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NEWS LETTER

OIL TECHNOLOGISTS' ASSOCIATION OF INDIA
WESTERN ZONE

Inside This Issue

This news letter is for free circulation only to the members of OTAI-WZ

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OIL TECHNOLOGISTS' ASSOCIATION OF INDIA WESTERN ZONE

IN MEMORIUM

23-03-1923

Mr. P. P. Sarma, Founder-President, Servotech, Mumbai passed away on 29-1-2012 at Hyderabad, after a brief illness. He was a doyen of Vegetable Oil Processing Technology. He was responsible for building over 200 projects of solvent extraction, Oil Refining hydrogenation, in India and surrounding countries and was a well-known personality. His legacy is being continued by Servotech Engineers Ltd., Mumbai, We pray for peace and well-being of his soul.

From the Editors's Desk

What is happening around? It is Camel, Camel ...? No, no it is 'Camelina' Camelina Satura ! Seed gives oil for Biodiesel. Residue pumps in protein to cattle and poultry. Grows on marginal lands and wastelands. Sparse rainfall sufficient. Rings a bell. Yes. It is Jatropha surging forward. Flying high, literally. Major aircraft flights on jatropha-based fuel. A new generation of renewable fuels on the horizon. Process schemes for production of fuels on the horizon. Process schemes for production of fuels to replace kerosene and diesel ! where does it leave us? We need to pursue break-through technologies like zero trans-fat oils. No refrigeration to preserve foods and medicines, use biotech methods to swamp the spoilers !

Let us break the chains and surge forward with revolutionary throughts.

Trade & Commerce

Industry to be worth Rs 20,000 cr by 2014: ASSOCHAM

OUR BUREAU, MUMBAI

ESTIMATED at Rs 10,000 crore, the Indian cosmetic industry is all set to double its size to Rs 20,000 crore by 2014, according to a study by the Associated Chambers of Commerce and Industry of India (ASSOCHAM).

The association believes that the main reason behind this boost is the emergence of a young urban elite population with rising disposable incomes and increase in working women looking for lifestyle-oriented and luxury products. The industry has mainly been driven by improved purchasing power and rising fashion consciousness among people and industry players spending heavily on the promotional activities to increase consumer awareness.

Releasing the findings, D S Rawat, secretary-general, ASSOCHAM, said that the companies have started going for rural expansion and offering specialised products to generate revenues from all the corners of the country. Improvement and strengthening of the Indian economy in the coming years will also pave the way for the Indian cosmetics market over the forecast period and develop the cosmetic industry.

According to a report, women in the age group of 30 and above are getting very selective about the type of products they choose. "As older women have more cash and are more conscious of their appearance, especially skin, they are willing to spend more on separate sets of creams and lotions that target problem areas. These women also are more open to buying higher-priced products."

Products falling under the price range of Rs 50 to Rs 200 are in the mass-market category. The middle-market price can range from Rs 200 to Rs 1,000. In the high-end market, pricing can range from Rs 1,000 to Rs 10,000. Finally there is the premium range of products where the pricing can touch up to Rs 50,000.

Countrywide survey

According to the report, a countrywide survey was undertaken by ASSOCHAM'S team seeking views of over 6,000-odd consumers in cosmetics.

On an average, in this segment, a good majority of respondents felt that they would spend less than Rs 1,000 on cosmetic use during the year 2000, which now exceeded Rs 5,000 per month and the main reasons for this massive advertisements both in electronics and print have influenced the customers in this segment that these were inspired for increased allocation of their monthly expenses towards these articles.

The survey also came out with interesting facts, highlighting that males have developed a special craze for cosmetic application as compared to their females counterparts and their monthly expenses rose by about 60%-80% during the period, reveals the survey.

However, the consumption pattern of cosmetics of teenagers went up substantially between 2000 and 2011 because of increasing awareness for upkeep of teenagers exterior as 95% of them admitted this.

Over 65% teenagers said, "Their branded cosmetic consumption has gone up by about 75% in last 10 years. 62% of male youth said that their expenses on cosmetics application have risen by 45% as against 57% upper middle age group, claiming that they spend nearly 42% in buying cosmetics products to maintain their exterior."

About 75% male teenagers have increased their expenditure on cosmetics to Rs 3,000-4,000 per month as against their average expenditure of less than Rs 1,000 in year 2000 increased over 300%

due to growing awareness.

Over 75% of women consumers tend to buy cosmetic, apparel items from any shop of their convenience rather than a single shop. They buy all their items from different shops rather than a single shop. Quality is given utmost preference by the women consumers.

It also mentioned that a quarter each of the housewives and executives spent more than Rs 2,500-3,500 per month for cosmetics & apparel. 32% of the respondents belonging to the student community had expenditure in the range of Rs 800-1,200 per month. Around 35% of the teachers, a quarter of businessmen, 23% of the government employees had expenditure in the range of Rs 2,500-3,000.

The survey also pointed out that quality was considered as the major criterion for brand selection among the students (71%), teachers (67%), businessmen (58%), housewives (52%), professionals (50%), and executives (43%). Price was the main concern while purchasing cosmetics, apparel and mobile among government employees (45%). This may be because of the limited source of income available to these people to purchase cosmetics.

Brands such as Lakme, Maybelline, and Color Bar are being pushed as mass market products and focus on younger women and women with lower buying power.

Industry trends

With the beauty service industry growing rapidly in India, the spa segment in India is also attracting a lot of attention. The spa industry over the last five years has shown tremendous growth, not only in the number of spas, but also in the diversity of spas and products available.

The flourishing Indian fashion / film industry is fuelling growth into the cosmetic industry in India by making Indians to realise the importance of having good looks and appearances.

The Indian cosmetics industry is defined as skin care, hair care, colour cosmetics, fragrances and oral care segments which is estimated at Rs 15,000 crore and is expected to grow at over 10% annually, according to the report.

Today herbal cosmetics industry is driving growth in the beauty business in India and is expected to grow at a rate of 12% as more people shun chemical products in favour of organic ones.

The Indian cosmetics industry has a plethora of herbal cosmetic brands like Forest Essentials, Biotique, Himalaya, Blossom Kochhar, VLCC, Dabur and Lotus and many more.

The paper further highlighted, “India’s per capita cosmetic and toiletries consumption is 40 times lesser than that of Hong Kong, 18 of Japan, 15 of Taiwan, 12 of Philippines and Malaysia and half of China, despite high penetration levels for cosmetic products because of its population and size-based.”

Conclusion

The survey reveals that increasing market size is the direct result of the changing socio-economic status of the Indian consumers, especially women. Higher paying jobs and increasing awareness of the Western world and beauty trends there have served to change the tastes and customs of the middle-class and higher strata of society, with the result that a woman from such social strata now is more conscious of her appearance and is willing to spend extra cash on enhancing it further. This actually has fuelled a growth in certain product categories in the market that hardly were experiencing it earlier. Two such categories are colour cosmetics and sun care products that have shown tremendous growth.

(Courtesy : Ingredients South Asia, December 16-31 2011, Vol.5 Issue 6)

"SURVIVAL OF THE FITTEST"

Small & medium cos fighting it out for survival

JOSEPH ALEXANDER, NEW DELHI

PUSHED to the wall in the fight for existence, the small- and medium-scale pharmaceutical units that remain still in the fray in north India are yet to give up but barely managing to survive.

Interestingly, though dwindling in the number game, these units which remain in existence across major pharma clusters like Baddi in Himachal Pradesh and Uttarakhand have chosen to go GMP-compliant (good manufacturing practices) while imbibing a fresh spirit of fight for the general interest of the country which hugely depends on SMEs (small and medium enterprises) to stabilise and control the drug prices.

However, the larger picture in north India, which once was the heartland of pharma revolution of India by setting a direction for the rest of the country, remained more or less same with biggies continuing to grow and small players getting extinct under pressure from competition, especially in the non-excise-free zones.

The inertia in policy matters and lack of determined efforts on the part of the government, that marked the pharma sector across the country last year, hit the northern belt badly as it always looked for some life-saving dose from the authorities.

Fighting spirit

Riding on a three-year project by the World Bank and the UK Department for International Development, in association with the Small Industries Development Bank of India (SIDBI), Uttarakhand's 200-odd pharmaceutical companies, mostly SMEs, are making an intense effort to get competitive.

Under the project, the units especially the SMEs will implement GMP and impart training in information and communication technology (ICT), energy-saving and skill enhancement. APITCO, a Hyderabad-based technical consultancy organisation, was the facilitator. Haridwar, Roorkee, Dehradun and Rudrapur are the main hubs of pharmaceutical firms in Uttarakhand.

"Nearly 20 companies have already become WHO-GMP-certified and I am sure this cluster is going to be the country's best export hub," states Pankaj Gupta, president, Industries Association of Uttarakhand. The Dehradun pharma cluster is one of the leading ones in India. There are 12 large enterprises and 182 SMEs, with an investment of Rs 1,100 crore and a turnover of Rs 2,500 crore. These firms export pharma products worth Rs 250 crore a year and employ 8,000 persons.

Likewise, Baddi and some other pockets in Himachal with over 300 units, are implementing Schedule M in a bid to stay healthy in the fight for existence. Though no concrete assistance has come in from the government, the units are making use of the available resources to stay fit and go GMP-compliant, according to some industry leaders from the state.

Wider picture

Notwithstanding the resolve by the SMEs, the general picture of north Indian pharma sector remained as grim as before with contradictions, complexities and widening gap between the leaders and the rest in the pack. The small-scale players continue to run out of steam in the battle for survival while big players grow from strength to strength. The biggies call it as a phase of consolidation and standardisation of the industry for the better, especially to compete with the best in the world.

But the small units term it as degeneration of pharma industry and detrimental not for just the entrepreneurs, but for the entire population of India, as it would jack up prices of drugs. With little support in concrete terms from the authorities and flattened by increasing regulatory burdens, the small players are on the path of extinction in the northern region and this trend has already hit more regions elsewhere.

The only steam they have in the fight is the extension of tax holiday for some more time in states like HP and Uttarakhand.

However, the story remained further grim for those outside the excise-free zones. The shrinking sector continued to grapple with multiple challenges and still sit waiting for some concrete measures from the government to save them, though many schemes are being proposed.

Migrating outside

But the north India, compared to other regions, is not a major force to reckon with. Over the years, many have migrated to the excise-free zones while those outside the zones bowed out due to growing pressure.

"The challenges we face continue to be same in a grimmer manner. More than the fight from the big pharma companies, what is depressing is the lethargic attitude of the government in helping the SMEs with some proactive measures. North Indian pharma has already lost its sheen compared to other regions. But, we are not ready to quit," said a senior leader from the industry.

With the introduction of Schedule M, hundreds of SMEs were closed down. The government has been completely indifferent in tackling the issues of small pharma. The Pharma Technological Upgradation Fund (PTUF) which was supposed to provide financial support for SMEs to make their units Schedule M-compliant is still stuck up in the pipeline. It is a well accepted fact that making pharma units GMP/Schedule M-compliant requires a lot of financial investment. However the Indian government has not been proactive in rendering any financial support to SMEs in this regard. The Najma Heptulla Committee which studied this issue very closely is expected to submit its report very soon, according to an industry leader.

The small-scale industry wants the government to hold a comprehensive study to ascertain the current status of the industry in north India and extend some concrete steps to help them out. "Excise duty is better deterrent for price control. Taxation disparities created by tax holidays not to be supported. Since the government is ending up with huge loss due to CST, GST is more beneficial for the government as well as patients," according to them.

(Courtesy : Ingredients South Asia, January16-31 2011, Vol.5 Issue 8)

"THE KICK OFFS"

Performance Lifts FMCGs to New Heights

R. Yegya Narayanan

Shining MNC indicates purchasing power of people

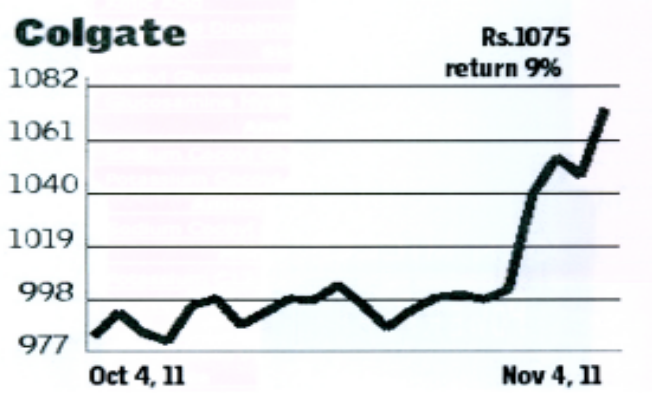
WHILE the market was basking in the glory of FMCG major Hindustan Unilever Ltd (HUL) stock hitting the year's high in the bourses after its stellar Q2 results early this week, two other FMCG giants have quietly joined HUL in the FMCG summit with their stocks hitting 52-week high in the exchanges.

