agency action on our Provisional and Nonprovisional SE Reports. This memorandum is available in our attached comments.

[33] FDA provides a tracker of SE marketing orders available at https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm339928.htm#2

[34] 79 Fed. Reg. at 3,745.

[35] *Id.* at 3,744 (emphasis added).

[36] 82 Fed. Reg. 42,501 (Sept. 8, 2017). This docket was part of the Agency's implementation of Executive Order 13,771 entitled "Reducing Regulation and Controlling Regulatory Cost" and Executive Order 13,777 entitled "Enforcing the Regulatory Reform Agenda."

[37] *See* Docket No. FDA-2017-N-5095 (82 Fed. Reg. 42,501, Sept. 8, 2017) — Comments on "Review of Existing Center for Tobacco Products Regulatory and Information Collection Requirements." Filed Feb. 5, 2018. *Available at* https://www.regulations.gov/document?D=FDA-2017-N-5095-0026.

[38] 83 Fed. Reg. at 26,481.

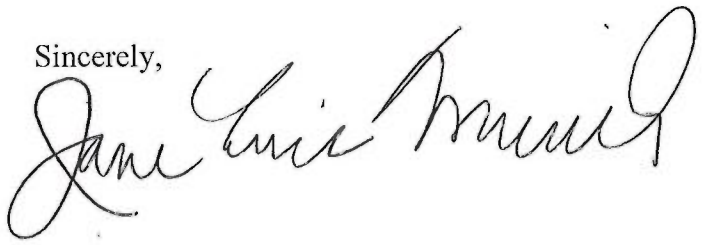
products and animal drugs.[39] FDA should categorically exclude all SE marketing orders to reduce paperwork and delay and benefit the public interest by eliminating unnecessary NEPA analyses. Doing so would allow FDA to "better focus their resources on other matters that could have a direct impact on public health."[40]

## IV. Conclusion

We urge FDA to categorically exclude all categories of SE applications from the EA requirement to help drive simplicity and efficiency into FDA's SE processes; drive down costs for both FDA and regulated entities; and help "FDA to focus its environmental resources on situations likely to have an effect on the environment – a key goal of NEPA and CEQ."[41]

We appreciate the opportunity to submit these comments. If you have any question or need any additional information, please contact me at (804) 335-2879.

Sincerely,



[39] *Id.* at 26,479-81.
[40] 79 Fed. Reg. at 3,747.
[41] *Id.* at 3,747-8.

# Attachment


James E. Dillard III
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April 8, 2014

*Via Electronic Submission*

Division of Dockets Management (HFA-305)
Food and Drug Administration
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Re: Docket No. FDA-2013-N-1282 (79 Fed. Reg. 3742 (Jan. 23, 2014)) — Comments on "Proposed Rule: National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions" ("Proposed Rule")

Altria Client Services Inc. ("ALCS"), on behalf of Philip Morris USA Inc. ("PM USA") and U.S. Smokeless Tobacco Company LLC ("USSTC"),[1] submits these comments to the U.S. Food and Drug Administration ("FDA" or "the Agency") in response to the above-captioned *Federal Register* notice ("Notice").

We support the Agency's proposal to amend 21 C.F.R. Part 25 to provide a categorical exclusion ("CE") for FDA's actions related to substantial equivalence ("SE") reports for "provisional" tobacco products ("Provisional SE Reports") under Section 910(a)(2)(B) of the Federal Food, Drug and Cosmetic Act ("FDCA"). We agree with FDA that the best available information demonstrates that those actions will not significantly affect the quality of the human environment individually or cumulatively. In fact, we believe that the same information also supports CEs for FDA's other actions relating to SE reports – namely, FDA's actions on SE reports under Section 910(a)(2)(A) of the FDCA for non-"provisional" tobacco products ("Non-Provisional SE Reports"), and on FDA actions on requests for an exemption from demonstrating substantial equivalence under Section 905(j)(3) of the FDCA ("SE Exemption Requests").

[1] PM USA and USSTC are wholly-owned subsidiaries of Altria Group, Inc. ALCS provides certain services, including regulatory affairs, to the Altria family of companies. "We" and "our" are used throughout these comments to refer collectively to PM USA and USSTC.

