The Chemical Consultant

Association of Consulting Chemists and Chemical Engineers, Inc.

Scientific, Engineering, Business & Management Consultants

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FUTURE MEETINGS

SEP 28

Snuffy's Restaurant
Scotch Plains, NJ
Dr. Romit Ramachandran
Rutgers University

OCT 26

Ben's Deli,
New York City

Annual Membership Meeting
Talk by
Dr. Richard M. Goodman

Non-members are invited, so they may learn about ACC&CE and how to become a consultant

ABOUT THE ASSOCIATION

The Association of Consulting Chemists & Chemical Engineers (ACC&CE) is a network of senior-level consultants with a broad range of functional expertise and many years of experience in the chemical and allied industries.

The purposes of the organization are:

To furnish support to its members as they conduct their consulting practices.

To offer prospective clients a "clearing house" which they can use to find the most qualified consultants or team of consultants whatever their particular problem may be.

This newsletter is intended to support those purposes as well as to educate prospective new members and prospective client organizations about ACC&CE, and how we can be most helpful to them.

The ACC&CE has an interactive website – www.chemconsult.org, that allows prospective clients either to input their problem or to search for those consultants most skilled in their area of concern.

IN THIS ISSUE

In this issue, we feature several documents compiled by Bill Hoffmann, relating to the Gulf of Mexico oil spill and aftermath. Three members have presented ideas regarding such steps, at least two ideas of which were sent to BP. We reproduce the proposals in this issue.

This issue includes an important message from President Richard Goodman. Richard discusses some fundamental changes being contemplated for the Association.

Also included in this issue is an excerpt of an article by Girish Malhotra which appeared in Pharm Pro Magazine, and another column by your editor following up on earlier columns related to crude oil prices and supply and demand.

Joe Porcelli, Editor

SEPTEMBER MESSAGE FROM THE PRESIDENT

I will review the changes, if any, in the status of ACC&CE since my last newsletter message in the Spring. The last meetings in the Spring were well received as have most of our programming over the last year (kudos to Program Chair Tom Borne).

As President I can testify that I received an inquiry through our website which has led to payment for consulting services and I sent my commission to the treasurer. I hope that other members will also be so fortunate.

We have instituted some significant cost savings in the operations of ACC&CE. Nevertheless, ACC&CE is still facing a serious financial problem: our membership remains perilously low and barely able to pay expenses. We are discussing even further cuts, if possible, to maintain the presence of ACC&CE but at a lower cost.

In a different vein we are instituting the establishment of a lifetime membership category. Members in good standing for a total of at least fifteen years (not necessarily contiguous membership) can for a one-time fee secure rights as a full time member for as long as they are actively in the chemical consulting field. The board is considering the one-time fee of $600.00. Your comments on this are welcome.

We are exploring the possibility of establishing ACC&CE as a certifying group for chemical consultants in a more visible public manner. We‘re seeking a possible formal protocol with the ACS or AIChE- in early discussions, but your inputs will be welcome.

Again I solicit our members to tell me why they are members of ACC&CE. If you know of any colleagues who could be but are not members of ACC&CE I want to know why they aren’t. Perhaps we can use the responses from both groups to guide our recruitment of new members.

Thank you for reading this message.

Richard M. Goodman, Certificate #747

RICHMAN CHEMICAL INC.