Incidentally, the two other FMCG companies are also MNCs, reinforcing the unshakable hold MNCs have in the FMCG space. It is also interesting to note that while two of them — HUL and Colgate Palmolive — share some common product presence in the oral health care segment, the other FMCG, GSK Consumer Health Care, was in an entirely different product segment, which probably reflects the growing purchasing power and aspiration levels of the people across the country.

ROBUST RESULTS

HUL, which surprised the markets with its robust Q2 numbers, saw its share price hit a high of Rs 378.15 after the company announced that its Q2 net profit saw a 22 per cent jump and net sales went up by 18 per cent.

Subsequently on November 1, the stock hit a fresh 52-week high of Rs 393.20.



It has seen some selling pressure since then and the scrip closed at Rs 378.85 on the BSE. Its 52-week low price in the BSE is Rs 264.50 on March 21 this year.

COLGATE PALMOLIVE

Colgate Palmolive India's shares too touched a high of Rs 1,084.30 on the BSE.

Though it later declined marginally to close at Rs 1,075.90, the stock had gained Rs 26.85 or 2.56 per cent.

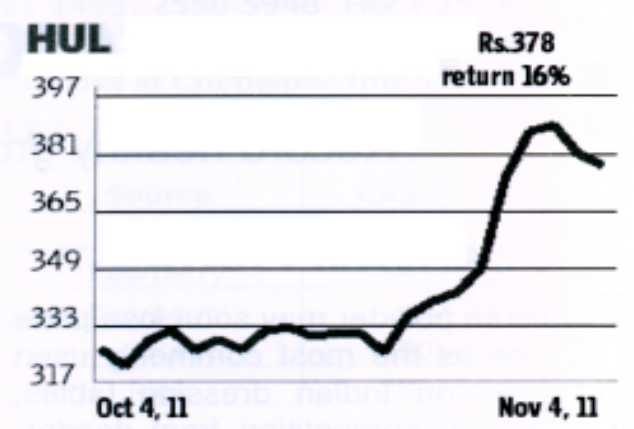
The stock has gained nearly 35 per cent since hitting its 52-week low of Rs 783.20 on February 2, on the BSE.

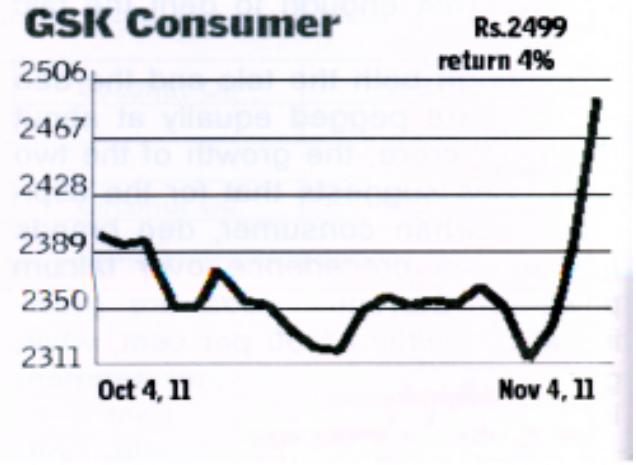
Despite its product range not being so wide as its arch MNC rival HUL and is mostly limited to oral hygiene (tooth paste, mouth wash etc), that the stock has been appreciating indicated the dominant position it enjoyed in its product segment.

GSK CONSUMER HEALTHCARE

GlaxoSmithKline Consumer Healthcare also raced to its 52-week high on the BSE, hitting a high of Rs 2,554. This stock also yielded ground at close, ending the day at Rs 2,499.30. But the day's gain was a massive Rs 104.35 or 4.36 per-cent.

These two stocks like HUL also seem to be riding on the back of their excellent Q2 results. While GSK Consumer Healthcare posted a near Rs 100-crore jump in Q2 sales at Rs 720.07 crore (Rs 612.58 crore), its net profit saw a near-20 per cent jump at Rs 103.03 crore (Rs 78.57 crore). In





its arsenal are nutritional products that are market leaders such as Horlicks, Boost, Viva and Maltova and OTC products like Crocin, Eno and lodex.

Colgate, in Q2 of this year, saw a 19 per cent increase in net sales to Rs 657.2 crore (Rs 551.77 crore) but the net profit at Rs 99.68 crore was marginally less than last year's corresponding quarter's net profit of Rs 100.30 crore.

What has worked wonders for the shareholders of Colgate Palmolive (India) was its decision in 2007 to reduce its share capital by refunding Rs122.40 crore to its shareholders and cutting the face value of its shares from Rs 10 toRel.

This has brought down the size of its equity capital to a mere Rs 13.60 crore, boosting in turn the EPS.

(Courtesy : Soaps, Detergents & Toiletries Review, December, 2011)

"SAFFRON FLYING HIGH"

Kashmir Govt offers Rs.8.7 crore incentive to saffron farmers

OUR BUREAU, NEW DELHI

THE Government of Jammu and Kashmir has provided incentives to hundreds of farmers in the Kashmir Valley to pursue saffron cultivation and to ensure that more farmers to growing saffron.

Cheques worth Rs. 25,000 were distributed to several hundred saffron-growers owning one kanal of land to help take care of labour charges and other expenditure involved in saffron cultivation by the state's agriculture minister Ghulam Hassan mir during a function held in the saffron hub of Pampore in Pulwama district recently.

In a drive launched by the agriculture department under the National Saffron Mission, new corms were distributed among the growers and the sowing of the saffron was done under the supervision of agriculture experts.

"They were told to sow eight gram corms according to scientific methods, even though they had never sowed such corms earlier, as feels that this new technology is useful for him," said Mir.

He said a total of Rs. 8.7 crore would be distributed among 1,872 farmers in the state.

Stalls set up by different comapnies also sold improved seeds and latest agricultural equipments at the event that attracted many villagers. They hailed the government's initiative.

" We will benefit from the steps taken by the government under the saffron mission and we hope that the youngsters will take up this work," said Manzoor Wani, a saffron -grower.

The state government also plans to establish spice park under the mission at an estimated cost of Rs. 22 crore in which growers will have quality control and e-marketing facilities at their doorstep.

The Rs. 376 crore saffron mission was flagged off by the Central government in 2010 to support the saffron crop. It aims to increase saffron production and sales. The mission offers several incentives and benefits to saffron farmers to increase saffron productivity and quality.

(Courtesy : Ingredients South Asia, January16-31 2011, Vol.5 Issue 8)

"THE POETIC SOOTH SAYER"

ISDC 2011 - A GRAND SUCCESS!

Inaugural speech by MR NADIR B GODREJ

specially written in verses delivered at Nehru Centre, on 11th December 2011

ISDC is here to stay.
But this time it's in Bombay.
(No matter how much I try,
I rarely seem to say Mumbai).
For me it's nice to stay at home
But most of us love to roam
And many of you will agree
The real home of ISDC
Should be Goa where it started.
And though this year, we may
have parted,
The consensus surely seems to be
That Goa is more leisurely.
It is the place for relaxation.
After a day of deliberation
We can unwind on the beach
While seeing dolphins roll
and breach,
Eat spicy seafood on the sand
And listen to a lively band
As a daring fire eater prances
And top it off with lively dances.
Now with your whetted appetite
I should say that we well might
Let Goa again be the site
For our next ISDC.
Do clap your hands if you agree.
The Indian news is full of gloom
But I don't think it should spell doom.
The Rupee has quite quickly sunk.
And businesses are in a funk.
The RBI keeps raising rates
The FM confidently states
That soon, inflation will abate.
How long will we have to wait?
Capital formation's very slow
And industrial growth is very low.
Parliament's more out than in
The government's in quite a spin.
But services have withstood
And rural India has it good.
And that is why we still see
Such good growth in HPC.
8% for detergent's fair
But double that for skin and hair.
This is quite a steady trend
And it's unlikely soon to end.
Now each Chinese consumes
much more
But that's no reason to be sore.
Where they lead we always follow,
An argument that's hard to swallow
In this despondent time.
But reason, as well as rhyme
Indicate that India will grow
This is something that we know.
The demographic dividend
Will help maintain this steady trend.
China now is past its peak
And on this count things are bleak.
China now is quickly aging
And economists are presaging
Much slower growth in coming years.
In India we have no such fears.
In India very few are old
As the young decline, we're told,
The working age will dominate
The growth rate will accelerate.
But we won't argue who'll do finer
Whether it's India or it's China.
The Asian region as a whole
For everyone will be the goal.
With high levels of aspiration
And half the world's population
And most economies with
good traction
This will be the place of action.
In India the first to come was Lever
Indeed an early believer.
But since then, year after year,
More and more are coming here.
But now Indian companies are
on the go
And so we see a reverse flow
Of Indian firms in HPC,
Bravely putting out to sea.
This globalizing trend holds true
For all the suppliers too.
The supplier base has much to offer

But now perhaps they need to proffer
New chemicals in every field.
I hope the deliberations yield
New ways in which to proceed
And make the industry succeed.
The industry wants to be green.
But of course this has to be seen
Not just within the organization.
In most people's quick estimation
This is necessary but not sufficient.
Our customers should be
made efficient.
If water and power are conserved
Both planet and customer are served.
With ecological packing
And vendor training and tracking
The chain will be green from
end to end
And that would be a desired trend.
And in this conference much
will be said
On how we should proceed ahead.
Now India's a centre of global action
And conference will see much
interaction.
Of course in all the conference halls,
In meeting rooms and exhibition stalls.
But we know that what really makes
A conference is the coffee breaks.
So mingle, wander, run or walk,
Argue, yell or gently talk.
But get to meet every one
And years of work will get done.
And after the next two days
I'm sure we'll find many ways
To improve our industry.
I really hope that we can see
Our standards, all harmonized,
All our capacities right sized.
Our products will, I'm sure be seen
As being both good and green.
Success is what I wish you all.
And when in time you hear
the call
And feel the need for rejuvenation,
About three years in our
estimation,
All our problems will abate
As once again we congregate.

(Courtesy : Ingredients South Asia,
December 16-31 2011, Vol.5 Issue6)

"SOUND OUTLOOK"

Gujarat accelerating at great speed wants a few large companies in the auto sector

THE industry is set a target and to grow at a rate to ensure the exports double in the next three years. The industry-government-end users are now in a flux to move ahead and achieve results albeit the weaknesses and threats that the industry is faced with. States like Gujarat that is accelerating at great speed wants a few large companies in the auto sector etc. that in quick setting up will provide huge employment and development of the region. Obviously the smaller units in the Chemical industry that are not doing well will not be given the same consideration it enjoyed 15 to 20 years back. It is important for the Chemical industry leaders to provide the much needed inspiration and inputs for the overall growth of their own units and also for those that it may have to compete, complement, connect and collaborate.

(Courtesy : CHEMEXCILLENSE, Vol.6,
January 2012).

Technology

"BE SURE"

Validation of automated systems and improve the system

DEEPAK MAKHIJANI

FDA regulatory compliance is a mission-critical requirement. If the PDA finds a manufacturer to be non-compliant to or in violation of PDA rules, the consequences can be severe with warning letters, mandatory product recalls, temporary shutdowns, criminal penalties and fines depending on the severity of the violation. These penalties imposed by PDA could seriously dent the manufacturer's brand image and at times could even cripple the manufacturer financially.

IF a manufacturing process is highly automated, the basic process control system will play an important role in obtaining quality certification for the process. Every organisation, which utilises such systems, has a support structure of personnel and procedures to maintain and modify these systems, albeit in many cases this infrastructure may be lacking in documentation, producing a system that can be insecure and vulnerable for a process seeking quality certification. Whether trying to achieve certification or improve the integrity and security of this vital piece of operating equipment, one should take this opportunity to develop a methodology that not only documents the system's logic, but also documents the personnel and procedures that support the system, as well. Accurate documentation is very vital.

This documentation provides guidance to persons, who in fulfillment in a statute or another part of PDA's regulations to maintain records or submit designated information electronically and, as result, have become subject to part 11. Part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in agency regulations. Part 11 also applies to electronic records submitted to the agency under the Federal Food, Drug and Cosmetic Act and Public Health Act (the PHS Act), even if such records are not specifically identified in agency regulations. The underlying requirements set forth in the Act, PHS Act and FDA regulations (other than part 11) are referred to in this guidance document as predicate rules.

21 CFR part 11 demands

• A common enterprise wide II system to provide visibility into the processes and per-. formance metrics at various operational and management levels

• Enterprise solution also should immutably be linked to all components of manufacturing (including equipment, raw materials and inventories) analytical laboratories as well for the distribution - purview of USFDA for capturing nonconformance out of spec production, tracking and managing the corrective action process

• IT systems have to have audit trail for ensuring successful implementation of recommendations

• IT system should also improve efficiency and speed in operations as well as regulatory process.