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Accordingly, we propose that the Agency revise the proposed rule to provide CEs for all classes of actions involving an affirmative SE determination or the granting of an SE exemption under the FDCA. In addition, we urge the Agency to revise its descriptions of the extraordinary circumstances applicable to the new CEs so that the descriptions more closely follow the language of the regulations codifying them.[2]

## I. Introduction.

Categorical exclusions apply to categories of agency actions that have been determined not to have a significant effect on the quality of the human environment either individually or cumulatively. Because actions qualifying for a CE should not meet the "significance" threshold triggering National Environmental Policy Act ("NEPA") review, those actions generally do not need an environmental assessment ("EA") or an environmental impact statement ("EIS") under the statute.[3]

Federal courts often address the propriety of categorically excluding agency actions from NEPA's EIS requirement in terms of those actions' effects on the status quo. Courts have explained that where an agency action would not change the status quo, an EIS is not necessary.[4] Courts, therefore, recognize that CEs are appropriate in situations where the agency action does not result in a change to the status quo.[5] FDA's proposed CE for actions on Provisional SE Reports reflects the rationale of those courts.

## II. FDA's Proposed Categorical Exclusion of Actions on Provisional SE Reports is Appropriate.

As described in the Notice, FDA proposes to issue a CE for Agency actions related to making SE determinations for "provisional" tobacco products. "Provisional" tobacco products are those that first entered the marketplace or were modified between February 15, 2007, and March 22, 2011, and for which an SE report was submitted to FDA by March 22, 2011.[6] These products may remain on the market unless FDA issues an order that they are not substantially equivalent to a tobacco product or products marketed in the United States as of February 15, 2007.[7] We agree that the Agency's SE determinations on Provisional SE Reports should be covered by a categorical exclusion.

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[2] Compare 79 Fed. Reg. 3742, 3746 (descriptions) to 21 C.F.R. § 25.21(a) and (b) (regulations).
[3] 40 C.F.R. § 1508.4.
[4] See e.g., San Louis & Delta Mendota Water Authority v. Jewell, 2014 U.S. App. LEXIS 4781, 173-74 (9th Cir., March 13, 2014); Upper Snake River Chapter of Trout Unlimited v. Hodel, 921 F.2d 232, 235 (9th Cir. 1990); Pacific Coast Fed'n of Fishermen's Ass'ns v. DOI, 2014 U.S. Dist. LEXIS 015072, 79-80 (E.D. Cal., Feb. 6, 2014) ("an action that does not change the status quo cannot cause any change in the environment and therefore cannot cause effects that require [NEPA] analysis").
[5] See Sierra Club v. Hassell, 636 F.2d 1095, 1099 (5th Cir. 1981); see also Nat Res. Def. Council v. Vaughn, 566 F. Supp. 1472, 1475-1476 (D.D.C. 1983).
[6] 21 U.S.C. § 387j(a)(2)(B).
[7] *Id.*

FDA correctly recognizes in the Notice that its actions related to Provisional SE Reports will not significantly affect the quality of the human environment individually or cumulatively. Determining that a "provisional" tobacco product is substantially equivalent for purposes of Section 910(a)(2)(B) simply allows that product to remain on the market.[8] By their nature, "provisional" tobacco products are the products currently being manufactured, used and ultimately disposed. They are part of the environmental baseline – indeed, some of these products could have been on the market for over seven years.

An FDA determination allowing a product that already is on the market to remain there will neither increase overall consumption of tobacco products in the United States, nor alter consumption trends.[9] As a result, FDA's actions on Provisional SE Reports will not alter the environmental impacts currently associated with the manufacture, use, or disposal of tobacco products. In other words, FDA's actions on Provisional SE Reports will not significantly affect the quality of the human environment because they do not alter the status quo.

## III. FDA Also Should Issue CEs for the Other Classes of Agency Actions Involving "Substantially Equivalent" Tobacco Products.

In addition to providing a CE for Agency actions related to Provisional SE Reports, FDA should provide CEs for two other types of FDA actions: (1) Agency actions on Non-Provisional SE Reports under Section 910(a)(2)(A) of the FDCA; and (2) Agency actions on SE Exemption Requests under Section 905(j)(3) of the FDCA.

