

To: ATCC Consensus Standards Partnership (CSP)  
From: Trish Hugunin for Joseph B. Perrone, ScD  
Subject: SDO/CSP Activity Update  
Date: April 13, 2007

**From the Office of the Director of the ATCC Standards Developing Organization (SDO):**

Welcome aboard to each and every one of you! Your participation as a stakeholder in the diverse membership of the CSP brings a fair, balanced and representative cross-section of the biomaterials community to this critical standards development activity. Again, thank you for your participation.

Joseph B. Perrone, ScD

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**Update:**

At this time, more than 65 organizations have joined our growing partnership. These organizations represent a stakeholder cross-section of major corporations, government agencies, academic and regulatory groups. For your information we have attached a current membership list sorted by stakeholder representation category.

We are continuing to solicit general CSP membership and are currently in the process of establishing the CSP Steering Committee. Ten individuals have accepted the invitation to serve on the Steering Committee. In the interest of maintaining representative balance, several more invitations will be issued and the final composition of the Steering Committee will be announced at a later date.

This week ATCC submitted an application for accreditation as an American National Standards Institute (ANSI) Standards Developing Organization (SDO). Accreditation activities will continue as we develop a timeline for SDO/CSP activities.

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**Q & A:**

Q. What is the CSP and its role in consensus standards development?

*The CSP general membership is the review, comment and voting body of the ATCC Standards Developing Organization (SDO). After the review, comment and voting process is completed and an affirmative consensus is achieved by the CSP for a specific draft standard, that standard will be completed and submitted by the ATCC SDO to ANSI as a voluntary consensus standard for publication. Standards for biodefense materials and processes will be among the first standards to be addressed by the ATCC CSP.*

Q. What level of involvement is expected of me?

*The level of participation in the ATCC CSP is really up to you and your organization. The general CSP membership will be asked to review, comment and vote upon draft standards that are developed. Members may recommend specific topics for standard development to the Steering Committee and they may be asked to participate on specific standard-development workgroups.*

*For a general CSP member we would anticipate 2-3 hours per month (virtual) to review and comment upon draft standards. Members invited to serve voluntarily on the Steering Committee or specific standard workgroups (Technical Committee (TC) or Technical Advisory Group (TAG)) may need to meet in person on occasion as well as work virtually and by teleconference.*

Q. How long will it take before I see a draft standard for review, comment and vote?

*Once the Steering Committee is in place, they will also have up-front work to do prior to the development and circulation of draft standards. All in all, it will take several months before any draft standards are developed and out for membership review.*

Q. What is the role of the Steering Committee?

*The Steering Committee is the executive committee (National Steering Committee) for the ATCC SDO and the CSP. In this role it will provide a critical link between the CSP and our standards development organization in the identification and development of ISO-compatible American National Standards for biomaterials. The Steering Committee will receive and review recommendations for specific standard topics, select the initial standards for development, solicit membership for committees and workgroups from the general membership and oversee the work of these subcommittees.*

Please forward any additional questions that you might have concerning the SDO and/or the CSP that might be answered for the entire membership in this informational format. Send to [thugunin@atcc.org](mailto:thugunin@atcc.org).

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### **We need your help!**

- We are considering several methods for routine information distribution to and communications with the entire CSP membership, including email newsletters, a SDO/CSP handbook, posting to the website, etc. If you have any ideas on how best to do this, please share them with us.
  - Please recommend individuals for general CSP membership if you know of a stakeholder organization/group that you see is not currently represented.
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**FYI:** We anticipate that our first standard will be derived from work done by the Expert Panel on the Development of Standards for Biodefense in April 2006. You may wish to review the proceedings of the panel's April 2006 meeting – <http://www.biodefensestandards.org>.

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**SDO/CSP Contact Information:**

Joseph B. Perrone, ScD  
703-365-2746  
[jperrone@atcc.org](mailto:jperrone@atcc.org)

Trish Hugunin  
703-365-2746  
[thugunin@atcc.org](mailto:thugunin@atcc.org)