Points need to be understood

• Any IT solution not linked to enterprise level is not going to serve the purpose

• Any IT solution not linked to production, equipment, operators is going to fail the compliance test

• Any IT solution at enterprise level, linking to

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facilities but not having audit trail would also fail (corollary: if an organisation does employ electronic records and signatures but fails to comply with the systems requirements, the USFDA would cite the firm for violating the underlying regulation - 21 CFR 211.198(b)). As a outgrowth of its current Good Manufacturing Practice (cGMP) initiative for human and animal drugs and biologies, FDA is re-examining part 11 as it applies to all FDA regulated products. We anticipate initiating rulemaking to change part 11 as a result of this re-examination. FDA issued final part 11 regulations, which provide criteria for acceptance by FDA under certain circumstances, of electronic records, e-signatures and handwritten signatures executed to e-records as equivalent to paper records and handwritten signatures executed on paper. These rules that apply to all PDA program areas, were intended to permit the widest possible use of IT compatible with PDA's responsibility.

Definition of part 11 records

PDA considers part 11 to be applicable to the following records or signatures in electronic format (part 11 records or signatures)-

• Records that are required to be maintained under predicate rule requirements, and that are maintained in e-format in place of paper format. Also, records (and any associated signatures) that are not required to be retained under predicate rules, but that are nonetheless maintained in e-format, are not part 11 records.

• Records required to be maintained under predicate rules, that are maintained in e-format in addition to paper format, and that are relied on to perform regulated activities. In some cases, actual business practices may dictate whether you use a computer to generate a paper printout of the e-records, but you however rely on the e-record to perform regulated activities, the agency may consider to be using the e-record instead of paper record. That is, the agency may take your business practices into account in determining whether part 11 applies.

Thus, we suggest that, for each record required to be maintained under predicate rules, you decide in advance if you plan to rely on the e-record or paper record to do regulated activities. We say that you document this decision (e.g. in a Standard Operating Procedure), or a specification document.

• Records submitted to PDA under predicate rules (even if such records are not specifically identified in agency regulations) in e-format (assuming the records have been identified in docket number 92S-0251 as the types of submissions the agency accepts in e-format). But, a record, not itself submitted, but is used in generating submission, is not a part 11 record unless it's otherwise needed to be maintained under a predicate rule and it's kept in e-format. • E-signatures that are intended to be the equivalent of handwritten signatures, initials and other general signings required by predicate rules. Part 11 signatures include e-signa-tures that are used, for example to document the fact that certain events or actions occurred in accordance with the predicate rule (e.g. approved, reviewed and verified).

Approach to compliance to part 11

PDA holds that decision to validate computerised systems, and the extent of the validation, take into account the impact the systems have on your ability to meet predicate rule requirements. One should also consider the impact those systems might have on the accuracy, reliability, integrity, availability and authenticity of needed records and signatures. Even if there's no predicate rule requirement to validate a system, in few cases it may be important to validate the system.

The agency intends to exercise enforcement discretion regarding specific part 11 requirements related to computer generated, time stamped audit trails. Persons must still comply with all applicable predicate rule requirements related top documentation of, for example, date, time or sequencing of events, as well as any requirements for ensuring that changes to records do not obscure previous entries.

Even if there are no predicate rule requirements to document, for example, date, time or sequence of events in a particular instance, it may nonetheless be important to have audit trails or other physical, logical or procedural security measures in place to ensure the trustworthiness and reliability of the records. We recommend that you base your decision on whether to apply audit trails, or other appropriate measures, on the need to

comply with predicate rule requirements, a justified and documented risk assessment, and a determination of the potential effect on product quality and safety and record integrity. We suggest that you apply appropriate controls based on such an assessment. Audit trails can be particularly appropriate when users are expected to create, modify or delete regulated records during normal operation.

The objective of audit trail

• To check application commitments and to verify authenticity and accuracy of data contained in submissions

• To assure that the product development was done justifying process attributes

• To ensure development facilities comply with GMP standards

• To ensure manufacturing facilities comply with GMP standards

• To ensure related controlled facilities (like water, clean steam, HVAC, gases, raw materials delivery, vendors etc.) comply with GMP standards

Pharma companies can get the audit by keeping records as below

Option A: Hard copies of data and documents as is the current practice

Option B: Hybrid system of converting data into documents and then using DMS. DMS with the features like - Preparation, Approval, Control, Amendment, Withdrawal, Distribution and Archival.

Option C: Total IT based audit system, where software needed are - ERP/SAP/ CAMMS with audit trail functionality, DMS and special software modules for process validation and analytical testing validation.

'Option A' needs one to keep log reports over a considerably long time period, and is cumbersome to adhere for validation. 'Option B' is an improvement, but, there is considerable time and effort required in preparation to archival of the records. 'Option C' is the latest and the most sophisticated solution.

The process validation of the system is documented based on the process parameters that are provided by the owner. However, templates provided by the software vendor aid in asset qualification and validation. The 21 CFR Part 11 Validation Plan includes compliance approach, organisation, system validation, risk evaluation, system gap analysis and remediation. The software package supports SOP's (Standard Operating Procedure) which needs to be worked as per compliance approach by the client. The detailed module covers internal as well as external expertise levels validation. The system validation covers various system validation related to Process and Analytical know how and associated risks. In Gap Analysis, unaddressed requirements and program/module/interface - integrity documentation is tested. Subsequently, the Ivel of risk evaluated is mitigated based on the client's requirements.

The Agency intends to exercise enforcement discretion with regard to specific part 11 requirements for generating copies of records and any corresponding requirement. You should provide an investigator with reasonable and useful access to records during an inspection. All records held by you are subject to inspection in accordance with predicate rules.

FDA recommends that you supply copies of electronic records by - producing copies of records held in common portable formats when records are maintained in these formats, and using established automated conversion or export methods, where available, to make copies in a more common format (examples of such formats in-

clude, but are not limited to, PDF, XML OR SGML).

In each case, we recommend that the copying process used produces copies that preserve the content and meaning of the record. If you have the ability to search, sort or trend part 11 records, copies given to the agency should provide the same capability if it is reasonable and technically feasible. You should allow inspection, review and copying of records in a human readable form, at your site using your hardware and following your hardware and following your established procedures and techniques for accessing records.

FDA also intends to exercise enforcement discretion with regard to the part 11 requirements for the protection of records to enable their accurate and ready retrieval throughout the records retention period, and any corresponding requirement. Persons must still comply with all applicable predicate rule requirements for record retention and availability. We suggest that your decision on how to maintain records must be based on predicate rule requirements, and that you base your decision on a justified and documented risk assessment and a determination of the value of records over time.

FDA does not intend to object if you decide to archive required records in electronic format to nonelectronic media such as microfilm, microfiche, and paper or standard electronic file format (examples of such formats include, but are not limited to, PDF, XML or SGML). Persons must still comply with all predicate rule requirements and the records themselves, and any copies of the required records should preserve the meaning and content.

As long as predicate rule requirements are fully satisfied and the content and meaning of the records are preserved and archived, you can delete the electronic version of the records. In addition, paper and electronic record and signature components can co-exist (i.e. hybrid situation) as long as predicate rule requirements are met and the content and meaning of those records are preserved.

Application and benefits

The compliance to 21 CFR part 11 offers several benefits, such as - cost benefits-by aiding the production of systems that are fit for purpose, meet user and business requirements, and have acceptable operation and maintenance costs; better visibility of projects to ensure delivery on time, on budget, and to agreed quality standards; increased understanding of the subject and introduction of a common language and terminology; reductions in the cost and time taken to achieve compliant systems; improved compliance with regulatory expectation by defining a common and comprehensive life cycle model and clarification of the division of responsibility between user and supplier.

As an example, consider the application of BPCS (Batch Process Control System) in one of the plants of Glaxo SmithKline. The size of the automation system is approximated at 4500 I/O, 40 batch operations of varying sizes, over 800 programs and approximately 580 process and safety interlocked measurements. With the exception of three small annuciator panels, the BPCS provides the entire operator interface for the various automation systems. The majority of the initial programming was performed by the engineering firm contracted to provide the detail design and construction of the three units. As a result of this contract, various electronic files of software documentation were provided to plant personnel upon startup. The plant automation support group decided to maintain these documents as they were an invaluable tool for troubleshooting and optimising such a vast amount of software. Because of the closely scheduled start-ups, this period proved to be very active for the software of all three units. Therefore, it was desirous to have a method to document what modifications had been requested, and which requests had been completed for any given unit since the last shift cycle. Two simple spreadsheets were quickly developed to request modifications as needed and to post, daily, the last 30 modifications completed, sorted by unit. Unknown to the DCS support group at the time, all of these documents would become the infrastructure of the DCS Quality System.

Development of the ‘e-records’ from DCS itself continues to evolve and improve, and has provided countless opportunities to support the work of the DCS group, which maintains it. The DCS Quality Control Log Sheet documents every modification made by date, item modified (i.e.

tag, program, graphic), short description and initials of the person making the modification. This historical value of this database is priceless as it is referred to on a regular basis: The log sheet is an invaluable tool for troubleshooting the performance history of a specific loop or program. Queries are made regularly to determine the number of modifications performed concerning a specific tag or program, when they're made, and what modifications're made. The log sheet entry identifies the original process automation request in the quality record filing system by date - if more detail is needed concerning the modifications made.

Start ups and shutdowns of BPCS and SIS equipment are rare enough that even experienced DCS support personnel need reminders of the most efficient method to minimise the downtime of the process units.

The BPCS/SIS Start-up Checklist has been used on many occasions, such as unexpected power failures, post-software upgrades check-outs, and planned maintenance outages. The checklist continuously improves as more items are added - which further ensure the systems are operating properly after any interruption. The 'shut-down procedure' has also proven beneficial because it documents a complete system shutdown, as well as the most effective partial shutdown of the automation equipment. In the event of an unplanned power outage, the BPCS and SIS are operating from limited UPS battery sources. A partial shutdown procedure documents the most effective way to conserve energy without losing the process controlling components and providing minimal operator interfaces. On several occasions, this strategy has made the difference between no shutdown at all and a two-hour start-up of the BPCS equipment at a time when this equipment is urgently needed. Previous annual releases of some documents are kept on file as quality records for some specified number of years. An example of such a document is the units' interlock matrices. The interlock systems, both process and safety, are documented using a cause/effect matrix methodology. The previous five (+) annual releases of these matrices are available on file, and have been used on several occasions to discuss the history and evolution of the interlock system. Thus, the efforts to validate the automation system enable one to maintain and improve the system have been - and are genuine investments in time and patience. However, the documented knowledge-base which has grown as a result of this commitment over the last few years has been well worth these investments for those of us who currently support and operate the equipment and for those who will follow us in the future. •

(Courtesy : Process India No. 6, December 2011, Volume I).

"KEEP GOOD"

Managing product's shelf life

Every year chemical companies endure disposal and destruction cost of outdated materials amounting to millions of Euros. Shorter the shelf life higher is the cost. By means of some simple process optimisation measures costs can be reduced many times over.

COMPANIES, which do not organise their operational planning taking into consideration the limited shelf life of their products, waste substantial process and material costs.

Source; OPC-Otganisations - 6 Projekt Consulting GmbH.

Especially, auditors pay close attention to the fact that, the time frame between storage of material after production completion and delivery to the customer, does not exceed the official shelf life. In tact, even the additional time of storage at the customer needs to be considered. "Companies, which do not organise their operational planning taking into consideration the limited shelf life

Companies,which do not organise their operational planning taking into consideration the limited shelf life of their products, waste substantial process and material costs.

of their products, waste substantial process and material costs," explains Omar N. Farhat, Managing Director of the Dusseldorf based Management Consultancy OPC GmbH. The expert for process optimisation in the chemical industry mentions an example based on a producer of resins and varnishes, who was looking for means of how to reduce his destruction and disposal costs. Due to these inefficiencies, the company had to endure costs of half a million Euros annually. The average shelf life of finished goods was between three to six months.

Manufacturing strategy

Initially the OPC experts challenged the present storage strategy and suggested to shift the focus of storage from finished goods to the intermediate and raw material side. The majority of material was subsequently placed in intermediate tanks. This type of storage approach assures longer shelf life of products, since the finished goods are only filled and completed for specific customer orders. Based on this shift of strategy, finished goods storage was substantially reduced.

Minimum order quantity

Minimum order quantities were defined for products that were not stored as intermediates, and which had irregular sales requirements. This way an optimised balance between production batch sizes and sales volume was achieved.

Packaging

The analysis of the packaging variety indicated that 10 out of 50 packing types accounted for 96 per cent of the sales volume. Through systematic consolidation based on technical and logistical needs, the packaging variety was reduced to 18 packaging types. Thereby, enabling the company to reduce the level of repackaging, and further increase product shelf life.

Chemical formulation

The R&D department was made responsible for analysing formulations with a short shelf life and to find potential correlations. The findings showed that, a number of products were filled and completed, before the end of the actual chemical reaction time. The resulting secondary reaction inversely affected the stability of the products. Through the introduction of new manufacturing guidelines, the overall shelf life was further improved.

These measures towards process optimisation accounted for an overall reduction of finished goods destruction and disposal of 65 per cent - whilst enabling the reduction of finished goods stock by 15 per cent.