FDA's assessment of reasonably foreseeable environmental effects associated with manufacturing and use of products covered by the proposed CE for Provisional SE Reports applies equally to Agency actions on Non-Provisional SE Reports and on SE Exemption Requests. For reasonably foreseeable impacts associated with product manufacturing, FDA considered the 2011 Toxics Release Inventory ("TRI") National Analysis and concluded that "the amount of waste released, recycled, and treated due to the manufacture of ***all tobacco products*** on the market is a fraction of the total toxic waste released from and managed in industrial facilities in the United States."[10] For possible impacts from product use, the Agency considered tobacco product consumption rates, secondhand smoke from cigarettes, and environmental impacts resulting from the use of smokeless tobacco products and concluded "that ***any new tobacco products*** that receive marketing authorization through the ***available pathways***" would have less or no more environmental impact than that of tobacco products currently on the market."[11] Because FDA's analysis of reasonably foreseeable impacts from product manufacturing and use accounted for the entire tobacco product market as well as any new tobacco products entering the market following FDA actions on Non-Provisional SE Reports and SE Exemption Requests, that analysis and the

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[8] *Id.*

[9] The FDA correctly observes that tobacco product consumption in the United States is steadily decreasing. *See* 79 FR 3742, 3745 (Jan. 23, 2014). Agency determinations allowing "provisional" SE products to remain on the market would not affect this trend.

[10] 79 Fed. Reg. at 3744 (emphasis added).

[11] *Id.* at 3745 (emphasis added).

proposed CE should apply to those types of FDA actions the same as it applies to FDA actions on Provisional SE Reports.

Other aspects of the rationale underlying FDA's proposed CE for Provisional SE Reports also support CEs for Non-Provisional SE Reports and SE Exemption Requests because FDA's actions on Non-Provisional SE Reports and on SE Exemption Requests are virtually identical to its actions on Provisional SE Reports. Non-Provisional SE Reports differ from Provisional SE Reports in that Non-Provisional SE Reports concern products not currently on the market. For several reasons, however, that difference should not cause the Agency's actions on Non-Provisional SE Reports to significantly affect the quality of the human environment.

First, when FDA makes an SE determination for a non-"provisional" tobacco product, that determination is unlikely to result in a larger overall tobacco product market. As with "provisional" SE products, the only reasonably foreseeable effect of FDA finding a non-"provisional" product substantially equivalent to a predicate product or products would be a potential change in the market share held by the manufacturer, but otherwise would not change the status quo. FDA's actions on Non-Provisional SE Reports, therefore, should not result in significant impacts on the quality of the human environment, either individually or cumulatively.

Second, FDA's SE determination for Non-Provisional SE products is based on the same standard as its determinations for Provisional SE products. That standard, set forth in the FDCA's definition of SE, will help ensure that agency actions on Non-Provisional SE Reports will not exceed NEPA's significance threshold.[12] The SE standard limits FDA's SE determinations to only those products that: (a) have the same characteristics (*i.e.*, materials, ingredients, design, composition, heating source or other features); or (b) do not raise different questions of public health compared to the predicate product or products.[13] As a result, the SE standard itself will help prevent FDA's actions on Non-Provisional SE Reports from significantly affecting the quality of the human environment. FDA's extraordinary circumstances review, requiring NEPA review in the rare case where the Agency's action on a "substantially equivalent" product may have significant environmental impacts, will further ensure protection of the quality of the human environment.

Finally, our experience providing environmental assessments for all of our Non-Provisional SE Reports supports the conclusion that "substantially equivalent" tobacco products are unlikely to result in significant environmental effects. Our consultant, ERM, has prepared all of the EAs for our SE Reports that include both Non-Provisional and Provisional SE Reports for both cigarettes and smokeless tobacco products. ERM's April 1, 2014, memorandum summarizes its approach and conservative assumptions for conducting our EAs.[14] ERM concluded that, even under worst-case scenarios, no significant environmental impacts were associated with the requested Agency action on our Provisional and Non-Provisional SE Reports.

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[12] 21 U.S.C. § 387j(a)(3)(A)-(B).
[13] *See id.*
[14] Attached as Appendix A.