CUSTOM MANUFACTURING
Custom Synthesis & Custom Sourcing
of Fine Chemicals
Edward Richman, Ph.D.
768 N. Bethlehem Pike, L. Gwynedd, PA 19002
Ph: 215 628-2946 . email: richmanc@erols.com
Fax: 215 628-4262 . www.richmanchemical.com

Jasprit Singh, PhD

JMS PROCESS

Process Plants
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Troubleshooting

P.O. Box 541
Grand Island, NY
14072
(716) 773-4666
(Fax) 773-6420

SCHAUER ASSOCIATES

Dr. Richard L. Schauer
Regulatory Consultant

P.O. Box 398, 1211 Dexter Corner Road
Townsend, DE 19734
Phone: (732) 586-5678
Fax: (302) 449-6012
E-mail: rschauer@schauerassociates.com

J. Stephen Duerr, Ph.D., P.E., CPC
Consulting Metallurgist/Chemist
chemlabconsulting, LLC

514 Corrigan Way, Cary, NC 27519
908-500-9333 (FAX 815-301-8348)
chemlabconsulting@gmail.com

SOLVING THE OIL SPILL PROBLEM—
A Possible New Role for ACC&CE

Earlier this year, Bill Hoffmann (Certificate 908) proposed the search for solutions for the long-lasting oil spill in the Gulf of Mexico as an opportunity for ACC&CE and its members to contribute to filling a critical need while demonstrating what our group could do to address future industry needs. This effort culminated in a CHI #4982 Proposals for Gulf Oil. The following article is a compilation by Bill of the proposals submitted by ACC&CE members.

Although the BP oil well explosion and release is apparently under control, during the course of finding workable solutions, BP encouraged knowledgeable people to present potential solutions to them for their consideration. To our (ACC&CE) knowledge, none of those presented from public sources was acted upon. We are not aware of the reasons why none were chosen.

Nevertheless, there may be occasions for some type of spill recovery, and despite current government actions, deep-well drilling will undoubtedly return, and with it some level of need for remediation.

Three members have presented ideas regarding such steps, at least two ideas of which were sent to BP. We reproduce the proposals here below, for the record, and for the ACC&CE Newsletter.

Two types of remediation proposals were presented. The first type covered means to block the flow of oil; the second means to remove oil from the surface.

Type 1.

Pump urethane resin and TDI (toluene diisocyanate down two separate concentric pipes of one inch and 0.5 inches so that they mix as they enter the well itself. They will polymerize to make a polyurethane foam that will be relatively impervious to the oil and less dense, so the foam will rise to the top of the well and also into the main pipe and block any oil leakage.

One could also implode the top of the solid well surface where the exit pipe for oil is and thus fill the hole in that was drilled.

-J. Bonacci, Fibonacci, Inc.

(Continued on next page)

Balloon angioplasty to clog the pipe. Dense metal cone leads train of one or more large PVC

Solving the Oil Spill Problem (Cont'd)

balls, deflated, mounted axially on 2" diameter threaded rods passing thru ball-centers, sealed with flanges and nuts, and containing 70-90% hydrogen peroxide to decompose and inflate the balls. The cone is quartered lengthwise to flare open and grip walls when ball size enables outflow to try to push it out.

PVC balls of the needed size and wall thickness are made as exercise balls (Pilates). Steel for the cone, threaded rod, flanges (rubber also), nuts, 70-90% hydrogen peroxide as decomposing (not explosive!) agent, are all readily available. The cone might also be made from spent uranium for added density (and reduced cross section).

Major equipment required is that needed to lower the above assemblage to and guide it into the pipe.

48 lb of 100% H_2O_2 will yield about 22,5lb of O_2, which in a vessel 20" in diameter at 5C (41F) will exert a pressure of about 148 atm or 2188 psi., inflating the ball against the pressure of the sea at 5000 ft. At the pressure and temperature, the water should condense as ice and occupy about 25L of the 49 L ball

The above calculation depends on direct decomposition of H_2O_2. MnO_2 catalyzes the decomposition, and the result is 1 H_2O for each 1/2 O_2.