(Courtesy : Process India No. 6, December 2011, Volume I).

"SUSTAINABLE"

Steps for sustainable development

Uniform standards in environmental management is must for continuous sustainable development

It is possible to do good business in the chemical industry, while protecting the interests of the community and the environment. In order to achieve sustainable development, it is quintessential for companies to invest in technology and innovation.

DR. JOERG STRASSBURGER

CONDUCTING business in a profitable manner, while keeping in view the interests of the society and minimising adverse impact on the environment is what we define as sustainable development. In today's age of rapid urbanisation and industrialisation - wherein we are consuming available natural resources at an alarming rate, sustainable development is certainly the need of the hour for the society at large. However, businesses and governments need to play a more active role in achieving this target. Irrespective of the size of the organisation, nature of business and geography, there is an incumbent need for everyone to take up this challenge of developing ways to meet the future demands, while maintaining the necessary balance in the environment.

Issues like scarcity of clean water and unexpected climatic changes across the globe are connected to the well-being of every individual on this planet, and hence these problems can only be dealt with a collective effort, driven by a mass consciousness.

Now that we understand why sustainable development is essential, there are few guestions before us. How do we achieve this balance on an ongoing basis? Who all or what will be required for an organisation to carry on their efforts for sustainable development? Which is the optimal methodology that offers minimum risk yet opens a path of constant innovation that is necessary to take this forward?

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We can understand this better with an example from the chemical industry. Every product that is manufactured must be analysed for the carbon footprint it lends, or emission of any other potentially hazardous gases both during its production and application. Industries which consume these chemicals to make their products must also evaluate the environmental impact of the final product. We must also look at the extent of consumption of the product in the society. The more widespread the consumption, the higher the risk, hence the evaluation should be more stringent.

At the same time, the cost of the product and the calculation of risk assessment should be borne in mind. If the overall cost is higher than the sales it meets, then the process will not be sustainable. So, businesses will have to evolve a methodology in which this process is sustainable in the first place. Organisations, which do not have scale, hence are unable to focus on areas like risk assessment and environmental impact of products. Nevertheless, it is important to invest in technology, people and processes in order to facilitate continuous research and development. Without this investment, it is difficult for organisations to identify areas of improvement both in terms of quality and envirari-mental impact of the product. In the context of the chemical industry, safety is a very important parameter as well. Safety standards maintained during the life cycle of the product, during product handling, packaging and transport is also vital.

Secondly, for continuous sustainable development, there has to be uniform standards in environmental management across the globe and every organisation should be equipped with tools

to measure and assess the environmental performance and risks at its areas of operation. This should be audited regularly by the organisations themselves and then reviewed by a body of global relevance.

These guidelines should be based on international industry practices and standards for environmental management and sustainable resource consumption. The guidelines must ensure that these standards are maintained across the supply chain of the business process. Suppliers, vendors, employees and other stakeholders who impact the business should all be informed and trained to abide by the same standards. These standards should meet all legal requirements in the area of operation, and should ensure compliance with statutory and environmental regulatory requirements. Overall, organisations should strive to reduce consumption of renewable resources, develop productive ways of reusing resources and recycling the used or waste resources. Health, Safety, Quality and Environment should form the key pillars of sustainable development.

This would gradually raise the bar for standards on protection of environment, utilisation of renewable resources, and most importantly it would foster innovation amongst the community to come up with safer and better ways of pursuing their operations.

Thirdly, in order to achieve sustainable development, it is quintessential for companies to invest in technology and innovation. Adoption of newer technologies and innovation in processes and practices would provide us the necessary tools to achieve higher standards of safety, quality and environmental protection. For the chemical industry, it is even more critical to innovate in order to make products that are high on quality, which have been developed by sustainable means and meet the future needs of the customer.

In summary, there is research and development involved in developing'new products -which are higher in performance and safer for the environment and the people, in creating more resource efficient production techniques and processes, in new manufacturing technology, in assessing the impact on environment and developing new ways of minimising that impact. Overall, Research and Development (R&D) is a specialised function that

Saltigo is capable of performing syntheses at many different scales - using laboratory glass equipment as well as large scale production units, among them reactors up to a volume of many cubic metres made of steel, glass-lined steel and special alloys.

calls for allocated resources in terms of financial investment, infrastructure like laboratories etc., and qualified people (technicians, scientists, environment engineers). Ideally this should be a centralised function at the core of the organisation, where every business unit and every employee can participate in a consistent manner. New ideas for resource optimisation can come from anywhere within the organisation.

Constant assessment, measurement, analysis of impact and controlling the outcome entails sustainable development. Not just the organisation but the entire supply chain dealing with the organisation must be geared up to meet the enhanced standards of sustainable development, starting from its own employees to suppliers and vendors, customers, end users among others.

At Lanxess; we believe that it is possible to do good business in the chemical industry, while protecting the interests of the community and the environment. All risks related to the health and safety of all stakeholders and environmental protection can be minimised to a great extent by adopting the following measures:

• Comply with applicable legal requirements and other requirements that relate to plant and process safety, occupational health and safety hazards and environmental protection.

• Continuously analyse and improve practices and processes to reduce their risk and adverse impacts on the health of the people and the environment.

• Encourage employees to actively participate in hazard identification, risk assessments, incident investigation and change management that may affect plant and process safety, occupational health and safety hazards and environmental protection.

Provide appropriate information and training on the plant and processes, work related safety, and the need and means of environmental protection to everyone working at the site.

(Courtesy : Process India No. 6, December 2011, Volume I).

"TIME TO RESPOND"

Sustainable technology beckons

A balanced focus between economy and ecology is essential

India has successfully positioned itself on the map of global chemical industry - being (volume wise) the sixth largest in the world and the third largest in Asia. However, the count'ry is yet to completely align itself with the new paradigm of chemical manufacturing. It is high time that our chemical industry unitedly put 'sustainability' at the top of its agenda.

PRASANTA KUMAR CHATTERJEE

Butyl rubber is widely used in automobile tires. Lanxess is working with US-based Gevo - a renewable chemicals and advanced biofuels company - to develop isobutene (used to make butyl rubber) from renewable and biological resources such as com. Also, it has plans to make bio-based ethylene from sugarcane. Ethylene is widely used in industry as a precursor and ends up in products such as insulated cable and footwear. Mitsui has entered into a definitive agreement with Dow Chemical Company to acquire a 50 per cent stake in Dow's cent per cent subsidiary Santa Vitoria Aciicar e Alcool, and form a joint venture targeting at production of biopolymers made from renewable, sugar-cane-derived ethanol in Brazil. Mitsui is focusing on the diversification of chemical feeds from not only conventional fossil fuels like crude oil and natural gas - but also from unconventional resources.

A plethora of such instances is available in today's chemical manufacturing world. The megatrend is towards becoming green - developing green products and manufacturing them through green engineering processes, in other words embracing 'green chemistry' and 'green engineering.'

A recent research, conducted by Pike Research, has predicted that the use of 'green chemistry' in a range of industrial activities will grow rapidly in the coming decade, offering significant direct cost savings as well as indirect savings in the form of avoiding liability for environmental and social impacts. Also, according to the cleantech market intelligence firm, the total amount saved, will reach $65.5 billion by 2020.

Green chemistry and engineering

According to US Environmental Protection Agency's (US EPA's) definition, 'green chemistry' is the design of chemical products and processes that reduce both the use and generation of chemicals that are hazardous to the environment and people's health. The term 'green chemistry' was first coined by Prof. Paul Anastas of US Environmental Protection Agency (EPA) in 1991. The root of today's 'green manufacturing' underlies in the basic 12 principles later laid down by him and his associate John C. Warner.

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Prof. Bruce H. Lipshutz at UC Santa Barbara (Photo details in page 47)

Prof. Dr. Anja-Verena Mudring at the RUB (Photo details in page 47)

Jim Hedrick, a researcher at IBM's Research facility (Photo details in page 47)

Later in 2003, US EPA defined 'green engineering' as the design, commercialisation and use of processes and products, which are feasible and economical while minimising generation of pollution at the source and risk to human health and the environment. According to EPA, 'green engineering' embraces the concept that decisions to protect human health and the environment can have the greatest impact and cost effectiveness when applied early to the design and development phase of a process or product.

(Courtesy : Process India No. 6, December 2011, Volume I).

"WATER WATER EVERYWHERE"

Sustainable water management

A knowledge sharing platform for the Indian water community

The fifth World Aqua Congress brought in a multidimensional exposure on developing and implementing innovative management approaches, and how to cope with the increasing complexity and uncertainties.

ORGANISED by Aqua Foundation, the fifth World Aqua Congress gathered people from various walks of water management under one roof in New Delhi recently. The congress, consisting of a symposium and an exhibition, concluded with some vital recommendations that India is supposed to meticulously focus on to ensure sustainable water management in the coming days.

Considering this as a key environmental challenge of the 21s' century, and as climate change is a vital issue - development and implementation of innovative management approaches in the field are absolutely essential. Also, to cope with the rising complexity and uncertainties, India needs the approach of Adaptive and Integrated H20 Management.

Use of modeling and simulations has to increase to predict the behaviours of floods and ground water levels. Also, they need to be updated on newer available data on regular basis. There should be efforts towards data sharing at all levels.

Pollution control boards should consider initiating water treatment by third party or an alternative mechanism, charging pollution creating industries for the same. Also, as groundwater contamination and deterioration of water qual-

(LtoR) Dr. D. K. Chadha, Ex-Chairman CGWA; V. H. Pala, Minister of Water Resources & Minority Affairs (GDI); S. Dhabai, Chief Functionary of CROC; and S. Sethi, MD, Subhash Projects and Marketing

Visitors are obtaining information about water managing solutions from exhibitors.

Vincent H. Pala is giving award to Shrikant S. Desai, DGM - Admin Services, BP.

A glimpse of the event on 'Climate change & implications for water management'

ity is a big concern today, corrective steps are required immediately.

Development of human resources (capacity building) for water resource development is urgently required. Extensive training to water professionals need to be imparted on for this purpose on continuous basis.

Region-specific clear guidelines are needed to be implemented. Model Recharge Centers can be developed at district levels to showcase and educate the type of recharge structure suitable for that area. Urban water utilities need to become more efficient and have to upgrade their infrastructure urgently. Also, modern techniques of drip irrigation, sprinklers etc., need to be deployed in agriculture, which is the biggest user of fresh water resources.

(Courtesy : Process India No. 6, December 2011, Volume I).

"HELP YOURSELF"

AYURVEDA FOR BETTERMENT OF HUMAN LIFE

AYURVEDA. the science of life, prevention and longevity is the oldest and most holistic medical system on the planet today. Before the advent of writing, the ancient wisdom of this healing system was a part of the spiritual tradition of the Sanatana Dharma, practised in India more than S.OOOyears ago. Now there is a renewed interest in Ayurveda and other herbal medicines all the world over partly due to the side-effects of modern medicines as well as a growing interest in going back to nature, which is the Zeitgeist of the 21 st century.

Hence the demand for traditional Indian medicines - Ayurveda, Siddha, Unani and other herbal products — has increased tremendously in India and the world over now. The world herbal market is estimated to be $62 billion out of which the share of China is $ 19 billion and that of India is only $one billion. There are around 10,000 ASU drugs manufacturing units in the country at present. With the Indian system of medicines getting increased attention from world over, the Department of Ayush is pushing the idea of setting up a Central Drug Controller for Ayush Drugs separately for ensuring Quality of drugs in the sector. The department has already forwarded a proposal in this regard to the Planning Commission and inclusion in the final Plan for the I 2th Plan period. However, according to the 38th Report of the Public Accounts Committee (2006-07), the share of Ayush in the total health plan at the Central level has been only two per cent in spite of the policy pronouncement of raising Ayush share to 10 per cent with desig-

nated growth of five per cent in every Five-Year Plan. Inadequate allocation for Ayush has been considered by PAC the main reason for not achieving the set targets.

Accordingly, the 12th Plan allocation for Central and Centrally Sponsored Schemes is proposed to be enhanced almost by seven times and 17 times respectively, including the transfer of Rs 10,000 crore from NRHM Flexipool. This has led to total projected allocation of Rs 47535.55 crore (about 12 time-hike from I I th Plan allocation) to pave for effective implementation of projects in strategic thrust areas identified above and to step up the process of mainstreaming of Ayush.

Though with the advance in modern medicine and technology many of the bacterial communicable diseases have been brought under control, new health problems in the form of chronic diseases have emerged. There is a growing disenchantment with inability of modern medicines to provide convincing answer to chronic diseases like psychosomatic diseases, AIDS and cancer. At the same time there is a growing interest in alternative therapies and holistic healing systems as people are becoming more aware of the psychosomatic nature of diseases and the concept of wellness at the physical, mental and spiritual levels. And also the awareness that modern medical solutions are inadequate to meet the needs at all these levels.