For SE Exemption Requests, the reasonably foreseeable environmental effects would be even less significant. As with FDA's actions on Provisional and Non-Provisional SE Reports, the environmental effects of the Agency's actions associated with SE Exemption Requests would be limited by the decreasing total tobacco product consumption, the definition of "substantial equivalence" under the FDCA, and the operation of FDA's extraordinary circumstances review. And, those effects would be limited further by the circumstances appropriate for granting SE Exemption Requests.

FDA may exempt a proposed tobacco product from the substantial equivalence requirements of Section 910(a)(3) of the FDCA only if it represents a "minor modification" of a tobacco additive in an existing tobacco product and an SE report "is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health."[15] Because SE exemptions are appropriate only in limited circumstances, FDA's actions granting SE exemptions do not alter the status quo and cannot significantly affect the quality of the human environment for purposes of NEPA.

Finally, authorizing CEs for Agency actions associated with Non-Provisional SE Reports and SE Exemption Requests, in addition to issuing a CE for Provisional SE Reports, would be consistent with FDA's regulatory approach to premarket clearances and approvals for other product categories regulated by the Agency. Nearly every other category of FDA-regulated products benefits from CEs that cover all classes of similar agency actions as long as each similar class of actions independently meets the criteria for a CE. For each of those categories of products, FDA has taken the reasonable position that NEPA analysis is not necessary if the agency actions for a product type are not expected to increase overall use of the product.[16]

Limiting CEs to only some FDA SE actions is not necessary given that none of FDA's three possible affirmative SE actions is expected to increase overall use of the product types in question or expand tobacco product consumption, and none is expected to significantly affect the quality of the human environment individually or cumulatively. The three FDA SE actions all should receive the same treatment that FDA accords similar actions for products in other industries with coverage under a CE.

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[15] 21 U.S.C. § 387e(j)(3).

[16] *See, e.g.*, 21 C.F.R. §§ 25.15(c) (agency actions that "do not significantly affect the quality of the human environment" are ordinarily excluded), 25.30(k) (labeling changes that do not affect levels of use are categorically excluded); 25.31(a) (new drug approval applications that will not "increase the use of the active moiety" are categorically excluded), 25.31(g) (bioequivalence determinations for human drugs and comparability determinations for biologics are categorically excluded), 25.32(f) (determinations that food is GRAS are categorically excluded if it is already marketed for the proposed use), 25.33(a) (new animal drug approval applications that will not increase use are categorically excluded), 25.34(b) (device classification determinations that will not increase or expand the use of the device are categorically excluded), 25.34(d) (class III medical device approvals are categorically excluded if the device is of the same type and use of a previously approved device), 25.34(f) (restricted device regulations that will not expand or increase the use of the product are categorically excluded).

The Agency should amend its Proposed Rule to include CEs in 21 C.F.R. Part 25 for all SE actions, including Non-Provisional SE Reports and SE Exemption Requests.[17] Such CEs would reduce paperwork and delay, and benefit the public interest by eliminating unnecessary NEPA analyses, thereby allowing the Agency to focus its resources on actions that are expected to significantly affect the quality of the human environment.[18] Finally, as a safeguard, FDA would retain the authority to require NEPA analysis based on extraordinary circumstances for all actions that are subject to a CE.

## IV. FDA's Descriptions of Applicable Extraordinary Circumstances Should More Closely Track the Language in its Regulations.

The Notice explains that FDA has identified in its regulations several examples of extraordinary circumstances in which a particular action would be ineligible for a CE. It then discusses two examples in particular that FDA states are applicable to tobacco products, and describes how those extraordinary circumstances would apply in the context of the proposed tobacco product CEs. Unfortunately, those descriptions are far broader than the promulgated extraordinary circumstances they attempt to describe, which could cause the exceptions to swallow the rules.