The faster reaction of titration requires 2 $KMnO_4$/5H_2O_2, and yields 1 O_2/H_2O_2 (double the yield) according to $2KMnO_4 + 5H_2O_2 + 3H_2SO_4 \rightarrow 2MnSO_4 + K_2SO_4 + 8 H_2O + 5 O_2$

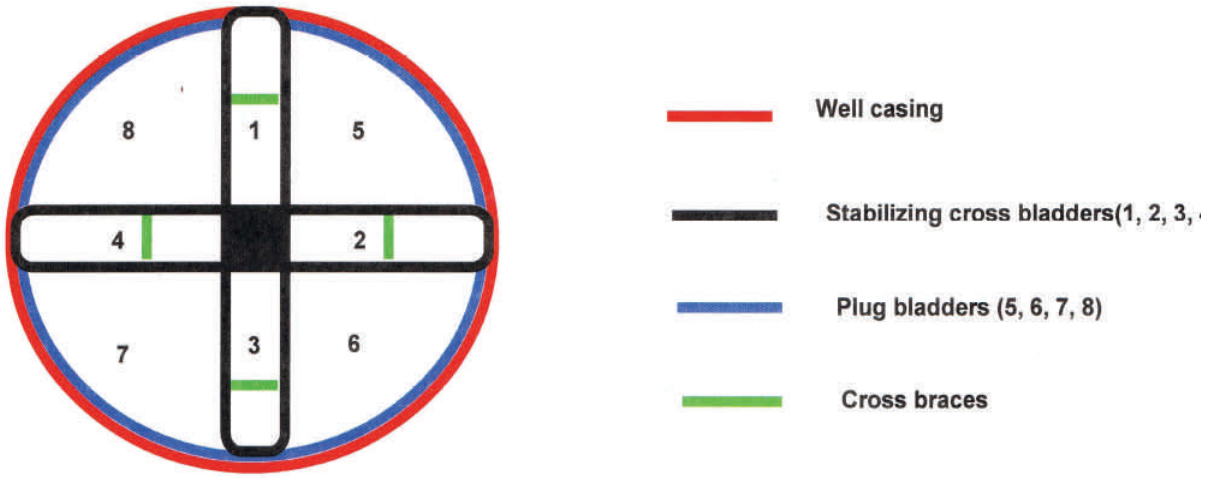
Overall the process involves dropping the split-nosecone into the running pipe (presumed to be 20" diameter), followed by the rigged rod/peroxide-loaded ball assembly, internally armed for either manual or electronic release of permanganate to decompose the hydrogen peroxide into water and oxygen, inflating the ball. As inflation advances, the flow of oil will push the assemblage back, flaring the nosecone and wedging the assembly in the pipe until full decomposition inflates the ball and closes off the opening.

W. A. Hoffman III, ROBILL Products

SEE FOLLOWING PAGE FORWARDED FROM R. SCHAUER, Schauer Associates

Solving the Oil Spill Problem (Cont'd)

A Method for Plugging Oil Well Casings



Cross Section View of An Oilwell Casing Plug

The purpose of this device is to provide temporary plugging of a damaged oilwell casing. The plug is a 50 - 100 foot long rubber tube of sufficient diameter to plug the casing when inflated. A 20 foot long metal pipe is mounted at the bottom of the tube to assist insertion of the plug into the well casing. A mainifold is mounted at the top end that contains 8 electically operated valves to control the sequence of bladder inflation (1 - 8). A single air hose, with a remote disconnect coupling, running from the manifold to the water's surface feeds air into the bladders.

The device would be positioned 200- 300 feet below the top of the casing lip. To make insertion of the device easier, the entire tube would be encased in a netting material that reduces the diameter of the plug. When inflation begins, the netting will break and allow the plug to fully expand.

The drawing shown above is a cross section view of the plug. The stabilizing cross bladders (1, 2, 3, 4) would be pressurized first to anchor the plug device in the casing. The stabilizing bladders will need cross braces to prevent the side walls from buldging out when fully inflated. Because the thickness of the plug bladders is thinner than the thickness of the stabilizing bladders, the walls will fold inward and oil can easily escape between the outer walls of the plug bladders and the casing wall. Thus, the pressure will not build up to blow the plug out before the plug is fully installed.