Traditional systems like Ayurveda and Siddha Vaidya had been practised in India for centuries. Unfortunately, these practices were relegated to "alternative medicinal sciences" when Allopathy came to our shores. Most important for this shift is owing to the inability or unwillingness of these systems to subject themselves to the scrutiny of modern science, adopt modern manufacturing practices or use clinical testing based on "good clinical practices." Once these systems improve on all these fronts, traditional systems like Ayurveda could be effective, simple and cheap indigenous means of medical care^, for the betterment of humanity as a whole.

(Courtesy : Ingredients, South Asia, December 16-31, 2012, Vol. 5, Issue 6).

"AN EXCITING FOOD"

Versatile CAMELINA

The future of biofuel and much more

Eric J. Murphy

CAMELINA is the future of fuel. This is a bold statement, yet with its increasing demand as a here-and-now source of biofuel feedstock, this statement is more firmly based in reality now than ever before. Camelina-derived vegetable oil is a key emerging biofuel feedstock for next-generation biofuels and for traditional renewable biodiesel markets. The estimated demand for fuel for the aviation sector in the United States alone is 17 billion gallons (64 billion liters) per year, while the worldwide renewable diesel market (biodiesel and traditional diesel derived from vegetable oils) is more than I billion gallons per year. To meet these demands, it is critical to have a vegetable oil that can be produced economically on a large scale without any government subsidy. Camelina-derived oil meets this litmus test.

THE increased demand for camelina oil as a feedstock for biofuels is in many ways largely based on the food or fuel debate. Unlike traditional food crops that have crossed over to fuel production, such as corn, soybeans, and canola, camelina is not a food crop in the United States. In addition, its ability to produce high yields while growing on marginal lands with minimal chemical inputs means that it will not displace food crops from fertile land. An added bonus is that the resulting high-protein, high-energy meal can be used in livestock rations, thereby reducing the need for traditional food crops in these rations. In short, camelina is a sus-tainable crop for biofuels production.

Camelina: What is it?

Camelina sativa is a member of the family Brassicaceae, which includes mustards, rape, cabbage, kale, brussels sprouts, and cauliflower. Similar to these plants, camelina contains glucosinolates, but these gluco-sinolates are unique to camelina and, like all glucosinolates, offer a natural protection against consumption by insects, thereby reducing insect pressure. It is a high-yield oilseed crop that produces seeds containing approximately 40% oil, yet its meal has a high protein content of nearly 38%. Thus, it is an excellent oil producer for biofuels and provides a residual high-protein meal for use in livestock rations.

Camelina has been cultivated for more than 3,000 years in Europe, and the Romans used its oil as a lamp oil and its meal for livestock feed. The bulk of modern camelina production has been limited to Eastern Europe and Finland, where the oil is niche-marketed as a healthful edible oil. Camelina is a robust seed producer with an oil profile that contains nearly 40% a-linolenic acid (ALA, 18:3n-3) and 20% linoleic acid (LNA, 18:2n-6). (See Table 1.)

Unlike flax oil, camelina oil is stable owing to a high level of natural antioxidants and contains a more balanced amount of n-3 and n-6 fatty acids. The oil also contains fatty acids of up to 24-carbon chain length that are derived from elongation of mainly 18:ln-9, but also of 18:2n-6 and 18:3n-3, indicating a relatively robust level of elongase activity.

More than fuel: camelina meal in livestock rations

Production of large quantities of oil for biofuels results in a substantial amount of meal as a by-product. Camelina meal is an excellent source of protein and energy owing to the residual fatty acid content. Meal produced by Great Plains Oil and Exploration (GPOE; Cincinnati, Ohio, USA), has a residua] oil content of about 8% (by wt), and this oil is also rich in n-3 fatty acids. (Great Plains Oil and Exploration is a sister company to Agragen LLC, a Cincinnati-based biotechnology company for which I am chief scientific officer and executive vice president for research and development.) In laying hens, this level of residual n-3 fatty acids increases the egg n-3 fatty acid content, including

TABLE 1. Oil profile of field-grown and greenhouse-grown camelina[a]

Fatty acid	Greenhouse-grown		Field-grown
Lauric 12:0	BLD	BLD	BLD
Myristic 14:0	0.1	0.1	BLD
Palmitic 16:0	6.5	6.6	5.3
Stearic 18:0	3.1	3.0	3.0
Oleic 18:1n-9	17.9	19.2	18.7
Linoleic 18:2n-6	17.4	17.4	16.0
Linolenic 18:3n-3	27.8	25.6	38.1
Arachidic 20:0	2.2	2.1	1.4
Eicosenoic 20:1n-9	14.6	16.4	11.6
Eicosadienoic 20:2n-6	1.8	1.9	1.8
Eicosatrienoic 20:3n-3	1.5	1.3	1.3
Behenic 22:0	0.5	0.4	<1
Erucic 22:1n-9	3.6	3.7	2.5
Lignoseric 24:0	0.2	0.1	<1
Nervonic 24:1n-9	2.9	1.4	<1
Camelina parent line	Blaine Creek	GP68	Celina

[a]BLD, below limit of detection; <1% indicates trace fatty acids; all values represent mole%. Note: Other field-grown camelina varieties have 18:3n-3 content in the range of 34–41%.

Transgenic camelina is produced by transforming leaflets explants (upper left) into srouts, which are grown in agar (lower left) and later transplanted to soil (above) for greenhouse growth. This allows many plants with a particular genetic modification to be produced from just a small amount of material. Photos courtesy of Unicorp/ Agragen.

heart-healthy eicosa-pentaenoic acid (EPA, 20:5n-3) and docosahexaenoic acid (DHA, 22:6n-3). GPOE's proprietary production process produces a meal in which myrosinase, the enzyme that breaks down glucosinolates to isothiocynates and other antinutritive compounds, is inactivated, thus limiting the level of these antinutritive compounds in the meal. The net result is a more healthful meal for livestock, which was demonstrated in laying hens in which a ration containing 20% camelina meal had no adverse impact on hen health as determined by weight gain or egg-laying days.

However, to be consistent with an inclusion rate of not more than 10% camelina meal in rations for broiler chickens and cattle set by regulatory agencies, we requested from the US Food and Drug Administration (PDA) the same inclusion rate for camelina meal in laying hen diets and received from the EDA a letter of no objection for laying hen rations to contain up to 10% camelina meal. The ultimate large-scale production of camelina for biofuels provides a high-quality meal as a by-product that will provide options for livestock producers to reduce the amount of other grains also used for human consumption in livestock diets, such as barley or corn in cattle or soy meal in poultry.

Lessons from camelina: trials and tribulations of introducing a new crop

While Agragen, LLC and Unicrop, Oy (Helsinki, Finland) have more than 14 years of experience in using biotechnology approaches to introduce agronomic improvements to camelina via our patented technology platform, GPOE has worked diligently to introduce a new crop to US and Canadian farmers, while also expanding operations around the globe. Growing more than 100,000 acres (40,000 hectares) of camelina in 12 states in the United States and four Canadian provinces, GPOE has been at the forefront of introducing camelina for large-scale agriculture. As the world's largest producer of camelina seed stock and producer of camelina-derived oil and meal, GPOE has experienced the pitfalls of introducing a crop that has had minimal development of best farming practices. It is estimated that in the United States alone, there are 20 million acres of marginal land that could be used to grow camelina. Because of its 90-day growth cycle from emergence to harvest, camelina offers farmers who grow cotton and soybeans a double-crop option in certain regions of the country such as Texas, Oklahoma, and Arkansas. This dramatically increases the number of available acres for camelina in the United States alone.

Camelina grows well on marginal lands and requires minimal inputs in terms of fertilizer or herbicide applications. Combined with no need for spraying and single-pass harvesting, the planting and harvesting of camelina requires minimal field work, resulting in a low carbon footprint for its growth. Because it grows well in areas with 6-8 inches (15-20 cm) of precipitation and on marginal lands, camelina can be grown in regions with poorer soils not suitable for corn or soybeans.

In areas such as the Pacific Northwest (PNW) of the United States, where cropping options are limited, camelina offers a good option for farmers as a rotational crop. It is an excellent rotation option for dry-land wheat operations. When used as a rotational crop with wheat, the yield of the wheat crop following camelina increases up to 15%. However, GPOE has experienced crop failures in this region due to residual amounts of class-2 herbicides in the soil. This indicates that camelina is highly susceptible to class-2 herbicides, which are heavily used in wheat operations in this region. This presents a unique problem for camelina in the PNW, one which Agragen worked to solve using a biotechnology approach.

Biotechnology and camelina: lessons learned

When initially presented with the puzzling problem of PNW crop failure, we immediately speculated that this failure was due to residual class-2 herbicides in the soil. This was a problem that scientists at Agragen and Unicrop solved using biotechnology to engineer specific mutations in the gene encoding the enzyme acetolactate synthase (ALS). ALS is the first committed step for branched-chain amino acid biosynthesis and the target enzyme inhibited by class-2 herbicides. By combining specific amino acid changes in the active site, we achieved a herbicide-dependent increase in tolerance between 1,000- and 10,000-fold in two different varieties of camelina.

We have also used a biotechnology approach to introduce specific changes in camelina fatty acid composition and in its oil content. Again, these strategies use multiple gene constructs and our

In the greenhouse, transgenic camelina goes on to flower (left) and produce seed pods (above) of its own. Photos courtesy of Unicrop/ Agragen.

patented high-throughput transformation protocol. We have produced a high lauric acid (12:0) camelina while preserving the ALA (18:3n-3) content. This is important for using the meal as a high-energy, residual n-3 fatty acid source for poultry applications. With an academic third party we have introduced specific genes in the triacyl-glycerol biosynthesis pathway and have entered into collaboration with another academic partner to enhance the oil content of camelina using a novel strategy.

Agragen's and Unicrop's strong intellectual property portfolio in terms of issued patents and in proprietary technology in camelina plant science offers a number of different partners the capacity to rapidly make agronomic changes in the plant using our nonselection transformation technology. This strategy is important for downstream commercialization efforts to produce a meal without any genes that impart antibiotic resistance. Our rapid, high-throughput transformation technology is highly effective with a very high level of transformation efficiency. This is important because common strategies for transformation of camelina are ineffective, although a number of laboratories and competitors have had success using a floral dip transformation strategy. In our hands this method has not been overly successful in meeting the needs of a commercial high-throughput operation, and its use for commercial applications may be limited by our recently awarded patents for our transformation method in the United States and the European Union. Nonetheless, the floral dip method does offer noncommercial entities interested in camelina options with regard to transformation.

Beyond biofuels: plant-made pharmaceuticals

Agragen, LLC was founded as a plant-made pharmaceutical company with the vision of producing biological pharmaceuticals at a much lower price than the traditional method of producing drugs in mammalian cells. After our acquisition of Unicrop, Oy, we shifted our emphasis to producing cyto-kine trap molecules for use in a variety of disease states. Why is camelina an ideal platform for producing these biological pharmaceuticals? Simply, camelina is for all essential purposes a self-pollinating plant and a nonfood crop. Hence, the possibility that pharmaceutical-producing camelina might cross with weeds or other plants is extremely limited, and its use as a crop only for biofuels limits the liability seen with other food crops such as corn or rice.

Agragen's lead compound, AGR131, is a cytokine trap designed to reduce the levels of tumor necrosis factor alpha in patients with inflammatory conditions, such as rheumatoid orpsoriatic arthritis. It binds the target cytokine with an affinity equal to or greater than Enbrel, a well-known drug in this drug class. Using our patented protein expression system combined with our patented rubisco [ribu-lose-l,5-bisphosphate carboxylase/oxygenase] promoter technology, we have developed a very efficient sprouting expression system, putting our expression of proteins on par with yeast or slightly better than mammalian cells. Additional proprietary technology limits the addition of plant-derived sugars, overcoming a significant challenge that had limited the growth of the plant-made pharmaceutical industry. Because we harvest the seed and use our sprouting technology, we can efficiently recover the protein from the sprouts with yields approaching 85% and a purity of the final protein product exceeding 99%. Thus, although camelina is the future of fuel, it very well may be the future of biological pharmaceutical production, lowering the cost point of these drugs to enhance their afFordability. Who knew that camelina would be so versatile? •

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(Courtesy : Process India No. 6, December 2011, Volume I).

CAMELINA

A designer biotech oilseed crop

Traditionally, vegetable oils have been used primarily for food purposes; however, an increasing amount is being used for transportation biofuels, including biodiesel and jet fuel, leading to growing competition between the two uses. Development of a non-food oilseed crop as a renewable source of fuel that can grow well on nonprime agricultural land is necessary to alleviate our dependence on petroleum (Lu etal., 2011).