FDA's regulations define the first extraordinary circumstance as "[a]ctions for which available data establish that, at the expected level of exposure, there is the potential for serious harm to the environment."[19] The Agency significantly expands on this in the Notice, however. It states that this extraordinary circumstance would preclude use of a CE "[i]f any tobacco product submission indicates that the action could result in **the *exposure of substances harmful to some biological mechanisms or systems in the environment.***"[20]

FDA's regulations define the second extraordinary circumstance as

> [a]ctions that adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Flora and Fauna to be endangered or threatened or wild flora or fauna that are entitled to special protection under some other Federal law.[21]

But in its proposal, the Agency paraphrases the rule and significantly expands upon its scope by stating that this extraordinary circumstance would preclude the use of a CE "[i]f any tobacco product submission indicates that the action . . . may cause harm to a protected or endangered species . . . ."[22]

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[17] Correspondingly, the Agency would need to remove the requirement to perform an environmental assessment for SE Exemption Requests in 21 C.F.R. § 1107.1(b)(9).

[18] In its justification of its proposed CE for Provisional SE Reports, FDA states that "this rule would benefit the public health by allowing both FDA and industry to better focus their resources on other matters that could have a direct impact on public health." 79 Fed. Reg. at 3747.

[19] 21 C.F.R. § 25.21(a) (quoted in the Notice at 79 Fed. Reg. 3746).

[20] 79 Fed. Reg. at 3746 (emphasis added).

[21] 21 C.F.R. § 25.21(b).

[22] 79 FR at 3746.

In each case, FDA's description of the extraordinary circumstance and its applicability in the context of tobacco product regulation goes far beyond the actual language of that extraordinary circumstance in the Agency's regulations. That regulatory language is important because it provides express standards and criteria. The descriptions of the extraordinary circumstances in the Proposed Rule, though, would inject ambiguities and broad generalizations into the NEPA process. To correct these problems, FDA should replace the descriptions of 21 C.F.R. §§25.21(a)-(b) found in the Notice with descriptions that more closely follow the language of the Agency's regulations.

Finally, in evaluating the use of extraordinary circumstances, the Agency should not engage in a "worst case" analysis of low probability events.[23] An effect is "reasonably foreseeable" only if it is "sufficiently likely to occur that a person of ordinary prudence would take it into account in reaching a decision."[24] Revising the descriptions of the two extraordinary circumstances discussed above will better enable FDA to comply with these standards as part of its analysis.

**Conclusion**

We appreciate the opportunity to submit these comments. We look forward to further opportunities to work with the FDA as it revises its NEPA implementing regulations to categorically exclude certain actions related to tobacco products.

Sincerely,

James E. Dillard III

Attachment

[23] Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 355-56 (1989) (NEPA "does not mandate that uncertainty in predicting environmental harms be addressed" through conjectural "worst case" analysis). Rather, the correct level of review is based on the long-standing principle that an agency must only evaluate impacts determined to be "reasonably foreseeable." Village of Bensenville v. FAA, 457 F.3d 52 (D.C. Cir. 2006); Airport Impact Relief, Inc. v. Wykle, 192 F.3d 197 (1st Cir. 1999).

[24] Gulf Restoration Network v. Dep't of Transp., 452 F.3d 362, 368 (5th Cir. 2006).

# Memorandum

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| | |
|---|---|
| **To:** | Altria Client Services on behalf of Philip Morris USA and US Smokeless Tobacco Company (USSTMC) |
| **From:** | Donna D. Morrall, Ph.D.<br>Salvatore T. Giolando, Ph.D. |
| **Date:** | 1 April 2014 |
| **Subject:** | Federal Register Vol. 79, No. 15/Thursday, January 23, 2014/Proposed Rules, National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions, 21 CFR Part 25 [Docket No. FDA-2013-N-1282] |

ERM

At the request of Altria Client Services (ALCS), Environmental Resources Management, Inc., (ERM) is summarizing below the findings of the numerous environmental assessments we prepared in support of cigarette and smokeless tobacco product substantial equivalence reports. After compiling and analyzing the best available science for the products addressed in each of those reports, we concluded in each instance that the requested FDA action would pose no significant environmental effects, even when applying extremely conservative assumptions.