Once the stabiling bladders are fully inflated, the plug bladders 5 & 7 would be fully inflated. Finally plug bladders 6 & 8 can be inflated to completely stop the flow of oil. Once bladdert 6 & 8 are inflated, pressure in all of the all of the bladders can be increased if necessary. The surface of the plug in contact with the well casing should provide sufficient resistance to prevent a blowout.

If the well is to be abandonded, cement, or other suitable plugging material can be pumped into the casing to provide a permanent seal.

The advantages of this inflatable plug is that closure can be accomplished in a controlled fashion

Solving the Oil Spill Problem (Cont'd)

Type II

Oil on the surface was to have been burned off as part of the remediation process, but this was delayed or alternatives considered because of the removal of oxygen due to combustion. It is known that among the concerns about leaving the oil to be decomposed by natural processes is the increase in BOD due to the growth of oil-consuming organisms, presumably counterproductive (one way or the other) vis-à-vis surface combustion. An answer, akin to the use of dispersion aids, would be to add hydrogen peroxide to the surface water. During combustion, peroxide decomposition would restore oxygen levels and/or assist the surface combustion. Upon entering deeper waters, the dilute hydrogen peroxide would still support the increase in BOD, by its slow decomposition resulting from iron, cobalt, manganese and other transition metals in the Gulf.

W.A. Hoffman III, ROBILL Products

None of the proposals have been tested so far as we know, and others might have had critiques of them which could have led to exchange and improvement, on the fly, in a context of internet brainstorming, if BP had shared the possibilities broadly.

This presentation of the small set of proposals is meant to encourage that very process, and the above may provoke others' thoughts that we could expand and improve upon, against the day, hopefully many years hence, when another large spill occurs.

-compiled for publication in the ACC&CE Newsletter
W.A. Hoffman III
10/8/10

Excerpts from a Member's Publication

Girish Malhotra, PE, President, EPCOT International (Certificate #861) submitted a link to a publication he had written, which appeared in Pharma Pro Magazine and elsewhere. Your editor has done his best to reproduce portions of that article, due to space limitations. The full article can be found by going to: http://www.wiley.com/WileyCDA/WileyTitle/productCd-0470487542,subjectCd-CG00.html

The Path Towards Continuous Processing

In recent years, there has been discussion of value manufacturing technology innovations (batch vs. continuous manufacture, PAT, QBA, QBD) for active pharmaceutical ingredients (API) and formulations. In addition, the branded pharmaceutical companies are changing the playing field in order to bolster their revenues and profits. This combination will impact the global pharmaceutical business. I am presenting my observations of the circumstances that can improve manufacturing technologies, revenues and profits. They are different for ethical (branded) and generic drugs.

Market Conditions

Generics are continuously challenging brand company revenues through patent challenges. In addition, due to patent expiration in the next few years, branded pharmaceuticals are projected to lose about $80 billion in revenue. With the loss of revenue due to dwindling patent protected products, drying pipelines and uncertainties of new blockbuster drugs (bio-tech/small molecule), the brand companies have started to reduce drug prices in high growth markets (the developing countries) (1,2,3). They are also selectively establishing relationships (4,5,6,7,8,9) with companies in developing countries to have market presence. It is their hope that the larger market size will replenish some of their lost revenue and profits. The current practice of batch manufacturing will assist, but it will take longer time compared to using continuous processes (10). With continuous processes, in addition to regaining revenue quicker, they will generate higher profits, produce higher quality products and simplify the total business process. API suppliers, formulators, pharmaceutical companies and customers will benefit from better manufacturing technologies.

Brand companies, in order to regain their lost revenue, have also started to increase drug prices in the countries where they can (11). This can have negative connotations and can also create opportunities for generics in the brand company's most profitable markets.

Manufacturing Technologies

Ethical (brand) companies resort to batch processes due to the following boundary conditions.