JILLIAN E.COLLINS-SILVA, CHAOFU LU, AND EDGAR B.CAHOON

Camclina saliva (sometimes called false flax or gold-of-pleasure) is an emerging Brassicaceae oilseed crop, grown in the northwestern regions of the United States and Canada, that historically has been cultivated in parts of Europe. The latest interest in developing this plant as a viable oilseed crop can be ascribed to a number of attributes, including its high oil and protein content, which allow the meal to be fed to livestock, and its ability to grow well on less productive land with less water and fertilizer inputs compared to other oilseed crops. Camelina can be considered a practical agronomic oilseed crop that could easily fit into currently used agricultural infrastructure and in rotation with other crops such as wheat. These unique attributes resulted in a large reduction of greenhouse gas emissions in a recent life cycle analysis study (Shon-nard et al., 2010). Moreover, camelina oil has been used successfully in a renewable jet fuel blend in test flights by a number of airlines and the US military.

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Although the oil that naturally accumulates in camelina seed can be used in fuel blends, its oil composition is not ideal for any single purpose without alteration or additives (Table 1). Camelina oil is high in polyunsaturated fatty acids, rendering it prone to oxidation. As a result, modification of its oil is required for camelina to become a competitive, profitable oilseed crop. Fortunately, camelina can be genetically engineered through a simple method developed by Chaofu Lu's group at Montana State University (Bozeman, USA) using Agrobacterium tumifaciens (Lu and Kang, 2008). By down-regulating the camelina A12-oleate desaturase (FAD2) genes in seeds, the same group demonstrated that the engineered camelina oils contained increased amounts of oleic acid (18:1*") and decreased levels of linoleic (18:2J9>l2) and a-linolenic (18:3A9' u 1S) acids (Kang et al., 2011). Further increase of oleic acid was attained by Edgar Cahoon's group at the University of Nebraska (Lincoln, USA) through simultaneously down-regulating the FAD2 and the fatty acid elongase (FAE1) genes. The increased oxidative stability of this high-oleic acid oil makes it well suited for biodiesel use compared to conventional camelina oil.

Genetic improvements such as these can be accomplished with relative ease and in a shorter time using camelina compared to more established oilseed crops such as soybean. The stable introduction of genes into the genome of a host plant is a process referred to as genetic transformation and is a key component of plant metabolic engineering. Camelina can be transformed by dipping the flower buds into a solution of Agrobacterium that harbors the desired gene(s), and the transformation efficiency can be greatly increased when this process is done in a vacuum chamber. This

A relatively short growth cycle of camelina makes it an excellent model for transplanting laboratory results for the field. Ohoto originally published at http ://www.brownenvelopedseeds.com/Reprinted with permission.

transformation method requires minimal training and no tissue culture expertise, and the first transgenic seeds can be harvested within six to eight weeks after Agrobacterium treatment. By comparison, soybean transformation requires dedicated, skilled technicians working mostly in tissue culture and takes eight to ten months for the first transgenic seeds to be harvested. Camelina also has a shorter life span than soybean, which allows for more rapid transgenerational evaluation of traits. The limited investment in time and resources needed to introduce trait genes make camelina an attractive metabolic engineering platform to achieve novel oil compositions.

Rapid and efficient metabolic engineering of camelina is further facilitated by the development of an extensive genetics toolbox, including vector systems for the delivery of multiple genes, a collection of antibiotic and herbicide resistance genes and fluorescent proteins for selection of transgenic plants, and a series of promoter elements that allow introduced genes to be expressed only in seeds. With this toolbox in place, it is now feasible to introduce large numbers of genes into camelina to reconstruct complicated biochemical pathways for higher value oils from plants with limited agronomic potential or even from organisms other than plants. Examples of this include ongoing research in the Center for Advanced Biofuel Systems (CABS), an Energy Frontiers Research Center supported by the US Department of Energy. CABS researchers are working to identify critical biosynthetic and metabolic genes for short- and medium-chain fatty acids from plants such as Cuphea species that naturally produce vegetable oils rich in

TABLE 1. Fatty acid content of canola, soybean, and camelina[a] (% of oil)

Fatty acid	Canola	Soybean	Camelina
Palmitic (16:0)	4.6	10.5	6.8
Stearic (18:0)	2.1	4.1	2.7
Oleic (18:1)	64.3	22.5	18.6
Linoleic (18:2)	20.2	53.6	19.6
Linolenic (18:3)	7.6	7.7	32.6
Arachidic (20:0)	0.7	Trace	1.5
Eicosenoic (20:1)	Trace	Trace	12.4
Erucic (22:1)			2.3
Other fatty acids	0.5	1.6	3.5

[a] Adapted from Moser, B.R., and S.F. Vaughn, Evaluation of alkyl esters from *Camelina sativa* oil as biodiesel and as blend components in ultra low-sulfur diesel fuel, *Bioresource Technol.* 101:646–653 (2010).

C8 and C10 fatty acids (Dehesh, 2001). By transferring the correct combination of Cuphea genes into camelina for seed expression, it is anticipated that oils will be generated that mimic the hydrocarbon composition of jet fuel. Similarly, in the European Commission Framework Programme 7 ICON project, researchers are identifying genes from plants such as jojoba, maize, and Arabidopsis and from organisms, including Euglena and bumblebees, that can be transferred to camelina to produce wax ester-type oils for biobased lubricants. Undoubtedly, the list of novel industrial oils produced in camelina will grow and metabolic engineering targets will likely expand to include high-tfalue protein and small-molecule co-products that enhance the overall value of camelina seeds.

Despite its promise as a metabolic engineering platform, a number of challenges lie ahead for the commercial realization of biotech camelina. Complementing genetic engineering efforts, researchers are working to improve agronomic traits such as yield, seed oil content, and herbicide resistance through marker-assisted breeding. Heretofore, little attention has been directed at germplasm improvement in camelina despite its long history as a crop. Given the large enhancements in yield and seed oil content that have been achieved through breeding in its close relatives rapeseed and canola, we believe that camelina's full genetic potential as an oilseed crop has yet to be tapped. In addition, more knowledge of the biochemical and genetic control of carbon flux in seeds and improvements in gene insertion technologies will facilitate more predictive metabolic engineering. Ultimately, markets and processing infrastructure will need to be in place for the commercial success of biotech camelina.

In addition to its economic potential, the ease of transformation and relatively short growth cycle of camelina make it an excellent model for translating laboratory results to the field. Though it is a hexaploid and lacks a published genome sequence, it is closely related to the widely used model plant Arabidopsis thaliana, from which large amounts of genetic information can be gleaned. As a crop species, it is ideally suited for extrapolating basic findings in Arabidopsis to the development of traits, such as drought tolerance and disease resistance, that impact agronomic performance. In this way, camelina can provide proof of principle under real field conditions for the plethora of discoveries that have been made in Arabidopsis but have remained untested outside of growth chambers and greenhouses.

Overall, we believe that camelina can become an important cash crop for the United States, especially with focus on its use as a metabolic engineering platform for biofuel and other industrial products. As a high-oil crop that is productive on land with modest rainfall and marginal fertility, camelina is a promising renewable resource to lessen our dependence on petroleum.

(Courtesy : Process India No. 6, December 2011, Volume I).

"STARTLING DISCOVERIES"

A new generation of renewable fuels is on the HORIZON

A new generation of technologies to generate renewable fuels is nearing commercialization. Some of these are focused on producing ethanol and other alcohols from cellulosic biomass using fermentation technologies. These alcohol-based fuels can be used as a substitute for gasoline.

WAYNE SEAMES

ANOTHER group of technologies is focused on producing fuels that replace kerosene and diesel fuels. These technologies take advantage of the chemical composition of crop oils, such as camelina, to generate organic chemical mixtures that are more similar to existing kerosene (jet fuel) and diesel products than current biofuels such as biodiesel. Crop oils contain a group of chemicals known as triacylglycerides (TG).

A TG molecule consists of three carbon chains ending in a carboxylic acid group, with each carbon chain (known as a fatty acid) connected to a glycerol backbone. Plants and animals naturally synthesize TG as a means to store energy, as do some algae and bacteria.

Two process schemes are nearing commercialization for the production of fuels to replace kerosene and diesel: hydrotreat-ing and noncatalytic cracking. Both process schemes manipulate TG oils to generate renewable fuels and by-products.

Hydrotreating

As the name implies, hydrotreating involves the reaction of TG oils with hydrogen. The TG oil and hydrogen are fed into a reactor where a combination of heat, pressure, and time induce chemical reactions that will (i) remove the fatty acids from the glycerol backbone and (ii) replace the carboxylic acid group on the fatty acids with a hydrogen atom, producing hydrocarbons. A catalyst is typically used to increase the efficiency of the hydrotreating reactions. Some versions of the hydrotreating process also use a catalyst to induce some of the fatty acids/hydrocarbons to rearrange to introduce side chains onto the base carbon chain, a process known as isomerization. The catalyst formulation is also used to encourage any double bond-connected carbon pairs to transform into single bond-connected carbon pairs. After hydrotreating/isomerization, the reactor outlet mixture is separated into product fractions. In some versions, reactions to cleave some of the carbon bonds are performed during or interspersed with the purification steps to decrease the average carbon chain length of the fuel. This carbon bond cleavage process is known as cracking. Hydrotreating processes typically produce diesel, kerosene, propane, and syngas products.

Recently, a kerosene product known as synthetic paraffinic kerosene (SPK, a renewable kerosene product with limited aromat-ics content) was produced from camelina oil and used by the US Air Force and Navy in full-scale performance tests. The SPK was mixed 50:50 with petroleum-derived military specification-grade JP-8 jet fuel, then tested in current military aircraft. Based on the success of these tests, a number of commercial airlines have begun testing 50:50 SPK blended fuels in their aircraft (see inform 22:497-499, 2011).

Commercial production facilities based on hydrotreat-ing process technology are likely to be in service within the next couple of years. These

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This Gulfstream G450 jet landed in Paris, France, in June 2011, after flying from New Jersey, USA, on a 50:50 blend of camelina oil-based and petroleum-based jet fuels. Courtesy of Honeywell Aerospace.

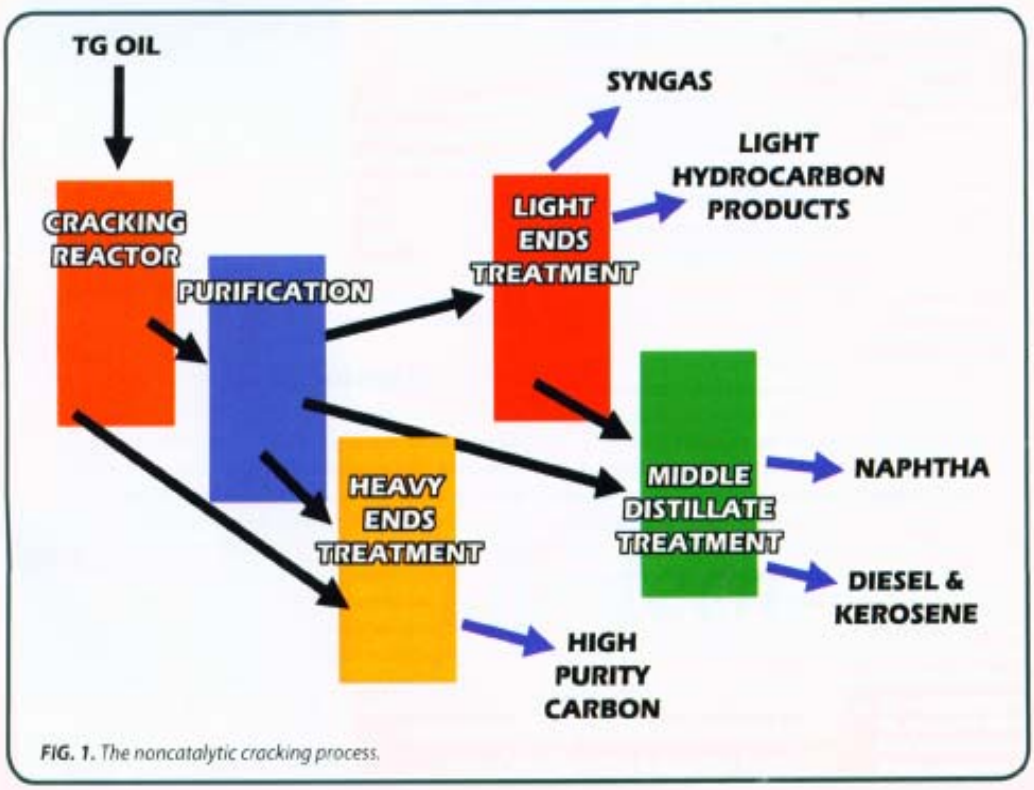

FIG. 1. *The noncatalytic cracking process.*

TWO PROCESS SCHEMES ARE NEARING COMMERCIALIZATION FOR THE PRODUCTION OF FUELS TO REPLACE KEROSENE AND DIESEL: HYDROTREATING AND NONCATALYTIC CRACKING.

fuels will supplement existing petroleum sources without requiring substantial changes in the infrastructure supporting current fuel generation, storage, and supply systems.

Noncatalytic cracking

The other process that is nearing commercialization is the University of North Dakota's noncatalytic cracking process (patents pending). In this process (Fig. l), TG oil is fed into a reactor where heat, pressure, and time are used to induce cracking reactions in the TG molecules.