**Tobacco Product Environmental Assessments**

ERM has developed environmental assessments, at the request of ALCS, for Altria Group Inc. (Altria) on behalf of Philip Morris USA (PM USA) and US Smokeless Tobacco Company (USSTC) to comply with 21 CFR Part 25 when submitting Substantial Equivalence Reports for both "provisional" tobacco products and non-"provisional" tobacco products under Section 910(a) (2) (A) and (B) of the Federal Food, Drug and Cosmetic Act ("FDCA"). Using a very conservative set of assumptions, all EAs developed for the cigarette and smokeless products resulted in a conclusion in each assessment that a "Finding of No Significant Impact" was warranted due to the absence of significant environmental effects associated with manufacture, use and disposal of the products.

ERM conducted the environmental assessments in accordance with 21 CFR §§ 25.20 and 25.40 and relevant aspects of the FDA's technical guidance document(s) including the *Guidance for Industry: Environmental Assessment of Drug and Biologics Applications, Section III.A.2 (July, 1998)*. ERM used an extremely conservative set of assumptions for all EAs to help assure that any uncertainties were outweighed by double and triple counting of product volumes and by assuming that each product would be

introduced into environmental matrices where it would be unlikely to be introduced. For example, ERM assumed that the entire production volume of each product would be introduced into commerce and enter the environment. ERM further assumed that there would be no metabolism or significant environmental depletion of each product's ingredients that would mitigate toxicity once they entered the environment. Then ERM identified the individual ingredients (by CAS number) in each product and analyzed each ingredient for any potential impact on the atmospheric, aquatic, and terrestrial environments.

ERM's assessments also considered potential impacts from product use, disposal and misuse by applying similarly conservative assumptions. For example ERM assumed that the entire production volume of each product would enter the aquatic environment through misuse even though only a small proportion of some ingredients likely will enter the aquatic environment through human excretion or environmental transport. For the terrestrial assessment, the non-burned constituents of each product should all be disposed of to landfill. However, some improper use does occur. Therefore, ERM assessed the impact of non-burned constituents to land by assuming that the entire production volume for each product would be improperly disposed of on land and by assessing the potential impact if individual units of the improperly disposed of product would be dropped, unused, onto the ground. In addition, burned constituents of each product are considered to go to air, land, and landfill as either gases or ash. When properly used, the majority of ash should be disposed of to landfill. However, some ash does go into the air, and some ash is improperly disposed of to the ground. Thus, ERM's assessments conservatively assumed that air and land would be exposed to ash from the entire production volume of each product. Further, land exposure to burned constituents is unlikely except for ash. However, during smoking, burned constituents do enter the filter. Because filters are in some instances improperly disposed of, we also have calculated the concentration of the total production volume of burned constituents that could potentially go to land due to improper disposal of filters. Finally, we considered the potential for the entire unused product to be disposed of as another assumption in the environmental assessments.

Finally, ERM's assessments for cigarette products also considered the reasonably foreseeable impacts to air resulting from the combustion of tobacco product constituents, including banded paper, the ingredient package, adhesives, and monogram ink. Again, we used an extremely conservative set of assumptions in estimating the chemical composition of the combustion by-product (which is similar to burning wood) and the levels of ash and carbon monoxide released into the air. The assessments each found that, even with these conservative estimates, exposure levels to carbon monoxide were several orders of magnitude lower than the Recommended Exposure Limits set by the National Institute of Occupational Safety and Health and that ash exposure was negligible. The extremely low

concentration in the air of by-products produced from the burned constituents of tobacco products, combined with the expectation that there would be minimal and temporary exposure to smoke in the environment, provides the basis for the conclusion that the burning of tobacco products would not have a significant environmental effect.

Even with these very conservative assumptions, ERM concluded in each assessment (for both provisional and non-provisional Substantial Equivalence Reports) that the requested action would not pose the risk of significant environmental effects and that a Finding of No Significant Impact was warranted.

Donna Morrall, Ph.D.
*Senior Project Manager,*
ERM Global Product Stewardship

Salvatore T. Giolando, Ph.D.
*Partner in Charge,*
ERM Inc.

Attachments:
CV of Dr. Donna Morrall
CV of Dr. Salvatore Giolando

# Donna D. Morrall, Ph.D.

Dr. Donna Morrall is a Senior Project Manager within ERM based in Cincinnati, Ohio. She has more than 20 years of experience in environmental monitoring, risk assessment, environmental toxicology, and insilico modeling.