1. Batch processes are easier and simpler to develop, scale-up and commercialize.
2. Pressure of first to market lowers the possibility of using a continuous process.
3. Since the success of a molecule is not known, batch process is the logical choice.
4. Patent protection negates the need for technology innovation.

Due to the factors listed above and limited patent life after approval; the effort needed to comply with the necessary regulations and convert a batch to a continuous process has not been a branded drug company's priority. However, the market conditions might change this in the near future. In addition, my conjecture is that due to lack of competition and the ability of API manufacturers and drug formulators to achieve their profit margins, there is no push to incorporate "quality by design (QBD)" methods in the manufacturing methods. Chemists and .

Excerpts from a Member's Publication (Cont'd)

chemical engineers are taught to develop, design and implement QBD processes but since the pharmaceutical manufacturing culture is "quality by analysis (QBA)", it prevails and they have to conform.
After the patents have expired, any company can produce API molecules after appropriate approval. They can use a continuous process, if the chemistry/volume warrants it. Under the current business conditions generic companies have higher possibilities of designing processes that follow the QBD regimen and using continuous processes for their manufacturing versus brand companies.

We need to understand why the pharmaceutical industry or the technology innovators have not adopted continuous processes or have had difficulty in improving their current batch processes. One reason could be due to significant price differential between the average wholesale price and the cost of APIs and formulated drugs (12). This difference gives them sufficient monies for the development of new molecules and shareholder profits. Compared to the gains due to price differential, financial benefits due to manufacturing technology innovation are very low, making such investments unacceptable. In addition, since the generics take over the business after patent expiration, the brand companies have no incentive to invest in the products they will not produce.

Contract API manufacturers and formulators have sufficient financial incentive for technology innovation but have not made any progress. The industry's hesitation to introduce innovation and the reasons are enumerated in the U.S. FDA's PAT Guidance for Industry (13).

Since the brand companies are beginning to encroach on the "pharmerging" markets, we could see generic companies, who also produce API's, in order to keep their markets, incorporating continuous processes, as they would not want to loose their market share on their home turf. Continuous processing through lower costs would allow them to retain/increase their market share and margins. This is a challenge they have to take. I foresee that we will see generic companies incorporating continuous processing as part of their manufacturing practices. Adoption of continuous processes will demand implementation of QBD methods for the manufacturing technologies.

Review of APIs
Market size and drug dosage determine the volume of the API (12). Process chemistry will determine the feasibility of a continuous process. I am using four APIs that have varying yearly needs to illustrate the viability of continuous processing.

Some of these products can be produced using standard commercially available equipment that is used for the production of various fine and specialty chemicals. For the lower volume products, modular plants could be used to have a continuous process. Such methodologies have not been considered. Innovative use of equipment would be needed. Creativity and imagination would be valuable.

Excerpts from a Member's Publication (Cont'd)

In each of the processes, it is expected that we have the necessary knowledge and understanding of the chemistry, kinetics, physical properties and their interaction and unit operations to design an economic commercial plant that will produce the desired product.

Editor's note—the following products are described in detail in the full article:

Metformin hydrochloride (Glucophage)
Bupropion hydrochloride (Wellbutrin)
Omeprazole
Modafinil

Opportunities

A latent reason for lack of pharmaceutical manufacturing innovation could be due to the fact no one wants to disturb the demand/supply apple cart. Another reasons could be the daunting task of regulatory re-approval and associated costs or lack of financial justification. Since 2005, generics have caused a perturbation in the global pharmaceutical business. A new business model might be needed as the demand for proven drugs is ever increasing in developing countries. Since we humans want to live forever, there is high demand for the drugs that will extend or assist in extending life. Demand (21) exists. It is possible that the population that cannot afford the drugs might not be included in the demand projections. If it is so, then global drug needs are underestimated. Management guru Dr. C. K. Prahalad said it right "If you build for the poor, the rich can come. If you build it for the rich, the poor can't come (22)."