This generates a complicated mixture—we've identified more than 250 separate chemical compounds in the reactor products—that is dominated by short-chain fatty acids, paraffins (hydrocarbons with all single-bond carbon-pair connections), and aromatics (compounds containing a six-carbon ring with three double-bond carbon-pair connections). The reactor product stream is then separated into intermediate product fractions and further processed into a final suite of fuels and byproducts. The noncatalytic cracking process typically produces diesel, kerosene, naphtha, light hydrocarbon fuels, and syngas. Another byproduct stream is a suite of very heavy, viscous compounds, typically labeled as "tars." These are long-carbon-chain chemicals that are formed when multiple fatty acid fragments, produced during cracking, combine. These tars can be recovered and converted into purified carbon products such as high-purity granulated carbon for spark plug rods and carbon nanotubes or into a mesophase pitch that can be spun into carbon fibers.

There are some advantages in noncatalytic cracking. First, an external hydrogen source is not required. The cracking process generates hydrogen as it produces aromatic compounds. This hydrogen can be recovered from the syngas and used to convert the carboxylic acid groups in fatty acids into hydrocarbons, where required.

Second, the first step in the process—cracking—does not use a catalyst. Because of this, the process can tolerate more impurities in the feedstock TG oil than processes that use a catalyst, such as hydrotreating processes. This is not a concern for edible crops, such as soybeans or corn, since these sources will likely treat their TG oils for human consumption. But this can substantially reduce the costs for extraction and treatment of nonedible crops such as camelina. This feature also means that noncatalytic cracking facilities will be feedstock flexible, capable of changing or blending TG oil feedstocks in response to market conditions.

Third, the noncatalytic cracking process produces fuel products that contain aromatics in concentrations that are similar to those contained in petroleum jet and diesel fuel products. For example, a complete Jet A commercial jet fuel can be produced solely from this process. There is no requirement to mix this renewable jet fuel with petroleum jet fuel, as with SPK. Thus, these fuels can completely replace or be indiscriminately blended with existing petroleum fuels without impacting the infrastructure supporting the generation, storage, and transportation of existing fuels.

One of the challenges for renewable fuel producers is the low gross profit margins that can be realized in the fuels market. Petroleum refining is extremely efficient, and fuel sales prices can be sustained at levels that are challenging for renewable alternatives. The noncatalytic cracking process provides greater flexibility to generate higher margin byproducts than many other processes. For example, instead of converting all of the short-chain fatty acids generated during cracking into hydrocarbons, they can be extracted from the cracking reactor product, purified, and sold as separate chemical products.

As with hydrotreating, commercial facilities are expected within the next few years. Both

noncatalytic cracking and hydrotreating processes will initially use crop oils such as camelina as their feedstocks. Technologies to produce TG oils from other sources of TG oils, such as microbe- and algae-derived oils, are expected to evolve to allow high volumes of oil to be cost effectively produced. When this occurs, both noncatalytic cracking and hydrotreating pathways will be able to accommodate these feedstocks as well.

Other technologies

Researchers are pursuing a number of other strategies for the generation of renewable fuels. One pathway is often labeled the "thermochemical pathway." Biomass material is reacted under specific conditions of heat, pressure, and time to break down the TG oil through pyrolysis or gasification. These reaction processes are similar to cracking. The gasification versions generate a syngas that is then fed to catalytic reaction steps that induce the recombination of the syngas molecules into larger molecules to generate liquid transportation fuels. Another strategy is to use yeasts, microbes, or algae to directly synthesize hydrocarbons that can be purified into fuels.

(Courtesy : inform November/December 2011, Vol.22 (10)).

"SURGING FORWARD"

Renewable Diesel Biofuels in the air

THE aviation industry continues to demonstrate its interest in incorporating biofuels into its future plans (see inform 22:497-499, 2011). Since the Paris Air Show, held in June 2011, additional companies have announced trials and test flights as well as limited commercial flights to evaluate the performance of biofuels under daily operating conditions (see Table 1 on page 22). The present article updates the 2011 inform article.

Beijing-based Air China flew its first test flight on October 28 using a commercial passenger plane powered with biofuel. The one-hour flight used 13.1 metric tons (MT) of biofuel blend (50% conventional jet fuel and 50% jatropha-based biofuel) in one of four engines of a Boeing 747-400 passenger plane; the other three engines were fueled with conventional jet fuel. The jatropha oil was produced and refined by PetroChina from plants grown on 80,000 hectares of low-quality farmland in southwest China's Sichuan and Yunnan provinces and was processed by Honeywell UOP. PetroChina plans to build a refinery by 2014 to produce 60,000 MT of biofuel annually. [Sources: tinyurl.com/ China-biofuel; tinyurl.com/China-aviation].

Air France completed a flight on October 13 from Toulouse to Paris-Orly Field that achieved a fuel efficiency of 2.2 liters per passenger per 100 kilometers. CO_2 emissions were half those of a normal flight. Each engine of the Airbus A321 aircraft was powered by a 50% blend of biofuel, supplied by the Dutch aviation biofuels company SkyNRG (tinyurl. com/AirFrance-SkyNRG). Optimized air traffic management procedures, including a continuous descent approach, contributed to allowing the flight to claim CO_2 emissions of 54 grams per passenger per kilometer (g/ passenger/km). According to the Air France-SkyNRG article, the best-performing airlines average over 100 g/passenger/km.

Two airlines — United Continental Holdings and Alaska/Horizon (parent group Alaska Air Group)— wound up competing to be the first US airline to fly a regularly scheduled flight or flights using biofuels. United came out the winner—by two days. Its one-off flight traveled from Bush Intercontinental Airport in Houston, Texas, to Chicago's O'Hare Airport on November 7. Fuel that was manufactured from algae by Sola-zyme, Inc. (South San Francisco, California) powered the Boeing 737-800 flight. United has announced its agreement with Solazyme to purchase 20 million gallons (76 million liters) of jet fuel a year, as early as 2014. This is equivalent to 0.6% of the airline's jet fuel consumption, according to Jimmy Samartzis, United s managing director of global environment affairs and sustainability (tinyurl.com/ United-biofuel). The price of the fuel was not disclosed.

On November 9, Alaska Airlines and its sister carrier Horizon Airlines initiated regularly scheduled flights powered by biofu-els. Alaska Airlines flew one one-way flight a day for 11 days from Seattle-Tacoma International Airport (SeaTac;

TABLE 1. Commercial airlines flying biofueled flights: Part II[a]

Airline	Plane(s)	First flight	Company name(s) of fuel source	Fuel feedstock (ratio biofuel to jetfuel)	Route	Distance (km)
Iberia Lineas Aereas de Espana SA	Airbus 320	October 3	Repsol YPF; UOP/Honeywell	Camelina (25:75)	Madrid to Barcelona	500
Aeromexico[b]	Boeing 737	October 4	UOP/Honeywell	Jatropha (25:75)	Mexico City to San José, Costa Rica	1,900
Air France	Airbus A321	October 13	SkyNRG	Used cooking oil (50:50)	Toulouse to Paris	680
Air China	Boeing 747-400	October 28	PetroChina; UOP/Honeywell	Jatropha (50:50), in 1 of 4 engines	N/A[c]	N/A
United Airlines	Boeing 737-800	November 7	Solazyme; UOP/Honeywell	Algae (40:60)	Houston to Chicago	1,490
Alaska Airlines[b], Horizon Air[b]	Boeing 737; Bombardier Q400	November 9–20	SkyNRG; Dynamic Fuels	Used cooking oil (20:80)	Seattle to Washington DC; Seattle to Portland	3,700 230

[a]For Part I, see *inform* 22:498 (2011).
[b]These airlines conducted a series of regularly scheduled commercial flights. Other airlines in this table have not yet announced regularly scheduled flights.
[c]N/A, not available.

Washington, USA) to Ronald Reagan Washington National Airport in Washington, DC. Horizon Airlines flew three one-way flights a day for a total of 64 flights from SeaTac to Portland, Oregon. Alaska Airlines reported paying $476,000 for the 28,000 gallons of biofuel to power these flights, or $17 per gallon ($4.49 per liter). Conventional jet fuel currently costs a little over $3 per gallon.

In a company statement, Alaska Air Group estimated that the 20% biofuel blend used for these 75 flights reduced greenhouse gas emissions by about 10%, or 134 metric tons, the equivalent of taking 26 cars off the road for a year (tinyurl.com/Alaska-Horizon).

Biofuels on the seas

The US Navy is investing more than $500 million in the biofuel industry to further its goal of reducing its dependence on petroleum-based fuels for its fleet by 50% over the next decade. (More than 50% of the Navy's fuel goes to maritime use.)

To this end, the US Navy sent its decommissioned destroyer Paul H. Foster on a cruise between San Diego, California, and Port Hueneme (near Los Angeles) on November 16-17, 2011. The 185-mile (300-kilometer) trip was powered by a 50:50 blend of petroleum (F-76) and a hydro-processed algal oil produced by Solazyme, Inc. (South San Francisco, California). Data on ship performance were collected during the cruise and compared with baseline data collected while the ship made the same trip earlier from Port Hueneme to San Diego on petroleum.

For the algal oil trial, the Paul H. Foster had been fueled so that 100% of the ship's propulsion power and 50% of its service power came from the algal oil/F-76 fuel blend. No changes had to be made to the infrastructure of the ship or the fueling pier for the test.

As reported by Marine Log, a business-to-business marine magazine, Mike Wolfe, the underway project officer, who is stationed with the Naval Surface Warfare Center Port Hueneme Division, said, "The fuel burned just like the traditional fuel we get from the Navy and have been burning for years. We could not tell the difference."

The Navy has already tested algae-based fuel in smaller vessels, such as in yard patrol craft at the US Naval Academy and in river-going boats.

Neste Oil (Espoo, Finland), the Port of Rotterdam, and the Rotterdam Climate Initiative announced that they would start trials of Neste's NExBTL renewable diesel, fueled at a 100% level, in a Port Authority patrol boat. The trial, whose start date was not specified in the original announcement, was planned to last a total of 1,000 hours. Exhaust emissions and engine performance were to be monitored, and operators would have the opportunity to gain experience with this new fuel. Neste's NExBTL can be produced from a wide range of vegetable oil and waste-based raw materials, such as waste animal food from food manufacturing.

(Courtesy : inform January 2012, Vol.23 (1)).

"MORE ABOUT JATROPHA"

Mission NewEnergy and Jatropha

AUSTRALIA'S Mission NewEnergy, a vertically integrated company growing jatropha and marketing oil from the seeds of the plant, was granted International Sustainability and Carbon Certification for its jatropha contracting model in the fourth quarter of 2011. This recognition certifies that the entire supply chain including indirect land use materially reduces green house gas emissions according to European Union-Renewable Energy Directive parameters.

BioFuels Journal (tinyurl.com/Biofu-elsJ-Mission) quoted Mission NewEnergy's Chief Executive Officer Nathan Mahalingam as saying, "The European biodiesel market represents a multi-billion dollar opportunity, and we are honored to be the first commer-scale provider of jatropha to receive this important endorsement." [Source: tinyurl.com/jatropha-sustainability].

The company's contract farming policy has provided some of India's poorest farmers a means to acquire education, exercise entre-preneurship, and experience upward mobility. For example, at the start of the fourth quarter, Mission Energy had materially completed its 2011 jatropha tree-planting efforts, adding 40,264 new acres (16,294 hectares) and 14,331 new jatropha contract farmers. The company now has a total of 234,587 acres (94,934 hectares) under contract representing a total of over 164 million trees.

Mission expects to receive 115 barrels of jatropha oil over the lifespan of each acre. This planting season, the company has planted high-yielding jatropha varieties from third parties, includingJOil (Singapore) and Quin-vita Ltd., based in the United Kingdom. These varieties are expected to increase yield and reduce the maturation cycle.

(Courtesy : inform January 2012, Vol.23 (1)).

"WHAT A FIGHT"

Fighting fat with fat

THE fat we typically think of as body fat is known as white fat. But another type — known as brown fat—does more than just store fat. It actually burns fat.

Researchers once thought that brown fat disappeared after infancy, but recent advances in imaging technology led to its rediscovery in adult humans. Because brown fat is so full of blood vessels and mitochondria—which is why it is brown—it is effective at converting kilocalories into energy, a process that malfunctions in obesity.

In a study published in Cell Metabolism (M:478-490, 2011, see http://tinyurl.com/ Orexin), researchers at Sanford-Burnham Medical Research Institute (Orlando, Florida, USA) discovered that orexin, a hormone produced in the brain, activates calorie-burning brown fat in mice. Orexin deficiency is associated with obesity, suggesting that orexin supplementation could provide a new therapeutic approach for the treatment of obesity and other metabolic disorders. Whereas most current weight loss drugs aim to reduce a person's appetite, an orexin-based therapy would represent a new class of fat-fighting drugs—a class that focuses on peripheral fat-burning tissue rather than the brain's appetite control center.