Donna brings diverse industry experience in global product stewardship (15 of those years at Procter & Gamble Co.), with a focus on environmental risk assessment and the development of computational models to predict performance and safety. Donna has extensive experience in the development of aquatic monitoring programs to support chemical safety. She also has designed, managed and helped implement global modeling and training programs focused on integrating the process of chemical design, product performance, safety and consumer acceptance.

Donna is well versed in the use of QSAR/SAR and weight of evidence modeling related to international regulatory compliance issues and is familiar with USEPA TSCA and FIFRA ; EU REACH, CLP, Dangerous Substances, Dangerous Preparations, and Safety Data Sheets. She has extensive experience working with international multistakeholder teams.

**Professional Affiliations & Registrations**

- The Society of Toxicology and Chemistry (SETAC)

**Fields of Competence**

- Stream Ecology
- Data analysis and experimental design
- Environmental and Human Risk Assessment
- Computational modeling (QSAR/SAR/Similarity analysis/Domain analysis/Systems Modeling)
- Global Regulatory Compliance (e.g., EU REACH and CLP, TSCA, FIFRA, etc.)
- Technical External Relations and Communications

**Key Industry Sectors**

- Consumer Products
- Chemicals

**Education**

- B.A. Wittenberg University U.S.A., 1984
- M.S. Michigan Technological Univ. U.S.A., 1986
- Ph.D. Virginia Technological Univ. U.S.A., 1990

**Languages**

- English, native speaker
- Italian, conversational
- Spanish, minimal

ERM

**Key Projects:**

- **Modelling and development of environmental monitoring plans to support chemical safety**
- **Read across and QSAR strategies**
- **Preparation for 2013 Reach Registrations**
- **Preparation of technical dossiers and CSRs**
- **Technical and toxicological support for key global customers**

**Industry Experience:**

***Environmental Impact***

Environmental impact projects included local and global efforts. Impacts such as fishing, land use, and sewage treatment plant effluents were evaluated. Effects were evaluated in relation to populations, geomorphology, aquatic structure, material transport and processing, and toxicity. Selected studies include:

- Completing a field study of triclosan loss rates in river water.
- Conducting monitoring studies to determine removal rates of chemicals by sewage treatment plants and release rates to the environment.
- Using changes in biota to determine of zones of impact for risk assessment.
- Understanding physical and biological linkages within stream geomorphic hierarchies to predict the distribution of solutes and aquatic organisms;
- Identifying factors affecting ammonium uptake in streams – an inter-biome perspective.
- Identifying factors contributing to the collapse of lake herring populations in Lake Superior; and
- Determining effects of forest disturbance on particulate organic matter budgets of small streams.

***Data Analysis and Experimental Design***

Data mining and analysis efforts are critical precursors to environmental risk assessment and modeling. They allow efficient use of available data prior to spending effort developing new information. Data Q/A is imperative for the development of quality models. Laboratory and field projects utilized classic experimental design procedures as well as SAS JMP Design of Experiments (DOE) techniques. Data development projects included:

- Design of a database to house a large body of environemental toxicity data and transfer from a text based system;
- Mining of datasets for similarity analysis and "readover" opportunities, and training and test sets for models;
- Design of a data collection program to support an integrated series of models designed to develop new chemistries and optimize consumer product performance; and
- Comparison of similarity and substructure analysis procedures and development of guidance on when and how each procedure should be used.

***Risk Assessment and Hazard Communication***

Risk assessment and hazard communication projects ranged across consumer product chemistries such as surfactants, metals, chelants, polymers, dyes, amines, nutrients, etc. Risk assessments were conducted for individual companies as well as part of trade and industry associations. Much of this work is confidential but efforts of note include:

- Evaluatoin of methods for calculating surfactant log P values and their use in risk assessments and models.
- Running experimental stream studies on high volume surfactants and selected polymers. These studies were supported with stable isotope ($^{13}C$ and $^{15}N$) research to track chemical fate and integrated with stable isotope studies used to demonstrate comparability between natural and experimental streams for environmental risk assessment.
- Development of concepts and methods for assessing solute dynamics (Solute work group).
- Using stable isotopes tracers to predict the fate and effects of natural and man-made materials on stream biota.