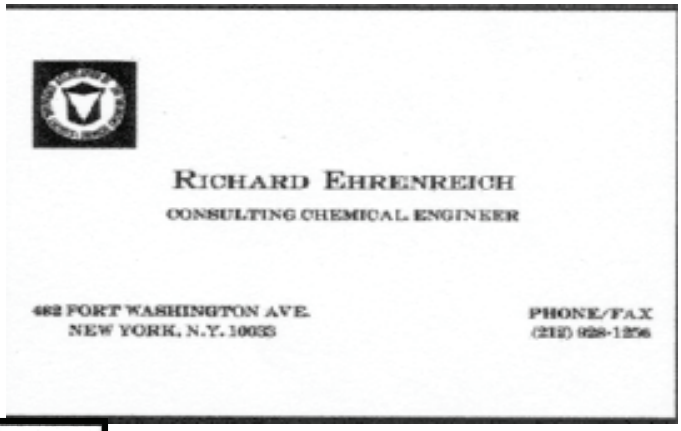
If the "medicines of mass need" can be made available at affordable prices through manufacturing innovation, be it a batch or a continuous process, we could see growth of 10+% per year drug sales, i.e., the market could reach about $2.0 trillion dollars in the next ten years or sooner. With the potential for such a high revenue market, it is very possible that companies from the developing countries could capitalize on and satisfy the unmet market need through better technologies. This scenario would have been unthinkable 5-8 years ago, but with the changing landscape anything is possible. The fastest way to innovate would be to move from "chemistry centricity" methods to "process centricity" methods (23).

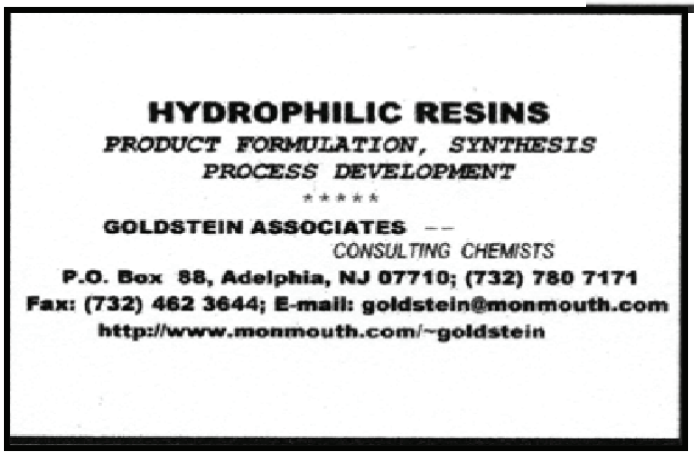
Manufacturing innovation will benefit every pharmaceutical company especially companies who are API producers, formulators, and sell to mass merchandisers, as every one will generate higher profits through larger markets and lower costs. Regulatory bodies and the industry have to find common ground and rules to reduce the time for the re-approval process and associated costs. Until rules of the game for incorporation of process of continuous improvement in pharmaceutical manufacturing are simplified there will be no game.

We just have to do the right things to meet the demand of over six billion people on this planet. It is an opportunity for technology innovation, reduction of carbon footprint, sustained profits and serving human needs. Why should we not do it?

References appear in the full article, or by request to editor.


Poly(Chem-Tech)
CHEMICAL CONSULTING
Industrial
Consumer Product
Healthcare
TechnologyTransfer
Dental Products
Polymers
DANIEL KRUH, Ph.D
President
8 Braddock Street
East Brunswick, NJ 08816
Voice/Fax: (732) 238-3182
Email: DanKruh@aol.com