"Our study provides a possible reason why some people are overweight or obese despite the fact that they don't overeat—they might lack the orexin necessary to activate brown fat and increase energy expenditure," explains Devanjan Sikder, senior author of the study and assistant professor in Sanford-Burnham's Diabetes and Obesity Research Center.

Sikder's team, which included postdoctoral researchers Dyan Sellayah and Preeti Bharaj, looked at mice genetically engineered to lack orexin. These mice weighed more than their normal counterparts did, but they actually ate less, suggesting that overconsumption was not the cause of their

obesity. Rather the oresin-deficient mice lacked diet induced thermogenesis (heat production); in other words, when fed a high-fat diet, the mice failed to dissipate the extra calorie as heat the way that normal mice (and people) do. Instead, they stored that energy as fat.

This finding prompted the team to look at the animals' brown fat - a source of themogenesis. What they found is that brown fat in mice lacking orexin did not develop properly at the embryonic stage. This shortage had lasting effects on energy expenditure and weight, even in adulthood.

Taking the opposite approach, the researchers then gave the defective mice more orexin. With the hormone present, brown fat developed properly before birth and continued to be active into adulthood. What is more, adding orexin to stem cells in a laboratory dish caused them to differentiate into brown fat cells, creating more of this fat-burning engine.

"Without orexin, mice are permanently programmed to be obese. With it, brown fat is activated and they burn more calories," said Sikder. "We are now taking the next steps in determining how orexin — or a chemical that has the same effect—might be used in humans to therapeutically prevent or treat obesity."

(Courtesy : inform January 2012, Vol.23 (1)).

"BREAKTHROUGH"

Refining of rice bran oil by neutralization with calcium hydroxide

De, B.K., and J.D. Patel,
Eur. J. Lipid Sci. Technol.ll3-A 161-1167, 2011.

THE applicability of calcium hydroxide (lime) in the neutralization of rice bran oil (RBO) was investigated. Crude RBO samples of three different free fatty acids (FFA) (3.5-8.4wt%) were degummed, dewaxed, bleached, and neutralized with lime and deodorized. The oils obtained thus were characterized by determining the color, peroxide value (PV), content of unsaponi-fiable matter (UM), and FFA. Conventionally practiced caustic soda neutralization (at 80-90°C) of FFA has in the present investigation been replaced by a high-temperature (150-210°C) low-pressure (2-4 mm Hg) reaction with lime. It was observed that neutralization with Ca(OH), at high temperature (210°C) and under low pressure (2-4 mm Hg pressure) may substantially reduce the FFA content (0.8 wt%, after 2 h). The deodorized oil was found to be of acceptable color, PV, and content of UM and FFA. Neutralization of oil was also carried out by using NaHCO(and Na,CO,, nonconventional alkalies for neutralization, and the results were compared with NaOH and Ca(OH),. Overall recovery of oil in Ca(OH), refining process (88.5 ± 0.6 wt%, for Sample 1 containing 8.4 wt% FFA) was found to be more than other competitive processes studied.

(Courtesy : inform January 2012, Vol.23 (1)).

"FASHIONATING"

Specialty actives and the personal care market

THERE is big money in the specialty actives market: nearly $240 million in US sales in 2010 and just under $240 million in Europe during the same time period. That's according to Kline & Co., a market research firm based in Parsippany, New Jersey, USA.

"Specialty actives" is defined by Kline as active ingredients used in personal care products to deliver specific functionality, such as botanical ingredients used to delay or lessen the effects of aging.

"In the natural products arena, the presence of plant-based ingredients in the formulation used to be enough to encourage personal care consumers to purchase the products," comments Anna Ibbotson, an industry manager in Kline's Chemicals & Materials unit. "However, consumer awareness concerning product activity has increased, and the product's function and efficacy are regarded [as being] at least as important as the active ingredient source."

Continued demand for "natural" products will sustain growth in the botanicals segment, Kline says, which currently is the largest specialty actives category with a 38% market share. The fastest-growing category involves products produced through biotechnology. For more information about the report, see klinegroup.com/reports/y571f.asp.

(Courtesy : inform January 2012, Vol.23 (1)).

AOCS member bringing clean water to developing nations

Did you know that the water in your toilet is cleaner than the water nearly a billion people have to drink? Or that about 2.5 billion people do not have access to a toilet? Or that women the world over spend 200 million hours each day collecting water? (That effort is equivalent to constructing twenty-nine 100-story skyscrapers, according to www.water.org.) Lack of access to clean water exacts a considerable toll: More than two million people—mainly children—die every year because of unsafe drinking water.

LONG-TIME Surfactants and Detergents Division and AOCS member David Sabatini has taken these realities to heart and then some. Sabatini is the David Ross Boyd Professor in Civil Engineering and Environmental Science and Sun Oil Company Endowed Chair at the University of Oklahoma in Norman (OU; USA). He is also a founding director of the Water Technologies for Emerging Regions (WaTER) Center at OU.

"I began my career examining how contaminants migrate through the environment and dealing with their remediation, which is how I got into the surfactants field," Sabatini says. "It also meant that I traveled around the world, including travel for the cooperative graduate program the OU Institute for Applied Surfactant Research (IASR) runs in Thailand." Sabatini is associate director of the IASR.

This travel allowed Sabatini to experience the plight of the "bottom billion" of Earth's human population of 6.75 billion, who live on less than $ 1 per day. He began to realize, he says, "the more basic challenges they face, such as mortality rates that are 10 times those in the developed world. In fact, their mortality rates—if you think about it—are what ours were 100 years ago. We have simply had the good fortune to advance."

In 2006, Sabatini co-founded the multidisciplinary WaTER Center (http://water.ou.edu) with environmental engineer Keith A. Strevett and hydrologist Randall L. Kolar. In addition to Sabatini, the Center currently has four co-directors (Yang Hong, Robert C. Knox, Kolar, and Robert W. Nairn) and a core leadership group of five others. Additional expertise represented by the team includes groundwater hydrology, treatment ecosystems, water resource/climate change, civil engineering, anthropology, geography, education, business, and public health.

The wide range of expertise reflects the multifaceted benefits and challenges posed by developing water technology for emerging regions.

"Access to safe water, better sanitation, food, and health care can lead to longer lifetimes, more education, and a move up the development spectrum—all of which can lead to an increase in hope, peace, and stability," Sabatini notes.

P&G provides clean drinking water

AOCS Silver Level Corporate Member The Procter & Gamble Co. (P&G; Cincinnati, Ohio, USA) is working with a number of international humanitarian organizations and the Clinton Global Initiative to provide more than 300 million liters of clean drinking water to victims of drought in East Africa.

The collaboration will provide 31 million PUR™ packets made by P&G to more than two million persons without access to clean drinking water. The packets use a powder technology developed by P&G that removes contaminants from water while killing viruses and bacteria. Each packet can purify 10 liters of contaminated water, creating enough clean water for one family for a day.

"This commitment is estimated to prevent more than 10 million days of illness in the region and represents a total investment of more than $3 million," the company said in a statement.

An engineer by training, he found that technology alone is not the answer. Local residents have to be involved in the process and contribute to the effort, even if only minimally, in order for changes to be sustained. The use of indigenous materials, including waste materials that can be treated and processed, can provide economically viable solutions while promoting local entrepreneurs and businesses. Also critical is an understanding of the cultural attitudes toward water and sanitation that impact people's choices and behavior, he says.

As an example, WaTER Center staff have been involved in southern Cambodia, where groundwater in some areas is contaminated with arsenic at levels as high as 3,000 parts per billion (ppb). Arsenic also occurs naturally in Oklahoma; the city of Norman abandoned half of its wells, because they are no longer in compliance with the new US Environmental Protection Agency standard of 10 ppb for arsenic.

In the United States, arsenic remediation generally is accomplished using proprietary iron-based materials that are expensive for use in the United States and thus out of reach for use in Cambodia. Instead, the WaTER Center team is developing a water treatment technology using iron oxide that will mimic the properties of the proprietary material. In 2011, Sabatini and several OU graduate students conducted the first field test of the material in Cambodia, with promising results. In the next year or two, they hope to do a pilot study comparing the Center system to the proprietary material.

WaTER Center teams are also working in a number of other countries, including Bolivia, Pakistan, and Ethiopia, following a similar strategy. The problem in Ethiopia is an excess of fluoride. One solution—using charred cattle bones from local slaughterhouses—is effective at removing fluoride but might not be acceptable to all cultures and religions, so other simple materials are being developed.

"I once thought that I perhaps should have been a medical doctor so I could help those people in the 'bottom billion,'" Sabatini says. "Since founding the WaTER Center, though, medical doctors have commented on our work. They point out that whereas doctors only treat people once they are sick, we keep people from getting sick. And, further, because we bring safe water, our help continues long after we return home."

Those interested in enabling the work of the OU WaTER Center through a charitable donation should contact OU Development Director Jill Hughes at jillq(S)ou.edu.

(Courtesy : inform January 2012, Vol.23 (1)).

"THE TRUTH"

Ads can't make unsubstantiated product claims

THE regulations are pretty clear that you cannot accept a certificate of analysis at face value anymore. You need to do something to qualify that vendor and make sure your supplier is supplying a quality ingredient."

The PDA has long maintained GMP regulations as a means of ensuring quality for pharmaceuticals and medical devices. Now, with the new GMP regulations for dietary supplements, vitamins, minerals, herbals, and other nutritional products in the US are now being manufactured and labelled in much the same way as foods and pharmaceuticals.

Another key ruling focussed on regulating dietary supplement advertising involving the Federal Trade Commission (FTC). DSHEA did not change FTC's authority to regulate the advertising of dietary supplements. Because of confusion in the industry about FTC substantiation standards, the FTC issued guidelines on dietary supplement advertising in November 1998.

Ads, like product labels and other marketing materials, cannot make unsubstantiated product claims.

The consumer view point

Consumers need to understand why there are so many types of disease claims in books, newspapers and magazines. Most of these claims are not based on peer-reviewed scientific evidence and in many cases, do not present the possible adverse side effects and drug interactions of many dietary supplements. Certain companies, websites

and authors are more responsible than others in this area, but the larger problem is that many of the side effects and interactions are not known because many substances have not been scientifically studied. While many manufacturers standardise dietary supplements, without patent protection most companies will not make the huge investment to perform the proper studies on their ingredients and products. As a result, it is still a “buyer beware” market.

The bottom line is if a consumer does not feel a product works, he will not buy it again, and he will tell friends. So just how does the use of quality ingredients play an important role?

“An age-old question, with a time-proven answer,” says Shaheen Majeed, US marketing director for Sabinsa Corporation.

Majeed states, “Quality is at the heart of what matters most. If a single ingredient, be it an active or even an excipient, is without quality, it can destroy, degrade and damage the final product and even worse, cause harm to humans. Quality must be present in every aspect, from the people you employ, the equipment that is used, and the analysis that is done, plus the systems and procedures you have in place. Quality matters.”

(With more than 25 years of marketing experience, the writer has developed and managed a wide range of successful corporate marketing programmes. He can be contacted at SBaker@BakerDillon.com).

(Courtesy : Ingredients South Asia, January 16-31, 2012, Vol.5, Issue 8)

“HERE, IT IS”

Catalyst discovery potential has to revolutionize chemical industry

http://www.sciencedaily.com

UNIVERSITY of Alberta Chemistry Professor Steve Bergens and his graduate student Jeremy Johns have discovered a catalyst that has the potential to revolutionize the chemical industry by reducing its environmental footprint, improving efficiency and minimizing risks.

Their findings were published in a top international chemistry journal Angewandte Chemie this month and provide the chemical industry with a potential solution to issues surrounding economics, efficiency and environmental factors.

"Our findings are a game changer that people having been seeking an answer to for decades," said Bergens.

Bergen said researchers have been working for more than 50 years to find a "clean" and stable catalyst that produces little to no waste and also has a capacity to provide multiple turnovers. In February of this year his student Jeremy Johns created such a catalyst in his laboratory.

"After years of producing disappointing results I was thrilled to see the results that came out of this particular experiment," said Dr Bergens.

"The chemical industry is making huge efforts to reduce its environmental footprint and their economists and accountants are also looking to reduce the cost of not just transporting catalyst but improving its efficiency," said Dr Bergens.

He said the February 2011 discovery opens numerous doors to make these things happen for industries ranging from pharmaceuticals to agrochemicals. "Catalysts are notoriously unstable and challenging to transport, and the waste products the reactions to produce chemicals produce are equally challenging," Bergens added.

John's catalyst only produces hydrogen as a waste, something that is easy to burn off or react to produce water.

Bergens says early indications are the catalyst is not just safe but also efficient. The researchers have pushed the experiment to produce 7000 turnovers for one unit of catalyst.

"We are hugely excited , and the challenge now is to identify exactly how this catalyst is made up and how we can produce it in amounts to further advance this^ discovery," said Bergens.

(Courtesy : CHEMEXCIL LENSE, January - 2012, Vol.6)