### *Computational Modeling*

Modeling projects ranged from the evaluation of regulatory models, use of available models to predict the properties or toxicity of a single ingredient to the development of complex integrated sets of environmental and product performance models. Modelling efforts included developing modeling programs and implementation plans for a consumer products division to guide their efforts to optimize chemical performance and minimize toxicity. Examples of projects include:

- Development of models based on surfactant properties and data to optimize consumer product formulations;
- Predicting the effects of copper toxicity to algae in lake ecosystems;
- Developing a genetic algorithm to predict the toxicity of surfactants to algae;
- Identifying Acute and Chronic Aquatic Toxicity Structure Activity Relationships for Alcohol Ethoxylate Surfactants;
- Development of a coordinated suite of approaches (similarity analysis, substructure search, domain analysis, nearest neighbor evaluation) to predict aromatic amine mutagenicity and carcinogenicity;
- Evaluation of EPI Suite™ for use with specific classes of compounds;
- Using QSAR for the design and optimization of laundry brighteners;
- Developing guidance on techniques for the use of domain analysis;
- Development of a new weight of evidence approach to building chemically-intuitive predictive models building techniques to determine effective variable selection and reduction approaches;
- Development of fish population models (Lake Superior Coregonus artedii) and stream ecosystem models;
- Identification of ecological applications of genetic progamming: predicting organism distributions in complex physical habitats;
- Fusing of genetic algorithms and genetic programming techniques for symbolic regression;
- Development of state of the art ecological modeling by Genetic Algorithms; and
- Applying the results from a variety of Genetic Algorithm applications to show the robustness of the approach.

# Salvatore T. Giolando, Ph.D.

Associate Partner

Dr. Giolando is based in our Cincinnati, Ohio office.

Dr. Giolando brings over 25 years of global industry and consulting experience, currently as an ERM Partner focusing on Global Product Stewardship and integrated product support across the ERM business lines. He holds a BS in Chemistry and a Ph.D. in Environmental Health. His career is highlighted by 10+ years in industry working for the Procter & Gamble Company managing global product safety and regulatory compliance for numerous brands and innovative technologies during tenures in both Cincinnati and Brussels, Belgium.

Since 2002 Sal has been developing domestic and international product stewardship programs with several multi-national clients, especially in the area of EU REACH regulation. He will be focused on developing a North American Center of Excellence in global product stewardship, product safety and global regulatory compliance programs as he integrates his Cincinnati/North American team with the existing Global ERM team collaborating in this area.

Dr. Giolando is an internationally recognized and respected GPS expert and a proven leader with vision and key insights into GPS emerging markets. In addition to GPS professional services, Sal's specific areas of technical expertise include: Strategic GPS planning and program implementation; EU REACH and related international chemical product regulatory schemes; TSCA, the Globally Harmonized System for Hazard Classificzation and Labelling(GHS); Sustainability; Risk Assessment; Industrial Hygiene, Exposure Assessment; Government Relations; Bioavailability; and Environmental Fate/Modeling.

**Professional Affiliations & Registrations**

- Member, Society for Environmental Toxicology and Chemistry
- Member, American Chemical Society

**Fields of Competence**

- Product Stewardship
- Peformance Assurance
- Strategic Planning
- Industrial Hygiene
- REACH CLP & Chemical Control
- Environmental Fate/Modeling
- Bioavailability
- Risk Assessment/Management

**Education**

- Ph.D., Environmental Health, University of Cincinnati, College of Medicine, 1991
- Appointed Graduate Scholar in Biotechnology, 1989
- B.S., Chemistry, Canisius College, 1986

**Languages**

- English, native speaker
- Conversational French

**Key Industry Sectors**

- Consumer Products, Industrial Chemicals, Pesticide/Biocide, Oil & Gas, Aviation, Automotive, Pharmaceutical, Food Contact, Batteries and Electronics

**Certification and Training**

- Certified Hazardous Materials Manager, CHMM #2204 – 1990 and 1991
- Certified OSHA Competent Person – Asbestos Abatement Contractor/Supervisor, 1990
- Industrial Hygienist in Training 1990