RICHARD EHRENREICH
CONSULTING CHEMICAL ENGINEER
482 FORT WASHINGTON AVE.
NEW YORK, N.Y. 10033
PHONE/FAX
(212) 928-1256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GOLDSTEIN ASSOCIATES --
CONSULTING CHEMISTS
P.O. Box 88, Adelphia, NJ 07710; (732) 780 7171
Fax: (732) 462 3644; E-mail: goldstein@monmouth.com
http://www.monmouth.com/~goldstein

déjà vu All Over Again - Living with Cyclical Oil Prices

By Joe Porcelli (Certificate #906) with attribution to Yogi Berra

It has been over a year since my last column on energy appeared in Vol 21-1 of this newsletter. It was entitled "The World Economy and the Perfect Storm", and in it I expressed my concern that the lessons of the previous oil market boom and bust would not be learned. We were just about at the bottom of the economic and oil price crash when it went to print, and we were wondering what kind of recovery we would have – "L-shaped", "V-shaped", "W-shaped", or something else. Unfortunately, it appears to have turned out to be the deadly "W". In the last month or two, the US (and presumably Europe) have fallen back into recession, and even China is seeing its growth rate slow down. Despite this, the crude oil price, which was at about $45/barrel in April 2009 now stands at about $70. Having dropped from $80 in the last few weeks.

There are at least two reasons for this continued strength in the crude oil price despite the relatively poor global economic conditions and forecasts. First is that in the US, the population has adjusted to the higher price levels, and has gotten used to it. Driving is down, but not decreasing further. Second, even though China is slowing down, the growth in auto ownership there and in India continues at high rates. Therefore, the overall demand for automotive fuels is continuing to increase despite the gloomy economic conditions.

A few months ago, I gave a talk on "Business, Energy and Technology in Today's Environment", and in the course of my preparation for that talk, I came across an interesting set of data published by the EIA (Energy Information Administration). Table 1 was extracted from that data

Table 1

Petroleum Uses in US, 2008	
Transportation	70.9%
Industrial	22.9%
Residential/ Commercial	5.1%
Electric Power	1.1%
	100.0%

Reviewing the first table, it can be seen that the great majority of the petroleum used in the US is for transportation needs, with a substantially small amount for industrial use (refinery and chemical feed stocks and utilities) and still lesser amounts for residential and commercial uses, and for generating electricity. Obviously wide price fluctuations affect each sector proportionately.

déjà vu All Over Again - Living with Cyclical Oil Prices (Cont'd)

Table 2 which follows was also extracted from the same data set.

Table 2

Transportation Uses in US, 2008	
Petroleum	94.6%
Natural Gas	2.5%
Coal	0.0%
Renewable Energy	2.9%
Nuclear Electric Power	0.0%
	100.0%

Table 2 is more telling. About 95% of our transportation fuel in 2008 was from petroleum, and 2.5% each from renewables (primarily ethanol) and 2.5% from natural gas (primarily compressed natural gas in fleet vehicles.) Furthermore, a separate piece of data states that the amount of petroleum we import is approximately equal to the amount of petroleum going to transportation. Thus only a reduction in fuel consumption (smaller cars, hybrids and electrics) and a large increase in biofuels production can move the country towards less dependence on imported oil. If the current slowdown causes crude oil and gasoline prices to drop too far, it will discourage the efforts to produce alternative and renewable fuels and energy sources, setting us up for still another cycle in the future. The case for a long-term energy plan for the country continues to seem clear.

EDITOR'S NOTE

Incorporated in 1928, ACC&CE is planning to hold their 82nd Anniversary Annual Membership Meeting on Tuesday, October 26, 2010.

Dr. Richard M. Goodman, ACC&CE President, will speak at the Annual Membership Meeting at Ben's Deli, 209 West 38th Street, New York. Please join us for dinner and networking.

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The Association of Consulting Chemists
& Chemical Engineers
P.O. Box 297
Sparta, NJ 07871
Phone: 973-729-6671
FAX: 973-729-6671 Call first
accce@chemconsult.org
www.chemconsult.org
Opinions expressed herein are not necessarily those of ACC&CE.